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Computer algorithms, telemedicine capabilities give clinicians new options

New-age wound care solutions drive improved efficiency, outcomes, and patient satisfaction

High-tech documentation solutions not only free up clinicians to spend more time on patient care, but also assist them in tracking outcomes and targeting quality improvement initiatives. Such innovations take time to work their way into healthcare delivery—in part because they often require fundamental changes for practitioners. However, one area that is ripe for these types of solutions is wound care management, a field that requires mounds of documentation for both clinical and financial reasons. Further, some estimates suggest that wound care accounts for as much as 5% of U.S. healthcare costs.

A handful of innovators are, in fact, already leveraging the power of information technology to improve wound care delivery, and they are beginning to see results. Here, DMA profiles two innovative approaches—one that uses both telemedicine and sophisticated algorithms to deliver evidence-based care, and another that uses

computers to streamline the complicated documentation required in wound care so practices can operate more quickly and efficiently. Both are taking advantage of new technologies to drive clinical and financial outcomes.

Caroline Fife, MD, established a wound center at Houston-based Memorial Hermann Medical Center in 1990, but it wasn't long before she became frustrated by the countless hours she spent on required paperwork that could have been better used for patient care. Just to keep up, Fife woke at 5 a.m. every morning to complete documentation from the day before.

"I would dictate histories and physicals on the hospital dictation system. Then I would dictate letters to the referring physicians, which contained much of the same information—a brief review of the history and treatment plan that I designed. Then I would have to fill out by hand a piece of paper that [an accrediting organization] required that included all of the patients' medical conditions, surgeries, and their medications," she explains. "So I would have just done the same thing, basically, three times."

The paperwork didn't end there. In order to be reimbursed for wound care services, physicians have

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Wound care

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a long, complicated list of items that they must document. And to help patients and families carry out her recommendations appropriately, Fife provides them with a written summary of what has taken place during their consultation and a clear outline of what they need to do to take care of their wounds at home.

It dawned on Fife that there must be a more efficient way to complete these overlapping tasks. "By and large, we only have five diagnoses that we treat, and we do the same kinds of things moment after moment, and the documentation is so repetitive that there was really no excuse for not developing some sort of framework for it," says Fife.

From paper documents to an EMR

This realization ultimately led in 1998 to the first version of Fife's clinical documentation system for wound care, an approach that streamlined all of the required pieces of documentation so the clinician did not have to keep entering the same information into different formats. "You could then just pull pieces like cut and paste, only the computer was doing the cut and paste," says Fife. "I could then automatically generate a letter to the referring physician and give the patient a copy as he [or she] left my office."

Although the early versions of Fife's software offered significant dividends in productivity and efficiency, she eventually decided to get away from paper documents. At this point, she partnered with **David Walker, CHT**, to create the Intellicure Clinical Documentation Software program, an electronic medical record (EMR) designed specifically for wound care.

With the new system, documentation begins when the patient enters the clinic and registers at the front desk. Typically, the front-office staff will enter the patient's demographic and insurance information as well as contact information about the referring physician and any other providers involved with the patient's care.

The EMR is then further enhanced when the patient is taken to the exam room and seen by the nurse. In most wound centers, the nurse will record vital signs, go through what medicines the patient is

taking, and perhaps review symptoms and medical history, documenting each item in the software system using a computer in the exam room.

The system will automatically populate appropriate data entry points based on information that the nurse has entered. For example, if the nurse enters a medication used to treat diabetes—a critical diagnosis in wound care—the software system will automatically document that the patient has diabetes and introduce a series of questions to guide the nurse toward accurate diagnoses and ICD-9 coding (see **Figure 1** on p. 3).

Likewise, the system will automatically select appropriate documentation, depending on what type of wound the clinician designates. For example, if the clinician indicates that the patient has a diabetic foot ulcer, the system will pull up the Wagner grading system—the most commonly used classification system for foot ulcers.

Alternatively, in the case of a pressure ulcer, the system will pull up the staging system recommended by the National Pressure Ulcer Advisory Panel.

In many clinics, the nurse will also measure and photograph the wound using a digital camera attached by cable to the computer. "The picture is archived in relation to the place where the nurse indicates the wound is, so if she said it was on the left lateral ankle, the picture will always relate to [that specific location], and whenever a clinician clicks on 'left lateral ankle' that picture will show up," says Fife.

This feature is critical because many clinics don't document their wound photographs until the end of the day or the next day, Fife says. "A lot of people end up with completely worthless photographs because they later can't identify either who the patient was or what part of the body it was taken on," she says. To further complicate matters, it is common for Fife to see patients presenting with as many as 10 wounds.

Prompts streamline patient evaluation

By the beginning of the physical exam, the patient's record is often already populated with all of the basic information, but the physician will continue to enhance or amend these findings as appropriate. Further, the system will provide additional prompts so the physician can quickly

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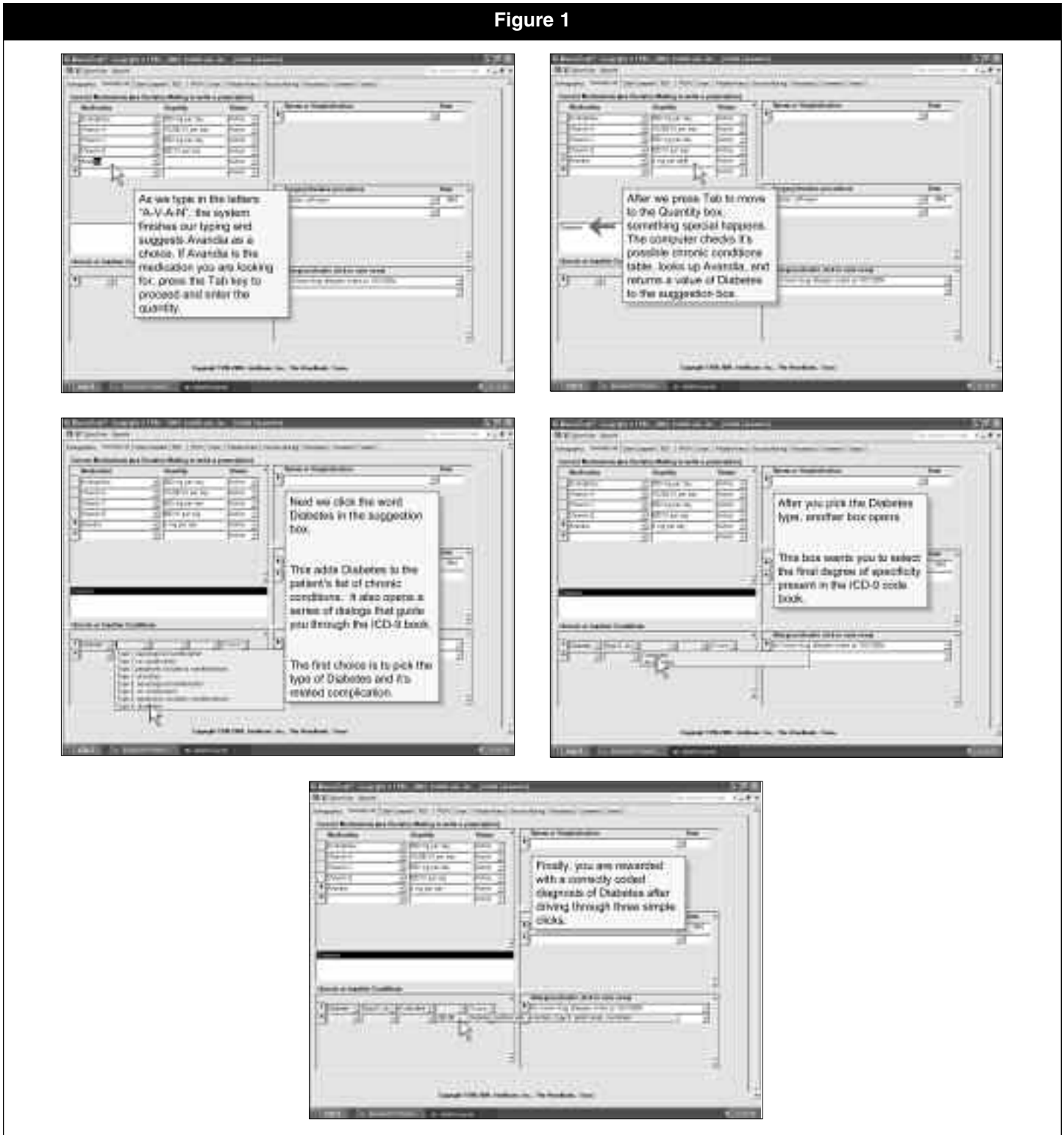
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- order additional tests or procedures
- denote reasons for ordered tests or procedures so they are appropriately coded
- create home nursing orders
- make referrals to other specialists
- write new prescriptions
- select patient education material

When the physician clicks the print button, the system automatically generates the patient's history and physical, referrals, orders, prescriptions, and any other materials that the physician has selected, thereby bypassing the need for additional paperwork.

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Figure 1



Wound care

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Although improvements in efficiency have been easy to document with the Intellicure system, developers have not yet studied the approach's effect on wound healing rates. However, such evaluations are planned when the next iteration of the software is unveiled, as it will include an array of clinical suggestions for the provider based on nationally accepted clinical guidelines.

In addition to providing decision support functions, providers will be able to find the basis or research behind each clinical suggestion, Fife says. "The clinician will be able to go through the recommendations, click on the ones that are appropriate, and then they will populate the appropriate fields for orders, labs, and testing. Further, physicians will receive report cards indicating the frequency with which they have followed the clinical suggestions, she adds.

Another feature that will be added to the software alerts clinicians when wounds they are treating have not healed as quickly as they should. This feature is possible because of the wealth of data that Intellicure has collected thus far on wound healing trajectories. Fife believes that the warnings are important because they offer the clinician a timely reminder that he or she is not meeting the target, and that it may be time to try revascularization or another treatment modality.

It will not be easy to measure the precise clinical impact of the new decision support functions. However, they may well shorten healing times by decreasing time delays for critical tests and procedures, Fife says. "We would like to think that the clinical suggestions will front-load all of the important tests and then push people through to whatever their management plan should be at a quicker pace."

Consistency is a problem

Recognizing that elderly diabetic patients are particularly susceptible to wounds and related complications, Hollywood, FL-based Wound Technology Network (WTN) has devised a system that combines telemedicine support with in-person consultation for every patient encounter. This approach makes it easier to treat patients who have difficulty getting around, as well as those who reside in nursing homes or assisted living facilities. The company maintains that it has been able to drastically reduce patient care costs for the health plans with which it works.

WTN was established in 1999 by **Jeffrey Galitz, MD**, its current chief medical officer and CEO. At the time, Galitz had other business interests that included

providing podiatric services to patients in nursing homes, and he was frustrated with the level of care that the clinicians were providing. "We were having issues concerning getting the doctors and the clinicians to do what was proper in a consistent manner," he says. "Even with sophisticated documentation systems, we still weren't achieving the levels of care that we wanted to."

Galitz concluded that a system that incorporated telemedicine, artificial intelligence, and in-person care would be able to deliver the kind of consistency he wanted to see. And he believes that is exactly what he achieved with WTN. "Now, we are able to ensure that wherever the patient is—in a nursing home, assisted living facility, home health, or in a clinic setting—he [or she] is provided the same level care [as every other patient], based on evidence-based guidelines," he says, noting that the system is equipped with triple redundancy. "Every single visit is a consultation involving two people and a computer system figuring out the best way to treat this person."

Computer-based algorithms guide care

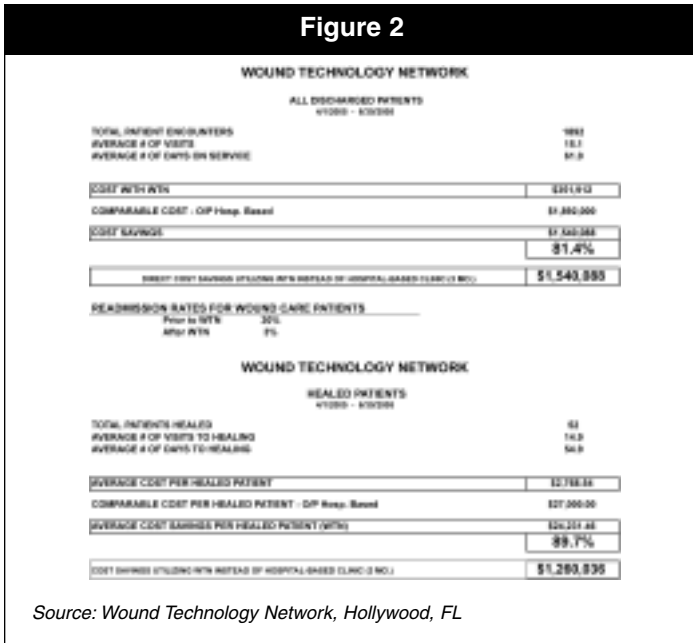
When a patient is referred to WTN for care, a patient care coordinator immediately begins gathering data and making arrangements for the first patient visit, which can take place in a clinic setting or in the patient's residence. WTN's field clinicians are typically nurse practitioners, physicians, or physician assistants who have been certified in wound care.

When the field clinician arrives for the patient encounter, he or she uses a portable computer to set up a live encounter with another specialist at WTN's call center. At this point, the call center specialist will go through the long series of questions required in wound care, entering the answers into a sophisticated computer database. Additionally, the in-person clinician will photograph the wound using a camera that is attached to the computer. "The computer system will instantly generate a report with charts, graphs, and an individual photograph that is instantly faxed to the PCP's office," says Galitz. "If the PCP has any questions, he [or she] can contact the clinician while still at the patient's bedside."

The plan of care—as stipulated in the computer-generated report—can then be carried out through subsequent encounters and in consultation with the PCP. Galitz emphasizes that WTN clinicians will continue treating the patient until the wound heals. "On a weekly basis, we are recording 250,000 points of wound care data," he says. "On average we lower costs by 80%, and we reduce hospitalizations by 95%."

As with Intellicure's system, WTN's computerized data collection process facilitates the tracking of

Figure 2



utilization and costs. Consequently, WTN can provide its health plan customers with quarterly reports

outlining its performance on a range of clinical and financial measures (see Figure 2 at left). "We sit on the world's largest wound care database right now, and are able to get a lot more data than we ever thought we would," says Galitz. "It gives us the ability to analyze why people are healing and why they are not healing. It gives us, really, total control."

In fact, Galitz believes his "triple redundancy" approach has the potential to also improve care consistency, and adherence to evidence-based care for other chronic diseases as well. Consequently, the company is in the process of rolling out new programs focused on hypertension, diabetes, and CHF, and there may be additional programs to follow. "We are saving money, we have improved outcomes, and our patients are happier," says Galitz. ♦

Editor's note: For more information on Intellicure, visit the organization's Web site at www.intellicure.com. Information on Wound Technology Network can be accessed at www.woundtech.net.

QI needs to target identified gaps in recommended care

Opportunities for improvement abound in the care of obstructive lung diseases

Amid fresh evidence that the quality of care provided to people with obstructive lung diseases such as asthma and chronic obstructive pulmonary disease (COPD) is inadequate,¹ the medical community has made new calls for system-level changes that could help providers with the dizzying number of tests and procedures that national guidelines recommend.

The help is certainly needed. Not only is quality of life at stake for the patients and families affected by these illnesses, but the complications associated with inadequate care cost the country dearly: More than \$50 billion is spent annually on COPD-related complications with an additional \$50 billion spent on indirect costs, according to the Centers for Disease Control and Prevention.

If there is good news, it is that some experts believe that chronic conditions such as COPD are beginning to receive the attention they deserve from healthcare organizations and providers. Further, there is now a solid base of research to rely upon when making treatment decisions. What still needs work is dissemination of best-practice information and new ideas on how to translate this information into clinical practice.

Intriguing findings

The latest research about the care provided to patients with COPD and asthma comes from a RAND Corporation study published in the December 2006 *CHEST*, which suggests that patients receive only 55% of recommended care (see Figure 1 on p. 6). It's a disturbing figure, but not particularly surprising, according to Richard Mularski, MD, MSHS, FCCP, the lead author of the study and a clinical investigator at Kaiser Permanente's Center for Health Research in Oakland, CA. "These deficits are not different than what we find in nearly every other chronic condition, with the amount of [recommended] care that Americans receive for disease management somewhere in the mid-50s," he says.

More intriguing, however, are differences investigators found between the care provided to patients with asthma versus COPD. For example, although investigators found that routine care of asthma was quite good, fewer than 50% of patients with exacerbations from the disease received recommended interventions. However, in the case of COPD, investigators observed the opposite: Care providers were doing a good job of treating exacerbations of COPD according to recommended care, but adherence to routine management was only 46%.

Mularski speculates that one reason why routine

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Improvement opportunities

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care of asthma has improved in recent years may be because the disease has received high-profile attention by researchers, healthcare organizations, and parents. “For 20 years, the [United States] has worked though a number of mechanisms to improve the routine care of asthma,” he says. “We haven’t seen any targeted efforts with regard to COPD—at least not up to this point.”

Guidelines reflect scientific evidence

One organization that is attempting to change this picture—not just in the United States, but worldwide—is the Global Initiative for Chronic Obstructive Lung Disease (GOLD). In fact, the group has just unveiled updated clinical guidelines for the diagnosis, management, and prevention of COPD, and it is taking steps to make clinicians aware of new changes in the recommendations and to assist them in translating those changes into practice.²

A new concept reflected in the updated guidelines

is the elimination of the “at risk” category from the spirometric classification system of disease severity for COPD outlined in the first GOLD guidelines, published in 2001. This was done because investigators found no scientific evidence that people who have symptoms of COPD actually go on to develop the disease. “The concept is that before you even start thinking ‘COPD’ [the patient] probably should have some sort of alteration in lung function,” says **Suzanne Hurd, PhD**, GOLD’s scientific director. “If you have a patient who is a smoker and he [or she] is coughing, that is not normal. And you should at least consider that this is a patient you should follow. But we are not saying this patient has COPD.”

The amended spirometric classification of disease severity outlined in the guidelines includes four stages, ranging from mild to very severe.

Comorbidities are important

The guidelines also emphasize—more strongly than in their first iteration—that providers need to pay close attention to treating the whole patient and not just the COPD. “Throughout the report, we recognize that when

Figure 1

*Quality of Health Care Delivered for Obstructive Lung Disease Patients**

Process Indicator	All Obstructive Lung Disease Care, 4,058 Eligible Events	Asthma Care, 2,394 Eligible Events	COPD Care, 1,664 Eligible Events
Overall	55.2 (51.2–59.1)	53.5 (49.8–57.3)	58.0 (51.7–64.3)
Sensitivity subset†	52.0 (48.7–55.2)	51.4 (48.5–54.0)	53.1 (46.3–60.0)
Type of care			
Routine	61.9 (57.6–66.2)	66.9 (62.7–71.1)	46.1 (36.8–55.3)
Exacerbation	52.9 (47.7–58.1)	47.8 (41.4–54.1)	60.4 (53.8–67.0)
Mode of care‡			
History	41.4 (36.7–46.1)	33.8 (29.7–37.8)	51.6 (43.6–59.7)
Physical examination	80.2 (75.7–84.8)	90.4 (86.0–94.9)	75.1 (68.1–82.0)
Immunization	60.9 (52.3–69.5)	60.9 (52.3–69.5)	No indicator data
Laboratory/radiology	40.1 (36.5–53.6)	40.1 (25.9–54.4)	39.8 (24.1–55.5)
Medication	77.7 (72.3–83.1)	81.4 (76.4–86.5)	56.4 (45.8–67.1)
Encounter	29.0 (19.5–38.5)	11.2 (1.7–20.6)	43.5 (32.0–55.0)
Function§			
Diagnosis	59.0 (52.3–65.6)	34.4 (22.6–46.3)	60.3 (53.5–67.1)
Treatment	54.0 (49.9–58.0)	54.5 (50.3–58.8)	47.9 (40.0–55.9)

*Data are presented as unadjusted % of recommended care delivered (95% CI).

†Sensitivity analysis was done with subsets of quality indicators that are consistent with the Global Initiative for Chronic Obstructive Lung Disease and American Thoracic Society/European Respiratory Society Task Force guidelines for evaluation of COPD care and the National Asthma Education and Prevention Program (National Heart, Lung, and Blood Institute) guidelines for the diagnosis and management of asthma 1997 report and the 2002 update for evaluation of asthma care (details in Supplemental Web-based Table 1). Quality rates are not different than the unrestricted analysis at the $\alpha=0.05$ level.

‡Mode of care categorization of indicators refers to predominant aspects of care delivery as follows: history as documentation of prior aspects of care or disease, physical examination as objective evaluation, immunization as provision of vaccine, laboratory/radiology as ordered evaluation, medication as prescriptions, or encounter as specific response to needed care indicated at a specific care interaction; further details are available at: http://www.rand.org/health/mcglynn_appa.pdf.

§Function of care categorization refers to indicators that evaluate for recommended diagnostic interventions (diagnosis) or evaluate for provision of a recommended therapy (treatment); further details are available at: http://www.rand.org/health/mcglynn_appa.pdf.

Source: Mularski R, Asch S, Shrank W, et al. “The Quality of Obstructive Lung Disease Care for Adults in the United States as Measured by Adherence to Recommended Processes.” CHEST 2006; 130:1844–1850.

providers are treating COPD or thinking about COPD, they should also be very aware of all of the other extra systemic effects—the comorbid conditions,” says Hurd. “There is even some indication that people with COPD may be at increased risk for some of these other diseases such as heart disease and osteoporosis.”

Further, in a slight modification of the definition of COPD outlined in the guidelines, the terms “preventable” and “treatable” have been added in an effort to stress to providers that there are options to prevent and treat this disease.

However, because cigarette smoking is the primary cause of the disease in this country, there has always been a tendency among providers to blame the patient. “That attitude and way of thinking has prevailed for many, many years, and so that may explain why even today some PCPs, who are very busy people—they have between five and 10 minutes for every patient they see—do not pay the attention they should to this condition,” says **Claude Lenfant, MD**, former director of the National Heart, Lung, and Blood Institute.

In general, however, Lenfant and Mularski agree that the chief underlying reasons for poor adherence to recommended care are not related to providers, but to system failures. “Especially for many of these routine diagnostics that might be recommended, you really need to change the way that healthcare is delivered in this country and come up with systems that approach this through a multidisciplinary focus—and not rely on individual providers to try and remember to do everything within a busy 15-minute visit, but rather to have many of these things happen automatically, like we see in the airline industry, for example,” says Mularski.

Reimbursement changes needed

The deployment of electronic medical records and decision-support technology should ultimately close

some of these gaps. But Hurd emphasizes that changes in reimbursement policies are needed as well. “There is a lot of interest in trying to get payers to [reimburse] for rehabilitation for COPD as well as to pay for smoking cessation, neither of which are well covered,” she says. “Until someone pays for those kinds of things, it is going to be very difficult for physicians to encourage active participation in well-established programs that can help patients—especially those early in the course of their disease.”

A second issue that needs much attention—is in terms of reimbursement and provider training—is lung function testing. Hurd says that physicians and medical students need to understand the importance of lung function in a medical examination. “This is woefully poor in this country, and that in many ways depends on not only who is going to pay for doing the test, but also on [who is going to pay] for interpreting the results,” she adds.


Despite the many problems that clearly need to be addressed, Lenfant is optimistic about the prospects for quality improvement (QI) in COPD care. “We are in the middle of an evolutionary period here, which is eventually going to do a lot of good for patients,” he says. “And my prediction is that in five years, we will have a very different picture of this condition.” ♦

Reference

¹Mularski R, Asch S, Shrank W, et al. “The Quality of Obstructive Lung Disease Care for Adults in the United States as Measured by Adherence to Recommended Processes.” *CHEST* 2006; 130: 1844–1850.

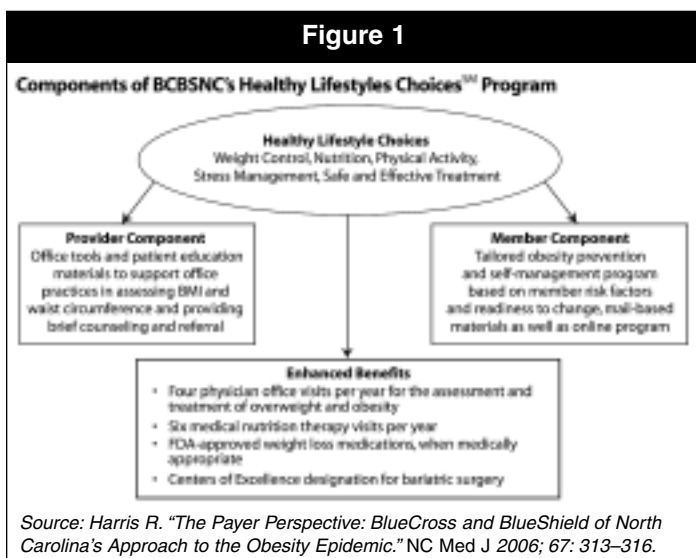
²*Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease*. Copyright 2006 MCR Vision, Inc.

Editor’s note: The GOLD clinical guidelines for COPD can be accessed at www.goldcopd.org.

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New approaches and unique partnerships take on childhood obesity

There is little doubt that healthcare policy-makers and providers understand the growing threat that obesity poses to the nation's health. Numerous studies point out that healthcare costs are roughly 30% higher in overweight individuals, and excess pounds are a key risk factor for many chronic diseases including diabetes, hypertension, cardiovascular disease, and some cancers.



Despite the compelling data, however, payers have been reluctant to take on obesity with funding or interventions because of the scant evidence showing any treatment strategy—short of surgical intervention—would succeed. Fortunately though, a few pioneering organizations have begun to develop the kind of comprehensive approach that many experts maintain is essential to fighting a stubborn problem that requires fundamental alterations in lifestyle.

In fact, given that preventing obesity or excess weight offers tremendous advantages over the long term, a number of organizations are now attempting to tackle the issue in children. Although working with the pediatric population poses unique challenges, many experts believe that addressing the problem at this early stage offers the best chance of achieving meaningful behavior change.

Data prompt action

Armed with data showing that one-third of its covered pediatric population is overweight or at risk for becoming overweight, BlueCross and BlueShield of

North Carolina (BCBSNC) has unveiled a pilot program that it hopes will provide families and children with the information and resources they need to move toward healthier eating habits, higher activity levels, and more appropriate body mass indexes.

The approach is modeled after BCBSNC's Healthy Lifestyle's Choices™ Program for adult members, which was launched in 2004. The adult program incorporated new tools for providers to discuss weight management with patients, six nutritional therapy visits per year for patients, and mail-based/online program materials for patients (see **Figure 1** at left). Patient-reported data suggest that the multipronged design is effective. According to surveys conducted before program implementation and at six months following enrollment,

- 47% of participants who indicated that they wanted to lose weight lost an average of 9.5 lbs
- 83% of participants with either stage 1 hypertension or prehypertension moved to a lower-severity hypertension category
- 46% of participants reported an increase in days of exercise
- 90% of participants reported being satisfied or very satisfied with the program

More rigorous measurement of clinical and financial outcomes is planned, but the early data were enough to convince BCBSNC that a pediatric program equipped with the same types of education and interventions—modified as appropriate for families and children—made good sense.

Program begins with education

Beginning in January, the first of 500–700 families will be invited to participate in the pilot effort. These will include the families of children who have been diagnosed with asthma or diabetes as well as those who have expressed interest via survey in participating in the program. These families will be invited to complete an enrollment survey that enables program administrators to collect baseline data for later use to gauge participants' progress.

Families that complete and return the survey will then receive a series of educational mailings designed to help families make appropriate changes in their nutritional habits and look at healthy ways to increase physical activity. For example, every family that returns the survey will receive a "health organizer" that includes food and activity trackers, guidance on how to use them, and information on how to communicate effectively with providers.

"Subsequently, in the second mailing, we will get

Figure 2

Prevalence of obesity in the U.S. and implications for Arkansas

BMI \geq 30 or ~ 30 lbs overweight for 5'4" person



Source: Behavioral Risk Factor Surveillance System (BRFSS), CDC, 2004.

more specific about physical activity and nutrition," says Dawn Porter, MPH, the program innovation manager at BCBSNC. Further, recognizing that there are vast differences between toddlers and 16-year-olds, Porter explains that the materials have been designed for three age groupings: two to four-year-olds, five- to 11-year-olds, and 12–17-year-olds.

A third mailing, which is also organized by age group, will include additional information and tools focused on nutrition and physical activity. This mailing will be followed by an evaluation survey for the family to complete, offering their insights on the effectiveness of the program.

In addition, families will have the option to work with a telephonic health coach. "The health coach will assess their readiness to change and what the person's needs are in order to go to the next step," says Porter. "And then [he or she] will provide ongoing support—as much or as little support as the family needs, whether that involves just one or two phone calls or several more intensive calls."

This is one area in which the pediatric program differs from the adult program, because the health coach will often be working with a parent as opposed to the child or some combination of the two. "It is hard to have a template for everybody because it is going to be different, case by case, depending on what the complicating issues may be," says Porter, adding that the health coaches are all registered nurses, but there are also nutritionists on staff for consultation as needed.

Additionally, although pediatricians are not involved with the health coaches or the program materials, they receive the same types of benefits and materials that are incorporated into the Healthy Lifestyle Changes program for adults. These include

- physician toolkits that include support tools and guidance that clinicians can use to address issues

related to weight management in their practice

- the ability to refer patients to up to six visits per year with a nutritionist
- reimbursement for an office visit related to the diagnosis of obesity

The pediatric program is just beginning its pilot phase, but Porter emphasizes that BCBSNC plans to move quickly to evaluate the program, make any needed changes, and make it available to the health plan's larger population as early as 2008.

PHS designs community-based program

Also shifting into high gear this month is a unique effort in Arkansas. The state is working with New York City-based Pfizer Health Solutions (PHS) on a community-based initiative that developers hope will show promise in reversing, or at least slowing down, the escalating incidence of obesity and its associated costs. Statistics from the Centers for Disease Control and Prevention suggest that obesity rates are particularly high in a handful of states including Arkansas, and Governor Mike Huckabee—who has publicly dropped more than 110 lbs through difficult lifestyle changes—has made tackling the problem a top priority of the state (see Figure 2, above).

The approach, dubbed "Balance it Out: Arkansas," was designed by PHS, but will be implemented in partnership with various state agencies, including Medicaid and an advocacy group called Arkansas Advocates for Children and Families. "We will work first through the school systems and then very quickly thereafter through the families to not only prevent disease, but also to help educate and work with those who have disease today so they don't exacerbate and develop more complications

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Pediatric obesity

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down the road," says John Sory, vice president of PHS.

The effort began in late 2006 with PHS conducting a series of health screenings with Arkansas' Department of Education to gain insight about the underlying risk factors for obesity and to identify individuals at risk so they can be brought into the health system for intervention. However, the larger effort begins in January and is concentrated on children and families within three primary school districts.

Program administrators are conducting both school- and community-based health screenings and behavior assessments so more intensive interventions can be directed toward at-risk families. "For those who need more support—we estimate about 300 Medicaid families with chronic illnesses—they will receive not only prevention and wellness education, but also health coaching to really work on their chronic care needs," says Sory.

The program is designed to curb obesity, but Sory says the conversation with families is always focused on what steps they can take to improve their overall health. "Then you begin to tailor the intervention specifically to the family environment and the individual," he says. "These are three very distinct communities in Arkansas, so like any good care management program, the interventions are going to be specific to the person, making sure that we speak to people in their language."

Sory underscores the point that the program is community-based—involving nurses, care managers, health coaches, and educational materials that are all supplied through Arkansas. "We are working with partners there who are on the ground. These are community health workers who understand how to go into a person's home, identify local resources, and help make them see and understand the steps that they can take because the [health workers] are right there with the person," he says.

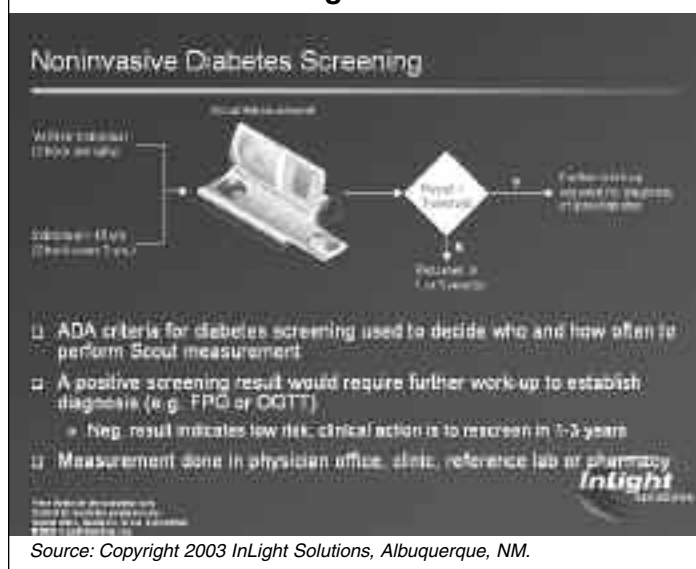
For the time being, the Arkansas program is a three-year initiative limited to three districts, but PHS hopes to produce positive interim results within the year. Sory anticipates that the approach will be expanded to include the entire state. "One of the reasons Medicaid is our partner here is we have claims information that comes through the Medicaid system, so for those patients whose medical costs are covered by Medicaid, we will be able to track their claims information and see if this intervention actually helped to improve their health and reduce their overall costs," says Sory. "We believe strongly that the total cost will be reduced and that risk will be reduced, and access to that claims information will really be able to tell the story." ♦

Simple-to-use, desktop device offers intriguing possibilities

Noninvasive approach to diabetes screening and monitoring shows promise

Diabetes is epidemic in this country, and healthcare professionals understand that early diagnosis and treatment offer the best hope for preventing the costs and debilitating complications associated with the disease. And yet only about one in five Americans at high risk for developing diabetes is screened for the disease each year.

Figure 1



Part of the problem is that the most commonly used screening method, fasting plasma glucose (FPG), requires an overnight fast and an invasive venous blood draw. And data suggest that it misses roughly half of all undiagnosed diabetics. Consequently, even though providers are well aware that huge numbers of diabetics remain undiagnosed, inconvenient and imperfect screening methods continue to stand in the way of improved care.

However there may soon be an alternative screening method available that is both noninvasive and highly sensitive. Early data suggest that a device made by Albuquerque, NM-based VeraLight, Inc., is able to outperform both the FPG and HbA1c tests in terms of accurately identifying diabetic patients. Additionally, there are indications that the test is also sensitive enough to pick up patients with prediabetes. More extensive clinical studies are planned, and the device—called Scout™—has yet to be FDA approved, but it is generating interest among clinicians and researchers who are keenly aware of the limitations presented by conventional testing procedures.

Scout offers a wealth of information

The Scout instrument employs fluorescence spec-

troscopy to measure advanced glycation endproducts (AGE) in the dermis of a person's forearm. This provides a wealth of information, because the concentration of AGEs in the skin is an indicator of cumulative hyperglycemic exposure and is, therefore, highly correlated with the development of diabetes complications.

"When you are looking at how skin reacts to light, the light as a function of wavelength can be absorbed, scattered, or generate fluorescence in the skin," explains **John Maynard**, VeraLight's vice president of product development. "That wavelength dependence—the amount of light that is returned—actually contains information that is useful in discerning the different chemicals in the skin, so we use the chemical information that is encoded in the light that we detect to then tell whether someone is at risk of prediabetes or diabetes."

The test is simple to perform, requiring less than a minute to carry out. To undergo testing, a person places the palm side of his or her forearm onto the device, which then shines various wavelengths of light onto the skin. This causes the AGEs to emit a fluorescent light signature, indicating diabetic risk. Clinicians can then immediately interpret the result that is indicated by a number that appears on the device's screen, which can also be printed out.

"We have, essentially, a baseline for a person at normal health at a given age. And we look at the measurement of a particular individual to see whether it is consistent with the normal population or is progressing away from that line of normalcy toward prediabetes or diabetes," Maynard says.

Research presented at the World Diabetes Congress of the International Diabetes Federation in Capetown, South Africa, in December 2006, showed that a prototype Scout system device outperformed both FPG testing and HbA1c testing in head-to-head evaluations of 351 people at risk for diabetes or prediabetes. Investigators report that the Scout system was able to identify 30% more people than FPG testing and 17% more people than HbA1c testing. "What we used as our determination of truth was the two-hour oral glucose tolerance test," says Maynard. "We were able to show that our test agreed much more [than the other testing procedures] with the oral glucose tolerance test, which is the gold standard for diabetes screening and diagnosis."

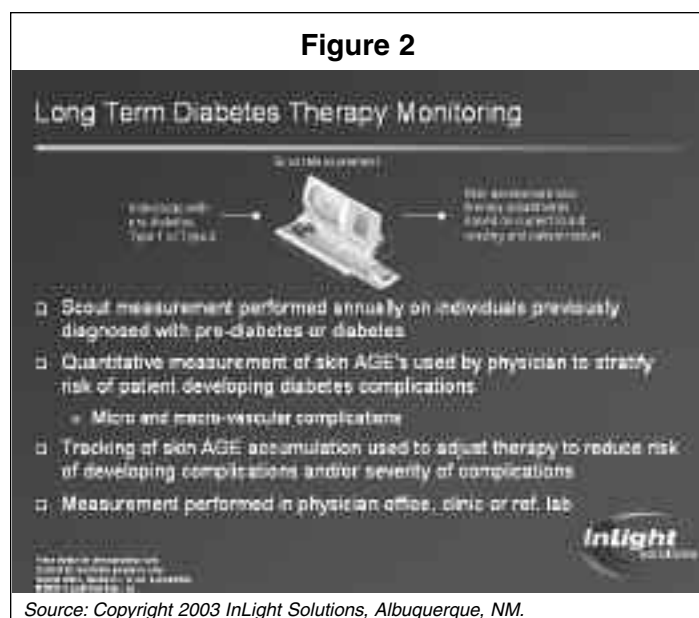
VeraLight is now gearing up for a much larger clinical study so that it can collect data to submit to the FDA for approval of the device. The company anticipates being able to present findings to the FDA in late 2007, and with the FDA's approval, to be able to make the Scout system available to the marketplace by 2008.

Initially, the company envisions the screening device being used to screen people according to guidelines

established by the American Diabetes Association (see **Figure 1** on p. 10). By those criteria, most of the people referred for screening would be age 45 or older and have one or more of the following risk factors for the disease:

- A family history of type 2 diabetes
- Overweight
- A lipid disorder
- Hypertension
- A history of CVD

For women, the list of risk factors also includes a history of gestational diabetes or polycystic ovary syndrome, or having a baby that weighs more than nine lbs. "The main reason you would use [the Scout system's] test is because it is more sensitive," says Maynard. "You are more likely to pick up someone in the early stages of the disease."



In addition to annual screening for people with risk factors for diabetes, Maynard suggests that the Scout system also has an early application for long-term diabetes monitoring. By tracking AGE accumulation, clinicians could make better decisions about risk stratification and therapy adjustments (see **Figure 2** above).

Reimbursement will take time

Infrared or fluorescent-based technologies have a somewhat patchy record in the diabetes field, according to **Bruce Buckingham, MD**, a pediatric endocrinologist and associate professor at Stanford University in Palo Alto, CA. However, he is intrigued by the Scout system, and believes that it could offer valuable information to both researchers and clinicians. "One blood sugar doesn't tell you much, and an HbA1c test gives you several

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Diabetes screening

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months of data, but it often takes 10 years of elevated glucose levels to get complications," he says. "So the skin may be a better measure because it is a better long-term marker [of the accumulated damage]."

By having a window into what is happening at the tissue level, Buckingham suggests that clinicians could do a better job making treatment decisions. Additionally, as a simple screening tool, Buckingham could see the device being applied in public health screenings, clinicians' offices, and even pharmacies. "I don't think people would consider it as a gold standard because they don't have that much experience with it, but it might be something that could be used as a front-line, noninvasive, relatively simple initial screen."

That, in fact, is exactly how **Donald Moore, MD**, would like to use the device if clinical testing ultimately proves that the approach is valid. Moore is a provider with Western Rockingham Family Practice in Madison, NC, and has been watching development of the technology. "Being able to screen for diabetes in an easy way without having [to use needles] would be an incredible advantage," says Moore, noting that he sees patients with undiagnosed diabetes all of the time. "We have an industrial nurse, and we are always doing health fairs, so I can really see it as very beneficial in helping to diagnose diabetes at an earlier stage and getting people in to be treated and educated."

However, Moore says that winning provider buy-in to the approach will be a tough hurdle. "If providers see the numbers are going to compare favorably [with conventional testing], and maybe even pick up new people in a more sensitive way . . . then I think physicians will buy into it, but the real bottom line is getting reimbursement for doing the test."

Anticipating that reimbursement will take time, Maynard suggests that the first applications of the Scout system will likely be in private pay settings. However, he says that potential application of the device is huge. "There is a large number of people with undiagnosed diabetes, and there is an even bigger group of people who have prediabetes," he says. "If you want to shift the care model from treating the symptoms and complications to preventive medicine—which is what we are going to have to do with diabetes because we just won't be able to afford it—then you want to pick up people in the prediabetes stage." ❖

Editor's note: For more information about VeraLight or the Scout screening system, visit the company's Web site at www.veralight.com.

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