

'Road Maps' Chart Use of New Diabetes Drugs

BY DIANA MAHONEY
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The availability of new agents for the treatment of type 2 diabetes, as well as new indications for existing agents, has broadened the therapeutic landscape for the disease, but without a map, the region can be difficult to navigate. To provide direction, the American College of Endocrinology and the American Association of Clinical Endocrinologists recently revised its "Road Maps for the Prevention and Treatment of Type 2 Diabetes."

The three road maps—one each for treatment-naïve patients, treated patients who had not reached the hemoglobin A_{1c} (HbA_{1c}) target, and patients at high risk for progression to diabetes—were introduced in 2005 to provide guidance for meeting existing diabetes treatment guidelines.

"We needed to update [them] because there have been a number of new products introduced, including inhaled insulin, basal insulin analogs, pramlintide, and DPP-4 inhibitors," said Dr. Paul S. Jellinger, cochairman of the Road Map Task Force. "There are also new indications for some of the drugs already in use. For example, exenatide is now approved for use with [thiazolidinediones] in treatment-naïve patients presenting with initial A_{1c} between 7%-8% who haven't achieved the target A_{1c} goal of 6.5% or lower with other therapies."

Although other treatment algorithms

have not yet included mention of the newer agents, "we've included recommendations on when and how to use them, based on A_{1c}-lowering data from FDA- [Food and Drug Administration] approved clinical trials and large randomized trials, as well as expert opinion," said Dr. Jellinger, who is in private practice in Hollywood, Fla. "We want patients and clinicians to be able to take advantage of the newer-approved therapies without having to wait 10-20 years for more outcome data."

The road maps also give physicians guidance and specificity all the way through the disease process, said Dr. Jaime A. Davidson, the other task force cochairman. "Rather than taking a treat-to-failure approach by waiting for patients to fail and then giving them a pill, the road maps use a treat-to-target approach from day 1, clearly indicating when to initiate therapy and with what agent. They also specify when to move on. For instance, instead of wasting a year to see if metformin by itself will get a given patient to target, the road maps define what agents to add if target is not met within 3 months."

In addition, the road maps are geared to the needs of individual patients, continued Dr. Davidson, an endocrinologist at Medical City Dallas Hospital. "Rather than saying, 'We're going to start everyone who comes in with treatment-naïve disease on metformin,' the road maps differentiate based on A_{1c} percentages. If someone comes in

with an A_{1c} between 10%-11% and is symptomatic, they get insulin from day 1."

That stratification is very important, Dr. Jellinger said. "Patients presenting with an A_{1c} between 10%-11% certainly require different treatment than those presenting at 7%-8%." Although an HbA_{1c} greater than 10% is an indication for insulin in most patients, "other algorithms don't provide clear stratification, and many lump together everyone with an A_{1c} over 7%," the glycemic target recommended by the American Diabetes Association.

As in the earlier road maps, the revised versions also advocate an "uncompromising treat-to-target" approach, in which the treatment targets are an HbA_{1c} value of 6.5% or less, fasting/preprandial glucose levels less than 110 mg/dL, and a 2-hour postprandial glucose level less than 140 mg/dL, as per guidelines from the American Association of Clinical Endocrinologists, said Dr. Jellinger. The goal "is to get patients to target as quickly as possible and to keep them there."

The road maps help achieve this by targeting, in particular, the treatment of postprandial hyperglycemia in the lower HbA_{1c} ranges, which also distinguishes the resource from other algorithms. "Studies have shown that the postprandial glucose is higher in the lower A_{1c} ranges, while fasting hyperglycemia increases in the higher A_{1c} ranges," said Dr. Jellinger. "This is why we recommend agents that affect

postprandial control, such as the [meglitinide derivatives] and DPP-4 inhibitors, more prominently in treatment-naïve patients in the lower A_{1c} range."

To best meet and maintain AACE glycemic goals, therapeutic agents should be monitored and adjusted every 2-3 months. "If a treatment is not working as well as it should, change it. The road maps clearly tell you what to do, step by step, to meet and maintain the 6.5% A_{1c} goal," said Dr. Jellinger.

In terms of prevention, the road maps stress early identification of high-risk individuals and describe lifestyle modifications and pharmacologic options that have been shown to stave off progression to type 2 diabetes. The document lists four glucose-lowering agents that have, in clinical studies, effectively delayed the onset of type 2 diabetes in high-risk patients, but the agents are not FDA-approved for prediabetes and, as such, AACE does not advocate their off-label use, Dr. Jellinger noted. "The drugs are listed because we recognize that physicians do use them to treat prediabetic individuals, particularly those with impaired glucose tolerance and multiple cardiovascular risk factors." The AACE is currently developing a consensus conference on the treatment of prediabetes. ■

The revised road maps are available on the AACE Web site at www.aace.com/meetings/consensus/odimplementation/roadmap.pdf.

Education Tool Helps Diabetics Focus on Self-Management

BY PATRICE WENDLING
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CHICAGO — Health care professionals are trying a new tack to better engage patients in the self-management of their disease.

The American Diabetes Association (ADA) and Healthy Interactions Inc. are launching an initiative centered on a series of visual aids called U.S. Diabetes Conversation Maps. The 3-by-5-foot "maps," which depict symbolic images that can be used as conversation starters to help small groups explore a variety of diabetes-related facts and issues, are designed to be used in conjunction with a structured series of questions and activities.

The aim is for the maps to shift diabetes education from a one-way lecture to an interactive discussion that increases patients' ability to understand and manage their illness, said diabetes educator Martha M. Funnell, R.N., past president of health care and education for the ADA, and member of the ADA team that helped develop the content for the maps.

"One of the reasons I'm so excited about these maps is they provide an opportunity to be truly patient centered in our delivery of education," Ms. Funnell said at a press briefing during the annual scientific sessions of the ADA, where the initiative was unveiled.

About 150 training sessions are planned for 2007, with a goal to have more than 10,000 health care professionals incorporate

the maps into their diabetes education programs within the next 3 years.

The U.S. Diabetes Conversation Maps initially are being promoted to the 2,800 ADA-recognized education programs, but also will be available to other health care professionals conducting group education including physicians and pharmacists. The five Conversation Maps will be provided free to those who complete the 3-hour training program, thanks to corporate sponsorship from Merck & Co., Peter Gorman, president of Healthy Interactions, said at the press briefing.

The five maps—diabetes overview, healthy eating, blood glucose monitoring, natural course of diabetes, and gestational diabetes—are designed for either type 1 or type 2 diabetes. They contain up-to-date clinical content, and address a wide range of topics, from food and exercise to ways to talk more effectively about the emotional and behavioral component of the disease.

Each map comes with a guide and a set of questions that the facilitator uses as a framework to lead the discussion. For example, the first question patients are asked



The Diabetes Conversation Maps can help facilitate discussion about diabetes-related topics in small groups of patients.

when using the diabetes overview map is to explain their understanding of what diabetes is and the difference between the two types of diabetes. For women using the gestational diabetes map, much of the discussion centers on diet and exercise plans, as well as on what to expect after childbirth and with subsequent pregnancies.

"A lot of people don't even believe they have diabetes," Mr. Gorman said in an interview. "So we have a lot of conversations and activities that get them to look at their assumptions and [whether] those assumptions are correct. It's through those questions and answers that they come to their own conclusions and [to] conclusions they are willing to act on."

All patients are asked to identify near-

and long-term goals and to write out an action plan detailing how they will engage their health care team and family to support their accomplishment of those goals. "People can talk about things they want to do, but until they take an active step of writing things down, it doesn't get done," Mr. Gorman said. The action plan also provides educators with something concrete to follow up on at the next session.

A similar approach to diabetes education was introduced last year in Canada, and preliminary data showed high satisfaction among both patients and educators. At one pilot site with an already well-established diabetes education program, the patient return rate increased 15% between the first and second education sessions, and by 50% between the second and third sessions, Mr. Gorman said.

The company has not evaluated how effective the Canadian maps have been in improving outcomes such as reaching target hemoglobin A_{1c} levels or medication compliance. A protocol is under development in the United States to evaluate such outcomes in the future, Mr. Gorman said.

Michael Weiss, past chair of the ADA board and member of the ADA content team, said the only education he received in 1984 when diagnosed with type 1 diabetes was a single session devoted to how the pancreas works. "This is the validation that patients have a seat at the table. To my knowledge, this is the only educational product developed by physicians and patients working together." ■