

Recommendations for Community-Based Screening for Prediabetes and Diabetes AADE White Paper Issued December 1, 2014

The high prevalence of prediabetes and diabetes represents a major health problem in the United States (U.S.). According to the Centers for Disease Control and Prevention (CDC), in 2012 persons with diabetes in the U.S. accounted for 9.3% of the nation's population or 29.1 million people. Of those affected, only 21.0 million people were diagnosed with diabetes; thus, 8.1 million individuals (27.8%) were undiagnosed.¹ In addition, the 2012 CDC statistics for the US population estimated that there were 86 million adults with prediabetes.¹ Clearly, an unacceptably high percentage of persons with or at risk for diabetes in the U.S. are undiagnosed and, as a result, not receiving proper care to avoid or manage diabetes and its complications. Groups within the population who are at higher risk include individuals over 45 years of age, racial and ethnic minorities, women who have had gestational diabetes but do not receive adequate follow-up testing postpartum, and those without access to medical care, such as the uninsured.^{1.2.3} Given that our current prevalence of diabetes (9.3%) is nearly triple that of 1990 (3.6%), there is almost universal agreement that we must take effective steps to reduce the growth of this epidemic.

Among such steps, there is strong support for earlier diagnosis and intervention to minimize the progression of diabetes and the development of associated complications.⁴⁻⁶ In response to the diabetes epidemic, many diabetes stakeholder groups and organizations in the U.S., especially at the local level, advocate for community-based screening (CBS) in venues such as health fairs or diabetes awareness events. Thousands of individuals throughout the nation have been and continue to be screened at such events in the hope that those who are undiagnosed will be discovered and helped to find medical care.

However, for many years expert opinion has been grounded in caution regarding the approach to CBS for prediabetes and diabetes.⁷ For example, the American Diabetes Association (ADA), while agreeing with the need to identify more individuals who have or are at risk for diabetes, recommends that such screening be confined to medical settings.^{5,8} The ADA notes that after CBS, individuals may not have access to appropriate follow-up testing and care. They also caution that poor targeting is likely with CBS, including failure to test those most at risk and inappropriate testing of those at low risk (the "worried well") or those already diagnosed.⁵ The CDC recommends that screening for prediabetes and diabetes be conducted only in healthcare settings.⁹

Diabetes educators often find themselves torn between stakeholder groups or organizations that ask for their assistance in staffing CBS events, and the recommendations from the ADA and CDC to restrict screening to medical settings. Educators may also perceive that organizers of such events will find other less qualified individuals to perform the screening, should they refuse. Because of the focus on prohibition, there has been little or no guidance available to diabetes educators who are faced with these dilemmas and little professional dialogue regarding quality control of CBS. The purpose of this paper is to provide diabetes educators with background, perspective, and recommendations regarding CBS that will enable them to constructively influence the planning and implementation processes for these events. This white paper should not be construed as advocating CBS for prediabetes and diabetes; its sole intent is to provide helpful information and direction to diabetes educators participating in local CBS events.

Moreover, we would preface the discussion of CBS for prediabetes and diabetes by noting that serious consideration should be given to the option of developing an event that focuses on public education and limits risk assessment for prediabetes and diabetes to a questionnaire-based approach. This would largely address concerns raised by experts in the field, although the possibility remains that some participants might consider the results of the questionnaire either less compelling or a substitute for blood glucose evaluation.

In the event that a decision is made to go forward with developing a CBS event, the following recommendations should be used to help guide the planning process.

- **Target CBS for those at higher risk.** Given the concern raised that CBS may result in poor targeting (failure to test those most at risk and inappropriate testing of those at low risk or those already diagnosed), CBS should be conducted in areas or among groups where the risk of diabetes or the prevalence of undiagnosed diabetes is known to be high, e.g., among individuals over 45 years of age, ethnic and racial minorities, and women with gestational diabetes.
- Begin with a non-invasive risk assessment. The first stage of CBS should be a noninvasive web- or paper-based test that identifies those at high risk for prediabetes or diabetes.^{10,11} In preference to self-report, CBS should include on-site measurement of weight and height to determine Body Mass Index (BMI) as well as blood pressure. The results of these measurements should be used where applicable to answer questions on the paper or web-based risk test. Subsequent blood glucose evaluation should be restricted to those individuals found to be at higher risk for prediabetes and diabetes on the web or paper-based test.
- Explain the meaning of test results to participants. In view of the concern that CBS events may not offer adequate discussion of abnormal results, it is important that CBS organizers make every effort to ensure that the individuals who are screened understand what their results mean and the implications of the results for their health. They need to understand that a single elevated blood glucose evaluation does not meet the criteria for diagnosis of prediabetes or diabetes and no such implication should be expressed or implied. Written materials explaining prediabetes and diabetes, risk factors for these conditions, the tests used for screening, and the meaning of test results, must be provided to all individuals screened. To ensure comprehension, verbal explanation in the language spoken by the individual should also be provided.
- Insure adequate follow-up testing and diagnosis. To address the concern that CBS may result in inadequate follow-up testing and diagnosis for those with positive results, it is important that results for those found to be at risk following CBS are communicated, with appropriate written consent, to the individual's primary care provider for diagnostic

testing and follow up. In instances where an individual has no primary care provider, they should be counseled regarding the importance of following up with providers who have agreed to assist with follow-up testing and diagnosis. CBS organizers must provide individuals who are identified as being at risk with a written report of the screening results and contact information for identified providers. Community-clinical partnerships must be solidly in place well in advance of the day of the screening. No later than one month prior to the screening, CBS organizers should contact local clinics, medical practices, diabetes education programs, health departments, and departments of social services to establish a direct relationship and referral process for people who have no primary care providers. CBS organizers should also provide individuals with information regarding coverage for follow-up diagnostic services and care under the Affordable Care Act.

- Form partnerships with providers of follow-up and emergency care in advance. In light of the concern that CBS may offer inadequate follow-up care for those diagnosed with prediabetes or diabetes, CBS organizers should provide individuals who are thus diagnosed with contact information for providers of diabetes care and education who have agreed to accept referrals. Planning should include considerations such as providers who accept uninsured, underinsured, Medicaid, and Medicare patients. CBS organizers should partner with reputable healthcare programs and community-based fitness and weight loss programs to provide follow-up lifestyle change intervention for these individuals. In addition, a plan must be in place to provide care for people requiring immediate medical attention at the event, e.g., those with extreme hyperglycemia or hypertension. Emergency medical services must be notified in advance of the event and guidelines developed regarding levels of blood pressure, blood glucose, or A1C that would trigger consideration of emergency transport and care.
- Limit blood glucose testing to qualified providers. Blood glucose testing should be conducted by healthcare professionals who possess appropriate licensure and are trained to use the measurement devices reliably. Many measurement devices are more aptly viewed as measurement systems involving multiple steps that must be carried out

correctly to avoid introducing additional measurement error. Training and experience are essential in this regard.

- **Observe essential safety practices.** Of paramount importance is ensuring the safe use of medical devices with multiple people in CBS. To prevent the spread of infection, standard safety practices associated with the collection, handling, and disposal of devices and equipment exposed to blood must be followed. These include wearing gloves, changing gloves and performing hand hygiene between contacts with individuals and after contact with contaminated surfaces, proper disposal of all blood borne waste, and keeping testing surfaces covered and clean, e.g., through changing the covering.¹²
- Restrict the use of fingerstick and measurement devices to those intended for assisted monitoring of blood glucose (AMBG). The current literature on safety practices related to blood glucose monitoring distinguishes between self-monitoring of blood glucose (SMBG) and assisted monitoring of blood glucose (AMBG).¹³ SMBG refers to practices and procedures associated with the testing of one person, wherein the use of fingerstick devices, meters, supplies, and other equipment is limited to a single individual, such as traditional home testing conducted by a person with diabetes. AMBG refers to testing in situations such as assisted living facilities, home healthcare, hospitals, health fairs, and CBS, where multiple individuals will be tested by others with the potential for the sharing of fingerstick devices, meters, supplies, and other equipment among individuals. Due to serious concerns about the transmission of HIV and Hepatitis B and C in AMBG, 12,13,14,15 ONLY FINGERSTICK AND MEASUREMENT DEVICES INTENDED FOR AMBG SHOULD BE USED FOR CBS. Reusable fingerstick devices should never be used in AMBG, only single-use, auto-disabling fingerstick devices.¹² It would be prudent to regard all over-the-counter meters marketed to patients as being inappropriate for use in AMBG. The Food and Drug Administration (FDA) has issued new draft guidance for manufacturers of blood glucose meters that distinguishes between over-the-counter meters intended for use by patients (SMBG) and those intended for point-of-care professional use (AMBG).¹⁶ In light of the fact that approval and labeling requirements for blood glucose meters are evolving and the intended use information accompanying older meters is often unrevealing or confusing with regard to AMBG, CDC has issued the following best practice guidance: "Whenever possible, blood glucose

meters should be assigned to an individual person and not be shared. If blood glucose meters must be shared, the device should be cleaned and disinfected after every use, per manufacturer's instructions, to prevent carry-over of blood and infectious agents. If the manufacturer does not specify how the device should be cleaned and disinfected then it should not be shared. "¹² The American Association of Diabetes Educators (AADE) issued a Practice Advisory in December of 2013 stating essentially the same thing.¹⁷

• Use recommended measures for blood glucose assessment. ADA currently recommends three methods of testing for diabetes in asymptomatic adults: A1C, fasting plasma glucose, and a 2-hour, 75-gram, oral glucose tolerance test (OGTT).⁵ Random blood glucose testing is not recommended because of the difficulty of interpreting results. While it is too time consuming and impractical to employ OGTT in CBS, either A1C or fasting blood glucose (FBG) testing is a workable approach to measurement. There is a significant and growing body of research on the relative accuracy of A1C and FBG,^{18,19,20} which in the future may reveal a decisive advantage for one of these methods in screening situations. Currently, ADA standards support the use of either method and it is interesting to note that the National Health and Nutrition Examination Survey (NHANES) employs both in its national surveillance of undiagnosed diabetes.²⁰ For CBS, the selection of one method over the other is likely to be based on a variety of factors such as availability and affordability of equipment and supplies, the feasibility of participants attending in a fasting state, and the preferences, training, and experience of participating healthcare providers.

To summarize, acceptable blood glucose measures and measurement device options for CBS should be limited to point-of-care A1C or FBG testing using measurement devices intended for AMBG.

Acknowledgements

J. Terry Saunders, PhD; Kathleen Gold, RN, MSN, CDE; Joan V. C. Hill, RD, CDE, LDN; Carolyn Jenkins DrPH, APRN-ADM, RD, LD, FAAN; Andrew S. Rhinehart, MD, FACP, CDE, BC-ADM, CDTC; Jennifer Goldman-Levine PharmD, CDE, BC-ADM, FCCP

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