

# Patient Outcomes Research and Type II Diabetes

The Agency for Health Care Policy and Research focuses on improving patient outcomes

HOWARD A. FISHBEIN, DRPH

“The time has come for a thorough, nationwide review of what works and what doesn't to determine which medical treatments produce the best outcomes for patients with specific health conditions. In this way, we can not only help physicians deliver the best care, but at the same time we can reduce unnecessary or ineffective treatment.”

Louis Sullivan, MD  
Former Secretary of Health and Human Services, 1989

AHCPR was created in 1989, within the U.S. Public Health Service, with a special mandate to seek answers to such research questions as:

- What difference do health interventions make with respect to patient outcomes?
- When more than one treatment option is available, which one is best?
- Do decisions about treatment alternatives reflect patients' values?

AHCPR supports numerous empirical studies that assess the appropriateness and effectiveness of alternative uses of health services and procedures in the prevention, diagnosis, management, and treatment of clinical conditions. These studies are one component of the agency's MEDTEP. Other components include the development of data bases and clinical practice guidelines, and the dissemination of MEDTEP products—all of which focus on the urgent need to build a knowledge base to reduce clinical uncertainty, enhance patient participation in decision making, and foster more cost-effective care.

Criteria for clinical conditions selected for MEDTEP study and funding are those that affect large numbers of individuals, involve significant expense, show wide variations in patterns of care, have data relatively accessible, and are significant to the Medicare and Medicaid programs.

FROM THE AGENCY FOR HEALTH CARE POLICY AND RESEARCH, CENTER FOR MEDICAL EFFECTIVENESS RESEARCH, ROCKVILLE, MARYLAND.

ADDRESS CORRESPONDENCE AND REPRINT REQUESTS TO HOWARD A. FISHBEIN, DRPH, AGENCY FOR HEALTH CARE POLICY AND RESEARCH, CENTER FOR MEDICAL EFFECTIVENESS RESEARCH, 2101 E. JEFFERSON STREET, ROCKVILLE, MD 20852.

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TYPE II DIABETES, NON-INSULIN-DEPENDENT DIABETES MELLITUS; TYPE I DIABETES, INSULIN-DEPENDENT DIABETES MELLITUS; AHCPR, AGENCY FOR HEALTH CARE POLICY AND RESEARCH; MEDTEP, MEDICAL TREATMENT EFFECTIVENESS PROGRAM; PORT, PATIENT OUTCOMES RESEARCH TEAM; HMO, HEALTH MAINTENANCE ORGANIZATION; IPA, INDEPENDENT PHYSICIAN ASSOCIATION.

Along with several other clinical conditions, type II diabetes meets these criteria. In addition, although many prevention and treatment strategies exist, the relative effectiveness of most in improving patient outcomes for type II diabetes is not well documented.

AHCPR has funded several studies that focus on the treatment of diabetes. The most significant MEDTEP effort, however, is the ongoing Diabetes PORT.

## The Diabetes PORT

As is the case for 13 other PORTs, the Diabetes PORT consists of a multidisciplinary team of investigators, involves multisites, and is funded at ~\$1 million annually over a 5-yr period. The PORT will identify and analyze outcomes and costs of alternative interventions for treating type II diabetes and will develop and test methods for reducing inappropriate or unnecessary variations in the use of services and procedures. The diabetes PORT is housed at Tufts University and the New England Medical Center in Boston, MA, and is directed by Sheldon Greenfield, MD.

The Diabetes PORT is in its third year of a prospective observational study of patients with type II diabetes. The PORT has five specific aims:

- To develop a comprehensive data base for monitoring costs, quality, and outcomes of care for patients with type II diabetes in each of three health-care delivery organizations;
- To relate usage and costs for care of people with type II diabetes to blood glucose level to the early detection and treatment of complications and quality of life;
- To quantify the relationship of the quality of medical care and interpersonal care, and the interaction of these with usage, costs, and quality of life;
- To derive or confirm recommendations for optimal medical care based on a comprehensive literature review, decision analyses, and analyses of the data base that will be developed;
- To develop and test an intervention designed to change specific physician

behaviors with respect to usage, clinical management, and delivery of care.

In developing the data base, 6000 patients are being identified through physician practices from Group Health Cooperative, Seattle, WA, a staff model HMO of family physicians with predominantly middle-class patients; Regenstreif Health Institute, Indianapolis, IN, an academic medical center of general internists with predominantly poor African-American patients; and Tufts Associated Health Plan, Boston, MA, an IPA with predominantly middle-class patients.

Approximately 2000 patients per site will complete an extensive baseline questionnaire and will be followed up at 6-mo intervals. The length of follow-up will be 2 yr. The questionnaire has batteries of questions on general health status, diabetes severity and risk for decline, health conditions and complications, cognitive information, health habits and personal characteristics, compliance and regimen adherence, diabetes knowledge and education, patients' opinion of doctor's care, health-care system characteristics, beliefs about health care, and social and family support.

An observational study of patients within an office setting requires that specific methodological concerns be addressed. These include:

- A method to identify patients likely to experience a decline in functional status or an increase in disease severity during the study interval;
- A method to anticipate changes in severity and status, recognizing that such changes can occur independent of effective patient care;
- A method to adjust for patient differences in baseline risk that will allow for

treatment effectiveness to be compared across physicians and different health systems.

Techniques used by the PORT to address these concerns were developed from the experience of other studies of disease-specific severity measures, especially the Medical Outcomes Study (1). The PORT has added to this work by crafting measures or indexes to assess the severity of disease in the patient with type II diabetes. The basis for these measurements comes from two sources: 1) patients' laboratory tests and 2) patients' reports of diseases, complications, and symptoms. Using these newly developed indexes, adjustments can be made for differences in the baseline risk of patients, allowing for comparisons of outcomes in a cross-sectional cohort of type II patients.

A questionnaire will be completed by the 200 physicians involved in the PORT study (50–75 per site), who are mostly primary-care practitioners. Analysis of data collected from physicians and patients will lead to an educational intervention for physicians designed to improve patient outcomes. This intervention will target the reduction of variation in patient care for type II diabetes and the improvement of health outcomes. It will build on feedback from patients and physicians, with special emphasis on functional status and strategies to motivate and reinforce behavior change.

#### **Importance and utility of Diabetes PORT findings**

The Diabetes PORT will benefit diabetes prevention, treatment, and control programs across the country. The study will have one of the largest prospective data

bases of type II diabetic patients available, which will help support future investigations. Of particular importance is the PORT's plan to integrate physiological measures of health with the patient's perception of quality of life and overall health status.

Diabetes PORT findings likely will be incorporated into diabetes education programs for physicians and patients. Outpatient diabetes education programs for type I and type II diabetic patients flourished in the 1980s—similar education programs could be the conduit for PORT research findings.

Changes in treatment strategies for diabetes ultimately will come from studies like the Diabetes PORT where patients and physicians are involved in making clinical decisions. Methods used in patient outcomes research, such as decision analysis and patient preference scaling, will help shape decisions about how to structure successful, cost-effective management plans. Specific PORT findings, clinical recommendations, and other products will be available by 1995 and should help people with type II diabetes attain the best state of health possible.

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#### **References**

1. Stewart AL, Ware JE (Eds.): *Measuring Behavioral Function and Well-being: The Medical Outcomes Study Approach*. Durham, NC, Duke University Press, 1992