

## Roundtable Discussion

# The Role of Collaboration In Improving Diabetes Care

Diabetes places a tremendous morbidity burden on American society: 8 per cent of the U.S. population has been diagnosed with the disease, and the percentage is growing. Economically, diabetes now consumes \$174 billion a year, or 10 percent of all healthcare dollars, and that amount also is increasing.

Numerous studies and programs have been undertaken to reduce the toll of diabetes through improved screening, treatment and clinical studies. But, there is much about this chronic disease that remains unclear, including the optimum approach to glucose control and the appropriate role of measures and guidelines.

To examine how shared experiences and collaborative endeavors might help answer some of the issues surrounding diabetes care, the non-profit Institute of Federal Health Care convened a roundtable discussion that included representatives from federal agencies, Capitol Hill, academia, industry, professional organizations and beneficiary groups.

Roundtable participants emphasized the importance of basing treatment guidance in solid evidence and of tailoring care to the individual patient, rather than adopting a “one size fits all” approach.

They suggested that collaborative studies be undertaken to help provide the evidence needed to resolve such issues as optimum A1C targets for various population groups

and the effect of co-morbid conditions in diabetes control.

Observations and recommendations made at the roundtable include:

- *There is uncertainty about current guidelines for glucose control.* Current guidelines that set strict levels for A1C (a form of hemoglobin used to identify the average plasma glucose concentration over prolonged periods of time) are arbitrary in that they generally lack evidence for determining the best target for the individual patient.

Confounding factors such as age, socioeconomic status, co-morbidities and interaction with other prescribed medications generally are not taken into account in current guidelines.

Further, there is “dissonance” among organizations that set guidelines over the “proper” target A1C level — should it be 7, or less, or more, and under what circumstances? Roundtable participants agreed there can be no single answer to this conundrum, and too often the target level becomes its own end, without underlying data.

Proposals were made for collaborative studies to gather evidence and tease apart the various factors that influence the course of diabetes and its treatment, such as the relationship between severe hypoglycemia and cardiac mortality, the optimum approach to pre-diabetes, the comparative benefits of different oral agents for glycemic control in different

## Discussion Highlights

- **Diabetes treatment must be patient-centered, with the risk versus benefit of various treatments examined for each patient.** “A single level of A1C cannot be used as the perfect level.”
- **Collaboration among federal agencies is difficult because data sources often aren’t compatible. The Diabetes Mellitus Inter-agency Coordinating Committee has no funding to support collaborative efforts and no authority to mandate studies.**
- **Treatment of the individual patient is different from population health, but the two should be synergistic.** “Our role is to provide the greatest good for the greatest number of patients.”
- **Flexible guidelines for providers are necessary; without them, most primary care physicians would be “lost” when it comes to diabetic care — but, guidelines must be based in evidence.**
- **Cardiovascular safety is a “hot” issue in glucose control. Should medications entering the market be required to show cardiovascular benefit? Currently, such agents are required to show no cardiovascular risks without adequate consideration of associated benefits. More data are needed.**
- **There is a shortage of endocrinologists. For example, there are only 15 endocrinologists in the entire Army Medical Department. The American Association of Clinical Endocrinologists estimates a 25 to 30 percent shortage in U.S. by 2020.**

population groups, and how lifestyle changes mesh with other measures.

- *“Pay for performance” has become de rigueur in medicine, but performance measures focusing on glucose control targets can be misleading and may not represent a true indication of quality.* A central goal of performance measures should be patient safety, not just accountability for performing a test that is ahead of the evidence.

- *Patient compliance is a significant factor in the glycemic control equation.* Participants agreed that, in the end, A1C levels depend on patient adherence to recommended medication schedules and lifestyle changes. “We need to invest in self-management education,”

- *The value of glycemic control in Medicare beneficiaries remains to be calibrated.* These patients often carry high disease burdens — disability, end-stage renal disease, psychiatric illness — that may augur for treatment goals different from those for younger diabetics. Does glucose control and monitoring even make a difference for such patients?

Roundtable participants expressed dismay at the lack of data about the effect of glycemic control in the elderly, and particularly in nursing homes. “The information is basically nil.”

### Other Research Considerations

- *Further study is needed to understand how glucose control affects the macrovascular complications of diabetes.* While there is “no doubt” as to the beneficial effect of glucose control on the microvascular effects of the disease (retinopathy, neuropathy, renal disease), its influence on macrovascular disease (cardiovascular) remains unclear.

Further, there is little evidence to indicate the effects of long-term treatment and who will benefit from it — for both microvascular and macrovascular disease — as most studies focus only on the near-term.

A recent study from the United Kingdom showed significant long-term benefit from *early* treatment — a “legacy effect” from initiating glucose control early in the disease process. Diabetics who tightly controlled their blood sugar levels early-on showed lower risk of heart disease and death even a decade later.

Roundtable participants again urged additional collaborative studies to determine what levels of A1C to aim for and which medications to use under which circumstances.

- *Barriers to research must be addressed.* For example, current Institutional Review Board requirements are so onerous and lengthy that they serve to discourage needed studies. The IRB approval process can take as long as a year — meaning that endocrinology fellows interested in a proposed study may already have left their fellowship positions by the time the study can begin.

- *More data are needed in the drug approval process.* New oral medications for glucose control have burgeoned over the past two decades, but pre-marketing studies offer scant information about the effects of long-term use or of effects in population groups such as the elderly and minorities.

New requirements for larger study populations and for post-marketing surveillance may help develop such data, but details remain to be determined — how large such post-marketing surveillance studies should be, for example, and who should be included.

One proposal made during the roundtable was for creation of a national registry for all diabetics to help identify risk factors, delineate causative from associated factors, and “get everyone on the same page.”

Participants uniformly expressed concern about the growing use of bariatric surgery to treat diabetes and the lack of evidence to show its impact on long-term outcomes. This is another area, they said, that is ripe for a collaborative clinical trial.

Participants in this roundtable: David Aron of the Veterans Health Administration; Paul Baker of the National Alliance for Hispanic Health; Barbara Bartman of the Agency for Healthcare Research and Quality; Cynthia Bassetta of the Government Accountability Office; Kathleen Briggs of sanofi-aventis; John Class of MOAA; Barbara Cohoon of the National Military Family Association; John Crum of Humana Military Healthcare Services; Jon Donenberg of the House Committee on Oversight and Government Reform; Roslyn Douglas of the National Medical Association; Rick Erdtmann of the Institute of Medicine; Judith Fradkin of the National Institute of Diabetes and Digestive and Kidney Diseases; Howard Garber of Johns Hopkins Healthcare; Tiffary Gary of Johns Hopkins University; Richard Hodge of sanofi-aventis; Sandy Jones of the Centers for Medicare and Medicaid Services; Elizabeth Koller of the Centers for Medicare and Medicaid Services; John Kugler of the Defense Department; Henry Kurban of Johns Hopkins Healthcare; Tracy Malone of the US Family Health Plan Alliance; Mary Parks of the Food and Drug Administration; Shira Perl of the National Institute of Diabetes and Digestive and Kidney Diseases; James Pessetto of sanofi-aventis; Leonard Pogach of the Veterans Health Administration; James Schlicht of the American Diabetes Association; Kendall Van Pool of the American Diabetes Association; Robert Vigersky of the Endocrine Society.

The roundtable was moderated by Linda Dunbar of Johns Hopkins Healthcare. IFHC Managing Director is Nancy Tomich ([www.fedhealthinst.org](http://www.fedhealthinst.org)).