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Is the Current Lifestyle Modification Approach to Diabetes Prevention in the U.S. a Success?

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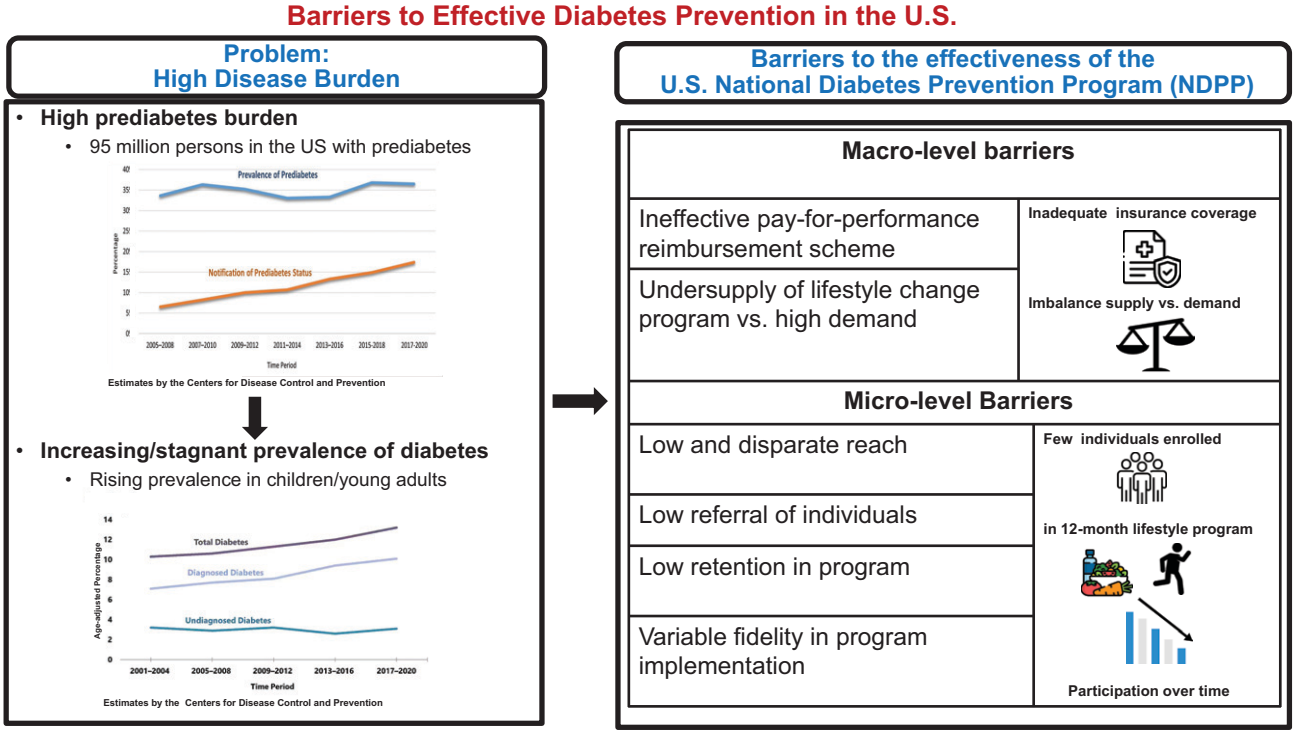

ARTICLE HIGHLIGHTS

- **Why did we undertake this study?**
  Prediabetes is highly prevalent in the U.S., but the extent of its management is unknown.
- **What is the specific question(s) we wanted to answer?**
  What are the gaps in our current approach to addressing prediabetes in the U.S.?
- **What did we find?**
  Policy, implementation, and intervention barriers and deficits impede progress wherein ~95 million Americans with prediabetes are not accessing, completing, or benefiting from current efforts to prevent diabetes. Hence, the current national diabetes prevention strategy, aimed at delivering lifestyle modification to individuals, has not translated into quantifiable benefits.
- **What are the implications of our findings?**
  Our analysis points to the need for a multipronged approach involving a combination of synergistic societal and more precise individual-level interventions to prevent type 2 diabetes.

Is the Current Lifestyle Modification Approach to Diabetes Prevention in the U.S. a Success?

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Prediabetes is an intermediate stage between normal glycemia and diabetes and is highly prevalent, especially in adults, but is also increasingly common in young individuals. Randomized clinical trials have demonstrated that lifestyle modification is cost-effective in preventing diabetes. Implementation studies showed the feasibility of delivering real-world structured lifestyle modification programs adapted from the U.S. Diabetes Prevention Program trial. However, the current approach to diabetes prevention in the U.S. has been largely inadequate thus far, as evidenced by the stagnant numbers of people with prediabetes and the growing number of those with diabetes. The many gaps in the implementation of the National Diabetes Prevention Program (NDPP) can be characterized as due to macro-level barriers (failures of pay-for-performance reimbursement, an undersupply of lifestyle change programs), micro-level barriers (low and disparate reach, low referral and retention rates in the program), variable fidelity in implementation, and limitations of a one-size-fits-all intervention. All of these issues point to a need for reexamining strategies for diabetes prevention in the U.S., which is yet to show benefits or value at the population level. This article details how prediabetes is currently suboptimally addressed in clinical practice and communities in the U.S. and articulates why there is an urgent need to rethink our approach to addressing prediabetes, possibly through integration of synergistic individual- and societal-levels approaches.

Prediabetes, an intermediate stage between normal glucose regulation and diabetes, is a major public health problem, but it largely remains unaddressed. In 2017–2020, the national U.S. prevalence of prediabetes was 38% among adults aged ≥18 years (1), which corresponds to one in three adult Americans (∼97 million) having prediabetes (1). Prediabetes prevalence was roughly similar across racial and ethnic groups, ranging from 35.4% among Hispanic adults to 39.2% of non-Hispanic Black adults (1). Over the past two decades in the U.S., the prevalence of prediabetes has increased steadily across all racial and ethnic groups and across all adult age-groups (2–4). It increased from 32.1% in 2005–2006 to 39.6% in 2007–2008 and then plateaued to 38.6% in 2017–2020 (5). Over the same period, the prevalence of diabetes among adults increased from 10.9% to 14.3% (6), indicating substantial progression of prediabetes to diabetes.

Over the last two decades, the prevalence of prediabetes among U.S. youth has escalated more steeply, from 11.6% in 1999–2002 to 36.2% in 2015–2020 (7). The expanding population of young adults with prediabetes (8) has undoubtedly further

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escalated the burden of diabetes. This is reflected by the increasing incidence of type 2 diabetes in children and young people. In the SEARCH for Diabetes in Youth (SEARCH) study, age-, sex-, and/or ethnicity-adjusted incidence of type 2 diabetes increased 5.3% annually from 9.0 cases per 100,000 per year in 2002–2003 to 17.9 cases per 100,000 per year in 2017–2018 (9). Until recently, there were no formal recommendations for prediabetes screening and management among children and young people (10,11).

The burden of morbidity and costs associated with prediabetes is high. Approximately 3%–4% of those with prediabetes annually progress to diabetes, and ∼30% are at high cardiovascular risk at diagnosis (12). In 2017, prediabetes in the U.S. was associated with annual costs of $43.4 billion (13).

In the proof-of-concept diabetes prevention trials, prediabetes was shown to be responsive to intensive lifestyle modification (12). Implementation studies showed that the delivery of the U.S. Diabetes Prevention Program (DPP) trial lifestyle intervention in real life through routine health care programs was feasible (14) and associated with cardiometabolic benefits (15,16). However, the uptake and effectiveness of these interventions in real-world settings in the U.S. have thus far been largely inadequate. In contemporary U.S. medical practice and community settings, there are many gaps in the identification and care for prediabetes. These gaps, and their implications, have seldom been fully described. The aim of this article is to critically evaluate the evidence on effective care for prediabetes in contemporary U.S. clinical and public health practice.

A FRAMEWORK FOR WHY DIABETES PREVENTION HAS BEEN FAILING

The growth in diabetes prevalence represents a failure of diabetes prevention. This could be related to four major issues (see graphical abstract available in the online version of the article).

First, at the macro-level (e.g., systems level), fee-for-service structures and market principles do not support coverage for evidence-based preventive services for diabetes that require proactive behavior changes, require continuity of engagement, and have a long breakeven time horizon. This leads to a low supply of diabetes prevention services nationally.

Second, at the micro-level (e.g., at the individual level and operationally), diabetes prevention requires identifying people at risk, connecting them with the supply of effective interventions, and that individuals adopt and maintain behaviors that have been proven to lead to better health. The effective connection of high-risk individuals with recognized lifestyle modification programs largely depends on identification of risk, the knowledge of the existence of such programs, referral by clinicians, and uptake by individuals (17). Moreover, the behavioral processes of engaging in disease screening and prevention ask a lot of individuals: understanding their risk and motivation and agency to act sustainably. Making behavior changes itself is challenging given our preference for the status quo. These micro-level factors help explain why demand for and engagement in diabetes prevention are low (18).

Third, the implementation of these programs may not be as intensive as or in line with fidelity to the original DPP trial protocol. Fourth, we may have to accept that our one-size-fits-all approach is failing. We discuss each of these separately below.

MACRO-LEVEL BARRIERS

Structure of the U.S. National Diabetes Prevention Program and Payment Scheme

The Centers for Disease Control and Prevention (CDC) established the U.S. National Diabetes Prevention Program (NDPP) (19), which has four core elements: training, a recognition program, lifestyle change program delivery, and a payment model.

The training aims at expanding the workforce to meet the high prevalence of prediabetes, which includes health professionals and lay community workers who can deliver the lifestyle change program (19). CDC-accredited entities provide training services for lifestyle coaches who deliver the lifestyle change program (20).

The CDC Diabetes Prevention Recognition Program (DPRP) maintains a registry of organizations recognized for their ability to deliver a 12-month effective lifestyle change program; it also provides technical assistance to organizations to help them deliver effective lifestyle modification and achieve and maintain recognition at no cost. The DPRP standards (required components for the program) are used to ensure the quality of the lifestyle change program, which helps with the decisions of individuals to participate, helps health care professionals to refer patients, and helps insurers to pay for the program.

The 12-month lifestyle change program is offered at many locations, including community-based organizations, worksites, and health care facilities. It can be delivered in person, online, or through a combination approach. It includes a minimum of 22 sessions—at least 16 weekly sessions during the first 6 months and at least monthly sessions during the second 6 months (21).

Payment is a critical component of ongoing delivery of the lifestyle change program. Over the years, a number of health insurers (commercial and noncommercial payers) have partnered with the CDC to cover the costs of the NDPP lifestyle program (22,23). There is currently no insurer that reimburses a diabetes prevention lifestyle program for children. The Centers for Medicare & Medicaid Services (CMS) is the largest payer, offering coverage for prediabetes since 2018 for all seniors. Both commercial payers and Medicare follow a pay-for-performance model, and reimbursement is conditional on a number of parameters: *1*) attending a CDC-recognized lifestyle program, *2*) achievement by an individual of ≥5% weight loss to receive covered services in months 7–12 of the lifestyle intervention, and *3*) completion of the program (24). The proposed reimbursement amounts are low. The current payment model offers up to $768 for each participant who completes the yearlong program and loses 5% of their body weight at 6 months and further maintains this loss at 12 months (23). However, organizations will only be reimbursed up to $550 for each of the many participants who will attend all the required sessions of the lifestyle program and do not lose weight—a difference of $218 per person. Thus far, the published economic analyses have indicated underpayment by Medicare for NDPP (25,26), suggesting that the Medicare payment structure for

NDPP does not support a sustainable business model. A challenge with pay-for-performance models is that program delivery organizations must finance the program regardless of participant performance. If costs cannot be reimbursed, organizations will be unable to support program delivery long-term. The likely consequences of low reimbursement rates are coverage gaps and insufficient capacity to serve Medicare recipients. Thus far, rigorous economic analyses of the NDPP are yet to be conducted, and to date there is no report published of actual costs by amount of weight loss.

Undersupply of the U.S. NDPP: Low Number of Suppliers Compared With the Number of People Needing Services

The supplier data from CDC and CMS registries suggest that availability and access to NDPP programs are not aligned with population estimates of diabetes risk or prediabetes prevalence (27). As of February 2022, 2,098 NDPP suppliers existed and only 3% of adults with prediabetes have participated in the program (27). Furthermore, only ∼40% of diabetes prevention program providers had full CDC recognition status, which is achieved when program milestones are met such as mean participant weight loss of 5% (27). This translates to roughly 1 supplier per 10,000 cases of diagnosed prediabetes (27). Only 50% of NDPP suppliers listed on the CDC registry appear to offer services to the general public (i.e., not an employer-based or membership-based program), and ∼25% offer distance learning (27). The free market approach, therefore, is not meeting the needs of the population.

The Medicare Diabetes Prevention Program (MDPP), launched in April 2018, is a structured group class promoting lifestyle change for weight loss, that closely follows the evidence-based NDPP. As of 2022, there were 244 unique supplier organizations that offered MDPP across 940 Medicare sites in 46 states and Washington, DC, and no sites in Nevada, Rhode Island, South Dakota, or Vermont (27,28). Only 14 states currently include the program as a Medicaid benefit (27).With ∼61 million Medicare beneficiaries, this equates to 1.5 sites per 100,000 Medicare beneficiaries (28). Two states (i.e., Connecticut and New Mexico) and Washington, DC, had only 1 site for 640,932 beneficiaries, which is equivalent to 213,644 Medicare beneficiaries per site (28). Although only 10.3% of MDPP suppliers are community-based organizations, they represent more than half (55.7%) of sites where beneficiaries can access the program (29). The Medicare beneficiaries are only eligible to receive MDPP service once per lifetime.

The Unclear Cost-effectiveness of the U.S. NDPP

The cost-effectiveness of diabetes prevention in trial settings has been demonstrated. However, the translation of those impactful findings to implementation at scale has been less than successful. This is because there has been little interest from insurers in covering diabetes preventive interventions. Firstly, prevention accrues benefits for the insurer over several years. Secondly, due to annual changes in health plans that beneficiaries enroll in due to employment changes or choice, insurers do not want to invest in preventive interventions that will benefit the future insurers of these beneficiaries. Thirdly, reimbursements for diabetes prevention are low and conditioned on adherence and achieving a threshold of weight loss. This pay-for-performance model discourages providers of preventive services, as the outcome based on which they are assessed and paid (i.e., the behaviors of eligible users) is out of their hands. Lastly, market-oriented payments for prevention mean that those delivering the service might be able to keep a larger amount of the payment they receive from payers by lowering expenditures and engaging in cost containment, which could lead to underresourced and ineffective services.

In prior studies with examination of the cost-effectiveness of lifestyle modification programs, the following were not accounted for: the select, motivated groups of adults who engage in trials; the intensity of the intervention evaluated; and the durability of the effects. Lifestyle modification programs are especially challenging for real-world adults with prediabetes who also face food insecurity and geographical and financial access barriers.

In a recent study investigators examined the real-world cost-effectiveness of the NDPP for individuals with prediabetes in a large workforce with employer-sponsored health insurance over 2 years (30). Although the results of this study suggested that NDPP could be cost saving, it was not cost-effective in terms of the incidence of diabetes. Moreover, this study did not include data on incident cardiovascular disease or chronic kidney disease (30).

MICRO-LEVEL BARRIERS

Poor Reach and Referrals to the U.S. NDPP

An analysis of the participant-level results from the first 4 years of implementation of the CDC NDPP indicated poor reach of the program and a number of disparities in reach (31). Among adults, despite a high number eligible for screening, there are low rates of real-world screening for prediabetes in the U.S. Based on 2010–2020 U.S. national survey data and based on the risk estimated with the American Diabetes Association algorithm to determine risk (32), 30% of the population is potentially undiagnosed with prediabetes (27). Furthermore, in a nationally representative U.S. survey, 73.5% of those with diagnosed prediabetes and 50.6% of those with risk factors reported receiving any advice or referrals to reduce risk; of those advised, 35.0%–75.8% of those with diagnosed prediabetes and 33.5%–75.2% with risk factors reported engaging in various risk-reducing activities or programs in the past year (18). Low screening rates for prediabetes contribute to limited awareness of prediabetes among high-risk individuals (27,33).

Currently, after nearly 15 years of NDPP implementation, of the 97 million Americans eligible for diabetes prevention, fewer than 1 million adult individuals with prediabetes have been enrolled in the NDPP and have 12-month data. This indicates a low uptake of the NDPP (34). Those who enrolled in NDPP were predominantly women (80% women vs. 20% men), older adults (2.4% age 18–29 years, 14.5% age 30–44 years, 23.0% age 45–54 years, 29.2% age 55–64 years, and 30.9% age ≥65 years) and White individuals (54.6% non-Hispanic White, 14.6% non-Hispanic Black, 8.6% Hispanic, and 22.2% other race and ethnicity). The study showed that one-third of participants were successful in reaching the 5% weight loss goal and many more

were close to reaching it, resulting in a mean weight loss of 4.2%. Less than half of the participants reporting achieved the physical activity goal of 150 min per week (31). Two subsequent analyses (35,36), examining enrollment until 2019, confirmed the persistence of low enrollment. Overall, more efforts are needed to improve the engagement of men and of racial and ethnic minorities.

Low enrollment rate in the NDPP can partly be attributed to a low referral rate. Indeed, among 14.6 million adults in the 2016–2017 National Health Interview Survey with elevated BMI (overweight or obesity) and diagnosed prediabetes, only 4.9% reported receipt of a referral to a diabetes prevention program (18). In a national Web-based survey among family practitioners, nurse practitioners, pharmacists, and internists in 2018, only 15.2% reported making a referral to the NDPP (17). They were more likely to make referrals if they were familiar with the program, reported knowledge of its availability, believed it was important to make referrals to the program, and used electronic health records to manage patients with prediabetes (17). In a 2017 survey of primary care clinicians, 38% were aware of a CDC-recognized lifestyle change program and 27% screened patients for prediabetes using a risk test, while 97% ordered recommended blood tests (33). Referrals were more likely in areas with more lifestyle change programs.

Establishing clinical-community linkages with lifestyle change programs can increase the likelihood of referral by primary care providers (37). Referrals can be facilitated by the use of electronic medical records (EMR), especially if both the referring provider and the diabetes prevention program supplier use the same EMR platform. Factors such as low reimbursement for services and limited enrollment also lead to fluctuation in the supply and local availability of diabetes prevention programs.

The variability of criteria that qualify individuals across organizations that offer diabetes prevention programs may also impact rates of referral. Individuals cannot qualify for the CMS-coordinated MDPP solely on the basis of a diabetes risk survey (38), whereas CDC-coordinated NDPPs accept a high risk score (e.g., CDC Prediabetes Risk Test) as one of the eligibility criteria (39). The laboratory criteria to identify patients with prediabetes for these two programs also differ (40). The MDPP defines prediabetes according to fasting plasma glucose (FPG) 110–125 mg/dL, hemoglobin A_{1c} (HbA_{1c}) 5.7%–6.4%, or a 2-h post–glucose challenge test (GCT) result of 140–199 mg/dL, while the NDPP defines prediabetes according to FPG 100–125 mg/dL, HbA_{1c} 5.7%–6.4%, or a 2-h post-GCT result of 140–199 mg/dL.

FIDELITY AND IMPLEMENTATION BARRIERS

Of those effectively enrolled in an NDPP, a significant proportion do not complete the program. An analysis of 41,203 individuals enrolled in CDC-recognized in-person NDPP lifestyle change programs over January 2012–February 2017 showed low retention rates (34). The attrition rates weekly were typically $<$1.0%–2.0% but were 3.5%–5.0% at week 2. The percentage of participants retained through 18 weeks, when session frequency typically transitions from weekly to monthly, varied by age (45.9% for 18–29 year olds, 53.4% for 30–44 year olds, 60.2% for 45–54 year olds, 66.7% for 55–64 year olds, and 67.6% for $\geq$65 year olds) and race and ethnicity (70.5% for non-Hispanic White individuals, 60.5% for non-Hispanic Black individuals, 52.6% for Hispanic individuals, and 50.6% for other) (34). Approximately 63.1% of participants were retained in the program through the 18th week and 31.9% through the 44th week (34).

The DPRP recognizes delivery of NDPP through distance learning and online platforms also, but fidelity to the original intervention may vary with use of these platforms, particularly the online platform, which delivers the program asynchronously. Retention also varies across delivery platform; in another analysis of NDPP covering the January 2012–December 2018 period, the average number of weeks in the program was highest for in-person participation (28.1 weeks), followed by distance learning (20.1 weeks), online (18.7 weeks), and combination (18.6 weeks) (36). Both retention and fidelity/intensity are associated with poor effectiveness of the NDPP in terms of impacting diabetes incidence.

LACK OF EFFECTIVENESS—DO WE HAVE THE RIGHT INTERVENTION?

Outside of randomized clinical trials (41) and translation and implementation trials (16), there have been few data from diabetes prevention programs delivered on a subnational or national scale. In the U.S., evaluations of the NDPP conducted by CDC and CMS included session attendance and weight change as key outcome measures to assess program effectiveness but fail to examine changes in blood glucose measures or incident diabetes among program participants to ensure that programmatic success correlates with diabetes risk reduction in real-world settings (31,42). Thus far there are no effectiveness data from NDPP showing that its implementation leads to declines in diabetes incidence at the population level. Furthermore, diabetes prevalence and absolute numbers of cases of diabetes continue to grow in the U.S.

Data on the effectiveness of lifestyle change programs for diabetes risk reduction from other countries can provide insights into their effectiveness, but these are also scarce and have been limited to weight change among those who completed follow-up—with no national or subnational estimates of diabetes incidence. An example of national data on the effectiveness of programs on incidence was the recent quasi-experimental evaluation of the U.K. National Health Service (NHS) Diabetes Prevention Programme, which has been ongoing since 2016. Among 298,822 individuals who were eligible and referred for the program, there was a 3-kg reduction in weight (2.99 kg [95% CI $-$4.38 to $-$1.61]) and 0.85 mmol/mol improvement in HbA_{1c} (95% CI $-$1.46 to $-$ 0.24), but there are no data on attendance of lifestyle classes and the mechanisms through which the effects were observed. Additional data from the NHS Diabetes Prevention Programme show that the probability of not converting to diabetes at 36 months since referral was 87.3% (95% CI 86.5–88.2) for individuals referred to the Diabetes Prevention Programme and 84.6% (95% CI 83.9–85.4) for those not referred (43).

On a larger level, the scientific community may have oversimplified recommendations that all high-risk individuals would benefit from structured lifestyle modification diabetes prevention programs. Type 2

diabetes is, in fact, not one disease. The pathophysiological defects and precursor phase of prediabetes can vary widely in individuals with different genotypes and phenotypes (44). As such, a one-size-fits-all approach may be inappropriate for all high-risk individuals.

For example, the evidence regarding diabetes prevention via lifestyle modification was positive in people with isolated impaired glucose tolerance (IGT) (isolated IGT: FPG <110 mg/dL and 2-h postload glucose [2-h PG] 140–199 mg/dL and no glucose-lowering medications) or impaired fasting glucose [IFG]+IGT (FPG 110–125 mg/dL and 2-h PG 140–199 mg/dL and no glucose-lowering medications) (45,46). But recent data show that leaner individuals with suboptimal insulin secretion and isolated IFG (isolated IFG: FPG 110–125 mg/dL and 2-h PG <140 mg/dL) do not benefit from lifestyle modification or metformin (46). Studies focused on interventions that lower diabetes incidence among individuals with the IFG phenotype are needed to unlock opportunities for precision prevention of diabetes.

An additional challenge is that primary care clinicians rarely screen for prediabetes and diabetes using oral glucose tolerance tests (OGTTs), which are needed to identify individuals with IFG or IGT. This is because of the increased demands placed on patients and staff to conduct OGTTs in comparison with HbA_{1c} or fasting blood glucose testing. In fact, the U.S. National Clinical Care Commission recently advocated for better coverage of HbA_{1c} for prediabetes and diabetes screening to simplify and improve diabetes prevention and management efforts (47). Adoption of precision prevention approaches should include consideration of opportunities to characterize prediabetes phenotypes using novel data sources that may be more accessible in real-world settings such as EMR data (for other relevant biomarkers related to cardiometabolic risk) or continuous glucose monitoring results.

ALTERNATIVES TO THE CURRENT U.S. MODEL OF DIABETES PREVENTION

Lifestyle modification counseling and adherence to healthful diets, moderate-to-vigorous physical activity regimens totaling >175 min per week, adequate sleep, moderation in alcohol intake, and avoidance of tobacco are all important for metabolic health. These should be a minimum goal for population health and clinical practice universally, to optimize longevity and well-being, especially since diet and physical activity account for 15%–26% of death and disability in the U.S. (48). However, what we have argued here is that this approach may not lead to diabetes prevention and certainly not in everyone with prediabetes. Indeed, as shown in the U.S. Diabetes Prevention Program Outcomes Study, despite intense lifestyle interventions, a sizeable number of individuals with prediabetes still went on to develop diabetes (at least 50% in the interventions groups after 15 years) (49), especially those at increased genetic risk of β-cell failure (50). This suggests that in some individuals, lifestyle modification alone may not be enough to alter the course of the natural history of the disease.

There are a number of ongoing and recent studies suggesting that diabetes prevention may be possible through means other than current guideline-recommended structured lifestyle modification interventions. For example, in the Diabetes Remission Clinical Trial (DiRECT) in the U.K. low-calorie diets with maintenance counseling have been tested for at least 12 weeks, showing sustained benefits among those who lost ≥10 kg in terms of diabetes remission for 45% at 2 years, and 26% of those with remission at year 2 remained in remission at 5 years (51). Similarly, medications such as the thiazolidinediones, glucagon-like peptide 1 (GLP-1) receptor agonists, and dual GLP-1 and glucose-dependent insulinotropic polypeptide (GIP) receptor agonists have all shown promise for diabetes prevention (12,52–54). However, as one would expect, none of these interventions change the underlying pathophysiology sufficiently to stop the progression of prediabetes to diabetes, and when the medications are removed blood glucose levels become elevated (12). For most medications tested for diabetes prevention, after their cessation glycemia typically returns to the original prediabetes range, whereas lifestyle modification has a more sustainable effect (12). However, it is important to point out that GLP-1 receptor agonists may present with a comparative advantage over other drugs for diabetes prevention, given the considerable weight loss associated with these pharmacological therapies (52,53). Thus far, no U.S. payer covers any of the available medications for the prediabetes indication, as these are not approved by the U.S. Food and Drug Administration for such an indication. Metabolic surgery is also a consideration for addressing prediabetes, as it has also been shown to prevent the incidence of type 2 diabetes among individuals with obesity (presumably including some individuals with prediabetes) in nonrandomized studies (55,56).

There may also be a role for precision prevention of diabetes, whereby individuals with specific phenotypes or genotypes of prediabetes would be given interventions that specifically target their unique underlying pathophysiology. However, there are likely three impediments: *1*) definitive trials testing these avenues are needed; *2*) costs and access to medications remain daunting, especially for underinsured populations and other populations with low socioeconomic status; and *3*) current screening approaches using HbA_{1c} alone impede characterization of individuals' pathophysiological deficits (e.g., hepatic insulin resistance vs. β-cell dysfunction) as defined by OGTT and costly tests (e.g., fasting insulin). As such, more targeted research is needed that addresses type 2 diabetes as a collection of diseases where one size does not fit all. There may be possibilities for tailoring interventions for preventing diabetes to the patient phenotype. For example, as previously mentioned, the IFG phenotype appears to be less responsive to lifestyle intervention than IGT, in terms of preventing progression to prediabetes (46). As such, testing alternative methods to prevent diabetes in isolated IFG, a group who account for at least one-third of those with prediabetes, is a high priority. Moreover, in the DPP trial, the relative risk reduction for diabetes incidence among those receiving metformin therapy was significantly greater (53% [95% CI 27–80]) in individuals with initial BMI >35 kg/m^2 versus in those with lower BMI (57) (3% in those with BMI 22–30 kg/m^2 [95% CI −36, 30]). Deriving any benefit from the use of drugs requires effective implementation of recommendations and sustained use (41). Thus far, of those with prediabetes eligible for

drug therapy using metformin as recommended by the American Diabetes Association, only ~8% are currently prescribed the medication (12,58).

Data-driven phenotypes defined according to insulin deficiency, insulin resistance, obesity, and/or age provide additional opportunities to tailor prevention approaches. However, the evidence on and availability of biomarkers to classify and risk stratify are somewhat limited. A task force to investigate and advance guideline development is needed. Furthermore, studies where medications are sequentially offered along with ways to maintain the effects of those medications when they are discontinued—especially for the GLP1-receptor agonists, which are associated with weight regain and hyperglycemia on discontinuation (59)—are critically needed.

As the accessibility to medications such as GLP-1 receptor agonists becomes more commonplace, especially for people with obesity, this may ultimately have an influence on the incidence of diabetes. However, the effect of their use in real-world settings on the incidence of diabetes would need to be evaluated using appropriate study designs and compared vis-à-vis economic feasibility with current options such as lifestyle modification programs and metabolic surgeries. To date, there are no studies comparing lifestyle modification programs, GLP-1 receptor agonists, and metabolic surgeries or the durability or economics of these different interventions. Cost-effectiveness studies with comparison of these alternatives will be helpful to guide the choices of therapies by health care professionals and patients, as well as decisions on coverage by insurers.

Interventions that are operational through modifying the microbiome and possibly epigenetic factors are considerations for additional approaches to address prediabetes (60). It is important to point out that the current infrastructure developed to scale diabetes prevention efforts through lifestyle modification alone is not well suited to the study of precision prevention for diabetes. However, our improving understanding of prediabetes phenotypes, coupled with the increasing use of novel tools such as continuous glucose monitors and the availability of large-scale patient-level data from EMRs, provides unique opportunities to investigate precision prevention. With more precise interventions to prevent diabetes, a reexamination of the supply needed, training and resources, and payment models will also be needed to advance diabetes prevention in the coming decades.

An approach of considering prediabetes (and ultimately diabetes) as a public health manifestation of a societal problem may also be warranted. Low levels of physical activity and unhealthy diets, which drive the occurrence of diabetes, may be viewed not only as consequences of individual choices but as also as the product of broader societal issues such as the food system and the built environment. Preventive interventions that influence these societal issues have the potential to significantly influence behavioral risk factors and thus the frequency of prediabetes and diabetes. Indeed, small changes in a large number of individuals in the whole population can translate into a sizeable population-level impact. It appears logical for a sound prevention strategy in the U.S. to include societal-level interventions in addition to the current NDPP that focuses on individuals.

CONCLUSIONS

Prediabetes is currently suboptimally addressed in the U.S. The current national diabetes prevention strategy, aimed at delivering lifestyle modification to individuals, has not translated into quantifiable benefits. Our analysis reveals that policy, implementation, and intervention barriers and deficits impede progress wherein nearly 95 million people are not accessing, completing, or benefiting from current efforts to lower diabetes incidence nationally. This points to the need for a multipronged approach involving a combination of synergistic societal and more precise individual-level interventions to prevent type 2 diabetes.

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