



Metzger. A conference is being planned to address this issue and to potentially establish new diagnostic and treatment guidelines.

Metzger noted that the criteria for the diagnosis of gestational diabetes, established more than 40 years ago, were set to identify women at high risk for

the development of diabetes after pregnancy, not to identify pregnancies with increased risks for perinatal effects.

New research should shed light on the effects of elevated maternal glycemia on newborns and outcomes of interventions. For example, a clinical trial sponsored by the National Insti-

tute of Child Health and Human Development is currently recruiting pregnant women without prior diabetes to a study that will determine whether treating mild gestational diabetes improves the health of newborns (<http://clinicaltrials.gov/ct/show/NCT00069576?order=10>). □

## Poor Patient Adherence May Undermine Aim of Continuous Glucose Monitoring

Mike Mitka

CHICAGO—The approval in 2006 of continuous glucose monitoring (CGM) devices brought hopes that providing patients with type 1 diabetes with real-time information from a sensor implanted just under the skin would allow them to achieve better glycemic control. However, researchers have had a tough time showing efficacy of CGM in the clinic due to such factors as problems with device calibration and a lack of rigorous trial data.

A study presented at the American Diabetes Association's 67th Scientific Sessions, held here in June, suggests that yet another element may limit how well CGM translates into glycemic control: patients who are indifferent to taking action to adjust their blood glucose level based on the information generated by CGM.

In a 6-month randomized multicenter trial, 138 experienced insulin pump wearers with initial hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) levels above 7.5% (7.0% or lower is the recommended target level for patients with diabetes) were randomized to CGM or the conventional fingerstick method to monitor and act on adjusting their glucose levels. At 6 months, HbA<sub>1c</sub> levels for both the CGM and control groups decreased from a mean of about 8.5% to 7.8%, reported Irl B. Hirsch, MD, medical director of the University of Washington Diabetes Care Center in Seattle.

In a subset analysis of the data, Hirsch and colleagues found a linear relationship

between CGM compliance and lower HbA<sub>1c</sub> levels. Those with 100% or more adherence (defined as using the sensor at least 6 days per week) saw their average HbA<sub>1c</sub> drop from 8.56% to 7.69%. Those with less than 60% adherence saw their baseline HbA<sub>1c</sub> levels actually rise from a mean of 9.45% to 9.63%.

"These people with the higher [HbA<sub>1c</sub> levels] were not taking care of their diabetes before the trial, and if they're not interested and focused, this won't help them," Hirsch said.

For future trials, Hirsch said, investigators should enroll motivated patients if they expect to see any impact of CGM on glycemic control. "We used the wrong population because diabetes is lifestyle—patients have to be interactive with their sugars, and if they're not involved, we can't help them."

For patients who are motivated to play an active role, CGM is the kind of technological advance that warrants stud-

ies to evaluate its efficacy, said Aaron Kowalski, PhD, director of strategic research projects with the Juvenile Diabetes Research Foundation International (JDRF), in New York City. "Glucose control has been very difficult for patients with diabetes, and a major contributor has been inadequate tools," said Kowalski, who has type 1 diabetes and has used CGM himself. "But now there's interest in a new generation of technology that many of us in the field think [is] functional . . . but now we want to demonstrate through studies that it works."

To that end, the JDRF is sponsoring a randomized controlled trial, the Randomized Study of Real-Time Continuous Glucose Monitors in the Management of Type 1 Diabetes (<http://clinicaltrials.gov/ct/show/NCT00406133?order=1>), which began enrolling 450 patients at 10 sites in December 2006. Trial participants are randomly assigned to either CGM or the



A continuous glucose monitor makes frequent measurements that provide patients an opportunity for improved glycemic control.



fingerstick method of glucose monitoring for 6 months, with frequent follow-up visits and telephone contact to review their diabetes management. After the initial study period, those in the CGM group will be monitored for an additional 6 months with less intensive contact (fewer follow-up visits and telephone contacts) to see if any benefits from the first 6 months are sustained; those in the control group will initiate CGM with less intensive contact with clinicians.

The study's primary end points at 6 and 12 months are HbA<sub>1c</sub> levels, epi-

sodes of severe hypoglycemia, and percentage of blood glucose sensor values in the range of 70 mg/dL to 180 mg/dL (3.89 mmol/L to 9.99 mmol/L). Six-month results are expected by the middle of 2008, with final results by the end of that year.

Given the lack of efficacy data (and of long-term studies showing that CGM reduces morbidity and mortality associated with diabetes), it is not surprising that payers have been reluctant to reimburse for CGM, which can cost thousands of dollars for the initial pur-

chase of the devices and hundreds of dollars annually for replaceable sensors. Another potential barrier to its use is physicians fearing information overload as they try to incorporate the new data provided by CGM into clinical practice settings where they may have only 20 minutes to work with a patient.

Kowalski is hopeful the JDRF-sponsored trial will show benefit for CGM. "When we ask payers how we can get [CGM] into the hands of people with diabetes, they say they need to see [Hb]A<sub>1c</sub> reduction," he said. □

## In Era of Tight Funds, NIH Seeks to Nurture New Scientists and Novel Ideas

Mike Mitka

**F**OR MOST MEDICAL RESEARCHERS, the quest for funding consumes exorbitant amounts of time. And this pursuit is becoming more arduous as the National Institutes of Health (NIH), the major funding institution for medical research, remains hampered in an era of federal budget constraints.

Although the NIH budget doubled to \$27.2 billion between fiscal years 1998 and 2003, funding since then has remained relatively flat. With a stagnant budget, estimated to be \$29.2 billion for fiscal year 2007, the NIH, which historically funded 30% of applications, now funds only 20%. For first-time submissions, the acceptance rate is only 10%. Such low rates have raised concerns about nurturing new researchers and novel ideas.

"The greatest risk in science is to stop taking risks," notes NIH Director Elias A. Zerhouni, MD. To help ensure that original but risky ideas are not stillborn and that promising but fledgling investigators have a chance to test their wings, the NIH has just launched a new program appropriately named EUREKA (Exceptional, Unconventional Research Enabling Knowledge Acceleration). It is the latest of a series of funding initiatives that the

agency has developed to provide money for new researchers, for innovative ideas, and for investigators who face federal funding cutoffs that would prematurely curtail worthy research efforts.



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### "WILD AND CRAZY" IDEAS

EUREKA Awards recognize "the need for investigators to have opportunities to test unconventional, potentially paradigm-shifting hypotheses, and to attempt to use novel, innovative approaches to solve difficult technical and conceptual problems that impede sci-

entific progress," according to the National Institute of General Medical Sciences (NIGMS), which was expected to begin the program by the end of July.

Laurie Tompkins, PhD, a program director with the NIGMS' Division of Genetics and Developmental Biology who helped design the EUREKA awards, said EUREKA is looking for "wild and crazy" ideas that may lead to clinical or biological breakthroughs.

"This is not about preliminary research," Tompkins said. "The questions in the application ask how important is the problem, who will it affect, and how big and wide is the impact."

EUREKA will offer qualifying researchers up to \$800 000 over a 4-year period (not to exceed \$250 000 in any 1 year) to cover direct costs. At 8 pages, the application is considerably shorter than those of traditional NIH funding groups, as is the biographical request, with the NIGMS seeking only up to 10 published article citations to support a researcher's application. The NIGMS expects to award between 13 and 17 grants yearly.

To keep the focus on funding innovative research, Tompkins said EUREKA will concentrate on reminding reviewers that they are considering proposals off the beaten path. "One