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DIABETES MANAGEMENT™

The Complete Diabetes Disease State Management Resource

INSIDE

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ADA: 'No more excuses' for poor glycemic control

UK study of Type II diabetics confirms urgency

The Alexandria, VA-based American Diabetes Association (ADA) has raised the torch of tight glycemic control even higher after the release of the largest ever study of Type II diabetics, the United Kingdom Prospective Diabetes Study (UKPDS).

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

The study also shows tight control of hypertension among diabetics has equally dramatic results in terms of managing 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 angiotensin-converting enzyme (ACE) inhibitor captopril and the beta-blocker atenolol worked equally well.

As with 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.

KEY POINTS

- The United Kingdom Prospective Diabetes Study is the largest study on Type II diabetics with 5,102 subjects, all newly diagnosed.
- Intensive glycemic control reduces risk of major diabetic eye disease by 25%.
- For every 1% 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 death from diabetes-related causes by 32%.

The final message, the final piece of evidence, is here," he 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," he warns.

Furthermore, Kahn believes the burden of responsibility for improved care rests squarely on the 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 explains his position with these points:

❒ **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,'" he says. "Health care professionals are not taking this disease seriously."

A call for aggressive treatment

The ADA, in a position paper issued shortly after the UKPDS' release in September, 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. And it is incumbent on the health care system to provide the necessary resources for both to be successful."

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

All patients were placed on diet control alone for the first three months and then randomly divided into groups that received drug therapy and those who remained on diet control. Those with hypertension were divided into "tight" and "less tight" control, and administered ACE inhibitors or beta-blockers. 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 with 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 deaths, a 7% reduction in all-cause mortality, and an 18% reduction in combined fatal and nonfatal 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 mmHG 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 mmHG.

❒ While a 16% reduction in the risk of combined fatal or nonfatal 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%

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UKPDS provides answers, fuel for debate

By **Ralph Hall**, MD
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The results of the long-awaited United Kingdom Prospective Diabetes Study (UKPDS) are now available, and they 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 II 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 were the evaluation measurements used in the study. These risks were sudden death from hyperglycemia or hypoglycemia, fatal or nonfatal 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.

Compared with 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 has 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 II diabetes patients.

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 II Diabetes" (UKPDS 34). The mean HbA_{1c} 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.

Because the addition of metformin to the sulfonylureas early on in treatment is associated with a less favorable outcome and the use of metformin alone results in a more favorable outcome, there is cause for 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 Journal* were aimed at measuring the effect of tight blood pressure control on the risk of macrovascular and microvascular complications in Type II diabetes (UKPDS 38) and the efficacy of atenolol and captopril in reducing macrovascular as well as microvascular complications in Type II 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 the DCCT studies, which documented that improved control decreases microvascular diseases in Type I diabetes by demonstrating that improved blood glucose control also lowers the risk of microvascular diseases in Type II 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 Alexandria, VA-based American Diabetes Association's (ADA) 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 angiotensin-converting enzyme 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 counselling.

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. ■

reduced risk of diabetes-related deaths and cardiovascular events. However, a small sample of patients who were given a maximum dosage of sulfonylureas and then had metformin added showed an increase in diabetes-related deaths. The ADA says the results were affected by design aspects of the 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 a 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 7.0%. "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 says, 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, the lecture circuit and a flurry of public education materials.

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

Success for intensive nurse case management

Patients learn at their own pace

Prudential's Center for Health Care Research has already discovered that investing time and attention to patient education yields medical benefits for members of its HMO. Now researchers expect they will find it is also a cost-effective means of disease management. Furthermore, they hope to be able to devise a similar education model for less-structured managed care settings.

The study published in the *Annals of Internal Medicine* was part of Prudential's quest for "simple low-cost methods translating guidelines into clinical care" that involve less of the relatively expensive time of a physician and more of the comparatively lower cost time of nurses and other clinicians.

Evaluating impact and logistics

The 12-month randomized trial involved 137 members of Prudential's Jacksonville (FL) Health Care Group HMO (17 with Type I and 121 with Type II) and compared a nurse case management model with usual diabetes management in a primary care setting.

"It was a standard benefit, so that program was contracted by Prudential," says **Robert Aubert**, PhD, senior health care analyst at the Prudential Center for Health Care Research in Atlanta. "We've done this in San Antonio, also in a group model HMO. What we are looking at currently is to evaluate potential impact and the logistics of doing this in other network IPA-type health care delivery settings."

Jacksonville patients were ineligible if they had a recent HBA1c of less than 7%, uncontrolled hypertension, unstable angina, myocardial infarction, two or more episodes of seizures, documented alcoholism or drug abuse, late-stage complications of diabetes, or were pregnant.

The results: Type II patients in the nurse case management model experienced a mean decrease in HbA1c of 1.7% (from 9.0% to 7.3% after 12 months) and 43 ml/dL in fasting glucose levels, compared to a .6% decrease in HBA1c (8.9% at baseline compared to 8.3% after 12 months), and 15 ml/dL decrease in fasting

KEY POINTS

- Study shows that patient education not only improves patient care but also slashes costs.
- The intensive three-month nurse case management program is designed to bring patients to the point of responsible self-management.
- Patients are enrolled in a five-week, 12-hour, hospital-based diabetes education program involving nurse case managers, dietitians, and exercise therapists.

glucose for the usual care group.

The results held true for Type I diabetics in the nurse management group, who experienced a 1.2% decrease in HbA1c compared to .2% in the usual care group.

Researchers found no significant differences between the two groups in terms of blood pressure, serum cholesterol, and triglyceride levels or body weight, although the intensive management group had fewer members of ethnic minorities, more smokers, and more insulin-treated patients.

"During the first three months, the patients just need to be titrated, educated, and have somebody giving them some attention," says **Janice Waters**, RN, diabetes disease management specialist with Prudential Center for Health Care Research in Jacksonville, and Atlanta. "I really think that first three months is very critical in an intensive management program like this."

Patients in Prudential's program are enrolled in a five-week 12-hour hospital-based diabetes education program. In total, they receive more than four hours of individual counseling by program staff and hospital staff, including a nurse case manager, dietitians, and exercise therapists — and they get more time if they need it. They also receive group education sessions and can avail themselves of a wide variety of a published materials and videotapes.

Goal of patient responsibility

All patients in the hospital-based diabetes education program received counseling in nutrition, exercise, blood glucose monitoring, medication and insulin, psychosocial adjustments, stress management, acute and chronic complications, and optimal health habits.

The intensive three-month nurse case management program is designed to bring patients to the point of responsible self-management in that time frame. The curriculum was developed by a multidisciplinary team, which included endocrinology, family medicine, nursing, pharmacy, health services research, and epidemiology.

After an initial assessment by the nurse manager, patients were placed on a glucose monitoring schedule, asked to keep a log, and scheduled for a follow-up with the nurse two weeks later.

At the follow-up visit, patients were given medication adjustments, if necessary, and assisted in meal planning and exercise reinforcement. In addition, patients on insulin received weekly telephone calls. All others received a telephone call from the nurse every two weeks. And the nurse manager met with the physician or endocrinologist every two weeks to review the patient's progress.

Aubert says researchers learned that most of the change in terms of glycemic control happen in the first three to six months, "So in terms of implementing the program, we are looking to try to do that intensive management part of three to six months and then try to roll people into a maintenance phase where there is less frequent contact."

Waters says flexibility is built into the program. "Not everyone learns at the same pace. Shock and denial are the first things that most people experience with a new diagnosis. That's a health care professional's call. Maybe this person needs a little bit more reinforcement or more calls or some individual time."

Some younger patients lost to follow-up

The study also showed a significant loss of patients to follow-up in both groups, the majority of them between 18 and 44 years old, which lost 11 of the 14 members of the intervention group.

Aubert says, "We may need to be a little more flexible, not as intensive. We also need to analyze data a little more. It could be that we just had more people change health plans who happened to be in nurse case management and were younger. The younger population tends to be more of a challenge in a lot of ways."

Waters adds, "I think the Type Is who have had diabetes for a long time require just a little bit more attention. For a younger person's active lifestyle, sometimes it is not easy to be quite so rigid."

She notes there were no pump patients in the program and says she has recommended it to several younger more active patients because "it allows for more flexibility as far as the injection and the convenience."

Prudential Health Care is delving more deeply into the data generated by the Jacksonville study and hopes to release results soon about cost-effectiveness and the translatability of the program to less-structured health care programs.

For more information, contact: Ronald Aubert, PhD, senior health care analyst, Prudential Center for Health Care Research, Atlanta. Telephone: (770) 801-7880. E-mail: ronald.aubert@prudential.com. ■

Alert: All diabetics need flu shots

Increased risks for flu complications

Diabetics are at far greater risk of death from complications of the flu than the general population, yet fewer than half the diabetics in the United States received flu shots in a recent year.

All diabetic patients, their families, and caregivers need flu shots now to avoid infection during this flu season, which runs from now until March, warns the Centers for Disease Control and Prevention (CDC) in Atlanta as it prepares for a severe winter.

Much greater risk from flu

Diabetics are three times as likely as the general population to die of complications from flu, more specifically pneumonia, so epidemiologists say it is essential for flu shots to be administered to every diabetic. "When they get the flu, the complications are more severe since people with diabetes are more susceptible to all types of infection," says **Rodolfo Valdez**, PhD, an epidemiologist in the CDC's division of diabetes translation.

Researchers say they do not know precisely why this is so, but they theorize that diabetes compromises the immune system in general. "Pneumonia is the seventh cause of death in the United States," Valdez says, "and diabetics are three times more likely to get pneumonia and to die of pneumonia."

The CDC also recommends a pneumonia shot (pneumococcal polysaccharide) for all diabetic patients every five to ten years.

The CDC released statistics stating:

• Death rates for diabetics increase 5% to 15% during flu epidemics.

• Mortality is particularly high when multiple risk factors exist, especially for those over 65 and those with cardiovascular disease.

• People with diabetes are at increased risk of hospitalization from flu-related pneumonia.

• In a recent year, only 40% of adults with diabetes were immunized against flu and fewer than one in five against pneumococcal disease, the cause of the leading form of pneumonia.

Valdez says he is perplexed that patients and physicians do not take advantage of this safe, easy, and cheap life-protecting immunization. "They are not getting the flu shots the way they should be getting them," he says. "It could be the physician; it could be their HMO. It could be that they don't get the word, or they don't request it. Or maybe the doctors think that because [these patients] have diabetes, the flu shot might be damaging to them."

There have been no known serious complications from flu shots, which do not contain a live virus, according to CDC researchers.

Valdez says epidemiologists are bracing for a severe flu season this winter in the wake of National Weather Service forecasts for a colder and wetter than normal season and in the presence of the La Nina phenomenon, the cold weather-carrying antithesis of El Nino.

For more information, contact: Rodolfo Valdez, PhD, Centers for Disease Control and Prevention, Atlanta. Telephone: (770) 488-1050. ■

PATIENT EDUCATION

Professionals: Educate yourselves, your patients

Responsibility's equally patients', providers'

Diabetes is serious.
It's:
Common
Costly
Controllable

This eye-catching message and the slogan "Control your diabetes for life" from the National Diabetes Education Program are echoing across the airwaves and being beamed into physician and clinic waiting rooms as diabetes educators search for ever more effective ways to get the attention of health care professionals and the public.

As the evidence for strict glycemic control

Diabetes Care at-a-Glance Chart

1. Criteria for Diagnosis of Diabetes

Fasting plasma glucose	≥ 126 mg/dl[1]
Random plasma glucose	≥ 200 mg/dl[1]

[1]Repeat to confirm on subsequent day

2. Glycemic Control Goals for Type 1 or Type 2 Diabetes

Level of Control	Hemoglobin A1c
Excellent	< 7%
Good	≤ 8%
Take action	> 8%

Self-monitoring Blood Glucose (BG)

Preprandial BG goal:	80-120 mg/dl
Bedtime BG goal:	100-140 mg/dl

3. Management Schedule

At every visit:
- Measure weight and blood pressure.
- Perform foot exam (high-risk feet).
- Review self-monitoring BG record.
- Review/adjust medications.
- Review self-management skills, dietary needs, and physical activity.
- Counsel on smoking cessation.

Twice a year:
- Order HbA1c in patients meeting treatment goals with stable glycemia (quarterly if not).

Annually:
- Order fasting lipid profile, serum creatinine urinalysis for protein and microalbumin.
- Order dilated eye exam, dental exam, and influenza vaccine.
- Perform foot exam (low-risk feet).

* The numbers are based on American Diabetes Association Clinical Practice Recommendations. *Diabetes Care* 21 (Suppl.1):523-535, 1989.

4. Category of Risk Based on Lipoprotein Levels in Adults

Risk	LDL Cholesterol (mg/dl)	HDL Cholesterol (mg/dl)	Triglyceride (mg/dl)
Higher	≥130	<35	≥400
Borderline	100-129	35-45	200-399
Lower	<100	>45	<200

5. Treatment Decisions Based on LDL Cholesterol Levels in Adults

	Medical Nutrition Therapy		Drug Therapy	
	Initiation Level	LDL Goal	Initiation Level	LDL Goal
With CHD, PVD, or CVD	>100	≤100	>100	≤100
Without CHD, PVD, or CVD	>100	≤100	≥130	<130*

Data are given in mg/dl.
**For diabetic patients with one or more CHD risk factors, some authorities recommend and LDL goal < 100 mg/dl.*

6. Hypertension in Adults with Diabetes

	Systolic mmHg		Diastolic mmHg
Definition	≥140	and/or	≥90
Treatment Goal	<130		<85

For more information, call 1-800-438-5383 or visit our Web site at http://adep.nih.gov. The National Diabetes Education Program is a joint program of the National Institutes of Health and the Centers for Disease Control and Prevention.

expands, diabetes educators are expanding their search for ways to help patients bring their disease under control. And they are looking for ways to help lift the burden from time-pressured primary care physicians.

"Right now we don't have a health care system that is fully supportive of prevention, since you will hear again and again that physicians only have 10 or 15 minutes with people with diabetes," says **Faye Wong**, MPH, RD, co-director of the National Diabetes Education Program (NDEP) at the Centers for Disease Control and Prevention in Atlanta.

She says short-shrifting patients in terms of physicians' time is unfair. "Patients are set up for failure; patients are set up to be victims. They are set up to be blamed for the disease." She adds, "The system is not set up to adequately provide patients with the knowledge they need, the skills they need, or the support to carry them through."

Of course, Wong concedes, there is a tremendous storehouse of knowledge that needs to be transferred to newly diagnosed patients, but she cautions that it shouldn't happen all at once. Wong says she blames health care professionals for attempting to download "six years of education on a patient in five minutes" and then being puzzled why outcomes are not better.

"In our society, we tend to treat everybody the same," she says. "The health care professional walks in the door and says 'Here's the ten things I have to tell you' and then you tell them those ten things and say goodbye."

Not only do newly diagnosed patients need time to adjust to the distressing news they have a disease that will require intensive management

for the remainder of their lives, they need programs tailored to individual needs, Wong explains.

The NDEP says the team approach is the answer. Recent experience backs the concept with measurable results. If a physician moves toward team approach, the patient can benefit from the combined experience of nurses, dietitians, pharmacists, diabetes educators, and other providers who are familiar with diabetes — treating diabetes and educating people with diabetes.

"Oftentimes, there are providers who are more knowledgeable about diabetes than the doctor himself or herself, especially in the case of family practitioners who have to know every disease. It's overwhelming for them," Wong says.

It's important to bring the broader community — family members, friends, and the community patients live in — in the team approach to diabetes education, she says, because "these are important support mechanisms for people with diabetes."

Wong and her NDEP colleagues are strong proponents of assessing where patients stand in terms of the disease before thrusting them into programs that might not be suitable for their needs.

"If you take a group of people, you find people at the extremes and in the middle," she says. "You might find one group, the minute they hear about diabetes, they will be doing the right thing immediately because they are very self-motivated people. On the other hand, some people, no matter what you tell them even under a death sentence, they won't do the right thing."

It's all about motivation, but tailored to the individual, educators say.

Health educators need to do a better job of staging people and assessing them than they are doing right now, Wong urges.

"Are they at the full denial stage where it is a waste of time telling them anything? Or are they at a stage where they are ready to start reading, but not necessarily take action? Or are they are the stage where they are ready to try one thing?" she asks. **(For examples of educational material, see box, p. 83, and principles for physicians, at right.)**

"What's important is to keep them going."

For more information, contact: Faye Wong, MPH, RD, Co-director of the National Diabetes Education Program, Centers for Disease Control and Prevention, Atlanta. Telephone: (770) 488-5037. E-mail: flw2 @cdc.gov. ■

Guiding Principles for Diabetes Care

✔ **Principle 1: Screening high-profile people and diagnosing diabetes**
One third of people with diabetes remain undiagnosed. Finding and treating diabetes early can improve health outcomes for people with diabetes. Therefore routine screening and correct diagnosis are essential.

✔ **Principle 2: Ongoing care**
People with diabetes should always receive high quality care on an ongoing basis to ensure that they are taking good care of their diabetes and to make changes in their treatment plans when needed to achieve control of the disease.

✔ **Principle 3: Diabetes education**
People with diabetes and their family members have the right to accurate information and education needed for diabetes self-care.

✔ **Principle 4: Treating hyperglycemia**
Blood glucose levels should be kept as near to normal levels as is safely possible. The target range should be based on an overall assessment of the person's health.

✔ **Principle 5: Self-monitoring of blood glucose control and hemoglobin A1c (HbA1c)**
Blood glucose levels and hemoglobin A1c values should be measured on a routine basis using current, reliable methods.

✔ **Principle 6: Preventing and diagnosing long-term diabetes problems**
Excellent diabetes care can greatly lower the chances of developing long-term diabetes problems.

✔ **Principle 7: Screening for and treating long-term diabetes problems**
People with diabetes should have regular exams to help find and treat long-term diabetes problems. All long-term diabetes problems have effective treatments.

The full text can be downloaded from the National Diabetes Education Program Web site at http: //www.ndep.nih.gov. Or copies can be ordered from the National Diabetes Information Clearinghouse at (800) 438-5383.

IDC creates curriculum that works

Results-oriented program focuses on adult models

Results-oriented education for adult diabetics is the watchword of the International Diabetes Center (IDC).

More than 300 patients walk through the doors of the main center in Minneapolis each month, most of them as participants in the IDC's six-month diabetes education program.

"It's designed to show results," says **Patti Rickheim**, MS, RN, CDE, manager for patient education at the IDC.

And it's working.

A random sample showed the average group of patients began with a HbA1c of 9.5%, and that dropped to 7.2% by the end of the program.

IDC uses the team model to work with primary care physicians, internists, and family practitioners. The team includes nurses, dietitians, and psychologists — 90% of them certified diabetic educators.

"We consider ourselves part of their team," Rickheim says. Physicians within the IDC's system of 13 satellite clinics and a central location refer patients for diabetes education.

Learning by repetition

The basic program for newly diagnosed Type II diabetics is focused on models for the adult learner. "They learn by doing repetition and seeing results and by basing their information on their experiences," Rickheim says.

"They need to have knowledge in order to make change, but they also need to see results. We've designed the sequence of the stages of the visits so that as adult learners they can learn something and then practice it and come back and see results of what they've done," she explains.

In the first two visits, patients are seen both in group and individual settings. They are given basic information about diabetes, and the point is driven home that "diabetes is a serious disease, and we let them know they can manage it," she says.

Patients are taught to do glucose monitoring and asked to test every day for two weeks until the next visit. They work on a meal plan and keep a diary.

"Interestingly enough," notes Rickheim, "they have made some really keen observations about how their body works based on their blood sugar. It's helping them understand how their body does respond to food and to exercise. Patients begin to see that certain things do make a difference, that even small changes can make a difference in their blood sugar.

"We've designed our program to provide certain information and content at different visits, so we have sequenced the learning based on research models," Rickheim explains.

Programs are also available for those newly started on insulin and for maintenance of previously diagnosed patients.

The last two visits for Type II patients delve more deeply into applying the knowledge to everyday life. "We work with them to make behavioral changes along the way," she says. "It's a lifestyle change they must make since diabetes is a chronic disease. They aren't going to make it in one visit or because they've learned something one time."

Motivating and encouraging patients

Information is fed carefully to patients as they are ready to assimilate the knowledge.

"They need to be encouraged. We see ourselves more as facilitators who work with the patient with the goal of empowering the patient to make their own choices and decisions but with providing them with information, suggestions, or feedback so that they will be more successful," says Rickheim.

Along the way, staff maintain close touch with primary care physicians to make recommendations in terms of behavioral and drug therapy.

Medication adjustments are frequently made, including insulin adjustments after telephone monitoring. "There is a fair amount of latitude. Our physicians are quite confident in the work we do; they pretty much leave it to us to make insulin changes and such," says Rickheim.

In addition, IDC is working on a plan to intensify management by closer monitoring of comorbidities. Many IDC patients have hypertension and lipid problems, so the staff not only discuss complications with them but are preparing the next phase, to review patient records and generate referrals for lipid testing, eye exams, microalbumins, perhaps even automatically generating pre-authorized lab slips and returning results to physicians.

Rickheim's advice to diabetes educators: "Look at outcomes and look at overall goals and plans. Keep in mind that more is not better. Sometimes simpler is better.

"What is the need-to-know information? Sometimes it's too much, and even adults can't take it all in. We want to give them the tools where they can make change and be successful because it is for life," she adds.

The IDC plans to publish its Type II curriculum in early 1999. The guide will walk patients and staff through each section, including the rationale, the research, and clinical information as well as explaining the reasons underlying the learning objectives. It will also provide suggestions to staff to address behavioral change.

To purchase copies of the IDC curriculum when it is published, contact Patti Rickheim, MS, RN, CDE, Manager for Patient Education, International Diabetes Center, Minneapolis. Telephone: (612) 993-3393. ■

Viagra: Limited success among diabetic men

Be careful of prescribing for sedentary patients

Viagra has proven a wildly popular success by restoring sexual function to millions of men who suffered from a variety of dysfunctions for a variety of reasons. Since 60% of diabetic men suffer from erectile dysfunction caused by their disease, many hoped Pfizer Pharmaceuticals' wonder drug would be a magic pill to restore them to normal sex lives.

Not always the right choice

However, the reality is somewhat less glamorous, and there are serious caveats for a practitioner considering prescribing Viagra for a diabetic patient. Some specialists say other methods are probably safer and certainly more reliable.

While Pfizer's clinical trials including 3,500 men, 16% of them diabetic, showed a 59% success rate for diabetics using Viagra, some specialists report a significantly lower rate of success and others say the drug is very effective. **(See box, p. 87.)**

J. Francois Eid, MD, associate professor of urology at Weill Medical College of Cornell University in New York City and director of the Male Sexual Function Center of New York Presbyterian Hospital, also in New York City, says 55 % of his patients have achieved success with Viagra.

And his colleague at Columbia Presbyterian Medical Center in New York City, **Gerald Hoke**, MD, MPH, a urologist specializing in erectile dysfunction, says Viagra works for about half of his diabetic patients. **(See chart, below.)**

Different physical characteristics

Eid, who participated in the Phase 3 Viagra trials and began prescribing the drug to non-insulin-dependent diabetes mellitus and insulin-dependent diabetes mellitus patients in 1995, notes a particular pathology of the penis among diabetic men.

"While in non-diabetics, the main arteries feed blood to the penis to cause an erection, in diabetics, the small arteries are obstructed," Eid says. These men have scarring, shrinkage, deformities, or plaques in the penis known as Peyronie's disease with a characteristic abnormal penile curvature." Because the disease is degenerative and the characteristics are not seen in other types of erectile dysfunction, Viagra is less than the wild success patients had hoped for, Eid says.

With 123 reported deaths, 69 of those directly attributed to Viagra, specialists warn against prescribing Viagra for diabetic men without a thorough investigation.

"Obviously you can't give it to anybody taking

Success of Viagra

Clinical trials of 4,000 men	Success rate
Patients with spinal cord injuries	83%
Non-diabetics	68%
Diabetics	55%
Patients with prostatectomies as a result of cancer	40%

Source: J. Francois Eid, MD, Weill Medical College of Cornell University, New York City.

Pfizer Clinical Trials

Of 3,500 men participating in the pharmaceutical company's clinical trials, 16% were diabetics.

- ❒ Diabetics achieved a 59% success rate.
- ❒ Placebo group had a 16% success rate.

Source: Pfizer Pharmaceuticals, New York City.

nitrates, and a lot of our patients have heart diseases and are taking nitrates, so they just can't use it," says **Kathryn Tuck**, MD, associate director for clinical trials at Naomi Berrie Diabetes Center at Columbia Presbyterian Medical Center and assistant professor of medicine at Columbia University.

Tuck, an endocrinologist who reports a high success rate among her patients at the newly opened Naomi Berrie Diabetes Center, says, "The other big worry is that there have been some deaths reported in men who have used Viagra and weren't taking nitrates, but presumably had heart disease. Since we always think that diabetic men could have heart disease but are asymptomatic, we need to be careful."

All three specialists agree that stress tests should be administered to any diabetic patient at risk for complications before a prescription for Viagra is dispensed.

Tuck is particularly leery of prescribing the drug for sedentary patients. "If they haven't been exercising much and they have risk factors for heart disease, I would probably give them an exercise test before I gave them Viagra to make sure they don't have any heart disease."

Eid concurs, "Primary care physicians know which patients are couch potatoes. Since they experience an increase in oxygen demands during sex, if a patient is totally sedentary or has a history of myocardial infarction, that raises a red flag."

He notes that a sexual encounter will increase the heart rate to 120 to 130 and that with Viagra, there is a delayed ejaculation, so the man will be thrusting for a longer period of time.

Hoke says one-third of all men who resume intercourse have signs of ischemia and about 7% of them actually develop clinical signs of chest pain up to 24 hours after intercourse. "We had a discussion as to whether or not you need to do an extensive workup [before prescribing Viagra for diabetic men]," Hoke says. "I don't know if you do or don't, but clearly you have to be very cautious in diabetic men who also have other signs of coronary heart disease, especially if they haven't had intercourse for quite a while."

"You really need to use your common sense," he continues. "If the guy says, 'Well, I jog three miles a day,' you probably don't need to do a stress test. But if the guy's a little overweight and hasn't had sex in two years, and maybe smokes, then you probably should do one."

Other complications are comparatively minor and appear to be temporary.

Tuck says she had one patient who "started having some chest pain, so he got nervous and stopped using it."

Hoke says he had one diabetic patient who had visual disturbances slightly different than those described by the manufacturer, and his lasted a bit longer. "His visual field became dark as opposed to the blue haze that has been described, and he

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said it lasted until the next morning," Hoke says. "It turns out that this particular guy probably has some retinopathy."

Retinopathy is not yet a disqualifier for the drug, but Hoke says it needs to be watched. "I think if we see this type of complication coming out, it probably will [become a contraindication]. I don't think we really understand fully the reason why we have visual disturbances."

Some refuse to take Viagra

Many diabetic men are so fearful of the possible complications of Viagra that they refuse prescriptions. Eid notes that many of his patients on penile injections who were candidates for Viagra declined prescriptions for sildenafil because they were worried about possible heart problems "even though there was no clinical reason why they should not have a good result." Also, he says, many patients were happy with the predictability of erection achieved through penile injections and did not want to experiment with a new product.

Physicians should counsel patients about the use of Viagra, the experts say, to be sure patients understand that the drug is not an aphrodisiac but requires considerable sexual stimulation to be effective.

Eid says Viagra is only a small part of his arsenal against diabetes-induced impotence. He is highly enthusiastic about Caverject (alprostadil) because of its high success rate, about 85%, its low cost (about half the $7.50 to $10 cost per pill) of Viagra, and the fact that Medicaid, Medicare, and some managed care organizations will pay for it.

He says diabetic men are not usually as squeamish about needles as their non-diabetic peers "and with the neuropathy most diabetic men have, they do not even feel the injection of a fine needle at the base of the penis."

He is also enthusiastic about the penile prosthesis because of its almost unfailing success rate (99%). "It's very discreet. For some men, their wives don't even known they have a prosthesis," Eid says. "The penile prosthesis is the most successful procedure in the whole field of urology, even more so than the treatment of kidney stones, which is only 85% effective."

Eid concludes that he is puzzled that so many men, diabetics in particular, fail to seek treatment for erectile dysfunction when many effective solutions are available.

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CE objectives

After reading this month's issue, the continuing education participant should be able to:

- Cite the benefits of strict glycemic control as demonstrated in the UKPDS and DCCT studies.
- Cite the time frame in which Prudential's Center for Health Care Research bring patients to the point of responsible self-management.
- Understand the increased risks for diabetics who contract the flu or pneumonia.
- Explain why a stress test is recommended before prescribing Viagra to diabetic men. ■