AMERICAN HEALTH CONSULTANTS®

DISEASE STATE MANAGEMENT™

Managing Chronic Illness Across the Continuum

INSIDE

JANUARY 1999

VOL. 5, NO. 1 (pages 1-12)

American Health Consultants® is A Medical Economics Company

UK study of Type 2 diabetics confirms urgency of glycemic control

ADA says 'no more excuses' for poor control

The American Diabetic Association (ADA) raised the bar of tight glycemic control even higher after the release of the largest ever study of Type 2 diabetics, the United Kingdom Prospective Diabetes Study (UKPDS).

The landmark 20-year study complements the findings of the Diabetic Control and Complications Trial (DCCT) for Type 1 diabetics: Strict glycemic control results in a dramatically reduced risk of common complications of diabetes once considered inevitable — retinopathy, nephropathy, and possible neuropathy.

The new study also shows tight control of hypertension among diabetics has equally dramatic results in terms of heart disease. It also shows the efficacy of sulfonylurea, insulin, and metformin in lowering blood glucose and found both anti-hypertensives used in the study: the ACE inhibitor captopril and the beta-blocker atenolol worked equally well.

Like the DCCT, the UKPDS employed intensive treatment designed to achieve near-normal glycemia by whatever means necessary.

That means the face of diabetic practice in America must change and there will be no more excuses for failures, says **Richard Kahn**, PhD, the ADA's chief scientific and medical officer.

"We've got all the proof that we need . . . The final piece of evidence

KEY POINTS

- Intensive glycemic control reduces risk of major diabetic eye disease by 25%.
- For every 1% point reduction in HbA1c, there was a 35% reduction in damage to eyes, nerves, and kidneys.
- Aggressive control of hypertension in diabetic patients reduces risk of heart failure by 56%, stroke by 44%, and diabetes-related death by 32%.

is here," Kahn says. "It's a done deed, so let's get on with this and improve glycemic control for all people with diabetes."

Kahn throws down the gauntlet to health care professionals without hesitation.

"There's no excuse for having a patient with poor glycemic control. There are plenty of drugs. The medical evidence is clear and convincing."

Furthermore, Kahn believes the burden of responsibility for improved care rests squarely on the broad shoulders of medical professionals: Overall in diabetes care in America, treatment is suboptimal and we need to do something about it.

While conceding patient compliance is a significant issue in diabetes care, "We shouldn't just hang it on the patient," he says.

Kahn elaborates:

- Exams are not given frequently enough.
- There is not enough proper follow-up.
- Not enough attention is given to glycemic control.
- Some physicians even underplay the seriousness of the disease.

"Many people are still told, 'you have a touch of sugar or borderline diabetes,'" Kahn says. "Health care professionals are not taking this disease seriously."

The ADA, in a position paper issued shortly after the September UKPDS release, issued a call to arms: It is time for all health professionals to treat diabetes aggressively. It is also time for patients to take their diabetes with utmost seriousness. It is incumbent on the health care system to provide the necessary resources for both to be successful.

The Oxford-based UKPDS involved 5,102 newly diagnosed patients recruited throughout the United Kingdom between 1977 and 1991. Patients in 23 clinical centers in England, Northern Ireland, and Scotland were followed for an average of 10 years in the randomized controlled trial.

All patients were placed on diet control alone for the first three months, and randomly divided into two groups that received either drug therapy or remained on diet control. Those with hypertension were divided into "tight" and "less tight" control and administered ACE inhibitors or beta-blockers.

Major findings

During the study, blood glucose and blood pressure levels were measured more frequently than usual**.**

The major findings are as follows:

- Patients who achieved a median HbA1c of 7% compared to those on conventional therapy at 7.9% had 25% fewer microvascular complications.
- For every 1% drop in the HbA1c rate, there was a 35% reduction in the risk of complications; a 25% reduction in diabetes-related death; a 7% reduction in all-cause mortality; and an 18% reduction in combined fatal and non-fatal myocardial infarction.
- Patients receiving insulin therapy had a highest average annual incidence of major hypoglycemic events at 2.3%.
- Lowering blood pressure to a mean 144/82 mm Hg caused a significant reduction in strokes, diabetes-related deaths, heart failure, microvascular complications, and vision loss. However, the ADA continues its recommendation that blood pressure be maintained below 130/85 mm Hg.
- While a 16% reduction in the risk of combined fatal or non-fatal myocardial infarction and sudden death was observed after lowering blood glucose, researchers did not consider it statistically significant.

The study failed to provide definitive evidence of the role of hypoglycemia in cardiovascular complications.

It also produced mixed results on metformin. With the drug, obese individuals had a 33% reduced risk of diabetes-related deaths and cardiovascular events. However, a small sample of patients given a maximum dosage of sulfonylureas and added metformin showed an increase in diabetes-related deaths. The ADA says the results were affected by design aspects of the

COMING IN FUTURE MONTHS

- Trends in chronic pain management
- Using telemedicine in diabetes treatment
- CHF program cuts re-admissions by 83%
- Parents explore alternative therapies for pediatric asthma patients
- Strategies for achieving physician buy-in for diabetes management

study and does not recommend any change in the use of metformin.

The UKPDS did not determine if tight control could produce positive outcomes for those who already have serious complications, but Kahn says his best guess is that complications are reversible "if they have not progressed too far."

The results of the UKPDS are achievable, says the ADA position paper, which notes patients in the UKPDS began with an HBA1c of 9.1%. While the conventional treatment group achieved a 10-year median level of 7.9%, the intensively treated group was able to maintain a level of 7%.

"Perhaps the most important ingredient leading to therapeutic success was persistence," the ADA position paper comments.

What now needs to change in conventional practice of diabetes management, Kahn believes, is that physicians must pull out all the stops to achieve near-normal blood glucose — closer monitoring, closer attention, more frequent office visits, more counseling and support, stronger medications — "whatever it takes."

The ADA has already begun its public and professional awareness campaign through traditional means: through the media, lecture circuit, and a flurry of public education materials.

"There is a message now for both consumers, employers, as well as the medical establishment that glycemic control is very important and has a huge breadth and depth of impact," Kahn concludes. ■

UKPDS provides answers, fuel for debate

Bottom line is "no more excuses"

By **Ralph Hall**, MD

The results of the long-awaited UKPDS are now available and may best be summed up by the title of an accompanying editorial by David Nathan, "Some answers, more controversy, from UKPDS."

These findings of the UKPDS were presented in four papers published in the *Lancet* and *British Medical Journal* in September.

The first of the studies (UKPDS 33), "The Intensive Blood-Glucose Control with Sulfonylureas or Insulin Compared with Conventional Treatment and Risks of Complications in Patients with Type 2 Diabetes," covered a period of 10 years. The HbA1c was 7% in the intensive group compared to 7.9% in the conventional group. The risks for any diabetes-related endpoint (sudden death from hyperglycemia or hypoglycemia, fatal or non-fatal myocardial infarction, angina, heart failure, stroke, renal failure, amputation, vitreous hemorrhage, retinopathy requiring photocoagulation, blindness in one eye or peripheral vascular disease, and all-cause mortality) were the evaluation measurements used in the study.

Compared to the conventional group, the risk in the intensive group was 12% lower for any diabetes-related endpoint; 10% for any diabetes-related death and 6% lower for all-cause mortality. Most of the risk reduction was due to a reduction in microvascular endpoints. None of the individual drugs had an adverse effect on cardiovascular outcomes.

An important finding was that the intensive group had a reduction in albuminuria accompanied by a 67% risk reduction in patients who had a two-fold increase in plasma creatinine. This is critical because of the high incidence of renal failure in Type 2 diabetes patients.

Metformin mystery

A more controversial part of the study according to Nathan and **Richard Kahn**, chief scientific and medical officer of the American Diabetes Association, was "The Effect of Intensive Blood Glucose Control with Metformin on Complications in Overweight Patients with Type 2 Diabetes" (UKPDS 34). The mean HbA1c was 7.4% in the metformin group and 8% in the conventional group. Those allocated to metformin had risk reductions of 32% for any diabetes-related endpoint, 42% for diabetes-related death, and 36% for all-cause mortality. However, when metformin was added early in treatment to sulfonylurea-treated groups, it was associated with an increased risk of diabetes-related deaths. The UKPDS study concluded that because of less weight gain and a decrease in diabetes-related endpoints, metformin may be the first line of pharmacological therapy of choice for obese diabetes patients.

With the addition of metformin to the sulfonylureas early on in treatment being associated with a less-favorable outcome, and the use of metformin

alone resulting in a more favorable outcome comes the concern that there is a statistical problem with the complicated analyses of these studies. This will be a topic of debate for some time.

The studies reported in the *British Medical Journa*l were aimed at measuring the effect of tight blood pressure control on the risk of macrovascular and microvascular complications in Type 2 diabetes (UKPDS 38); and efficacy of atenolol and captopril in reducing macrovascular as well as microvascular complications in Type 2 diabetes (UKPDS 39).

These studies showed that tight control of hypertension with atenolol or captopril decreased risks significantly. Heart failure risk was reduced by 56%, stroke by 44%, and death from diabetes-related causes by 32%.

The findings of UKPDS add to the findings of the DCCT studies, which documented that improved control decreases microvascular diseases in Type 1 diabetes by demonstrating that improved blood glucose control also lowers the risk of microvascular diseases in Type 2 diabetes.

The metformin findings, although somewhat confusing, are important. Metformin, unlike sulfonylureas, does not promote vasoconstriction. Metformin does promote favorable changes in the quality of the lipoproteins, changing small dense lipoproteins to a more buoyant and less atherogenic form.

Others have found more favorable outcomes with metformin albeit it in small and less well-structured trials. The ADA's representatives, however, feel that this aspect of the study needs verification before these observations are used in clinical practice.

Two issues are clear, however. There is no longer an excuse for poor diabetes blood glucose control; and hypertension in all diabetics should be treated vigorously with beta-blockers and / or ACE inhibitors.

All of these findings mean there will have to be a greater effort to manage diabetes more effectively, Kahn said in his statement for the ADA. This means more physician and patient education, more frequent office visits, closer monitoring and more counseling.

The results of such efforts are likely to improve every aspect of the diabetic's well-being as well as lowering the cost of care.

[Ralph Hall, MD, is professor emeritus of medicine at the University of Missouri-Kansas City School of Medicine, Kansas City, MO.] ■

ACE inhibitors, awareness lowers CHF mortality rate

CDC says more physician awareness reduces deaths

Heart failure is a killer. There's no doubt about it. And there's no doubt that it is the fastest growing diagnosis leading to hospitalization.

Recent figures from the Centers for Disease Control and Prevention (CDC) in Atlanta may show the stranglehold of the disease is loosening just a little.

Mortality attributed to heart failure in patients 65 and over declined from 116.9 per 100,000 standard population in 1988 to 107.6 in 1995 — about an annual average decline of 1.1%.

The decreased death rate was most striking for African-Americans: 3% per year for men, 2.2% for women. Mortality among white men decreased by 1.7% per year, and for white women, .5%.

The study suggests "improved survival for older adults with heart failure, or misdiagnosis of the underlying cause of death among adults with heart failure," according to the CDC narrative published in the Aug. 13, 1998 issue of *Mortality and Morbidity Weekly Report*.

Experts have varying theories on the causes.

Janet Croft, PhD, cardiac epidemiologist for the CDC's cardiovascular health unit, offers four possible factors:

- There is an increased use of angiotensin-converting enzyme (ACE) inhibitors.
- Patients with high blood pressure are being treated with cholesterol lowering drugs and not deteriorating to congestive heart failure (CHF).
- Patients who have had myocardial infarctions are managing their heart disease better and not developing CHF.
- There could be changes in the means of reporting on death certificates.

The bottom line, in Croft's mind: Physicians need to be familiar with clinical guidelines in treating heart failure.

Most heart patients (78%) are likely to see a family practitioner, general practitioner or internist, Croft adds, and statistics show these physicians are less likely to prescribe ACE inhibitors than cardiologists.

"Obviously, cardiologists know about ACE inhibitors and their value," Croft says. "Perhaps the message hasn't gotten down to the family practitioners, general practitioners, and internists."

KEY POINTS

- Mortality attributed to heart failure in patients 65 and over declined an average of 1.1% per year between 1988 and 1995.
- Black men made the biggest gains with a 3% decrease in death over the same period.
- Researchers say biggest contributors to increased longevity is the use of ACE inhibitors.
- Trend may simply reflect better reporting.

With 4.9 million Americans living with congestive heart failure, 400,000 new cases diagnosed each year, and 20% of heart attack victims expected to be disabled by CHF within six years of their MIs — Croft challenges physicians to contain the disease.

An American Heart Association spokesman said the outlook is improving for CHF patients in view of new methods of identifying those at high risk, better treatment of patients with MIs, and the availability of more effective drug treatments.

Croft concedes the declining death rate from CHF could be connected to changing reporting methods. "We always have to consider that," including the possibility that the declining death rate among black men may be due in part to physicians coding more accurately.

Croft scoffs at the idea that lifestyle changes may account for the reduced mortality.

"CDC data show no improvement in exercise or diet, although there has been some decline in smoking," she says.

K. Lance Gould, MD, professor of medicine, University of Texas Medical School, division of cardiology in Houston, couldn't disagree more.

Gould, author of *Heal Your Heart: How You Can Prevent or Reverse Heart Disease*, thinks Americans are doing a good job of reducing risk factors through "better diets and less smoking," although "there are still large numbers of overweight people." He particularly castigates the food industry for its marketing strategies that contribute to obesity.

"Go to Europe and you'll see that [American] portions are twice the size," he says.

Gould urges physicians not only to encourage low-fat diets for their patients, but also to encourage patients to consume low-carbohydrate, low-calorie diets.

Gould says heart failure is a "complicated social issue" among black men, and attributes the declining CHF death rate to "greater awareness of the risk factors and a greater determination among [them] to eat right and stay lean."

He adds that physicians need to engage in better risk factor management, including the use of cholesterol-lowering drugs.

He challenges health care professionals to pay more attention to cholesterol levels, which he believes are "grossly undertreated," noting data he says show that 50% of all bypass patients are not on cholesterol-lowering drugs.

"That's crazy," Gould concludes.

Alan Wasserman, MD, chairman of the Department of Medicine at George Washington University in Washington, DC, believes longevity is directly tied to more effective medical therapy.

"The use of ACE inhibitors has revolutionized treatment in the last three or four years," Wasserman says. "We really got the word out that everyone with poor left ventricular function should be on ACE inhibitors."

He echoes the "need for primary care physicians to make an impact" by providing aggressive therapy for CHF patients.

Most common therapies — diuretics, digoxin and ACE inhibitors — can be managed by primary care physicians, Wasserman says, "But there are advanced therapies that can be applied, like beta blockers, that need to be used carefully and slowly."

"Most generalists are not comfortable with that, so they need to realize when patients need other therapies and they need to refer."

[For more information, contact Janet Croft, PhD, Centers for Disease Control and Prevention, Atlanta. Telephone: (770) 488-5528.] ■

Strong predictor of sudden death found

Watching for heart rate variability risk

American heart failure experts are cautiously optimistic that a simple test may be a powerful new tool to recognize congestive heart failure (CHF) patients at high risk of death within a year and to give physicians an opportunity to provide the intensive treatment that may save their lives.

The effectiveness of the 24-hour heart rate variability test (HRV) in identifying patients at high risk of death within a year was studied by British researchers and reported in the Oct. 13, 1998 issue of the journal *Circulation* **(see accompanying story on methods, p. 7)**.

The result: CHF patients with a low variability rate were at 10 times the risk of death as those with high swings in heart rate.

In fact, of 433 patients in the study — 18 to 80 years of age — with congestive heart failure for at least three months, half with low heart rate variability, died during the study follow-up period (+/- 482 days). Of those with normal variability rates, only 5.5% died.

Those whose HRV was between the extremes had an annual death rate of 12.7%.

HRV test as research tool

At this point, says **David A. Meyerson**, MD, a national spokesman for the American Heart Association (AHA) and senior cardiologist at Johns Hopkins University in Baltimore, "It is an excellent research tool that we can use to help design interventions that will help people live longer with congestive heart failure."

The HRV test is already in limited use in the United States as an investigative tool, Meyerson said.

In a press release issued at the time the study was made public, lead author **James Nolan**, MD, of St. James's University Hospital in Leeds, England, recommended HRV tests for all CHF patients.

Meyerson and his colleagues think it's not yet time for the HRV test to be in routine use in the United States.

"Physicians can be aware that literature exists, and HRV is helpful in predicting who is at high risk," he said. "We will all look forward to the next meetings of the AHA where interventions will have been developed that will minimize this variability and hopefully help predict who we can help do better."

Lee Dykstra, MD, director of the congestive heart failure unit at the Kaiser-Permanente Foundation Hospital in Bellflower, CA, thinks CHF patients who are reasonably healthy and expected to survive another five years can benefit most from an early predictor like the HRV.

"If true, then this is a piece of information that is likely to help us focus our efforts on those patients who are likely to benefit. We have therapy that will help them, but until now we have not been able to identify who can benefit," he says.

"I couldn't tell you that I think we're going to improve outcomes by 5%, 10%, 20%. I don't know, but I think it's the right thing to do."

Dykstra adds, "Whether it's going to help all that much, we'll have to wait and see."

Like many of his colleagues, he praises the use of angiotensin-converting enzyme (ACE) inhibitors.

"We are just coming out of the Dark Ages in congestive heart failure. ACE inhibitors have reduced mortality by 30% in the past five years because they prevent the condition from worsening by lowering the blood pressure. Best of all, the more you take, the more benefits you get."

Ace inhibitor dosage

Dykstra says there is a general feeling among American cardiologists that many patients on ACE inhibitors would do better with higher dosages.

"General practitioners, family practitioners and internists may not be as aggressive in this as they should be," he says.

"I sympathize with the primary care physicians that they have to worry about cholesterol screening, cancer, blood pressure, and remember everything else and try to do some education, all in the course of a 15-minute visit," Dykstra added.

Nolan estimates that the early predictor HRV test can benefit 40% of CHF patients with extra treatment.

Nolan's study is an evaluation of results of the UK-Heart (Heart Failure Evaluation and Assessment of Risk Trial) that showed that patients with a low HRV following a heart

KEY POINTS

- Heart rate variability test can be an early and accurate predictor for high risk of death.
- Patients with low heart rate variability are at greatest risk.
- Early predictors give physicians an opportunity to prescribe more advanced therapy and possibly save lives.
- The American Heart Association (AHA) says the current value of the test is as a research tool.

attack had a lower chance of survival.

"Our aim was to recruit a wide spectrum of ambulant outpatients with mild to moderate symptoms treated with optimal contemporary drug therapy, and characterized according to simple, widely available clinical techniques," Nolan wrote.

Patients from four hospitals were analyzed between December 1993 and April 1995.

All subjects had CHF; those with confounding factors or co-morbid diseases such as diabetes, chronic renal failure, a history of alcohol abuse, clinical evidence of autonomic neuropathy or recent myocardial infarction, and a variety of other cardiac factors were eliminated.

Baseline data were collected for each patient, including chest X-rays, ECGs, left ventricular functions; and cardiothoracic ratios, electrolytic concentrations, renal and liver functions measured. In addition, left ventricular ejection fraction and fractional shortening indices were calculated according to standard formulas.

The majority of patients (76%) were diagnosed with ischemic heart disease and were being treated with diuretics (97%) and ACE inhibitors (82%).

Recording results

All patients were registered with the UK national death reporting system, which notifies researchers of all deaths. Death certificates, autopsy findings and hospital and physician records were reviewed by independent researchers at the University of Edinburgh in Scotland.

Nolan concluded, "Our data relating to mode of death are based on relatively small numbers of events; many deaths in heart failure patients are difficult to classify. The results should therefore be viewed with caution, but they do provide insights into the relationship between autonomic activity and mode of death in CHF."

Finally, the study says, "Data in relation to mode of death suggest that 24-hour ambulatory ECG may be useful in guiding the prescription of additional therapy for patients with symptomatic CHF who are already established on a diuretic and ACE inhibitor."

[For more information, contact: David Meyerson, MD, Johns Hopkins University, Baltimore. Telephone: (410) 750-5555.] ■

Heart rate variability testing methods

British researchers studying the relationship between heart rate variability (HRV) and mortality in congestive heart failure patients needed data from ambulatory patients.

Information was gathered from 433 congestive heart failure patients of both sexes aged 18 to 80, with a mean age of 62.

Subjects wore miniature battery-operated tape recorder ECGs (Tracker model from Reynolds Medical Ltd.) similar to that employed in common clinical practice in the United States. They engaged in 24 hours of normal, unrestricted activity.

Essential technology

The recorder includes a crystal-generated time reference track that allows correction for recording and replay speed errors to within .5%, which researchers considered essential for an accurate measurement of HRV.

The 24-hour ambulatory ECGs were replayed through a Pathfinder arrhythmia analyzer (Reynolds Medical Ltd.) to document the presence of ventricular arrhythmias. U.S. experts say the key to charting HRV lies in the analysis of the left ventricular function.

Ambulatory ECGs less than 16 hours in duration or with less than 90% of recording suitable for analysis were excluded.

After initial analysis, the remaining normal-to-normal RR levels were measured and time-domain analysis of HRV was carried out. ■

CHF study finds gaps in diagnosis, treatment

Discharge instructions fall short as well

A study of congestive heart failure (CHF) patients recently completed by the Missouri Patient Care Review Foundation (MPCRF) in Jefferson City, MO, indicates that physicians don't always provide the best diagnoses and don't always adequately treat the disease.

The foundation's Regional CHF Cooperative

Project looked at whether patients were receiving left ventricular function assessments and whether they were put on ACE inhibitors to improve left ventricular diastolic dysfunction, according to **Carl Bynum**, DO, MPH, principal clinical coordinator for MPCRF, which contracts with the federal Health Care Financing Administration (HCFA) to monitor quality of care for Medicare beneficiaries. The study revealed that the assessment is "not routinely done," Bynum says. "Lots of times physicians are evaluating and making a diagnosis based on symptoms. To accurately diagnose [left ventricular diastolic dysfunction] you have to evaluate the function of the heart. It's important because it determines what medication the patient should be placed on."

The assessment of cardiac function was performed in 72% of the patients studied, Bynum says, and most of the patients deemed ideal to be put on ACE inhibitors were given that treatment. That means the study did not consider patients who were allergic to ACE inhibitors or had some other reason for not taking the medication, he adds.

"Of ideal patients, 80% were put on ACE inhibitors," Bynum notes. "That's not too bad, but there are still another 20% that had the potential of being on the medication."

Prepare for post-discharge

The foundation is working with the hospitals involved in the study to implement plans to educate their physicians and to change their processes, he says. "This is an important aspect of the overall treatment of these patients, and we need to make sure there are processes in place to evaluate that."

Another aspect of the study looked at discharge planning for the patients, Bynum says. It found that 46% received instructions on medication, 27% received instructions on diet, and only 10% were instructed on weight monitoring. "We looked at what was written in the chart, and for our purposes, if it wasn't written in the chart, it didn't happen," he adds.

Post-discharge monitoring is a very important part of preventing complications from CHF, Bynum points out. "For patients to recognize that they might be retaining fluid, that they need to call the physician, or make some changes" is crucial, he says.

Hospitals that fell short in this area might want to develop a preprinted form or take some other action to alert nurses and physicians to the importance of discharge planning, he suggests.

MPCRF continues to analyze data from the study, which was initiated by the Kansas City regional office of HCFA with final outcomes due in December. The study involved eight states, but the percentages cited apply only to the Missouri patients. ■

HOT study recommends new blood pressure lows

Lowering diastolic blood pressure below the current targets can reduce stroke and heart attack risks, especially for diabetics. Currently, the recommended level for diastolic pressure is 90 mm Hg. A recent study, called the Hypertension Optimal Treatment (HOT) trial, reveals that even an eight-point reduction can make a difference.

Cardiologist **Nicholas Tsapatsaris**, MD, who coordinated the Burlington, MA-based Lahey Clinic's participation in the trial, says, "Based on research findings, it appears that lowering the number from 90 mm Hg to 82 mm Hg can save lives in terms of reducing the numbers of deaths from heart attack and stroke." He adds that according to a related study, a patient's quality of life suffers no negative impact from the eight-point reduction.

Subject categories

The subjects were randomly placed in three target (diastolic) blood pressure groups: 90 mm Hg, 85 mm Hg or 80 mm Hg. Out of the 724 cardiovascular events analyzed, the incidence of heart attacks was 84 in the 90 mm Hg group, 64 in the 85 mm Hg group and 61 in the 80 mm Hg group. The findings were drawn from a five-year follow-up of 18,790 patients in 26 countries.

Other key points of interest:

- Patients with diabetes and a diastolic blood pressure of 90 mm Hg were more susceptible to cardiovascular disease-related deaths than those with diastolic blood pressure of 82 mm Hg.
- Taking aspirin in addition to high blood pressure medication further reduced the risk of death from cardiovascular disease.
- A majority of subjects required combinations of different drugs to reach an 82 mm Hg diastolic reading.

[For more details, see Hansson L, Zanchetti A,

Carruthers SG, et al. Effects of intensive blood pressure lowering and low-dose aspirin in patients with hypertension: Principal results of the Hypertension Optimal Treatment (HOT) randomised trial. Lancet *1998; 351:1,755-1,762.]* ■

Free help is available for outcome measures

Peer review organizations are QI firms

Free of charge to medical groups: nurses to abstract outcomes data from patient charts; outcomes experts to analyze data and provide comparisons; feedback sessions to discuss interventions, education, and consensus-building.

Would you jump at that offer? Peer review organizations around the country hope you will.

Armed with contracts from the Health Care Financing Administration to improve care for Medicare patients, these organizations are developing collaborative projects with medical groups and other providers. If you have the desire for quality improvement, they will provide the means.

"We do the project design, data collection, analysis, feedback sessions. We assist them with quality improvement plans and provide them with tools to use in their interventions," says **Linda Gaskell**, RN, CPHQ, project manager of the Ohio Diabetes Project for Peer Review Systems in Columbus, OH. "We offer them a lot. Most physician offices have scant resources when it comes to quality improvement."

Collecting and using data

The Ohio Diabetes Project provides an example of such a collaborative. So far, 12 medical groups have signed on to measure and seek to improve on 12 indicators, which include patient education, HbA1c and cholesterol testing, foot exams, and ophthalmology referrals.

As the first groups completed their remeasurement after a year-long period of intervention, initial results show improvement. While their data remain confidential, other medical groups will learn of their successes, says **Stephani J. Wilmer**, community relations manager for Peer Review Systems.

"We're able to identify the collaborators who have the best practice and highlight [it]," she says.

Collaboratives such as the Ohio Diabetes Project represent a fundamental shift from retrospective review of Medicare care that occurred several years ago to a proactive approach. "We've always been concerned with the quality of health care provided to Medicare beneficiaries," says Wilmer. "The method we use to assess that care has changed."

The Ohio Diabetes Project actually began when a medical group approached Peer Review Systems with a proposal. PRS officials also had been considering a focus on outpatient diabetes care.

"We formed a study group of diabetes experts from Ohio," says Gaskell. "We developed the study design and methodology, the data collection tool, the definitions."

Collaborative efforts

The indicators were based on practice guidelines from the American Diabetes Association (ADA), and are updated to reflect any changes. Medical groups receive free forms that may help them improve their care: Checkpoints, a flowchart that is attached to the patient record, and Checkmate, an educational tool that allows patients to track needed care.

Once the first medical group successfully completed the one-year program, PRS began soliciting new collaborators. There is no limit on the number of Ohio medical groups that can participate, and no time limit on the life of the project.

"Every time a collaborator comes on board, we consider that a separate project with them," Gaskell says. "We look at one year period of care because a lot of [diabetes] indicators are based on annual events."

Themes for improvement

As PRS gathered baseline data, one consistent problem area arose: On average, only 24% of diabetic patients received a foot exam every visit. Gaskell recommends medical groups to include that indicator in their intervention programs.

"I think sometimes clinics are surprised at their results because the physicians think they're doing better than what our report may show for a particular indicator," says Gaskell. "To stimulate change you need to give physicians comparative data, not just education. You have to show them how they're doing and how they compare to others."

Medical groups in the Ohio Diabetes Project design their own interventions, so they all may make different changes in their processes based on their individual needs. But Gaskell has noticed some basic themes as the first groups show improvement:

1. Ensure physician buy-in before launching your quality improvement project.

One medical group used the small group consensus process to promote physician buy-in, which involves meetings in which physicians first reach agreement on the standards of care. In the case of the Ohio Diabetes Project, many of those standards are set by the American Diabetes Association guidelines.

Then, they identify the opportunities where they want to improve based on their baseline data. They brainstorm with a focus on barriers and possible solutions. In this case, the group even used a pre- and post-test on ADA standards and attitudes toward practicing using the standards of care, says Gaskell.

2. Involve patients in their own clinical improvement.

Physicians have a better chance of improving both clinical outcomes and quality indicators with the support and interest of patients. The Checkmates form helps patients monitor their own care, including cholesterol screening, foot and eye exam, and blood glucose.

"It encourages patients to become more aware of the kind of care they should be receiving and to get them more involved," says Gaskell. "We suggest that [physicians] ask patients to bring it to every visit. There's even a place where patients can list their goals, such as blood sugar level," she says. "They can use this to talk to their doctor."

3. Use a team approach to guide improvement.

The Ohio Diabetes Project requires participating medical groups to appoint an interdisciplinary team to work on improvements. In addition to physicians, that team may include nurses, diabetes educators, and the office manager.

Even simple changes can make a difference, Gaskell noted. For example, the staff person who guides a patient into a room can make sure that patient removes his or her socks. The doctor then will find it easier to conduct a foot exam — and harder to forget. ■

New once-a-day inhaler is quite effective

Physicians believe it will aid in compliance

The once-a-day Pulmicort Turbuhaler, approved by the Food and Drug Administration (FDA) in October, has created quite a stir among asthma patients and physicians.

With some qualification, experts agree the device by Astra Pharmaceuticals of Westborough, MA, will be effective in encouraging compliance among mild to moderate asthmatics.

Linda Ford, MD, president of the American Lung Association who practices at the Asthma and Allergy Center in Omaha, NE, says the product is not effective for severe asthmatics.

"Where those with milder asthma can get by on once-a-day inhaled steroids — whether it is Pulmicort or any other product — severe asthmatics need a heftier dose," Ford says. "We know that inhaled steroids work best when divided into several doses during the day."

> "For that group of mild to moderate persistent asthmatics, I think the biggest advantage of single daily dosing will be improving compliance."

On the other hand, Ford thinks once-a-day dosage will improve compliance among appropriate patients who use it.

Tailoring asthma treatment

She says patients with mild persistent asthma who have peak flow plans and follow them can use Pulmicort or any other inhaled steroids on a once-a-day basis, although Astra is the only company that has done a study on that type of usage.

"It's nice to know, but it's probably not brand specific, but class specific," she adds. "We've been doing it that way for a long time with mild asthma."

KEY POINTS

- FDA approves once-a-day inhaler, Pulmicort Turbuhaler by Astra Pharmaceuticals.
- Product is approved for adults and children over six.
- Experts say not only Pulmicort, but several inhaled steroids, can be effective disease management for mild to moderate persistent asthma.

However, Pulmicort may have a very specific affect on "real world" compliance, says **James L. Sublett**, MD, FAAAI, national medical director of Vivra Asthma and Allergy Research Institute in Louisville, KY, and a practicing allergist who participated in the Pulmicort clinical trials.

"For that group of mild to moderate persistent asthmatics, I think the biggest advantage of single daily dosing will be improving compliance," Sublett said.

"I think the patients' perception of single daily dosing is better and the likelihood of them following a treatment plan will be enhanced," he said.

Pulmicort is not much different from several other inhaled steroids not technically approved by the FDA that could be used with the same results in mild to moderate persistent asthmatics, Sublett says, "It's just that they (Astra) are the first ones to get FDA approval."

Sublett sees Pulmicort and Flovent (Glaxo-Wellcome's new and slightly more potent inhaled steroid) as "the next generation of asthma treatment drugs."

And while clinical results show a slightly better outcome for patients with twice-daily dosing, Sublett says, "When you come down to real-world situations, a lot of patients miss dosages anyway . . . in quality of life studies, a lot of times single daily dosage is just as effective."

Ford agrees.

"People who have mild persistent asthma don't have a lot of symptoms, and don't like taking medications two times or three times a day. So they are probably doing that (taking one dose a day) anyway."

Tailoring asthma treatment

To Ford, there is another key benefit to this new generation of drugs: it lets physicians know that single daily dosage steroids can provide day-to-day disease management for mild to moderate asthmatics.

"If it (the FDA approval of Pulmicort) does nothing more than to teach physicians that . . . you can alter, step up and step down therapy with inhaled steroids, it would be helpful," Ford explains.

She says many physicians may not realize that with a competent management plan, severe or moderate persistent asthmatics can be converted to a mild persistent form of the disease and benefit from once-a-day dosage over time.

What's different?

Ross Rocklin, MD, senior director of clinical research, says Pulmicort is different from other inhaled steroids because most inhaled steroids

Disease State Management (ISSN# 1087-030X) is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Piedmont Center, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodical postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Disease State Management**, P.O. Box 740059, Atlanta, GA 30374.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291, (custserv@ahcpub.com).

Hours of Operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday.

Subscription rates: U.S.A., one year (12 issues), $429. Outside U.S., add $30 per year, total prepaid in U.S. funds. One to nine additional copies, $215 per year; 10 or more additional copies, $129 per year. Call for more details. Missing issues will be fulfilled by customer service free of charge when contacted within 1 month of the missing issue date. **Back issues**, when available, are $38 each. (GST registration number R128870672.)

Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@medec.com).

Associate Publisher: **Milo Falcon,** (404) 262-5541, (milo.falcon@medec.com).

Production Editor: **Nancy McCreary**.

Editorial Questions

For questions or comments, call **Milo Falcon** at (404) 262-5541.

are administered two to four times a day. "We were originally approved for twice-a-day dosing and this approval is to have once-a-day dosing. This means a patient receiving a total dose of 400 mcg a day in two, three or four doses can be transferred to two inhalations of Pulmicort either in the morning or evening and you can achieve or maintain the same clinical control."

"The advantage for the patient is for compliance," he says. "They can take it once a day, but get their full dose with Pulmicort."

Rocklin says the Turbuhaler delivery system is unique, as the first dry powder inhaler to win FDA approval two years ago: "The advantage is that it delivers approximately twice as much drug to the lung" as other inhalers.

As a delivery system, Sublett and Ford agree, Astra's Turbuhaler gets good reviews from patients and physicians alike.

Special delivery system

The non-aerosol, non-fluorocarbon inhaler works on a different principle than other types, requiring the patient to breathe in slowly and hold for a count of ten to release the drug.

"For some people who have difficulty taking inhalers and can't get that eye-hand coordination, this works quite well," Ford says. "It's like a sucking action. The inspiratory pressure has to be quite high."

Sublett says the non-metered dose inhalers are probably "the wave of the future."Patients like the Turbuhaler because "you can't feel the drug going in at all, which in some ways is a plus because you don't have to worry about the taste factor. But it is different from what some patients are used to."

He believes that new drugs like Pulmicort provide the quality of life for patients and positive outcomes in terms of ER admissions. "It's another tool we can use to improve our care," Sublett says.

He noted that technology is rapidly changing in terms of asthma management. Several new drugs and delivery systems are on the horizon, including a nebulizer solution for Pulmicort nearing FDA approval that provides "very dramatic" results in asthmatics as young as a year old.

[For more information, contact the American Lung Association, at (800) LUNGUSA, or Ross Rocklin, MD, Astra Pharmaceuticals, (508) 366-1100.] ■