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Prevention of Type 2 Diabetes: The Strategic Approach for Implementation

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Abstract

A growing need exists to deliver effective and affordable prevention programs and to take urgent action to address the major public health challenge that diabetes represents. Achieving prevention of type 2 diabetes requires moving through a series of steps from basic science discovery to widespread distribution of effective interventions. Understanding the cellular level influences on diabetes prevention will help target particular interventions to those who may be most responsive. Several randomized controlled trials conducted throughout the world have demonstrated that type 2 diabetes can be prevented or delayed. Subsequent real-world translation studies have provided important information necessary to reduce cost and increase access. Ultimately achieving a population impact in diabetes prevention requires widespread distribution of effective interventions, which is supported by policies that help achieve sustain-ability and reach. The use of a global stakeholder network can help to share experiences and build on partner knowledge gained.

Keywords

type 2 diabetes; diabetes prevention; visceral fat; public health; global diabetes survey; implementation

Introduction

Moving from scientific discovery to broad population-wide implementation requires a series of steps, each of which builds on the previous ones' achievements (Fig. 1). Diabetes prevention provides an example of the necessity of moving from basic science to widespread distribution of proven interventions. For nearly a decade, the potential to prevent or delay type 2 diabetes in high-risk individuals by lifestyle intervention has been firmly established. Subsequent translation studies have provided important information about real-world implementation of diabetes prevention programs. In some countries, efforts to scale diabetes

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interventions for the at-risk population have begun. However, achieving sizeable regional and national programs presents many challenges. The scaling of regional or national programs requires a competent work-force of lifestyle intervention providers, as well as health services professionals, health economists, public health professionals, and community-based organizations able to work with policymakers and gain political support to develop national action plans and policies for expansion of diabetes prevention programs.

Basic Science in Diabetes Prevention

Exploring the molecular physiology of the prevention of type 2 diabetes is crucial to both understanding the pathomechanisms of diabetes prevention and to developing targeted intervention programs to prevent diabetes. Insulin resistance always precedes the development of impaired fasting glucose, a warning the diabetes could be about to develop [1]. Visceral fat mass and visceral obesity seem to play a critical role in triggering the development of insulin resistance [2]. The profile of adipokines that visceral fat secretes directly influences inflammatory processes and insulin resistance development which, in turn, directly influences diabetes risk [3]. Furthermore, along with an increasing level of circulating insulin, proinsulin might also be a major factor in triggering diabetes development and, subsequent cardiovascular disease and cardiovascular morbidity [4]. To understand these pathomechanisms, we must explore the genetic basis of the regulation of insulin resistance and to understand visceral obesity and the combined pathophysiology behind it. Genetics account for a relatively small proportion of the total diabetes pathophysiology [5,6]. However, current investigations suggest that a link between genetic susceptibility and the outcome in preventive interventions exists [7,8]. No known intervention can reduce diabetes risk to zero in all participants. These failures of interventions might be partially explained by unmeasured genetic or phenotypic factors. A significant future challenge is the development of pathophysiology-targeted prevention programs and the identification of persons likely to be nonresponders, so that interventions that will work for these persons can be applied.

Efficacy in Diabetes Prevention

To test intervention concepts and to generate evidence about intervention structures, diabetes prevention programs should ideally be tested in randomized controlled trial (RCT) settings. While RCTs can be difficult, considerable evidence showing that sustained lifestyle change prevents or delays type 2 diabetes in a substantial portion of the population exists [9,10}. A number of large RCTs have shown that interventions, focusing on improved physical activity and nutritional intake, along with strategies and supports for behavior change, reduced the incidence of type 2 diabetes by up to 58%. Furthermore, many diabetes drugs are also of value in the prevention of type 2 diabetes [10,11]. Lifestyle interventions *and* drug treatment do not show an additive effect, and the evidence about the combination that does exist is conflicting. Lifestyle intervention was more effective in older adults and less in obese people than the drug metformin. Metformin was more effective in younger, heavier people, and women with a history of gestational diabetes in the United States Diabetes Prevention Program (U.S. DPP) [10]. While efficacy trials have shown that type 2

diabetes can be prevented, barriers exists to the implementation of the knowledge about how to prevent diabetes and studies in the real-world are needed [12].

Effectiveness in Diabetes Prevention

After RCTs are completed, the knowledge gained must be translated into real-world settings. Such translation is not always easy, it generates a number of new challenges and requires a critical discussion about the necessity and practicability of what was done in the RCTs and what is applicable to real-world settings. A number of translation studies have tried to do this and have found ways to reduce costs and achieve weight loss comparable to what was achieved during the RCTs. One challenge in moving from RCTs to real-world implementation in diabetes prevention is screening to identify those at high-risk, it is unrealistic to believe that performing 2 OGTTs for screening, which is done in some countries, can be appropriate for prevention programs in real-world settings except possibly in very high risk people (e.g., women with a history of GDM). Implementation design often depends on limited financial resources and is driven by circumstances in the environment that enable screening and intervention. These limits mean that translation efforts can fail short of what was done in the RCTs. Screening procedures and interventions must adapt to the existing environments, driven by the hypothesis to test the feasibility and applicability of an intervention program to the real-world setting [13].

A number of translational trials have been performed in several parts of the world, with different experiences. Finland has led the way with F1N-D2D, a large-scale implementation covering a quarter of the Finnish population [14]. The subsequent translation studies of the U.S. DPP have shown that by delivering the program in a group setting (instead of one-on-one) and utilizing lower-cost trained health educators and community organization staff, the program can be delivered effectively and cost-effectively [15–18]. Another landmark was a profusion of published implementation trials including GOAL and the Saxon DPP in Europe [19], and the Greater Green Triangle DPP in Australia. Other projects, such as those in Yukon, Canada, Let’s Beat Diabetes in New Zealand and the Diabetes in Europe - Prevention using Lifestyle, Physical Activity and Nutritional Intervention initiative [20,21 {involve novel methods for community-wide implementation of diabetes prevention with various degrees of effectiveness.

Efficiency of Diabetes Prevention

After we have learned from the implementation trials and put together practical evidence from effectiveness studies, our next challenge is to modify programs or their implementation to achieve the largest effect for the most people who need the intervention. Efficacy research studies often have a relatively small number of participants and are applicable only to a limited segment of the population. Effectiveness trials are more likely to use participants from a more broadly defined high risk population, but using interventions that have proven effective in real-world settings still may not help us address factors that will enable us to scale the intervention to reach the most people. At this stage, policy perspectives and plans for cost-effective expansion of the intervention usually come into play. RCTs or effectiveness trials cannot tell us how to achieve the greatest benefit for the most people;

that information must be obtained by networking with specialists and stakeholders from neighboring fields in medicine and public health and gaining expertise in fields such as management, economics, and policy development. To be efficient in the preventing type 2 diabetes at the population-level, we need support from local and/or national policy-makers to build effective diabetes prevention plans. These plans help relevant specialists and stakeholders network so they can agree on concerted actions involving different resources from societal and individual life to operate an efficient type 2 diabetes prevention program. Efficiency in diabetes prevention programs requires that scientific and practical information be made available in a condensed form that can be used in practice implementation. Based on the experiences from the clinical trials, as well as from the "real world" implementation programs, the Development and Implementation of a European Guideline and Training Standards for Diabetes Prevention (IMAGE) Study Group collated information in a systematic manner. The IMAGE deliverables include evidence-based guidelines on type 2 diabetes prevention [22], a practice toolkit for diabetes prevention [23] and guidelines for program evaluation, and quality indicators in type 2 diabetes prevention [24]. A European training curriculum also was developed for prevention managers performing diabetes prevention intervention programs. In the United States, Congress passed legislation that authorizes the U.S. Centers for Disease Control and Prevention (CDC) to manage the National Diabetes Prevention Program and establish a network of evidence-based lifestyle intervention programs for those persons at high risk of developing type 2 diabetes. One element of the U.S. National Diabetes Prevention Program was to organize a training curriculum for lifestyle coaches and high risk program participants [15].

Availability of Diabetes Prevention Programs

After addressing the efficiency of diabetes prevention through developing a practical framework of stakeholders, as well as obtaining support from policymakers and sufficient resources to have a population-level impact, it is necessary to address program availability. Availability includes having an adequate number of easily accessed programs in the communities, adequate personnel resources to train the prevention managers, and an adequate number of prevention managers. Development of the European curriculum for training prevention mangers is an achievement that can be used to standardize intervention procedures and craft "train the trainer" strategies. As part of the National Diabetes Prevention Program, the United States has developed the Diabetes Training and Technical Assistance Center at Emory University to help train master trainers and lifestyle coaches and coordinate training efforts [15]. Policies that support adequate resources and coordination are vital at this stage and support from scientists and medical experts in the field are essential to drive policy decisions and ensure program availability.

Distribution of Diabetes Prevention

The best program will fail if it cannot reach - or be reached by - those most at risk [19]. To be effective, any preventive action must be performed in the environment in which the people with increased risk live and work [25,26]. Structures and policies must be established to identify high-risk individuals and manage intervention follow-up and evaluation. Scientific evaluation standards based on findings from the RCTs need to be translated into

the public health care setting. Since the public health care setting usually has very limited resources, this must be done with care. Such translation has been achieved in Europe by the international IMAGE consortium with a quality management structure [24]. In the United States, the National Diabetes Prevention Program contains a recognition program that sets standards that help assure program quality and consistency. The CDC is responsible for conducting this recognition program and reporting on the distribution and quality of diabetes prevention programs across the United States [15].

Fulfilling the Development of National Diabetes Prevention Programs

The existence of a national policy for supporting diabetes prevention does not always equate with a positive outcome, but it is a mandatory first step for successful public health implementation. An adequate scientific basis provided by basic research, efficacy studies in highly controlled environments, and effectiveness studies in real-world environments performed by clinical researchers and public health experts are necessary to prevent type 2 diabetes. To scale diabetes preventive actions to the population level, program strategies must be adjusted to have the best effect for a relevant proportion of the population, as well as the supply and diffusion of the intervention into the population. Policy development is a necessary part of the latter 3 steps. The development of national diabetes plans, which are supported by local prevention management and adequate networking and stakeholder involvement, are necessary to address this challenge and guide implementation of diabetes prevention. Only 5 out of 27 countries within the European Union have a national diabetes plan; only one has a national diabetes prevention program [27]. The European Coalition for Diabetes, together with the EU Diabetes Working Group, has formed working groups to address the need for delivering adequate care for diabetes in Europe. Those working groups have elaborated recommendations to the EU institutions and other governments to take urgent action to address the major public health challenge that diabetes represents. In Asia, the situation is similar to that in Europe, with a progressive increase in the number of countries including diabetes prevention in their national policies [28]. The United States is currently expanding the CDC-led National Diabetes Prevention Program [15].

To enhance the capabilities for developing and implementing national diabetes prevention and management plans, the University of Dresden, together with a number of stakeholders from more that 91 countries worldwide, are planning to perform a global diabetes survey that annually will gather information about the degree of implementation of national diabetes plans worldwide. This global diabetes survey presents a unique opportunity to establish a primary care-based monitoring instrument. By assessing the methods, successes, and challenges that diabetes prevention programs face, the survey will help us improve the performance of national diabetes plans and increase the quality of prevention and care of diabetes. For this purpose, a representative group of experts from all sectors of diabetes care, including patients, will be consulted as volunteers in a structured and standardized way. The instruments of the survey are currently undergoing validation by using a Delphi procedure. The survey will be administered online and will consist of a standardized and structured assessment designed to enable a realistic appraisal of diabetes plans and programs nationally. The participants' responses will be analyzed to discern the status and situation of national diabetes plans in each country that has survey participants. Anyone who is

associated with diabetes care can participate as a volunteer and is invited to do so at www.globaldiabetessurvey.com.

Statement

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention.

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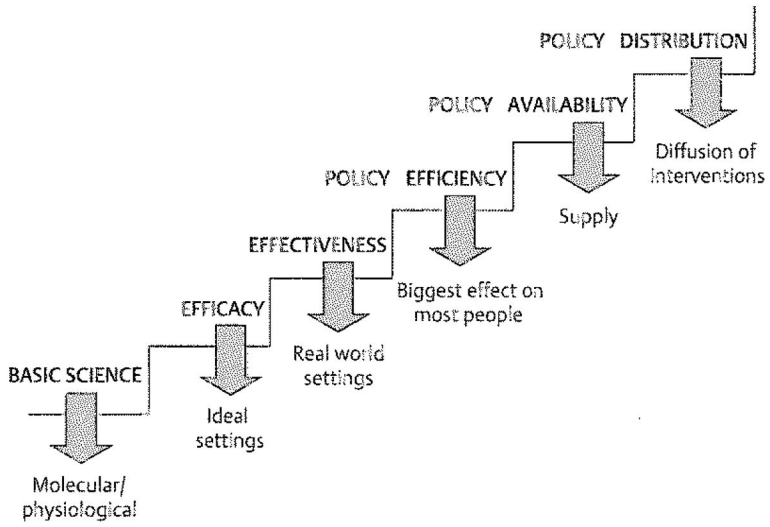

Fig. 1.

Steps from scientific discovery to population-wide implementation. The graphic representation is adapted from information in references [29,30].