

DM DISEASE MANAGEMENT ADVISOR™

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User-friendly system adaptable to other chronic illnesses

Decision support DM tool boosts hypertension care

No one questions the potential value of technology-based decision support to boost outcomes and promote quality improvement. However, for a variety of reasons, this potential has not been fully realized. Organizational differences, technological limitations, and provider resistance often sabotage attempts to implement these modern day DM tools. However, when steps are taken to adequately address each of these issues, the chances for success are enhanced.

That, at least, has been the experience of an innovative group based at the VA Palo Alto Health System in California. Working with partners from Stanford Medical Informatics, the group has developed an automated decision-support system designed to prompt providers with evidence-based recommendations for the treatment of hypertension at the point of care.

Called ATHENA (Assessment and Treatment of Hypertension: Evidence-based Automation), the system is designed to work in primary care settings that use an electronic medical record (EMR), and early studies suggest the approach can not only improve evidence-based prescribing for hypertension, but may also offer similar benefits when the system is adapted for use with other chronic conditions.

Inside This Month...

- **As demand for programming grows, obesity DM diversifies.** *With weight-related chronic disease eating up huge chunks of corporate profits, employers and health plans are clamoring for programs that can help people shed extra pounds -- and keep them off. As a result, obesity DM is taking the shape of more traditional programs, complete with risk stratification and several layers of intensity Page 76*
- **A DM program for patients on injectable drugs.** *Getting patients to take their medications as directed is always tough, but there are extra barriers to contend with when these drugs must be injected. However, a CA-based PBM has discovered that a program of support designed around the unique concerns of these patients can go a long way toward improving compliance and effectively managing drug costs Page 80*
- **New approach to amputation prevention shows early promise.** *Diabetics are particularly vulnerable to complications that can leave them at risk for amputation. However, experts agree that the vast majority of amputations are, in fact, preventable. Now there is a new laser-assisted procedure available that has shown early success at salvaging the limbs of patients who were not good candidates for alternative limb salvation methods. Not everyone is sold on the approach, but early users are enthusiastic about its potential Page 82*

Keying in on hypertension

Work on the ATHENA project grew out of a strong desire to develop tools and strategies to promote continuous quality improvement, according to **Mary Goldstein**, MD, MS, the clinical director of Geriatrics Research and Education at the VA Palo Alto Health Care System, and a core faculty member at the Center for Health Policy and the Center for Primary Care Outcomes Research at the Stanford School of Medicine. "The reason we started with hypertension is because it is a very highly prevalent problem in adult medical practice, and there are very good guidelines for what is the best management of hypertension," she explains. "It is very important to manage it well because it makes a big difference in patient morbidity."

Despite the wealth of evidence-based guidelines to manage hypertension, however, there is also ample evidence that providers are simply not following those recommendations. "We wanted to

develop something that would be a method of getting information out to physicians at the point in time when they are ... seeing a patient in the office," notes Goldstein. "And we also wanted a system that could be revised pretty easily because there are always new clinical trials coming out, prompting changes in the guidelines. So we didn't want to have a system where there was very complicated programming code that would be difficult to update and maintain in the face of new clinical evidence."

Researchers had good reason to believe that physicians would respond positively to electronic messaging because they had previously investigated physician response to paper-based recommendations. In a randomized clinical trial, they found that the paper-based messages improved prescribing for hypertension in accordance with evidence-based guidelines. Adds Goldstein, "We were very encouraged that if we sent information to the clinicians, there would be some response to it."

Software selection

Early on in the process, Goldstein began looking for a software system that could be adapted for use as a hypertension decision support tool, and this search led to a collaboration with developers at Stanford Medical Informatics (SMI). "They had a knowledge acquisition program that allows you to encode knowledge in a system, and it makes it very easy for users to browse the knowledge, view what is in there, and to update it," she explains. Developers coupled this program with an execution engine/guideline interpreter capable of processing patient data against the knowledge base, then generating recommendations specific to a particular patient. (See Figure 1.)

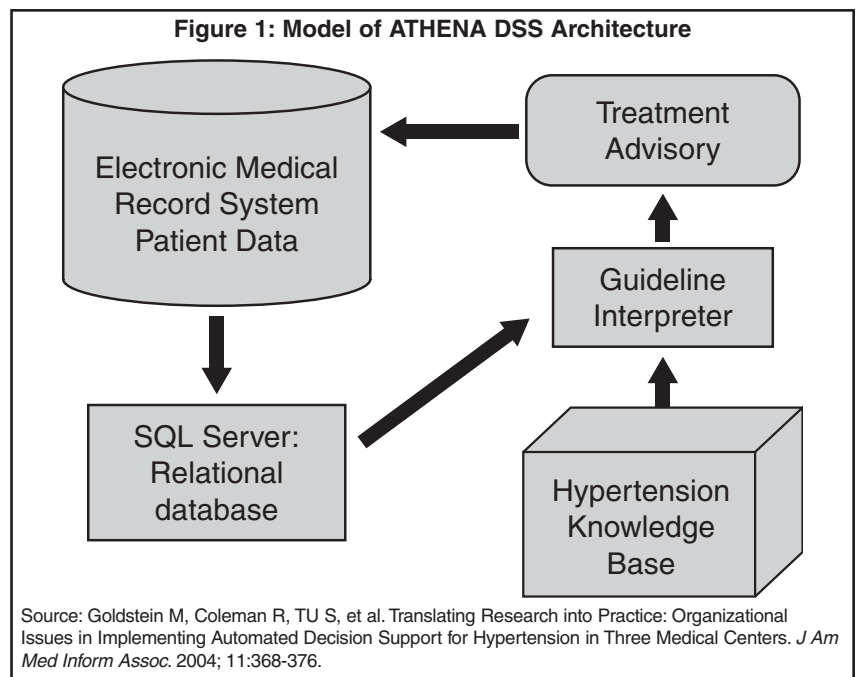
"It takes a patient's current situation in terms of their BP, lab values, diagnoses, and medications, and then it processes the information against what the guidelines say about what should be

done," notes Goldstein. "Then it issues recommendations about what would be the next steps in management for this patient."

Beyond technical matters

Having a system in place that is capable of responding to clinical data is important, but Goldstein stresses that developers spent a considerable amount of time determining how to set up the system so that it would have the best chance of positively impacting provider behavior.¹ For example, they wanted the system to notify physicians when a change in therapy was indicated, but they knew that the recommendations might be ignored if they popped up too frequently at inconvenient times.

"For the purposes of hypertension, we felt the most appropriate time for [the recommendations] to be sent out was when a patient had a previously scheduled office visit ... so we established that as one of the triggers," explains Goldstein. When a physician logs into the computer and selects a patient, if the patient meets the eligibility criteria for having hypertension recommendations sent out, and that patient has a



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previously scheduled office visit, then when the physician opens the cover screen for that patient a little window pops up on the screen that shows him the information. "It will indicate whether the patient's BP is under control according to the target BP established for the patient, and it will display recommendations for what would be the next things to do." (See Figure 2.)

Another issue that developers grappled with was whether they should enable physicians to easily bypass the recommendations, or mandate that they interact with them in order to proceed on to other matters. "We recognized that at some of these patient visits, hypertension was an important priority and perhaps the main reason the patient was there. But for other visits, it was way down on the priority list because the patient had something else that was a much larger concern for them on that day," notes Goldstein. "[Consequently], we decided that if hypertension was not the priority, then we didn't want providers to have to interact with our screen. So we made it very easy for people to bypass it, and we made sure they knew that as part of their training."

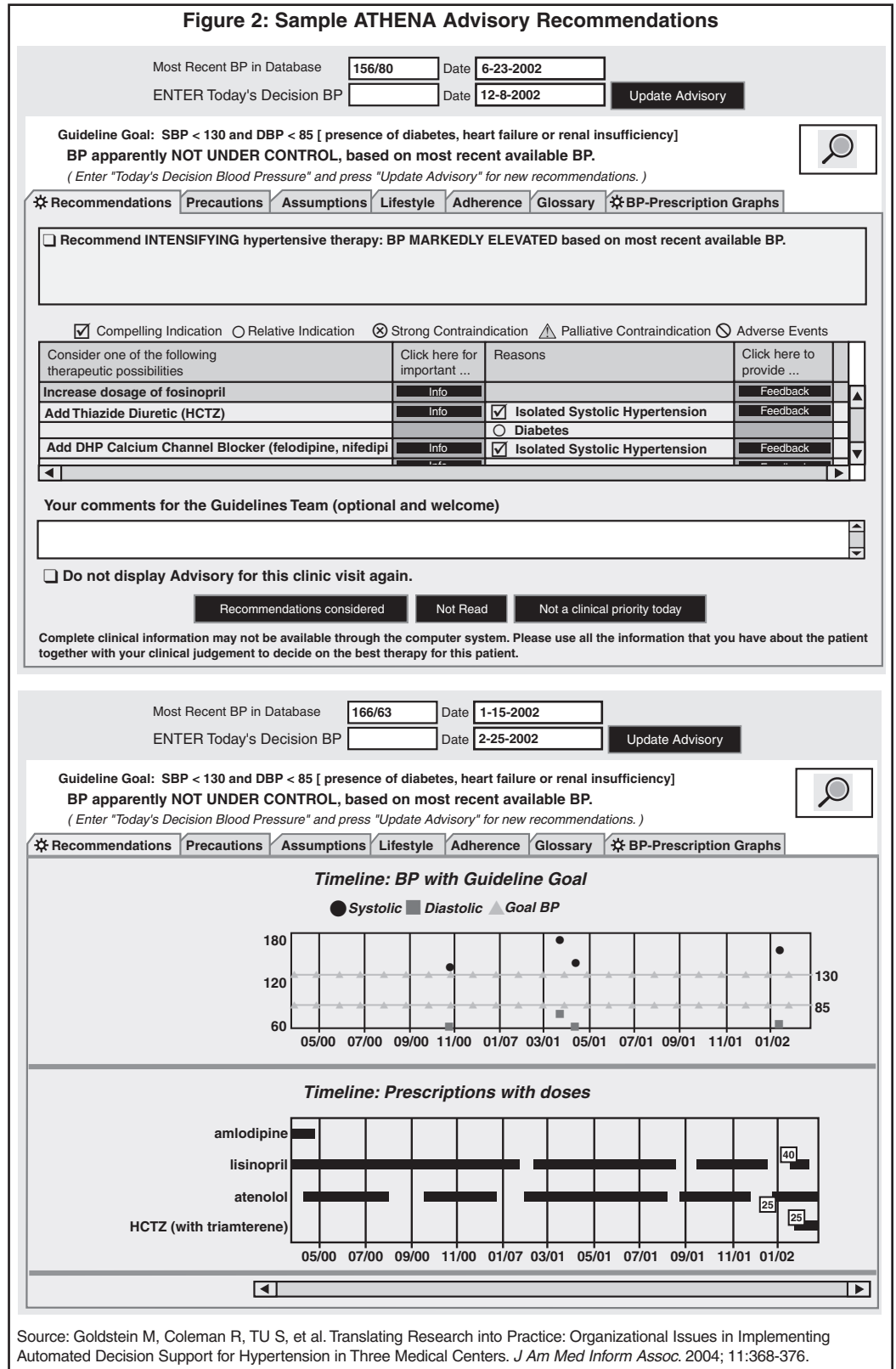
Little training needed

In fact, Goldstein stresses that providers needed very little training in order to understand the system and how to interact with it. When the system was implemented at VA sites in Palo Alto, San Francisco, and Durham, NC as part of a clinical trial, she notes that much of the individual provider training was implemented over the course of a 10-minute telephone call.

"The physician would be in front of his computer and he would see what was happening on the screen, and we would walk them through the system and explain it to them," she says.

The clinical trial, which lasted for 15 months, compared patients managed with the ATHENA system against a control group. The

Figure 2: Sample ATHENA Advisory Recommendations



Source: Goldstein M, Coleman R, TU S, et al. Translating Research into Practice: Organizational Issues in Implementing Automated Decision Support for Hypertension in Three Medical Centers. *J Am Med Inform Assoc.* 2004; 11:368-376.

results have not yet been published, but Goldstein reveals that the system did have a positive impact on clinician adherence to guidelines. "When a patient's BP was above the target BP, clinicians [in the ATHENA group] were more likely to intensify therapy than those in the control group," she says.

This enhanced adherence in the ATHENA group did not translate into improved BP readings in the course of the study period, but Goldstein points out that many of the patients in the study only had one clinic visit after their BP medication was intensified, allowing little time for improvement to be observed.

Researchers have now turned their attention to a much larger study of the ATHENA system that will include five VA medical centers in New England, and several smaller studies are underway utilizing the ATHENA system in different ways. For example, the Durham VA hospital is investigating the impact of putting ATHENA in the hands of a DM nurse rather than a PCP.

"The additional thing we are doing is home monitoring of BP values, which are then transmitted by a modem line into a central server," explains **Eric Oddone**, MD, MHSc, director of the Center for Health Services Research in Primary Care at the Durham VA, and chief of Internal Medicine at Duke University Medical Center. "We are using those home values to trigger ATHENA for recommended changes, and then the nurse implements those with a patient over the telephone. All of this is happening outside the context of the clinic visit ... and we are comparing the approach with usual care."

Oddone emphasizes that all the prescrip-

tion changes are being made under the supervision of a physician advisor, who makes the changes in consultation with the patient's PCP. However, all of this interaction is being done electronically. "The key thing is that these are established patients in a primary care setting," he says. "We wouldn't do this with patients who are just floating in and out of the health care system."

New applications

With the work focused on hypertension well underway, researchers are also now interested in adapting the system so that it can be used to manage patients with chronic pain, chronic kidney disease, diabetes, and other complications related to CVD. Further, while all of the research thus far has occurred within the context of the VA's EMR, Goldstein emphasizes that ATHENA was designed to be highly versatile, and she is looking forward to collaborating with other groups to study ATHENA in the context of different EMR systems.

Ultimately, developers hope to make the power of ATHENA widely available. "We are really committed to not making this a commercial system," stresses Goldstein. "We want this to be carefully studied and then made available through an open source license."

Reference

1. Goldstein M, Coleman R, TU S, et al. Translating Research into Practice: Organizational Issues in Implementing Automated Decision Support for Hypertension in Three Medical Centers. *J Am Med Inform Assoc.* 2004; 11:368-376. ❖

Purchasers clamor for weight management options

Obesity DM begins to take the shape of more traditional programming

Realizing that obesity is behind the alarming increase in diabetes, and that it is a strong contributing factor to many other chronic conditions, health plans and employers are desperate for DM programs that offer some hope of helping people lose excess pounds and adopt healthier lifestyles over the long term.

It's a huge challenge: More than two-thirds of America's adult population is overweight or obese, and nearly one-third of children and adolescents fall into this category. (See **Figure 1 on page 77.**) However, the eco-

nomics case for action has never been stronger. Studies suggest that obesity-related diseases are costing corporations more than \$13 billion annually, a sum that has driven health care expenses to the point where they are eating up more than 50% of corporate profits. (See **Figure 2 on page 77.**)

In light of the substantial demand for programming, obesity DM is quickly beginning to look and operate like more traditional programs, with risk stratification on the front end, layers of programming geared to individuals with different needs, and a strong behavioral health component. Further, health plans and employers are making every effort to engage individuals in wellness initiatives in the hope that preventive steps now will curb weight-related diseases and costs later on.

The patient side of the equation

One of the newest entries into the obesity DM arena, Forward Health, has the backing and resources of Eatontown, NJ-based QMed, its parent company, as it rolls out an assortment of integrated services aimed at helping participants change their behavior, according to **Randall Burt**, president of Forward Health. "QMed has always really focused its DM efforts and its business model on the physician side of the equation," he explains, noting that the company has specialized in arming providers with information to help insure that the treatments they are providing to patients are optimized. "But QMed decided and really embarked upon under-

standing that the physician is only half of the equation.... And one of the things that became clear to the company is that one area no one has addressed very diligently is obesity."

Set to launch in August, the suite of programs being offered under the Forward Health umbrella is designed to address not just weight management, but all of the issues and concerns employers or health plans might have that are impacted by obesity. "That can include back injuries, and the co-morbidities that go along with obesity such as diabetes and hypertension," notes Burt. But he emphasizes that it also includes issues such as absenteeism and productivity, and the company's programming is also

Figure 1: Obesity is Reaching Epidemic Levels in the United States

Percentage of adult Americans who are either overweight or obese today:



Percentage of children and adolescents in the U.S. who are either overweight or obese today:



Source: QMed, Eatontown, NJ.

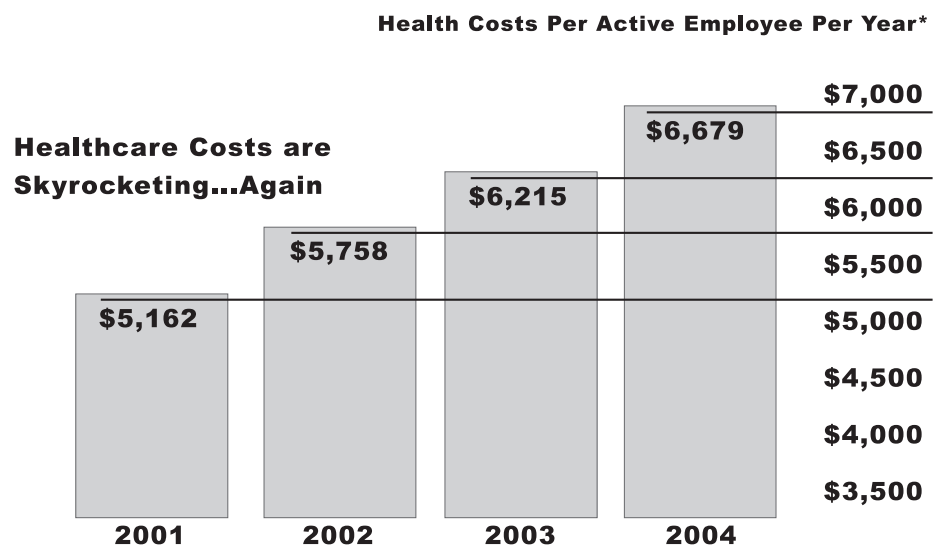
Figure 2: Corporate Healthcare Costs Have Risen by 45% in Just Four Years

Fact:
Cardiovascular Disease
Cost- \$368.4
Billion

Fact:
Type-2 Diabetes
Cost- \$132
Billion

Fact:
Hypertension
Cost-- \$55.5
Billion

Over 50% of corporate profits now go to healthcare costs versus only 7% three decades ago



* Mercer Human Resource Consulting, 2004

(projected 10% increase for 2005)

Source: QMed, Eatontown, NJ.

equipped to help effectively manage the high-cost area of bariatric surgery. "The goal is to either prevent or avoid unnecessary surgery because someone was given an opportunity to be in the program and subsequently lost weight, so by using the program they didn't need the surgery. Or they go through the program for whatever period is appropriate, and we show that they are better prepared for that surgery, and complications are reduced."

Three levels of programming

In many cases, employers and health plans have already identified patients in need of weight-management intervention through their own health risk assessments, but Burt notes that Forward Health can also identify appropriate candidates through its own HRA process, or through claims analysis. Mechanisms can also be built into the program for physician or case management referral, or self-referral.

Client organizations can choose three different levels of programming. A web-only application enables individuals to enter information about their health status and health history, and then gradually build a personalized program that is designed around their interests, health status, and health concerns. For example, there are sections devoted to customized meal planning, education around how to eat outside of the home, exercise videos that are geared to a person's fitness level, and behavioral modules tailored to the data that has been entered into the program. "They actually build a personal health record within their own web site, and that is all put into their personal home page," explains Burt. "Then, every day they click on it and see what their 'to dos' are for the day, they can look at their exercise routine, they can see what is in the learning center, and [they can check on] the meal planning for that day."

Participants can also use tools from their home page to track their accomplishments. For example, a bar graph will illustrate what their weight, blood sugars, or BPs have been over time because they have been entering this data. Adds Burt, "It actually gives them a visual depiction of how they are doing compared against their goal."

Keeping people engaged

The next level of programming includes both the web application and telephonic health coaching with a registered dietitian. Participants in this program receive regularly scheduled guidance in going through the web application and setting reasonable weight and health goals, notes Burt. "The phone sessions last for 10 to 15 minutes every

week or every other week, and the coach will use that time to discuss the participant's progress, address any questions or concerns that have come up, and continue to motivate the individual to stay involved," he says. "We have structured the program to last a minimum of 60 weeks, including 13 weeks of very specific education modules in the learning center that people take on a sequential basis, and an additional 48 weeks that can be taken at the participant's leisure."

Burt emphasizes that there is no fixed length to the program because the goal is to keep people engaged for as long as possible. "We are trying to create not just persistency, but also as people begin to lose weight, we want to give them tools, education, and support to help them maintain those losses."

Biometric data collection

The third layer of programming has been designed to address the needs of severely obese patients. It includes system architecture capable of collecting biometric data including weight, BP, and/or blood glucose via the telephone line. "In most cases, if we are collecting objective data, it does increase compliance and accountability as opposed to relying on self-reported data," notes Burt. "Some people like [this level of programming], and some do not. But the system can do it, and it is available for purchase from groups who want the program to have the ability to collect this data."

Regardless of the level of intensity, the programming includes mechanisms to facilitate physician involvement in cases where participants are interested in having their providers apprised of their progress. Armed with a password, physicians can go into the site and see how their patient is doing; they can communicate with the patient via text messaging; and there is calendaring capability whereby a physician can request that the patient come into the office for a follow-up visit on a specific date.

Set to launch

In pilot tests of the approach, investigators are tracking hard measures such as weight, BP, blood glucose levels, and functional status, but they are also looking at softer parameters including participant satisfaction, web site usage, and readiness to change. Burt anticipates that the company will be able to share outcomes from these early experiences soon.

"Our plans are to pay very close attention to the employer and health plan markets. We have several groups that are waiting for the new roll-out, and we have several we are in discussions

with regarding the possibility of doing new pilots," he says. "We also have our eye on launching in mid to late August initiatives around a direct-to-consumer effort where consumers will be able to sign up for the program and pay for it using their credit card."

Diversity of options

Bannockburn, IL-based MSO Medical has specialized in bariatric surgery for more than a decade, mainly serving patients through centers in the Midwest and on the east coast, but this company has also taken steps to respond to the fast-growing demand for a diversity of DM approaches to weight management. Working with its partner, Austin, TX-based Resources for Living, the organization offers a four-tiered program, with different levels of intensity geared toward patients in different BMI ranges.

The first tier includes a self-directed web-based program that includes health education content, tracking tools, and several different assessments that users can take based on their individual needs and risks. "It's an online toolkit that pulls everything together in one place to allow patients to learn about the complexity of issues that they are addressing," explains **Ashley Karpinski**, MP, LPC, the director of business development at Resources for Living. "The goal is to have robust medical content that individuals can rely on to answer some of their questions."

The next level of intensity includes the web-based program, but also adds telephonic health coaching that has three areas of focus: behavioral, psychosocial, and physical, explains **Patricia Kentgen**, RN, who directs clinical program integration for MSO Medical. "It is not a typical nursing-driven program. It is driven by a combination of Masters-prepared, licensed therapists who are coupled up with registered dietitians," she says. Developers believe this combination of expertise is needed to effectively deal with the complexity of weight loss and obesity.

"Working with participants, we have found that without dealing with emotional distress, as well as family, cultural, and financial issues, people aren't as successful," stresses Karpinski. "The physical part is just as important, but we have what we call wellness coaches who are leading the charge, and making sure that we address psychological and behavioral issues as they come up."

Pre and post surgery

Patients engaged in the second tier program tend to have BMIs in the 25 to 34.9 range, and they are not generally candidates for bariatric

surgery. However, patients engaged in the tier-three level of intensity typically are considering surgical options. "In cases where we use MSO Medical criteria to identify good candidates for surgery, we prefer -- and many health plans require -- that they go through a medically supervised weight-loss program that also has a behavioral component," stresses Karpinski, noting that this is what the tier-three level of intensity provides. "The program ranges from three to six months in length, depending on the insurance requirement. And while we are doing the behavioral coaching, we are helping to facilitate that patients have the proper documentation should they end up as a candidate for surgery when the program concludes."

Patients engaged in tier four are either in the process of getting ready for bariatric surgery, or they are being supported from a case management perspective in the months immediately following surgery. "We do dietary analysis and help people see what their post-surgical lifestyle is going to be like. Additionally, we do psychosocial coaching and work with families in preparation for what the individual will experience when they have lost a substantial amount of weight," explains Karpinski. "There is a full gamut of things we are trying to prepare them for. The surgery is a couple of hours, but the impact on these patients' lives is forever."

Growing demand

While bariatric surgeries are on the increase across the country, MSO Medical is also seeing a growing demand for its non-interventional programs, which are available nationwide. In fact, many organizations do not offer the surgery as a covered benefit, but they are eager to provide their members or employees with a weight-management program.

Karpinski notes that pilot tests of the organization's non-interventional programming suggest it is effective at producing weight loss in the range of 5% to 10% of body weight over six to 10 months, and most of the patients served have been in the severely obese category. She adds, "The goal of the different services is to intervene at all the appropriate places so that people can ultimately get the outcomes they are looking for, regardless of what tier they are in."

Editorial note: For more information about MSO Medical, visit the organization's web site at www.msomedical.com. A new corporate web site will be unveiled soon for Forward Health, but for the time being, those interested can learn more about the program at www.qmedinc.com. ♦

Boost outcomes by tackling tough compliance barriers with patients on injectable drug regimens

Getting patients to take their medications as directed is always an uphill battle, but when these drugs must be injected, there are even more barriers. Instructions on how to take the medications are more involved, the drugs are often more expensive, and when there is pain associated with the injection, patients can be even more reluctant to maintain compliance. However, in many cases involving injectable drugs, compliance is especially critical to effective DM.

For all of these reasons, Irvine, CA-based Prescription Solutions has developed a Specialty Pharmacy Disease Therapy Management (DTM) program designed specifically to address the issues and concerns of patients who are on injectable medications. There is a steadily growing population of individuals who fit this profile, and the related pharmaceutical costs are considerable. Some estimates suggest specialty pharmacy is already a \$40 billion market, and that it will nearly double in size by 2008. Effectively managing these costs is one important aim of the DTM program, but case managers are especially focused on boosting compliance so that optimal clinical outcomes can be achieved.

Filling a need for support

The idea for a Specialty Pharmacy DTM program grew out of the observation that there was a general lack of coordination of programs and services to help patients and their families manage complex illnesses, explains **Susan Davis**, MSN, RN, a case manager at Prescription Solutions. "The cost of specialty pharmacy drugs runs between \$1,000 and \$1,500 per month ... and yet some patients have difficulty completing their treatments because of side-effects [or other issues], so we wanted to provide some support."

Typically, the PBM reaches out to patients as soon as they have been identified as being on an injectable drug. The program includes patients with multiple sclerosis, RSV, hepatitis C, rheumatoid arthritis, and bleeding disorders. All eligible individuals are sent program information that includes an enrollment packet describing the program, provides an overview of their particular disease, and offers information on the drugs they are taking.

"We also let their physician know that we have sent out an enrollment packet, and we give the physician an overview of the program and physician-oriented information about the drugs

the patient is taking," notes Davis. "We then follow up with a phone call to the member to describe the program further and set up an appointment for an initial phone consultation."

The patient takes the lead

A program case manager uses the first consultation with a patient to gather any information pertaining to barriers that may be interfering with compliance. This process typically covers several domains including medical issues, pharmacy issues, psychological problems, environmental or social support concerns, and spiritual issues, emphasizes Davis. "What we do is work on the patient's key issues, so during our conversation we will use an interview guide [that prompts the case manager to cover all the domains of concern], but usually the patient takes the lead in communicating to us what problems they are having."

From this information, the case manager creates a care plan that addresses each of the domains discussed during the consultation with recommendations, strategies, and/or resources the patient can use to deal with side-effects or other barriers that have been interfering with compliance, or could potentially do so. "What we do is recap the interview, so I might say: 'based on our conversation, you mentioned that you were having difficulty obtaining medications. Here are some resources that you could try,'" notes Davis. "Alternatively, someone might be having problems with a bad taste in their mouth -- a problem that seems to affect women more than men. In this case, I might give the person some strategies [to counteract the effect]."

A collaborative process

In many cases, however, resolving an issue requires more than suggested strategies and education. In these instances, the Prescription Solutions case manager obtains the patient's consent to interact with the patient's health plan. "I work pretty closely with case managers [at the health plan] so that they understand why I am making a referral," explains Davis. "I have had patients tell me that they don't have enough to eat, or they cannot get to their doctor appointments, or they cannot get their lab work drawn."

In these instances, the health plan can activate home health services, contact the patient's physician for further guidance, or make appropriate referrals to resolve the situation. "We have an ongoing collaborative process," explains **Catherine Giardina**, BSN, RN, PHN, CCM, a case manager with PacifiCare, a client and sister company to

Prescription Solutions. "Sometimes it is just a matter of their case manager working with our case manager, but it can also involve physicians, social workers, and community resources."

Two-way referrals

Giardina emphasizes that the referrals can work both ways. Particularly in instances where polypharmacy is an issue, the health plan will refer patients to Prescription Solutions for consultation. "If we, from our perspective, identify a member who is getting multiple medications from multiple providers, and they have multiple co-morbidities, the expertise from Prescription Solutions will be able to help us streamline that process, make sure the medications are cost-effective, and educate the member of their particular disease process," stresses **Jean Enrico**, RN, BS, CCM, the manager of clinical operations for case management at PacifiCare.

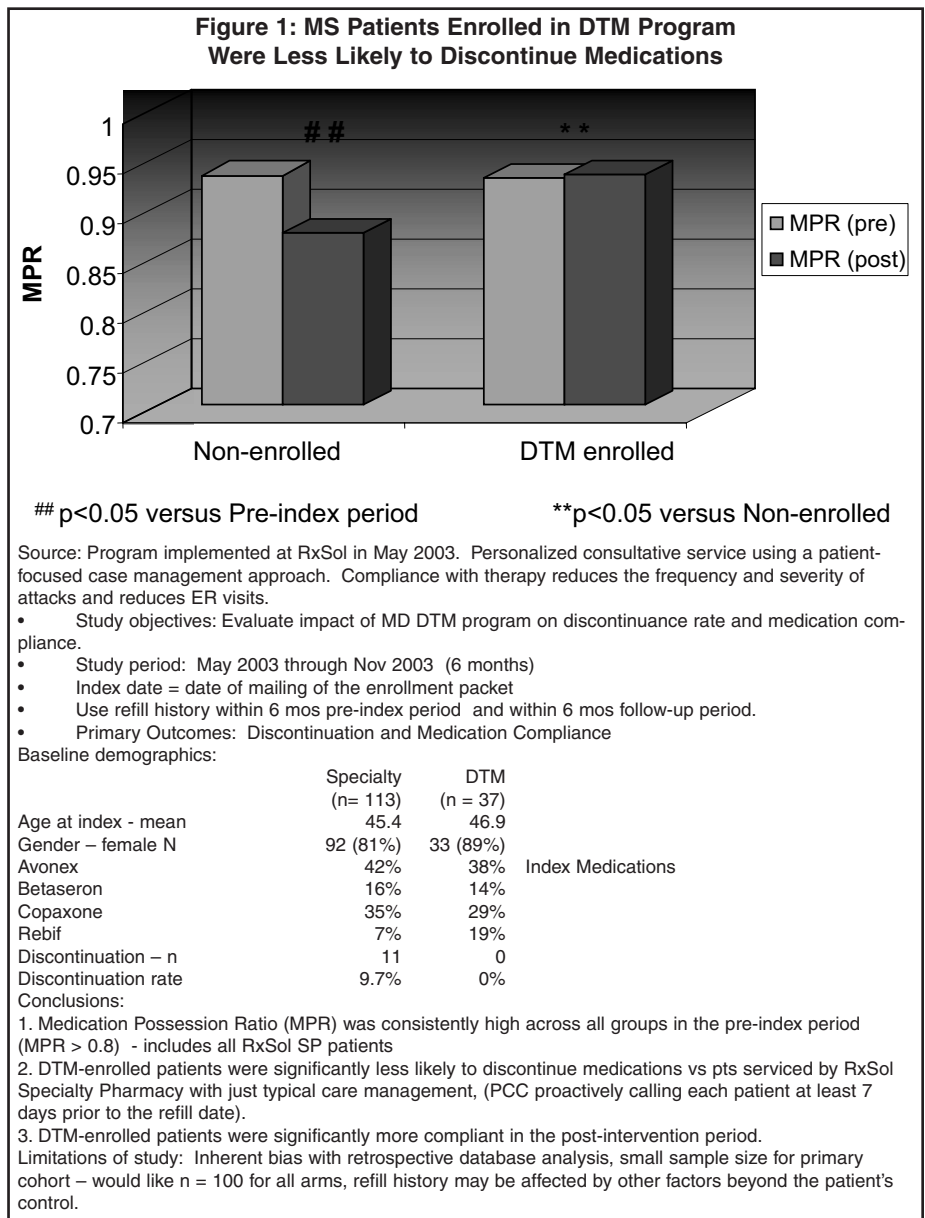
In addition to having clinical nurse case managers on hand to deal with these types of cases, the Specialty Pharmacy DTM program also includes patient care coordinators, clinical pharmacists, and project coordinators. "If a member has a new diagnosis of rheumatoid arthritis, the staff at Prescription Solutions have that expertise and detail behind the medications and how they interact with the disease," adds Enrico. "And they have really been helpful in not only educating the members, but also helping to educate our case managers so that they can continue to learn."

Helping patients to manage adverse side-effects is a routine part of Davis' job, but it is also not unusual in this population to interact with patients who have difficulty giving themselves injections. In these instances, Davis has a number of strategies at her disposal to resolve the problem. In some instances she can coordinate with the health plan to have a home health nurse come out and give the injections, or she can arrange to have the patient go to his or her doctor's office to get the injections there. "There are also auto-injectors available, and many of the drug companies that provide the medications will also provide a nurse to

come out and teach patients how to take the medicine via auto-injector," points out Davis, noting that most of the drugs her patients are prescribed can be taken in this way. "Sometimes not seeing the needle makes a big difference."

Another common problem that interferes with compliance is depression. Davis notes that this can be a particularly difficult problem to resolve because patients are often reluctant to discuss their feelings. "In some cultures, to speak about being depressed goes against their nature," she explains. "Sometimes we have problems with men, in particular, not wanting to get treatment for depression because they feel that they just have to tough it out."

In these instances, Davis coaches the patient on how to communicate more effectively with the physician, and in appropriate cases she will help the patient understand that the depression



is related to their treatment, and that any antidepressants prescribed may be discontinued once the treatment is concluded. Further, when the patient has a behavioral health benefit through their health plan, Davis arranges for the patient to work with the appropriate practitioner to resolve whatever issues are interfering with compliance above and beyond side-effects.

Program impact

Once a care plan has been fully implemented, Davis continues calling patients on a monthly basis until all of their issues have been resolved. "Then the patient and I will collectively decide whether I should call again in two months or three months time," she says, noting that patients are always welcome to call her with questions or concerns. "Patients can remain in the program as long as they like."

It is difficult to quantify the impact of this

type of program because there are always multiple factors involved that are difficult to control. However, administrators take steps to ascertain whether the care plans drawn up by the Prescription Solutions case managers have been effective. In one study involving multiple sclerosis patients, for example, results suggest that patients receiving the intervention were more likely to continue on their medicines than patients receiving routine care. (See Figure 1 on page 81.)

While no financial analyses of the program have been conducted, case managers are confident that ER visits are being prevented because patients are more compliant with their treatment, and they have an immediate resource they can tap when side-effects or other issues that impact compliance arise.

Editor's note: For more information about Prescription Solutions, visit the organization's web address at www.rxsolutions.com. ❖

Potential advance in diabetes treatment

Laser technique shows promise in patients at high-risk for amputation

Every year, more than 80,000 people lose a lower limb due to complications from diabetes. For patients, it's always devastating because of the impact amputation has on quality of life, but it also dramatically heightens the risk of mortality and often signals an acceleration in health care expenditures.

For all of these reasons, amputation prevention is a top priority for both patients and clinicians. And health care experts agree that a vast majority of amputations are, indeed, preventable. Certainly, optimal control of diabetic risk factors is critical over the long term, but there are also new options on the table for patients at high risk for amputation who may not be candidates for more traditional limb salvation techniques.

One approach receiving considerable attention involves using an excimer laser to essentially vaporize plaque that has built up in arteries leading to the lower extremities, thereby restoring blood flow to threatened limbs. Some experts in limb salvation techniques remain cautious, and even skeptical that these newer approaches to the problem will ultimately outperform more traditional procedures. However, advocates of the approach remain convinced that laser-assisted techniques are an important addition to the arsenal of tools available to prevent limb amputation in diabetic patients, and early data are promising.

More powerful tools

Craig Walker, MD, medical director of the Cardiovascular Institute of the South in Houma, LA, has been a pioneer in the use of Cool Laser Revascularization for Peripheral Artery Therapy or CLiRpath. The procedure uses an excimer laser and catheter system developed by Colorado Springs, CO-based Spectranetics Corporation to clear away blockages in the arteries and restore blood flow to threatened limbs.

Walker, who is now a member of the board of directors at Spectranetics, maintains that while lasers and catheters have been around for a number of years, clinicians did not always know how to use those instruments correctly, and previous designs were not as powerful or effective as the newer catheters which can deliver substantially more energy. "The older catheters sometimes got the job done okay ... but the newer catheters can basically make the [artery] channel the size of the laser in almost 100% of the cases in which they are used," he explains. "The tool is very effective at removing both plaque and clots, and that is important."

In April 2004, the FDA approved use of the laser system to treat total blockages in the leg arteries that are not crossable with a guide wire. Results published in February from a multicenter trial suggest the approach is effective in patients who are poor candidates for surgical revascularization.¹ "With CLiRpath catheters in the LACI (Laser Angioplasty for Critical Limb Ischemia) clinical trial, they were able to save 93% of the

limbs in one year, and the participants were people who had been told their only option was amputation," notes Walker, adding that similar results have been achieved in subsequent trials.

Caution and skepticism

Since FDA approval, use of the CLiRpath procedure has grown rapidly to the point where it is now being performed at centers across the country by a variety of specialists, including cardiologists, surgeons, and radiologists who have undergone appropriate training. "There is, perhaps, a new class of physician coming up who uses tools other than the knife and the scalpel to open up vessels," observes Walker, a cardiologist who now trains other clinicians in how to perform the procedure. He adds that clinicians at his center in Louisiana have performed the procedure on patients from several foreign countries and from all 50 states. "It is just like laparoscopy was in its infancy. It occurs at bigger centers first, and then disseminates out very quickly."

Despite the growing enthusiasm for the procedure, however, some experts in limb-salvaging techniques are not yet sold on the approach. "The history in this field has been one of early optimism based on early success, but subsequent disappointment and abandonment," stresses **Frank Veith, MD**, a professor of surgery at the Cleveland Clinic Lerner College of Medicine at Case Western Reserve University, and a pioneer in the diagnosis and treatment of peripheral vascular disease. "On that basis I remain somewhat cautious and a bit skeptical as to whether this device will prove better than other lasers or other means of treating these patients."

Veith acknowledges that he has no experience with the CLiRpath procedure, but he emphasizes that in most cases limbs can be saved through more traditional methods. "I think this technology is interesting like many, many other [technologies], but historically I think most of us who work in this field would say we need to see long-term results, and we need to see proof that this is better than some of the less expensive techniques."

A strong case for intervention

Experts may disagree on treatment methodologies, but there is consensus on the need for prompt intervention in patients who show any signs of critical limb ischemia. These symptoms include pain in the legs even when the patient is at rest, development of an ischemic ulcer on the feet or toes, or gangrenous changes in the toes or feet. "If the physician sees a patient with any of

these things, it represents an emergency because if the person has to have an amputation, it absolutely impacts not just his quality of life, but his quantity of life," stresses Walker. "Amputation is more morbid, more mortal, and more expensive than revascularization."

A patient who has a below-the-knee amputation even at one of the world's best hospitals has a 5% to 8% chance of dying within 30 days, and if he has an above-the-knee amputation, he has an 8% to 12% risk of dying within 30 days. Within both of those groups, nearly half are dead within one year, stresses Walker. "Amputation clearly has all the morbidity that people typically think of -- the inability to walk, the need for handicapped access, and even the need to change the toilets in the house, but it is a lot more than that. It carries a bit of a death sentence," he says, "and we know that if you can, indeed, achieve limb salvage that those patients have much better survival rates."

Ideally, physicians should be focused on the problem long before a patient develops critical limb ischemia. Diabetics are particularly vulnerable because they have altered neurological sensations. Consequently, Walker advises clinicians to measure the pressures in their arms and legs at least once a year. "If the pressures are diminished, it doesn't necessarily mean that they have to get their arteries opened up right away, but it tells the clinician that this patient is at much higher risk than a patient who has no sign of blockages," he says. "And this patient should realize that he must get his cholesterol perfect, he must not smoke, and he must control his BP. Because if he doesn't do these things, he has a very poor prognosis over the long term."

Advances take time

Despite all the negative consequences associated with amputation, thousands continue to be done every year. Walker attributes this reality in part to ignorance on the part of both clinicians and patients. "Many patients wait and allow rest pain to lead to very advanced forms of gangrene because they are worried that amputation may be done," he says. "Secondly, many of the newer techniques -- both surgical and non-surgical -- take a long time to catch on, but they are coming."

Editor's note: More information on the CLiRpath procedure can be obtained at www.Spectranetics.com.

Reference

1. Laid J, Zeller T, Gray B, et al. Lim Salvage Following Laser-Assisted Angioplasty for Critical Limb Ischemia: Results of the LACI MULTICenter Trial. *Journal of Endovascular Therapy* 2006; 13:1-11. ❖

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