



American Dietetic Association

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120 South Riverside Plaza, Suite 2000
Chicago, IL 60606-6995
800/877-1600
www.eatright.org

Policy Initiatives and Advocacy
1120 Connecticut Avenue, Suite 480
Washington, DC 20036-3989
202/775-8277 FAX 202/775-8284

June 2, 2004

Secretary Tommy G. Thompson
Department of Health and Human Services
Washington, DC

RE: 2004S-0170 Medicare Prescription Drug, Improvement and Modernization Act of 2003, Section 1013: Suggest Priority Topics for Research

Dear Secretary Thompson:

The American Dietetic Association welcomes this opportunity to offer comments and suggestions for research priorities to improve the quality, effectiveness, and efficiency of the Medicare, Medicaid, and SCHIP Programs. With nearly 70,000 members in a multitude of disciplines ranging from research to community health, and from clinical to the foodservice industry, the American Dietetic Association is the nation's largest organization of food and nutrition professionals. ADA members are the most experienced healthcare professionals in the food and nutrition field providing nutrition care and services that improve and save lives every day.

Burden of Diabetes

Section 1013 states that research "may include health care items or services.....which may be ...underutilized and which may significantly improve the prevention, treatment, or cure of diseases and conditions (including chronic conditions) which impose high direct or indirect costs on patients or society."

The burden placed on our society by diabetes mellitus is enormous. In the last 22 years (1980-2002), the number of Americans living with diabetes more than doubled from 5.8 million Americans in 1980 to 13.3 million in 2002. In the five years between 1997 and 2002, new cases of diagnosed diabetes jumped 47%.¹

The 2002 total cost estimates of diabetes in the United States is \$132 billion, \$92 billion of which is for direct medical costs. The other \$40 billion of indirect costs are tied to disability, work loss, and premature mortality. The nation spends nearly \$13,243 on each person with diabetes, compared to \$2,560 for those who don't have the disease.

People aged 65 or older account for almost 40% of the population with diabetes, and in the Medicare population, diabetes ranks among the five most common conditions.² According to the findings from the 1999 Medicare Current Beneficiary Survey, almost one in five of all non-institutionalized beneficiaries and one-third of fee-for-service Medicare expenditures are related to diabetes.

Prevalence rates for diabetes are higher among minorities. CDC reports higher rates of diabetes in both Hispanic and Black men and women that approach 25% percent, compared to 15% in their white counterparts.³ They also have higher rates of obesity.

Perhaps most troubling are the statistics from the pediatric population. Once seen only in adults, now type 2 diabetes has been increasing steadily in children. African American, Hispanic American, and American Indian children are especially at risk. In children, as in adults, type 2 diabetes is closely linked to being overweight, inactive, and having a family history of diabetes.

This rise in Type 2 diabetes coincides with the rise in the prevalence of overweight and obesity. Although type 2 diabetes was virtually unknown in children and adolescents 10 years ago, it now accounts for almost 50 percent of new cases of diabetes in some communities.

Almost 15 percent of our children and adolescents are overweight. That's nearly eight million of our youth. Furthermore, rates of obesity have increased more rapidly in our youth of African and Mexican decent. Obesity in the United States is truly epidemic, and rates of type 2 diabetes have reached epidemic proportions as a consequence.

We would also like to draw your attention to another emerging issue: prediabetes. The American Diabetes Association defined this condition in 2004, resulting in an estimated 41 million Americans falling under the new definition and being classified as having prediabetes. This is more than double the previous number of Americans estimated with prediabetes using the original classification.⁴

According to the American Diabetes Association, some studies show that most people with prediabetes go on to develop type 2 diabetes within 10 years unless they make lifestyle changes -- diet and exercise -- to reduce the risk of diabetes. The American Diabetes Association states that "medical nutrition therapy aimed at producing 5-10% loss of body weight, exercise, and certain pharmacological agents have been variably demonstrated to prevent or delay the development of diabetes in people with impaired glucose tolerance."⁵

As of January 1, 2002, Medicare Part B recognizes registered dietitians (RD) and nutrition professionals as providers of medical nutrition therapy for diabetes and renal disease (non-dialysis kidney disease and kidney post-transplants). Medical nutrition therapy (MNT) services are defined in Medicare MNT statute as "nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional ... pursuant to a referral by a physician."

When providing MNT, RDs use nationally recognized protocols, such as the ADA MNT Evidence-Based Guides for Practice-Nutrition Practice Guidelines, which are listed in AHRQ's National Clearinghouse. ADA's practice guides for diabetes types 1 and 2, gestational diabetes, and chronic kidney disease (non dialysis) are among the highest quality of evidence-based practice guidelines in medicine.

Studies have shown MNT for diabetes and other conditions to be cost-effective and to increase patient health and well-being, productivity and satisfaction levels through decreased doctor visits, hospitalizations and reduced prescription drugs use. Unfortunately, MNT is a widely underutilized service. This may be because physicians are not generally well trained in nutrition and are unfamiliar with the benefit or that they are unaware it is covered by Medicare.

Research Priorities

Members of the American Dietetic Association who serve Medicare, Medicaid, and SCHIP beneficiaries unanimously agree that the exploding epidemic of diabetes in the United States is a disease that fits with

the intent of Section 1013. And equally important and intimately linked to diabetes, is obesity, a major risk factor for diabetes. How can we better deliver health care to prevent and treat these two diseases efficiently, effectively, and earlier? The American Dietetic Association recommends that the delivery of MNT for diabetes and obesity be selected to improve the medical outcomes for diabetes care and treatment of Medicare, Medicaid, and SCHIP beneficiaries. The American Dietetic Association proposes the following research questions, most of which can be addressed through evidence-based analysis:

1. To what extent do primary providers refer a child who is above the 95-97 percentile on the growth chart to an RD for obesity intervention (SCHIP or EPSDT)? For example, in the state of Ohio, there are data that the growth charts are being used, but no data about what is done with the information. Obesity is closely tied to diabetes in children. Early intervention may save a lifetime of costs.
2. What is the effectiveness of the chronic care model in treating and managing obesity in the Medicare, Medicaid, and SCHIP populations? This model is being advocated by physicians and being implemented in private plans. Why not in all CMS programs? What is the effect of ongoing disease management of obesity in preventing or delaying the onset of diabetes, hyperlipidemia, or hypertension? During a recent conference sponsored by America's Health Insurance Plans titled "Excessive Pounds, Portions, and Costs: The Growing Role of Obesity Management in Member Health," Dr. William Dietz, Director of Nutrition and Physical Activity at the Centers for Disease Control and Prevention, stated that the cost of aggressive diet therapy for severe obesity is justified and not as expensive as lifetime drug intervention.⁶
3. What will be the costs and savings associated with MNT for pre-diabetes resulting in preventing or delaying the development of full-blown diabetes? 41 million Americans are estimated as having prediabetes. MNT, that includes physical activity as an intervention component, is indicated as a first-line treatment in prediabetes by the American Diabetes Association.
4. With the advent of disease management of chronic diseases, what is the minimal effective 'dose' of MNT for diabetes for children, adults, and the Medicare elderly population? What is the most effective mode of delivery over time: in-person, group, telephonic, or electronic interventions?
5. What percent of the Medicare, Medicaid, and SCHIP beneficiaries has received diabetes education? What percent has received MNT by an RD?
6. To what extent are adults and children diagnosed with diabetes referred to a registered dietitian for MNT? What triggers are most effective in alerting the primary provider to make the referral?
7. Is non-pharmacological (lifestyle) therapy more, less, or equally effective than pharmacological therapy for controlling plasma glucose in the elderly?
8. What types of nutrition and/or physical activity interventions are most effective in the elderly, including population segmentation to examine the effects of other chronic diseases, risk factors, and living circumstances (i.e. institutional, homebound, active)?
9. What is the average reduction in cost of diabetes medications for individuals with Type 2 diabetes who receive MNT provided by a RD? What is the average reduction in cost of reducing the amount of medication that is needed by individuals with selected cardiovascular diseases and renal disease that receive MNT provided by an RD?

We understand the current emphasis of HHS on studies that compare pharmacological agents within a specific disease and support such research. However, it is the position of the American Dietetic

Association that the application of MNT and lifestyle counseling as part of the Nutrition Care Process is an integral component of the medical treatment for management of specific disease states and conditions and should be the initial step in the management of these situations. If optimal control cannot be achieved with MNT alone and concurrent pharmacotherapy is required, then the Association promotes a team approach to care for clients receiving concurrent MNT and pharmacotherapy, and encourages active collaboration among dietetics professionals and other members of the health care team.⁷

The ADA is deeply concerned that all US citizens have access to quality healthcare and nutrition therapy to improve the health and productivity of our country. We feel that there is an urgent need to provide intensive nutrition counseling to those at greatest risk for developing diabetes, especially our children, to harness the escalating costs of healthcare associated with obesity and diabetes.

Thank you for the opportunity to offer these comments and suggestions by the members of the American Dietetic Association. Please do not hesitate to contact Dr. Mary Hager, Senior Manager, Regulatory Affairs for the American Dietetic Association, for more information or me. Her email address is: mhager@eatright.org.

Best regards,

Marianne Smith Edge/mhh

Marianne Smith Edge, MS, RD, LD, FADA
President 2003-2004
The American Dietetic Association

¹ http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2003.pdf. Accessed May 19, 2004.

² Foote S. Population-based disease management in fee-for-service Medicare. Health Affairs, Web Exclusive, 2003;July30:W3-350.

³ <http://www.cdc.gov/diabetes/statistics/prev/national/fig2002.htm>. Accessed May 18, 2004.

⁴ The American Diabetes Association. Diagnosis and Classification of Diabetes. Diab Care. 2004;27 (supp 1):S5-S10.

⁵ Ibid.

⁶ America's Health Insurance Plans. Excessive Pounds, Portions, and Costs: The Growing Role of Obesity Management in Member Health. May 20, 2004.

⁷ The American Dietetic Association. Position of the American Dietetic Association: Integration of medical nutrition therapy and pharmacotherapy. J Amer Diet Assoc. 2003;103:1363-1370.