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INSIDE

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Finally, practical tools for measuring asthma outcomes in clinical practices

AOMS offers flexible, patient-based approach to managing asthma

There is a great need to monitor asthma-specific health outcomes for the more than 12 million people impaired by the debilitating effects of asthma, but the practical ability to do so in clinical practice has been missing. However, an ongoing project of the Joint Council of Allergy, Asthma and Immunology (JCAAI) and QualityMetric in Lincoln, RI, is close to solving this problem.

The research has yielded an approach called the Asthma Outcomes Monitoring System (AOMS), which uses patient-based outcomes assessments to monitor adult and pediatric patients with asthma. The goal is to perfect a set of assessment tools and data-collection and processing technologies while standardizing the definition and measurement of asthma outcomes across practice settings, thus making it possible to document and compare outcomes.

A large part of this work has been accomplished. The tools, for the most part, are ready. A yearlong pilot program in 23 JCAAI-member practices involving about 35 board-certified allergists, 400 adults, and 400 children is nearing completion. This shakedown cruise for the assessment tools has ironed out most of the wrinkles. The job ahead is to automate the tools and make the program available to the industry.

The JCAAI, which is jointly sponsored by the American Academy of

EXECUTIVE SUMMARY

- With the refinement of several short forms, it is now practical to monitor asthma outcomes in the practice setting.
- The Asthma Outcomes Monitoring System (AOMS) has developed scientific, patient-based measures that have been proven effective in a pilot program in the office practices of board-certified allergists.
- AOMS is working to automate these measurement tools, making them available through commercial vendors while guaranteeing that the underlying standards stay constant regardless of the application.

Allergy, Asthma, and Immunology and the American College of Allergy, Asthma, and Immunology, put that task into the hands of executives at QualityMetric, a company founded by John E. Ware, developer of the SF-12 and SF-36 forms. A number of top researchers at The Health Institute at the New England Medical Center in Boston are also officers at QualityMetric.

"We're working with different data collection and processing vendors to provide services using the AOMS and to do so with a variety of different technologies, so that people have access to this program using whatever technology for data capture or processing they think will work," explains **Martha Bayliss**, MSc, senior director for clinical applications at QualityMetric. Bayliss also is project director for the AOMS.

That technology ranges from manual forms to a number of different electronic approaches. **(See list of initial vendors, p. 7.)** This will give users unprecedented versatility in configuring their data-collection systems, allowing them to be as automated as they want to be or can afford to be within the constraints of their organization's budgets. Of course, the more automated the system, the faster the data get back to the doctor and he or she can incorporate it into the treatment regimen.

"So if somebody wants a touch screen in his or her office, we can make that happen," she says. "If someone likes the paper and pencil approach and sending the forms in for processing, we can make that work. If someone wants an Internet approach for keying the data in, we can make that happen. Our job is to make sure that the questioning, scoring, and reporting are constant across all those different platforms so that everyone is confident about the data, although they can vary the way they collect it and how much that costs them and who they deal with."

It all adds up to unprecedented choice and flexibility in how you can monitor asthma outcomes, with a guarantee that your outcomes are being measured in the same way that every other AOMS users are. That's the beauty of the program. The underlying science remains constant for any of the technologies. And that science is considerable.

The AOMS team has developed forms that monitor generic and asthma-specific functional health and well-being, patient satisfaction, asthma symptoms, disease severity, treatment, and utilization of services. An "encounter" form is completed for each interaction with the patient.

An intake form is filled out when the patient is enrolled in the program. Quarterly surveys are mailed to the patients to assess quality of life, functionality, and satisfaction with treatment. Also, each time a patient makes an office visit, he or she completes a patient encounter form, and the physician completes an encounter form as well. **(See excerpts from forms, pp. 3-5).**

"This lets us keep on top of the treatment regimen," explains Bayliss, "to get a measure of clinical lung functioning, etc. We're also interested in how closely the physician assessment of the patient functioning matches up the patient's self-assessment. We think that if you want to know how a person feels, you have to ask the person. But we also would like to know how far the doctor is from the patient in making that evaluation."

Every patient form includes both generic and asthma functioning. For adults, the short form SF-12 is used for generic functioning, and the longer SF-36 is used for asthma-specific functioning. For children, functional health is assessed using the CHQ PF [Landgraf JM, Abetz L, Ware JE. *Child Health Questionnaire (CHQ): A User's Manual, First Edition*. Boston: The Health Institute, New England Medical Center; 1996] complemented by a new asthma-specific module.

The AOMS team was careful to develop a series of questions within every assessment form that replicates asthma severity staging as outlined in the National Heart, Lung and Blood Institute's asthma standards of care guidelines.

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COMING IN FUTURE MONTHS

- Otitis media: Functional outcomes for pediatric patients
- Joint reconstruction: Measuring functional outcomes before and after surgery
- Hypertension: Quality-of-life measures for disease management
- Neonatal care: The Lovelace Episode of Care program
- Home care: Cost-effective utilization of OASIS

AOMS Screening Form for Clinicians (excerpt)

AOMS Clinician Encounter Form (excerpt)

AOMS Quarterly Health Survey (excerpt)

Source: Copyright QualityMetric Inc., JCAAI, Lincoln, RI.

Physicians like tools, are anxious for info

Docs want data to negotiate MCO contracts

For **Lawrence A. Caliguiri**, MD, the ability to track the outcomes of his asthma patients holds promise on many fronts. As a board-certified allergist practicing in Pittsburgh, he will use the outcomes data to tweak individual patient treatments.

As president of an independent practice association (IPA), he will use aggregate data to help establish optimum treatment regimens and best practices for the IPA. And as a small business entrepreneur negotiating with managed care companies, the data will help him sell his IPA's services more advantageously.

These were the reasons Caliguiri became involved in the Asthma Outcomes Monitoring System pilot program. He's very positive about its potential, as are many of his 12 association colleagues, who practice in 29 counties in western Pennsylvania. The AOMS tools compare very favorably against some other instruments he has used, he says. And although administering the assessment tools probably increased his staff's work about 25% during patient visits, he staunchly maintains that they are worth the effort.

"I like them for several reasons," Caliguiri says. "First, they allow the patients to organize their thoughts so that when we interview them during a visit, which is typically quite short, we can hold more substantial conversations, get more done.

"Secondly, the objective criteria, the clinical measures, are quite important because they give us a quick review of how the patient is doing," he continues. When the technology is in place to get this data to doctors at the point of service, it will be especially valuable in fine-tuning individual treatment regimens, he says.

"And thirdly, I think it is very important for us to look at the treatment plans we have in place and try to improve them on a continuing basis," Caliguiri adds. This is where the aggregate data will be most useful, he says. "Each month, we get together as an IPA and we discuss our data, but what we have lacked in the past has been data on outcomes. Having outcomes data will make a tremendous difference in our discussions."

Most patients responded very well to the program, saw the benefit of the surveys and conscientiously filled out their encounter forms. Only one of his patients said he didn't have time to complete the questionnaires, says Caliguiri, who also is a clinical professor of pediatrics at the University of Pittsburgh School of Medicine.

Martha Bayliss, senior director of clinical applications at QualityMetric in Lincoln, RI, and project director for AOMS, recalls that early in the pilot many of the quarterly surveys were returned with notes that said, "Thank you for asking me these questions."

"The point is that something had been missing from their encounters," says Bayliss, "something that they cared deeply about and were so pleased that someone was asking them about. Now that puts the ball in our court to say to the doctor, 'Now you know that your patient is not doing the things that he or she wants to do, and you have an obligation to do something about it.'"

That kind of interaction will only be possible when the outcomes data are available on a timely basis, says Caliguiri, which means the vendors must make the automation offered to practices like his both efficient and cost-effective. So far, in talking with vendors, he has been disappointed in what they are offering. But it is still early in this phase of AOMS development, so he hopes that as more vendors get involved, he'll find a technology solution that both fits his practice and his pocketbook.

Meanwhile, the aggregate data from the pilot and his IPA's ongoing participation in the project should help him negotiate better contracts with managed care companies, Caliguiri says. "We have the impression that we have better care and better outcomes, but until we have the objective data, we cannot prove that to be true," he says. "MCOs say, 'show us,' and until we do, they just won't listen to us."

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"We think that is important because this is information that the physicians already know about — severities 1, 2, 3, and 4 — so our data can then provide a link from what they already know to new kinds of information they might not be familiar with," Bayliss says.

Building national standards

The AOMS team's long-term goals are to make the AOMS instruments the national standard for outcomes assessments in asthma and build a national database of patient outcomes from which benchmarks can be drawn. Two critical factors are working in its favor. First, the AOMS survey forms are available royalty-free to any clinician who wants to use them (reselling is prohibited without licensing and royalties, and applies for the most part only to vendors and consultants). Permission to use the forms is routinely granted by QualityMetric or the JCAAI. Further, QualityMetric and the JCAAI have teamed up to develop scoring and analysis tools that are available for a modest royalty fee. And the AOMS team has the sponsorship of the country's two leading asthma organizations, as well as the considerable reputation of the research done by The Health Institute.

Second, the approach the team has taken in disseminating the tools not only offers the user a great deal of flexibility, but ensures a standardized platform across all vendors. No one wants to invest in monitoring asthma outcomes only to find that the data are not comparable or that the methodology is deemed substandard by the institutions crafting standards of care for asthma in the industry.

The national database of asthma outcomes is a bit further in the future, but market trends — such as the provider's need to predict demand and prove quality of care — should help it become established as well.

"That will be a new use for this kind of information," Bayliss explains, "for prospective purposes, for predicting who's going to use a lot of services in the coming year. Typically, we've focused on a retrospective look at how the treatment has worked up to the present. I think this is a turning point for the field and a new orientation to understanding what these kind of data can do for different people."

The outcomes database would be built from outcomes reported by physicians using the

AOMS Vendor Network

The Asthma Outcomes Monitoring System (AOMS) package is distributed through a network of Health Care Information Systems vendors who are approved by QualityMetric Inc. and the Joint Counsel of Allergy, Asthma, and Immunology (JCAAI). Current AOMS vendors are listed below. If vendors you are interested in are not on the list, please encourage them to contact the AOMS for information on how they can be included.

❒ **Behavioral Health Outcomes Systems Inc.**

William Berman, PhD
5 Old Mamaroneck Road, Suite 1-L
White Plains, NY 10605
Telephone: (800) 494-2467
Fax: (718) 817-3816
E-mail: bhos_berman@compuserve.com

❒ **InfoMedics**

Michael A. Euele
800 W. Cummings Park, Suite 4400
Woburn, MA 01801
Telephone: (781) 938-6700
Fax: (781) 938-5303
E-mail: meuele@infomedics.com

❒ **National Research Corporation**

Joe Carmichael
Gold's Galleria
1033 O St.
Lincoln, NE 68508
Telephone: (402) 475-2525
Fax: (402) 475-9016
E-mail: jcarmichael@nationalresearch.com

❒ **Questar Data Systems**

Dan A. Woodbury
2905 West Service Road
Eagan, MN 55121-2199
Telephone: (612) 688-0089
Fax: (612) 688-0546
E-mail: dwoodbury@questarweb.com

❒ **Velocity Healthcare Informatics**

Ken Bence
8441 Wayzata Boulevard
Suite 105
Minneapolis, MN 55426
Telephone: (800) 844-5648
Fax: (612) 797-9993
E-mail: kenb@velocity.com

AOMS programs. QualityMetric would house and maintain the database, Bayliss says.

The database would be unique in that it would consist of outcomes that have been collected by a single methodology, whose quality assurance is tightly controlled and guided by the asthma organizations that set standards of care in the field.

"The data would be anonymous and stripped of anything that could identify the patient or practice," Bayliss says. "It would become part of a national repository which builds national norms for asthma patients, according to severity levels, different age groups, different practice characteristics, different payment arrangements, and so forth. That has a lot of value. [AOMS users] will have the ability to access this data repository and compare their practices to the rest of the country. It will provide benchmarks."

Before QualityMetric can build the database, however, the AOMS tools must become more widely used. Meanwhile, the company is developing assessment tools for rhinitis, similar to the AOMS instruments. As with AOMS, the idea is to create national standards and tools for outcomes measurement, while promoting their homogenous use by providers.

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Short-term gains possible with diabetes outcomes

Program pays for itself within a year

EXECUTIVE SUMMARY

- While long-term studies have shown that strict monitoring of blood sugars among diabetic populations can dramatically reduce complications, there has been little data on whether short-term gain would be possible.
- A new program, Diabetes NetCare, has not only improved outcomes significantly in pilot programs but paid for itself several times over in the first year. This program proves that short-term gains are possible based on strict monitoring of several key disease conditions.

It was six years ago that the landmark Diabetes Control and Complications Trial (CCT) proved conclusively through an intensive nine-year study that tight glucose control reduces the risk of complications by 50% to 75% in patients with Type I (insulin-dependent) diabetes. This was good news for the nearly 14 million Americans who have diabetes.

The DCCT study proved once and for all that long-term management of blood sugar levels would pay off in improved outcomes. But does intensively managing diabetic populations reduce costs? And are there any short-term gains?

The DCCT wasn't set up to answer those questions, nor has a study been done in the intervening years to focus on cost issues. The National Institutes of Health did some modeling based on the DCCT that projects the additional costs involved in long-term glucose management, but the models don't fully address whether the costs are offset by the reduction in complications.

Lacking short-term incentives, managed care companies (MCOs) have been slow to embrace comprehensive disease management programs for diabetic populations. They have believed that the return on their investment would be long in coming, if ever, given that the enrollees may not stay in the MCO's plan long enough to justify the cost.

Now there is evidence that even short-term, intensive management of blood sugar levels and other clinical measures can drastically improve outcomes and pay for a program in its first year. And best of all, this proof comes from the front lines of medical care — the physician's office, which means it's based on real-world data, not a carefully controlled clinical study or a projection based on historical models.

Nashville, TN-based Diabetes Treatment Centers of America (DTCA) has developed just such a disease management program, called Diabetes NetCare. A pilot of 115 patients showed an 83% drop in inpatient admissions within six months of implementation, while direct health care costs fell by nearly 26%, from $546 to $405 per month.

Now DTCA is conducting the program for insurers and managed care companies in diabetic populations as large as 2,500 people. The NetCare client base includes 10 health maintenance organizations,

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Excerpt from DTCA's Electronic Medical Record

Source: Diabetes Treatment Centers of America, Nashville, TN.

Source: Diabetes Treatment Centers of America, Nashville, TN.

including Principal Healthcare in Kansas City, MO, and five other locations, Health Options in three markets in Florida, and United Healthcare in one market in Texas. Together, these programs comprise nearly 16,000 enrollees with diabetes. CIGNA in Hartford, CT, has just rolled out another version of the program in two markets involving 17,000 patients.

While DTCA executive vice president **Robert E. Stone** doesn't promise the pilot's 26% savings, he does expect results significantly better than the 8% to 9% savings promised in DTCA's contracts, and in many contracts, it is necessary for the program to pay for itself in its first year. The savings in the pilot were due almost entirely to an 89% reduction in inpatient utilization and a 67% decrease in emergency department utilization.

Other results garnered with this small group of patients include: patients receiving retinal eye exams rose from 28% to 80%; patients getting annual foot exams increased from 3% to 99%; patients receiving serum creatinine tests to assess kidney function grew from 55% to 90%; and glycosylated hemoglobin percentages decreased about 10% for both Type 1 and Type 2 patients.

What gets measured

As these results show, the program is predicated on a number of critical indicators. "We measure a variety of clinical outcomes and we measure both process and what percentage of the population got what tests over time," explains Stone. "Some of that is tied to the existing standards of care and some isn't. It's just a function of what we're looking at. We also measure objective outcomes, particularly with respect to hemoglobin A1C, which is the gold standard marker for metabolic control in this population."

In addition to measuring hemoglobin A1C, the

rate of foot exams, dilated retinal exams, and the rate of microalbumin urine testing, DTCA measures current health status. These inputs do two things, Stone says. They give DTCA the data to evaluate the effectiveness of the program, and they drive the stratification model, which dictates the nature, frequency, and types of interventions patients get.

The stratification model recognizes that not every person in a diabetes population is at the same clinical level. "Some of them are essentially walking healthy and well-managed," says Stone. "And some are at a level where complications and other health problems are beginning to manifest. Some are in an acute situation. Then some defy classification: teenagers, for instance. Women who are pregnant or are contemplating pregnancy are in a group by themselves because there are all kinds of issues associated with them."

But basically the stratification model has three levels: Level I is the walking healthy. Level II includes those having some sort of manifestation of disease. It may be just elevated A1Cs, or it may be something like beginning retinopathy. Level III is an acute management phase. It includes the teenagers and pregnant women and any other patient who needs frequent contact, such as those with comorbid conditions like congestive heart failure or respiratory disease.

The underlying standards

In deciding what to measure, DTCA began with the American Diabetes Association (ADA) guidelines, which is a consensus document developed by physician members in that organization. Then DTCA's medical advisory and scientific advisory councils combed over the standards and current literature, adding to and modifying the guidelines to augment care. For example, DTCA's standards of care include the recommendation for aspirin therapy for those patients at risk for cardiac disease, a recommendation that appeared in the literature after the last version of the ADA standards was approved.

"We have the advantage of getting a significant amount of real-world, real-time physician input into all of our processes and program designs," Stone says. "So we'll start with a generally accepted standards package, and then expand upon that based on the experience that our affiliated physicians are having with patients in their offices every day."

The standards-of-care document is then given to the client's medical director and physician leadership committee for review. It's not always a smooth transition. "You can't walk up to a doctor and say, 'OK, with your diabetics, you've got to do these 20 things,'" admits Stone. "It becomes a question of how you educate and support the provider network into changing their behaviors in a way that will be consistent with best outcomes. And so we may choose to focus on two or three things in the beginning part of the process

Program addresses consumers' concerns

Diabetes program must build loyalty to payer

As a disease management service, Nashville, TN-based Diabetes Treatment Centers of America's (DTCA) diabetes management program has to address those issues deemed most important by the MCO and the payer, as well as the consumer. DTCA executive vice president **Robert E. Stone** says there are essentially four priorities:

1. Improve health care status for the populations, and in particular, for the populations with chronic diseases. "Payers are coming to recognize that there are no cost savings possible without improved health care status," explains Stone. "The way you reduce costs for this population is to make and keep them healthy."

2. Reduce costs.

3. Improve member and provider satisfaction. "Most of the health plans that we talk to recognize that their two biggest assets are membership and their provider network," says Stone. "As local competition for market share becomes more intense, they're very interested in programs that more effectively bind the membership and provider network to the organization."

4. Demonstrate to customers improved productivity in terms of reduced lost-work time, reduced sick days, etc. "So they're looking at how to market these programs upstream to their employer customers," Stone says. "That's a very early trend." ■

Success hinges on managing population

Help the acute patient; don't let well get sick

The underlying philosophy behind Nashville, TN-based Diabetes Treatment Centers of America's NetCare program is to treat the entire diabetic population, not just to concentrate on the "frequent flyers," says **Robert Stone**, executive vice president.

"One of the things that we have discovered about diabetes over the years is that if you only manage the high-risk patients, you are dooming yourself to disaster," Stone says. "The reason for that is that 80% of next year's high-risk population is not this year's high-risk population. So if you only focus on the very tip of the iceberg, so to speak, you make no long-term progress against avoiding people becoming sicker."

Look beyond the sicker patients

Stone sees the propensity among disease management programs to concentrate on the sickest patients as an industrywide problem that must be overcome. Yes, there is significant financial opportunity in emphasizing care for the sickest, but emphasizing that care to the exclusion of managing the rest of the population is self-defeating, he maintains.

"So our operating and value proposition is significantly different from what anybody else is going to find out there for pretty much any disease because we are responsible not only for the entire population with diabetes in a plan, but we are responsible for managing and integrating their interactions with the entire health care system, irrespective of what the reason for that interaction is," Stone maintains. "So when a member with diabetes has an auto accident and ends up in the ER with a broken leg, that's our problem to manage."

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in terms of our interactions with the physicians, although our staffs in the market are working on all of the interventions.

"What we're about is getting both physicians and patients to change their behavior and then to sustain that behavior change. That doesn't happen easily. If it did, it would have already happened."

Nancy Tilson-Mallett, MD, FACP, is a physician in the Medical Group of Kansas City (MO) and sits on the principal physician board that oversees the Diabetes NetCare program. She says her colleagues are very comfortable with DTCA's approach, as well as the guidelines and research underpinning the program. "All physicians are naturally defensive about someone telling them what to do in their practice, but DTCA was very professional in their approach. We were extensively involved in setting up the guidelines, and we're very happy with the results."

Data come back to her in the form of quarterly reports by mail and faxes on information that is required for point-of-service interaction with the patient. While she knows that care for all her diabetic patients has improved, she is most impressed with the degree of compliance she observes among her patients today. And she admits, her own behavior has changed as well.

"I'm much more in tune with the treatment regimens for all my diabetic patients," she says. "For instance, I now look at feet every time I see a diabetic patient. I didn't use to do that. In fact, I have a poster on my wall that says, 'If you're diabetic, take off your shoes.'"

Who does the measuring?

The NetCare program uses the provider's existing physician network, supplemented by DTCA physician extenders: diabetes educators, nurse case managers, and dietitians. Most of the nurses are RNs with some type of advanced practice training. The physician assistants are housed in offices in each market, i.e., city, town, or county. Through telephone calls and office and home visits, the DTCA personnel track and monitor all diabetic patients within an HMO's plan, creating an electronic medical record for each of these patients. Those records are housed in DTCA's mainframe in Nashville.

Tilson-Mallett also has met all of the nurses that serve her patients from the local DTCA office and is enthusiastic about their interventions. "I've reviewed their credentials and their training, and

it's excellent," she says.

At each interaction with the patient, a report is generated that eventually becomes part of that medical record. For example, if the patient comes in for an office visit, that visit and whatever transpired during the visit is logged. If follow-up is necessary, the case manager for that patient will find a prompt on her computer screen the next morning, with information on the nature of the follow-up.

"When our people come in every morning and turn on their computers, they get a hot list of things they need to do for the members they are assigned to," adds Stone. "They make sure that the various processes of care and interventions that are called for by the current stratification level are being carried out on a timely basis."

In most cases, lab and pharmacy data are transmitted directly to DTCA from the labs and pharmacy benefit managers. When an electronic record is not available from the doctor's office or the laboratory or pharmacy, the DTCA case managers work with providers to secure the information themselves. The idea is to have a seamless record of the patient's interaction within the provider's systems.

The HMO also provides claims data on each patient directly to DTCA. This is a crucial step in the process because it allows DTCA to track costs per patient as well as health status and outcomes. The company is using The Lewin Group in Reston, VA, to verify outcomes on this huge database.

"The client doesn't do any of the input or measuring at this time," says Stone. "Hopefully, we can avoid that. There are some rubs; it's not all a smooth, downhill ride. In some circumstances, we can't get contract lab data, so we fall back to a more manual system of chart review. In some cases, we don't get an automatic return of information we request from ophthamologists from the dilated retinal exams, so we follow up. So there's a lot of physician interaction that is necessary in order to make the database as complete as it can possibly be."

Tools are modified for diabetics

The survey tools DTCA uses to measure its patients' outcomes and health status are a mix of proprietary instruments developed in-house and modified industry standards. To assess patient function and quality of life, DTCA uses a QofL survey from Solution Point (which merged with DCG Research in 1996) in Dallas. It also uses Solution Point's survey tools to assess patient and physician satisfaction.

The patient self-assessment instrument is a modified SF-12. The forms for assessing each of the patient interventions (e.g., eye exams, foot exams, A1Cs, etc.) are electronic forms developed by DTCA and are part of its proprietary program. **(See sample form, p. 9.)**

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GUEST COLUMN

Patient-based outcomes measures are coming

Measures change care for patient and provider

By **Sharon Sokoloff**, PhD
Executive Vice President
Medical Outcomes Trust, Boston

The Medical Outcomes Trust brought together eight prominent leaders of US health care and invited them to share their thoughts about the future of health-related quality of life (HRQoL) outcomes measurement through the year 2005. This article includes a summary of the major themes that emerged from that interchange. While the experts contributed a variety of perspectives, there was remarkable consensus about one central point: *patient outcome measures will soon be integral to and routinely used in clinical practice as well as virtually all systems that organize, deliver, and finance care.*

Patient outcomes improve accountability and choice in health care

The vast majority of the quality measures in use to date are process measures, an indicator of the still-formative stage of the field of quality measurement. Our goal is to establish a more comprehensive quality measurement strategy to include process and outcome measures. Such a

system promises consumers, payers and purchasers increased: 1) accountability for the quality of care provided and 2) choice for health plans and physicians.

Purchasers will increasingly require scientifically sound information about the results of care and the health of populations over time. Already, key organizations in the field, e.g., AHCPR, NCQA, JCAHO, and FACCT, are engaged in work aimed at accelerating the quality and diversity of the outcomes measures available, the adoption of the measures and the resolution of the methodological challenges affecting progress in this field, e.g., risk adjustment and continuous enrollment in managed care settings. Notably, HCFA has demonstrated significant leadership in the field spearheading initiatives that incorporate health status and outcomes measures of HRQoL in nursing homes, home health care and managed care settings.

Several examples of how readily accessible and standardized information about the results of care will be used to increase accountability follow. Outcomes studies: 1) will be used to reveal that certain clinical modalities have no effect on health outcomes and thus, the use of those procedures, technologies, or treatments could be discontinued, 2) will be used to evaluate alternative health care practitioners and to address issues of regulation and oversight of non-physician practitioners, and 3) will impact the pharmaceutical and medical device industries holding them accountable for patient outcomes with regard to the products they develop.

Patient outcomes support the improvement of clinical practice

An important achievement in the coming years will be the acceptance of the complementary nature of process and outcomes measures in the continuous quality improvement cycle. All health care sectors will realize the debate about "process *versus* outcome measures" is over. Efforts will be aimed at implementing strategies that link the evaluation and improvement of processes and outcomes with the goals of such a strategy including: 1) understanding the results associated with various processes of care, specifically, which practices yield the best outcomes and 2) guiding an ongoing, iterative process of improving the value of health care. Managing clinical processes and managing patient outcomes are two integral parts of a comprehensive and sound measurement strategy.

Outcomes measurement systems must be standardized to achieve success

The need for *standardized and comparable data and information* is a cornerstone of the science and use of outcomes measurement. For much of our history, competing systems have been used to measure quality and clinical effectiveness. However, experts both hope for and expect a "shakedown" and consolidation favoring standardized measures that subscribe to a scientific base. Without standardization and scientific rigor the result could be years of fragmented and ineffectual efforts.

Significant progress has been made by and among purchasers in the movement toward the achievement of standardized quality performance measures in the 1990s. Specifically, purchasers have acted in a coordinated way to make buying decisions on the basis of information that is standardized and based on good science recognizing that they cannot afford not to standardize and to make information about the results of care as comparable as possible.

Patient outcomes will be linked to payment systems

As payment systems evolve they will continue to change from cost reimbursement to more and more capitated models to a range of incentive-based payments methods. Increased competition will lead to greater buyer emphasis on value, i.e., *an interest in quality and benefit as well as cost.* All forms of outcomes measurement will assume increasing importance in judging value including: traditional biological and clinical measures, symptoms, utilization, cost, functional status and well-being, and satisfaction with care. Our experts agreed that if payment systems are going to be dependent on the quality of outcomes information, as they believe they will be, then we will see physicians begin to accept these measures. In markets where managed care predominates, there has already been significant behavior modification on the part of physicians.

Physicians must "buy in" and contribute to outcomes measurement methodologies

Outcomes measures promise tremendous improvements in clinical care particularly for patients with chronic medical conditions such as asthma, diabetes mellitus, chronic obstructive

pulmonary disease, congestive heart failure, and depression. There is no doubt that cross-sectional health status and longitudinal outcomes information will be integrated into routine patient care, in all settings, as a complement to the information available through more conventional care practices, e.g., the history and physical, and analysis of laboratory data. To date, the integration of patient outcomes into clinical practice has been slow, the rare exception rather than the rule.

However, software technology designed to collect, organize and analyze standardized patient-based outcomes data in a matter of seconds is already widely available today. If medical schools, residency programs and physician organizations support the use of these measures, significant progress could be made by 2005. It is encouraging to see that the AMA and a handful of physician specialty organizations have begun to take a leadership role in this area.

Physician experts in the field of health outcomes stress that acceptance of outcomes measures by the medical profession will be predicated on two conditions: 1) physician input in the implementation process, and 2) the use of scientifically rigorous measures. There is a tremendous gap in practicing physicians' understanding about what these measures are about, i.e., the actual challenges and benefits of their use. For some, this results in outright hostility and for others, "simply" a state of misinformation. Until we educate the people who will be using these measures about what they mean, what their strengths are, what their limitations are, and how they fit into the whole thrust of total quality management, we will be missing a major opportunity. Because the human instinct is not to be measured, it is critical that physicians are involved in the processes of systematizing outcomes measures in order to obtain their support and "buy-in" in the programs.

Outcomes measures add value to the clinical encounter

Clinicians' acceptance and use of outcomes measures will be predicated on the availability of tools that: 1) are as simple as possible, 2) are scored in rapid time, and 3) generate information for review at the time of clinical encounters. To the extent that technology makes it so simple that the information facilitates efficient and effective patient care, it will be accepted. To the extent that it is a burden, it will not be accepted or used.

If the tools help physicians, they will use them. Thus, the real challenge is to develop tools and systems useful to physicians. There are models of successful implementation strategies for systems-wide changes, e.g., the implementation of a clinical computerization initiative, in which retired "emeritus physicians" became powerful advocates for the new tools and systems. The idea of involving physicians to carry the message to their peers, particularly physicians who are well-respected, has been demonstrated to have excellent results.

Patients must be involved to improve health outcomes

Consumers are playing an increasingly active role in the movement to improve the results and value of health care. Consumer information about the experience of their health in various domains, e.g., physical function, social functioning and energy, as well as their preferences about and satisfaction with their health care is central to maximizing the value of health care.

We have the ability today to use technology to elicit rich and detailed information from patients about their status, everything from their physical to psychosocial status, and to do so in a standardized, easy and efficient way. We have the ability to collect information from patients while they are sitting in the physician's waiting room and to organize and analyze it so that when she walks into the doctor's office, the doctor would know a tremendous amount about her status, how it has changed since her last visit and her preferences. The more patients are involved in their own care, the more they will be empowered to make informed choices about lifestyle and treatment.

Final note

As we approach the year 2000, the field of health outcomes measurement is at a formative and exciting stage. It is no longer a question of "if" but rather "when and how" patient-based health-related quality of life outcomes will be used on a widespread basis in virtually all health care sectors. Two key factors find us poised on the threshold of widespread implementation of these measures: 1) significant changes in public and private health policy that are requiring and/or otherwise promoting the use of patient outcomes, and 2) major advances in software technology that promise highly precise, standardized

patient outcomes information in rapid turnaround time. While formidable challenges exist, particularly related to the implementation of outcomes measures in practices and systems of care, over time, a significant investment will be made and HRQoL measures will soon become integral to the way health care is delivered, evaluated, regulated and paid for in the US and abroad.

[I'd like to acknowledge my debt for the ideas presented in this column to a group of experts who participated in a Medical Outcomes Trust roundtable. They are: Wade Aubry, MD, national medical consultant, Blue Cross Blue Shield Association; Helen Darling, manager, Healthcare Strategy & Programs, Xerox Corp.; William Jacott, MD, board member of the American Medical Association, associate professor and head of the Department of Family Practice and Community Health, University of Minnesota; Jonathon Lord, MD, senior advisor for clinical affairs, American Hospital Association; Walter J. McNerney, professor of health policy, J.L. Kellogg Graduate School of Management, Northwestern University; Dennis O'Leary, MD, president, Joint Commission on Accreditation of Health Care Organizations; Cary Sennett, MD, PhD, vice president for Performance Measurement, National Committee for Quality Assurance; and Helen Smits, MD, MACP, president, Health Right, Inc., Hartford, CT.

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Key to CHF compliance is monitoring measures

Quick feedback saves $3 million in care

One of the difficulties in managing chronic illness is that provider systems can easily get left behind by rapidly advancing treatment protocols if they are not diligent in staying current with best practices. Nowhere is this more important than in congestive heart failure.

CHF is responsible for almost one million hospitalizations every year and is the most common diagnosis in hospital patients age 65 and older. It accounts for about $20 billion in health care costs each year.

EXECUTIVE SUMMARY

- Maintaining best practices in congestive heart failure patients can be daunting, given the fast pace of new drugs and regimens for this disease.
- If your CHF program is not current with best practices, you may not be monitoring the correct outcomes or collecting the data necessary for improvements.
- A provider system in New York solved this problem by hiring a disease management company that constantly monitors the literature and recommends updates to best practices as necessary. The program has achieved dramatic improvements in CHF care and outcomes.

If you're not using best practices with your CHF patients, not only do your patients suffer, but your bottom line will suffer as well. Such was the case with NYLCare Health Plans of New York. "Congestive heart failure was costing us a fortune," admits **John Roglieri**, MD, NYLCare medical director.

By all measures, NYLCare was not effectively managing its CHF populations: 47% were readmitted to the hospital within 90 days, 72% of hospital admissions were related to CHF, and only 25% were treated with drugs, specifically the ACE inhibitors recommended by national guidelines.

Program cuts costs, increases compliance

NYLCare opted to bring in a disease management firm to design a program to decrease hospitalizations while cutting costs and increasing compliance. According to Roglieri, the program has saved his company $3.1 million since it was implemented in October 1995 and has paid for itself many times over. **(See chart on p. 17 for the type of utilization improvements that made these savings possible.)**

The key to the program's success was identifying several crucial clinical measures to monitor, then educating physicians and patients to bring them into compliance with best care practices. The disease management company, Stuart Disease Management Services in Wilmington, DE, began with national guidelines from the Agency for Healthcare Policy and Research in Washington, DC.

"The AHCPR Left Ventricular Systolic

CHF Program Outcomes

	Participants (n = 149)		CHF Population	
	Pure	*Related*	*Pure*	*Related*
Admissions	↓ 83%*	↑ 25%	↑ 63%*	↑ 7%
Readmissions (30 days)	↓ 100%	↓ 20%*	↑ 75%*	↑ 7%
Readmissions (90 days)	↓ 83%*	unchanged	↑ 74%*	↑ 4%
Length of Stay	↑ 10%	↓ 47%*	↑ 26%	↑ 21%*
Emergency Room Visits	↓ 100%	↓ 100%	↑ 14%	↑ 16%
Hospitals Days	↓ 82%*	↓ 33%*	↑ 73%*	↑ 27%*

*Significance at p<0.05

Source: Stuart Disease Management Services, Wilmington, DE.

Function Guidelines were the backbone of our guideline, and we supplemented that with other pieces in the literature, such as the American College of Cardiology and the American Heart Association practice parameters," explains **Kenneth McDonough**, MD, medical director for SDMS. Then this "guideline template" was submitted to NYLCare's physician leadership for review and customized with its input.

"If national guidelines meet local practice customs and are approved by the audience, they are much more apt to be examined and followed," McDonough says. He emphasizes that the guideline is not a static document. His company provides regular updates as necessary to keep it current.

With the document for delineating best practices complete, SDMS then developed a program for measuring and monitoring in four major areas: clinical outcomes, patient satisfaction, quality of life, and economic outcomes.

Patients surveyed on quality of life

Literature searches did not turn up any widely accepted satisfaction survey for CHF patients, so SDMS developed its own, which it is continuing to improve, says McDonough. For quality of life, SDMS uses the Minnesota Living With Heart Failure Questionnaire.

The clinical measures are designed to show how well the patient is functioning and his or her degree of compliance with treatment regimens. Physicians measure each patient's ejection fraction (a measure of heart function), and stratify his or her disease state according to the New York Heart Association classifications (Class I through IV), based on symptoms and degree of impairment.

"We also look at weight," continues McDonough. "We look at some scoring of patient symptoms and whether they've run out of medication and those kinds of things. And finally, we look at their specific medication usage, if they are staying on medication suggested by their doctor or recommended by the practice guideline."

Constant contact keeps patients on track

To monitor these patients, SDMS uses nurse case managers who call patients weekly or more often if the patient is unstable, and/or arrange for a home visit by a home agency, whose nurses have been contracted and trained by SDMS. Patients also receive monthly educational mailings.

"The patient owns the disease," explains Roglieri. "If you've got congestive heart failure, it's probably going to kill you. We don't know when. Your doctor's got 22 patients in the morning and another 30 in the afternoon. It has to be your deal. You've got to take your medications, avoid salt, get some exercise, weigh yourself every day. We're going to call and ask you how you're doing. That's patient empowerment."

The telemonitoring is housed in SDMS' Wilmington offices, but SDMS' personnel identify themselves as NYLCare agents when talking with patients. Physicians receive feedback on their patients either by mail, a fax, or a phone call. If the information is urgent, then the physician gets both a fax and a phone call.

Reports are generated by each home visit,

telephone call, and physician office visit. Aggregate data go to NYLCare corporate offices, where they are integrated with claims data to generate financial outcomes. **Jim Skelly**, RN, NYLCare director of disease management programs, gets utilization reports quarterly, and weekly or biweekly updates on who's in the plan or out of it.

Patients are enrolled in the plan based on claims data and their physician's or SDMS' recommendation. About 340 patients are currently enrolled in programs in New York, Texas, and North Carolina, says Skelly, but he'd like to see that grow to several thousand. "Certainly, we've got the population to support that," he says.

Interestingly enough, when surveying their insureds, many CHF patients "did not see CHF as an important force in their lives," Skelly notes, alluding to the patient education necessary to make a program like this work. The physicians in their provider networks, however, have been very pleased.

"Physicians love it," Roglieri says. "We get the patients off their backs. We tell them when a patient's getting into trouble. The patients wait for our phone call instead of theirs. What's not to like? Every physician needs an extra pair of hands and an extra pair of ears, and that's what we're giving them."

One of the chief benefits that provider and payer systems realize from a program like this is that the information technology burden for tracking, collecting, analyzing, and compiling the data into reports is shouldered by the disease management firm. This allows companies like NYLCare and its provider systems to enjoy state-of-the-art outcomes tracking and reporting technology, without the capital investment in the systems or the maintenance.

Information technology speeds reports

At SDMS, the nurses type their phone reports directly into SDMS' database. Many of the home care nurse agencies provide their staff with laptops, which carry SDMS forms so the data can be downloaded electronically directly into SDMS' information systems. SDMS also takes care of integrating any data that must be manually loaded into the system, such as physician reports or lab data. SDMS ships its reports to NYLCare by e-mail, which facilitates fast and easy dissemination both between the companies and within NYLCare.

McDonough says financial analysis of the pilot program done for NYLCare shows that the payer enjoyed a 4:1 net return on its initial investment. "We don't know if that will hold up when we take it out to other plans," he admits. "But that return could shrink some and still be a significant return."

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More work needed in depression outcomes

Health state utilities are one approach that works

Writing recently on his research into depression-related outcomes, **Dennis A. Revicki**, PhD, concluded that future clinical trials should consider including measures of health state utilities.[1]

The only problem is that there just hasn't been much done in this area, he says. Revicki, vice president for MEDTAP International in Bethesda, MD, has pioneered some work applying standard gamble techniques to derive utilities for health states in patients with major depression disorder.

EXECUTIVE SUMMARY

- It's a chicken-and-egg dilemma: Managed care companies will not view behavioral health in the same light as other disease management issues until there are outcomes data that prove disease management works for these groups of patients.
- Very little work has been done in developing patient-based outcomes measures for behavioral health because of the difficulties in eliciting information from these patients.
- A new program that has developed health state utilities for depression patients using standard gamble techniques offers new insights into how this problem might be solved.

His small study was with two outpatient primary care groups of patients, 40 patients from a family practice clinic in Toronto, Ontario, and 30 from a community-based primary care practice in San Diego. These were patients who had completed at least eight weeks of antidepressant treatment and were currently receiving treatment or had completed an antidepressant treatment regimen within the last two months.

Standard gamble methods were used to generate utilities for 11 depression-related hypothetical health states and for the patient's current health state. Health status was measured using the Medical Outcomes Study Short Form 36 and the Medical Outcomes Study cognitive function scale. Clinicians rated depression severity using the 17-item Hamilton Depression Rating Scale.

Only a few patients (3%) could not complete the standard gamble interview, and 25% rated severe depression as the equivalent to or worse than death, a not unexpected finding. Revicki's work correlated well with earlier work in assessing utilities for depression related states[2] that had found that the utility for moderate, untreated depression was 0.32. His own study found a utility of 0.30 for the same stage.

Revicki's work was a follow-up of a drug study comparing cost-efficiency and clinical effectiveness between older generation tricyclic antidepressants (TCAs) and newer serotonin selective reuptake inhibitors (SSRIs). Basically, the SSRIs have fewer side effects and are equally effective, but managed care companies balk at paying the higher prices for the newer drugs.

Revicki maintains that when patient preferences (as measured in compliance with treatment regimens) and quality-of-life measures are factored in, the SSRIs emerge as the clearer choice. But because so little work has been done on patient utilities for depressive disorders, these patients get short shrift when MCOs make formulary decisions for anti-depressants.

"Given the comparable clinical efficacy between the newer antidepressants and the TCAs, treatment decisions may need to rest on patient preferences and the effect of treatment on patient functioning and well-being, which incorporate the impact of both changes in depression severity and side effects," he said in his latest paper on the subject[1].

When interviewed for *Clinical Outcomes Measurement*, Revicki cautions that his standard gamble approach may not be the "magic bullet" that solves this problem. It's complicated, some patients cannot do it, and it requires an investment in training of personnel up front. "I think it would be possible to adapt [this approach], but you'd really have to do your homework and work on the implementation of it," he advises.

"The real application for this is for evaluating cost-effectiveness of various treatments, various interventions, such as packages of physicians visits and medications for psychotherapy or psychological counseling," he maintains.

Meanwhile, he worries that not enough is being done in outcomes research for depression. As has been the case with other chronic disorders, such as asthma, diabetes, and congestive heart failure, the managed care companies need to address the treatment of depression in terms of cost-effectively managing the disease, Revicki argues.

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Editorial Questions

For questions or comments, call **Susan Hasty** at (404) 262-5456.

"It's time to really look at the patient outcomes side, to try to collect data and analyze data that will help them identify the patterns of care that produce the best outcomes," he says.

While managed care companies have certainly embraced this approach for disease management outside the behavior health field, few inroads have been made for behavioral disorders. With more work like Revicki's, perhaps that will change.

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SOURCES

For information about outcomes programs and research projects:
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Web site: www.outcomes-trust.org

For information on the SF-12, SF-36, Consumer Satisfaction Survey, and Child Health Questionnaire:
Health Care Assessment Lab
The Health Institute, NEMCH
750 Washington St., Box 345
Boston, MA 02111
(617) 572-9394

For information about national standards of care guidelines:
Agency for Health Care Policy and Research
2101 East Jefferson St., Suite 500
Rockville, MD 20852
(301) 594-1400
Web site: www.ahcpr.gov

A commercial site for obtaining some standard survey forms on-line (including SF-36, SF-12, HSQ, HSQ-12, HEDIS, OASIS-B and MDS):
AutoData Systems
6111 Blue Circle Drive
Minnetonka, MN 55343-9108
(612) 938-4710
Web site: www.autodata.com

AMAP, JCAHO and NCQA Will Coordinate Measures

The country's dominate health care accrediting organizations — the American Medical Accreditation Program (AMAP), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the National Committee for Quality Assurance (NCQA) – will collaborate to design performance measurements, according to an agreement announced in late May.

The agreement establishes the Performance Measurement Coordinating Council (PMCC), a 15-member group that will coordinate the effort. The PMCC will begin work at its first meeting this summer, and will meet three to four times per year. Work groups addressing specific issues will meet in person and via conference call more frequently.

Formation of the PMCC dovetails with the recent recommendation from President Clinton's Advisory Commission on Consumer Protection and Quality in the Health Care Industry urging greater coordination in health care performance measurement efforts. The PMCC expects to work through the Forum for Health Care Quality Measurement and Reporting, a group being formed by Vice President Albert Gore, that will seek to incorporate existing private sector efforts.

The PMCC has developed a consensus statement, "Principles for Performance Measurement in Health Care," that outlines areas of purpose: the rationale behind performance measurement efforts; appropriate uses of performance data; specific areas on which measures should focus; guidelines for using performance data for comparative purposes; general requirements for cost effective measurement; and specific opportunities for collaboration.

The PMCC will also tackle issues such as standardization of risk adjustment, which is a key issue for measuring performance at the physician, facility and health plan levels. ■