

JOINT STATE GOVERNMENT COMMISSION

General Assembly of the Commonwealth of Pennsylvania

DIABETES IN PENNSYLVANIA:

PREVENTION AND MAINTENANCE PROGRAMS

Fifth Biennial Report

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*Serving the General Assembly of the
Commonwealth of Pennsylvania Since 1937*

REPORT

(HR 936 of 2014)

*Diabetes In Pennsylvania:
Prevention and Maintenance Programs*

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The Joint State Government Commission was created in 1937 as the primary and central non-partisan, bicameral research and policy development agency for the General Assembly of Pennsylvania.¹

A fourteen-member Executive Committee comprised of the leadership of both the House of Representatives and the Senate oversees the Commission. The seven Executive Committee members from the House of Representatives are the Speaker, the Majority and Minority Leaders, the Majority and Minority Whips, and the Majority and Minority Caucus Chairs. The seven Executive Committee members from the Senate are the President Pro Tempore, the Majority and Minority Leaders, the Majority and Minority Whips, and the Majority and Minority Caucus Chairs. By statute, the Executive Committee selects a chairman of the Commission from among the members of the General Assembly. Historically, the Executive Committee has also selected a Vice-Chair or Treasurer, or both, for the Commission.

The studies conducted by the Commission are authorized by statute or by a simple or joint resolution. In general, the Commission has the power to conduct investigations, study issues, and gather information as directed by the General Assembly. The Commission provides in-depth research on a variety of topics, crafts recommendations to improve public policy and statutory law, and works closely with legislators and their staff.

A Commission study may involve the appointment of a legislative task force, composed of a specified number of legislators from the House of Representatives or the Senate, or both, as set forth in the enabling statute or resolution. In addition to following the progress of a particular study, the principal role of a task force is to determine whether to authorize the publication of any report resulting from the study and the introduction of any proposed legislation contained in the report. However, task force authorization does not necessarily reflect endorsement of all the findings and recommendations contained in a report.

Some studies involve an appointed advisory committee of professionals or interested parties from across the Commonwealth with expertise in a particular topic; others are managed exclusively by Commission staff with the informal involvement of representatives of those entities that can provide insight and information regarding the particular topic. When a study involves an advisory committee, the Commission seeks consensus among the members.² Although an advisory committee member may represent a particular department, agency, association, or group, such representation does not necessarily reflect the endorsement of the department, agency, association, or group of all the findings and recommendations contained in a study report.

¹ Act of July 1, 1937 (P.L.2460, No.459); 46 P.S. §§ 65–69.

² Consensus does not necessarily reflect unanimity among the advisory committee members on each individual policy or legislative recommendation. At a minimum, it reflects the views of a substantial majority of the advisory committee, gained after lengthy review and discussion.

Over the years, nearly one thousand individuals from across the Commonwealth have served as members of the Commission's numerous advisory committees or have assisted the Commission with its studies. Members of advisory committees bring a wide range of knowledge and experience to deliberations involving a particular study. Individuals from countless backgrounds have contributed to the work of the Commission, such as attorneys, judges, professors and other educators, state and local officials, physicians and other health care professionals, business and community leaders, service providers, administrators and other professionals, law enforcement personnel, and concerned citizens. In addition, members of advisory committees donate their time to serve the public good; they are not compensated for their service as members. Consequently, the Commonwealth receives the financial benefit of such volunteerism, along with their shared expertise in developing statutory language and public policy recommendations to improve the law in Pennsylvania.

The Commission periodically reports its findings and recommendations, along with any proposed legislation, to the General Assembly. Certain studies have specific timelines for the publication of a report, as in the case of a discrete or timely topic; other studies, given their complex or considerable nature, are ongoing and involve the publication of periodic reports. Completion of a study, or a particular aspect of an ongoing study, generally results in the publication of a report setting forth background material, policy recommendations, and proposed legislation. However, the release of a report by the Commission does not necessarily reflect the endorsement by the members of the Executive Committee, or the Chair or Vice-Chair of the Commission, of all the findings, recommendations, or conclusions contained in the report. A report containing proposed legislation may also contain official comments, which may be used to construe or apply its provisions.³

Since its inception, the Commission has published over 400 reports on a sweeping range of topics, including administrative law and procedure; agriculture; athletics and sports; banks and banking; commerce and trade; the commercial code; crimes and offenses; decedents, estates, and fiduciaries; detectives and private police; domestic relations; education; elections; eminent domain; environmental resources; escheats; fish; forests, waters, and state parks; game; health and safety; historical sites and museums; insolvency and assignments; insurance; the judiciary and judicial procedure; labor; law and justice; the legislature; liquor; mechanics' liens; mental health; military affairs; mines and mining; municipalities; prisons and parole; procurement; state-licensed professions and occupations; public utilities; public welfare; real and personal property; state government; taxation and fiscal affairs; transportation; vehicles; and workers' compensation.

Following the completion of a report, subsequent action on the part of the Commission may be required, and, as necessary, the Commission will draft legislation and statutory amendments, update research, track legislation through the legislative process, attend hearings, and answer questions from legislators, legislative staff, interest groups, and constituents.

³ 1 Pa.C.S. § 1939.



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September 2021

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To the Members of the General Assembly of Pennsylvania:

This is the fifth in a series of reports by the Joint State Government Commission in response to the mandate of 2014 House Resolution 936 (Pr. 's No. 4098), which provides for an ongoing study of the public health problem posed by diabetes in Pennsylvania. The Commission's task is to describe, evaluate, and make recommendations to improve the Commonwealth's response. This edition discusses at length the complex, multifactorial interaction between COVID-19 and diabetes, severe COVID-19 outcomes in patients with diabetes, and changes in diabetes care during the pandemic.

As discussed in the pages that follow, diabetes education remains a vital part of the strategy to help people prevent and manage the disease through lifestyle changes. Self-management and, when necessary, preventive measures, monitoring, and therapeutic interventions are key components in the fight against this disease. We hope these reports will assist the Commonwealth in mounting a vigorous and effective response to this serious and growing public health problem.

Sincerely,

Glenn J. Pasewicz
Executive Director

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INTRODUCTION

This is the fifth in a series of reports by the Joint State Government Commission (JSGC) in response to the mandate of 2014 House Resolution 936, which provides for an ongoing study of the public health problem posed by diabetes in Pennsylvania. The resolution directs the JSGC, in collaboration with several other state departments and agencies, to “assess the financial impact and reach diabetes has on the residents of this Commonwealth and the State departments and agencies collaborating on the report”; to conduct “an assessment of the benefits of implemented programs and activities aimed at controlling diabetes and preventing the disease”; and to provide recommendations “for the control and prevention of diabetes for consideration by the General Assembly,” with the goal of reducing the impact of diabetes, pre-diabetes, and diabetes complications.⁴

In 2019 and 2020, Pennsylvania legislators confirmed their continued commitment to fight diabetes by adopting several resolutions. House Resolution 615, session of 2019, recognized November 14, 2019, as “World Diabetes Day” in Pennsylvania.⁵ “World Diabetes Day” was first introduced by the International Diabetes Federation (IDF) and the World Health Organization (WHO) in 1991 to raise awareness of the escalating incidence of diabetes worldwide, and it became an official United Nations international observance in 2007. Every year, “World Diabetes Day” is focused on a particular aspect of living with diabetes, its treatment and prevention. The theme of “World Diabetes Day” in 2019 was “Family and Diabetes.” The purpose was to enhance awareness of the impact that diabetes has on the patient’s family and to promote the role of family in management, care, prevention, and education of diabetes. House Resolution 615 urges residents, government agencies, public and private institutions, businesses, and schools “to recommit our communities to increasing awareness and understanding of diabetes and the need for appropriate and accessible services for all people with diabetes and the need for appropriate and accessible services for all people with diabetes.”⁶

House Resolution 557, session of 2019, designated the week of November 10 through 16, 2019, as “Diabetes and Cardiovascular Disease Awareness Week” in Pennsylvania.⁷ The month of November is “American Diabetes Month.” The resolution seeks to increase awareness of the connection between diabetes and cardiovascular disease. Though cardiovascular disease accounts for over two-thirds of deaths in individuals with type 2 diabetes and accounts for an estimated 28 percent of \$12.9 billion of diabetes treatment costs in the Commonwealth, studies have shown that over a half of adults living with type 2 diabetes are unaware that they are at an increased risk of cardiovascular disease. As “appropriate awareness and education about the cardiovascular risks associated with diabetes can effectively improve outcomes and reduce the overall financial burden

⁴ HR936, P.N. 4098 (2014).

⁵ HR615, P.N. 2902 (2019).

⁶ Ibid.

⁷ HR557, P.N. 2653 (2019).

of the illness,” House Resolution 557 encourages all residents and stakeholders “to promote education and awareness of the connection between diabetes and cardiovascular disease.”⁸

In November 2020, the national focus of “Diabetes Awareness Month” was on youth who have diabetes. Diabetes is one of the most common chronic conditions in school-age youth in the United States, so this attention is quite warranted. In addition, diabetes prevention in children may curtail incidence of diabetes in adults and, this, have long-term positive impact.

February is “American Heart Month.” House Resolution 656, session of 2020, highlighted the cardiovascular risks associated with diabetes and designated the week of February 9 through 15, 2020, as “Cardiovascular Disease and Diabetes Awareness Week” in Pennsylvania, with the goal “to promote education and awareness of the connection between cardiovascular disease and diabetes.”⁹

Prevalence of Diabetes and Its Economic Burden in Pennsylvania and Nationwide

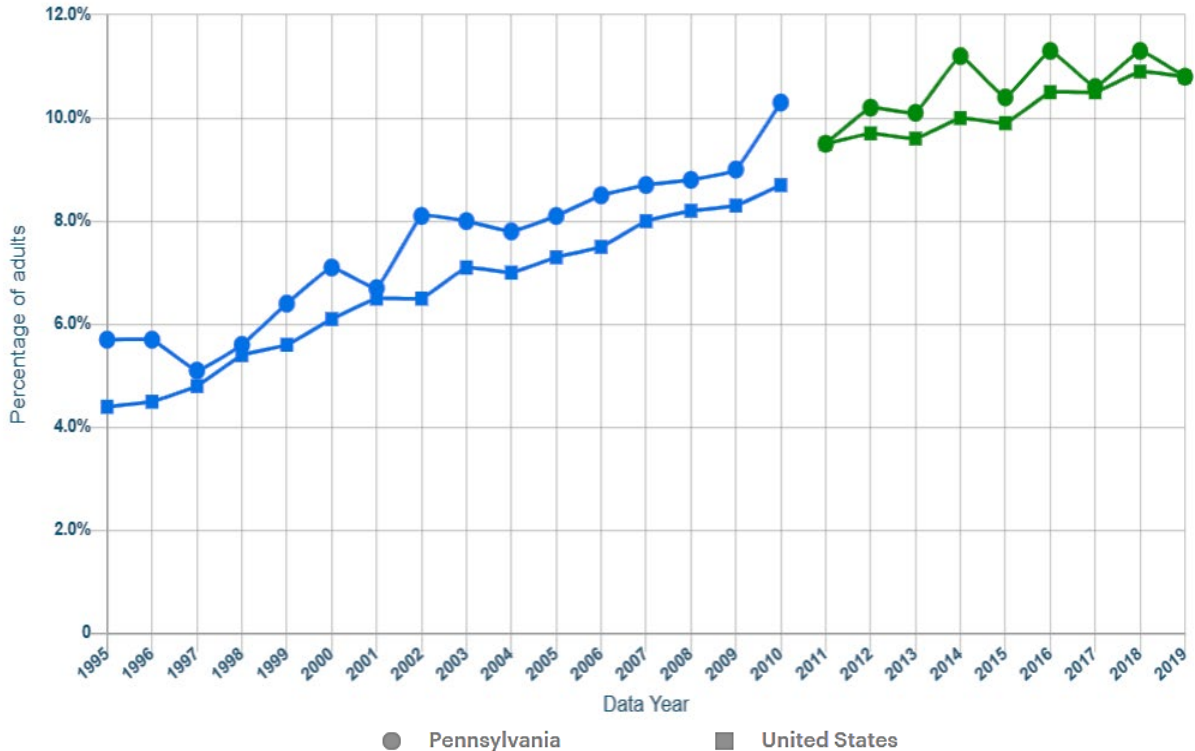
The Centers of Disease Control and Prevention (CDC) Behavioral Risk Factor Surveillance system consistently tracks the prevalence of diabetes and other chronic conditions nationwide. This system’s data demonstrate a growing trend for diabetes both in Pennsylvania and in the United States as a whole, with slight drops in Pennsylvania in 2015, 2017, and 2019.¹⁰

⁸ Ibid.

⁹ HR656, P.N. 3091 (2020).

¹⁰ United Health Foundation. *America’s Health Rankings Analysis of CDC Behavioral Risk Factor Surveillance System: Annual Report, 2020*, <https://www.americashealthrankings.org/explore/annual/measure/Diabetes/state/PA>, accessed August 17, 2021.

Trend: Diabetes, Pennsylvania, United States



Percentage of adults who reported being told by a health professional that they have diabetes (excluding prediabetes and gestational diabetes).

Source: CDC, Behavioral Risk Factor Surveillance System

According to the 2020 annual report, based on the 2019 data (the latest available), the prevalence of diabetes in Pennsylvania was 11.0 percent among women (compared to 10.7 percent in the U.S.) and 10.5 percent among men (compared to 11.4 percent in the U.S.). The rate of diabetes among young adults (ages 18-44) equaled that on the national level: 2.9 percent. Percentage of diabetes among adults ages 45-64 and ages 65+ in the Commonwealth was slightly lower than the national level: 13.1 percent in Pennsylvania versus 14.6 percent in the US and 21.7 percent in Pennsylvania versus 23.0 percent in the U.S., respectively. When the numbers are subdivided by race/ethnicity, Pennsylvania numbers are very close to those of the U.S. in general among white adults (10.6 percent versus 10.3 percent respectively); they are slightly higher among black adults (16.2 percent versus 14.8 percent), but notably lower among Hispanics – less than a half of the nationwide number – 5.6 percent versus 11.7 percent. Subdivided by income, Pennsylvania numbers are very close to the national values.¹¹

¹¹ Ibid.

CDC periodically publishes the *National Diabetes Statistics Report*, which provides information on the prevalence and incidence of diabetes and prediabetes as well as risk factors for complications, acute and long-term complications, death, and costs. These data are intended to focus efforts on prevention and control diabetes across the United States. The 2020 edition of the National Diabetes Statistics Report contains the following crude estimates for 2018 among the U.S. population overall:

- 34.2 million people of all ages – or 10.5% of the U.S. population – had diabetes.
- 34.1 million adults aged 18 years or older – or 13.0% of all U.S. adults – had diabetes.
- 7.3 million adults aged 18 years or older who met laboratory criteria for diabetes were not aware of or did not report having diabetes (undiagnosed diabetes). This number represents 2.8% of all U.S. adults and 21.4% of all U.S. adults with diabetes.
- The percentage of adults with diabetes increased with age, reaching 26.8% among those aged 65 years or older.¹²

Adding up the number of adults aged 18 years or older with diagnosed and undiagnosed diabetes (26.8 million and 7.3 million, respectively) brings the total to 34.1 million (31.6-36.6 million with 95% confidence interval).¹³

A detailed look at the numbers reveals that among the U.S. population overall, crude estimates for 2018 were:

- 26.9 million people of all ages – or 8.2% of the U.S. population – had diagnosed diabetes.
- 210,000 children and adolescents younger than age 20 years – or 25 per 10,000 U.S. youths – had diagnosed diabetes. This includes 187,000 with type 1 diabetes.¹⁴

Among U.S. adults aged 18 years or older, age-adjusted data for 2017-2018 indicated marked differences among demographic groups:

- Prevalence of diagnosed diabetes was highest among American Indians/Alaska natives (14.7%), people of Hispanic origin (12.5%), and non-Hispanic blacks (11.7%), followed by non-Hispanic Asians (9.2%), and non-Hispanic whites (7.5%).
- Among adults of Hispanic origin, Mexicans (14.4%) and Puerto Ricans (12.4%) had the highest prevalences, followed by Central/South Americans (8.3%) and Cubans (6.5%).

¹² Centers for Disease Control and Prevention. *National Diabetes Statistics Report 2020: Estimates of Diabetes and Its Burden in the United States*. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2020, <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

¹³ Ibid.

¹⁴ Ibid.

- Among non-Hispanic Asians, Asian Indians (12.6%) and Filipinos (10.4%) had the highest prevalences, followed by Chinese (5.6%). Other Asian groups had a prevalence of 9.9%.
- Among adults, prevalence varies significantly by education level, which is an indicator of socioeconomic status. Specifically, 13.3% of adults with less than a high school education had diagnosed diabetes versus 9.7% of those with a high school education and 7.5% of those with more than a high school education.¹⁵

New in 2020, the *National Diabetes Statistics Report* features trends in prevalence and incidence estimates over time. Tracing trends in prevalence of diabetes demonstrates consistent growth: “during 1999-2016, the age-adjusted prevalence of total diabetes significantly increased among adults aged 18 years or older.” Notably, during this period, the age-adjusted prevalence significantly increased for diagnosed diabetes while “no significant change in undiagnosed diabetes was detected.”¹⁶

Incidence of diagnosed diabetes (newly diagnosed diabetes) among the U.S. adults aged 18 years or older was estimated for 2018 at 1.5 million cases.¹⁷ Incidence rates were significantly higher among adults aged 45 to 64 years old and those aged 65 years and older.

Among adults aged 18 years or older, the age-adjusted incidence of diagnosed diabetes was similar in 2000 (6.2 per 1,000 adults) and 2018 (6.7 per 1,000 adults). A significant decreasing trend in incidence was detected from 2008 (8.4 per 1,000 adults) through 2018 (6.7 per 1,000 adults).¹⁸

Among children and adolescents, trends of incidence were different. For the period 2002-2015, overall incidence of type 1 diabetes among U.S. children and adolescents aged less than 20 years significantly increased, and for the period 2002-2015, overall incidence of type 2 diabetes among U.S. children and adolescents aged 10 to 19 years significantly increased.¹⁹

A recent extensive study revealed that “in 6 areas of the US from 2001 to 2017, the estimated prevalence of diabetes among children and adolescents increased for both type 1 and type 2 diabetes.”²⁰ The study was based on the data collected from clinical centers located in six areas: California, Colorado, Ohio, South Carolina, Washington State, and (coordinated by the Colorado Center) Indian Health Services users in select areas of Arizona and New Mexico. This observational, cross-sectional, multicenter study included a mean of 3.47 million youths for each prevalence year from these six areas in the U.S. The findings indicated that “the estimated prevalence of type 1 diabetes among those 19 years or younger increased significantly, from 1.48 per 1000 youths to 2.15 per 1000 youths, and the estimated prevalence of type 2 diabetes among

¹⁵ Ibid.

¹⁶ Ibid.

¹⁷ Ibid.

¹⁸ Ibid.

¹⁹ Ibid.

²⁰ Lawrence, Jean M. et al. “Trends in Prevalence of Type 1 and Type 2 Diabetes in Children and Adolescents in the US, 2001-2017.” *JAMA*. August 2021. Vol. 326. No. 8, doi:10.1001/jama.2021.11165.

those aged 10 to 19 years increased from 0.34 per 1000 youths to 0.67 per 1000 youths.”²¹ Significant increase in the estimated prevalence of diabetes (both type 1 and type 2) among American children and adolescents is, obviously, a matter of concern.

This study examined race and ethnicity because of their association with diabetes prevalence. The findings showed that from 2001 to 2017, “the absolute increases in the estimated prevalence of type 1 diabetes were greatest among Black and White youths” while “type 2 diabetes remained more common among racial and ethnic minority youths, with the absolute increases in estimated type 2 diabetes prevalence being greatest among Black youth and Hispanic youth.”²²

The investigators point out that increases in prevalence can be driven by increased incidence, declining mortality, or both. The etiology of type 1 diabetes remains unknown; however, it is suspected that environmental factors, such as infectious and mucosal exposures in the first two years of life, interacting with type 1 diabetes susceptibility genes may play a role. Increasing prevalence of type 2 diabetes among children and adolescents is likely driven by increases in type 2 diabetes incidence. Experts believe that changes in anthropometric risk factors play a significant role. Specifically, childhood obesity increased by almost 5 percent - from 13.9 percent in 1999-2000 to 18.5 percent in 2015-2016, with Black and Mexican American teenagers experiencing the greatest increase in prevalence of obesity/severe obesity from 1999 to 2018, which may contribute to race and ethnicity differences.²³ “Other contributing factors may include increases in exposure to maternal obesity and diabetes (gestational and type 2 diabetes” as well as exposure to environmental factors.²⁴

Increasing awareness of type 2 diabetes in youth may have led to enhanced screening practices that may also have contributed to the increases. Careful screening and early diagnosis are, obviously, to be encouraged and supported.

Another concerning trend is an increase in diabetes rates among pregnant women in the U.S. A significant increase in gestational diabetes has been observed in the past several years. A serial, population-based, cross-sectional study of 12, 610, 235 individuals at first live birth aged 15 to 44 years found significant increase in gestational diabetes across all race and ethnicity groups: “the age-standardized gestational diabetes rate increased from 47.6 to 63.5 per 1000 live births from 2011 to 2019.”²⁵ While gestational diabetes rates increased in all racial and ethnic subgroups, differences in absolute gestational diabetes rates were observed across subgroups, with the highest rate (129.1 per 1000 live births) among Asian Indian women.²⁶ Pregestational diabetes rates in individuals at first live birth also increased significantly from 7.3 to 9.0 per 1000 live births from 2012 to 2019.²⁷ In 2019, relative to non-Hispanic White individuals, rates of pregestational diabetes were significantly higher among non-Hispanic Black individuals and Hispanic-Latina individuals; relative to non-Hispanic White individuals, the rates of pregestational diabetes among

²¹ Ibid.

²² Ibid.

²³ Ibid.

²⁴ Ibid.

²⁵ Shah, Nilay S. et al. “Trends in Gestational Diabetes at First Live Birth by Race and Ethnicity in the US, 2011-2019.” *JAMA*, August 2021. Vol. 326, No. 7, doi:10.1001/jama.2021.7217.

²⁶ Ibid.

²⁷ Ibid.

non-Hispanic Asian subgroups were significantly higher in Filipina individuals, and the rates of pregestational diabetes in Hispanic/Latina individuals were significantly higher in Mexican and Puerto Rican individuals.²⁸ Similar magnitude and direction of pregestational diabetes trends overall and in all race and ethnic groups were observed from 2016 and 2019.

Prevalence of prediabetes among adults has not shown any significant changes from 2005-2008 to 2013-2016: about one-third of U.S. adults had prediabetes over the entire period. In 2018, an estimated 88 million adults aged 18 years or older had prediabetes.²⁹ It is of concern that only 15.3 percent of adults with prediabetes reported being told by a health professional that they had this condition. The trend in awareness has been moving in the right direction: it almost doubled between 2005-2008 and 2013-2016 – from 6.5 percent to 13.3 percent; however, awareness clearly remains insufficient.

The *National Diabetes Statistics Report, 2020* includes the number of emergency department (ED) visits and hospitalizations for people with diabetes. In 2016, a total of 16 million ED visits were reported with diabetes as any listed diagnosis among adults aged 18 years or older, with almost equal number for hyperglycemic crisis and hypoglycemia.³⁰ In 2016, a total of 7.8 million hospital discharges were reported with diabetes as any listed diagnosis among U.S. adults aged 18 years or older (339.0 per 1,000 with diabetes).³¹

Diabetes is the leading cause of new cases of blindness among adults aged 18-64 years. Among U.S. adults aged 18 years or older with diagnosed diabetes, crude data for 2018 indicated that 11.7 percent reported vision disability, including blindness.³²

In 2017, diabetes was the seventh leading cause of death in the United States. CDC based this finding on 83,564 death certificates in which diabetes was listed as the underlying cause of death (crude rate, 25.7 per 100,000 persons); in the same year, 270,702 death certificates listed diabetes as the underlying or contributing cause of death (crude rate, 83.1 per 100,000 persons).³³

Recently, an extensive study was performed to determine trends in prevalence of diabetes and control of risk factors in diabetes among the U.S. adults between 1999-2000 and 2017-2018. The study included ten cycles of cross-sectional National Health and Nutrition Information Survey (NHANES) data between 1999-2000 and 2017-2018. For the purposes of the study, diabetes was defined by self-report of diabetes diagnosis, fasting glucose level of 126 mg/dl or more, or hemoglobin A1C (HbA1C) level of 6.5 percent or more, and the three risk factors control goals were individualized HbA1C targets, blood pressure less than 130/80 mm Hg, and low-density lipoprotein cholesterol (LDL-C) level less than 100 mg/dL.³⁴ The primary objective of this study

²⁸ Ibid.

²⁹ Centers for Disease Control and Prevention. *National Diabetes Statistics Report 2020: Estimates of Diabetes and Its Burden in the United States*. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2020, <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

³⁰ Ibid.

³¹ Ibid.

³² Ibid.

³³ Ibid.

³⁴ Wang, Li et al. "Trends in Prevalence of Diabetes and Control Risk Factors in Diabetes Among US Adults, 1999-2018." *JAMA*. Published online June 25, 2021, doi: 10.1001/jama.2021.9883.

was to provide updated national estimates to evaluate prevalence of diabetes and proportion of adults with diagnosed diabetes who achieved risk factor control goals, overall and by sociodemographic variables.

The authors remind that the estimated prevalence of diabetes among U.S. adults increased from 5.3 percent in 1976-1980 to 11.3 Percent in 2011-2014, growing at a rate faster than the global increase during the same period.³⁵ It has also been associated with increased risk of cardiovascular disease. Cardiovascular disease prevention in patients with diabetes requires appropriate management of well-established risk factors such as hemoglobin A1C level, blood pressure, and serum cholesterol level.

The findings of this serial, cross-sectional study of the nationally representative NHANES data indicated that “the estimated age-standardized prevalence of diabetes increased significantly, from 9.8% in 1999-2000 to 14.3% in 2017-2018. Only 21.2% of adults with diagnosed diabetes achieved all 3 risk factor control goals in 2015-2018.”³⁶ The significant increasing trends in the estimated prevalence of diabetes are attributed to a number of factors, including improved survival in diabetes, increasing burden of diabetes among children and young adults, more widespread screening for diabetes, increasing body mass index and waste circumference, and decreasing incidence of diagnosed diabetes among U.S. adults. The data show that the estimated prevalence of diabetes “continued to increase significantly among subgroups disproportionately affected by diabetes, including Mexican American adults and those with abdominal obesity.”³⁷ The investigators observed that “underdiagnosis was common, and the estimated prevalence of undiagnosed diabetes did not decrease significantly over time.”³⁸

The burden of diabetes among U.S. young adults has been increasing, which has been the tendency among young adults in many other countries as well. It is known that compared with later-onset diabetes, young-onset diabetes is associated with worse glycemic control, more rapid development of adverse cardiometabolic risk profiles, and greater lifetime risk of vascular and nonvascular complications. It is of concern that, according to this study, “young adults were significantly less likely than older ones to achieve individualized HbA1c targets, LDL-C level less than 100 mg/dL, and all 3 goals combined.”³⁹ Based on their findings, the investigators underscore that “early detection and management of diabetes among young adults is critical, but the estimated percentage of diabetes that was undiagnosed remained high and unchanged during the previous 2 decades.”⁴⁰

The authors concluded that “the improvement in risk factor control reported before 2010 did not continue despite extensive public health investments, as well as advances in therapeutic management of diabetes in the past 2 decades.”⁴¹ The data indicated stagnation in risk factor control in 2003-2018, although the treatment goals are theoretically achievable for most people by means of pharmacologic and lifestyle therapies. The study demonstrated significant racial and

³⁵ Ibid.

³⁶ Ibid.

³⁷ Ibid.

³⁸ Ibid.

³⁹ Ibid.

⁴⁰ Ibid.

⁴¹ Ibid.

ethnic differences in risk factor control. To improve risk factor control in people with diabetes, recommendations include “designing effective tailored approaches for improving adherence to medications and healthy lifestyle behaviors, as well as providing necessary health care access and resources, education, and self-management support for improving adherence and maintaining achieved adherence.”⁴² Earlier diagnosis and effective risk factor control are key to curtailing the increasing trends in prevalence of diabetes, delaying or averting complications, and, accordingly, decreasing the personal and economic burden of diabetes on individuals and society at large.

In 2021, the U.S. Preventive Services Task Force (USPSTF) updated its recommendations for screening for prediabetes and type 2 diabetes. The USPSTF recommendations are based on the belief that “screening asymptomatic adults for prediabetes and type 2 diabetes may allow earlier detection, diagnosis, and treatment, with the ultimate goal of improving health outcomes.”⁴³ The current recommendation statement reads as follows: “The USPSTF recommends screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity. Clinicians should offer or refer patients with prediabetes to effective preventive interventions.”⁴⁴ The USPSTF decreased the age at which to begin screening from 40 years to 35 years based on data suggesting that incidence of diabetes increases at age 35 years compared with younger ages and on the evidence for the benefits of interventions for newly diagnosed diabetes. Lifestyle interventions may slow or prevent progression from prediabetes to diabetes. Lifestyle interventions were shown to be effective in all subgroups, and, according to some studies, treatment effects did not differ by age, sex, race and ethnicity. An updated evidence report and systematic review undertaken to inform the USPSTF’s decision indicates that “trials of screening for diabetes found no significant mortality benefit but had insufficient data to assess other health outcomes”; however, and it is important to note, “for persons with recently diagnosed (not screen-detected) diabetes, interventions improved health outcomes; for obese or overweight persons with prediabetes, interventions were associated with reduced incidence of diabetes and improvement in other intermediate outcomes.”⁴⁵ The USPSTF advised further research on the effects of lifestyle interventions and medical treatments for screen-detected prediabetes and diabetes on health outcomes over a longer follow-up period, “particularly in populations reflective of the prevalence of diabetes,” as well as clinical trials and additional modeling studies “to better elucidate the optimal frequency of screening and the age at which to start and stop screening.”⁴⁶

In its commentary on the new USPSTF recommendations for screening for prediabetes and type 2 diabetes, a *JAMA* editorial calls for long-term randomized trials to assess the potential effects of screening, detection, and intervention simultaneously. The editorial points out that “given increasing life expectancy after diagnosis and potentially increasing multimorbidity, challenges of screening may now be less important compared with the challenges and benefits of successfully providing long-term glycemic control and sustaining cardiovascular risk factor

⁴² Ibid.

⁴³ “Screening for Diabetes and Type 2 Diabetes: US Preventive Services Task Force Recommendation Statement.” *JAMA*, August 24/31. Vol. 326. No. 8, doi:10.1001/jama.2021.12531.

⁴⁴ Ibid.

⁴⁵ Jonas, Daniel E. et al. “Screening for Prediabetes and Type 2 Diabetes Updated Evidence Report and Systematic Review for the U.S. Preventive Services Task Force.” *JAMA*, August 2021. Vol. 326. No. 8, doi: 10.1001/jama.2021.10403.

⁴⁶ “Screening for Diabetes and Type 2 Diabetes: US Preventive Services Task Force Recommendation Statement.” *JAMA*, August 24/31. Vol. 326. No. 8, doi:10.1001/jama.2021.12531.

management among populations with diabetes who live decades after diagnosis.”⁴⁷ In view of experts, the group that is most likely to benefit from early detection and intervention is young adults; “addressing barriers to glycemic and cardiovascular risk factor control among young adults with newly diagnosed diabetes, who by default of their younger age carry the highest lifetime risk of diabetes and diabetes-related complications” may have the biggest impact.⁴⁸ The *JAMA* editorial underlines that “the delivery of effective preventive interventions for people with prediabetes represents an ongoing missed opportunity” and expresses hope that the new USPSTF recommendations will facilitate “the development of a broader framework for diabetes prevention that matches risk tiers to diverse evidence-based interventions to serve individuals at varying levels of risk and that provides more personalized prevention.”⁴⁹ It is important for policymakers and other stakeholders to understand that “although multicomponent lifestyle interventions are beneficial for glycemic control and cardiovascular risk factor control across the full spectrum of risk, they are most cost-effective among groups with the highest levels and glycemic risk.”⁵⁰

It is well-known that diabetes is one of the most expensive diseases. The American Diabetes Association’s assessment of the economic burden of diabetes is as follows:

- The total direct and indirect⁵¹ estimated costs of diagnosed diabetes in the United States in 2017 was \$327 billion.
- Total direct estimated costs of diagnosed diabetes increased from \$188 billion in 2012 to \$237 billion in 2017 (2017 dollars); total indirect costs increased from \$73 billion to \$90 billion in the same period (2017 dollars).
- Between 2012 and 2017, excess medical costs per person associated with diabetes increased from \$8,417 to \$9,601 (2017 dollars).⁵²

People with diagnosed diabetes, on average, have medical expenditures approximately 2.3 times higher than what expenditures would be in the absence of diabetes.⁵³

Contemporaneous studies that included prediabetes, gestational diabetes, and undiagnosed diabetes statistics into the calculations, in addition to diagnosed diabetes, came up with much higher estimate than the ADA’s report: according to these analyses, diabetes cost the American

⁴⁷ Gregg, Edward W. and Tannaz Moin. “New USPSTF Recommendations for Screening for Prediabetes and Type 2 Diabetes: An Opportunity to Create National Momentum.” *JAMA*, August 24/31 2021. Vol. 326. No. 8, doi: 10.1001/jama.2021.12559.

⁴⁸ Ibid.

⁴⁹ Ibid.

⁵⁰ Ibid.

⁵¹ Indirect costs were calculated by incorporating absenteeism and reduced productivity while at work for the employed population, reduced productivity for those not in the labor force, inability to work because of disease-related disability, and lost productivity due to premature deaths attributed to diabetes.

⁵² American Diabetes Association. “Economic Costs of Diabetes in the US in 2017.” *Diabetes Care*. Vol. 41. May 2018, <https://doi.org/102337/dci18-0007>.

⁵³ Ibid.

population \$404 billion in 2017.⁵⁴ Medical expenses related to gestational diabetes added \$5,800 per pregnancy to total cost.⁵⁵

According to the American Diabetes Association (ADA), most of the cost for diabetes care in the United States (67.3 percent) is provided by government insurance, including Medicare, Medicaid, and the military. The rest is paid for by private insurance (30.7 percent) or by the uninsured (2 percent).⁵⁶ Notably, people with diabetes who do not have health insurance have 60 percent fewer physician office visits and are prescribed 52 percent fewer medications than people with insurance coverage, but they also have 168 percent more emergency department visits than people who have insurance.⁵⁷ It is important for policymakers and all stakeholders to realize the clinical and economic implications of proper insurance coverage.

In their attempt to determine policy implications of the recent comprehensive information on the economic burden of diabetes-related conditions, authors recommend increasing access to programs to prevent diabetes, prediabetes, and risk factors associated with these conditions such as obesity and insufficient exercise; they support their recommendation by citing Medicare studies that indicated diabetes prevention programs were associated with significant reductions in Medicare spending, inpatient admissions, and emergency department visits in the intervention group relative to the comparison group.⁵⁸ The authors also point out that “the high cost of treating undiagnosed diabetes highlights the need to increase early detection and management,” and they endorse enhanced efforts in this area, especially addressing barriers associated with social determinants of health (SDOH).⁵⁹ In addition to screening, which would ensure early detection, social determinants of health similarly affect participation in diabetes self-management and support programs, that can be cost-effective. It is well-known that diabetes prevention and treatment services have difficulty reaching high-risk populations; these commentators believe that an important future direction would be to estimate the economic burden introduced by SDOH: “Evaluation of programs and policies designed to reduce the burden in high-risk populations may then better describe the economic burden of diabetes and prediabetes as well as the direct costs, effectiveness, and cost-effectiveness of the programs and policies that target high-risk populations.”⁶⁰

Prevalence of Obesity in Pennsylvania and Current Trends

One of the major risks factors for diabetes is obesity. A special term has even been coined to describe obesity-related diabetes: “diabesity.” Both obesity and diabetes type 2 can

⁵⁴ Cardiometabolic Health Congress. “Economic Burden of Diabetes on the Rise.” *CMHC PULSE*, <https://www.cardiometabolicehealth.org/2019/07/23/economic-burdeeeee-of-diabetes-on-the-rise>.

⁵⁵ *Ibid.*

⁵⁶ American Diabetes Association. *The Cost of Diabetes*, <https://www.diabetes.org/resources/statistics/cost-diabetes> (accessed 01.06.2021).

⁵⁷ *Ibid.*

⁵⁸ O’Connell, Joan M. and Spero M. Manson. “Understanding the Economic Costs of Diabetes and Prediabetes and What We May Learn About Reducing the Health and Economic Burden of These Conditions.” *Diabetes Care*. September 2019, <https://doi: 10.2337/dci19-0017>.

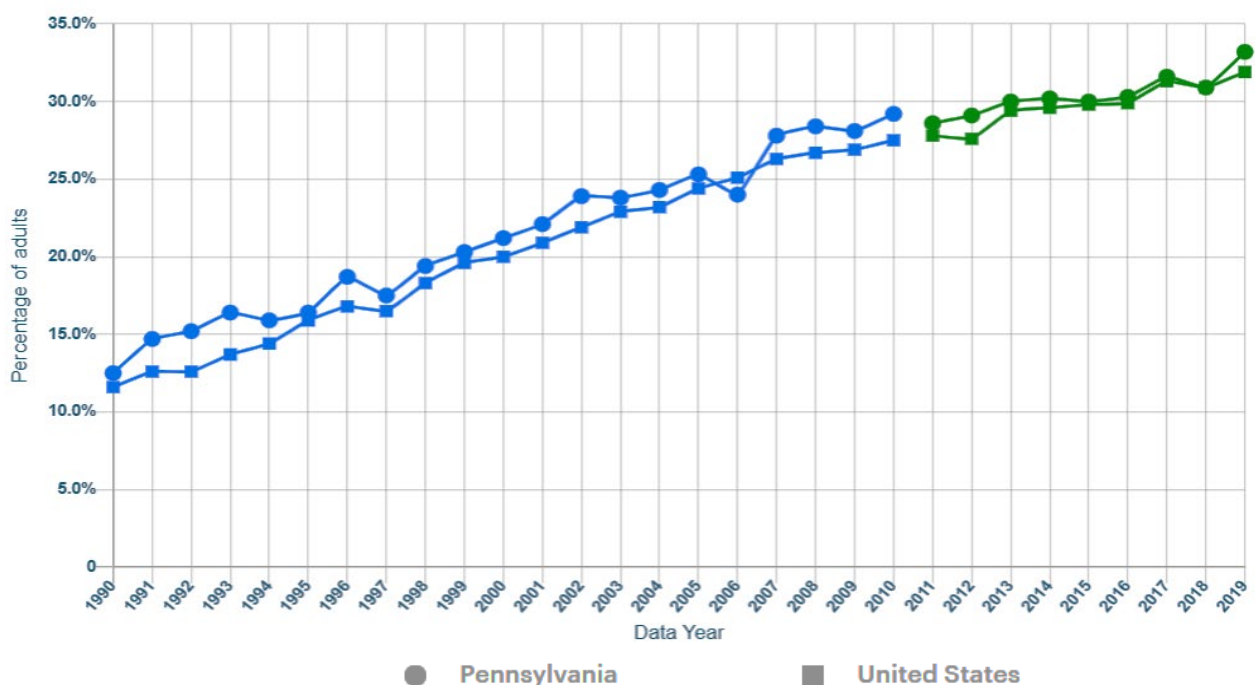
⁵⁹ *Ibid.*

⁶⁰ *Ibid.*

“substantially decrease life expectancy, diminish quality of life and increase healthcare costs.”⁶¹ For individuals of all ages, the risk of type 2 diabetes rises with increasing body weight. Citing the data from the National Institutes of Health, National Institute of Diabetes, Digestive and Kidney Diseases, the Obesity Action Coalition cautions that “the prevalence of type 2 diabetes is three to seven times higher in those who are obese than in normal weight adults, and is 20 times more likely in those with a body mass index (BMI) greater than 35 kg/m.”⁶²

An adult is considered obese if he or she has “a body mass index of 30.0 or higher based on reported height and weight.”⁶³ Percentage of adults with this body mass index has been growing consistently both in Pennsylvania and in the United States in general.

Trend: Obesity, Pennsylvania, United States



Percentage of adults with a body mass index of 30.0 or higher based on reported height and weight.

Source: CDC, Behavioral Risk Factor Surveillance System

⁶¹ Rogers, Joanne Z. and Christopher D. Still. *Obesity and Type 2 Diabetes*, <https://www.obesityaction.org/community/article-library/obesity-and-type-2-diabetes/>.

⁶² Ibid.

⁶³ United Health Foundation. *America’s Health Rankings Analysis of CDC Behavioral Risk Factor Surveillance System: Annual Report, 2020*, <https://www.americashealthrankings.org/explore/annual/measure/Diabetes/state/PA>, accessed August 17, 2021.

Pennsylvania's rank among other states is 33, with its obesity rate slightly higher than the national average: among women, it is 33.2 percent in the Commonwealth versus 32.1 percent in the U.S., and among men, it is 33.3 percent in Pennsylvania versus 30.6 percent in the U.S.⁶⁴ In the Commonwealth, obesity rates are slightly higher than the national level in all age groups: 30.0 percent in Pennsylvania versus 28.4 percent in the U.S. among adults ages 18-44, 38.2 percent in Pennsylvania versus 36.8 percent in the U.S. among adults ages 45-64, and 31.9 percent in Pennsylvania versus 29.3 percent in the U.S. for individuals 65+ years old. Subdivided by race/ethnicity, percentages are slightly higher than the national level among black and white Pennsylvanians, but slightly lower than the national averages in the Hispanic and multiracial subgroups.⁶⁵

A matter of concern is high prevalence of obesity among the Commonwealth youth. In Pennsylvania, "14.5% of youth ages 10 to 17 have obesity, giving Pennsylvania a ranking of 26 among the 50 states and D.C."⁶⁶ Obesity rate among children ages 2-4 participating in the Women, Infants, and Children (WIC) program is 12.2 percent; among children ages 10-17, it is 14.5 percent; and among high school students, it is 15.4 percent, putting Pennsylvania in the 17th place of 51 state ranks in this category.⁶⁷

Preventing and treating obesity may decrease children's risk of diabetes and help adults who are at high risk for diabetes to prevent or delay its development; it may also improve glycemic control in individuals who already have diabetes. Obesity can be treated by lifestyle changes; in certain cases, medications or bariatric surgery may be appropriate.

A large-cohort, case-control study of cases from an electronic health records database provided by an integrated health system in the Middle Atlantic region found that "not only is BMI strongly and independently associated with the risk of being diagnosed with T2D, but also that the magnitude of this positive association is larger for higher BMI values."⁶⁸ Higher BMI values are associated with poorer health outcomes and higher costs. Medical expenditures increase significantly with higher BMI values.

When a team of researchers examined electronic medical records and insurance claims data from the Geisinger Health System "to assess the real-world healthcare costs of being overweight or obese at different glycemic stages, including normal glycemia, pre-diabetes (PreD), and type 2 diabetes (T2D)," they found positive associations between healthcare costs and BMI levels within each glycemic stage and concluded that "management of body weight is important in reducing the overall healthcare costs, especially for subjects with PreD or T2D."⁶⁹ The investigators observed that the costs of being overweight and obese, relative to normal BMI (18.5-24.9 kg/m²), were much

⁶⁴ Ibid.

⁶⁵ Ibid.

⁶⁶ Robert Wood Johnson Foundation. *The State of Childhood Obesity*, <https://stateofchildhoodobesity.org/states/pa/>, accessed August 17, 2021.

⁶⁷ Ibid.

⁶⁸ Ganz, Michael L. et al. "The Association of Body Mass Index with the Risk of Type 2 Diabetes: A Case-Control Study Nested in and Electronic Health Records system in the United States." *Diabetology and Metabolic Syndrome*. 2014. Vol. 6. No. 50, <http://www.dmsjournal.com/content/6/1/50>.

⁶⁹ Li, Qian et al. "The Economic Burden of Obesity by Glycemic Stage in the United States." *PharmacoEconomics*. 2015. Vol. 33, doi: 10.1007/s40273-014-0248-5.

higher among subjects with T2D than those with normal glycemic levels” and “extreme obesity had a noticeable impact on healthcare costs within each glycemic stage.”⁷⁰ Their findings led the authors to the conclusion that “targeted weight-control programs aimed at people with PreD, or at-risk normal glycemic subjects, as well as those with T2D, should be able to generate a significant return on investment by effectively reducing the economic burden of overweight and obesity in the US.”⁷¹

A study specifically designed to estimate the medical care cost savings that can be achieved from a given amount of weight loss by people with different starting values of BMI, with and without diabetes, found that adult obesity significantly raised annual medical care costs; moreover, “the relationship of medical care costs over BMI is J-shaped; costs rise exponentially in the range of class 2 and 3 obesity (BMI \geq 35).”⁷² The investigators concluded that “the savings from a given percent reduction in BMI are greater the heavier the obese individual, and are greater for those with diabetes than for those without diabetes.”⁷³ These estimates may be useful to policymakers and healthcare payers who are trying to calculate the cost effectiveness of interventions to prevent and treat obesity.

Projection of the Future Diabetes Burden

In the past several decades, diabetes has increased rapidly, exceeding prior predictions. The data from the Centers for Disease Control and Prevention (CDC) indicate a nearly three-fold increase in the prevalence of diabetes in the adult population -- from 3.5 to 9.1 percent -- between 1980 and 2014.⁷⁴ Prevalence estimates were 9.5 percent in 1999-2002 and 12 percent in 2013-2016.⁷⁵ Projections from earlier studies turned out to be lower than the observed prevalence. The diabetes population was predicted to reach 20 million and 9 percent of the population by 2025; however, “data from the National Health Interview Survey (NHIS) showed that those projected levels were already reached in 2010.”⁷⁶ Several reasons may account for the underestimate, from the kind of the models used to changes in incidence and the demographic composition of the population. Researchers note that “prevalence, incidence, and mortality have all changed since the previous projection studies.”⁷⁷ For example, the decline of mortality rates for people both with and without diabetes has had a significant impact on diabetes prevalence: “The decline of mortality in the diabetes population means more people live with diabetes, and the decline in mortality in the non-diabetes population means more people are at risk of developing diabetes before they die.”⁷⁸

⁷⁰ Ibid.

⁷¹ Ibid.

⁷² Cawley, John et al. “Savings in Medical Expenditures Associated with Reductions in Body Mass Index Among US Adults with Obesity, by Diabetes Status.” *PharmacoEconomics*. 2015. Vol. 33, doi: 10.1007/s40273-014-0230-2.

⁷³ Ibid.

⁷⁴ Centers for Disease Control and Prevention. *Long-term Trends in Diabetes*, https://www.cdc.gov/diabetes/statistics/slides/long_term_trends.pdf.

⁷⁵ Centers for Disease Control and Prevention. *National Diabetes Statistics Report 2020: Estimates of Diabetes and Its Burden in the United States*. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2020, <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

⁷⁶ Lin, Ji et al. “Projection of the Future Diabetes Burden in the United States through 2020.” *Population Health Metrics*. 2018. Vol. 16. No. 9, <https://doi.org/10.1186/s12963-018-0166-4>.

⁷⁷ Ibid.

⁷⁸ Ibid.

A recent study used a dynamic model to project the number and percent of U.S. adults with diagnosed diabetes and was based on relatively stable estimates of diabetes incidence over the past 30 years, including the lower incidence rates observed since 2008. The study incorporated both the higher and the lower incidence rate scenarios, with the higher incidence representing a worst-case scenario in which diabetes incidence would rise due to increases in risk factors such as obesity, and the lower incidence representing the more optimistic scenario in which future diabetes incidence is reduced by widely implementing effective diabetes prevention strategies such as lifestyle interventions.

According to the study findings, both the number and percent prevalence of diagnosed diabetes among U.S. adults are projected to increase continually through 2060:

- The number of adults with diagnosed diabetes would increase from 22.3 million (9.1%) in 2014 to 39.7 million (13.9%) in 2030, and then reach 60.6 million (17.9%) in 2060.
- The overall diabetes population size will increase by an average of 1.0 million people per year before 2030 and by 0.6 million per year thereafter.
- The increase would vary by age group. People aged 65 years or older would have larger increases in both number and percent prevalence than younger adults. The number (percent) of people with diagnosed diabetes in the 65 years or older group would increase from 9.18 million (19.8%) in 2014 to 21.0 million (28.1%) in 2030, and 35.2 million (35.0%) in 2060. As a share of the total diabetes population, those aged 65 years or older accounted for 41.1% in 2014. This share would increase to 53.0% and to 58.0% in 2060.
- All race-sex groups would experience an increase in both diabetes population size and percent prevalence through 2060, but the magnitude of the increase would vary. Starting with a similar percent prevalence in women (9.0%) and men (9.2%) in 2014, the rate in women would rise to 19.2%, compared to 16.6% in men, by 2060. By race, the 2014 percent prevalence were 12.4, 8.6, and 8.5% among blacks, whites, and people of other race, respectively. By 2060, blacks would still have the highest percent prevalence (23.3%), but prevalence in the other race group (18.8%) would exceed that in whites (16.6%). Measured in population size, however, whites with diabetes outnumbered blacks and people of other race with 16.7 million in 2014 and would continue to do so with 39.1 million in 2060.
- Among all race-sex groups, black women had the highest percent prevalence in 2014 (12.5%) and would continue to have the highest rate through year 2060 (25.2%), followed by black men with 12.2% in 2014 and 21.1% in 2060. In terms of the magnitude of the increase, women of other race would have the largest relative increase in both number of cases (0.9 to 5.8 million, 6.4-fold increase) and percent prevalence (8.4 to 20.2%, 2.4-fold increase) from 2014 to 2060.

- Changes in diabetes incidence could have large effects on future diabetes number and percent prevalence. A 20% higher incidence rate than assumed in the base case would increase diabetes prevalence to 44.58 million (15.6%) in 2030 and 70.26 million (20.7%) in 2060. A 20% lower incidence would reduce diabetes prevalence to 34.7 million (12.2%) and 50.4 million (14.9%) in 2030 and 2060, respectively.⁷⁹

The researchers who developed this updated projection of the future diabetes burden using a dynamic model and the most recent available data caution that, according to their results, large health and economic burdens that diabetes imposes on individuals with the disease, their families, the national healthcare system, and society as a whole, would increase in the future if no actions were taken. They propose taking steps to prevent or delay type 2 diabetes, which accounts for the majority of the diabetes population: “Implementing effective prevention strategies to slow the increasing burden of type 2 diabetes is an urgent public health priority. According to our analysis, if we were to reduce the diabetes incidence rate by 20%, we would reduce the number of people with diabetes by 5 million in 2030 and 10 million in 2060.”⁸⁰

The authors draw special attention to the future diabetes burden from the population 65 years and older. Their findings indicate that starting in the late 2020s, half of the diabetes population would be in that group. “Among all persons aged 65 years or older, approximately one in three in 2030 and two in five in 2060 would have diagnosed diabetes.”⁸¹ This significant increase would result from a number of factors. Aging of the future U.S. adult population would “play a substantial role in the rapid increase in the number of older people with diabetes. However, the increase in the age of the diabetes population would exceed the increase in age of the general population due to the higher incidence of diabetes among older people.”⁸²

The steep increase in the number of adults aged 65 years or older with diabetes would increase healthcare resources for this age group. As the Medicare-eligible diabetes population would double in the early 2020s and quadruple in the 2050s under the current enrollment policy, the researchers who developed the projection suggest that “the Centers for Medicare and Medicaid Services may need to consider the increased burden of diabetes when planning the future health care resources. More importantly, wide implementation of effective diabetes prevention strategies should also be considered.”⁸³

The projection also suggests that public policies targeting prevention efforts to higher-risk groups such as blacks and people of other race, women in particular, may be needed in order to reduce the racial disparity.

⁷⁹ Ibid.

⁸⁰ Ibid.

⁸¹ Ibid.

⁸² Ibid.

⁸³ Ibid.

This recent projection, based on improved estimates for diabetes incidence and current prevalence, the latest census projections, and a refined mortality analysis, indicates that the number of U.S. adults with diagnosed diabetes “would nearly triple from 2014 to 2060 and over one in six adults would be diagnosed with diabetes by year 2060.”⁸⁴ The future health and economic burden imposed by diabetes would increase accordingly if no actions were taken. The researchers strongly recommend wide implementation of effective prevention strategies that “could mitigate future increases of the diabetes burden.”⁸⁵

⁸⁴ Ibid.

⁸⁵ Ibid.

DIAGNOSIS AND CLASSIFICATION OF DIABETES MELLITUS

Definition and Description

Diabetes mellitus is defined as “a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both.”⁸⁶

Diabetes develops as a result of several pathogenic processes, ranging from autoimmune destruction of the beta-cells of the pancreas with consequent insulin deficiency to abnormalities that result in resistance to insulin action. “Deficient insulin action results from inadequate insulin secretion and/or diminished tissue responses to insulin at one or more points in the complex pathways of hormone action. Impairment of insulin secretion and defects in insulin action frequently coexist in the same patient, and it is often unclear which abnormality, if either alone, is the primary cause of the hyperglycemia.”⁸⁷

Acute, life-threatening consequences of uncontrolled diabetes are hyperglycemia with ketoacidosis or the nonketonic hyperosmolar syndrome.⁸⁸ Hypoglycemia (abnormally low level of blood sugar), which is often associated with diabetes and its treatment, can also lead to severe consequences and can sometimes be life-threatening as it is a potential cause of acute cardiovascular events.

The chronic hyperglycemia of diabetes (abnormally high level of blood sugar) is associated with long-term damage, dysfunction, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels. Long-term complications of diabetes include retinopathy with potential loss of vision; nephropathy leading to renal failure; peripheral neuropathy with risk of foot ulcers and amputations; and autonomic neuropathy causing gastrointestinal, genitourinary, and cardiovascular symptoms and sexual dysfunction. Patients with diabetes have an increased incidence of atherosclerotic cardiovascular, peripheral arterial, and cerebrovascular disease.⁸⁹

Classification

Diabetes is currently classified into the following general categories:

1. Type 1 diabetes (due to autoimmune β -cell destruction, usually leading to absolute insulin deficiency, including latent autoimmune diabetes of adulthood)

⁸⁶ American Diabetes Association. *Diagnosis and Classification of Diabetes Mellitus*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2797383>.

⁸⁷ Ibid.

⁸⁸ Ibid.

⁸⁹ Ibid.

2. Type 2 diabetes (due to a progressive loss of β -cell insulin secretion frequently on the background of insulin resistance)
3. Specific types of diabetes due to other causes, e.g., monogenic diabetes syndromes (such as neonatal diabetes and maturity-onset diabetes of the young), diseases of the exocrine pancreas (such as cystic fibrosis and pancreatitis) and drug- or chemical-induced diabetes (such as with glucocorticoid use, in the treatment of HIV/AIDS, or after organ transplantation)
4. Gestational diabetes mellitus (diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation)⁹⁰

One of the current trends in understanding diabetes and approaches to treatment is the acknowledgement of significant overlap across the spectrum of diabetes. Today's consensus in the diabetes research community is that "in both type 1 and type 2 diabetes, various genetic and environmental factors can result in the progressive loss of β -cell mass and/or function that manifests clinically as hyperglycemia."⁹¹ When hyperglycemia occurs, patients with all forms of diabetes are at risk for developing the same chronic complications, although rates of progression may differ. Doctors believe that "the identification of individualized therapies for diabetes in the future will require better characterization of the many paths to β -cell demise or dysfunction."⁹² This remains an important area of research, with the goal of optimizing treatment approaches for various subsets of diabetes.

Most common forms of diabetes are type 1 diabetes and type 2 diabetes.

Type 1 diabetes, or immune-mediated diabetes, previously called "insulin-dependent diabetes" or "juvenile-onset diabetes," accounts for 5-10 percent of diabetes and is due to cellular mediated-autoimmune destruction of the pancreatic β -cells; it is identified by the presence of one or more specific autoimmune markers.⁹³ This form of diabetes commonly occurs in childhood and adolescence, but, as has been recently acknowledged, it may occur at any age. As most of the mutations that cause diabetes are dominantly inherited, it leads to important genetic considerations. The ADA guidelines underscore that "the importance of genetic testing is in the genetic counseling that follows."⁹⁴ Islet autoantibody testing of individuals genetically at risk for type 1 diabetes (for example, relatives of those with type 1 diabetes or individuals from the general population with type 1 diabetes-associated genetic factors) identifies individuals who may develop type 1 diabetes. When such testing is coupled with education about diabetes symptoms and close follow-up of these individuals, it may enable earlier identification of type 1 diabetes onset.

Type 2 diabetes, previously referred to as "noninsulin-dependent diabetes" or "adult-onset diabetes," accounts for 90-95 percent of all diabetes; this form "encompasses individuals who have

⁹⁰ American Diabetes Association. "Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes – 2021." *Diabetes Care*. 2021. Vol. 44 (Suppl. 1), https://care.diabetesjournals.org/content/44/Supplement_1/S15.

⁹¹ Ibid.

⁹² Ibid.

⁹³ Ibid.

⁹⁴ Ibid.

relative (rather than absolute) insulin deficiency and have peripheral insulin resistance.”⁹⁵ There are various causes of type 2 diabetes. It is often associated with a strong genetic predisposition, and the risk of developing this form of diabetes increases with age, obesity, and lack of physical activity. There are also other known risk factors. The ADA acknowledges, however, that “the genetics of type 2 diabetes is poorly understood and under intense investigation in this era of precision medicine.”⁹⁶ Type 2 diabetes often remains undiagnosed for many years because hyperglycemia develops gradually and, at earlier stages, is not severe enough for the patient to recognize the classic diabetes symptoms. Even undiagnosed patients are at increased risk of developing macrovascular and microvascular complications and the duration of glycemic burden is a strong predictor of adverse outcomes, so the American Diabetes Association strongly recommends early detection and early intervention, underscoring the availability of simple tests to detect preclinical disease and the existence of effective interventions that prevent progression from prediabetes to diabetes and reduce the risk of diabetes complications.⁹⁷ Multiple controlled trials and computer simulation modelling studies suggest that “major benefits are likely to accrue from the early diagnosis and treatment of hyperglycemia and cardiovascular risk factors in type 2 diabetes,” and, “moreover, screening, beginning at age 30 or 45 years and independent of risk factors, may be cost-effective (<\$11,000 per quality-adjusted life-year gained).”⁹⁸ The ADA “Standards of Medical Care in Diabetes – 2021” contain an extensive discussion of various approaches to screening and testing for prediabetes and type 2 diabetes in asymptomatic adults, children, and adolescents.

Gestational diabetes mellitus (GDM) has been traditionally defined as “diabetes that develops during pregnancy,”⁹⁹ or, in other words, as “a condition in which carbohydrate intolerance develops during pregnancy.”¹⁰⁰ In the latest edition of its *Standards of Medical Care in Diabetes*, the American Diabetes Association called in question a broad definition of GDM as “any degree of glucose intolerance that was first recognized during pregnancy” as this definition “facilitated a uniform strategy for detection and classification of GDM, but this definition has serious limitations.”¹⁰¹ First, the ADA points out that many cases of gestational diabetes represent preexisting hyperglycemia that is detected by routine screening in pregnancy as nonpregnant women of reproductive age are not routinely screened for diabetes. Secondly, the ADA underscores that “it is the severity of hyperglycemia that is clinically important with regard to both short- and long-term maternal and fetal risks.”¹⁰² The ADA enjoins further investigation into the first trimester screening because “hyperglycemia that would be diagnostic of diabetes outside of pregnancy and is present at the time of conception is associated with an increased risk of congenital malformations that is not seen with lower glucose levels.”¹⁰³ As the number of women with type

⁹⁵ Ibid.

⁹⁶ Ibid.

⁹⁷ Ibid.

⁹⁸ Ibid.

⁹⁹ US Preventive Services Task Force. “Screening for Gestational Diabetes: Recommendation Statement.” *JAMA*. August 10, 2021. Vol. 326. No. 6, doi:10.1001/jama.2021.11922.

¹⁰⁰ American College of Obstetricians and Gynecologists. “ACOG Practice Bulletin No. 190 Summary: Gestational Diabetes Mellitus.” *Obstetrics and Gynecology*. February 2018. Vol. 131. No. 2, doi:10.1097/AOG0000000000002498.

¹⁰¹ American Diabetes Association. “Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes – 2021.” *Diabetes Care*. 2021. Vol. 44 (Suppl. 1), https://care.diabetesjournals.org/content/44/Supplement_1/S15.

¹⁰² Ibid.

¹⁰³ Ibid.

2 diabetes, often undiagnosed, has increased, the experts argue that it is reasonable to test women with risk factors for type 2 diabetes in early pregnancy, at their initial prenatal visit, using standard diagnostic criteria, and manage them differently, dependent on the results. Other women should be rescreened for GDM between 24 and 28 weeks of gestation. It has been found that “GDM is often indicative of underlying β -cell dysfunction, which confers marked increased risk for later development of diabetes, generally but not always type 2 diabetes, in the mother after delivery.”¹⁰⁴ Therefore, the ADA recommends that women diagnosed with GDM should receive lifelong screening for prediabetes (at least, every three years) to allow interventions to reduce diabetes risk and for type 2 diabetes to allow treatment at the earliest possible time. Women with a history of gestational diabetes mellitus found to have prediabetes “should receive lifestyle interventions and/or metformin to prevent diabetes.”¹⁰⁵

Gestational diabetes is associated with well-known short- and long-term adverse effects and risks for women and their offspring. In mothers, hazard ratios for future diabetes after gestational diabetes ranged from 6.3 in Asian individuals to 9.9 in Black individuals in a retrospective cohort in Southern California; in addition, a metaanalysis showed that gestational diabetes is associated with a relative risk of 2.0 for future cardiovascular disease.¹⁰⁶ In offspring, fetal exposure to gestational diabetes in utero has been linked to macrosomia (growth beyond a specific threshold) and adiposity (severe overweight) in newborns as well as impaired glucose tolerance and obesity in childhood, “thereby increasing risks for adverse cardiometabolic outcomes for offspring across the lifespan.”¹⁰⁷ Experts advocate for targeted screening for and proper management of GDM: “Addressing modifiable prenatal risk factors and implementing strategies to prevent gestational diabetes and postnatal diabetes in all individuals, with particular focus on groups with disproportionately high gestational diabetes rates, may help to reduce disparities in long-term cardiovascular and metabolic disease outcomes.”¹⁰⁸

Considering potential preventable burden associated with GDM, the U.S. Preventive Services Task Force (USPSTF) “recommends screening for gestational diabetes in asymptomatic pregnant persons at 24 weeks of gestation or after.”¹⁰⁹ The USPSTF concluded that the current evidence was insufficient to assess the balance of benefits and harms of screening for gestational diabetes in asymptomatic pregnant women before 24 weeks of gestation.¹¹⁰ The findings presented in the evidence report underpinning the latest USPSTF recommendations indicated that “treatment versus no treatment was associated with reduced risk for some pregnancy and several neonatal/fetal outcomes.”¹¹¹

¹⁰⁴ Ibid.

¹⁰⁵ Ibid.

¹⁰⁶ Shah, Nilay S. et al. “Trends in Gestational Diabetes at First Live Birth by Race and Ethnicity in the US, 2011-2019.” *JAMA*, August 2021. Vol. 326. No. 7, doi:10.1001/jama.2021.7217.

¹⁰⁷ Ibid.

¹⁰⁸ Ibid.

¹⁰⁹ “Screening for Gestational Diabetes: US Preventive Services Task Force Recommendation Statement.” *JAMA*, August 10, 2021. Vol. 326. No. 6, doi:10.1001/jama.2021.11922.

¹¹⁰ Ibid.

¹¹¹ Pillay, Jennifer et al. “Screening for Gestational Diabetes: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force.” *JAMA*, August 10, 2021. Vol. 326, No. 6, doi: 10.1001/jama.2021.10404.

CURRENT MEDICAL CARE GUIDELINES AND RECENT POSITION STATEMENTS FROM KEY STAKEHOLDERS

The ADA Standards of Medical Care in Diabetes - 2021

The American Diabetes Association (ADA) underscores that diabetes is “a complex, chronic illness requiring continuous medical care with multifactorial risk-reduction strategies beyond glycemic control. Ongoing diabetes self-management education and support are critical in preventing acute complications and reducing the risk of long-term complications. Significant evidence exists that supports a range of interventions to improve diabetes outcomes.”¹¹² Every year, the ADA issues its *Standards of Medical Care in Diabetes* intended to “provide clinicians, patients, researchers, policy makers, and other interested individuals with the components of diabetes care, general treatment goals, and tools to evaluate the quality of care.”¹¹³ The ADA *Standards of Care* are updated on an annual basis and are considered the most authoritative source for current guidelines for diabetes care.

The field of diabetes care is constantly changing with the emergence of new research, technology, and treatments that have the potential of improving the health and well-being of people with diabetes, and the ADA’s annual updates reflect these new developments. Each annual edition of *Standards of Medical Care in Diabetes* includes a section summarizing the latest revisions. The main revisions in the 2021 update include the following:

- Additional information and a new recommendation on social determinants of health in diabetes
- Addition of the concept of “cost-related medication nonadherence” to the subsection on cost considerations
- More discussion about use of the term LADA (latent autoimmune diabetes in adults)
- Additional evidence regarding early diagnosis and treatment of cystic fibrosis-related diabetes (CFRD) as well as reported increases in CFRD
- A new subsection “Delivery and Dissemination of Lifestyle Behavior Changes for Diabetes Prevention,” which describes evidence for broader dissemination of and national efforts for lifestyle behavior change programs to prevent diabetes
- Additional guidance and data in the newly named “Prevention of Vascular Disease and Mortality” subsection, which includes data from longer-term follow-up diabetes studies
- Modification of one of the recommendations regarding ongoing management, which now includes overall health status, risk of hypoglycemia, and cardiovascular risk using the risk calculator

¹¹² American Diabetes Association. “Introduction: Standards of Medical Care in Diabetes – 2021.” *Diabetes Care*. 2021. Vol. 44 (Suppl. 1) // <https://doi.org/10.2337/dc21-SINT>.

¹¹³ Ibid.

- Significant revision of the “Immunizations” subsection, with inclusion of a table containing CDC-recommended vaccinations for people with diabetes, more extensive discussion of each vaccine, and important considerations related to COVID-19
- Additional evidence on hearing impairment in the “Sensory Impairment” subsection
- Revision of the table “Components of the Comprehensive Diabetes Medical Evaluation at Initial, Follow-up, and Annual Visits” to include a number of additional factors such as social determinants of health and identification of surrogate decision-maker and advanced care plan
- Additional recommendations regarding barriers to diabetes self-management education and support (DSMES)
- Additional evidence on the usefulness of DSMES and ways to address barriers
- Additional guidance and studies related to carbohydrates and fats
- Additional recommendation in the “Physical Activity” subsection to address baseline physical activity and sedentary time and to encourage the promotion of nonsedentary activities above baseline for sedentary individuals with diabetes
- Additional recommendation for smoking cessation, which can be addressed as part of diabetes education programs
- Addition of the concept of “mindful self-compassion” to the “Diabetes Distress” subsection, discussing its effects on diabetes
- Renaming of the “A1C” subsection, which is now titled “Glycemic Assessment” and includes respective changes to recommendations to allow for other glycemic measures aside from A1C
- Revision of the “Glycemic Goals” subsection to include other glycemic measures and time-in-range goals
- Expanded “A1C and Microvascular Complications” subsection
- Revision of the recommendation regarding hypoglycemia assessment, which now calls for a review of the occurrence of and risk for hypoglycemia at every encounter and investigation as indicated
- Revised recommendations regarding continuous glucose monitoring (CGM)
- Revision of the “Insulin Delivery” subsection, with revised recommendation on insulin pump use
- Revised recommendations on obesity management for the treatment of type 2 diabetes, including addition of the concept “patient-centered communication that uses nonjudgmental language and updates to the subsection on “Diet, Physical Activity, and Behavioral Therapy”
- Revised recommendations on pharmacologic approaches to glycemic treatment, along with the related discussion
- Revision of the subsection on “Cardiovascular Disease and Risk Management,” with several additional recommendations based on evolving evidence from cardiovascular trials
- Modified recommendations for chronic kidney disease to individualize treatment based on renal function and risk of cardiovascular disease
- Modified recommendations and one added recommendation on hypoglycemia in older adults
- New recommendations in the “Children and Adolescents” section

- Revised recommendations on management of diabetes in pregnancy
- Revisions to the “Diabetes Care in the Hospital” section to include more guidance on glucocorticoid therapy.¹¹⁴

Diabetes is a complex disease. Effective treatment requires a comprehensive medical evaluation and assessment of comorbidities, which, in its turn, depends on beneficial interactions between the patient and the care team. The ADA consistently highlights the importance of the patient-centered collaborative care. To ensure this, the ADA recommends the following:

- A patient-centered communication style that uses person-centered and strength-based language and active listening; elicits patient preferences and beliefs; and assesses literacy, numeracy, and potential barriers to care should be used to optimize patient health outcomes and health-related quality of life.
- People with diabetes can benefit from a coordinated multidisciplinary team that may draw from diabetes care and education specialists, primary care providers, subspecialty providers, nurse, dietitians, exercise specialists, pharmacists, dentists, podiatrists, and mental health professionals.¹¹⁵

The two main goals of treatment for diabetes are to prevent or delay complications and to optimize quality of life. Treatment goals should be discussed with patients, and plans should be developed for them based on their individual preferences, goals, and values. This individualized management plan should take into account a wide variety of factors: the patient’s age, his or her cognitive abilities, school/work schedule and conditions, support systems, eating patterns, physical activity, social situation, financial concerns, cultural aspect, literacy and numeracy, diabetes history (duration, complications, current use of medications), comorbidities, health priorities, other medical conditions, preferences for care, and life expectancy. The ADA recommends utilizing various strategies and techniques to support patients’ self-management efforts, including providing education on problem-solving skills for all aspects of diabetes management.¹¹⁶

The complexity and intricacy of multi-factorial decision cycle for patient-centered glycemic management in type 2 diabetes is vividly reflected in a chart that originally appeared in the 2018 consensus report by the American Diabetes Association and the European Association for the Study of Diabetes and was reprinted in the ADA *Standards of Medical Care in Diabetes – 2021*.¹¹⁷

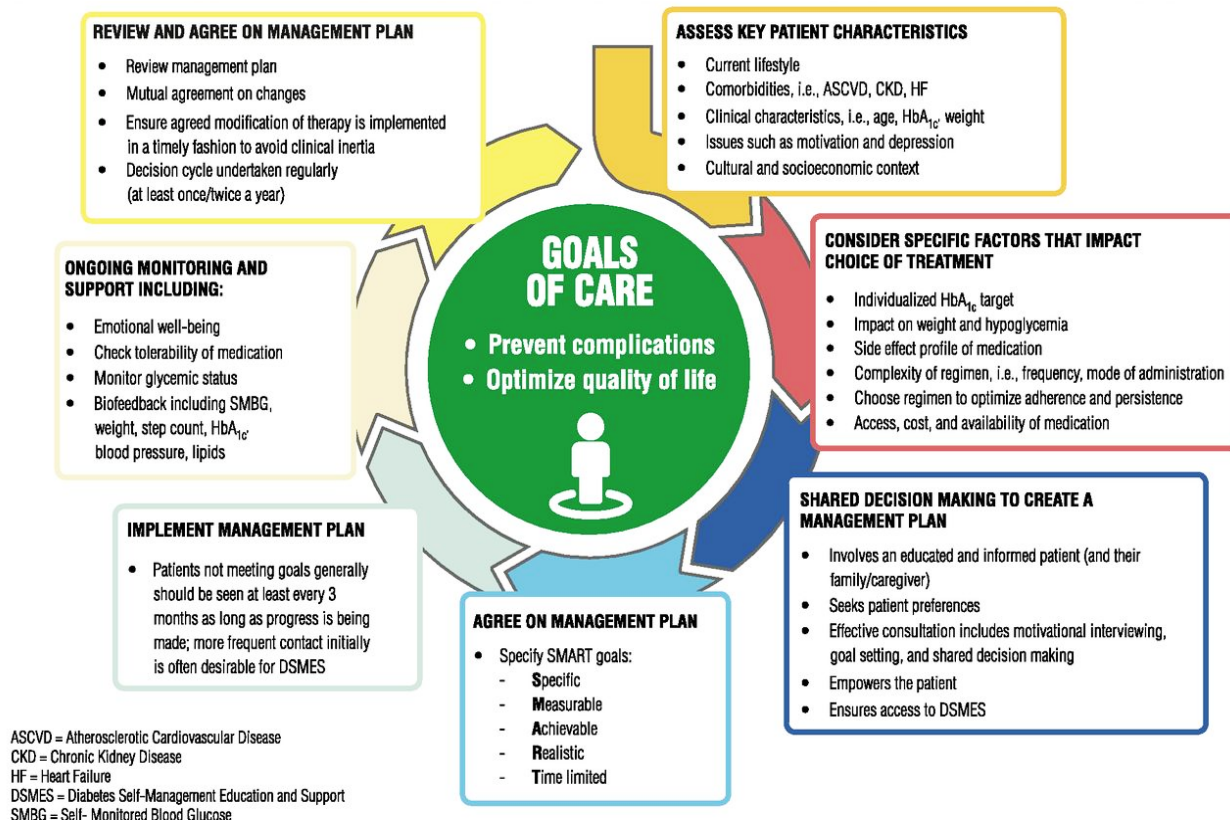
¹¹⁴ American Diabetes Association. “Summary of Revisions: Standards of Medical Care in Diabetes – 2021.” *Diabetes Care*. 2021. Vol. 44 (Suppl. 1) // <https://doi.org/10.2337/dc21-SREV>.

¹¹⁵ American Diabetes Association. “Comprehensive Medical Evaluation and Assessment of Comorbidities: Standards of Medical Care in Diabetes – 2021.” *Diabetes Care*. 2021. Vol. 44 (Suppl. 1) // <https://doi.org/10.2337/dc21-S004>.

¹¹⁶ Ibid.

¹¹⁷ American Diabetes Association. “Comprehensive Medical Evaluation and Assessment of Comorbidities: Standards of Medical Care in Diabetes – 2021.” *Diabetes Care*. 2021. Vol. 44 (Suppl. 1) // <https://doi.org/10.2337/dc21-S004>. Reprinted from: Davies, Melanie J.; D’Alessio, David A.; Fradkin, Judith et al. “Management of Hyperglycemia in Type 2 Diabetes: A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD).” *Diabetes Care*. December 2018. Vol. 41. No. 12, <https://doi.org/10.2337/dci18-0033>.

DECISION CYCLE FOR PATIENT-CENTERED GLYCEMIC MANAGEMENT IN TYPE 2 DIABETES



Source: The ADA *Standards of Medical Care in Diabetes – 2021*. Reprinted from: Davies, M. J. et al. *Management of Hyperglycemia in Type 2 Diabetes: A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)*.

DSMES Consensus Report

Diabetes self-management education and support (DSMES) is defined as “the ongoing process of facilitating the knowledge, skills, and ability necessary for diabetes self-management as well as activities that assist a person in implementing and sustaining the behaviors needed to manage his or her condition on an ongoing basis, beyond or outside of formal self-management training.”¹¹⁸ DSMES is widely acknowledged as “a critical element of care for all people with diabetes.”¹¹⁹

¹¹⁸ Beck, Joni; Greenwood Deborah A.; Blanton, Lori et al. “2017 National Standards for Diabetes Self-Management Education and Support.” *Diabetes Care*. October 2017. Vol. 40. No. 10, <https://doi.org/10.2337/dci17-0025>.

¹¹⁹ Ibid.

Diabetes self-management education and support “addresses the comprehensive blend of clinical, educational, psycho-social, and behavioral aspects of care needed for daily self-management and provides the foundation to help all people with diabetes navigate their daily self-care with confidence and improved outcomes.”¹²⁰

In summer 2020, several national medical organizations involved in diabetes treatment and education released a consensus report that is an update of the 2015 joint position statement on DSMES. These organization include the three national organizations that jointly published the original statement: the American Diabetes Association (ADA), the Association of Diabetes Care & Education Specialists (ADCES), and the Academy of Nutrition and Dietetics; they were joined by representatives of four other organizations – the American Academy of Family Physicians, the American Academy of PAs, the American Association of Nurse Practitioners, and the American Pharmacists Association; a patient advocate was also invited to participate. The purpose of a broader, more inclusive participation was to widen the reach and stakeholder input and collaboration. The panel of experts who authored the consensus report represented all the above-mentioned entities, and all seven contributing organizations reviewed and approved the consensus statement, so the recommendations contained in the document are the informed, expert consensus of all the contributors.

Even though DSMES is considered to be one of the essential elements of comprehensive diabetes care, along with medical nutrition therapy (MNT), it is often under-utilized. The consensus report identifies barriers to fuller and more effective utilization and proposes solutions to overcome these barriers. The authors of the consensus report postulate that “solutions begin with an organizational commitment to the value of access to, and participation in, DSMES” and encourage key stakeholders “to develop action plans for increased referral to and utilization of DSMES” with the purpose of increasing the focus “on achieving treatment goals early and maintaining them throughout a person’s lifetime.”¹²¹

The DSMES consensus report recommendations are addressed to two main groups and include the following:

Providers

1. Discuss with all persons with diabetes the benefits and value of initial and ongoing DSMES.
2. Initiate referral to and facilitate participation in DSMES at the 4 critical times: 1) at diagnosis, 2) annually and/or when not meeting treatment targets, 3) when complicating factors develop; and 4) when transitions in life and care occur.

¹²⁰ Powers, Margaret A.; Bardsley, Joan K.; Cypress, Marjorie et al. “Diabetes Self-Management Education and Support in Adults with Type 2 Diabetes: A Consensus Report of the American Diabetes Association, the Association of Diabetes Care & Education Specialists, the Academy of Nutrition and Dietetics, the American Academy of Family Physicians, the American Academy of PAs, the American Association of Nurse Practitioners, and the American Pharmacists Association.” *Diabetes Care*. July 2020. Vol. 43. No. 7, <https://doi.org/10.2337/dci20-0023>.

¹²¹ Ibid.

3. Ensure coordination of the medical nutrition therapy plan with the overall managing strategy, including the DSMES plan, medications, and physical activity on an ongoing basis.
4. Identify and address barriers affecting participation with DSMES services following referral.

Health policy, payers, health systems, providers, and health care teams

5. Expand awareness, access, and utilization of innovative and nontraditional DSMES services.
6. Identify and address barriers influencing providers' referrals to DSMES services.
7. Facilitate reimbursement processes and other means of financial support in consideration of cost savings related to the benefits of DSMES services.¹²²

The first consensus recommendation encourages providers to discuss with all persons with diabetes the benefits and value of DSMES. Citing multiple studies, the authors of the consensus report highlight key clinical benefits of DSMES: improved hemoglobin A1C with reductions that are additive to lifestyle and drug therapy as well as reduction in the onset and/or worsening of diabetes-related complications and reduction of all-cause mortality. Additional benefits of participation in DSMES services include psychosocial benefits such as improvements to quality of life, self-efficacy, empowerment, and healthy coping, with decreased diabetes-related distress.

The consensus report cites evidence supporting the association of better health outcomes with an increased amount of time spent with a diabetes care and education specialist such as significant reductions in mortality and A1C in patients who completed more than 10 hours of DSMES over the course of 6-12 months and those who participated in DSMES services on an ongoing basis compared with those who spent less time with a diabetes care and education specialist.¹²³ Moreover, the authors contend that DSMES is cost-effective by reducing emergency department visits, hospital admissions, and hospital readmissions. Lower acute care costs offset higher outpatient and pharmacy costs for those who use diabetes education.

As “DSMES improves quality of life and health outcomes and is cost-effective,” the consensus report encourages all members of the health care team and health systems to “promote the benefits, emphasize the value, and support participation in initial and ongoing DSMES for all people with diabetes.”¹²⁴

The panel of experts recommends enabling self-selection of a method that best meets a particular patient's specific needs. In addition to formal series of didactic classes at a health care facility location, DSMES services are now offered in various formats and settings such as those

¹²² Ibid.

¹²³ Ibid.

¹²⁴ Ibid.

located within patient-centered medical homes, community health centers, pharmacies, faith-based organizations, and home settings. Technology-based DSMES services including telehealth, web-based programs, mobile applications, and remote monitoring can enhance access and connectivity for ongoing management and support. Person-centered approaches are important to meet individual needs and preferences; without the focus on a person's beliefs, desires, and challenges, ongoing treatment goals can rarely be met.

As diabetes is a chronic disease that progresses over time, it requires continuous care, with periodic assessment, ongoing education and learning, and ongoing support, to ensure that changing physiologic needs and goals are met. Frequent DSMES visits may be necessary when the patient is starting a new diabetes medication such as insulin or has worsening clinical indicators. The progression of diabetes can exacerbate the emotional and treatment burden of the disease and increase diabetes-related distress. "The identification of diabetes-related complications or other individual factors that may influence self-management should be considered a critical indicator of the need for DSMES that requires immediate attention and adequate resources."¹²⁵ The consensus report includes a detailed checklist for providing and modifying DSMES at four critical times in the patient's life and enjoins a proactive approach in response to emerging changes in the individual's life circumstances.

The consensus report reminds of the need to coordinate medical nutrition therapy (MNT), which has been shown to reduce A1C by up to 2 percent,¹²⁶ with the DSMES plan, medications, and physical activity, all of which are essential components of diabetes care. An earlier consensus report on nutrition therapy also emphasized that MNT is "fundamental in the overall diabetes management plan" and should be "provided by a registered dietician nutritionist/registered dietician (RDN), preferably one who has comprehensive knowledge and experience in diabetes care." The overarching recommendation regarding MNT is that "ideally, an eating plan should be developed in collaboration with the person with prediabetes or diabetes and an RDN through participation in diabetes self-management education when the diagnosis of prediabetes or diabetes is made" and that nutrition therapy recommendations should be "adjusted regularly based on changes in an individual's life circumstances, preferences, and disease course."¹²⁷

Though usefulness and value of DSMES is widely acknowledged, it is vastly underutilized. Its low utilization is attributed to a number of barriers. The consensus report contains a detailed analysis of health system, or programmatic, barriers; referring health care providers' barriers; participant-related barriers; and environment-related barriers. The authors suggest that "in order to reduce barriers, a focus on processes that streamline referral practices must be implemented and supported system wide." These experts believe that "once this major barrier is addressed, the diabetes care and education specialist can be invaluable in addressing other barriers

¹²⁵ Ibid.

¹²⁶ Franz, M.J.; MacLeod, J.; Evert, A. et al. "Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process." *Journal of the Academy of Nutrition and Dietetics*, 16 May 2017. Vol. 117. No. 10, doi:10.1016/j.jand.2017.03.023.

¹²⁷ Evert, Alison B.; Dennison, Michelle; Gardner, Christopher D. et al. "Nutrition Therapy for Adults With Diabetes or Prediabetes: A Consensus Report." *Diabetes Care*. Published online April 18, 2019, <https://doi.org/10.2337/dci19-0014>.

that the person may have.”¹²⁸ One consensus recommendation is “to facilitate reimbursement processes and other means of financial support in consideration of cost savings related to the benefits of DSMES services.”¹²⁹ Joint efforts by providers, payers, and health systems are needed to identify and address existing barriers. It is very important that DSMES services “be designed and delivered with input from the target population and critically evaluated to ensure they are patient-oriented.”¹³⁰

The consensus report concludes with a strong statement that the “changing health care environment provides a platform to use DSMES services as an effective, cost saving, high-impact resource integral to a person’s ability to self-manage diabetes” and a recommendation that “a variety of culturally appropriate services need to be offered in a variety of settings, utilizing technology to facilitate access to DSMES services, support self-management decisions, and decrease therapeutic inertia.”¹³¹

Healthy People 2030

Healthy People 2030 summarizes goals and objectives developed by the U.S. HHS Office of Disease Prevention and Health Promotion (ODPHP). Noting that over 30 million people in the United States have diabetes and that diabetes is the seventh leading cause of death, *Healthy People 30* focuses on reducing diabetes cases, complications, and deaths. As stated, the goal is to “reduce the burden of diabetes and improve quality of life for all people who have, or are at risk for, diabetes.”¹³² *Healthy People 30* lists five general objectives:

- Reduce the number of diabetes cases diagnosed yearly
- Increase the proportion of adults with diabetes who have a yearly eye exam
- Reduce the rate of death from any cause in adults with diabetes
- Increase the proportion of people with diabetes who get formal diabetes education
- Increase the proportion of adults with diabetes using insulin who monitor their blood sugar daily.¹³³

¹²⁸ Powers, Margaret A.; Bardsley, Joan K.; Cypress, Marjorie et al. “Diabetes Self-Management Education and Support in Adults with Type 2 Diabetes: A Consensus Report of the American Diabetes Association, the Association of Diabetes Care & Education Specialists, the Academy of Nutrition and Dietetics, the American Academy of Family Physicians, the American Academy of PAs, the American Association of Nurse Practitioners, and the American Pharmacists Association.” *Diabetes Care*. July 2020. Vol. 43. No. 7, <https://doi.org/10.2337/dci20-0023>.

¹²⁹ Ibid.

¹³⁰ Ibid.

¹³¹ Ibid.

¹³² *Healthy People 2030: Diabetes: Overview and Objectives*, <https://health.gov/healthypeople/objectives-and-data/browse-objectives/diabetes>.

¹³³ Ibid.

Specific objectives address various aspects of diabetes care and management, its complications, and prevention. Three of these objectives refer to chronic kidney disease, which is one of the most serious diabetes complications:

- Increase the proportion of people on Medicare with chronic kidney disease who get recommended tests
- Increase the proportion of adults with diabetes who get a yearly urinary albumin test
- Increase the proportion of adults with diabetes and chronic kidney disease who get ACE inhibitors or ARBs.

Health care objectives are to reduce the proportion of adults with diabetes who have an A1C value above 9 percent and to reduce the rate of foot and leg amputations in adults with diabetes.

Two of the specific objectives are aimed at overweight and obesity as risk factors for diabetes: to reduce the proportion of adults who do not know they have diabetes, and to increase the proportion of eligible people completing CDC-recognized type 2 diabetes prevention programs.

Other specific objectives include reducing emergency department visits for insulin overdoses, reducing the rate of hospital admissions for diabetes among older adults, and reducing vision loss from diabetic retinopathy.¹³⁴

In addition to announcing the goals and objectives, *Healthy People 2030* offers an overview of evidence-based resources (EBRs) to inform stakeholders about proven, science-based methods to improve diabetes care and management. The list of evidence-based resources related to diabetes includes four:

- Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening
- Diabetes Management: Intensive Lifestyle Interventions for Patients with Type 2 Diabetes
- Screening for Prediabetes and Type 2 Diabetes Mellitus
- Medicare Diabetes Prevention Program.¹³⁵

The Medicare Diabetes Prevention Program (MDPP) expanded model is an expansion of the Diabetes Prevention Program (DPP) model test, which was tested through the Center for Medicare and Medicaid Innovation's Health Care Innovation Awards. The final rule establishing the expansion was finalized in the Calendar Year (CY) 2017 Medicare Physician Fee Schedule (PFS) final rule published in November 2016. In November 2017, the Centers for Medicare and Medicaid Services (CMS) issued the CY 2018 PFS final rule, which established policies related to the set of the MDPP services, including beneficiary eligibility criteria and the MDPP payment structure as well as supplier enrollment requirements and compliance standards aimed at enhancing program integrity. In CMS's 2021 Physician Fee Schedule (PFS), the agency suggested

¹³⁴ Ibid.

¹³⁵ *Healthy People 2030: Diabetes: Evidence-Based Resources*, <https://health.gov/healthypeople/objectives-and-data/browse-objectives/diabetes/evidence-based-resources>.

changes intended “to boost MDPP Supplier Enrollment and Medicare Beneficiary participation in the MDPP.”¹³⁶

Medicare beneficiaries are eligible for the MDPP if they are overweight or obese and have prediabetes. The MDPP began serving Medicare beneficiaries on April 1, 2018. The evaluation of the program performance from April 2018 to December 2019 indicated that “the initial beneficiaries that have enrolled in the MDPP have lost weight, thereby meeting a key short-term goal of the program. At this point, it is too early and there are not a sufficient number of participants to determine whether the program lowers Medicare expenditures, reduces utilization, or prevents diabetes.”¹³⁷ Weight loss and self-reported levels of physical activity among MDPP participants appear to be promising though it is too early to assess long-term health outcomes.

Consensus Statement on U.S. Health Care Reform for People with Diabetes

In November 2020, twelve independent, non-profit national diabetes organizations issued a consensus statement expressing their shared position on the problems people with diabetes are facing in the existing health care and medical insurance system and offering suggestions for improvement. The coalition was led by the Diabetes Leadership Council. Other participating organizations were the Association of Diabetes Care & Education Specialists, Beyond Type 1 / Beyond Type 2, the Certification Board for Diabetes Care and Education, the Children with Diabetes, the College Diabetes Network, the Diabetes Dietetic Practice Group of the Academy of Nutrition and Dietetics, the Diabetes Patient Advocacy Coalition, the DiabetesSisters, the diaTribe Foundation, the JDRF, and the T1D Exchange. These twelve national diabetes organizations convened in a virtual working group to align on a patient-centered framework for U.S. health care reform. The diabetes health care reform (DHCR) working group formulated its objective in the following way: “Articulate for policymakers and health care system stakeholders how our nation’s complicated health care and coverage system works for -- and sometimes against -- people with diabetes, and provide tangible ideas for improvement.”¹³⁸

The DHCR working group started its work before the COVID-19 pandemic, which added urgency to the U.S. need to address comprehensive health care reform and also indicated certain ways of improvement. Several of these improvements enacted temporarily during the pandemic present a unique opportunity to reduce access barriers and to find new pathways to care for millions of Americans who have diabetes.

¹³⁶ Centers for Medicare and Medicaid Services. *Medicare Diabetes Prevention Program (MDPP) Expanded Model*, <https://innovation.cms.gov/innovation-models/medicare-diabetes-prevention-program>.

¹³⁷ Centers for Medicare and Medicaid Services. *Medicare Diabetes Prevention Program (MDPP) Expanded Model: Evaluation of Performance April 2018 – December 2019*, <https://innovation.cms.gov/data-and-reports/2021/mdpp-firstannevalrpt-fg>.

¹³⁸ *Consensus Statement on U.S. Health Care Reform for People with Diabetes*. November 2020, https://www.diabeteseducator.org/docs/default-source/advocacy/diabetes_health_care_reform_consensus_statement.pdf?sfvrsn=2.

It is widely recognized that “diabetes is unaffordable without comprehensive health coverage.”¹³⁹ Based on 2017 data, the ADA assessed health care costs of people with diabetes to average \$16,750 annually, more than double than the amount for a person without diabetes.¹⁴⁰ The authors of the consensus report remind their readers that “affordable insulin is the bedrock of diabetes management for 1 in 3 people with diabetes,” and at the same time, insulin is “only one piece in a mosaic of medicines, medical devices, software, supplies, services, medical nutrition therapy (MNT) and diabetes self-management education and support (DSMES) the disease demands.”¹⁴¹ The consensus statement underscores that “diabetes care is preventive care. Long-term health care costs for people with diabetes are lower when they have the medications, devices and services they need to manage their disease.”¹⁴² Public and private health plans normally cover diabetes complications, including amputations, blindness, heart attack, stroke, and end-stage renal disease. These can be devastating for the patients and very expensive for the insurance companies. The consensus statement contends that “now is the time to ensure people with diabetes have adequate coverage for individualized care that can prevent or delay the onset of these costly and life limiting complications.” The argument is that the shift is not only better for people with diabetes and their families, but also “a wiser investment of health care dollars for payers, especially in the face of a diabetes epidemic.”¹⁴³ Advocates caution that too many people who have diabetes or are at risk for the disease do not have health coverage for life-sustaining care. Even those who do sometimes face serious problems. The consensus statement points out that “health benefit structures that shift costs to patients – including inflated list prices rather than discounted plan rates – create a reverse insurance system that disproportionately burdens people with chronic diseases like diabetes.”¹⁴⁴ The twelve national diabetes organizations that participated in the preparation of the consensus report strongly advocate for the evidence-based reallocation of the nation’s health care dollars that “shifts investment toward earlier diabetes care and education to help delay or prevent the onset of costly diabetes complications later in life”; it would be most beneficial for people with diabetes and their families.¹⁴⁵

Consensus findings and recommendations are the following:

1. Preservation of coverage gains afforded under the Patient Protection and Affordable

Care Act (PPACA), specifically pre-existing condition coverage and qualified health plan structure that would include essential health benefit (EHB) requirements, prohibit annual or lifetime coverage limits, and meet or exceed the minimum actuarial value standard.

¹³⁹ Ibid.

¹⁴⁰ American Diabetes Association. “Economic Costs of Diabetes in the US in 2017.” *Diabetes Care*. Vol. 41. May 2018, <https://doi.org/102337/dci18-0007>.

¹⁴¹ *Consensus Statement on U.S. Health Care Reform for People with Diabetes*. November 2020, https://www.diabeteseducator.org/docs/default-source/advocacy/diabetes_health_care_reform_consensus_statement.pdf?sfvrsn=2.

¹⁴² Ibid.

¹⁴³ Ibid.

¹⁴⁴ Ibid.

¹⁴⁵ Ibid.

2. Essential Diabetes Health Benefits (EDHBs)

Future U.S. health care reform should further define a set of chronic disease management or Essential Diabetes Health Benefits (EDHBs) to be covered pre-deductible, including safe harbor for High Deductible Plans (HDHPs) with and without Health Savings Accounts (HSAs). All U.S. Health plans should provide first-dollar coverage for insulin, glucagon, and other health care products and services prescribed to managed and insured's diabetes or diabetes-related conditions or complications. This includes prescription medicines, medical devices, software, services, supplies, medical nutrition therapy (MNT) and diabetes self-management education and support (DSMES).

3. Predictable cost benefits

People with diabetes should have no or low, predictable cost sharing for diabetes management tools and education, commensurate with other preventive care.

4. Rebate and discount pass-through

Patient out-of-pocket costs at the point-of-sale, particularly for medicines and devices, should fully reflect all related discounts and rebates negotiated or mandated across the supply chain. Rebate pass-through will help reduce patient costs in the near-term, but further national reforms are needed to eliminate or modify rebate policies and the misaligned incentives they cause in our health care system.

Reverse insurance, spread pricing or otherwise requiring patients to pay more than net price can make essential medicines like insulin unaffordable to people with diabetes. Prescription drug coverage should mirror coverage for office visits, lab tests, and other facets of care where patient cost sharing reflects discounted plan rates.

5. Limiting delays in diabetes care

Health care utilization management methods, like step therapy and prior authorization, unnecessarily restrict access to appropriate, individualized diabetes care when they are based on health insurer or pharmacy benefit manager (PBM) financial incentives rather than evidence-based clinical practice guidelines. Utilization management for prescribed diabetes products or services should be eliminated or strictly limited to avoid delays in care and ease administrative burdens on patients and providers. All diabetes coverage determinations should be adjudicated within 24-72 hours.

6. Patient and prescriber prevail

All U.S. plans should cover medically necessary prescription medications to treat diabetes and its complications or comorbidities, including non-formulary or non-preferred products. Given the complex and individualized nature of diabetes

management regimens, product selection should be a shared decision between the person with diabetes and his or her healthcare provider. The prescriber's determination that a product is medically necessary and warranted should be final, consistent with the doctor's reasonable professional judgment and clinical documentation of accepted use of such products.

7. Non-medical switching

Non-medical switching -- therapy changes prompted by insurance formularies rather than medical necessity or clinical efficacy -- rarely provides clinical value to patients and instead disrupts stable treatment regimens. Rebate-driven formulary changes prioritize plan revenue without necessarily reducing consumer costs. Health plans should not require people with diabetes to switch away from using products that work for them.

8. Patient-centered value

Transitioning our health care system from fee-for-service that pays for quantity of care to a system that pays for value or quality of care must utilize measures that patients value, particularly in chronic disease care. Value-based insurance design (VBID) in diabetes will fall short if payers and providers emphasize A1C but neglect time in range,¹⁴⁶ reducing hypoglycemia, cardiovascular and renal protection, behavioral health, improved quality of life and other measures that people with diabetes value.¹⁴⁷

The twelve national organizations that issued the consensus statement argue that diabetes “requires a different lens than many other chronic, progressive conditions”: it is self-managed and highly individualized, with the person of diabetes, his or her parent or guardian making multiple day-to-day diabetes care decisions.¹⁴⁸ The focal point of the consensus statement is that “we should eliminate barriers to diabetes care and coverage, rather than placing it beyond reach through high deductibles, exposure to list prices rather than net prices, restrictive formularies and administrative hoops.”¹⁴⁹ The authors provide multiple specific examples of these barriers and identify specific steps to improve health care provider access, facilitate faster care decisions, and improve coverage/care connections. An important area of diabetes care and management is affordable access to innovation.

¹⁴⁶ Battelino, Tadej; Danne, Thomas; Bergenstahl, Richard M. et al. “Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations from the International Consensus on Time in Range.” *Diabetes Care*. June 2019. Vol. 42. No. 8, doi: 10.2337/dci19-0028.

¹⁴⁷ *Consensus Statement on U.S. Health Care Reform for People with Diabetes*. November 2020, https://www.diabeteseducator.org/docs/default-source/advocacy/diabetes_health_care_reform_consensus_statement.pdf?sfvrsn=2.

¹⁴⁸ *Ibid.*

¹⁴⁹ *Ibid.*

The consensus report specifically addresses various aspects of diabetes management coverage in commercial insurance, Medicare, and Medicaid and suggests clear, consistent recommendations, which, if implemented, can lead to significant improvement in diabetes care.

Severe COVID-19 Outcomes in Patients with Diabetes and the Link of COVID-19 with New-Onset Diabetes

The COVID-19 pandemic presented additional threats and challenges to people with diabetes. Increased risks of COVID-19 to people with diabetes became apparent in the early stages of the pandemic. Soon after the World Health Organization (WHO) declared the COVID-19 outbreak to be a public health emergency of international concern in March 2020, the International Diabetes Federation (IDF) issued a warning to people with diabetes that they appeared to be more vulnerable to becoming severely ill with the COVID-19 virus. At that point, IDF indicated two possible reasons for this: “Firstly, the immune system is compromised, making it harder to fight the virus and likely leading to longer recovery period. Secondly, the virus may thrive in an environment of elevated blood glucose.”¹⁵⁰ IDF encouraged people with diabetes to keep informed of the latest developments by looking out for updates, to take extra precautions to avoid the virus if possible; it stressed that the recommendations widely issued to the general public are “doubly important to people living with diabetes and anyone in close contact with people living with diabetes.”¹⁵¹

In the U.S., CDC put type 2 diabetes mellitus and type 1 diabetes mellitus on the list of underlying medical conditions that place patients at increased risk of severe illness from the virus that causes COVID-19. Severe illness from COVID-19 “is defined as hospitalization, admission to the ICU, intubation or mechanical ventilation, or death.”¹⁵² The Centers for Disease Control and Prevention suggested a set of actions that people with diabetes can take based on their medical condition.

During the course of the pandemic, growing epidemiological data from a number of countries have confirmed that people with diabetes are at higher risk of severe clinical outcomes of COVID-19. In light of these findings, several diabetes federations around the world have issued statements and developed guidelines for people with diabetes so they could better understand their risk of COVID-19 and better manage their condition. In May 2020, an international panel of experts in the field of diabetes and endocrinology published in *The Lancet Diabetes & Endocrinology* practical recommendations for clinicians regarding the management of diabetes during the pandemic.

¹⁵⁰ International Diabetes Federation. *COVID-19 and Diabetes*. Update of March 11, 2020, <https://www.idf.org/aboutdiabetes/what-is-diabetes/covid-19-and-diabetes/1-covid-19-and-diabetes/>.

¹⁵¹ Ibid.

¹⁵² Centers for Disease Control and Prevention. *COVID-19. People with Certain Medical Conditions*, <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions/>. Accessed 01.06.2021.

The initial outbreak of COVID-19 in China immediately revealed that patients with diabetes who were infected had poor prognosis. Initial focus was on people with type 2 diabetes, but later it became clear that people with type 1 diabetes were also at risk of severe COVID-19. With more data available, doctors surmised that the reason for worse prognosis in people with diabetes was “likely to be multifactorial, thus reflecting the syndromic nature of the disease.”¹⁵³ A group of Italian physicians pointed to a variety of factors including age, gender, sex, ethnicity, comorbidities such as hypertension and cardiovascular disease, obesity, and pro-inflammatory and pro-coagulative state that could all contribute to the risk of worse outcomes. These experts also suggested that “severe acute respiratory syndrome coronavirus 2 infection itself might represent a worsening factor for people with diabetes, as it can precipitate acute metabolic complications through direct negative effects on β -cell function. These effects on β -cell function might also cause diabetic ketoacidosis in individuals with diabetes, hyperglycemia at hospital admission in individuals with unknown history of diabetes, and potentially new-onset diabetes.”¹⁵⁴

Early data from hospitals in Wuhan and from Great Britain showed that patients who had diabetes were more likely to require admission to an intensive care unit (ICU) or to die. One of the earlier studies coming from China pointed to unfavorable outcomes for COVID-19 patients who also had diabetes: “A higher proportion of intensive care unit admission (17.6% vs. 7.8%, $P = 0.01$) and more fatal cases (20.3% vs. 10.5%, $P = 0.017$) were identified in COVID-19 patients with diabetes than in the matched patients.”¹⁵⁵ Multiple studies from various countries had similar findings. A systematic review and meta-analysis of carefully selected relevant studies (13 in total), published between January 1, 2020 and March 20, 2020, investigated the clinical characteristics of COVID-19 patients with critical/mortal illness and non-critical illness and identified diabetes as a condition that could “greatly affect the prognosis of the COVID-19.”¹⁵⁶ The prevalence of diabetes and obesity was notably higher in individuals who had to be admitted to hospital than those not admitted. A meta-analysis of eight studies found diabetes mellitus to be the second among more frequent comorbidities and found that “diabetic patients with COVID-19 patients are at higher risk of ICU admission and show an higher mortality risk.”¹⁵⁷

¹⁵³ Apicella, Matteo et al. “COVID-19 in People with Diabetes: Understanding the Reasons for Worse Outcomes.” *The Lancet Diabetes and Endocrinology*. Published online July 17, 2020, [https://doi.org/10.1016/S2213-8587\(20\)30238-2](https://doi.org/10.1016/S2213-8587(20)30238-2).

¹⁵⁴ Ibid.

¹⁵⁵ Shi, Qiao et al. “Clinical Characteristics and Risk Factors for Mortality of COVID-19 Patients with Diabetes in Wuhan, China: A Two-Center, Retrospective Study.” *Diabetes Care*. July 2020. Vol. 43. No. 7, <https://doi.org/10.2337/dc20-0598>.

¹⁵⁶ Zheng, Zhaohai et al. “Risk Factors of Critical & Mortal COVID-19 Cases: A Systematic Literature Review and Meta-Analysis.” *Journal of Infection*. August 2020. Vol. 81. No. 2, doi: 10.1016/j.jinf.2020.04.021.

¹⁵⁷ Roncon, Loris; Zuin, Marco; Rigatelli, Gianluca; and Zuliani, Giovanni. “Diabetic Patients with COVID-19 Infection are at Higher Risk of ICU Admission and Poor Short-term Outcome.” *Journal of Clinical Virology*. June 2020. Vol.127. No.104354, doi: 10.1016/j.jcv.2020.104354.

A whole-population study in England assessed risks of in-hospital death with COVID-19 between March 1 and May 11, 2020. The results of this nationwide study show that “type 1 and type 2 diabetes were both independently associated with a significant increased odds of in-hospital death with COVID-19.”¹⁵⁸ That was the first study to investigate the relative and absolute risks of death in hospital with COVID-19 by type of diabetes, adjusting for key confounders, and the findings were disquieting. The researchers found that “a third of all hospital deaths with COVID-19 in England between March 1 and May 11, 2020 occurred in people with diabetes. Unadjusted mortality rates over the 72-day observation period were significantly higher for people with type 2 diabetes than for people with type 1 diabetes, with both being significantly higher than for people without diabetes.”¹⁵⁹ To achieve better precision and accuracy, the authors made various adjustments, and even with those adjustments, the results remained formidable: “After adjustment for age, sex, deprivation, ethnicity, and geographical region, people with type 1 diabetes had 3.5 times the odds of in-hospital death with COVID-19 and people with type 2 diabetes had twice the odds, relative to people without diabetes. Further adjustment for cardiovascular comorbidities slightly attenuated the odds for people with type 1 and type 2 diabetes, but these remained significantly greater than for people without diabetes.”¹⁶⁰ Mortality rates increased substantially by age group, but within each age group, rates were significantly higher for people with type 1 and type 2 diabetes than for those without diabetes. Modelling showed that “the relative effect of having diabetes was greater in young people, women, and those of black ethnicity.”¹⁶¹

As the pandemic went on, physicians continued their efforts to establish key pathophysiological mechanisms underlying the determinants of more severe outcomes of COVID-19 in people with diabetes. A worse prognosis for patients with COVID-19 who had diabetes was attributed to the concurring effect of multiple factors. One of them is common comorbidities, in particular obesity, hypertension, and cardiovascular disease. Several studies of patients with COVID-19 indicated that those with diabetes had a greater prevalence of hypertension, cardiovascular disease and cerebrovascular disease; moreover, “in the patients with diabetes, non-survivors had a greater prevalence of comorbidities than survivors.”¹⁶² Multiple reports have linked obesity to more severe COVID-19 illness and death. A French retrospective cohort study that analyzed the relationship between clinical characteristics, including BMI, and the requirement for invasive mechanical ventilation (IMV) in patients admitted in intensive care for COVID-19 showed a high frequency of obesity among patients admitted in intensive care for SARS-CoV-2 and an increase in disease severity with BMI. In fact, the risk for invasive mechanical ventilation was more than seven times higher in patients with a BMI of more than 35 kg/m than those with a BMI of less than 25 kg/m.¹⁶³

Obesity and diabetes are characterized by chronic low-grade inflammation. Low-grade chronic inflammation makes it more likely that patients with diabetes, when infected with COVID-

¹⁵⁸ Barron, Emma et al. “Associations of Type 1 and Type 2 Diabetes with COVID-19-Related Mortality in England: a Whole-Population Study.” *The Lancet Diabetes and Endocrinology*. October 2020. Vol. 8, [https://doi.org/10.1016/S2213-8587\(20\)30272-2](https://doi.org/10.1016/S2213-8587(20)30272-2).

¹⁵⁹ Ibid.

¹⁶⁰ Ibid.

¹⁶¹ Ibid.

¹⁶² Apicella, Matteo et al. “COVID-19 in People with Diabetes: Understanding the Reasons for Worse Outcomes.” *The Lancet Diabetes and Endocrinology*. Published online July 17, 2020, [https://doi.org/10.1016/S2213-8587\(20\)30238-2](https://doi.org/10.1016/S2213-8587(20)30238-2).

¹⁶³ Simonnet, Arthur et al. “High Prevalence of Obesity in Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) Requiring Invasive Mechanical Ventilation.” *Obesity*. July 2020. Vol. 28. No. 7, doi: 10.1002/oby.22831.

19, will respond with overproduction of pro-inflammatory cytokines, a so-called cytokine storm. The cytokine storm leads to high risk of vascular hyperpermeability, multiorgan failure, and death. It presents a grave danger to all patients with COVID-19; “those with diabetes are more susceptible to the destructive effect of the cytokine storm than those without diabetes.”¹⁶⁴

Another factor that may contribute to severe outcomes of COVID-19 in patients with diabetes is that COVID-19 has been associated with increased coagulation activity while diabetes is associated with a prothrombotic state, with an imbalance between clotting factors and fibrinolysis, which leads to an increased risk of thromboembolic events.

It has also been suggested that people with type 2 diabetes are at higher risk than the general population because they have more ACE2 receptors in many tissues, including those lining blood vessels, opening more doors to COVID-19 invasion (it is known that ACE2 is one receptor that the coronavirus’s spike protein uses to gain entry into cells).¹⁶⁵

Hyperglycemia, which is a defining feature of diabetes, appears to play a very important role in the outcomes of COVID-19 infection in patients with diabetes. Glycemic control appears to be important at various stages: before hospital admission, at the time of admission, and during hospital treatment. Several studies indicated that poor glycemic control was associated with a high risk of in-hospital death. Hyperglycemia at hospital admission turned out to be the best predictor of worst chest radiographic imaging results; it was also linked to a higher risk of ICU admission and mechanical ventilation. A retrospective observational study of laboratory-confirmed COVID-19 adults evaluated glycemic and clinical outcomes in patients with and without diabetes and/or acutely uncontrolled hyperglycemia hospitalized March 1 to April 6, 2020 in 88 U.S. hospitals. Based on their findings, the authors concluded: “Among hospitalized patients with COVID-19, diabetes and/or uncontrolled hyperglycemia occurred frequently. These COVID-19 patients with diabetes and/or uncontrolled hyperglycemia had a longer LOS [median length of stay – Y.K.] and markedly higher mortality than patients without diabetes or uncontrolled hyperglycemia. Patients with uncontrolled hyperglycemia had a particularly high mortality rate.”¹⁶⁶ In fact, mortality was more than four times higher in those with diabetes or hyperglycemia (28.8 percent) during the hospital stay than in those without diabetes or hyperglycemia (6.2 percent).¹⁶⁷ As hyperglycemia clearly contributes to worse prognosis in patients with COVID-19 and, on the contrary, good glycemic control was associated with a lower rate of complications and all-cause mortality, the authors, along with other clinicians, “recommend health systems ensure that inpatient hyperglycemia is safely and effectively treated.”¹⁶⁸ Various factors complicate this task, including specific mechanisms of the virus and the impact of certain therapies for COVID-19. Physicians observed that “diabetes management in patients with COVID-19 poses a great clinical challenge,

¹⁶⁴ Apicella, Matteo et al. Op. cit.

¹⁶⁵ Cooney, Elizabeth. “Why People with Diabetes Are Being Hit So Hard by COVID-19?” *STAT*, <https://www.statnews.com/2020/10/01/why-people-with-diabetes-are-being-hit-so-hard-by-COVID19>.

¹⁶⁶ Bode, Bruce et al. “Glycemic Characteristics and Clinical Outcomes of COVID-19 Patients Hospitalized in the United States.” *Journal of Diabetes Science and Technology*. July 2020. Vol. 14. No. 4, doi: 10.1177/1932296820924469. Published online May 9, 2020.

¹⁶⁷ Ibid.

¹⁶⁸ Ibid.

one that requires a much-integrated team approach, as this is an indispensable strategy to reduce the risk of medical complications and death as much as possible.”¹⁶⁹

With more data available, the scope of the investigations into the risk factors for worsening illness severity among the patients with diabetes has been enhanced. Specific studies were designed to distinguish between type 1 and type 2 diabetes as these are two pathophysiologically distinct conditions. A prospective cohort study based on the data from the Epic Clarity data warehouse at Vanderbilt University Medical Center (VUMC) sought to “quantify and contextualize the risk for coronavirus disease 2019 (COVID-19)-related hospitalization and illness severity in type 1 diabetes.”¹⁷⁰ This data warehouse encompasses an entire network of 137 primary care, urgent care, and hospital facilities that manages over two million ambulatory and in-patient visits annually. It allowed the researchers to examine a wider range of clinical outcomes across a broader spectrum of patients with type 1 diabetes infected with severe acute respiratory syndrome coronavirus (SARS-CoV-2). One of the strengths of this study is that it included not only every hospitalized patient, but also numerous patients in outpatient primary care, minor medical, and urgent care clinics (that is, many patients with milder symptoms) and even entirely asymptomatic patients who were tested by the hospital prior to their elective surgical procedures.

In their analysis of the data, the investigators categorized each patient by diabetes category: no diabetes, type 1 diabetes, or type 2 diabetes. To quantify the magnitude of COVID-19 severity, the researchers defined an ordinal outcome variable for illness severity with six mutually exclusive levels that occurred within 14 days of a positive PCR test for SARS-CoV-2:

- No hospitalization
- Hospitalization for any reason without any respiratory support
- Hospitalization for any reason with lower acuity respiratory support (e.g., oxygen by nasal canula, nonrebreather mask, or continuous or bilevel positive airway pressure)
- Intensive care unit (ICU) admission for any reason
- Endotracheal intubation and mechanical ventilation for any reason
- Death for any reason.

The data analysis showed that “next to age, the presence of diabetes was the most important factor in the multivariable ordinal regression model for illness severity.”¹⁷¹

¹⁶⁹ Apicella, Matteo et al.

¹⁷⁰ Gregory, Justin M. et al. “COVID-19 Severity Is Tripled in the Diabetes Community: A Prospective Analysis of the Pandemic Impact in Type 1 and Type 2 Diabetes.” *Diabetes Care*. Published online December 2, 2020, <https://doi.org/10.2337/dc20-2260>.

¹⁷¹ Ibid.

The investigators pinpointed two principal themes that emerged from their data regarding the severity of COVID-19 in type 1 diabetes:

1. After adjustment for age, race, and other risk factors, the odds of a COVID-19-related hospitalization and greater illness severity for patients with type 1 diabetes are three- to four-fold higher than patients without diabetes. This increased risk is approximately the same for patients with type 2 diabetes.
2. COVID-19 outcome severity in type 1 diabetes is associated with glycemic, vascular, and socioeconomic risk factors.¹⁷²

The authors of the Vanderbilt University study noticed that chronic hyperglycemia and vascular disease, social determinants of health, and decreased use of diabetes technology correlate significantly with outcome severity. Further elaborating on these findings, the investigators observed that “these factors represent common characteristics between type 1 and type 2 diabetes and suggest that addressing modifiable factors will reduce risk in all patients for diabetes.”¹⁷³

One of the life-threatening, acute complications of diabetes is diabetic ketoacidosis (DKA). To investigate a suspected increase in the frequency and severity of DKA due to the potential diabetogenic effect of COVID, a recent study focused specifically on patients with DKA with and without COVID-19. This cohort study included data from 175 hospitals located in 17 different states in the United States, collected from February 1 to September 15, 2020; the total number of patients was over 5,000.¹⁷⁴ The analysis revealed significantly higher mortality rates for DKA patients with COVID-19 compared to those without COVID-19: of patients without COVID, 5 percent died in the hospital compared with 30 percent among those with COVID-19.¹⁷⁵ Mortality increased with age among patients with and without COVID-19, but it was several times higher for patients with COVID-19 in all age groups. The overall in-patient mortality was 45 percent for patients older than 65 years with COVID-19 and 13 percent for those without COVID-19; in patients younger than 45 years, mortality was 19 percent for patients with COVID-19 compared with 2 percent in the non-COVID-19 group.¹⁷⁶ Other findings included the fact that patients with COVID-19 had higher insulin requirements and prolonged duration of computerized continuous insulin infusion with a longer time to resolution of DKA.¹⁷⁷ The researchers indicated several hypothetical contributing factors that could lead to higher mortality among hospitalized patients with DKA who had COVID-19, but stated that “the cause for the considerably higher mortality in the COVID-19-positive population is unknown” and encouraged further investigation.¹⁷⁸

¹⁷² Ibid.

¹⁷³ Ibid.

¹⁷⁴ Pasquel, Francisco J. et al. “Characteristics of and Mortality Associated with Diabetic Ketoacidosis Among US Patients Hospitalized With or Without COVID-19.” *JAMA Network Open*. 2021;4(3):e211091.doi:10.1001/jamanetworkopen.2021.1091.

¹⁷⁵ Ibid.

¹⁷⁶ Ibid.

¹⁷⁷ Ibid.

¹⁷⁸ Ibid.

A review of existing literature demonstrated multi-faceted two-way interactions between COVID-19 and diabetes mellitus:

Compromised innate immunity, pro-inflammatory cytokine milieu, reduced expression of ACE2 and use of renin-angiotensin-aldosterone system antagonists in people with diabetes mellitus contribute to poor prognosis in COVID-19. On the contrary, direct β -cell damage, cytokine-induced insulin resistance, hypokalemia and drugs used in the treatment of COVID-19 (like corticosteroids, lopinavir/ritonavir) can contribute to worsening of glucose control in people with diabetes mellitus.¹⁷⁹

Based on their findings, the authors concluded that “the two-way interaction between COVID-19 and diabetes mellitus sets up a vicious cycle wherein COVID-19 leads to worsening of dysglycemia and diabetes mellitus, in turn, exacerbates the severity of COVID-19. Thus, it is imperative that people with diabetes mellitus take all necessary precautions and ensure good glycemic control amid the ongoing epidemic.”¹⁸⁰

Other researchers, upon performing their review of multiple articles, encouraged further studies regarding the relationship between diabetes and COVID-19 and its clinical management and recommended “patient-tailored therapeutic strategies, rigorous glucose monitoring and careful consideration of drug interactions,” which might reduce adverse outcomes.¹⁸¹

In addition to the increased severity of COVID-19 in patients with diabetes, it has also been postulated that “SARS-CoV-2 exposure can precipitate type 1 diabetes onset.”¹⁸² In the fall of 2020, *The Lancet* editorial reported that data collected in London, UK, between March and June 2020 indicated an increase in the number of new type 1 diabetes cases in children compared with a typical year; although causality could not be established at that point, the findings caused grave concern.¹⁸³ Hospitals in the U.S. and in Italy also noticed increasing number of patients with COVID-19 who had elevated blood glucose levels. Many of those patients had no prior history of diabetes. Some patients who developed elevated blood sugar while they had COVID-19 returned to normal by the time they were discharged. “Others went home with a diagnosis of full-blown diabetes,” and some cases developed months after the virus was cleared from the body.¹⁸⁴ There were reports of diabetes diagnoses even after mild or asymptomatic coronavirus infections. According to an analysis performed by an international group of researchers who reviewed eight studies from different countries, as many as 14.4 percent of people hospitalized with severe

¹⁷⁹ Pal, Rimesh and Sanjay K. Bhadada. “COVID-19 and Diabetes Mellitus: An Unholy Interaction of Two Pandemics.” *Diabetes & Metabolic Syndrome*. July-August 2020. Vol. 14. No. 4, doi: 10.1016/j.dsx.2020.04.049.

¹⁸⁰ Ibid.

¹⁸¹ Hussain, Akhtar; Bhowmik, Bishwajit; and Nayla Cristina do Vale Moreira. “COVID-19 and Diabetes: Knowledge in Progress.” *Diabetes Research and Clinical Practice*. April 2020. Vol. 162. No. 108142, doi: 10.1016/j.diabres.2020.108142.

¹⁸² “COVID-19 and Diabetes: A Co-Conspiracy?” *The Lancet Diabetes and Endocrinology*. October 2020. Vol. 8, doi: 10.1016/S2213-8587(20)30315-6.

¹⁸³ Ibid.

¹⁸⁴ Blakemore, Erin. “New Diabetes Cases Linked to COVID-19.” *The Washington Post*. February 1, 2021.

COVID-19 developed diabetes.¹⁸⁵ The precise nature of the COVID-diabetes link is not fully understood yet. Physicians do not know the exact mechanism of COVID-19 triggering type 1 or type 2 diabetes. They speculate that the onset of diabetes may be a result of severe illness, or the direct impact of COVID-19 on β -cells or other structures in the pancreas, or treatment with steroids. There is even a suspicion that “the novel coronavirus may have spawned an entirely new type of diabetes that might play out differently from the traditional forms of the disease.”¹⁸⁶ Many clinicians are convinced there is an underlying connection between COVID-19 and diabetes that needs to be investigated further. A global registry of COVID-19-related diabetes, CoviDIAB, launched by a group of international experts in June 2020, “aims to investigate the extent and pathogenesis of new-onset diabetes and metabolic dysfunction in pre-existing patients with diabetes to help uncover novel mechanisms of disease and define the best interventions.”¹⁸⁷

Changes in Diabetes Care During the Pandemic

A comprehensive analysis of the pandemic’s impact on the diabetes community should include not only greater COVID-19 severity in patients with type 1 and type 2 diabetes, but also changes in diabetes care that occurred during the pandemic and their consequences.

As “diabetes and COVID-19 may lead the patient in a vicious cycle, with unpredictable and possibly unfavorable consequences,” endocrinologists around the world urged that “infection prevention measures should be strictly followed.”¹⁸⁸ Diabetes management directions during the pandemic included social distancing and good hygiene as “the norm of an effective prevention strategy”; tight glucose control; access to health care providers, which may be achieved via telehealth for some services; and adequate supplies of medication as well as glucose lancets, strips, or sensors for home use.¹⁸⁹ In addition, clinicians recommended involvement of social care professionals as stress management is crucial for mental and overall health.

Soon after the onset of the pandemic, diabetes experts realized that as well as “posing direct immediate risks” to people with diabetes, “COVID-19 also risks contributing to worse diabetes outcomes due to disruptions caused by the pandemic, including stress and changes to routine care, diet, and physical activity.”¹⁹⁰

Health and economic impact on people with diabetes turned out to be more severe than on other populations groups. The data collected by dQ&A, a social enterprise that specializes in quantitative and qualitative research and is committed to improving life for people with diabetes, showed “the disturbing trend within the diabetes population in the U.S. of high unemployment and

¹⁸⁵ Ibid.

¹⁸⁶ Ibid.

¹⁸⁷ “COVID-19 and Diabetes: A Co-Conspiracy?” *The Lancet Diabetes and Endocrinology*. October 2020. Vol. 8, doi: 10.1016/S2213-8587(20)30315-6.

¹⁸⁸ Doupis, John and Konstantinos Avramidis. “Managing Diabetes During the COVID-19 Pandemic.” *European Endocrinology*. October 2020. Vol. 16. No. 2, doi: 10.17925/EE.2020.16.2.85.

¹⁸⁹ Ibid.

¹⁹⁰ Hartmann-Boyce, Jamie et al. “Diabetes and COVID-19: Risks, Management, and Learnings from Other National Disasters.” *Diabetes Care*, August 2020. Vol. 43, <https://doi.org/10.2337/dc20-1192>.

worsening health outcomes as they are severely and disproportionately impacted by the COVID-19 pandemic.”¹⁹¹

In association with the American Diabetes Association, dQ&A conducted a national online survey of 5,000 people with diabetes, between June 26, 2020 and July 1, 2020. The survey details the economic strains experienced by this population at the time when they are already facing “a daunting threat from severe complications and outcomes from COVID-19.”¹⁹² The survey revealed how COVID-19 has compounded financial pressure on the diabetes community:

- In June 2020, the unemployment rate among people with diabetes was higher than the national rate: 18 percent versus 12 percent.
- Among those working, 33 percent of people with diabetes have lost some or all income, also higher than the general population rate.
- Two groups within the diabetes community are facing extreme impact:
 - Low-income: half have lost some or all income.
 - Self-employed: 7 in 10 have lost some or all income.
- 24 percent of people with diabetes have used savings, loans, or money from their stimulus checks for diabetes care in the past three months. Those on Medicare are no exception.
- Half of those who have lost income are using savings or stimulus money.
- People with poor diabetes management are leaning more on savings and stimulus money than those who have their diabetes under control.
- People with diabetes already face medical costs nearly 2.5 times higher than those without. What happens when their savings and stimulus money run out?¹⁹³

Additional economic strains caused by the pandemic have direct, significant impact on diabetes management as people with diabetes are rationing supplies to save money. According to the survey findings,

- A quarter of people with diabetes have turned to self-rationing supplies to cut the cost of diabetes care.
- Rationing insulin was already a problem, now made worse.

¹⁹¹ American Diabetes Association. *New Data Highlights Severe Health and Economic Impact of Pandemic on Millions Living with Diabetes: Press Release*. July 29, 2020, <https://www.diabetes.org/newsroom/press-releases/2020/new-data-highlights-severe-health-and-economic-impact-of-pandemic-on-millions-living-with-diabetes>.

¹⁹² Ibid.

¹⁹³ dQ&A - The Diabetes Research Company and the American Diabetes Association. *Diabetes and COVID-19: New Data Quantifies Extraordinary Challenges Faced by Americans with Diabetes During Pandemic*, https://www.diabetes.org/sites/default/files/2020-07/7.29.2020_dQA-ADA%20Data%20Release.pdf.

- 650,000 insulin patients are skipping injections or taking less insulin than prescribed.
 - 3 million people are skipping blood glucose tests.
- Self-rationing is the opposite of the CDC’s advice to people with diabetes during COVID-19. Worse still, people with high A1C are more likely to ration.
 - Rationing further increases the likelihood of bad outcomes from COVID-19 in the short term – and will drive up the cost of diabetes complications in the long term.¹⁹⁴

As COVID-19 poses especially high danger of severe disease and death to people with diabetes, all experts urge them to make every effort to avoid infection and to strenuously follow the social distancing guidelines. It is, however, impossible for a large part of people with diabetes in the workplace. The dQ&A survey demonstrates that lockdowns have left much of the diabetes community largely unprotected:

- Working from home is not an option for half of the working diabetes population.
- In March, 4 in 10 working Americans with diabetes were in jobs that could not be done from home.
- At the time of the survey, half of employed people with diabetes were going in to work full-time or part-time.
- 60 percent of these workers are in essential industries. 22 percent are in healthcare.
- 9 out of 10 are often or sometimes within six feet of others at work.
- Only 7 in 10 are required to wear a mask at work.¹⁹⁵

The researchers who conducted the survey point out that these numbers represent a conservative estimate of the pandemic’s impact on the diabetes community. Summarizing the survey findings, the founder of dQ&A, Richard Wood, said, “We have a population of 34 million people with diabetes who face deadly consequences if they contract COVID-19. They are facing financial hardship, rationing their diabetes care to make ends meet, and being exposed to extra risk in the workplace. Keeping them healthy should be our number one goal.”¹⁹⁶

Realizing the heightened danger of COVID itself for patients with diabetes and other serious chronic diseases as well as COVID-related barriers to care, the National Association of Chronic Disease Directors (NACDD), with funding from CDC, and in partnership with CBS

¹⁹⁴ Ibid.

¹⁹⁵ Ibid.

¹⁹⁶ American Diabetes Association. *New Data Highlights Severe Health and Economic Impact of Pandemic on Millions Living with Diabetes: Press Release*. July 29, 2020, <https://www.diabetes.org/newsroom/press-releases/2020/new-data-highlights-severe-health-and-economic-impact-of-pandemic-on-millions-living-with-diabetes>.

television, launched a nationally syndicated public service announcement series and a companion bilingual website, yourhealthbeyondcovid.org, “to help Americans manage chronic diseases safely during the COVID-19 pandemic.”¹⁹⁷ The website developed by Nicely Built and NACDD, in collaboration with the Black Creative Group and the Hispanic Communication Network, provides news and information for those with illnesses whose health could worsen during the pandemic, “whether through lack of treatment, lack of access to treatment, or by becoming ill from COVID-19.”¹⁹⁸ In addition to the website, the educational outreach strategy developed by NACDD included a series of broadcast and social media messages that would resonate with populations most impacted by COVID-19 and would facilitate safe chronic disease management during a pandemic.

An international panel of experts summarized evidence identified through reviews in several countries with high rates of COVID-9 in 2019-2020 (China, France, Italy, the U.K., and the U.S.) and analyzed various strategies these countries used to support people with diabetes during the pandemic. Leaders in diabetes care from these countries considered diabetes treatment and management in a broader perspective of long-term conditions during national emergencies and focused on various ways to mitigate the risks presented by such events.

The resulting report addresses various aspects of COVID-19 impact in people with diabetes: contracting the COVID-19 infection, disease severity, association between blood glucose control and COVID-19 outcomes, as well as indirect risks to people with diabetes posed by COVID-19 such as disruptions to health care services, diet and physical activity, and increased rates of anxiety and depression. Disruptions to health care services have already been shown to lead to worse diabetes outcomes during and after other national emergencies. Diet and physical activity are considered mainstays of diabetes self-management. Less healthy diet and limited exercise during the pandemic and similar events can increase the risk of worse outcomes in people with diabetes. Pandemic-related stress can be especially harmful to people with diabetes; anxiety and depression caused by social isolation may lead to poor adherence to medications.

The article written by the international panel of experts summarizes various considerations for diabetes management during national emergencies. It identifies appropriate forms of contact (telehealth or face-to-face) with health care providers dependent on the circumstances and delineates guidelines for community and self-management such as self-/remote monitoring of blood glucose; support for stress, diabetes-related distress, and mental health issues; community-based mechanisms to ensure access to appropriate foods; and encouraging regular physical activity while taking into account isolation constraints. Patient education, proactive review of patients, clear point of contact for all patients, and extended prescriptions for medical supplies are some of the highlights at all levels.¹⁹⁹

¹⁹⁷ National Association of Chronic Disease Directors. *NACDD Launches “Your Health Beyond COVID” Website with Bilingual Resources to Help Manage Chronic Disease During the Pandemic*, <https://www.prnewswire.com/news-releases/nacdd-launches-your-health-beyond-covid-website-with-bilingual-resources-to-help-manage-chronic-disease-during-the-pandemic-301234777.html>.

¹⁹⁸ Ibid.

¹⁹⁹ Hartmann-Boyce, Jamie et al. “Diabetes and COVID-19: Risks, Management, and Learnings from Other National Disasters.” *Diabetes Care*, August 2020. Vol. 43, <https://doi.org/10.2337/dc20-1192>.

Based on the experience of several countries, the authors compiled a list of guidelines and recommendations relating to routine care in patients with diabetes during the COVID-19 pandemic, incorporating various aspects of diabetes management. They also suggested several planning and response strategies for mitigating risks to management of long-term conditions during national emergencies.²⁰⁰

With regard to the United States, the authors noted that the lack of universal health coverage poses additional challenges to patients with diabetes and their care providers during the COVID-19 pandemic, when a number of patients have lost insurance coverage and many are experiencing problems with insulin and other diabetes medications and testing supplies.²⁰¹ In all countries, natural disasters tend to exacerbate existing health disparities.

The international experts caution that “a lack of access to routine care is a leading cause of morbidity and mortality after disasters; stroke, acute myocardial infarctions, and diabetes complications are all shown to increase after the immediate threat has dissipated,” and they conclude with a forceful statement: “History issues a stark warning here when considering the balance between diverting resources toward the acute COVID-19 crisis and maintaining routine care for people living with long-term conditions.”²⁰² This is a meaningful reminder to healthcare providers and policymakers.

Public health experts describe the COVID-19 pandemic as “a mass casualty incident of the most severe nature leading to unearthed uncertainties around management, prevention, and care.”²⁰³ Patients with diabetes were among those most severely affected by the pandemic, and changes in diabetes care were made by healthcare systems in response to this public health crisis. The analysis of these changes is important both for the understanding of diabetes care during this pandemic and for future decisions. A team of endocrinologists and public health specialists from Emory University in Atlanta, GA, reviewed a variety of emergent changes improvised to address the pandemic challenge, including both “adaptations in diabetes care in the hospital (i.e., changes in treatment protocols according to clinical status, diabetes technology implementation) and outpatient setting (telemedicine, mail delivery, patient education, risk stratification, monitoring)” and presented a set of “strategies to address and evaluate transitions in diabetes care occurring in the immediate short-term (i.e., response and mitigation), as well as phases to adapt and enhance diabetes care during the months and years to come while also preparing for future pandemics (i.e., recovery, surveillance, and preparedness).”²⁰⁴

In the hospital setting, one of the main challenges consisted in ensuring effective glycemic control in those with diabetes and COVID-19 as hyperglycemia was associated with severity of disease and poor outcomes while at the same time limiting bedside interactions between patients and healthcare providers. To reduce these interactions, limit exposure to COVID-19, and reduce the waste of personal protection equipment, the Food and Drug Administration (FDA) allowed the use of home-use blood glucose meters and the use of continuous glucose monitoring (CGM) devices in the hospital setting. Medical companies Abbott and Dexcom that produce CGM devices made efforts to supply them for emergent inpatient use though CGM has not yet been approved in this setting. Certain CGM devices,

²⁰⁰ Ibid.

²⁰¹ Ibid.

²⁰² Ibid.

²⁰³ Gujral, Unjali P. et al. “Preparedness Cycle to Address Transitions in Diabetes Care During the COVID-19 Pandemic and Future Outbreaks.” *BMJ Open Diabetes Research & Care*. 2020. Vol. 8: e001520, doi:10.1136/bmjdr-2020-001520.

²⁰⁴ Ibid.

such as the Freestyle Libre (Abbott) or G6 (Dexcom), are factory-calibrated and do not require additional point-of-care (POC) glucose testing to ensure accuracy in the outpatient setting. Their current implementation in hospitals to reduce bedside POC glucose monitoring requires analysis and systematic evaluations for safety and efficacy; the same is true with regard to novel DKA management protocols adopted by some hospitals during the pandemic.

Positive results in inpatient care were reported by the University of North Carolina (UNC) School of Medicine, whose division of endocrinology largely transitioned to a virtual care model in response to the COVID-19 pandemic. The UNC division of endocrinology launched a diabetes management service through a diabetes care team (DCT) in July 2019, with the goal “to improve glycemic control and support various services with automatic consults for hyperglycemia and co-management through insulin order placement.”²⁰⁵ The UNC team did not use CGM in their model though it was authorized by the FDA for inpatient settings during the pandemic. They compared the glycemic trends among DCT patients from before and after the transition to virtual care. Their findings showed (through limited data) that effective care can be provided by using a virtual model: “glycemic control has not been affected by transition to virtual care.”²⁰⁶ Data over a 15-week period indicated that “using virtual care for diabetes management in the hospital is feasible and can provide similar outcomes to traditional face-to-face care.”²⁰⁷ The researchers concluded that “transitioning to virtual care models does not limit the glycemic outcomes of inpatient diabetes care and should be employed to reduce patient and provider exposure in the setting of COVID-19.”²⁰⁸ Moreover, they believe that their findings have broader implications: “Applying these learnings may benefit inpatients with hyperglycemia in dispersed communities, especially in remote places where specialized diabetes care may not be available. Telehealth also may have the potential to reduce the risk of nosocomial infections in the future.”²⁰⁹

In outpatient care, the need to minimize potential exposures to COVID-19 resulted in rapid shifts toward alternative methods of patient care such as virtual encounters (video or phone) and mail delivery of medications. The reach and effectiveness of these approaches requires further assessment though pre-pandemic studies offered some promising indications that telemedicine interventions, including teleconsultation and telemonitoring (device-based), may be equally or even more effective than usual care in managing diabetes, especially in certain groups of patients, and that mail delivery of medications may be associated with increased medication adherence; it is well-known that medication adherence is of paramount importance for patients with diabetes.²¹⁰

During the process of recovery, after the immediate threat of COVID-19 has abated, a new “normal” of diabetes care is likely to emerge. In particular, healthcare specialists foresee implementation of hybrid models of care delivery which may incorporate a combination of telemedicine and in-person visits. While such models sound promising, their advantages and limitations need further research; besides, different care settings will have varying capabilities to care for patients with diabetes remotely. Clinicians urge for rigorous postpandemic evaluation of the

²⁰⁵ Jones, Morgan S. et al. “Inpatient Transition to Virtual Care During COVID-19 Pandemic.” *Diabetes Technology and Therapeutics*. 2020. Vo. 22. No. 6, doi: 10.1089/dia.2020.0206.

²⁰⁶ Ibid.

²⁰⁷ Ibid.

²⁰⁸ Ibid.

²⁰⁹ Ibid.

²¹⁰ Gujral, Unjali P. et al. “Preparedness Cycle to Address Transitions in Diabetes Care During the COVID-19 Pandemic and Future Outbreaks.” *BMJ Open Diabetes Research & Care*. 2020. Vol. 8: e001520, doi:10.1136/bmjdr-2020-001520.

achievements and shortcomings of care during the height of the pandemic, with close examination of clinical diabetes care benchmarks, “to assess the impact of rapid shifts to telemedicine on clinical parameters.”²¹¹ Qualitative and quantitative data collection and analysis today are essential for better understanding of the impacts of virtual care on diabetes care and outcomes both in the near future and in case of another pandemic, “where widespread emergent telehealth-based care may be needed.”²¹²

The American Telemedicine Association (ATA) has been in existence since 1993 and currently has over 400 member organizations. Its members feel that telehealth played a critical role in spring 2020, stepping into the breach in the healthcare system caused by the pandemic. According to the ATA estimates, approximately 20 percent of all medical visits in 2020 were conducted by telehealth.²¹³ The ATA reports high level of consumer satisfaction with remote visits and would like to see the former regulatory barriers to telehealth removed permanently when the pandemic is over. However, even the ATA enthusiasts acknowledge that telehealth, while a great tool when used appropriately, is not a cure-all. Important issues related to telehealth include privacy and patient experience.

Privacy is equally relevant to all demographic groups. The level of experience and computer literacy is an especially important factor to consider when taking care of older adults, who represent a significant group of diabetes patients. COVID-19 highlighted severe challenges that older adults encountered during the pandemic due to the varying complexity of their medical condition, frailty, and multimorbidity as well as the significant difficulty for many of them to take advantage of telemedicine, of diabetes share apps or platforms such as LibreView, Glooko, or Dexcom Clarity that have enabled many patients to upload the data from their glucometers, continuous glucose monitors, or insulin pumps so that their physicians can make informed and timely decisions. The recent experience clearly demonstrated that “it needs to be recognized that not all older adults with diabetes are tech savvy or have computer access. Furthermore, up to 44% of older adults with diabetes have some form of cognitive dysfunction. In these situations, a telemedicine visit may lead to frustration and distress for both the clinician and the patient.”²¹⁴ Experts from the Joslin Medical Center and Harvard Medical School recommend that clinicians identify such patients ahead of time and schedule longer phone appointments with them so that patients can read their glucose values over the phone. In case a patient does not show up for his or her appointment, it should prompt further investigation to find out whether the patient has fallen or experienced severe hypoglycemia. It is especially important when a patient is living alone or when stay-at-home advisories are in place. Reassessment of the diabetes treatment plan, simplifying it and prioritizing patient goals, may also be helpful. Ensuring that patients have adequate prescription refills, such as a 90-day supply, for diabetes medications, pump supplies, and glucose monitoring supplies may help prevent crisis situations.²¹⁵ During the pandemic, healthcare teams should strive to address various needs of the vulnerable older population. There are practical strategies that can be used to meet multiple challenges for older adults during the pandemic and other national disasters. Many of the lessons learnt during the pandemic should be kept in mind in the future as telemedicine will continue to be utilized for diabetes care.

²¹¹ Ibid.

²¹² Ibid.

²¹³ Zebley, Kyle. *Telehealth and the COVID-19 Pandemic: Presentation at the Pennsylvania Diabetes Action Network (DAN) Virtual Meeting on November 9, 2020.*

²¹⁴ Sy, Sarah L. and Medha N. Munshi. “Caring for Older Adults with Diabetes During the COVID-19 Pandemic.” *JAMA Internal Medicine*. September 2020. Vol. 180. No. 9, doi:10.1001/jamainternmed.2020.2492.

²¹⁵ Ibid.

As time passes, more data become available that allow for a better understanding of diabetes management and glycemic control during the pandemic. A recent extensive study compared weekly rates of diabetes-related outpatient visits, screening tests, medication fills, and patients HbA1c levels in 2020 versus 2019 in a national cohort of adults with type 2 diabetes. The study involved adult individuals with type 2 diabetes and continuous enrollment in commercial or Medicare Advantage health plans. The analysis revealed that across the entire pandemic period, adjusted use was lower in 2020 compared with 2019 for outpatient visits, HbA1c testing, retinopathy testing, and nephropathy testing. In contrast, medication fills were similar during the pandemic as compared with 2019; they were even slightly higher. Mail-order pharmacies and pharmacy delivery services are believed to have been key in ensuring patients receive their medications during that challenging time. Telehealth visits increased exponentially: “In 2019, 0.3% of cohort had 1 or more telemedicine visit, compared with 29.1% of the 2020 cohort during the pandemic period.”²¹⁶ The investigators surmised that the small increase in medication fill rates might have protected against disruptions in diabetes self-management during the pandemic and thus averted detrimental effects on glycemic control. This would be “consistent with diabetes disaster preparedness guidelines, which emphasize prioritizing access to medications over access to health care professionals during an emergency.”²¹⁷ The authors also hypothesized that the unprecedented increase in telemedicine visits observed during the pandemic, “although unable to overcome the overall decrease in visits, may have prevented substantive disruptions in medication prescribing.”²¹⁸ Further studies of diabetes management during the COVID-19 pandemic will throw more light on the effectiveness of available strategies and the variety of possible approaches to select.

²¹⁶ Patel, Sadiq Y. et al. “Diabetes Care and Glycemic Control During the COVID-19 Pandemic in the United States.” *JAMA Internal Medicine*. Published online July 6, 2021, doi:10.1001/jamainternmed.2021.3047.

²¹⁷ Ibid.

²¹⁸ Ibid.

DEPARTMENT OF HEALTH

The Pennsylvania Department of Health (DOH) is the leading agency in supervising programs aimed at prevention and management of diabetes. Most of the Commonwealth's diabetes programs are centralized within DOH to ensure that statewide efforts are coordinated. DOH works through Pennsylvania's healthcare system and coordinates its work with the other state departments, in particular the Office of Administration, to ensure diabetes prevention and management programs' coverage by the Pennsylvania Employees Benefit Trust Fund (PEBTF); the Department of Human Services Office of Medical Assistance Programs (OMAP) and Medicaid Managed Care Organizations, to collaborate in the Diabetes Self-Management Education and Support Program (DSMES) and to achieve Medicaid coverage for the Diabetes Prevention Program (DPP); with the Department of Aging, to promote prediabetes awareness and participation in DPP among older Pennsylvanians; and with the Department of Education, to offer recommendations and resources for the School Nurses Program.

This report will focus on two major programs currently administered by DOH: Diabetes Prevention Program (DPP) and Diabetes Self-Management Education and Support Program (DSMES). The report also contains an update on type 1 diabetes activity and funding allocation as well an overview of obesity as a significant risk factor of type 2 diabetes.

Diabetes Prevention Program (DPP)

The Diabetes Prevention Program (DPP) is an evidence-based lifestyle change intervention program for preventing or delaying type 2 diabetes among people of high risk. It is a long-term, structured program. Participants, who have prediabetes or are at risk of developing type 2 diabetes, meet in groups with a specially trained lifestyle coach once a week for six months (core phase) and then once or twice a month for six months (post-core maintenance period) to learn ways to incorporate healthier eating and moderate physical activity as well as problem-solving and coping skills into their daily lives. In order to accommodate various lifestyles, to respond to various clients' preference, and to improve attrition, DPP has lately utilized four delivery modes: in-person, online, distance learning, and a combination of these. The goals are to decrease each participant's weight by five to seven percent and to increase physical activity to 150 minutes per week.

Lifestyle changes have been shown to lower the risk for developing diabetes, as confirmed by several authoritative long-term studies. A 15-year follow-up in the Diabetes Prevention Program Outcomes Study has found that "lifestyle interventions or metformin significantly reduced diabetes development over 15 years"; specifically, during a mean follow-up of 15 years, diabetes incidence was reduced by 27 percent in the lifestyle intervention group and by 18 percent in the metformin group, compared with the placebo group, with declining between-group difference over time.²¹⁹ The result, thus, unequivocally supports the importance of diabetes prevention and the effectiveness of lifestyle intervention in achieving this goal.

²¹⁹ Diabetes Prevention Program Research Group. "Long-Term Effects of Lifestyle Intervention or Metformin on Diabetes Development and Microvascular Complications over 15-year Follow-up.: The Diabetes Prevention Program Outcomes Study." *The Lancet Diabetes and Endocrinology*. Vol. 3. No. 11. November 2015, doi: [http://dx.doi.org/10.1016/S2213-8587\(15\)00291-0](http://dx.doi.org/10.1016/S2213-8587(15)00291-0).

CDC's Division of Diabetes Translation (DDT) funds state and local health departments to support programs and activities aimed at preventing or delaying the onset of type 2 diabetes and improving outcomes for people diagnosed with diabetes. The Pennsylvania Department of Health is supporting the implementation of the CDC National Diabetes Prevention Program by facilitating grant applications submissions and working to increase the number of CDC-recognized lifestyle change programs available for adults with prediabetes or at risk for developing type 2 diabetes in the Commonwealth.²²⁰

For three years, activities aimed at expanding DPP in the Commonwealth proceeded according to the *Pennsylvania Action Plan to Scale and Sustain the National Diabetes Prevention Program*.²²¹ The goal set up in the plan has been successfully achieved. The final meeting of the DPP Action Plan Implementation Workgroup took place on June 23, 2020, to celebrate the achievements during the implementation period, particularly increasing enrollment by 5 percent of individuals with or at risk for prediabetes, and it concluded with a unifying call to action to develop physician engagement and to increase clinical referrals to DPP programs.

In 2020, Pennsylvania was featured in the National Association of Chronic Disease Directors' (NACDD's) *Collective Impact in Action* report highlighting the critical work and successes of state diabetes programs and partners to advance diabetes prevention. The NACDD's report highlighted Pennsylvania's achievements in several key areas of DPP such as actively engaged stakeholder partners, major growth in awareness and availability, gains in screening, testing, referral, and enrollment, successfully meeting coverage milestones, and addressing priority populations.²²²

In the past few years, DOH improved and strengthened its relationships with more than 250 new and former partners, including the Pennsylvania Medical Society, the Pennsylvania Pharmacists Association, and the National Nurse-Led Care Consortium. Active engagement with a stakeholder network helps DOH to deliver the National DPP lifestyle change program across the state, to promote awareness and referral by clinical teams, to increase enrollment, and to achieve private and public coverage for this program. Under the awareness pillar of the National DPP Action Plan, clinicians were selected as the main audience and addressed with messages on the need for and benefits of screening and testing for prediabetes and making referrals for the National DPP.

²²⁰ The following three subsections of the report are largely based on the information provided to the Joint State Government Commission by the Pennsylvania Department of Health in the personal e-mails from Ms. Barbara Orwan and Ms. Camelia Rivera, Public Health Program Administrators, DOH Bureau of Health Promotion and Risk Reduction, on July 15 and July 26, 2021.

²²¹ *Pennsylvania Action Plan to Scale and Sustain the National Diabetes Prevention Program 2018-2020*, http://www.communityclinicalintegration.org/sites/default/files/attachments/PA%20DPP%20Action%20Plan.FinalplantoNACDD.final_6.1.20.pdf.

²²² National Association of Chronic Disease Directors. *Collective Impact in Action*. September 2020. Pp. 28-30, <https://chronicdisease.org/collective-impact-in-action-report-2020/>.

Increasing availability is attested to by the following achievements:

- Pennsylvania added 23 sites where the National DPP lifestyle change program is now available.
- Pennsylvania added 54 National DPP lifestyle change program classes, among them nine classes for Spanish speakers and two classes for persons with mental and physical disabilities, including visual impairments.
- Pennsylvania trained approximately 220 lifestyle coaches.
- Of Pennsylvania's 92 CDC-recognized organizations listed in the Diabetes Prevention Recognition Program (DPRP) Registry, 32 achieved full recognition, 11 achieved preliminary recognition, and 49 are pending. Twenty-five of the recognized organizations offer the National DPP lifestyle change program in underserved areas of the state.
- The DOH and the Health Promotion Council (HPC) integrated National DPP resources into a centralized LiveHealthyPA website and utilized a lifestyle coach community platform.

Gains in screening, testing, and enrollment include the following:

- Pennsylvania has 43 organizations that reported screening for prediabetes using paper or electronic risk tests and 17 organizations that reported referring to National DPP lifestyle change programs.
- In January 2018, Pennsylvania Department of Human Services launched a pilot requiring all managed care organizations (MCOs) in the Commonwealth to provide a diabetes prevention offering to their enrollees. Effective July 2019, National DPP providers could enroll in Medicaid as network providers. Effective January 2020, all of Pennsylvania's MCOs were required to refer eligible members to CDC-recognized organizations. Seven CDC-recognized organizations have enrolled as Medicaid providers.
- Conemaugh Health System, which is the largest healthcare provider in West Central Pennsylvania, affords virtual delivery to its employees through support from NACDD's Scaling the National DPP in Underserved Areas project (1705)²²³ led by HPC as the Pennsylvania lead organization. With logistical support from the

²²³ DP17-1705 (1705), Scaling the National Diabetes Prevention Program in Underserved Areas, is a five-year CDC-funded cooperative agreement that began in September 2017 and funds 10 national organizations with affiliate program delivery sites in at least three states to deliver the National DPP lifestyle change program in underserved areas and to enroll both general and priority populations in new or existing CDC-recognized organizations. Prioritized populations include demographic groups that have been under-enrolled in the lifestyle change program despite relatively higher rates of type 2 diabetes, <https://www.cdc.gov/diabetes/programs/stateandlocal/funded-programs/dp17-1705.html>.

clinical support manager, marketing department, and internal health and wellness coordinator, more than 200 employees have enrolled in virtual classes offered by HOPE 80/20. In 2019, Conemaugh Health system formalized the National DPP as a wellness benefit for employees. Plans for 2020 included expansion of virtual classes for employees to additional hospitals in the network.

One of Pennsylvania's major successes was meeting coverage milestones. In January 2020, the Commonwealth achieved state public employee coverage for the National DPP. Prior to that, the Pennsylvania Employee Benefits Trust Fund conducted two pilots for state employees in collaboration with Harrisburg Area YMCA. Currently, Pennsylvania has more than 150,000 state employees and over 100,000 retirees and dependents who have coverage of the National DPP lifestyle change program available to them. Additionally, two commercial plans cover the lifestyle change program, which makes it available to 3 million people. Medicaid plans (MCOs) have also started to cover the National DPP.²²⁴

In its implementation of the National DPP lifestyle change program, Pennsylvania addresses the following priority populations: rural population, Medicare and Medicaid beneficiaries, noninstitutionalized people with visual impairments or physical disabilities, African Americans, and Hispanics.

Following the *Collective Impact in Action Report*, Pennsylvania was invited by NACDD to participate in a podcast series about partnering for diabetes prevention and management titled "Collective Voices for Diabetes: Partnering for Prevention and Management". Amy Flaherty, MA, Division Director of Nutrition and Physical Activity at the Pennsylvania Department of Health, and Kim Labno, MS, PMP, Assistant Director of Training and Capacity Building at the Health Promotion Council, participated in June 2021 in a 30-minute recorded interview with Dr. Tamara Demko, an independent public health consultant with NACDD, discussing innovative public health practices, collective approaches, and unique achievements in the field of partnerships for diabetes prevention. The podcast series will be disseminated to state health departments and their partner organizations working collectively to prevent and manage diabetes in their communities, as well as to professionals across other chronic disease areas, such as Chronic Disease Directors and CDC, who may find this information applicable to other bodies of public health efforts.

In Pennsylvania, Diabetes Prevention Program (DPP) work is completed under four funding sources:

1. Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke (CDC-RFA-DP18-1815) -- \$443,201.62
2. Preventative Health and Health Services Block Grant -- \$834,411

²²⁴ Medicaid coverage of the National DPP lifestyle change program is discussed in a separate section of the report. See P. 84.

3. CDC Federal Funding through the National Association of Chronic Disease Directors (NACDD) -- \$41,120
4. State Funding \$100,000

1. Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke (CDC-RFA-DP18-1815)

Grantees and partners: Health Promotion Council (HPC), Quality Insights (QI), Pennsylvania Department of Aging, Office of Medical Assistance Programs (OMAP) at the Pennsylvania Department of Human Services (DHS), Pennsylvania Employees Benefit Trust Fund (PEBTF), Latino Connection, ProVention Health Foundation.

HPC Activities: promote bidirectional referral pathways between at least four referring health care providers and DPP providers, provide intensive technical assistance to Lifestyle Coaches trained during previous fiscal year to start new National DPP cohorts, and identify an employer with readiness to offer the National DPP to its employees and provide technical assistance towards coverage of the National DPP.

QI activities: recruit and assist health care organizations with the assessment of referral processes, the addition of clinical decision support rules to their electronic health records system, the integration of Prediabetes Risk Test into clinical practice, and the development and implementation of communication and education tools and processes within the recruited practices.

Pennsylvania Department of Aging activities: promote awareness of prediabetes and DPP to older Pennsylvanians through the Pharmaceutical Assistance Contract for the Elderly (PACE) Program.²²⁵

OMAP: The Department of Health (DOH) has allocated \$10,000 to reimburse the application fee for up to 16 DPP Pennsylvania-based providers applying for Medicaid enrollment. However, these fees were waived during the COVID-19 public health emergency.

PEBTF: DOH conducted meetings and maintained ongoing conversations with PEBTF and Pennsylvania Office of Administration (OA), entities that oversee state employees' health benefits. Using state funds, three National DPP pilot cohorts for state employees were implemented in Harrisburg and one in Philadelphia, in collaboration with Harrisburg Area YMCA. Data from these pilots indicated high retention and weight loss and proved the benefits of making this program available to state employees as a covered benefit. Effective January 2020, 166,946 state employees and their dependents as well as 104,826 retirees and their dependents have access to the National DPP as a fully covered health benefit, through a decision of PEBTF and the OA.

²²⁵ The Pennsylvania Department of Aging activities are covered in detail in a separate chapter of this report. See P. 73.

Latino Connection activities: educate low-income Latinx population about prediabetes and National DPP through health and wellness events and through ads on screens at corner stores, disseminate the Prediabetes Screening Test at these events and refer eligible individuals to enroll in the National DPP.

DOH has allocated 1815 Grant funds to purchase a license of the Health and Lifestyle Training (HALT) diabetes software platform to deliver the National DPP online to up to 1,000 Pennsylvanians at risk for prediabetes and is working to finalize a contract with ProVention HALT Foundation to acquire access to this platform.

2. Preventive Health and Health Services Block Grant

One of the *Healthy People 2030* objectives (D-D01) is to “increase the proportion of eligible persons completing Centers for Disease Control and Prevention (CDC)-recognized lifestyle change programs.”²²⁶ The grant is targeted towards this goal.

Grantees and partners: HPC, Tobacco Regional Primary Contractors (American Lung Association, Adagio Health, Erie County Department of Health), Pennsylvania Pharmacists Association, Feeding Pennsylvania.

HPC: provide project management services for CDC-recognized National DPP organizations to deliver DPP at 15 cohorts across the Southeastern area of the state, provide organizations with technical assistance around enrollment as Medicare and Medicaid providers, plan and coordinate three online or in-person meetings of lifestyle coaches in Pennsylvania to encourage relationship building and networking, share successes and best practices, and identify needs that can be met by DOH.

Tobacco Regional Primary Contractors: provide project management services for CDC-recognized National DPP organizations to deliver DPP across five health district areas, provide organizations with technical assistance around enrollment as Medicare and Medicaid providers.

Pennsylvania Pharmacists Association: provide program management services to increase capacity for the National DPP at pharmacy locations, support pharmacy lifestyle coaches to become certified as master trainers, develop a best-practice document to assist pharmacies with implementing and maintaining DPP at their locations.

Feeding Pennsylvania: promote awareness of prediabetes and participation in the National DPP among the low-income populations served by two food banks in Southcentral and Northeastern areas. Weinberg Northeast Regional Food Bank has plans to apply for CDC-recognition and beginning in late 2021 to deliver the National DPP to its eligible clients.

²²⁶ *Healthy People 2030*, <https://health.gov/healthypeople/objectives-and-data/browse-objectives/diabetes/increase-proportion-eligible-people-completing-cdc-recognized-type-2-diabetes-prevention-programs-d-d01>.

This objective currently has developmental status, meaning it is a high-priority public health issue that has evidence-based interventions to address it, but doesn't yet have reliable baseline data. Once baseline data are available, this objective may be considered to become a core *Healthy People 2030* objective.

3. CDC Federal Funding through NACDD

This funding and technical assistance grant was awarded for the period August 1, 2019 to August 31, 2020 and extended to July 31, 2021. The purpose of this award was to address the system challenges related to the development, implementation, and evaluation for covering the National DPP in Medicaid. In July 2019, OMAP issued a Medical Assistance Bulletin detailing the Medicaid enrollment requirements and the provider type and specialty for DPP. To better understand their awareness, interest, and barriers in offering the National DPP to Medicaid beneficiaries, DOH in collaboration with DHS and with support from NACDD developed and disseminated an electronic survey to 85 CDC-recognized National DPP organizations in Pennsylvania during August-September 2019. Of 29 responders, 58 percent were very interested in enrolling in Medicaid, and 100 percent answered that by enrolling in the Medical Assistance Program to provide the National DPP to beneficiaries covered under one of the Medical Assistance managed care plans they would become able to help more people avoid developing diabetes. However, respondents identified as main barriers the low revenue compared to the effort required to enroll as Medicaid providers, although 76 percent were serving Medicaid beneficiaries at the time of the survey. The Survey Topline Report prepared by NACDD was to inform the agenda of the technical assistance in-person meeting session with National DPP providers in the Commonwealth as well as Pennsylvania Medicaid MCOs initially scheduled for April 29, 2020. Due to the COVID-19 pandemic, this meeting was rescheduled and held as a virtual event for National DPP providers on October 7th, 2020, and having as main highlights the Pennsylvania MCO Pilot, the data and the risk factors associated with COVID-19 and diabetes, the requirements for Medicaid enrollment (steps, screens, and resources related to the online application process), as well as two presentations on experience with Medicaid enrollment by Sight Center of Northwest Pennsylvania and Harrisburg Area YMCA.

Part of this funding was allocated to HPC to work on enrolling in the Umbrella Hub a Medicaid-enrolled National DPP provider or a provider with readiness to enroll in Medicaid, and to develop and implement outreach and recruitment efforts to enroll Medicaid beneficiaries in the National DPP. HPC was selected by CDC to participate in the National DPP Umbrella Hub Pilot with the goal of achieving sustainable delivery of the National DPP lifestyle change program by facilitating the sharing of infrastructure costs and by leveraging best practices.

4. State Funding

The state funding was allocated to Harrisburg Area YMCA to provide DPP services at four DPP sites (two in Harrisburg, one in Erie and one in Pittsburgh), including assistance with program promotion and marketing, tracking participant outcomes in an online data management system, and developing a bidirectional referral infrastructure with four healthcare providers. Harrisburg Area YMCA is both a Medicaid and Medicare DPP supplier and was able to successfully transition to online delivery during the COVID-19 pandemic.²²⁷

²²⁷ YMCA activities are covered in detail in a separate chapter of this report. See P. 89.

Diabetes Self-Management Education and Support (DSMES)

The Department of Health DSMES initiatives encourage people with diabetes to receive diabetes self-management education accredited by the Association of Diabetes Care and Education Specialists (ADCES) and/or recognized by the American Diabetes Association (ADA). DSMES is a collaborative process through which people with diabetes gain the knowledge and skills needed to modify their behavior and successfully self-manage the disease and its related conditions. The process incorporates the needs, goals, and life experiences of the person with diabetes and is guided by evidence-based standards. Effective DSMES, based on a personalized and holistic approach, becomes a significant contributor to clinical improvement and long-term positive health outcomes.

A comprehensive assessment of the current state of DSMES in the United States and new recommendations are presented in a consensus report by several leading national medical organizations involved in diabetes treatment and education. Their joint statement is reviewed earlier in this report.²²⁸

In Pennsylvania, Diabetes Self-Management Education and Support (DSMES) work is completed under two funding sources:

1. Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke (DP18-1815).²²⁹
2. Preventive Health and Health Services Block Grant.²³⁰

1. Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke (DP18-1815)

- 4.75-year grant, beginning September 30, 2018 and ending June 29, 2023
- Funding for DSMES Contractors:
 - SFY 2018-2019 (9 months) - \$238,088
 - SFY 2019-2020 - \$290,000
 - SFY 2020-2021 - \$357,500
 - SFY 2021-2022 - \$357,500
- Contractors for DSMES:
 - Health Promotion Council (HPC)
 - Pennsylvania Pharmacists Association (PPA)
 - Quality Insights (QI)
 - Latino Connection (LC)

²²⁸ See P. 26.

²²⁹ <https://www.cdc.gov/rfa-dp18-1815/index.html>.

²³⁰ <https://www.cdc.gov/phhsblockgrant/index.htm>.

- Funding also supports a portion of 1815 evaluation efforts provided by Evaluation Institute for Public Health, University of Pittsburgh, and Behavioral Risk Factor Surveillance System (BRFSS) Diabetes questions
- Activities:

The DOH is implementing evidence-based strategies to contribute to the management of diabetes in high-burden populations in Pennsylvania. Strategies improve care and management of people with diabetes by increasing access to and use of diabetes self-management education and support (DSMES) programs and medication management processes.

Through the Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke (1 NU58DP006541-01-00) (1815) cooperative agreement from the CDC, the Diabetes Prevention and Control Program (DPCP) is working, in partnership with the Cardiovascular Disease Program, to improve access to and participation in American Diabetes Association (ADA)-recognized and Association of Diabetes Care and Education Specialists (ADCES)-accredited DSMES programs in underserved areas and increase engagement of pharmacists in the provision of medication management or DSMES for people with diabetes.

The DOH is collaborating with the HPC and the PPA to increase access to recognized/accredited DSMES programs by providing technical assistance to programs seeking to achieve recognition or accreditation. Additional technical assistance is provided to support program sustainability. The DOH is also working with the PPA to identify how to incorporate medication management for people with diabetes into pharmacists' patient care process collaborations and best-practice protocols.

Through work with QI, the DOH is working to increase participation in recognized/accredited DSMES programs by educating providers, promoting DSMES within communities, and improving referral processes and networks. QI will engage health systems, independent practices, and electronic health record (EHR) vendors to assist in completing this work.

The DOH is working with LC to raise awareness of DSMES among the Latinx population through on-site educational outreach and message delivery within communities.

2. Preventive Health and Health Services Block Grant

- Funding for DSMES Contractors:
 - SFY 2020-2021 - \$178,550
 - SFY 2021-2022 - \$148,550
- Contractors for DSMES:
 - PPA
 - Multi-Cultural Health Evaluation & Delivery System (MHEDS)
 - Special Olympics Pennsylvania (SOPA)

- Activities:

Funding from the Preventive Health and Health Services Block Grant (PHHSBG) supports a comprehensive approach, integrating community-level efforts to strengthen foundational activities from 1815.

- PPA - The DOH is building on work in 1815 to increase access to DSMES by supporting pharmacist-led DSMES program sustainability. Through the PPA, the DOH will create and present programming to pharmacy-led ADCES-accredited or ADA-recognized DSMES programs to support program sustainability. Programming may be in-person or virtual and will focus on topics identified by the pharmacists. Topics may include recruitment of participants, retention of participants, and/or medical insurance billing practices.
- Multi-Cultural Health Evaluation & Delivery System - The DOH is collaborating with MHEDS to provide culturally tailored DSMES to people with diabetes from underserved populations. Underserved populations may include Asian (Bhutanese-Nepali, Burmese); Middle Eastern (Iraqi, Syrian); and African (Somali, Congolese) resettled refugees; Latinx; and black populations. Where necessary, cohorts will be educated with the assistance of bi-lingual cultural navigators.
- Special Olympics Pennsylvania - The DOH is working with Special Olympics Pennsylvania to increase awareness of DSMES and to provide outreach to adult athletes in the Special Olympics program who also have diabetes. The purpose of this activity is to increase participation in DSMES for people with both diabetes and intellectual disabilities and to improve health outcomes for this disparate population.

Type 1 Diabetes Activity

Funding sources for 2020-2021:

State Funding \$100,000

This funding was allocated to Cedar Crest College to develop and implement awareness, education, and outreach activities targeting key populations involved in the recognition and diagnosis of type 1 diabetes and diabetic ketoacidosis within the Lehigh Valley. During February 01, 2020 – June 30, 2020, Cedar Crest College developed and launched, in collaboration with a parent advocates and subject matter experts, three main promotional and educational tools and activities: The Better Kid Care Module as an online childcare training module for early childhood and school-age practitioners, the online Continuing Medical Education Module to reach current medical professionals and focused on recognizing and diagnosing T1D diabetes and diabetic ketoacidosis at any age, and a social media outreach including scheduled Facebook and Instagram posts to educate the public within the Lehigh Valley area about type 1 diabetes and diabetic ketoacidosis. As of July 2020, the Better Kid Module had been completed by 265 individuals in

Pennsylvania, and recently the Governor of Virginia purchased licenses to provide access to this module to 2,000 residents. The Continuing Education Module was promoted to health networks in the Lehigh Valley area and to Pennsylvania Coalition of Nurse Practitioners and is linked to the American Association of Nurse Practitioners. The Education Outreach component has produced and launched three Type 1 Diabetes public awareness videos: Type 1 Diabetes: Warning Signs; Living with Type 1 Diabetes: A Lifelong Journey; and a third video targeting the Spanish speaking population.

Obesity Prevention and Wellness Activities

The DOH Bureau of Health Promotions and Risk Reduction has a special Obesity Prevention and Wellness Section, dedicated to the coordination of various activities aimed at curbing this important risk by facilitating healthy eating and enhanced physical exercise among children and adults.²³¹

Obesity Prevention & Wellness strategies are supported by three funding sources:

1. State Physical Activity and Nutrition Program (CDC-RFA-DP18-1805) -- \$381,095
2. Preventive Health and Health Services Block Grant -- \$1,131,018
3. CDC Federal Funding through the National Association of Chronic Disease Directors (NACDD), Building Resilient Inclusive Communities -- \$219,250

These funding sources support several programs and initiatives in the Commonwealth.

1. PA Healthy Pantry Initiative (HPI)

Grantees and partners:

Feeding Pennsylvania, Central PA Food Bank, Philbundance, Greater Pittsburgh Community Food Bank, Second Harvest Food Bank of Northwest Pennsylvania, Public Health Management Corporation Strategy:

The PA Department of Health partners with Feeding Pennsylvania to increase access to healthy food and beverage options. Feeding Pennsylvania and its member food banks increase healthy inventory available to food pantries. A registered dietitian with Feeding Pennsylvania and a nutrition educator in the three participating food banks guide pantries through phases to increase healthy food and beverage options. The phases include assessing pantries to determine needs, using marketing materials and layout changes to nudge clients toward healthier choices, increasing

²³¹ The following subsection of the report is largely based on the information provided to the Joint State Government Commission by the Pennsylvania Department of Health in the personal e-mail from Ms. Tiffany Bransteitter, Obesity Prevention and Wellness Section Chief of the DOH Bureau of Health Promotion and Risk Reduction, sent on July 30, 2021.

healthier inventory, upgrading or adding materials to display and store healthier options, and offering hands-on nutrition education with pantry clients. Feeding Pennsylvania created its first nutrition policy, and participating food banks are working on nutrition policies to emphasize the importance of healthy options, which will sustain the healthy changes long-term.

Currently, 64 food pantries are participating in the program. The Public Health Management Corporation provides evaluation support for this strategy.

In 2021, under the Building Resilient Inclusive Communities (BRIC) grant, PA HPI began working to increase cultural inclusivity. SEAMAAC, a support and service organization for marginalized communities, joined the PA HPI partnership to survey pantry clients in Philadelphia on cultural needs and preferences. Later this year, SEAMAAC will use data gathered from the survey to review PA HPI materials through a health equity lens. PA HPI materials will be updated or created to meet the cultural needs and preferences of pantry clients.

The program aims to meet the Healthy People 2030 Objective NSW-07: Increase vegetable consumption by people aged 2 years and over.

Funding:

Preventive Health and Health Services Block Grant from the Centers for Disease Control and Prevention; 2021/2022 state fiscal year: \$304,606 National Association of Chronic Disease Directors (NACDD), Building Resilient Inclusive Communities; 2021 calendar year: \$6,000

2. Good Food Healthy Hospitals (GFHH)

Grantees and partners: Philadelphia Department of Public Health (PDPH), the Hospital and Healthsystem Association of PA (HAP), Philabundance Community Kitchen, Drexel University Food Lab, The Common Market, Public Health Management Corporation

Strategy:

Good Food, Healthy Hospitals (GFHH) is an initiative transforming Pennsylvania's hospital food environments by bringing healthier options to thousands of employees, visitors, and patients every day. The DOH partners with PDPH and HAP to increase the availability of and access to healthier food options by encouraging hospitals to adopt food service standards. The DOH and partners have scaled this initiative to hospitals and health systems across the Commonwealth. Under the guidance of a healthy food in healthcare specialist (who is a registered dietician), participating hospitals and health systems pledge to increase the availability of healthy foods across five different food domains: purchased foods and beverages, cafeteria meals, patient meals, catering, and vending. As a hospital continues to adopt standards, its GFHH designation increases from Participant (1 domain) up to Platinum (all 5 domains). Participating hospitals and health systems receive technical assistance on nutrition, menu planning, and food service guidelines (FSG) implementation. Participating food service stakeholders then adopt food service guidelines to create healthier food environments and attend task force meetings to collaborate with

other participating hospitals. GFHH currently has 39 hospitals in 10 health systems participating. The Public Health Management Corporation provides evaluation support for this strategy.

The program aims to meet the Healthy People 2030 Objective NWS-06: Increase fruit consumption by people aged 2 years and over.

Funding:

Preventive Health and Health Services Block Grant from the Centers for Disease Control and Prevention; 2021/2022 state fiscal year: \$75,884

State Physical Activity and Nutrition Program (SPAN) from the Centers for Disease Control and Prevention; 2021/2022 grant year: \$50,000

3. Food Service Guidelines in Community Settings

Grantees and partners: Erie County Department of Health, Public Health Management Corporation

Strategy:

The DOH partners with the Erie County Department of Health to support the implementation of food service guidelines in community settings in Erie County. In 2020, Erie County adopted the Blue Zones Food Service Guidelines policy. The Erie County Department of Health provides technical assistance to food service sites to implement this policy. It also monitors and assesses for compliance. The Erie County Department of Health also convenes a Food Policy Council to advance food service guidelines in Erie County, in addition to other food policy priorities. Public Health Management Corporation provides evaluation support for this strategy.

Funding:

State Physical Activity and Nutrition Program (SPAN) from the Centers for Disease Control and Prevention; 2021/2022 grant year: \$21,000

4. Breastfeeding

Grantees and partners: Pennsylvania Chapter of the American Academy of Pediatrics (PA AAP), Pennsylvania Breastfeeding Coalition (PABC), Public Health Management Corporation

Strategy:

The DOH is partnering with PA AAP to implement the Community-Based Breastfeeding-Friendly Practice Program “BEST Plus” to provide primary care practices, including pediatric, OB-GYN and Pennsylvania’s Community Health Centers (or Federally Qualified Health Centers - FQHCs) with a structured program to assist with implementation of high-quality breastfeeding continuity of care. BEST Plus is a quality improvement program designed to improve the quality

of care for breastfeeding during the postpartum period and beyond. The program helps pediatric, OB-GYN and family practices across Pennsylvania improve their knowledge of breastfeeding and delivery of evidence-based care, breastfeeding benefits and best practices and is designed to improve breastfeeding duration and exclusivity rates in their communities. This approach incorporates a 10-step curriculum toward a breastfeeding-friendly practice (based on the World Health Organization's *Ten Steps to Successful Breastfeeding*), making success more achievable. The program includes education, technical assistance, and resources to enable participating practices to progress through the 10 steps and obtain "Breastfeeding-Friendly Practice" status. In state fiscal year 2020/2021, 14 practices participated in the program, which included a Maintenance of Certification Program for affiliated pediatricians. Outcomes reported will include "Breastfeeding Friendly" achievement by practices, program growth, statewide impact, policy development, and innovative practices. Additional qualitative data in the form of case studies may be collected for the purposes of evaluation and participant education and motivation. The Public Health Management Corporation provides evaluation support for this strategy.

The program aims to meet the Healthy People 2030 Objective MICH-15: Increase the proportion of infants who are breastfed exclusively through age 6 months.

Funding:

Preventive Health and Health Services Block Grant from the Centers for Disease Control and Prevention; 2021/2022 state fiscal year: \$90,550

State Physical Activity and Nutrition Program (SPAN) from the Centers for Disease Control and Prevention; 2021/2022 grant year: \$66,027

5. Physical Activity Access

Grantees and partners: Pennsylvania Downtown Center, Pennsylvania Department of Transportation (PennDOT), Pennsylvania Department of Conservation and Natural Resources (DCNR), Public Health Management Corporation

Strategy:

The DOH partners with the Pennsylvania Downtown Center (PDC) to connect activity-friendly routes to everyday destinations that make it safe and convenient for people of all abilities to walk, run, bike, skate, or use wheelchairs. Through the WalkWorks program, a competitive application is released to municipalities and similar entities to apply to receive funding and technical assistance for the development of an active transportation plan that will identify and prioritize projects related to modes of active transportation with an emphasis of walking, biking, wheeling and public transit. WalkWorks also assists with the development of policies that include language in support of environmental changes for enhancing places for physical activity, with an emphasis on walking, biking, wheeling, and public transit. A minimum of eight communities are selected to develop a plan or policy from October through the following September. PDC provides ongoing technical assistance, resources, and other requested information, as needed, throughout

the duration of the funding period. To date, the program has supported the development and adoption of 26 plans or policies with 10 more expected to be adopted by September 30, 2021. The Public Health Management Corporation provides evaluation support for this strategy.

The program aims to meet the Healthy People 2030 Objective PA-01: Reduce the proportion of adults who do no physical activity in their free time.

In 2021, WalkWorks began to promote healthy living and reduce social isolation during the COVID pandemic through the Building Resilient Inclusive Communities (BRIC) Program. WalkWorks seeks to develop and implement a capacity-building action plan, focused on building active transportation capacity in vulnerable communities and to develop a plan to enhance equity and anti-racism throughout the WalkWorks program.

Funding:

Preventive Health and Health Services Block Grant from the Centers for Disease Control and Prevention; 2021/2022 state fiscal year: \$255,885

State Physical Activity and Nutrition Program (SPAN) from the Centers for Disease Control and Prevention; 2021/2022 grant year: \$66,068

National Association of Chronic Disease Directors (NACDD), Building Resilient Inclusive Communities; 2021 calendar year: \$2,145

6. Early Care and Education

Grantees and partners: Tuscarora Intermediate Unit (TIU), PA AAP Early Childhood Education Linkage System (ECELS), University of North Carolina (UNC), Pennsylvania Departments of Education and Human Services, Office of Childhood Development and Early Learning, Keystone Kids Go, Public Health Management Corporation

Strategy:

The Pennsylvania Nutrition and Physical Activity Self-Assessment for Child Care (PA NAPSACC) is a continuous quality improvement (CQI) process that is focused on obesity prevention practices and policies in early childhood education (ECE) settings. The DOH partners with TIU and ECELS to implement PA NAPSACC with a cohort of 100 early childhood education (ECE) programs annually. The PA NAPSACC CQI process uses the nationally recognized Go NAPSACC tool, developed by UNC to guide participating ECE programs through self-assessment, action planning, implementation, policy development, re-assessment, and reflection. Current funding supports 100 mini grants annually for participants.²³²

²³² A summary of past outcomes can be found at 2019-2020 PA NAP SACC Infographic (keystonekidsgo.org).

The implementation of obesity prevention strategies at the individual ECE level is enhanced by the DOH through support of the Keystone Kids Go (KKG) stakeholder group and efforts to embed high-impact obesity prevention standards into state ECE systems and system supports. KKG is one of the longest running statewide ECE partner networks in the country - 17 years strong. Members represent state agencies such as the Pennsylvania Departments of Education (PDE) and Human Services (DHS), PA AAP Early Childhood Education Linkage System (ECELS), Office of Child Development and Early Learning (OCDEL), Penn State Better Kid Care (BKC), Penn State Cooperative Extension and Tuscarora Intermediate Unit (TIU) as well as many other organizations with an interest in early childhood education. Over the past 3 years, KKG has utilized CDC's Spectrum of Opportunities Quick Start Action Guide to develop a results-oriented and equity-driven action plan. These activities aimed to harness a diversity of stakeholder expertise and ensure equitable access to obesity prevention resources and action planning opportunities. Several notable outcomes include

- Providing Equity, Diversity and Inclusion training to KKG Workgroup members through the Institute for Public Health Innovation;
- Incorporating all 9 national high-impact obesity prevention standards from Caring For Our Children into an infant feeding module for CACFP sponsors;
- Conducting “Tools for Promoting High-Impact Obesity Prevention Practices in Early Childhood Education: An Integrated Approach to Coaching” training for statewide technical assistance providers in Early Learning Resource Centers; and
- Creating a CACFP story map in partnership with Child Care Aware to identify areas of under-utilization and help partners identify potentially eligible programs to encourage them to participate in an effort to increase access to nutritious meals and snacks and curb disparities in food access across Pennsylvania.

The Public Health Management Corporation provides evaluation support for this strategy.

The program aims to meet the Healthy People 2030 Objective NWS-04: Reduce the proportion of children and adolescents with obesity.

Funding:

Preventive Health and Health Services Block Grant from the Centers for Disease Control and Prevention; 2021/2022 state fiscal year: \$249,169

State Physical Activity and Nutrition Program (SPAN) from the Centers for Disease Control and Prevention; 2021/2022 grant year: \$80,000

7. School Wellness

Grantees and partners: PA School Wellness, Slippery Rock University, Public Health Management Corporation, Pennsylvania Farm to School Network, including Pennsylvania Departments of Education (PDE) and Agriculture (PDA), Office of Child Development and Early Learning (OCDEL), The Food Trust and other statewide organizations representing farm-to-school interests

Strategy:

Growth screening data reported annually by school districts in Pennsylvania indicate obesity prevalence among enrolled students in kindergarten through 12th grade has increased from 17.15 percent in 2014 to 18.03 percent in 2018. Participation in the school wellness program is offered annually to three school districts reporting 25 percent or higher obesity prevalence and located in Pennsylvania counties with significant health disparities. The goal of the program is to create healthier school environments for children and adolescents by increasing opportunities for physical activity and high-quality physical education, as well as building capacity for Health and/or Physical Educators (H/PE) to develop leadership skills and become agents for change in their school buildings. Slippery Rock University's (SRU) School Wellness Education Department provides training and technical assistance to H/PE staff at the three school districts. Training includes curriculum review and assisting districts with transitioning from a traditional physical education model to a school wellness education model. Each training is based on the Whole School, Whole Community, Whole Child model, and the Society of Health and Physical Educators, national physical education standards and grade level outcomes. Trainings include strategies that schools can use to provide a greater focus on lifelong physical activity and student well-being.

The DOH also supports the administration of the Pennsylvania Farm to School Network and recent strategic planning efforts to grow Network capacity by expanding membership and collaborating with partners to promote and implement existing Farm to School initiatives.

Recent outcomes of this work include

- Collaborating with PA Department of Agriculture to administer the Farm to School Grant Program;
- Partnering with PA Department of Education to plan the February 2022 Farm to Child Nutrition Conference;
- Providing Pennsylvania Harvest of the Month promotional kits to 112 schools in the 20-21 school year; and
- Supporting Pennsylvania Harvest of the Month expansion to CACFP and ECE by offering 140 promotional kits.

The Public Health Management Corporation provides evaluation support for this strategy.

The program aims to meet the Healthy People 2030 Objective NWS-04: Reduce the proportion of children and adolescents with obesity

Funding:

Preventive Health and Health Services Block Grant from the Centers for Disease Control and Prevention; 2021/2022 state fiscal year: \$154,924

8. Building Resilient Inclusive Communities (BRIC)

Grantees and partners: PA Department of Aging; Obesity Physical Inactivity and Nutrition Task Force, PA State Health Improvement Plan Partnership; SEAMAAC; Feeding PA; Pennsylvania Downtown Center; Philadelphia Department of Public Health; SE Public Health Management Corporation (PHMC)

Strategy:

The National Association of Chronic Disease Directors (NACDD) provides BRIC funding to 20 states to promote healthy living and reduce social isolation during the COVID pandemic. The grant was awarded in January 2021, for one calendar year.

Through BRIC, strategies are implemented at the state and community level, specifically in Philadelphia to build sustainable systems and programming to improve safe access to physical activity, promote healthy eating through improved nutrition security, and reduce isolation and loneliness in older adults.

Core values of BRIC include a specific focus on reducing health inequities, promoting social justice for marginalized communities and people most impacted by the COVID-19 pandemic, and building state and community resiliency.

Nutrition Security: The DOH in collaboration with SEAMAAC, Feeding PA and PHMC is evaluating HPI materials, such as recipe cards to ensure that they are culturally relevant to the populations being served. Diverse pantry clients will inform new, culturally relevant materials. The DOH is also evaluating access to culturally relevant foods in food pantries and food systems. The DOH will work with partners to address barriers to providing culturally relevant foods for pantry clients.

Physical Activity Access: The DOH is utilizing BRIC resources to further support equity and inclusion in the development of a capacity-building plan that enables the DOH to better reach marginalized communities. Reaching priority communities has been challenging as they have limited resources and capacity to apply for WalkWorks grants. Community input will be gathered to develop the capacity building plan. The DOH is also committed to enhancing equity and anti-racism in WalkWorks, further enhancing the inclusion of diverse populations in development of community plans and policies.

Social Connectedness: The DOH is enhancing the collaborative partnership with the Department of Aging (PDA) to explore opportunities to include social connectedness objectives in the PA State Health Improvement Plan and to support and enhance equity objectives in the State Plan on Aging.

The DOH partners with the Philadelphia Department of Public Health (PDPH) to implement BRIC strategies in Philadelphia. Community-level activities focus on increasing access and connectivity to safe, healthy, and welcoming environments by supporting the co-creation of inclusive public spaces. PDPH implements these strategies in collaboration with many partners, including Philadelphia Parks and Recreation, Fairmount Park Conservancy, and others in communities in West Philadelphia. PDPH is enhancing partnerships to intersect all components of nutrition security and physical activity access strategies with social connectedness strategies. Community members are engaged to inform community investments. BRIC community investments include

- Expansion of the Philadelphia Community Garden Network in Fairmount Park, adding raised garden beds to increase accessibility;
- Establishment of a new farmers market at West Park;
- Cultivation, maintenance and winterization of Carousel House, a community farm;
- Installation of trail head gateway improvements in West Fairmount Park;
- Installation of wayfinding signage in Fairmount Park;
- Evaluation and assessment of equity in automated traffic enforcement systems to support implementation of the Philadelphia Vision Zero Plan;
- Implementation of the Mantua Community Traffic Safety Plan;
- Enhancement of partnership with AARP Philadelphia and the Philadelphia Livable Community Network;
- Engagement of older adults in social connectedness opportunities; and,
- Building social connectedness opportunities and programs into community-clinical linkage and referral systems.

The Public Health Management Corporation provides evaluation support for this strategy.

Funding:

National Association of Chronic Disease Directors (NACDD), Building Resilient Inclusive Communities; 2021 calendar year: \$219,350

DEPARTMENT OF AGING

The mission of the Pennsylvania Department of Aging (PDA) is to promote independence, purpose and well-being in the lives of older adults through advocacy, service and protection.²³³

PDA will strategically focus its efforts on the following five overarching goals in order to position Pennsylvania to meet the needs of and enhance services for older adults:

Goal One: Strengthen aging network’s capacity, promote innovation and best practices, and build efficiencies to respond to the growing and diversifying aging population.

Goal Two: Improve services for older adults and the ability to advocate for them by using evidence-informed planning, committing to data integrity, and being accountable for results.

Goal Three: Establish and enhance efforts to support healthy living, active engagement and a sense of community for all older Pennsylvanians.

Goal Four: Emphasize a citizen-first culture that provides outreach, embraces diversity, and honors individual choice.

Goal Five: Advocate for the rights of older adults and ensure their safety and dignity by raising awareness of and responding effectively to incidences of abuse, injury, exploitation, violence and neglect.”²³⁴

Health & Wellness Program

The Health & Wellness Program operates under the auspices of the PDA’s Education and Outreach Office (EOO). The Education and Outreach Office oversees health and consumer education programs initiated by PDA, including the Pennsylvania Medicare Education and Decision Insight, or PA MEDI, and the Health & Wellness Program.²³⁵

²³³ Pennsylvania Department of Aging. 2020-2024 State Plan, https://www.aging.pa.gov/publications/state-plan-on-aging/Documents/2020-2024_State_Plan_on_Aging.pdf.

²³⁴ Pennsylvania Department of Aging. 2020-2024 State Plan, https://www.aging.pa.gov/publications/state-plan-on-aging/Documents/2020-2024_State_Plan_on_Aging.pdf.

²³⁵ This chapter of the report is largely based on the information provided to the Joint State Government Commission by the Pennsylvania Department of Aging in the personal e-mail from Ms. Katrina Kyle, Health & Wellness Statewide Coordinator of the Department of Aging Education and Outreach Office, on July 31, 2021.

The role of PDA's Health & Wellness Program is to

- Research and interpret federal guidelines regarding the Older Americans Act (OAA) Title IIIID funding for disease prevention and health promotion services;
- Coordinate efforts among community resources;
- Act as a catalyst for the Area Agencies of Aging (AAA) and PDA's Health & Wellness initiatives;
- Provide training, technical assistance, and materials, as appropriate, for any of the PDA-endorsed evidence-based programs.

The goals of PDA's Health & Wellness program are to

- Abolish the myth that inevitable functional decline comes with age;
- Empower older adults with the information they need to age well;
- Support older adults in making lifestyle changes to improve their overall health;
- Reduce the utilization of the healthcare system.

PDA receives federal funding from the Administration for Community Living (ACL), through the OAA Reauthorization 2020 Title IIIID, to provide evidence-based disease prevention and health promotion services through the Health & Wellness Program. Under Title IIIID of the OAA, funding has been provided since 1987 to states and territories based on their share of the population aged 60 and over the programs that support healthy lifestyles and promote healthy behaviors.

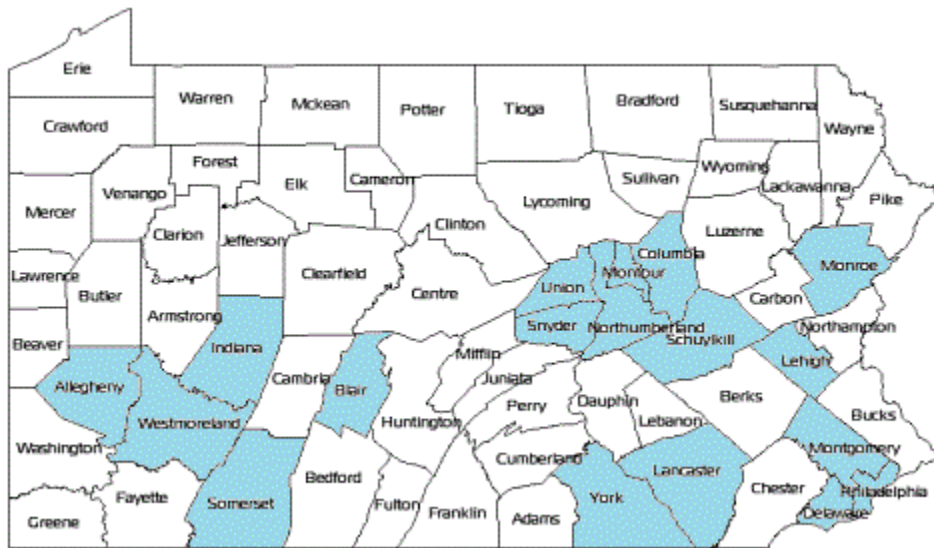
PDA issued Aging Program Directive (APD)# 19-04-01: Older Americans Act Title IIIID Funding for Evidence-Based Programs and Health & Wellness Program. APD# 19-04-01 outlines the roles, responsibilities, and directives between PDA's Health & Wellness Program and the 52 AAA's Health & Wellness Programs serving Pennsylvania's 67 counties.

Chronic Disease Self-Management Program (CDSMP) and Diabetes Self-Management Program (DSMP) are two of the PDA-endorsed evidence-based programs that the AAAs may choose to conduct in their service areas that address diabetes.

In March 2020, due to COVID 19 restrictions, senior community centers needed to close, thereby abruptly ending all Health & Wellness Programs. It was not until May 2020 that the Administration for Community Living provided direction to State Units of Aging in allowing programs such as CDSMP and DSMP to be conducted by video conferences or with toolkits mailed to consumers with weekly check-ins. Lay Leaders needed direction, technical assistance and materials to be able to provide these programs virtually. By July 2020, a Health & Wellness Committee was formed to develop guidance and direction in conducting virtual programs and to safely conduct Health & Wellness Programs during COVID-19 depending on access to other venues other than senior community centers. In October 2020, PDA issued the Health & Wellness Programs Virtual and In-Person Guidance, which provided AAAs instructions to safely conduct evidence-based programs either virtual or in-person with the Department of Health and Centers for Disease Control and Prevention guidelines.

In state fiscal year 2020-2021, there were 299 CDSMP Participants served by 16 AAAs covering 18 counties. Of those 299 CDSMP Participants, 27.1 percent reported they had been diagnosed with diabetes. In state fiscal year 2021-2022, AAAs are planning to provide CDSMP to 863 participants in 44 AAAs serving 57 counties.

SFY 2020-2021 CDSMP Workshops in Pennsylvania



Map provided by Pennsylvania Department of Aging.

CDSMP has received favorable reviews nationwide and in other countries and is available in many different languages. According to the National Council on Aging, a study found that participants who took the program demonstrated the following outcomes:

- A 3 percent reduction in hospital admissions;
- A 5 percent reduction in Emergency Room utilization; and
- An average of \$368 in healthcare savings per participant minus the cost of the program.²³⁶

Diabetes Self-Management Program

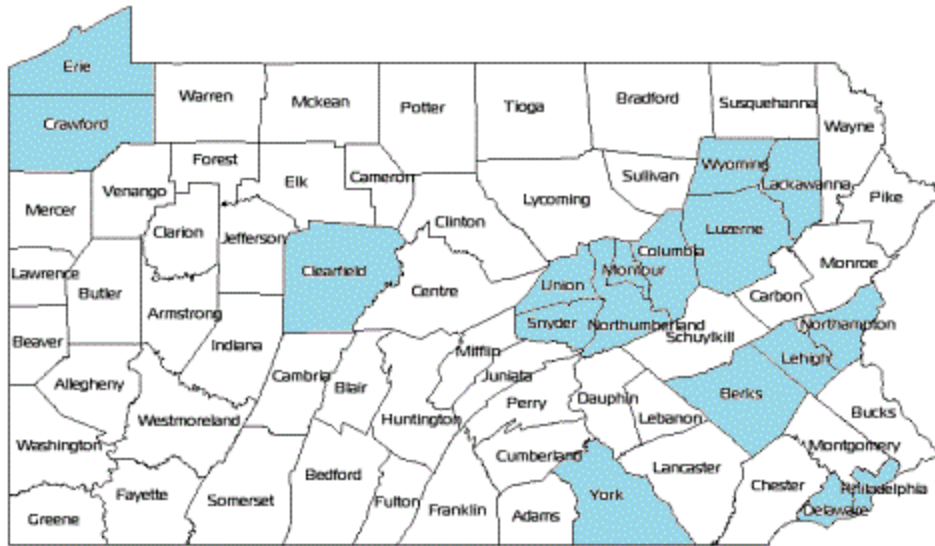
The Diabetes Self-Management Program (DSMP) was developed by Stanford University as a complement to the CDSMP. Similar to CDSMP, DSMP uses certified Lay Leaders or Master Trainers to conduct workshops to teach older adults who have diabetes how to manage their condition. Workshops take place in senior community centers, senior housing facilities, faith-based organizations, libraries, health centers, and various other community sites. In response to the pandemic DSMP is also available virtually by either video conference or with a DSMP toolkit mailed to the consumer with weekly conference calls.

In October 2015, the Health Promotion Council of Southeastern Pennsylvania, Inc. (HPC) was awarded a two-year Prevention and Public Health Fund (PPHF-2015) grant from the Administration on Community Living to expand DSMP in Pennsylvania. With the funding award, DSMP was added to PDA's SMRC license, and HPC was able to provide DSMP training for existing and new PDA Master Trainers and Lay Leaders as well as initial DSMP supplies. Once PDA Master Trainers were cross trained in DSMP, they were able to train new DSMP Lay Leaders. As of July 1, 2021, there are 20 DSMP active Master Trainers and 98 DSMP Lay Leaders serving approximately 30 counties.

In state fiscal year 2019-2020, there were 439 DSMP participants across 15 counties in 18 AAA service areas. Of these 439 DSMP participants, 57.4 percent reported they had been diagnosed with hypertension and 32.8 percent reported obesity as a health care concern.

²³⁶ National Council on Aging. *Improving Quality of Life and Health Care Outcomes through CDSME Programs*, July 17, 2019, <https://www.ncoa.org/healthy-aging/chronic-disease/>.

SFY 2019-2020 DSMP Workshops in Pennsylvania



Map provided by Pennsylvania Department of Aging.

In state fiscal year 2020-2021, there were only 171 DSMP participants and of those participants 37% reported obesity as a healthcare concern. These 171 DSMP participants were served by 10 AAAs covering 11 counties. In state fiscal year 2021-2022, AAAs plan to serve 427 DSMP participants, across 26 counties in 21 AAA service areas.

FY 2020-2021 DSMP Workshops in Pennsylvania



Map provided by Pennsylvania Department of Aging.

In addition to CDSMP and DSMP, the AAA network utilizes approximately 28 other evidence-based programs that address areas such as injury and disease prevention, exercise, chronic conditions, nutrition, mental health, medication management, and substance abuse. These programs are provided at no charge to those 60 years old and older.

PACE

Along with facilitating health and wellness programs which teach older adults practical skills that can help in maintaining good health, preventing illness and injury, and successfully managing their chronic conditions, the Department of Aging is also responsible for programs assisting eligible older Pennsylvanians in paying for their prescription medications. Taking the necessary medications is an essential part of disease management. It is especially critical for chronic conditions, such as diabetes.

The Pharmaceutical Assistance Contract for the Elderly (PACE) program and the PACE Needs Enhancement Tier (PACENET) program assist qualified older adults age 65 years or older in paying for their prescription medications. PACE covers all medications requiring a prescription in the Commonwealth, as well as insulin, insulin syringes, and insulin needles, unless a manufacturer does not participate in the Manufacturers' Rebate Program.²³⁷ PACE pays the cost of prescription drugs and insulin supplies over a copay. PACENET pays the cost of prescription drugs and insulin supplies after a cardholder meets the premium requirement and pays a copayment. The PACEPlus Medicare Program pays Medicare premiums for Part D for PACE and PACENET cardholders. PACENET cardholders repay the Part D premiums. With the goal of providing seamless coverage, the PACE and PACENET programs provide benefits when Medicare Part D does not. For example, benefits are paid during the deductible and the coverage gap, for drugs excluded by Part D or for drugs not in a plan's formulary, and for copayment differentials between the Part D plan coverage and the PACE and PACENET copayments. In 2019, 236,900 older adults were enrolled in the PACE and PACENET programs, 42,900 of whom received antidiabetic pharmaceutical assistance.

The Pennsylvania Patient Assistance Program Clearinghouse (PA PAP) provides the expertise necessary to determine eligibility for persons of all ages who seek assistance from manufacturers' medication programs. In 2020, 13,300 people received medication assistance, including diabetic agents, by contacting the Clearinghouse. PA PAP connects persons with other social service resources, initiates any new programs that are the result of Attorney General Lawsuit settlements, and assists Medicare Part D-enrolled cardholders with obtaining the Low-Income Subsidy benefit.

In 2020, PACE, through the Department of Health, received funds under the Preventive Health and Health Services Block Grant. This ongoing project promoted awareness of prediabetes and the Diabetes Prevention Program to older Pennsylvanians by distributing information to prescribing clinicians. The PACE Academic Detailing Program developed a teaching tool to

²³⁷ Pennsylvania Department of Aging, *PACE (Pharmaceutical Assistance Contract for the Elderly) Annual Report to the General Assembly, January 1 – December 31, 2019*, <https://www.aging.pa.gov/publications/annual-reports/Documents/2019%20PACE%20Annual%20Report.pdf>.

educate 500 clinicians, who care for PACE patients, about screening, testing and referring their eligible patients to local, no or low-cost Diabetes Prevention Programs.

An important component of the PACE program is updating physicians about changing therapies in complicated disease states. Type 2 diabetes is a common chronic condition with projected increases in prevalence for Pennsylvania that will continue to challenge health care providers. In April 2016, the program released an updated diabetes education module as part of its long-standing physician education program. Clinical educators completed 737 physician office visits in 2016-2018 on this topic. In April 2019, the diabetes module was updated again to reflect the new clinical trials and treatment guidelines that led to changes in diabetes medication utilization. From May 2019 through May 2021, 853 clinicians received one-on-one education.

The 2019 module includes

- Written evidence reports (print monograph)
- Summary document of top 4-5 key messages
- Academic detailing education sessions in physicians' offices delivered by trained outreach educators (pharmacists, nurses, physicians) who present the material face-to-face
- Reference cards for easy access to key materials
- Patient education brochures and tear-off sheets

The goals for the diabetes educational program are to help practitioners

- Choose an appropriate target HbA1C based on a patient's health status and response to treatments, with a goal of 7% for most patients with diabetes;
- Select metformin as first-line treatment for all patients with type 2 diabetes who require drug treatment, unless contraindicated;
- Choose appropriate additional therapeutic interventions for patients not controlled on metformin based on patient characteristics;
- Regularly recommend a healthy diet and regular exercise and assess adherence to medications before titrating doses;
- Select insulin as the agent of choice to be initiated promptly when non-insulin agents are not sufficient to achieve HbA1C target;
- Manage hypertension and hyperlipidemia aggressively to prevent type 2 diabetes-related complications.

Educational modules are found at www.alosahealth.org, under Our Solutions. PACE Academic Detailing Modules are designated for *AMA PRA Category 1 Credits* by the Harvard Medical School.

To evaluate the effectiveness of its academic detailing, the program conducted a collaborative research and evaluation project with Wilkes University. This program evaluation study specifically examined prescribing patterns before and after prescribers participated in the program's 2013 diabetes management module. The module provided information on the comparative effectiveness and safety of diabetes medications, presented evidence regarding appropriate therapy strategies, and weighed the benefits, risks, and value of treatment options with the intent to improve the quality of prescribing and patient care. This interrupted time series evaluation focused on the third diabetes educational outreach intervention that was presented to 704 prescribers in 2013-14. In addition to the group of prescribers who received the diabetes management training, the evaluation analysis also includes a comparison group of prescribers who did not receive the training.

The quality metrics identified for this study included

- Prescribing metformin in older patients with diabetes
- Prescribing of HMG-CoA reductase inhibitors (statins) in diabetic patients
- Prescribing of either an angiotensin-converting-enzyme (ACE) inhibitor or an angiotensin II receptor blocker (ARB) for patients who have both diabetes and hypertension
- Avoidance of long-acting sulfonylureas (chlorpropamide, glyburide) in older patients with diabetes.

The results did not demonstrate differences between the intervention and comparison groups with respect to the four metrics. However, most prescribers in the detailed group had been exposed to more than one wave of diabetes training since 2007, and the quality metrics have become the standard of care. The findings are consistent with a ceiling effect in the measured metrics, suggesting that most prescribers were following treatment guidelines during the evaluation period. These results have been accepted for publication in *American Health & Drug Benefits* in 2019.

DEPARTMENT OF HUMAN SERVICES

Medical Assistance (Medicaid)

In state fiscal year 2019-20 – the latest period for which data are available – there were 212,738 total Medicaid recipients with diabetes.²³⁸

The Department of Human Services' (DHS) Office of Medical Assistance Programs oversees the Physical Health component of the HealthChoices Program. The HealthChoices Program is the name of Pennsylvania's mandatory managed care program for Medical Assistance (MA, or Medicaid) recipients. Medicaid recipients gain access to medical care and appropriate physical health services through Physical Health Managed Care Organizations (MCOs).

Regular screenings are a key to successful diabetes management, to prevention, early detection, and prompt treatment of dangerous and expensive complications. As reflected in the table below, the number of these critically important screenings for Medicaid patients in the Commonwealth has been growing consistently or remaining constant in recent years.

HealthChoices Performance Areas Medical Assistance Recipients with Diabetes Average Annual Screenings by Type, 2018-2020			
Type of Screening or Exam	Percentages of Recipients		
	2018	2019	2020
BP Control (<140/90 mmHg)	69.2%	68.3%	70.7%
Eye	59.0%	58.6%	60.0%
A1C	87.2%	86.6%	87.6%
Nephropathy	89.6%	89.0%	89.8%

Education and outreach are an important part of improving diabetes control and maintenance.

²³⁸ This section of the report is largely based on the information provided to the Joint State Government Commission by the Department of Human Services on June 25, 2021.

All of the HealthChoices MCOs offer education and outreach to both providers and members concerning diabetes. Some of the information offered to providers describes best practices, how to code to identify diabetic members, and home lab testing and re-testing protocols for members with high results. Examples of member education offered are diabetes disease specific education, instructions for obtaining screening and follow-up testing, and medication adherence coaching. Examples of member outreach include Diabetes Trac phone text messages, tele-monitoring, tele-retinal in-home screening and community events, which offer hemoglobin A1C screenings and diabetic eye exams.

The MCOs also have implemented a community-based care management (CBCM) model of care to meet members in the community. The CBCM team may consist of licensed and non-licensed staff such as registered nurses, social workers, community health workers, or pharmacists depending on the need of the MCO's population. CBCM staff meet diabetic members face-to-face in their community or home to assist with filling out health care forms, making calls to the member's doctor's office to schedule an appointment, arranging transportation to the doctor's office or obtaining a referral for a specialist. To assist high volume practices with their diabetics Medicaid members, MCOs have embedded community health workers, pharmacists, diabetic navigators and/or social workers to assist with members who require higher touch interactions to ensure medical services that are needed are obtained. Diabetic navigators alert providers about their members who are due or overdue for testing. These navigators also educate members on diabetes, screenings and re-testing, medication adherence, scheduling appointments and ensuring appointments are kept, and assisting with any barriers that the member may have. These interactions are mostly face-to-face; however, they can also occur telephonically.

Some MCOs have implemented a Medication Therapy Management (MTM) program for their diabetic members. MTM involves a pharmacist who interacts with an MCO's diabetic member at the pharmacy to review the types, amounts, and duration of medications prescribed by the member's physician. Registered nurses or community health workers will also conduct home visits and review medications with the pharmacists by phone to ensure the member has the correct prescriptions and is taking them as prescribed.

In addition, some of the MCOs offer Food as Medicine programs through partnerships with the Metropolitan Area Neighborhood Nutrition Alliance (MANNA) in Philadelphia, Geisinger's Fresh Food Farmacy (FFF), and Family Food (FF) programs. These programs provide diabetes education, along with meals for members and their families.

In October 2018, DHS and DOH began participation in the Centers for Disease Control and Prevention (CDC) 6 | 18 Initiative to implement the coverage of CDC recognized Diabetes Prevention Programs (DPP) in the MA program. Starting in calendar year 2019, the MCOs were contractually required to implement a DPP pilot consistent with the CDC's DPP guidelines. DPP is an evidence-based lifestyle change program that requires a participant to complete all 22 sessions of the yearlong program (16 weekly sessions during the first six months and six-monthly sessions during the second six months). The program is designed for individuals 18 years or older who have prediabetes or are at-risk for type 2 diabetes, but who do not already have diabetes. The year-long program is delivered in-person, online, or through a combination approach using group support. The goal of the program is to increase prediabetic individuals' knowledge of proper nutrition and

eating habits, leading to weight loss, decreased hemoglobin A1C levels and decrease likelihood of becoming a type 2 insulin-dependent diabetic in the future.

On July 1, 2019, DHS began enrolling CDC-recognized DPP providers in the MA program so that they could begin to contract with the MCOs as in-network providers. As MCO network providers, these DPP providers will play an integral role in the MCOs' Diabetes Prevention Programs required within their Community Based Care Management programs. To date, a total of seven (7) DPP providers are enrolled in Pennsylvania's MA Program.

In 2020, DPP programming with MA continued to evolve along two parallel tracks, with focus on provider capacity development as well as increased outreach to MCO members. The CDC 6|18 initiative offered states with a second round of DPP technical assistance for 2020. The National Association of Chronic Disease Directors (NACDD) provided DPP technical assistance to the DOH and DHS. The collaborative efforts between DOH and DHS continue to provide lifestyle change services to recipients with type 2 diabetes under the DPP. During the second year of technical assistance, DOH and DHS met monthly with NACDD. These meetings and discussions led to an increase in DPP provider capacity. On October 7, 2020, DOH hosted an educational workshop with NACDD for CDC recognized DPP organizations who wish to enroll in the MA program. The workshop allowed MA provider enrollment staff to educate DPP providers on the process of applying to enroll in the MA program.

Due to the success of the DPP pilots implemented by the MCOs during 2019, the MCOs were contractually required to implement the programs on an ongoing basis beginning in 2020. MCOs were also required to refer members who are identified as pre-diabetic to CDC recognized or Medicare enrolled Diabetes Prevention Programs. As a result, 552 HealthChoices beneficiaries have been enrolled in Diabetes Prevention Programs. Throughout the year, MCOs expanded and sustained their pilot programs, developing unique DPP strategies based on population demographics within the regions they serve.

The greatest challenge the MCOs have faced in implementing DPP programming is retaining recipients in the lifestyle change program due to its duration and intensity. The COVID-19 public health emergency also presented challenges to the program. In March 2020, for example, a CDC-recognized DPP provider in the Southeast zone dissolved and furloughed staff. However, the public health emergency also offered an opportunity for innovation. MCOs have either implemented or are in the process of implementing a virtual DPP delivery option. The greatest success of the virtual programming is shown by a MCO in the Southwest that had robust enrollment and modest retention of members. This success demonstrated members are willing to be engaged and complete a DPP lifestyle change program, especially in a virtual manner. Some MCOs are leveraging opportunities to share best practices by participating in the Health Promotion Council (HPC) and Pennsylvania Community Living Initiative (PA CLI) Leadership Sustainability Group and the National Diabetes Prevention Program Virtual Learning Collaborative Statewide Engagement.²³⁹

²³⁹ Information on HealthChoices education and outreach was reported by each individual MCO in February 2021.

Community HealthChoices (CHC)

The Community HealthChoices (CHC) program is administered by the Office of Long-Term Living. It is intended for dually eligible individuals (Medicare and Medical Assistance), older adults, and individuals with physical disabilities. The data available is the 2020 data that indicates 26% of Community Health Choices (Managed Medicaid Long-Term Services and Supports) members carry a diagnosis of diabetes.

The Standards of Care set forth for the CHC program include the following:

- a) Maintenance of participants' blood sugars and hemoglobin A1c levels within ADA guidelines both as inpatients and outpatients.
- b) Maintaining appropriate diabetic diets and medications.

Some perceived challenges include

- a) Consistent monitoring of patients' blood sugar level and their A1c level, especially as they transition from settings such as hospitals and nursing facilities to a home- and community-based setting.
- b) Maintaining diabetic (consistent carbohydrate) dietary compliance in this population.
- c) Specific challenges are involved in the CHC population who carry a diagnosis of schizophrenia as this group is noted to have a high prevalence of diabetes.
- d) The diabetic population is at particular risk of morbidity and mortality from COVID-19 due to their immunocompromised status.

Strategies to address the above include the following steps:

- a) All CHC MCOs have developed individual person-centered service plans for every participant deemed nursing-facility clinically eligible, and these plans address diabetic education, monitoring, and medication usage and compliance.
- b) All CHC MCOs are reporting to both DHS and NCQA, annually, on the number of participants who are getting appropriate blood sugar and hemoglobin A1c checks.

New initiatives for 2020/2021 are largely related to COVID-19, and they include the following:

- 1) CHC plans to work with their service providers to educate participants that are immunocompromised and work to ensure that they have an understanding of the risks COVID-19 poses to the diabetic population.

- 2) From August to December 2020, the Regional Response Health Collaborative Program (RRHCP), working with the Long-Term Care Task Force, has undertaken over 13,900 missions to assist long-term care facilities, including personal care homes, nursing facilities, and congregate care facilities, providing testing, clinical support, and infection prevention. Included in this effort was special attention to the needs of the high-risk diabetic residents and staff in a facility with a COVID-19 outbreak.
- 3) The RRHCP program has administered monoclonal antibodies at both nursing facilities and personal care homes to diabetic residents who were identified as COVID-19 positive in order to avoid hospitalization and other severe disease outcomes for these individuals.

YMCA'S DIABETES PREVENTION PROGRAM

YMCAs play an important part in chronic disease prevention. Pennsylvania YMCAs, in particular, strive to increase awareness of type 2 diabetes and prediabetes and to offer people tools to reduce their risk for developing this disease and for improving their health outcome when they have it.

The YMCA's Diabetes Prevention Program uses a CDC-approved curriculum and is part of the CDC-led National Diabetes Prevention Program. The YMCA's Diabetes Prevention program is available to all qualifying individuals regardless of their insurance status and their Y membership or lack thereof.²⁴⁰

As with many other organizations, YMCAs across Pennsylvania were faced with challenges during the COVID-19 pandemic, which was officially declared a public health emergency. Some YMCAs had to furlough staff or switch existing staff's responsibilities from facilitating the Diabetes Prevention Program to other areas of the YMCA, which meant a halt in delivery. YMCAs that were able to continue the program had to do so on a virtual platform. This mode presented some challenges navigating the technological aspect of virtual classes, but it has also become apparent that it can eliminate barriers to access of programs.

YMCA's included in data pull

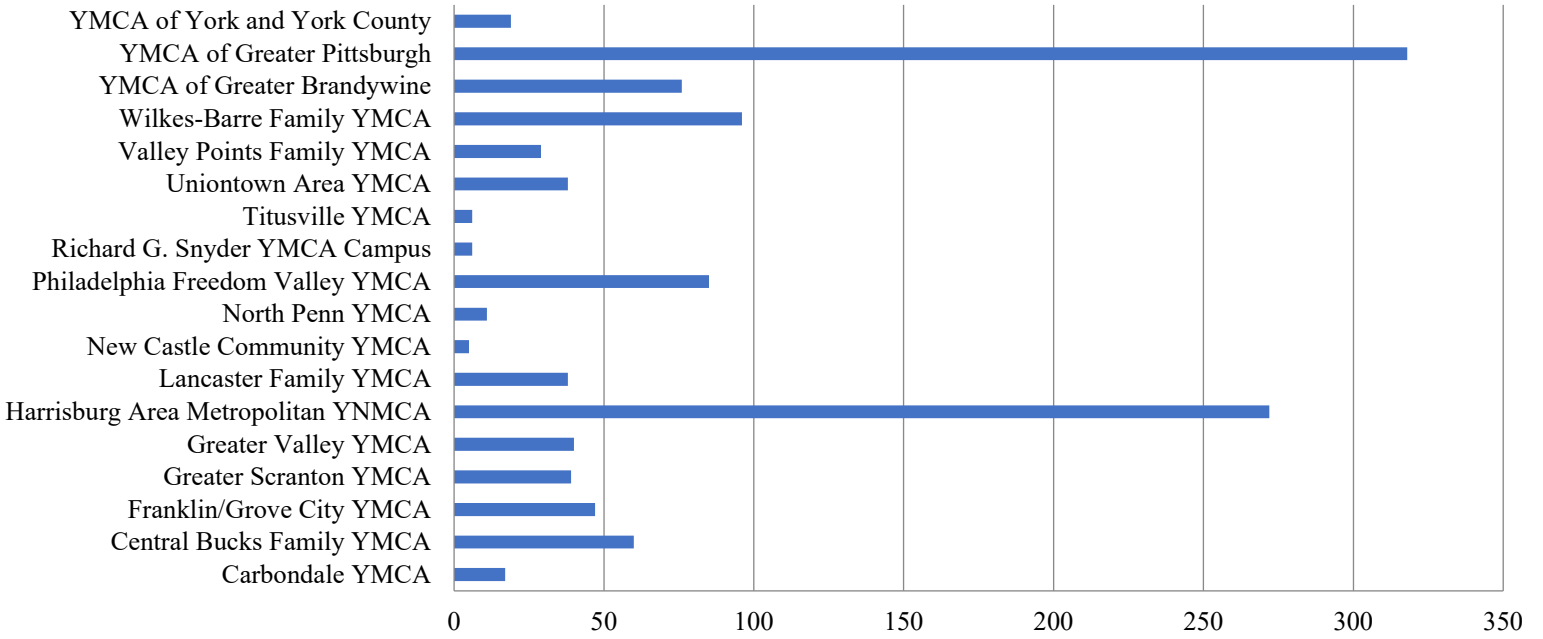
Carbondale YMCA	Philadelphia Freedom Valley YMCA
Central Bucks Family YMCA	Richard G. Snyder YMCA Campus
Franklin/Grove City YMCA	Titusville YMCA
Greater Scranton YMCA	Uniontown Area YMCA
Greater Valley YMCA	Valley Points Family YMCA
Harrisburg Area Metropolitan YMCA	Wilkes-Barre Family YMCA
Lancaster Family YMCA	YMCA of Greater Brandywine
New Castle Community YMCA	YMCA of Greater Pittsburgh
North Penn YMCA	York & York County YMCA

YMCA's not included in data pull

Berwick Area YMCA	Meadville YMCA
Blair Regional YMCA	Shenango Valley YMCA
Butler YMCA	YMCA of Greater Erie
Chambersburg Memorial YMCA	

²⁴⁰ The following section of the report is largely based on the information provided to the Joint State Government Commission by Ms. Megan Maurer, Senior Program Director, Harrisburg Area YMCA, in the personal e-mail of July 20, 2021.

Participants Enrolled



CITIES CHANGING DIABETES

The bulk of programs and activities aimed at controlling diabetes and preventing the disease are administered by state departments funded by the Federal Government and the Pennsylvania General Assembly. In addition, there are public/private initiatives that may also contribute to the fight against diabetes and obesity. One of such programs, Cities Changing Diabetes, is sponsored by Novo Nordisk, a global healthcare company, that aspires to bring together the private and public sectors “to find new ways to change the trajectory of diabetes, including reducing obesity, which is considered the biggest modifiable risk factor of diabetes, in their neighborhoods and communities.”²⁴¹

The Cities Challenging Diabetes program was launched in Philadelphia in 2019. Philadelphia is the second of the North American cities to join it (Houston, TX, started it in 2014). Philadelphia is among the cities in the U.S. that have the highest number of people with diabetes and is projected to stay in the top ten in 2030.²⁴² In Philadelphia, Novo Nordisk works on the program in collaboration with the Health Promotion Council (HPC), an affiliate of the Public Health Management Corporation (PHMC), along with other local medical and public-health institutions, social services and faith organizations. The Health Promotion Council is a nonprofit corporation in Southeastern Pennsylvania. HPC declares its mission is “to promote health and prevent and manage chronic diseases, especially among vulnerable populations, through community-based outreach, education and advocacy.”²⁴³ Cities Challenging Diabetes awards funding to innovative community-based programs to help combat diabetes and obesity. The programs are chosen by a screening team comprised of local health care, community, and public health experts. For 2021, five programs were selected to receive preliminary funding in the amount of \$20,000 from Novo Nordisk; programs will also receive further technical assistance to help with implementation. Each of these five initiatives “represents an innovation in disease prevention, care or management, and is supported by a coalition of Philadelphia-based non-profit and health care organizations.”²⁴⁴

The following five initiatives were selected for this year:

- Activate! Advocates for Diabetes Prevention
- Champions of Hope: Latinos Preventing Diabetes
- Developing a Peer & Community Approach for Managing Diabetes in Disability

²⁴¹ Novo Nordisk. *Cities Changing Diabetes Announces Five New Programs to Fight Diabetes and Obesity in Philadelphia*, <https://www.prnewswire.com/news-releases/cities-changing-diabetes-announces-five-new-programs-to-fight-diabetes-and-obesity-in-philadelphia-301207096.html>.

²⁴² *Metro Areas with the Highest Projected Diabetes Rates*, <https://psydprograms.org/projected-diabetes-rates-in-america/>.

²⁴³ Health Promotion Council, <https://www.phmc.org/site/affiliates/health-promotion-council>.

²⁴⁴ Novo Nordisk. *Cities Changing Diabetes Announces Five New Programs to Fight Diabetes and Obesity in Philadelphia*, <https://www.prnewswire.com/news-releases/cities-changing-diabetes-announces-five-new-programs-to-fight-diabetes-and-obesity-in-philadelphia-301207096.html>.

- Eat to Live, and
- Prison Pre-Release Health Initiative.²⁴⁵

The initiative Activate! Advocates for Diabetes Prevention, developed by HPC and PHMC, will train three cohorts of youth ages 13 to 18 to become community advocates for policy and environmental change solutions to prevent the rising epidemic of obesity, diabetes, and prediabetes among young people. These youth leaders will work on seeking solutions to public health challenges. The participants' activities will include a social media campaign and workshop series designed to engage other youth in conversations about obesity and type 2 diabetes prevention strategies and "to empower them to advocate at the city and county levels to transform the underlying social and environmental factors of obesity and diabetes."²⁴⁶

The Champions of Hope: Latinos Preventing Diabetes program was developed by Esperanza and Jefferson Health System / Thomas Jefferson University Hospital's Center for Urban Health / Thomas Jefferson University College of Population Health & College of Nursing. This inter-generational Latinx program is designed to engage youth leaders as catalysts for community health education. The program's cornerstone is declared to be "the empowerment of youth across the K-12 educational pipeline and the training of Community Health Workers drawn from a network of local community residents."²⁴⁷ The goal is for the youth leaders and Community Health Workers to work together in order to build capacity and momentum for sustained obesity and diabetes prevention programming in Hunting Park, the center of Hispanic North Philadelphia.

The initiative Developing a Peer & Community Approach for Managing Diabetes in Disability was developed by Temple University's College of Public Health. This community-based program is focused on a peer-based approach to connect individuals experiencing spinal cord injury, intellectual and developmental disabilities, or serious mental illness to sustainable and accessible resources necessary to manage their diabetes and maintain a healthy lifestyle. Faculty from the Temple's College of Public Health will train and employ a peer workforce comprised of individuals who have disability and diabetes to support others with these conditions, promote person-centered approaches to treating and preventing diabetes, and serve as "a critical voice for improving the health and well-being of individuals with disabilities."²⁴⁸

The initiative "Eat to Live," developed by Congreso de Latinos Unidos, Inc.; HMC, PHMC, and Sanctuary Farm, is expected to scale up the original Eat to Live pilot program, which integrates personalized non-medical interventions into the primary care services that patients already receive and provides participants with a peer support network, monthly produce baskets, nutrition lessons, cooking demonstrations, and behavioral health support. The program will be replicated at Congreso and expanded to other Federally Qualified Health Centers (FQHCs) in their network. The intention is to increase access to the program across the City of Philadelphia in FQHC settings that are already familiar to and trusted by the target population.

²⁴⁵ *Cities Changing Diabetes*, www.citieschangingdiabetes.com.

²⁴⁶ Ibid.

²⁴⁷ Ibid.

²⁴⁸ Ibid.

The Prison Pre-Release Health Initiative was developed by the Food Trust, the City of Philadelphia Reentry Coalition, Thomas Jefferson University College of Nursing, Action Wellness Health Services, Temple University College of Public Health Department of Rehabilitation Sciences, the Philadelphia Department of Prisons and Community-based Reentry/Recovery houses. This 6-week nutrition education/cooking series is designed for inmates and returning citizens to help them make healthier food choices in prison and learn how to shop and prepare healthy meals upon returning home. Approximately half of individuals in prison report having a chronic condition, including obesity, diabetes, and hypertension. When the formerly incarcerated return to the community, they often face financial insecurity and food insecurity; they frequently face challenges purchasing and eating healthy foods, which results in a negative impact on their health. This initiative is intended to help them address these challenges.

All the new initiatives selected by Cities Changing Diabetes target vulnerable populations in Philadelphia and are intended to help curtail the incidence and prevalence of diabetes and obesity by means of nutrition education, advocacy, and increased access to healthy foods. These initiatives deserve attention, especially in light of the growing awareness of the importance of social determinants of health. The programs' outcomes and impact will need to be evaluated in the future.

RECOMMENDATIONS

General Assembly Responses

Pass legislation banning non-medical switching.

Mandate that health plan policies significantly limit step therapy regulations for patients with diabetes and other chronic diseases. These should rely only on current clinical data, be transparent, and offer clear and concise exceptions to step therapy protocols based on medical necessity. A patient's switching from one health plan to another should not involve a restart of step therapy.

Pass legislation installing caps on out-of-pocket payment for insulin and other essential diabetes medications.

Consider mandating that health care plans treat insulin and essential equipment necessary for diabetes maintenance (glucometers, strips, et cetera) as preventive coverage so that it would require no copay.

Other Recommendations

Providers and healthcare systems should prioritize the delivery of patient-centered care.

All people with type 2 diabetes should have access to ongoing Diabetes Self-Management Education and Support programs (DSMES) offered in a variety of formats to meet patients' specific needs.

As better adherence leads to better outcomes, several steps need to be taken at various levels to facilitate that:

- Doctors should make treatment decisions collaboratively with patients, taking into account their individual preferences, prognoses, and comorbidities.
- Insurance companies should eliminate non-medical switching and significantly curtail step therapy regulations for patients with diabetes and other chronic diseases.

Emphasis should be put on early detection and management of diabetes among adolescents and young adults.

Healthcare providers should increase attention to gestational diabetes screening and maintenance.

Effective tailored approaches are required to improve risk factor control.

Improved early screening and effective preventive interventions for people with prediabetes need to be implemented broadly.

Development of a broader framework for diabetes prevention that matches risk tiers to diverse evidence-based interventions to serve individuals at varying levels of risk and that provides more personalized prevention would play a big part in decreasing the incidence of diabetes.

Effectiveness and cost-effectiveness of all programs aimed at diabetes prevention and obesity treatment should be thoroughly and continuously evaluated. It is important to realize that multicomponent lifestyle interventions are most cost-effective among groups with the highest levels of risk.

Experiences during the COVID-19 pandemic and recent natural disasters should be examined and evaluated; based on this analysis, medical providers, healthcare systems, pharmacies, employers, and insurance companies should develop and implement measures that would facilitate safe diabetes and other chronic diseases management during a pandemic and/or other national emergencies. Certain strategies and care delivery formats introduced during the pandemic may be useful in regular diabetes management as well; these include virtual care and education models and hybrid models of care delivery (when appropriate).

PRIOR PRINTER'S NO. 3907

PRINTER'S NO. 4098

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE RESOLUTION

No. 936 Session of
2014

INTRODUCED BY OBERLANDER, LONGIETTI, BAKER, BOBACK, V. BROWN,
CALTAGIRONE, CAUSER, COHEN, D. COSTA, DONATUCCI, FLECK,
GIBBONS, GINGRICH, GODSHALL, GRELL, GROVE, HARHART, HEFFLEY,
KAUFFMAN, KILLION, KIRKLAND, KOTIK, KULA, LUCAS, MAJOR,
MENTZER, MILLARD, MURT, MUSTIO, O'BRIEN, READSHAW, SONNEY,
SWANGER, TALLMAN, THOMAS, TOBASH, WHITE, YOUNGBLOOD, SCHLEGEL
CULVER, JAMES, BENNINGHOFF, BRIGGS, PICKETT, WATSON,
McCARTER, PYLE AND QUINN, JULY 1, 2014

AS REPORTED FROM COMMITTEE ON HEALTH, HOUSE OF REPRESENTATIVES,
AS AMENDED, SEPTEMBER 17, 2014

A RESOLUTION

1 Directing the Joint State Government Commission, in
2 collaboration with certain other State departments and
3 agencies, to develop a report on diabetes and to issue the
4 report to the House of Representatives.

5 WHEREAS, More than 990,000 adults in this Commonwealth have
6 been diagnosed with diabetes; and

7 WHEREAS, An estimated 517,000 Pennsylvanians are undiagnosed;
8 and

9 WHEREAS, An estimated 3.27 million Pennsylvanians are at risk
10 of developing diabetes; and

11 WHEREAS, Diabetes and its complications are the seventh
12 leading cause of death in this Commonwealth; and

13 WHEREAS, Diabetes will cost Pennsylvanians an estimated ~~\$1.7~~ <--
14 \$14.7 billion in 2015 and an estimated \$18.4 billion by the year <--
15 2025; and

1 WHEREAS, Statistics show that with appropriate management and
2 early identification, costs related to diabetes can be
3 significantly reduced; therefore be it

4 RESOLVED, That the House of Representatives direct the Joint
5 State Government Commission to submit a report on diabetes that
6 identifies goals and benchmarks and includes plans to reduce the
7 incidence of diabetes, improve diabetes care and control
8 complications associated with diabetes; and be it further

9 RESOLVED, That the Joint State Government Commission develop
10 the report on diabetes in collaboration with all of the
11 following:

- 12 (1) The Department of Health.
- 13 (2) The Department of Public Welfare.
- 14 (3) The Department of Education.
- 15 (4) The State Employees' Retirement System.
- 16 (5) The Health Care Containment Council.
- 17 (6) Any additional State departments or agencies the
18 commission deems appropriate to develop, research and prepare
19 the report;

20 and be it further

21 RESOLVED, That the Joint State Government Commission assess
22 the financial impact and reach diabetes has on the residents of
23 this Commonwealth and the State departments and agencies
24 collaborating on the report, and that the assessment include all
25 of the following:

- 26 (1) The number of individuals with diabetes impacted or
27 covered by the State department or agency.
- 28 (2) The number of individuals with diabetes and family
29 members impacted by prevention and diabetes control programs
30 implemented by the State department or agency.

1 (3) The financial toll or impact diabetes and its
2 complications placed on State department or agency programs.

3 (4) The financial toll or impact diabetes and its
4 complications placed on the State department or agency
5 programs in comparison to other chronic diseases and
6 conditions;

7 and be it further

8 RESOLVED, That the Joint State Government Commission conduct
9 an assessment of the benefits of implemented programs and
10 activities aimed at controlling diabetes and preventing the
11 disease, and that the assessment include the amount and source
12 for any funding from the Federal Government and the General
13 Assembly for programs and activities aimed at reaching those
14 with diabetes; and be it further

15 RESOLVED, That the Joint State Government Commission provide
16 a description of the level of coordination existing between
17 State departments and agencies on activities, programmatic
18 activities and messaging on managing, treating or preventing all
19 forms of diabetes and its complications; and be it further

20 RESOLVED, That the Joint State Government Commission provide
21 detailed plans and recommendations for the control and
22 prevention of diabetes for consideration by the General
23 Assembly, and that the plans and recommendations do all of the
24 following:

25 (1) Identify proposed action steps to reduce the impact
26 of diabetes, pre-diabetes and related diabetes complications.

27 (2) Identify expected outcomes of the action steps
28 proposed in the following biennium.

29 (3) Establish benchmarks for controlling and preventing
30 relevant forms of diabetes; and be it further

1 RESOLVED, That the Joint State Government Commission develop
2 a detailed budget blueprint identifying needs, costs and
3 resources required to implement the plans and recommendations of
4 each department or agency, and that the blueprint include a
5 budget range for all options presented in the recommendations
6 identified by each department or agency for consideration by the
7 General Assembly; and be it further

8 RESOLVED, That the Joint State Government Commission provide
9 the initial report on the estimated number of individuals with
10 diabetes, pre-diabetes or related diabetes ~~within~~ WHO ARE SERVED <--
11 BY each department or agency and any additional information the
12 commission deems appropriate to the General Assembly by March 1,
13 2015; and be it further

14 RESOLVED, That the Joint State Government Commission submit a
15 ~~final~~ COMPREHENSIVE report on the items listed in this <--
16 resolution to the Diabetes Caucus of the House of
17 Representatives and the Human Services Committee AND THE HEALTH <--
18 COMMITTEE of the House of Representatives by September 15, 2015,
19 and by September 15 of each odd-numbered year thereafter
20 following the release of the initial report.