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DIABETES PREVENTION PROGRAM SUMMARY OF EVIDENCE AND RESEARCH

1. Reduction in the Incidence of Type 2 Diabetes Lifestyle Intervention or Metformin

Reference:

Diabetes Prevention Program Research Group. "Reduction in the Incidence of Type 2 Diabetes Lifestyle Intervention or Metformin." *The New England Journal of Medicine*. February 7, 2002 Vol. 346, No. 6.

Summary:

Type 2 diabetes affects approximately 8 percent of adults in the United States (U.S.). Some risk factors such as elevated plasma glucose concentrations in the fasting state and after an oral glucose load, overweight, and a sedentary lifestyle are potentially reversible. The Diabetes Prevention Program (DPP) sought to determine the most effective way to prevent type 2 diabetes. The multi-center, randomized trial hypothesized modifying lifestyle factors such as weight and physical activity with an intensive lifestyle-intervention program or the administration of metformin would prevent or delay the development of diabetes.

Conclusions:

Lifestyle changes and treatment with metformin both reduced the incidence of diabetes in persons at high risk. The lifestyle intervention was more effective than metformin. The intensive lifestyle intervention demonstrated a 58 percent reduction in risk among the intervention group and an even greater risk reduction, 71 percent, was shown for adults age 60 and over. In comparison, those among the group that received metformin experienced a 31 percent reduction in the incidence of type 2 diabetes.

Useful Quotes and Statistics:

- The DPP trial and study demonstrated a reduction in the incidence in type 2 diabetes among adults at high-risk.
- The intensive lifestyle intervention demonstrated a 58 percent reduction in risk among the intervention group and an even greater reduction, 71 percent, was shown for adults age 60 and over. In comparison, those among the group that received metformin experienced a 31 percent reduction in the incidence of type 2 diabetes.
- Nearly half, 45.3 percent, of trial participants represented racial and ethnic minority groups.
- Overall 69.4 percent of participants had a family history of type 2 diabetes.
- Researchers utilized two separate blood glucose values to qualify trial participants – fasting blood glucose and oral glucose tolerance tests.

2. Translating Diabetes Prevention Program into the Community: The DEPLOY Study

Reference:

Ronald T. Ackermann, MD, MPH; Emily A. Finch, MA; Edward Brizendine, MS; Honghong Zhou, PhD; David G. Marrero, PhD. "Translating Diabetes Prevention Program into the Community: The DEPLOY Study." *American Journal Preventive Medicine*. 2008. Vol. 35, No. 4:357–363.

Summary:

This cluster-randomized clinical trial compared a group-based Diabetes Prevention Program lifestyle intervention delivered by the YMCA to a brief counseling (control) in adults who attended a diabetes risk-screening event at one of two semi-urban YMCA facilities. The purpose was to determine the feasibility of offering the DPP in community settings by evaluating group-based DPP lifestyle intervention delivery in partnership with the YMCA.

Conclusions:

After six months, 92 participants decreased body weight by 6 percent in the lifestyle intervention and by 2 percent in the control group. Intervention participants also had a greater change in total cholesterol. The lifestyle group decreased their cholesterol by 22 milligrams per deciliter, while the control group increased their cholesterol by 6 milligrams per deciliter. These differences were sustained after 12 months, and adjustments for races and gender did not alter these findings. The YMCA may be a promising channel for wide-scale dissemination of a low-cost approach to lifestyle diabetes prevention.

Useful Quotes and Statistics:

- The DEPLOY study evaluated the delivery of a group-based DPP lifestyle intervention in partnership with the YMCA.
- This study found that YMCA wellness instructors can be trained to deliver a group-based DPP lifestyle intervention and achieve changes in body mass after 6 and 12 months that are comparable to the DPP study.
- Much of the difficulty in disseminating the original DPP lifestyle intervention has been the relatively high cost of one-on-one delivery by behavioral experts.
- In this study, the hourly wage of YMCA group instructors was approximately one half that of behavioral experts in the DPP.
- DEPLOY demonstrated a nearly 75 percent cost savings from the original DPP study by using YMCA lay health workers to deliver the program.
- The study demonstrated the YMCA is a promising partner for wide-scale dissemination of a low-cost approach to lifestyle intervention diabetes prevention.

3. Diabetes Prevention Program Outcomes Study

Reference:

Diabetes Prevention Program Research Group. "Diabetes Prevention Program Outcomes Study." *The Lancet*. November 14, 2009. Vol. 374, No. 9702: 1677-1686.

Summary:

This study investigated the persistence of the long-term effects of the Diabetes Prevention Program randomized clinical trial. The DPPOS investigated the long term effects of the DPP trial. Participants in the original DPP study were assessed 10 years after the trial's start date to ascertain whether weight loss and diabetes incidence persisted after the DPP study ended.

Conclusions:

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During the 10 year follow-up since randomization to DPP, the original lifestyle group lost and then partly regained weight. The modest weight loss with metformin was maintained. Diabetes incidence in the 10 years since DPP randomization was reduced by 34 percent in the lifestyle group and 18 percent in the metformin group compared with placebo.

During follow-up after DPP, incidences in the former placebo and metformin groups fell to equal those in the former lifestyle group, but the cumulative incidence of diabetes remained lowest in the lifestyle group. This study demonstrated prevention or delay of diabetes with lifestyle intervention or metformin can persist for at least 10 years.

Useful Quotes and Statistics:

- After 10 years from the randomization in to the DPP trial participants' diabetes incidence rates were reduced by 34 percent in the lifestyle group and 18 percent in the metformin group, compared with the placebo.
- During the follow-up after DPP, incidences in the placebo and metformin groups fell equal to those in the former lifestyle group, but the cumulative incidence of diabetes remained lowest among the intensive lifestyle intervention group.
- Prevention or delay of diabetes with lifestyle intervention can persist for at least 10 years.

4. Statement for hearing entitled, "NIH in the 21st Century: The Director's Perspective"

Reference:

Statement of Francis S. Collins, MD, PhD, Director, National Institutes of Health, U.S. Department of Health and Human Services. "Statement for hearing entitled, 'NIH in the 21st Century: The Director's Perspective'." *Testimony before the Subcommittee on Health, Committee on Energy and Commerce, United States House of Representatives*. June 15, 2010.

Summary:

The Director of the National Institutes of Health (NIH), Francis S. Collins, MD, PhD, gave testimony to the U.S. House of Representatives outlining the importance of diabetes prevention and the NIH's role in funding lifestyle intervention studies to prevent type 2 diabetes.

Conclusions:

No conclusions based on research are stated in this testimony.

Useful Quotes and Statistics:

- "For type 2 diabetes, prevention appears to be the name of the game. This form of the disease, which accounts for more than 90percent of cases, often can be averted or delayed by lifestyle changes."
- "The NIH-funded Diabetes Prevention Program trial showed that one the most effective ways to lower the risk of type 2 diabetes is through regular exercise and modest weight loss. There is good reason to believe that such efforts may lead to a lifetime of additional health benefits. A recent follow-up study of DPP participants found the protective effects of weight loss and exercise persist for at least a decade. NIH also led research efforts to explore ways to implement DPP findings in real-world settings at lower cost, such as in YMCAs. The United Health Group has recently announced a partnership with YMCAs and Walgreen's pharmacies to implement on a national scale what we have learned from this groundbreaking NIH-funded research."

5. The United States of Diabetes: Challenges and Opportunities in the Decade Ahead

Reference:

UnitedHealth Center for Health Reform and Modernization, UnitedHealth Group. "The United States of Diabetes: Challenges and opportunities in the decade ahead." November 2010. Working Paper 5.

Summary:

With the goal of generating discussion and action around curbing the prevalence of diabetes, this working paper offers specific proposals, which use proven and transformational prevention and early intervention models. UnitedHealth Group's work is based on evidence-based, practical solutions derived from scientific research, pilot programs, and their own experience serving employer-sponsored consumers, seniors, and people with health benefits through the public sector. This paper includes costs estimates for diabetes and prediabetes.

Conclusions:

Many health promoting and potentially cost-saving intervention strategies depend on voluntary participation of individuals most likely to benefit. In this context, it is likely that a wide variety of environmental and social factors will influence the degree to which support for those interventions will result in optimal results. To support broader action to tackle prediabetes and diabetes, a number of policy changes could potentially make a positive contribution and simultaneously enhance the overall benefit of health system-based strategies. These could include:

- (1) Strengthen resources for public awareness.
- (2) The United States Preventive Services Taskforce should examine evidence for prediabetes screening.
- (3) Use predictive analytics in the meantime to help identify the population with prediabetes, in combination with patient outreach.
- (4) Expand the evidence base for diabetes care and treatments through comparative effectiveness research.
- (5) Ensure reimbursement for evidence-based diabetes interventions in federal health programs.
- (6) Updated CMS-approved diabetes screening options to include HbA1c test.
- (7) Raise reimbursement levels for primary care providers for evidence-based diabetes prevention and care.
- (8) Create new reimbursement models for community-based providers.
- (9) Employ incentives to strengthen employer wellness programs.
- (10) Provide incentives for consumers to participate.
- (11) Maintain continuity of care for people with diabetes.
- (12) Deploy network models in Medicare for complex case management.

Useful Quotes and Statistics:

- An analysis of community-based diabetes prevention program demonstrated an annual cost savings to employers and participants of \$1,622 to \$3,356.
- The costs of diabetes are projected to be \$500 million by 2040.
- Delivering an intensive group lifestyle intervention in community settings for less than \$400 per person over a two-year period is expected to significantly improve health outcomes among the participating population. For a typical population of 100 high-risk adults aged 50 and over, the following results might be expected over three years:

- Prevent 15 new cases of type 2 diabetes.
- Prevent 162 missed work days.
- Avoid the need for blood pressure or cholesterol drugs in 11 people.
- Add the equivalent of 20 years of good health.
- Avoid \$91,400 in health care costs.
- UnitedHealth estimates a net savings opportunity from initiatives that address obesity, prediabetes, and diabetes as described in the table below.

Expected Cumulative Health Care Cost Savings, Individuals by Source of Primary Coverage, 2011-2020 <i>in Billions of Dollars</i>					
Intervention	Private	Medicaid	Medicare	Other	Total
People with diabetes – Lifestyle Intervention	16	2	24	2	45
People with prediabetes – Intensive Lifestyle Intervention like the Diabetes Prevention Program	29	3	67	5	105
People with diabetes – Improved Medication Adherence	9	1	23	1	34
People with diabetes – Intensive Lifestyle Intervention (Look Ahead)	25	3	57	3	88

6. Long Term Effects of a Community-based Lifestyle Intervention to Prevent Type 2 Diabetes: The DEPLOY Extension Pilot Study

Reference:

Ronald T. Ackermann, MD, MPH; Emily A. Finch, MA; Helena M. Caffrey; Elaine R. Lipscomb; Laura M. Hays; and Chandan Saha. "Long Term of a Community-based Lifestyle Intervention to Prevent Type 2 Diabetes: The DEPLOY Extension Pilot Study." *Chronic Illness*. 2011 7:279.

Summary:

This study evaluated the long-term effects of the DEPLOY study, a lower cost and group-based adaptation of the DPP lifestyle intervention as offered by the YMCA. This study continued to analyze the trial participants in DEPLOY after they had completed the year-long intensive lifestyle intervention program. It also analyzed the control group that did not receive the program.

Conclusions:

In this follow up study, the DEPLOY control group (which received brief counseling and not the DPP lifestyle intervention) received the DPP lifestyle intervention to assess if similar weight loss and diabetes incidence results could be produced. At 28 months, both arms had statistically significant weight losses compared to baseline (brief advice controls: -3.6 percent; intensive lifestyle: -6.0 percent). Participants also experienced significant improvements in blood pressure and total cholesterol.

Useful Quotes and Statistics:

- After a 28 months analysis, participants in the DEPLOY study demonstrated sustained weight loss and reduction in diabetes incidence. Thus, showing the YMCA could deliver a cost-effective group-based lifestyle intervention program to reduce diabetes and participants could sustain results.

7. Using National Networks to Tackle Chronic Disease

Reference:

Taz Hussein and Michaela Kerrissey. "Using National Networks to Tackle Chronic Disease." *Stanford Social Innovation Review*, Winter 2013.

Conclusions:

There is evidence that national nonprofit networks can make a significant contribution to the effort. If government, philanthropists, public health researchers, and private sector funders support the move, the payoff could be enormous. The lessons learned from participating in one chronic disease intervention can be applied to the next initiative, until scaling interventions becomes an integral part of the skill set of national networks.

Useful Quotes and Statistics:

- Building on the experience gained from the YMCA's Diabetes Prevention Program, the Y is taking a close look at other evidence-based health interventions that it could potentially scale up such as arthritis self-management programs.
- The Y is rethinking its role as national organization to provide more leadership on broad health issues, with the aim of capturing and replicating more innovations emerging from local Ys and helping local Ys deliver national programs with greater fidelity than in the past.
- The Y's national leadership recognizes that health interventions are a departure from the services local Ys have traditionally offered—after all, no national network was actually designed to address chronic disease—but it also recognizes that capacity originally developed for other purposes may be exceptionally well suited to this vitally important work.

8. Economic Costs of Diabetes in the U.S. in 2012

Reference:

American Diabetes Association. "Economic Costs of Diabetes in the U.S. in 2012." *Diabetes Care*. March 6, 2013.

Summary:

The study uses a prevalence-based approach that combines the demographics of the U.S. population in 2012 with diabetes prevalence, epidemiological data, health care cost, and economic data into a Cost of Diabetes Model.

Conclusions:

The total estimated cost of diagnosed diabetes in 2012 is \$245 billion, including \$176 billion in direct medical costs and \$69 billion in reduced productivity. The largest components of medical expenditures are hospital inpatient care (43 percent of the total medical cost), prescription medications to treat the complications of diabetes (18%), anti-diabetic agents and diabetes supplies (12 percent), physician office visits (9 percent), and nursing/residential facility stays (8 percent).

People with diagnosed diabetes incur average medical expenditures of about \$13,700 per year, of which about \$7,900 is attributed to diabetes. People with diagnosed diabetes, on average, have medical expenditures approximately 2.3 times higher than what expenditures would be in the absence of diabetes. For the cost categories analyzed, care for people with diagnosed diabetes accounts for more than 1 in 5 health care dollars in the U.S., and more than half of

that expenditure is directly attributable to diabetes. Indirect costs include increased absenteeism (\$5 billion) and reduced productivity while at work (\$20.8 billion) for the employed population, reduced productivity for those not in the labor force (\$2.7 billion), inability to work as a result of disease related disability (\$21.6 billion), and lost productive capacity due to early mortality (\$18.5 billion).

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- Care for people with diagnosed diabetes accounts for more than 1 in 5 health care dollars in the U.S., and more than half of that expenditure is directly attributable to diabetes.
- Indirect costs include increased absenteeism and reduced productivity while at work for the employed population, reduced productivity for those not in the labor force, inability to work as a result of disease related disability, and lost productive capacity due to early mortality.

9. Awareness of Prediabetes – United States, 2005-2010

Reference:

Centers for Disease Control and Prevention. "Awareness of Prediabetes – United States, 2005-2010." *Morbidity and Mortality Weekly Report*. March 22, 2013. Vol. 62. No. 11:209-211.

Summary:

In 2010, approximately one in three U.S. adults aged 20 years and older, an estimated 79 million persons, had prediabetes, a condition in which blood glucose or hemoglobin A1c levels are higher than normal but not high enough to be classified as diabetes. Persons with prediabetes are at high risk for developing type 2 diabetes, which accounts for 90 percent–95 percent of all cases of diabetes. During 2005–2006, only approximately 7 percent of persons with prediabetes were aware that they had prediabetes. To examine recent changes in awareness of prediabetes and factors associated with awareness among adults aged 20 years and older, CDC analyzed data from the National Health and Nutrition Examination Survey (NHANES). This report describes the results of that analysis, which indicated that, during 2009–2010, approximately 11 percent of those with prediabetes were aware of their condition.

Conclusions:

During 2005–2010, estimated awareness of prediabetes was less than 14 percent across all population subgroups, different levels of health care access or use, and other factors. In the U.S., persons with prediabetes, including those with regular access to health care, might benefit from efforts aimed at making them aware that they are at risk for developing type 2 diabetes and that they can reduce that risk by making modest lifestyle changes. Efforts are needed to increase awareness.

Useful Quotes and Statistics:

- Diabetes affects 25.8 million people, or 8.3 percent of the U.S. population. Of this group 18.8 million people are diagnosed with diabetes and the remaining 7 million are undiagnosed.

- Applying this percentage to the entire U.S. population in 2010 yields an estimated 79 million American adults aged 20 years or older with prediabetes.
 - Diabetes is the leading cause of kidney failure, nontraumatic lower limb amputations, and new cases of blindness among adults in the U.S. Diabetes is a major cause of heart disease and stroke. Diabetes is the seventh leading cause of death.
 - As of 2012, 11 percent of people with prediabetes are aware that they are at risk for developing type 2 diabetes.
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10. A Coordinated National Model for Diabetes Prevention: Linking Health Systems to an Evidence-Based Community Program

Reference:

Vojta Deneen, MD; Timothy B. Koehler, BS; Matt Longjohn, MD, MPH; Jonathan A. Lever, EdM, JD; Nadine F. Caputo, MS. "A Coordinated National Model for Diabetes Prevention: Linking Health Systems to an Evidence-Based Community Program." *American Journal of Preventive Medicine*. 2013; 44(4S4):S301-S306.

Summary:

This article describes the YMCA's inaugural partnership the Diabetes Prevention and Control Alliance (DPCA) and the Centers for Disease Control and Prevention (CDC) to form National Diabetes Prevention Program.

Conclusions:

Large-scale prevention efforts can be scalable and sustainable with collaboration, health information technology, community-based delivery of evidence-based interventions, and novel payment structures that incentivize efficiency and outcomes linked to better health and lower future costs.

Useful Quotes and Statistics:

- Together, the Y, DPCA and CDC have demonstrated a national model for a diabetes prevention program delivered through partnerships that involve payors, community-based organization, and the government. Supported by a third-party performance-based reimbursement model, the YMCA has been successful in improving health outcomes and reducing health care costs.