Federal Agency Diabetes Guides and Guidelines

Information and Perspectives from Member Agencies of the Diabetes Mellitus Interagency Coordinating Committee (DMICC)
DMICC Meeting of August 1, 2011

Many of the member agencies of the DMICC either develop or contribute to the development of evidence-based guidelines for diagnosis, prevention, and treatment of diabetes and its complications, in order to improve care for people with the disease and to keep people without the disease healthy and diabetes-free. There is a great deal of harmony in the guides and guidelines that have been developed and/or adopted by the different agencies; differences tend to exist where there is less data and, hence, more room for differing interpretations of the data. Agencies focused on serving specific segments of the American population also tend to have concerns regarding broad guidelines. While the DMICC itself does not develop guidelines or recommendations, it does provide a forum for discussion of these issues. The DMICC met on August 1, 2011, to hear about examples of different types of guidelines for diabetes and other chronic diseases and how they are developed, disseminated, and applied, as well as to identify knowledge gaps that contribute to differences between diabetes guidelines that could potentially be resolved through more research and agency collaboration.

An Overview of the U.S. Preventive Services Task Force (USPSTF)—David Meyers, M.D., Agency for Healthcare Research and Quality (AHRQ)

The work of the USPSTF is focused on keeping asymptomatic people free of disease. The 16 member, volunteer Task Force is an independent body with diverse expertise that develops recommendations for primary care physicians based upon review of peer-reviewed research publications. These recommendations encompass preventive services items such as screening tests, counseling, and preventive medications. The Task Force does not address disease diagnosis, management, or treatment. AHRQ provides administrative, scientific, and technical support to the Task Force, whose members are appointed by the AHRQ Director; however, the Task Force is independent of AHRQ. Preventive services topics are nominated by the public and stakeholders. Nominations may be for a new topic, or for reconsideration of an existing topic; they are considered by the Task Force at least three times a year.

There is a multi-step process for evidence review and recommendation development by the Task Force, which includes a period of posting for public comment and review/incorporation of those comments as appropriate prior to publication. Review culminates in graded recommendations [A, B, C, D, and "I (insufficient evidence) statement"] that are based on the strength of the evidence on the harms and benefits of a specific preventive service. For example, for the preventive service of screening for type 2 diabetes in adults, the USPSTF recommends this screening in asymptomatic adults with sustained blood pressure (treated or untreated) greater than 135/80 mmHg (Grade B recommendation, suggesting moderate benefit), but concludes that there is insufficient evidence regarding the benefits and harms of screening other adults for type 2 diabetes ("I Statement") (June 2008). Similarly, the Task Force has concluded that there is insufficient evidence to recommend for or against routine screening for gestational diabetes mellitus (GDM) (May 2008). USPSTF recommendations are informational and advisory, not

mandatory, and thus can differ from final recommendations incorporated in federal documents—for example, the USPSTF recommendations on diabetes screening differ from the diabetes screening message espoused for diabetes prevention in "Healthy People 2020." On the other hand, Task Force recommendations can have implications for agencies—for example, an A or B recommendation can trigger, at the discretion of the Secretary of the Department of Health and Human Services, a national coverage determination process by the Centers for Medicare & Medicaid Services (CMS). More information on the USPSTF and its activities is available on the Web site: www.uspreventiveservicestaskforce.org/

Overview of the Guide to Community Preventive Services—Randy Elder, M.Ed., Ph.D., Centers for Disease Control and Prevention (CDC)

The Guide to Community Preventive Services, or "Community Guide," is a resource based on state-of-the-science systematic reviews that analyze evidence of the effectiveness of community-based interventions in public health, assess their economic benefit, and highlight critical research gaps. These reviews address numerous public health topics, and yield evidence-based findings for interventions, graded as "Recommended," "Recommended Against," and "Insufficient Evidence." Guide reviews and findings are developed by the Task Force on Community Preventive Services, an independent, non-federal body whose members are appointed by the CDC Director, and whose work is complementary to the work of the USPSTF—the former focuses on evaluating the effectiveness of preventive services delivered at the group, community, or population level, in a variety of community settings, by a variety of providers, while the latter focuses on clinical preventive services and settings. The intent of the Guide is to inform decision making regarding practice (initiatives and programs), policy, research, and funding for research and programs. An important aspect of developing the Community Guide is engagement and participation of stakeholders—policy makers, practitioners, researchers, communities, etc. Many federal agencies with health missions have liaisons to assist the work of the Task Force. Issues considered in Guide reviews include not only effectiveness, but also barriers to implementation, cost, and potential harms—e.g., not just harm to health, but harm to community quality of life. Currently, there are about 220 Task Force recommendations, including several regarding diabetes. For access to the Community Guide and more information on Task Force activities, see: www.thecommunityguide.org

National Heart, Lung, and Blood Institute (NHLBI) Clinical Guidelines—Denise Simons-Morton, M.D., Ph.D., NHLBI

NHLBI develops clinical guidelines for heart, lung, and blood diseases that address disease management and prevention. Guideline development is part of one of the three overarching Goals in the NHLBI's 2007 Strategic Plan. Several guideline development efforts are under way, including cardiovascular risk reduction in adults and in children/adolescents. The NHLBI has developed and issued guidelines related to prevention of adult cardiovascular disease (CVD) for many years—for example, they have issued recommendations on high blood pressure (HBP), high cholesterol, and obesity, starting with HBP in 1976. The Institute is now pursuing new directions in how these guidelines are developed, integrated, and implemented, including working to make sure that the approach to developing the guidelines includes systematic reviews, is standardized and consistent, and that the recommendations are clearly written. Also, a new, comprehensive National Program to Reduce Cardiovascular Risk is being established to coordinate national education efforts to reduce CVD risk, including implementation of the

guidelines. Guidelines are developed by external, expert panels, convened by the NHLBI, whose work will culminate in graded evidence statements ("High," "Moderate," and "Low") and recommendations ("A-Strong," "B-Moderate," "C-Weak," "D-Against," "E-Expert Opinion," and "N-No Recommendation"). The NHLBI system for grading recommendations differs slightly from that used by USPSTF, in that there is an Expert Opinion grade in the NHLBI system, but not in the USPSTSF system. There is not a 100 percent mapping of evidence statements to the recommendations because several evidence statements could lead to only one recommendation. The NHLBI anticipates that individual guideline updates for the CVD risk factors of high blood pressure, high blood cholesterol, and overweight/obesity in adults will be completed in 2012, with the integrated risk reduction guideline sometime after that. An integrated pediatric CVD risk reduction guideline is anticipated for completion in 2011. [Update: the summary report of pediatric guideline was released in November 2011 online and December 2011 in print in the journal Pediatrics; the summary and full reports are posted on the NHLBI website.] Topics relevant to the DMICC covered in this new pediatric guideline include nutrition, physical activity, overweight and obesity and diabetes and other conditions. Other guideline efforts at NHLBI address asthma and sickle cell disease. Regarding clinical implementation of guidelines to achieve the goal of improving patient health, multiple issues need to be considered, including policy issues, clinicians, their institutions, and the patients themselves. Information about NHLBI Clinical Guidelines is available at: www.nhlbi.nih.gov/guidelines/index.htm

National Kidney Disease Education Program (NKDEP): Improving the Care of People with Diabetes Mellitus and Kidney Disease—Andrew S. Narva, M.D., F.A.C.P., National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Data from the United States Renal Data System (USRDS) clearly demonstrate that: (1) type 2 diabetes is driving increases in the rate of incident end-stage renal disease (ESRD), and (2) this is a significant health disparities issue. A number of guidelines exist for the treatment of chronic kidney disease (CKD) to prevent progression to kidney failure and avoid other complications. For people with diabetes, the American Diabetes Association (ADA) has recommended annual tests of urine albumin levels in patients with type 1 diabetes of at least 5 years duration, and in all patients with type 2 diabetes, commencing with diagnosis. However, evaluation and treatment goals set forth in Healthy People 2010 for people with type 1 or type 2 diabetes and CKD have not been met. For these populations, defining optimal care (i.e., guideline development) does not seem to be the primary barrier to improved outcomes at the present time, but, rather, the major obstacle is delivering appropriate care to those who need it. Under-diagnosis of CKD, poor implementation of recommended care, and the feeling among many clinicians that they are inadequately educated in CKD diagnosis, clinical recommendations, management, and referral, seem to be the biggest challenges.

The NKDEP seeks to reduce morbidity and mortality by improving early detection of CKD, facilitating identification of patients at greatest risk for progression to kidney failure, promoting evidence-based interventions to slow progression of kidney disease, and supporting the coordination of federal responses to CKD. The NKDEP does not develop guidelines, but is promoting interagency discussions of how to develop and apply evidence-based guidelines, as well as what the implications are for agencies whose missions are directly affected by this implementation. The NKDEP is trying to bring a "systems change approach" called the Chronic

Care Model to bear in CKD, as a way to improve CKD detection and management and help reduce health disparities, thereby improving outcomes. Additionally, improvements in CKD care for all patients may come through making it a routine part of care for people with diabetes, who represent half the affected population. NKDEP offers a variety of tools, information, and resources for health professionals (especially those working in the primary care setting), patients, and populations at risk. More information about the NKDEP is available at: http://nkdep.nih.gov/

The National Diabetes Education Program (NDEP)—Ann Albright, Ph.D., R.D., CDC, and Judith Fradkin, M.D., NIDDK

The NDEP is a partnership of the NIH and the CDC, with the support of more than 200 public and private partners. Its goal is to reduce the burden of diabetes and facilitate the adoption of proven approaches to prevent or delay diabetes onset and complications. A major focus of NDEP messaging is early detection and management of diabetes and prevention of type 2 diabetes. Current priorities are promoting the Program's educational resources for consumers, health care professionals, and other professional and lay workers, supporting behavior change, evaluating NDEP activities, building effective partnerships, and maintaining a multi-cultural focus to help eliminate health disparities. A new web site, Diabetes HealthSense (see: http://ndep.nih.gov/resources/diabetes-healthsense/), has been launched to aid people with or at risk for diabetes and health care providers in implementing lifestyle changes as part of type 2 diabetes prevention or diabetes management. Type 2 diabetes prevention "toolkits" are available for health care providers and community health workers serving populations with a higher burden of diabetes. NDEP continues to support two core campaigns: (1) The "Small Steps. Big Rewards. Prevent Type 2 Diabetes" campaign, which is based on the results of the Diabetes Prevention Program clinical trial; and (2) Control Your Diabetes for Life, which is based on results of the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) and the United Kingdom Prospective Diabetes Study (UKPDS).

NDEP does not develop guidelines, rather, it utilizes guidelines from a number of sources, including the ADA, American Association of Clinical Endocrinologists (AACE), American College of Physicians (ACP), USPSTF, and NHLBI, as well as federal dietary and physical activity guidelines. However, the NDEP publishes a "Guiding Principles" document for diabetes care that emphasizes that the health care team should work in partnership with the patient to develop an individualized diabetes management and/or type 2 diabetes prevention plan. Next steps for the NDEP's Guiding Principles Task Group are to review the most recent (2009) version of the Guiding Principles documents well as major existing diabetes clinical guidelines, and develop an updated principles document built upon these multiple guidelines and clinical research findings and which will be "user friendly" and of value to health care professionals. It is hoped that a successful synthesis of the commonalities between available guidelines will be an outcome of this effort. Multiple health organizations are being invited to join in co-branding, supporting, and promoting the new document. More information on the NDEP is available at: www.YourDiabetesInfo.org

Veteran's Health Administration (VHA)-Department of Defense (DoD) Diabetes Guidelines: 1997-2011—Leonard Pogach, M.D., M.B.A., F.A.C.P., VHA

The military veteran population served by the VHA is heterogeneous and tends to be older, with a significant portion affected by multiple chronic comorbid conditions even in those less than 65 years of age. In those 65 and older, a significant proportion has serious CKD, receives insulin, and/or has dementia or cognitive impairment. Clinical judgment and shared decision making are essential given that clinical trials have not typically enrolled patients with similar levels of co-morbidities. Development of evidence-based clinical guidelines for diabetes treatment by VHA-DoD follows a process similar to that of the USPSTF. VHA-DoD grades recommendations from A-D based on evidence. Examples of the use of evidence for VHA policy decisions: A risk-stratified approach to diabetes management/treatment based on life expectancy and co-morbid conditions and using shared decision-making was first proposed in 1997, with three subsequent updates (2000, 2003, 2010). This approach recommended an individualized A1C target setting approach between clinicians and patients in contrast to ADA's recommendation (through 2010) of <7 percent in general. Based on this approach, VHA did not implement the National Committee for Quality Assurance (NCQA) <7 percent A1C ("controlled") and <130 mmHg blood pressure measures (that had no exclusions and applied to all individuals 18-75 years) for accountability (2007). It was felt that these measures are not universally applicable to all veteran populations based upon consideration of benefits and harms. As another example, VHA decided to remove rosiglitazone from the VHA formulary prior to U.S. Food and Drug Administration (FDA) actions restricting its use. In addition, the 2010 VHA-DoD diabetes guideline update addresses emerging evidence of racial differences in the A1C test and reemphasizes clinician awareness of A1C test accuracy and precision. VHA-DoD qualified the use of A1C for diagnosis of diabetes (unless >7% on two occasions) and did not recommend its use for diagnosis of pre-diabetes, instead recommending a fasting blood glucose. These issues were presented at the March 11, 2011 DMICC Meeting on A1c.The VHA-DoD is also seeking to promote a greater understanding of the evidence for diabetes management and treatment strategies, as well as interpretation of laboratory results among physicians, nurses, and patients through development of tool kits. Pictograms from the tool kits were incorporated into *The A1C Test and Diabetes*, developed by the National Diabetes Information Clearinghouse (NDIC), an information service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (www.diabetes.niddk.nih.gov/dm/pubs/A1CTest/A1C_Test_DM-508.pdf). The 2010 VHA-DoD Clinical Practice Guidelines for Management of Diabetes Mellitus in Primary Care document is available here: www.healthquality.va.gov/diabetes_mellitus.asp

Discussion—DMICC Members

Members generally agreed that guidelines cannot be "one size fits all." Guidelines should also not substitute for clinical judgment. CMS and VHA were particularly concerned about guidelines because their agencies serve/reimburse populations that tend to be less healthy and more diverse in their health needs than the general population.

Critical research gaps exist: Specific evidence of benefit for particular treatments, goals, etc., is lacking for many "subgroups" of patients, whether they are from the general population or the populations served by CMS or VHA—most evidence does not address every possible patient or situation. For example, while evidence for a recommendation may be drawn from large randomized, controlled clinical trials, these are typically not powered to look at all possible subgroups. Thus, it is important to be clear about the significance/applicability of evidence for particular populations.

Non-beneficial overtreatment is a risk in older and/or sicker populations if guidelines developed based on evidence for the general population are applied robotically; however, at the other end of the spectrum, there is an urgent need to encourage early detection, treatment, and control in less debilitated individuals, in order to stave off complications as long as possible. This represents a challenging balancing act in guideline development, application, and messaging.

The concept that tailoring the application of guidelines to individual patients would be beneficial to patients, practitioners, and payers emerged as a converging viewpoint among DMICC members that develop, use, and/or are affected by diabetes guidelines. Along these lines, it is anticipated that DMICC members will provide input on the development of the revised NDEP "Guiding Principles" document, which could help serve to reinforce this approach and could be disseminated across the agencies.