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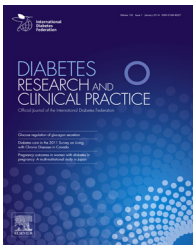

# Evaluation of non-invasive screening measures to identify individuals with prediabetes

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ABSTRACT

*Aims:* Because blood-based screening to identify those with prediabetes to take part in Diabetes Prevention Program (DPP) translation efforts can be costly and time-consuming, non-invasive methods are needed. The aims of this paper are to evaluate the ability of the American Diabetes Association (ADA) risk test in identifying individuals with prediabetes, as well as the use of body composition measures for this purpose. In addition the utility of these alternate methods to ascertain the presence of the metabolic syndrome was assessed.

*Methods:* Potential participants were recruited from a worksite and three community centers to take part in a DPP translation study. Participants completed onsite screening where anthropometric measures, fasting lipids and glucose, and hemoglobin A1c were assessed. Those with a BMI $\geq$24 kg/m$^2$ and prediabetes and/or the metabolic syndrome were eligible to participate. Non-invasive screening methods were evaluated for their ability to identify those with prediabetes and the metabolic syndrome based on clinically measured values.

*Results:* All non-invasive methods were highly sensitive (68.9% to 98.5%) in the detection of prediabetes, but specificity was low (6.7% to 44.5%). None of the alternatives evaluated achieved acceptable discrimination levels in ROC analysis. Similar results were noted in identifying the metabolic syndrome.

*Conclusions:* The non-invasive methods evaluated in this study effectively identify participants with prediabetes, but would also allow for enrollment of a large number of individuals who do not have prediabetes. Deciding whether to use these alternatives, blood-based measures, or a combination of both will ultimately depend on the purpose of the program and the level of flexibility regarding participant eligibility.

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## 1. Introduction

The Centers for Disease Control and Prevention (CDC) currently estimate that 25.8 million people in the United States (US) have diabetes, and an additional 79 million people are at high-risk with prediabetes, identified by impaired fasting glucose, impaired glucose tolerance or hemoglobin A1c [1]. The prevalence of the metabolic syndrome, a constellation of risk factors that increase the risk for diabetes has also been

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persistently increasing during the past decade [2]. It is estimated that nearly one third of the US population will have diabetes by 2050 due to increases in diabetes incidence and low mortality rates [3].

The US Diabetes Prevention Program (DPP) demonstrated that type 2 diabetes could be prevented or delayed through intensive lifestyle intervention, with the goals of moderate weight loss and increased physical activity levels [4]. The success of the DPP has led to a variety of translations of its lifestyle intervention that have been conducted in urban and rural areas, within the health care setting, through community groups, and at worksites and academic institutions across the US. Each has demonstrated some level of success in regard to reducing weight, increasing physical activity levels and even improving risk factors for diabetes and cardiovascular disease [11–16].

Accurate identification of high-risk individuals who will benefit the most from taking part in these diabetes prevention translation efforts is essential. In the DPP, eligibility criteria included age ≥25 years, Body mass index (BMI) ≥24 kg/m$^2$ or ≥22 kg/m$^2$ for Asian Americans, and impaired glucose tolerance diagnosed by a single 75-g oral glucose tolerance test (OGTT) [17]. However, the criteria used to identify high-risk participants who meet program eligibility among community translations of the DPP lifestyle intervention has varied considerably (Table 1) [18]. A common theme among these translation efforts was use of a BMI cut point (≥24 kg/m$^2$ or ≥25 kg/m$^2$), combined with at least one of the previously mentioned measures of diabetes risk listed in Table 1, including having the metabolic syndrome to determine eligibility [11–16,19–26].

Given the high numbers of people at risk for diabetes, a simple, inexpensive method, such as a paper risk test or anthropometric measurement, is needed to facilitate the identification of individuals with prediabetes who could subsequently benefit from lifestyle intervention. Published DPP translation efforts that employed a paper risk test have reported using the 7 question American Diabetes Association (ADA) paper risk assessment developed by Herman et al. [11,14,27]; however the ADA paper risk assessment was created to identify individuals at risk for undiagnosed diabetes, not those with prediabetes. The CDC National Diabetes Prevention Recognition Program (DPRP) guidelines focus on blood-based screening for identification of those with prediabetes for inclusion in diabetes prevention programs. However, while the DPRP standards and operating procedures require that at least half of those enrolled in diabetes prevention programs have documented prediabetes, the guidelines also include use of the ADA paper risk test [28] as an alternative screening method for up to half of enrolled individuals, likely due to a lack of viable, non-invasive screening methods [29]. To date, the ADA risk test has not been evaluated for its ability to identify those with prediabetes in the context of a diabetes prevention translation study.

In other efforts, anthropometric measurements such as BMI [30–33], waist circumference [30,31,33], and waist to height ratio [30,31,33,34] have been investigated for their ability to provide details about an individuals' future risk for type 2 diabetes. However, to the authors' knowledge, none of these anthropometric measurements have been evaluated for their ability to identify high risk participants in the context of a lifestyle intervention for the prevention of type 2 diabetes.

Therefore, the aims of this paper are to evaluate the ability of the ADA paper risk assessment test incorporated by the CDC DPRP as well as other non-invasive body composition measures to identify individuals with prediabetes. In addition

**Table 1 – Methods used to identify eligible participants and the order in which they were used if a stepped approach was employed.**

| Study author | Methods to identify prediabetes | | | | | Methods to identify other high-risk categories | | |
|---|---|---|---|---|---|---|---|---|
| | Blood-based screening | | | Diabetes risk test | Physician documentation | Blood based screening | Documentation of ≥1 diabetes risk factor | Physician documentation |
| | Random capillary glucose | Fasting finger stick | Fasting blood glucose | | | | | |
| Ackermann [11]* | X(2) | | | X(1) | | | | |
| Amundson [13] | | | | | | | | X |
| Boltri [14]* | | X(2) | X(3) | X(1) | | | | |
| Whittemore [15] | | | | | | | X | |
| Kramer [16] | | | | | X | X | | X |
| Matvienko [19] | | | | | X | | | X |
| Merriam [20] | | | | | X | | X | X |
| Katula [21] | | | X | | | | | |
| Kramer [22] | | | | | X | | | X |
| Kramer [23] | | | | | X | | | X |
| Seidel [24] | | | | | | X | | |
| McTigue [25] | | | | | | | | X |
| Barham [26] | | | | X | | | | |

*Numbers indicate order in which screening methods were used.

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