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New devices put investigators one step closer to an artificial pancreas

The promise of real-time continuous glucose sensors

With the incidence of diabetes reaching epidemic proportions in the United States, researchers are urgently searching for better methods to achieve optimal blood sugar control. Studies have definitively shown that good control of HbA1c levels offers the best hope for preventing the costly and debilitating complications of the disease, but it's a difficult task that requires constant attention.

Researchers are working on several fronts to address this problem, but one particularly promising approach involves the development of an artificial pancreas, a mechanical system that continually monitors a patient's blood sugar and automatically prompts a pump to inject insulin as needed. A first-generation artificial pancreas is still a few years away, but the nuts and bolts of such a system—real-time continuous glucose sensors and insulin pumps—are already available, and advocates maintain that judicious use of these innovations can deliver better outcomes now, especially in patients who have a difficult time controlling their disease.

Inside This Month...

- *Take steps to address chronic pain now. Why? Because it's costing the United States \$120 billion per year, and much of this expense is due to patients bouncing from clinician to clinician without ever finding relief. Some healthcare organizations and individual practitioners successfully address the problem by taking a multidisciplinary approach to care and equipping patients with strategies to help them take charge* 112
- *Setting the standard for patients with advanced HF. Although heart transplants are performed in much the same way all over the world, standards vary in regard to listing and selecting patients for transplants. This encourages patients and families to search for programs that offer the most advantageous criteria. However, an international panel of experts has now agreed on criteria that they hope will not only standardize the care of patients with advanced HF, but also create a fairer and more equitable system for listing and selecting transplant candidates* 116
- *House calls make a return in new model of care for frail elderly. Care for such patients is often so fragmented and expensive that the pioneers behind a Woodland Hills, CA, company believe that they can do a better job at less expense by delivering care in the home and giving patients direct access to their physicians at any time of the day or night. Some commercial health plans have already bought into the approach, and now CMS is taking a close look at the model as part of a three-year demonstration project* 118

Reimbursement as 'critical'

Having made development of the artificial pancreas a top priority, the New York City-based Juvenile Diabetes Research Foundation (JDRF) has just announced that it will dedicate \$5.5 million toward research this year. Some of the funds will go to the Artificial Pancreas Consortium, a multisite group that will collaborate to develop potential algorithms for a closed-loop system, linking continuous glucose sensors with insulin pumps. Other funding will go toward the Continuous Glucose Sensor Trial, a one-year project in which nine research centers will test the effectiveness of sensors in various populations of children and adults, and in different clinical settings (see "Continuous Glucose Sensor Human Clinical Trial's nine research centers" on p. 110).

According to the JDRF, early data already show that patients who use continuous glucose sensors spend approximately 26% more time in the normal glucose range than patients who do not use sensors, but more data are needed to secure insurance coverage for the devices.

"We want all people with diabetes who can benefit from these technologies to have access to them, and I think health plan reimbursement for

the technologies is critical," says **Aaron Kowalski, PhD**, director of strategic research projects for JDRF. "What we have done is met with a lot of medical officers from a number of the major plans and from CMS to determine what are the outcomes they want to see and what is the data set they want to see, and we have created this trial."

High interest from some patient groups

Although large-scale coverage for the sensors is not yet available, there are isolated instances in which private insurers are already picking up the tab, according to **Steve Sabicer**, a spokesperson for Northridge, CA-based Medtronic Diabetes, maker of the first FDA-approved, real-time continuous glucose monitor. Typically, this has occurred in cases in which a priority clinical benefit has been established. For example, a patient who is hypo-unaware (i.e., he or she does not experience symptoms that indicate risk for a hypoglycemic episode) has a particularly strong need for an alarm system to alert him or her when blood sugars are out of range. Similarly, a patient who is pregnant and also has brittle diabetes is clearly at elevated risk, so private insurers have covered the sensor systems in some of these cases.

Medtronic also sees high interest in the sensor systems among technology-savvy patients, patients who are on insulin pumps, and those who are particularly focused on achieving good control, Sabicer says. "For patients who really want the added information and are currently taking 10, 15, or even 20 fingerstick measurements per day, the added value of the continuous glucose sensor is very important to them, so they are adopting it," he says, noting many of these early-adopters are willing to pay for the technology out of pocket.

'Transition to motion pictures'

Making the transition to this new technology can have a dramatic effect on control, according to Sabicer. "It's basically like going from photographs to motion pictures," he says. When patients use fingerstick meters, for example, they only have static points throughout the day. But they don't know how their blood sugar is trending, or even what it is when they are not measuring it.

Alternatively, sensors provide patients with a "motion picture" of their blood sugar. "Every five minutes a new reading comes up, which is actually an average of instantaneous glucose measurements taken by the sensor over the previous five minutes," Sabicer says. "So they get, in some cases, up to 100, if not more, readings of their glucose on a daily basis."

In addition to providing continuous monitoring, sensor systems can alert patients when their blood sugars are out of range. This can be particularly beneficial to patients who worry that they may experience an episode of hypoglycemia in their sleep, which could lead to coma or even death. "Patients now have the ability to go to sleep with a better peace of mind, knowing that if their blood sugars go low, [the sensor system] will alarm them and wake them up, so they can react to their diabetes and better manage it," says Sabicer.

An extra layer of assurance

Interest in real-time sensors is coming almost exclusively from type 1 diabetics and, to a lesser extent, type 2 diabetics who are insulin-dependent. However, there may be a much wider application for the devices in the next few years. "Initially, what people thought was that you would use these devices to modify your insulin regimen, but what you really find is that the maximum benefit of a continuous glucose sensor is that it allows you a window to the glucose changes that you didn't see before, and [to] how food and exercise and just your daily routine affect those blood sugar levels," says Kowalski, a type 1 diabetic who has been using a

Continuous Glucose Sensor Human Clinical Trial's nine research centers

- Joslin Diabetes Center in Boston
- Kaiser Permanente Southern California in Pasadena, CA
- Nemours Children's Clinic in Jacksonville, FL
- Roybal Community Health Center at the University of Southern California in Los Angeles
- Stanford University in Stanford, CA
- University of Colorado in Aurora, CO
- University of Iowa Carver College of Medicine in Iowa City, IA
- University of Washington in Seattle
- Yale University in New Haven, CT

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sensor system for the past five months. “The benefit you gain is to some degree derived from changing your insulin, but I really think . . . the most benefit you get is from changing the way you eat a little bit and the time you exercise; it is a combination of things.”

Further, the sensor systems have particular appeal to the parents of children with type 1 diabetes, who live in constant fear that their children will experience a hypoglycemic episode. The devices’ alarm features offer an extra layer of assurance to parents that they will be able to intervene before such crises develop. Trials of the devices are underway in pediatric populations, but the FDA has not yet approved them for pediatric use.

Challenges and opportunities

A major obstacle to sensor systems is cost: They are considerably more expensive than fingerstick meters. The systems can cost up to \$1,000, but it is the sensors, which must be replaced every few days, that really drive up the expense.

Currently, two companies have FDA-approved devices on the market: Medtronic and San Diego-based DexCom. A third device, made by Alameda, CA-based Abbott Diabetes Care, is under FDA review, and other companies have devices in development as well. Further, in April, the FDA approved a Medtronic device that essentially combines the company’s insulin pump with its continuous glucose sensor. The sensor does not yet trigger

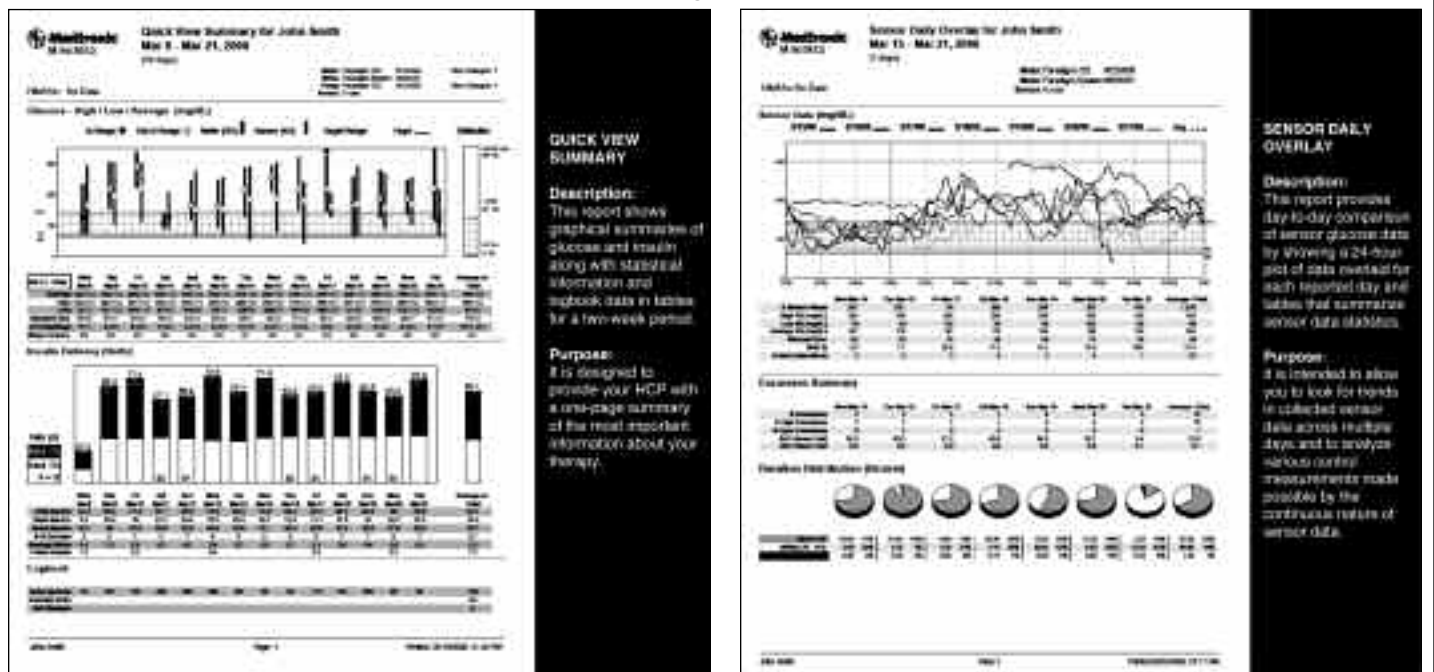
the pump to release insulin; that step still requires human intervention. However, it is one more step in the direction of the closed-loop system that the JDRF and many other advocates want to see.

The biggest challenge facing developers of closed-loop systems is the inability of mechanical devices to anticipate when a person is going to eat. People without diabetes begin to secrete insulin before they take in food, but the mechanical systems can only pick up blood sugar as it rises.

However, even with this limitation, Kowalski believes the first closed-loop systems can potentially deliver much better blood-sugar control than what the average person with diabetes can achieve right now. “The average HbA1c reading [for a diabetic] in the United States right now is above 8% . . . and that is well over double the mean blood glucose of someone without diabetes,” he says. “So there is plenty of room for improvement before we get to perfect. And the impact could be absolutely huge in terms of reducing diabetic complications, improving quality of life, and minimizing episodes of hypoglycemia.”

Medtronic’s goal is to produce a closed-loop system, but there is a series of advancements that developers need to accomplish first, says Sabicer. For example, the company is in the process of perfecting a longer-lasting sensor that could significantly reduce the costs associated with sensor systems. Currently, Medtronic’s sensor is indicated for 72 hours; the company is in the process of testing sensors that could last at least twice as long.

Figure 1



Source: Medtronic Diabetes, Northridge, CA.

Medtronic also plans to improve the accuracy of the sensors, which is critical to a closed-loop system. "You want to make sure that every blood-glucose reading is accurate. Otherwise, the device could provide too much or too little insulin," says Sabicer. "So we are looking at how to build redundancy systems where potentially that blood glucose reading is then backed up by or confirmed by a second glucose reading that is all done internally by the continuous glucose monitoring system."

Physician acceptance

Physicians who use Medtronic's diabetes management software can review historical data that have been collected by an insulin pump/sensor system and then stored on a patient's computer (see **Figure 1** on p. 111). Patients can bring their data to the office, or physicians can simply upload them from the patients' computers, review them, and then e-mail recommendations to the patients on how to manage their diabetes better.

With a closed-loop system, however, the company envisions that physicians will review their patients' blood-glucose data in real time and make recommendations to the device without even involving the patient. Sabicer estimates that these types of capabilities are probably five to seven years down the road, but he predicts that they will be widely adopted.

Such prospects are exciting, but Kowalski reiterates that the economics have to be made feasible, both in terms of reimbursement for sensor systems and for the time it takes clinicians to use these systems. "Doctors often are not getting reimbursed for the added level of work that is associated with this," he says, noting that JDRF-sponsored research is taking a look at this issue. "We want physician acceptance of this, and physicians need to be reimbursed." ❖

Editor's note: For more information on the JDRF's Artificial Pancreas Project, visit the organization's Web site at www.jdrf.org.

Multidisciplinary approaches give patients more control New Utah program helps curb runaway costs associated with chronic pain

As many as 75 million Americans suffer from chronic pain, costing the country as much as \$120 billion each year in medical costs and lost productivity, according to some estimates. And yet much of this expense delivers little in return, as utilization trends show that a sizable percentage of pain sufferers go from provider to provider in search of relief. In order to stem this money drain and help patients find relief faster, Utah's Medicaid program recently developed an approach to treat these patients more effectively.

Part of the challenge of treating chronic pain is that many generalist physicians lack training in how to effectively diagnose and treat chronic pain, or pain that persists for six months or longer. Additionally, they lack the time and resources that are often required to help patients learn how to manage their pain. Further complicating the problem is the fact that pain management—especially in cases in which there is no clear cause or source of the pain—is controversial. Even among experts, there is considerable disagreement on what drugs should be prescribed, when specialty care is needed, and what role behavioral health should play.

Despite all of these obstacles, individual practitioners can take certain steps to help patients control their pain much as diabetics can take control of their disease. Additionally, innovative programs that tackle the problem from several angles are

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making some headway in curbing the runaway costs associated with pain while giving patients a better quality of life.

Troubling indicators

Many indicators pointed to the need for action when administrators involved with Utah's Medicaid program began working on a chronic pain solution. State rules at the time prohibited providers from referring patients for pain management, the pharmaceutical usage of some patients was through the roof, and it was clear that patients in chronic pain needed intervention, says **Darlene Benson, RN, BSN, CCM**, a quality assurance specialist at Utah's Bureau of Managed Health Care.

"We also saw that pain was somewhat under-treated. Many times the PCP [primary care physician] had limited training in providing this type of care, and [he or she] had a lack of time," says Benson. "These patients are complex; they usually have comorbidities, and that is not the kind of patient most practices want."

Consequently, in addition to beginning the process of altering state rules to allow referrals for

pain management, Benson and colleagues began scouring the literature for approaches that had worked in other settings. They concluded that any successful program would need to offer a multidisciplinary approach to the problem, including

- psychological or psychiatric care
- physical therapy
- care from a board-certified pain specialist

The state also decided to mandate that PCPs who wanted to refer patients into the program needed to agree to keep these patients and help to manage them once they were enrolled.

'A road map to care'

The program began as a pilot with 54 patients enrolled. Most had huge claims costs, some reaching as high as \$100,000 per year. The patients took, on average, six pain medications, and most saw multiple providers. "These patients were bouncing between specialists, and every time they saw a specialist, the specialist worked them up so there would be labs, x-rays, and all of that," says Benson, adding that several of the patients had inpatient

Figure 1

Chronic Pain Management Referral Form

Use this form to request a patient's participation in the Utah Medicaid Chronic Pain Program. Include the following in your request:

- This form
- History and physical
- Letter of medical necessity
- Any other pertinent information

<p>Patient Information</p> <p>Patient Name: Martha Steal</p> <p>Patient Address _____</p> <p>City, State, Zip _____</p> <p>Date of Birth _____</p> <p>Medical ID# _____</p> <p>Male <input type="checkbox"/> Female <input type="checkbox"/></p> <p>Diagnoses</p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p> <p>4. _____</p> <p>5. _____</p> <p>Office Use Only</p> <p>Authorization _____</p> <p>Authorization# (if required) _____</p> <p>Secondary Insurance _____</p> <p>Medical Plan: <input type="checkbox"/> FFS <input type="checkbox"/> Molina <input type="checkbox"/> Healthy U <input type="checkbox"/> HIC</p>	<p>Referring Physician</p> <p>Name _____</p> <p>Provider Address _____</p> <p>City, State, Zip _____</p> <p>Phone _____</p> <p>Fax _____</p> <p>Reason for Referral - check all that apply:</p> <p><input type="checkbox"/> Pain is chronic, 6 months or more duration.</p> <p><input type="checkbox"/> Concerned by narcotic co-prescriptions.</p> <p><input type="checkbox"/> Efficacy for narcotic analgesia appears out of proportion to presenting symptoms and exam.</p> <p><input type="checkbox"/> Frequent visits for various subjective complaints; resulting in increased medication utilization.</p> <p><input type="checkbox"/> Frequent lost, stolen or destroyed prescriptions.</p> <p><input type="checkbox"/> Frequent request for early refills.</p> <p><input type="checkbox"/> I need consultation that I am prescribing the appropriate medications.</p> <p><input type="checkbox"/> Other: _____</p> <p>_____</p> <p>_____</p> <p>Previous Treatment, Medications and Outcome</p> <table border="0" style="width: 100%;"> <thead> <tr> <th></th> <th colspan="3" style="text-align: center;">Efficacy Rating</th> </tr> <tr> <th></th> <th style="text-align: center;">None</th> <th style="text-align: center;">Min</th> <th style="text-align: center;">Avg</th> </tr> </thead> <tbody> <tr> <td>High</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Treatments:</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>Medications</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>Mental Health:</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> <tr> <td>_____</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> <td style="text-align: center;">()</td> </tr> </tbody> </table>		Efficacy Rating				None	Min	Avg	High				Treatments:	()	()	()	_____	()	()	()	_____	()	()	()	_____	()	()	()	_____	()	()	()	_____	()	()	()	_____	()	()	()	_____	()	()	()	Medications	()	()	()	_____	()	()	()	_____	()	()	()	_____	()	()	()	_____	()	()	()	_____	()	()	()	_____	()	()	()	_____	()	()	()	Mental Health:	()	()	()	_____	()	()	()	_____	()	()	()
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(continued on p.114)

admissions for pain, and the number of ER visits for pain ranged from three to 57. "Their treatment was fragmented. Many of them had never had a mental health evaluation."

To streamline care for such patients, Medicaid set up the program so all three initial evaluations—mental health, physical therapy, and pain specialty care—take place on the same day, or as close to the same day as possible. Then information from all of the evaluations is compiled into a treatment plan that is shared with the patient's PCP. Benson refers to this treatment plan as a road map to care.

"These are very in-depth evaluations," Benson says, noting that they can be 15–20 pages long. "But they really help the PCPs know if they are providing the right treatment or not." She adds that the evaluations provide important documentary evidence for physicians who conclude that their patients need higher than usual dosages of pain medication, she adds.

Early feedback

Results from the pilot group were promising: Analysts observed decreased ER usage and spe-

cialty visits and a reduction in laboratory and radiology services. Alternatively, there were increases in mental health treatment and PCP visits and enhanced coordination of care by PCPs. As a result of these findings, Utah made the program available to all eligible Medicaid recipients early this year.

Benson emphasizes that patients must meet strict criteria for enrollment in the program, which are outlined in a referral form/screening tool that PCPs must use to refer patients into the program (see **Figure 1** on p. 113 and below). For example, patients must

- suffer from chronic pain, which is defined as pain that has persisted for six months or longer
- be over 18 years of age
- have a PCP

There does not have to be evidence of high utilization for a patient to enroll in the program, although that is frequently the case. Further, patients who have a substance abuse problem are not necessarily prohibited from enrolling in the program, but they must take steps to deal with their substance abuse first.

Figure 1 (continued)

Assessment:	
1. Patient is medically stable. <input type="checkbox"/> Yes <input type="checkbox"/> No If no, list any pending medical evaluations _____	9. This person has a history of: <input type="checkbox"/> lost medications <input type="checkbox"/> requesting early refills <input type="checkbox"/> misuse of opioids <input type="checkbox"/> getting medications from multiple providers <input type="checkbox"/> stolen medication
2. Patient is mentally stable. <input type="checkbox"/> Yes <input type="checkbox"/> No If no, list any pending mental health evaluations and mental health provider. Mental Health Provider: _____ Mental Health pt#: _____ If diagnosis is available, please list: _____	10. This person has history of: <input type="checkbox"/> excessive use: _____ pills per day <input type="checkbox"/> alcohol use: <input type="checkbox"/> daily <input type="checkbox"/> 1-2 days/week <input type="checkbox"/> 1-2 days/month <input type="checkbox"/> less than 1-2 days/month Type: _____ Amount: _____ <input type="checkbox"/> psychotropic prescription drugs <input type="checkbox"/> illegal drugs: <input type="checkbox"/> marijuana <input type="checkbox"/> cocaine <input type="checkbox"/> heroin <input type="checkbox"/> other narcotics Type: _____ Amount: _____ <input type="checkbox"/> long standing behavioral problems <input type="checkbox"/> numerous attempts at treatment <input type="checkbox"/> dizziness, blackouts, disorientation <input type="checkbox"/> falls, bruises, burns, poor hygiene <input type="checkbox"/> seizures, memory loss, incontinence <input type="checkbox"/> anxiety, headaches, depression, functional decline
3. Did you initiate opioid therapy? <input type="checkbox"/> Yes <input type="checkbox"/> No	11. This person has recently experienced: <input type="checkbox"/> death of spouse, parent or child <input type="checkbox"/> financial problems <input type="checkbox"/> physical impairment or disability <input type="checkbox"/> retirement <input type="checkbox"/> diminished social/family support <input type="checkbox"/> divorce <input type="checkbox"/> social isolation <input type="checkbox"/> other _____
4. Does this patient have pain which is significantly reduced by opioids? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments: _____ _____ _____
5. If the pain is neuropathic in origin, has the patient had adequate trials of drugs for neuropathic pain at the adequate dosage levels such as? <input type="checkbox"/> Neurontin: Dosage: _____ <input type="checkbox"/> Gabapin: Dosage: _____ <input type="checkbox"/> Topamax: Dosage: _____ <input type="checkbox"/> Desipramine: Dosage: _____ <input type="checkbox"/> Amitriptyline: Dosage: _____ <input type="checkbox"/> other neuropathic medication and dosage: _____	Physician/ Provider Certification Approval for the Chronic Pain Program requires involvement of the PCP. I, the PCP and I agree to continue as the primary care provider. I agree to coordinate the treatment plan with the Pain Center and will assume prescribing responsibility at the end of the evaluation. <input type="checkbox"/> Yes <input type="checkbox"/> No If no, provide the PCP name and phone: PCP Name: _____ PCP Phone: _____
6. Have increased dosage(s) of pain medication resulted in long term improvement in pain and/or function? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, describe the improvement and length of time of the improvement? _____ _____	
7. Have alternatives to medications for pain relief been tried? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> relaxation <input type="checkbox"/> meditation <input type="checkbox"/> physical therapy <input type="checkbox"/> biofeedback <input type="checkbox"/> occupational therapy <input type="checkbox"/> other: _____	
8. This person: <input type="checkbox"/> has sleep problem <input type="checkbox"/> is taking sleep medications <input type="checkbox"/> has been evaluated for sleep problem <input type="checkbox"/> does not have a sleep problem Comments: _____ _____	

Source: Bureau of Managed Health Care, Salt Lake City.

Mental health focus

Utah also established criteria for pain specialty providers. At presstime, Medicaid was working exclusively with the University of Utah's pain program, although Benson emphasizes that administrators hope to bring other providers on board.

Pain specialists wishing to participate in the program must be certified by the American Board of Anesthesiology or the American Academy of Pain Medicine and must be willing to provide the three-pronged approach that program developers believe is essential to effective care.

In fact, Benson says most patients end up requiring more of a mental health focus to their care. "We have had undiagnosed mental health problems including mood disorders and anger management issues, but depression is one of the big things," she says. Further, mental health providers frequently work with patients on coping strategies to help them live with their pain.

Work in progress

By providing patients and their PCPs with a comprehensive approach to care, the program aims to return patients to the care of their own community providers within six months. Initially, such an ambitious timetable raised some eyebrows among pain specialists, but Benson says they have become more comfortable with the approach and its focus on working collaboratively with PCPs over time. Further, she notes that PCPs are becoming better equipped to deal with chronic pain in their own practices.

The approach is still a work in progress, but Benson feels certain that it has at least stabilized costs for patients with chronic pain. And participating clinicians are clearly satisfied with the resource. "Every physician we have showed this to . . . has embraced it," she says.

Steps every physician can take

Unfortunately, many physicians do not have access to a multidisciplinary program into which they can refer patients. However, there are still steps that they can take to help their patients control chronic pain.

Such a process should always begin with an extensive history and evaluation of the problem. This includes gathering all of the previous information that other providers have collected about the patient, but also approaching the situation with a fresh eye, according to **Margaret Caudill-Slosberg, MD, PhD**, a pain specialist affiliated with Dartmouth College, and author of *Managing Pain Before It Manages You* (Guilford Press 2001), a book geared

toward clinicians as well as patients.

"The biggest mistake that generalists fall into is they trust either what the patient says in terms of sequence or cause, or what somebody has said who evaluated the person years ago," she says, noting that physicians often assume that nothing has changed.

Instead, physicians need to go through the basic process of taking the patient's history, finding out when the pain started, how it feels, and whether it has felt the same way the whole time or has changed. By establishing a good baseline, physicians are in a much better position to gauge the effect of subsequent treatments and recommendations.

Chronic pain can stem from a chronic inflammatory process such as rheumatoid arthritis or lupus, but it can also occur in the face of no pathological or identified disease. This type of pain is typically associated with such conditions as fibromyalgia, chronic fatigue syndrome, irritable bowel syndrome, and chronic daily headaches.

Unfortunately, there are often no tangible treatment options. "We just don't know how to turn off the pain system once it gets turned on, which is what happens in these central nervous system conditions," says Caudill-Slosberg.

In these cases, both the patient and the practitioner must acknowledge that the pain may not go away. However, this doesn't mean that there is nothing to be done. To the contrary, physicians should guide patients in pain strategies that can help them be active, establish a better quality of life, and take control of their lives. When done effectively, Caudill-Slosberg stresses that such patients stop feeling desperate and stop going from clinician to clinician in search of relief.

Activating patients

For example, in many cases, cognitive stress-management skills can help people overcome issues such as insomnia, depression, and social isolation that are directly related to their chronic pain. In these instances, the pain may not go away, but patients report a better quality of life once they get some of their symptoms under control. Similarly, exercises that are particularly well suited to individuals with pain include yoga, water workouts, and isometric toning exercises.

Internists often are not equipped to provide patients with the expert guidance that they need in these cases, but they can arm themselves with referral sources for the appropriate programs and specialists in their area. These should include physical therapists who have experience working with people with chronic pain, warm water aerobic exercise facilities, yoga programs, and cognitive behavioral therapists who have the appropriate skill set.

Managing chronic pain is a matter of getting people involved in their own care, an approach that is not unlike what DM programs across the country emphasize with respect to diabetes, asthma, and other chronic diseases. “The more activated people can become and the more involved they can become in terms of managing their symptoms, the more effective their treatment and their interaction with the healthcare system will be,” says Caudill-Slosberg. ❖

International effort seeks to standardize global care for patients awaiting transplant

Unprecedented guidelines focus on care of patients with advanced HF

Heart transplants are carried out in virtually the same manner in most countries throughout the world, but there is great variation in the kinds of patients who are referred for transplant. This sets up a system of care that encourages patients to shop from program to program to find one with the most advantageous criteria.

In an effort to curb this practice and standardize HF care and practice around the world, the International Society for Heart and Lung Transplantation (ISHLT) has released the first international guidelines for HF patient management, a set of standards that is particularly geared toward the care of patients under consideration for heart transplant.¹

The unprecedented guidelines highlight the optimal processes of care that an international panel of experts believes is important in potential candidates for transplant. However, the authors stress that they also go much further than current guidelines in addressing the care and treatment needs of patients with severe and advanced HF, a group of patients that is growing as the general population ages.

Assessment is complex

There was a time when physicians needed only to look at the ejection fraction of the heart to determine whether a patient was an appropriate candidate for transplant. However, with the plethora of new devices and treatment options now available, the assessment process has become much more complicated.

“I think the single most important thing about listing patients is that there is not a single test that is going to give you an answer,” says **Mariell Jessup, MD**, the ISHLT task force chair and a professor of medicine at the University of Pennsylvania in Philadelphia. “You need to look at a broad range of values and put them all together as way of assessing

whether the patient is ready for transplant or should be considered for transplant because all other standard medical therapies have failed.”

For example, although age is a particularly important factor to consider, Jessup notes that it should not be a disqualifying factor in and of itself. Further, there has been considerable debate about listing diabetic patients, patients with high body mass indexes, or patients who use tobacco products. The guidelines provide some context on how physicians should view these and many other factors, according to the expert panel and the evidence-based research that it reviewed.

“It is much easier for an individual transplant program to be able to say ‘Here is what a broad panel of people have said are the guidelines. Therefore, we are going to adhere to or follow them,’ ” Jessup says. “It diminishes [the practice of] patients going from program to program, from state to state, or even country to country.”

Numerous factors to consider

To help physicians through the decision-making process that is required when considering candidates for transplant, the guidelines include an extensive list of items that they should take into account—in most cases repeatedly—prior to the transplant (see **Figure 1** on p. 117). The sheer number of items included illustrates the complexity involved in making decisions regarding transplants, but it also underscores the importance of optimal care while awaiting a transplant.

“These are patients who really and truly are end-stage, and it is not enough just to be in contact with them over the phone. They need specific interventions or diagnostic tests periodically,” Jessup says. These include

- serial right heart catheterizations to ensure that patients are not developing irreversible pulmonary hypertension
- regular evaluations to ensure that patients don’t have low-output symptoms that may require a ventricular assist device (VAD)
- periodic blood work to ensure that patients do not develop end-organ dysfunction from low output

Further, although it is always important to gauge patient-reported symptoms, Jessup says that for many patients with chronic HF, it has been so long since they felt good that they tend not to complain, even in cases in which there may be profound depression of their cardiac output.

In most cases, optimal care for patients with advanced HF is going to be the same regardless of whether they are awaiting transplant, but there are some notable differences. For example, routine health screening procedures (e.g., mammography or

colonoscopy) might not make sense in the case of a patient with advanced HF who is not under consideration for transplant. However, physicians might consider higher-risk investigational procedures for such a patient. On the other hand, if a patient appears to be a good candidate for transplant, Jessup says the physician should approach the rest of the patient's care under the assumption that the person has a predictable future.

Treatment advancements

Although it is evident that variations in care

practices exist, Jessup says experts from all over the world agree that physicians, in general, do not do enough in regard to medical therapy before listing patients for transplant. For example, she notes that physicians may make a "stabbing attempt" to get patients on Angiotensin-Converting Enzyme (ACE) inhibitors and beta blockers, but then too quickly conclude that they cannot tolerate the drugs without fully exploring all the treatment alternatives. In some cases, the problem is that physicians have simply put patients on too many drugs at one time.

"The error that everyone felt all over the world was that physicians tend to wait too long and don't try medical therapy enough," says Jessup. "So they kind of hang on to patients and have them readmitted multiple times; they have them on intravenous inotropes, but they haven't really made an effort to systematically try drugs."

Clinicians need to understand that there is great potential for hearts to get better, and that medical treatment or nontransplant treatment has advanced greatly in recent years, she says. "There are a lot of things you need to try before you abandon the original heart."

Inadequate reimbursement

Part of the problem is that caring for HF is extremely labor-intensive and time-consuming. Physicians try to do the right thing, but ISHLT representatives from around the world report that clinicians are not adequately reimbursed for the time they must spend caring for these patients.

Once patients with decompensated HF leave the hospital, research shows that they tend to stay on the drugs on which they were discharged, Jessup says. "Physicians tend not to push up the doses of ACE inhibitors and beta blockers, and they are reluctant to initiate aldosterone antagonists, and I think this is mostly because they are very busy," she says. "Physicians just don't have the time to do it all."

The idea of bringing on pharmacists or HF nurses to take over some of the workload has

Figure 1: Recommended schedule for heart transplant evaluation

Test	Repeat				
	Baseline	3 months	6 months	9 months	12 months (and yearly)
Complete H & P	X				
Follow-up assessment		X	X	X	X
Weight/BMI	X	X	X	X	X
Immunocompatibility					
ABO	X				
Repeat ABO	X				
HLA tissue typing	Only at transplant				
HLA and flow cytometry	X				
> 10%	Every 1-2 months				
VRD	Every 1-2 months				
Transfusion	2 weeks after transfusion and then 3 months & 6 months				
Assessment of heart failure severity					
Cardiopulmonary exercise test with ECG	X				X
Echocardiogram	X				X
Right heart catheter (cardiac challenge) as indicated	X		X		X
ECG	X				X
Evaluation of multi-organ function					
Baseline lab work (BMP, CBC, LT)	X	X	X	X	X
PT/INR Max: transplant per protocol if on VRD or coumadin	X	X	X	X	X
Urea nitrogen	X	X	X	X	X
Cr (IDCAD) quadratic equation	X	X	X	X	X
Urinalysis (sample for protein excretion)	X	X	X	X	X
PFT with Arterial blood gases	X				
CXR (PA and lateral)	X				X
Abdominal ultrasound	X				
Carotid Doppler (if indicated or > 50 y)	X				
ABI (if indicated or > 50 y)	X				
DEXA scan (if indicated or > 50 y)	X				
Bone mineralization	X				X
Diethylstilbestrol: evaluation (if diabetic)	X				X
Infectious serology and vaccination					
Hep B surface Ag	X				
Hep B surface Ab	X				
Hep B core Ab	X				
Hep C Ab	X				
HIV	X				
HTLV	X				
HIV IgG	X				
CMV IgG	X				
Toxoplasma IgG	X				
EBV IgG	X				
Varicella IgG	X				
PPV	X				
Flu shot (1 year)	X				
Pneumococ (1 year)	X				
Hep B immunization: 1, 2, 3	X				
Hep B surface Ab (immunity)	4 weeks after third immunization				
Preventive and prognostic					
Stool for occult blood < 40	X				X
Colonoscopy (if indicated or > 50 y)	X				
Mammography (if indicated or > 40 y)	X				X
GynPap (if indicated or > 30 y sexually active)	X				X
PSA and digital rectal exam (men > 50 y)	X				X
General consultations					
Social work	X				
Psychiatry	X				
Finance	X				
Neurophys (if applicable)	X				

Source: Mehra M.R., Kobashigawa J., Starling R., Russell S., et al., "Listing Criteria for Heart Transplantation: International Society for Heart and Lung Transplantation Guidelines for the Care of Cardiac Transplant Candidates 2006," Journal of Heart and Lung Transplantation; 25:1024-1042.

been discussed and implemented in some models, but Jessup says such solutions still do not solve the reimbursement problem. Someone still has to pay for the ancillary staff.

Best practices

Obtaining adequate reimbursement for HF care remains a thorny issue, but the authors of the new guidelines hope that their work will at least begin a process of helping programs around the world identify and adopt best practices.

“Although we all approach transplant in the same way, some countries use certain drugs from a class and other countries use others, so one of our goals is to understand what the differences are internationally . . . and explore whether there

is a difference in outcomes,” says Jessup. “In this country, we tend to use the expensive [approaches] and whether the outcomes are any different is not always clear.”

Editor's note: To view the new international guidelines for HF in their entirety, visit the ISHLT Web site at www.ishlt.org. ❖

Reference

¹ Jessup M., Banner N., Brozena S., et al., “Optimal Pharmacologic and Non-pharmacologic Management of Cardiac Transplant Candidates: Approaches to Be Considered Prior to Transplant Evaluation: International Society for Heart and Lung Transplantation Guidelines for the Care of Cardiac Transplant Candidates,” *The Journal of Heart and Lung Transplantation* 2006, 25:1003-1023.

Physician house calls and easy access are hallmarks of a new care model

Home care may lead to cost-efficient management of frail elderly patients

Conventional wisdom suggests that a delivery model based on physicians making home visits to deliver medical care would be much too expensive, but that may not be the case in a population of frail, elderly patients at high risk for costly ER visits and hospital admissions. Administrators at Woodland Hills, CA-based Care Level Management (CLM) maintain that they can save money through such a model, and they have convinced CMS to include a pilot of the approach in its Care Management for High-Risk Beneficiaries (CMHCB) demonstration project.

The model, which CLM refers to as its Personal Visiting Physician™ program (PVP), provides patients with direct, 24-hour access to a physician who can come to their homes at any time of the day or night. It sounds expensive, but it is targeted at the 2% of Medicare recipients who are the most frail, chronically ill beneficiaries. The idea is that providing easy access to timely, in-home care can reduce or in some cases eliminate the need for hospital and ER visits.

In the first year of the three-year pilot, more than 5,000 beneficiaries have signed up for the delivery model, but that number is expected to at least triple in size this year, because CMS has just authorized expansion of the model to more than 13,000 additional beneficiaries.

Beyond dollars and cents

CLM already provided its PVP program to some commercial health plans when the Medicare

demonstration project began in September 2005. The commercial plans contracted with CLM primarily because they were having difficulty delivering quality care to frail elderly beneficiaries through conventional means, says **Oliver Goldsmith, MD**, president of CLM.

Many of these patients were unable to get to their doctors' offices for routine visits, and they had highly complex medical conditions. Further, the health plans recognized that crisis situations often occur during the evening hours and on weekends when it is difficult to get through to a PCP, and inevitably these patients were told to go to the ER. The health plans wanted a lower-cost alternative.

Working with managed care operations in six metropolitan areas, CLM reports that the PVP program has been able to reduce hospital admissions by an average of 60%, resulting in average net savings of 30% in institutional costs. However, CLM has also found that the benefits of providing in-home care to this high-need population extends beyond dollars and cents.

“What we discovered was that the immediate contact with a physician whom the patient knows often ameliorates the condition,” says Goldsmith. “The bonding that takes place between the physician and the patient is often just what the patient needs to reassure them.”

Outreach to beneficiaries

CMS has stipulated that beneficiaries participating in the Medicare demonstration must have two chronic conditions and a history of at least two hospital admissions within the previous 12 months. Additionally, CMS restricted the demonstration to fee-for-service beneficiaries who live in California, San Antonio, and the Orlando and Melbourne areas of Florida.

The way that the demonstration has been set up is that CMS identifies beneficiaries who are eligible to participate in the pilot, and then sends their names along with demographic information to CLM's enrollment center in Phoenix. At this point, staff make an outreach phone call to each beneficiary to gauge his or her interest in participating.

When patients indicate that they would like to participate in the program, CLM relays their information to CLM's local area network, which is located in the communities where the patients reside. "Once the patient says 'yes,' we are there within three or four days for that first visit," says Goldsmith.

Relationship-building

The assessment process that takes place during the physician's first visit to the patient's home marks the beginning of what CLM hopes will be a developing relationship. In addition to completing a comprehensive physical and history on the patient, physicians will typically review the home environment, identify sources of family/social support that are available to the patient, and carefully document and review which medications the patient has been taking.

"When we go to the home we often discover a pharmacy within a pharmacy within a pharmacy—not just a bag of drugs, but a whole cabinet of medications," says Goldsmith, who says that a person who is 78 years old may have as many as 100 medications in the home. "We sit down at the dining room table and we go through all these medications with the caregiver, and sometimes we find four beta blockers."

By the time that physicians conclude their initial assessment, Goldsmith says they make sure that patients and caregivers know which drugs to take and which drugs to discard. The physicians also provide direct-access phone numbers that patients can use to contact them should the need arise, and they let the patients know when they will come back for a second visit.

"We will make a number of outreach visits per month, and we do that because we find that the bonding that takes place and the comfort that it renders to the patient has a [positive] impact on health status and utilization of resources," says Goldsmith. Further, when patients have such easy access to their providers, they report problems at an earlier stage, and physicians can employ interventions before there is a crisis (see **Figure 1** below).

Working with community providers

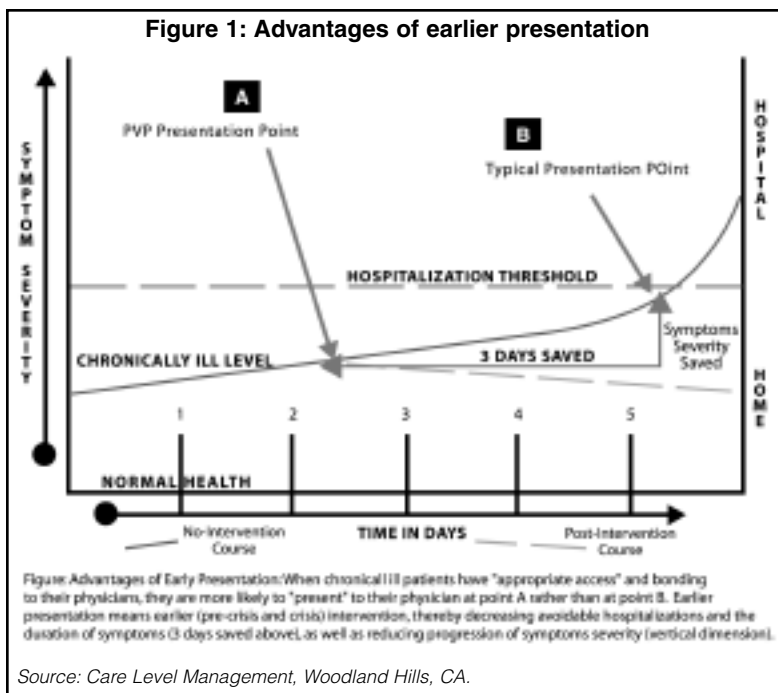
Despite the high-intensity care that the model provides, CLM maintains that it is not intended to replace a patient's PCP. In fact, upon completion of the initial assessment, the PVP faxes all of his or her notes to the patient's PCP, if there is one on record.

However, establishing a good working relationship with the PCP is not always easy, acknowledges Goldsmith. "Much of the time, we have a very good relationship. These physicians, who are caring people, realize they are not seeing these patients anyway, and this is a great help to them," he says. "However, on occasion the relationship is difficult because the physician is puzzled about who we are."

It is a big enough issue that CLM has on staff in each of its locations "community relations managers," whose primary responsibility is to explain the model to community physicians and answer any questions or concerns they may have about the care that CLM provides to their patients. "It is our job to make sure that physicians understand what the [demonstration] project is, and that we are in no way attempting to take away their business," says **Rob Tolle**, a community relations manager based in Tracy, CA. "On all the new enrollments, we attempt to work with the PCP's staff."

Tracking down PCPs

In fact, it is not unusual for patients to make their participation in the model conditional upon their PCP's approval of the approach. Even in these circumstances, however, Tolle notes that tracking down the PCP can be quite a challenge. For example, he is currently in the process of trying to find the PCP of one patient who didn't even have a working phone number for the physician. "I am going to go by the PCP's office and see if he has a working number, and if that



doesn't work, I will try to find out if he has moved to another care model," says Tolle.

Many of the patients selected for the demonstration have not seen their PCPs for a long time, because their illnesses make it difficult for them to get around, he says. "Sometimes these patients are moving in and out of the hospital system, and if they are in a retirement community, sometimes they are moving from level to level."

Tolle notes that when he does make contact with PCPs, he makes sure that they have his phone number, and that they understand that they can call him for information and assistance.

A possible future specialty

In the best of circumstances, PCPs work in collaboration with CLM to care for the patient. Such teamwork becomes essential in situations requiring a high degree of care coordination. For example, when a patient requires hospitalization, the PCP needs to take charge because CLM providers do not have hospital privileges. However, the patient may be able to be discharged early because the CLM provider can provide IV antibiotics, wound care, anticoagulation therapy, and other treatments along these lines in the home setting. "We are expanding all the time the kinds of things that we can do in the home," says Goldsmith. "We view this as a potential specialty in the United States."

CLM physicians typically each care for 100–120 patients. The census depends on the acuity level of the patient population, because patients requiring more intensive care will take up more of the provider's time. However, all of the physicians have the backing of nurses at the home office and at least one community resource manager in their vicinity to assist in carrying out their care plans for patients.

One year into CMS' CMHCB project, administrators at CLM are unaware of the results that the model has generated thus far, but they view the fact that CMS has significantly expanded the number of patients to be included in the project with enthusiasm. "There aren't enough hospitals in this country to take care of what is ahead," says Goldsmith. "We are on to something that is very important." ❖

Editor's note: For more information on CLM and its involvement with the CMS demonstration project, visit the organization's Web site at www.carelevel.com.

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