

# PREVENTING CHRONIC DISEASE

PUBLIC HEALTH RESEARCH, PRACTICE, AND POLICY



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# PREVENTING CHRONIC DISEASE

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SPECIAL TOPIC

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# Evaluation of the Diabetes Health Plan to Improve Diabetes Care and Prevention

O. Kenrik Duru, MD, MSHS; Carol M. Mangione, MD, MSPH; Charles Chan, MS; Abigail Keckhafer, MBA, MPH; Lindsay Kimbro, MPP; K. Anya Kirvan, RN, MS; Norman Turk, MS; Robert Luchs, MS; Jinnan Li, MPH; Susan Ettner, PhD

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## Abstract

Investigators from the University of California, Los Angeles (UCLA), and members of the leadership and data analysis teams at UnitedHealthcare (UHC) are partnering to evaluate the Diabetes Health Plan (DHP), an innovative disease-specific insurance product designed by UHC specifically for patients with prediabetes or diabetes. The DHP provides improved access to care management, telephone coaching, and enhanced Internet-based communication with enrollees. The evaluation will use a quasi-experimental design, comparing patients from employer groups that offer the DHP with patients from groups that do not, to determine the effect of the DHP on incidence of diabetes, adherence to metformin, and costs of care among patients with prediabetes. Other factors studied will be cardiovascular risk factor control, adherence to preventive services, health care use, and costs of care among patients with existing diabetes.

## Introduction

Although diabetes incidence in the United States is rising for all ages, people aged 45 to 64 are most affected; diabetes incidence among people in this age group is 30% higher than among adults aged 65 or older (1). Many of these middle-aged patients are at risk of current and future disability from diabetes-related complications, and the combined direct and indirect costs of diabetes care for people in this group, including decreased productivity at work and increased absenteeism, are substantial (2). Public health stakeholders and employers share an interest in decreasing complications among patients with existing diabetes and in slowing disease progression among patients with prediabetes through early identification and increased adherence to preventive care and treatments. The Diabetes Health Plan (DHP), developed by UnitedHealthcare (UHC), is an innovative, multifaceted approach to prevent diabetes and improve diabetes management among working-age adults with the disease.

The DHP incorporates several enhancements to standard employer-based commercial benefit plans, including financial incentives of \$150 to \$500 per year for enrollees. These enhancements typically include reduced or eliminated copayments for office visits and for medications that reduce incidence of and complications from diabetes, access to diabetes-specific care management and individualized telephone coaching, enhanced Internet-based communication with beneficiaries via online data and adherence tracking, and improved access to diabetes education and information (3). Although participating employers are not required to offer each of these DHP components, more than 95% discount patient copayments for enrollees and most employers provide the other services. Results of some studies indicate that reducing copayments for evidence-based medications (ie, value-based insurance design) can modestly improve adherence to these medications (4,5), although these studies were not diabetes-specific and examined a single outcome (medication adherence) for follow-up periods of 12 months or less. The study we describe will be the first comprehensive, controlled, longitudinal evaluation to assess whether reduced cost-sharing for these services among people with prediabetes and diabetes improves multiple outcomes.

This real-time evaluation of the DHP is being conducted jointly by investigators at the University of California, Los Angeles (UCLA), together with employees of the Innovations Group at UHC, under the auspices of a cooperative

agreement with the Centers for Disease Control and Prevention and the National Institute of Diabetes and Digestive and Kidney Diseases. Our collaboration is grounded in the principles of community-based participatory research (6,7) and builds on a long-standing partnership between the UCLA research team and the leadership and data analysis teams at UHC, 1 of the largest providers of health insurance in the United States. Our experience evaluating system-level interventions, analyzing health plan data, and disseminating findings tells us that these evaluations must be conducted in close partnership. The health plan side of the partnership brings intricate knowledge of employer group-specific aspects of program implementation, detailed knowledge about their data, and perspective on the interpretation of the results. The academic side of the partnership contributes state-of-the-art analytic modeling, grounds the hypotheses in findings from peer-reviewed scientific literature, leads an objective evaluation, and provides the needed policy context.

The design of the DHP was influenced by findings from the Translating Research into Action for Diabetes (TRIAD) study, which examined the effectiveness of care management (8) and the deterrent effect of high copayments on use of needed services and medications for people with diabetes (9,10). This partnered evaluation of the DHP is a logical next step in an innovative model of translational research over more than a decade (11). This study will provide evidence to determine whether a benefit design that is tailored to the needs of people with a specific condition and provides low cost-sharing will reduce incidence of diabetes among people with prediabetes and improve cardiovascular risk factors, reduce complications, and lower costs for patients with diabetes.

This study is being conducted in a real-world setting, similar to the way many new health insurance products are implemented in employer groups. The quasi-experimental design fits well into the framework of the Natural Experiments in Translation for Diabetes (NEXT-D) study's goals of evaluating natural experiments by using rigorous statistical methods. The findings from this study will provide useful information to employers, health plans, and public health stakeholders about the effectiveness of this type of multifaceted diabetes care and prevention approach.

## Study Population, Study Design, and Analytic Approach

The DHP was first introduced in 2009 and has been purchased by more than 2 dozen national and regional employers who contract with UHC. These employers represent a diverse spectrum, including industrial and manufacturing companies, service and retail companies, and public sector organizations. The DHP is an available option for employees and in most cases their spouses and immediate family members who are identified as having prediabetes or diabetes on the basis of laboratory history, diagnosis codes from medical claims, results of employer-based biometric screenings, or physician verification of the diagnosis. Although most beneficiaries in the DHP can maintain program benefits each year without conditions, several participating employers require adherence to "compliance criteria." These criteria require recommended diabetes and nondiabetes preventive care (eg, hemoglobin A1c and cholesterol screening, retinal eye exams, mammograms for women aged 40 or older) to maintain ongoing enrollment.

This study will test several hypothesized effects of the DHP. We hypothesize that among patients with prediabetes, those insured through employers offering the DHP will have greater initiation of and adherence to metformin for diabetes prevention, less progression to diabetes over a 3-year period, and lower costs of care than for comparable patients with prediabetes insured through employers that do not offer the DHP. We hypothesize that patients with diabetes who are insured through employers offering the DHP will have better glycemic and lipid control, better adherence to diabetes-specific and general preventive services, less emergency department use, fewer hospitalizations, and lower total costs than patients insured through employers that do not offer the DHP.

This study will treat the DHP as a "natural experiment" because the program is not a true research-designed experiment. However, the DHP represents a clearly defined set of new benefits provided by certain employers for their patients with diabetes and prediabetes. Therefore, changes in prespecified study outcomes among these patients, compared with outcomes for similar patients from other employer groups with an unchanging benefit structure, can be reasonably attributed to the effect of the DHP.

Using a quasi-experimental design to test our hypotheses is equivalent to comparing the change in outcomes over time among patients from employers that offer the DHP with changes among concurrent patients from employer groups that offered UHC insurance products other than the DHP. Unlike a simple pre-post comparison, our use of a comparison group allows us to adjust for the effects of secular time trends over a 3-year period; in turn, unlike a simple cross-sectional comparison, our use of longitudinal data allows us to adjust for any baseline differences between the DHP and non-DHP groups that may confound the comparison. The "difference in differences" analyses for each outcome (eg, number of diabetes-related hospitalizations among patients with existing diabetes), will be structured as follows: [(mean difference for patients of DHP employers expressed as follow-up minus baseline) – (mean difference for patients of non-DHP employers expressed as follow-up minus baseline)]. Although our quasi-experimental design requires an assumption that the secular time trends are similar for the DHP and non-DHP groups, we can test this assumption in cases in which multiple years of existing data are available for both the DHP and non-DHP groups. Because DHP enrollment may change from year to year depending on whether or not enrollees meet the compliance

criteria and whether their employer continues to purchase the DHP from UHC, we will include the DHP as a time-varying covariate.

## Dissemination of Study Findings and Potential Effect

The DHP incorporates a value-based structure in which patient cost-sharing is reduced for evidence-based therapies (eg, metformin to prevent diabetes, statins to prevent myocardial infarction). Millions of Americans will be exposed to value-based insurance products in the coming years, and results from this study will provide important information for patients deciding between health insurance options. In a 2011 survey, more than half of employers were considering adding a value-based insurance option in the next 3 to 5 years (12). Furthermore, section 2713 of the Affordable Care Act allows the US Department of Health and Human Services to establish guidelines for value-based insurance designs, including plans to be offered in health insurance exchanges (13).

The research team plans to publish in the peer-reviewed literature but will also write articles for trade journals read by health plan stakeholders and op-ed articles in mainstream media to publicize the findings for a nonacademic audience. Finally, the research team plans to produce user-friendly print materials for employees who are enrolled in DHP programs. The materials will be delivered with an eighth-grade literacy level or lower and will focus on explaining the specifics of the DHP in combination with information on the study findings.

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# Health-Plan and Employer-Based Wellness Programs to Reduce Diabetes Risk: The Kaiser Permanente Northern California NEXT-D Study

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## Abstract

Primary prevention of diabetes is increasingly recognized by both health plans and employers as an important strategy to improve the health of insured populations. As a part of the Natural Experiments in Translation for Diabetes (NEXT-D) network, the Kaiser Permanente Northern California (KPNC) Division of Research is assessing the effectiveness of 2 health plan-initiated programs to prevent the onset of diabetes in patients at high risk. The first study evaluates a telephonic health-coaching program that provides counseling on healthful eating, active living, and weight loss to KPNC members. The second evaluation examines a postpartum glucose screening and educational diabetes prevention program for women with gestational diabetes mellitus that KPNC implemented in 2006. Identifying effective approaches to preventing diabetes will be of value to health care systems, policy makers, and public health officials seeking to understand the roles systems and employers can play in preventing chronic illness.

## Introduction

Population approaches to improving health care and outcomes for patients with diabetes have been widely implemented by health plans and integrated delivery systems (1–4). Diabetes prevention is also increasingly emphasized by employers, who are major purchasers of health care insurance. Most companies with 50 or more employees offer worksite wellness programs (5), and nearly half of companies with more than 750 employees offer health risk assessment and screening (6). As awareness of diabetes risk grows in the employer/purchaser community, health plans and delivery systems are also adopting an active role in health promotion (7,8), with most offering primary prevention services such as health education and lifestyle programs (9–11). Efforts by health plans and employers to identify populations at high risk for developing diabetes and to focus prevention efforts on these populations are a promising strategy for reducing the incidence of the disease.

Health coaching to encourage healthy lifestyle choices (12–15) is a population-based approach to wellness and diabetes prevention that is being explored by health plans and purchasers. Health coaching, often via telephone, uses nonphysician health care providers to give patients the support, information, and skills required to improve self-efficacy and healthy behaviors. Health coaching may improve physical health status and healthy lifestyle behaviors (12–15) and may particularly benefit patients with prediabetes (16), who can benefit from coaching on lifestyle issues critical to diabetes prevention (17).

Women who have had 1 or more pregnancies marked by gestational diabetes mellitus (GDM) are another key group of health plan enrollees at heightened risk for diabetes (18). As the incidence of GDM rises, health plans are more often implementing guidelines to improve management of GDM during pregnancy and to encourage postpartum glucose screening for early identification and treatment (18,19) of those women who develop diabetes as well as promoting prevention strategies for those with prediabetes (20). As with other types of programs designed to decrease the risk of

diabetes in high-risk patients, the effectiveness of these resource-intensive programs when broadly implemented in real-world clinical populations remains a question of interest to health plans, purchasers, and other stakeholders.

Kaiser Permanente Northern California (KPNC) is an integrated medical delivery system covering an enrolled population of 3.3 million members. KPNC provides numerous wellness and prevention programs to members, many of which encourage participation through partnerships with purchasers. The Natural Experiments in Translation for Diabetes (NEXT-D) study provides a unique opportunity for KPNC researchers and operations leaders, partnering together using participatory research principles (21), to evaluate the effect of health-plan–based diabetes prevention programs on populations at high risk for developing the disease. We outline our plans to use quasi-experimental methods to evaluate 2 such programs focused on diabetes prevention: a Wellness Coaching program and a postpartum glucose screening and diabetes prevention program for women with GDM.

## Wellness Coaching Program Evaluation

KPNC's Regional Health Education Department launched a telephonic Wellness Coaching Center in January 2010 targeted at members interested in healthy behaviors and employers who want to encourage healthy lifestyles among their employees. Wellness Coaching is designed to help members set and reach goals in 5 key areas (healthful eating, physical activity, weight management, smoking cessation, and stress management) to reduce health risk and increase health-related quality of life. Coaches are trained in motivational interviewing (12), a patient-centered behavioral health approach that assists patients in addressing self-management and multiple health risks and behaviors. This approach to health coaching has been effective in improving patient physical and mental health status (12). A typical coaching engagement consists of 1 initial session (30 minutes) and up to 3 short (5 to 15 minutes) follow-up contacts. Wellness Coaching is available to all KPNC members, and the program recruits participants through mechanisms that include partnerships with employers and direct risk assessment and outreach.

Our evaluation of the Wellness Coaching program has 3 phases. Phases 1 and 2 focus on the 1,427 patients who participated in Wellness Coaching from January 1 through August 23, 2011. Patients who participated in coaching during this period were predominantly female (80%) and had an average body mass index (BMI) of 33.1 kg/m<sup>2</sup>. Approximately one-half of these patients (47%) were white.

Phase 1 consists of a patient survey designed to examine patient-centered experiences with the program and predictors of self-perceived coaching success. This cross-sectional survey, which was designed by the research team using validated metrics, focuses on 4 domains: patient satisfaction, reasons for using the wellness coaching program, self-reported changes in healthy behaviors, and patient engagement in their health care. Phase 2 of the evaluation will use an interrupted time series with concurrent control groups (22) to assess the effect of Wellness Coaching on levels of BMI, systolic blood pressure, and low-density lipoprotein cholesterol (LDL-c) levels. If phases 1 and 2 suggest that Wellness Coaching has a positive effect on outcomes, phase 3 will use a randomized trial to compare the effectiveness of 3 outreach methods (letters, interactive voice–response telephone messages, and secure e-mail) on increasing rates of Wellness Coaching participation among approximately 30,000 patients with impaired fasting glucose (IFG).

## Gestational Diabetes Program Evaluation

Within KPNC, the Regional Perinatal Service Center offers supplemental care via telephone counseling for women with pregnancies at high risk for adverse outcomes (such as preterm birth), including pregnancies complicated by GDM. Referral to the centers has been associated with decreased risk of macrosomia (excessive birth weight) and increased postpartum screening for diabetes (23). Beginning in 2006, the center has used a step-wise approach to ensure that all patients have a glucose test (standard oral glucose tolerance test [OGTT]) and appropriate educational and referral follow-up if postpartum glucose levels are elevated (diagnostic for IFG, impaired glucose tolerance, or diabetes). These increases in screening and the shift to the more sensitive OGTT should lead to greater detection of prediabetes and earlier detection of type 2 diabetes. We will evaluate whether the incidence of diabetes is decreasing because of these earlier detection and prevention efforts and because of treatment efforts launched after detection. We will compare the cohort of women with GDM who gave birth during 2001 through 2006 with the cohort who gave birth during 2006 through 2010 for subsequent diabetes incidence. For each cohort, follow-up begins at childbirth and continues until the diagnosis of diabetes, to the end of the study period (5 years follow-up for each person), or censoring because of leaving the health plan.

## Real-World Opportunity for Natural Experiments

Health systems, employers, and health plan purchasers recognize the urgency of determining whether their population-oriented infrastructure can be adapted to address primary prevention of chronic conditions such as diabetes. Given the large numbers of people at increased risk for these conditions, efficient approaches are needed to identify and support patients and providers in effecting lifestyle changes. Evaluating these approaches will be useful to policy makers dealing with questions of benefit designs and to public health officials seeking to understand the roles that

health systems and employers can play in preventing chronic disease. Health care policy initiatives emphasizing the patient-centered medical home and accountable care organizations (24,25) are being promoted as ways to enhance the integration of US health care delivery. Systems with high levels of integration such as KPNC offer real-world opportunities for natural experiments to assess the effect of health-plan and employer-based prevention and wellness programs on population health within this context.

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## PREVENTING CHRONIC DISEASE

PUBLIC HEALTH RESEARCH, PRACTICE, AND POLICY

EDITORIAL

Volume 10 — January 31, 2013

# The Importance of Natural Experiments in Diabetes Prevention and Control and the Need for Better Health Policy Research

Edward W. Gregg, PhD; Mohammed K. Ali, MD, MS; Bernice A. Moore, MBA; Meda Pavkov, MD, PhD; Heather M. Devlin, MA; Sanford Garfield, MD; Carol M. Mangione, MD, MSPH

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Diabetes has steadily increased in prevalence, becoming one of the nation's most challenging public health threats (1). Prevalence among adults is now more than 10%, and diabetes is the leading cause of nontraumatic lower-extremity amputation, end-stage kidney disease, and blindness; it more than doubles the risk of heart disease, stroke, and disability (1,2). Strong clinical trial evidence indicates that much of the illness caused by diabetes is preventable, further positioning diabetes as a public health priority (3,4) and stimulating a national emphasis on the quality of diabetes care and self-management (5–7). Although many such efforts have been successful, leading to better care, risk factor control, and reduced risk of complications, new challenges have arisen. The increases in obesity and in diabetes incidence demand that health systems and communities apply primary prevention strategies at the population level while simultaneously tackling the pervasive geographic and socioeconomic disparities in diabetes prevalence, care, and complications that remain (8,9).

Compared to the long list of clinical best practices to prevent diabetes complications, the evidence base is thin for population- and policy-level approaches to improve health behaviors, access to and delivery of care and preventive services, and the healthful attributes of communities. This imbalance of evidence calls for a new platform of public health research for diabetes. We contend that the imbalance can be corrected by a greater emphasis on natural experiments: rigorously designed quasi-experimental studies to investigate the health effects of naturally occurring population- and policy-level approaches emanating from health systems, communities, business organizations, and governments.

The gaps in evidence for naturally occurring population- and policy-level approaches have not resulted from a lack of such approaches. Numerous large-scale initiatives and health-related services to reduce the risk and consequences of diabetes are taking place. Employers, health plans, health systems, and communities regularly embark on screening and wellness programs and quality-improvement programs for entire populations; state and local governments have proposed or implemented policies such as taxes on unhealthful foods, vouchers for lifestyle and community programs, or restrictions on the way social services can be used. To remain competitive in a nation where large employers and government are the dominant purchasers of health insurance, health plans frequently develop new reimbursement and benefit designs that influence patterns of services provided to large populations. Finally, national and state legislatures adopt laws that fundamentally affect the access to and delivery, quality, and costs of care and preventive services for people at risk for or diagnosed with diabetes. By 2014, features of the Affordable Care Act of 2010 are likely to change access to services and quality of care, particularly for people who were previously uninsured.

The gaps in evidence for naturally occurring population- and policy-level approaches have resulted from a lack of rigorous health policy research: the objective, critical examination and evaluation of the benefits and drawbacks of such approaches. Health policy studies have typically lacked control conditions, which has limited the ability to distinguish between policy effects and secular trends and gauge true effectiveness (10). Randomized controlled trials establish causality and quantify efficacy under ideal conditions but are often impractical for the study of health policies in a complex world. Instead of seeking more rigorous nonrandomized alternatives, health policy research has frequently settled for cross-sectional or noncontrolled alternatives that lead to ambiguous or misleading conclusions.

Responding to both the need and opportunity for better health policy research for diabetes, the Centers for Disease Control and Prevention (CDC) and the National Institute of Diabetes and Digestive and Kidney Diseases has initiated a multicenter research network: Natural Experiments in Translation for Diabetes, or NEXT-D. The mission of NEXT-D is to examine the effectiveness of population-level health policies on diabetes prevention, control, and inequalities through rigorous health policy research. A collaborative approach was chosen because it facilitates multisite studies and the use of common measurements and indicators. Collaboration will also enhance the design, analysis, and dissemination of translational research. The ultimate goal of the collaboration is to provide stakeholders with a clear understanding of best practices that can be implemented by employers, health plans, health systems, communities, legislatures, or governments to prevent and control diabetes.

NEXT-D studies are also intended to inform the priorities of the CDC-funded Diabetes Prevention and Control Programs (DPCPs) in 58 state and territorial health departments (1). DPCPs bring together diverse stakeholders to implement population-based interventions to improve diabetes risk factors, control, and disparities and to drive state and territorial progress toward national public health objectives. Innovative DPCP strategies that are similar across states could become candidates for NEXT-D evaluations. Conversely, several components of the NEXT-D portfolio of natural experiments may have important implications for DPCPs, including diabetes care quality improvement, access to self-management education, access to lifestyle-based diabetes prevention programs, and healthy food environments in communities.

Articles in this *Preventing Chronic Disease* collection describe the NEXT-D natural experiments now under way – their rationale and importance, their design, and their intended effects. The objective of this collection is to share expertise and methods for addressing the complexity of real-world data. We hope to stimulate others to embark on and publish studies on natural experiments.

The NEXT-D studies have several attributes that will enhance their effect on diabetes health research and policies. First, interventions are being implemented naturally (ie, not for research purposes), and they take place among health systems, insurers, employers, the private sector, communities, and government agencies, each of which reaches a large population. As a result, study investigators do not use their own research funds for implementation, and interventions have high external generalizability. Second, the NEXT-D studies span several major public health themes, including the design of health care benefits, clinic–community partnerships, adoption of health information technology, and employer-based initiatives to screen and prevent diabetes. Third, the studies use longitudinal, controlled study designs involving diverse populations and rigorous analytic methods that aim to distinguish between policy effects and underlying trends. Fourth, through close partnerships with the organizations that implement these interventions in real-world settings, the NEXT-D studies will help to eliminate barriers to sustaining and disseminating approaches that are found to be effective at preventing and improving care for people who have diabetes. Fifth, by working in partnership with private sector and public policy decision makers, NEXT-D research teams can identify and analyze outcome indicators that are most informative (ie, provide actionable evidence) to those decision makers. Finally, the studies encompass primary and secondary prevention and complementary, nonredundant approaches. This new platform of public health research for diabetes – natural experiments – will fill the gaps in evidence for population- and policy-level approaches, correct the imbalance in the evidence base between clinical best practices and population- and policy-level approaches, and ultimately help to reduce the burden of diabetes.

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## PREVENTING CHRONIC DISEASE

PUBLIC HEALTH RESEARCH, PRACTICE, AND POLICY

SPECIAL TOPIC

Volume 10 — January 31, 2013

# Expansion of Electronic Health Record-Based Screening, Prevention, and Management of Diabetes in New York City

Jeanine Albu, MD; Nancy Sohler, PhD; Brenda Matti-Orozco, MD; Jordan Sill, MS; Daniel Baxter, MD; Gary Burke, MD; Edwin Young, MD

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PEER REVIEWED

## Abstract

To address the increasing burden of diabetes in New York City, we designed 2 electronic health records (EHRs)-facilitated diabetes management systems to be implemented in 6 primary care practices on the West Side of Manhattan, a standard system and an enhanced system. The standard system includes screening for diabetes. The enhanced system includes screening and ensures close patient follow-up; it applies principles of the chronic care model, including community–clinic linkages, to the management of patients newly diagnosed with diabetes and prediabetes through screening. We will stagger implementation of the enhanced system across the 6 clinics allowing comparison, through a quasi-experimental design (pre–post difference with a control group), of patients treated in the enhanced system with similar patients treated in the standard system. The findings could inform health system practices at multiple levels and influence the integration of community resources into routine diabetes care.

## Introduction

Significant progress has been made in controlling type 2 diabetes and its complications in primary care settings through the application of the chronic care model (CCM) (1–3). Evidence that CCM modifications to primary care practice can prevent type 2 diabetes is limited (4–6). Screening high-risk patients to detect diabetes and prediabetes was cost-effective (7–9), and prevention of type 2 diabetes in people with prediabetes through adoption of appropriate lifestyle changes and pharmacologic interventions has been successful in experimental settings (10). However, ongoing challenges in translating this evidence into primary care practice include the identification of appropriate target populations and the difficulty of incorporating time- and resource-intensive lifestyle interventions into routine clinical care (6). Although community and peer support systems have proven effective in preventing many chronic diseases (11,12), rigorous evaluations of integrated health care systems and community linkages for preventing type 2 diabetes are lacking (13).

Six clinics in a primary care network in New York City, 3 of which are federally qualified health centers, have established an evidence-based diabetes management system grounded in CCM principles in the context of developing a patient-centered medical home in each clinic (14). As defined by the National Committee for Quality Assurance, a patient-centered medical home is a health care setting that facilitates partnerships between patients and their physicians through the use of registries, information technology, and health information exchange. Our study will examine a standard and an enhanced diabetes management system. The standard system, already implemented, includes an electronic health records (EHR)-based, targeted screening program that is aimed at detecting previously undiagnosed diabetes (hemoglobin A1c [HbA1c] > 6.5%) and prediabetes (HbA1c 5.7%–6.4%). The enhanced diabetes management system is designed to facilitate the management of patients identified through the screening program as having diabetes or prediabetes. The enhanced system, which extends components of the CCM including community–clinic linkages to patient management, will be added to the standard system. The staggered implementation of the enhanced system across the 6 target clinics will allow comparisons of participant outcomes in the enhanced versus

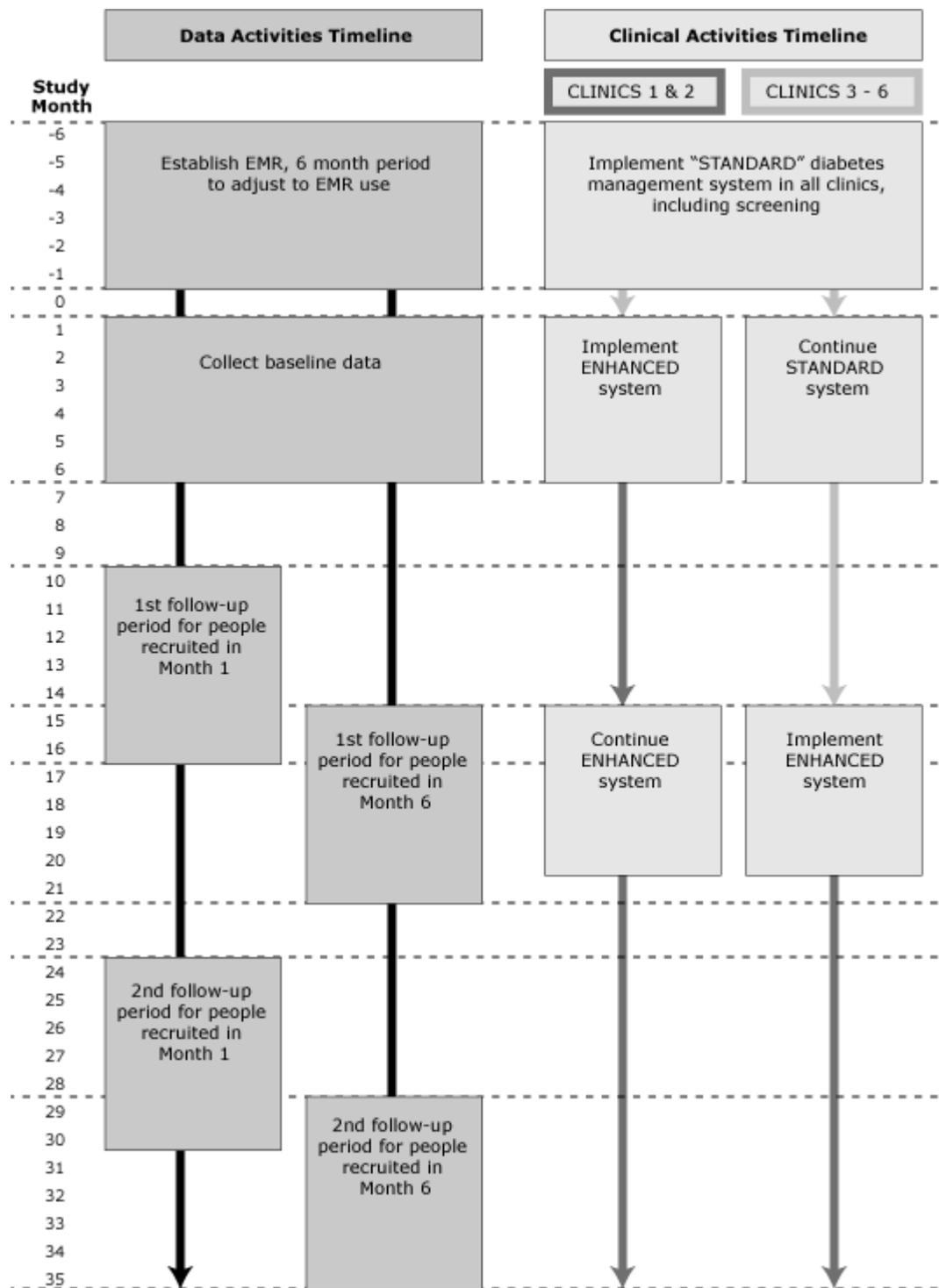
standard clinics through a quasi-experimental design (pre–post difference with a control group) by retrospective analyses of the data extracted from the EHR. The primary objective of these analyses is to test 3 hypotheses: first, that patients with newly diagnosed diabetes or prediabetes who will be exposed to the enhanced system will be more likely than patients exposed to the standard system to experience a reduction in HbA<sub>1c</sub> levels over 12 months; second, that any reductions in HbA<sub>1c</sub> levels observed in patients in the enhanced system will be sustained over a follow-up period of 30 months; and third, that patients in clinics adopting the enhanced system will be retained longer in appropriate health care than those in the standard system.

## Study Population

Patients seen in the 6 primary care clinics of the New York City health care system included in our study receive care that includes diabetes screening and management as determined by their health care provider. All patients who visit these clinics over a 6-month baseline period, are at least 18 years of age, and have not been previously diagnosed with diabetes are eligible for our study (15). Through an EHR-facilitated screening system (9,16,17), patients we identify as at risk for diabetes by American Diabetes Association (ADA) criteria (16) are referred for HbA<sub>1c</sub> tests. Those patients determined to have prediabetes (HbA<sub>1c</sub> 5.7–6.4%) or new-onset diabetes (HbA<sub>1c</sub> >6.5%) will be included in the study sample (15,16,18). All 6 clinics have patient populations with roughly similar sociodemographic and clinical characteristics.

## Study Design

All 6 clinics incorporated the standard diabetes management system over the first 6 months of 2012. Two clinics have been selected to start implementing the enhanced system within the following 6 months (from July through December 2012). For 12 months following implementation, these 2 clinics will use the enhanced system with all patients, while the remaining 4 clinics continue to use the standard system) until month 15 when they will also implement the enhanced system (Figure). We will follow all patients who meet study criteria and visit any of the 6 study clinics during the 6-month baseline period for a minimum of 30 months.



**Figure.** Data activities timeline and clinical activities timeline for standard diabetes management system and enhanced diabetes management system. [A [text description of this figure](#) is also available.]

Follow-up care in the standard system conforms to recommendations for diabetes prevention and management (16); that is, patients with newly diagnosed diabetes are prescribed treatment and asked to return to the clinics every 3 to 6 months to monitor progress. We will advise patients newly diagnosed with prediabetes of their diagnosis; advise them of ADA-recommended lifestyle changes (5) via an office visit, a telephone call, or mail; and ask them to return within 12 months to assess progress in reducing HbA1c levels.

The enhanced system, in addition to the standard-system practices, fully incorporates CCM principles specific to the management of prediabetes. It addresses 1) care delivery and clinical information systems redesign (prediabetes-

structured templates, planned visits, feedback on performance and point-of-care delivery prompts such as prediabetes order sets to ensure recommended clinical care); 2) decision support (education of physicians and ancillary staff in applying evidence-based prevention and treatment); and 3) patient self-management support (use of culturally appropriate tools, systematic referrals to established diabetes prevention programs in the community, and an inventory of available free or low-cost existing community resources that facilitate management of diabetes and prediabetes through lifestyle changes) (19,20). In the enhanced clinics, this self-management support system will also be available for patients with newly diagnosed diabetes. Patients with newly diagnosed prediabetes will be asked to return to the clinic within 6 months to monitor progress.

To ensure minimal losses to follow-up for our study, the staff in all 6 clinics will be instructed to contact all patients newly diagnosed with prediabetes or diabetes to ask them to return to clinic yearly.

## Data Analysis

We will conduct retrospective analyses on routine clinical data extracted from the EHR (Appendix). We will perform both intent-to-treat analysis and an as-treated analysis. Mixed-effects models accounting for clustering of patients within clinics will be used in our analyses. Our primary outcome, percentage change in HbA1c, will test our primary hypothesis that reduction in HbA1c observed at 12 months following initiation of the enhanced system in the selected clinics will be greater than reduction in HbA1c during the same period in the standard clinics. We will compare baseline HbA1c values to the average of HbA1c values obtained during the 12-month follow-up period. We will use this same outcome to test our second hypothesis, that observed HbA1c improvements in the enhanced clinics will be sustained over 30 months. To test our third hypothesis, that patients in clinics adopting the enhanced system will have greater retention in the health care system during the 12-month follow-up period than those exposed to the standard system, we will assess number of visits to a primary care physician and number of HbA1c tests performed. This will be a natural experiment; therefore, we anticipate some differences in the sociodemographic and clinical characteristics of participants across clinics. We will use propensity score-matching (21) to adjust for these differences, selecting from a wide array of patient measures in the EHR, including demographics, insurance coverage, clinical diagnoses, laboratory tests results, and information on use of health care services.

## Outcomes

This study will examine the effectiveness of an enhanced system for the management of newly diagnosed diabetes and prediabetes in participants identified through targeted screening in a primary care setting. This enhanced system will fully incorporate most components of the CCM (1,2) and as such, will involve policy changes at more than 1 level; however, its focus will be observation of the potential benefits of EHR in screening and monitoring outcomes and practice patterns (22). At the same time, this approach will involve a modest lifestyle change that leverages community-based resources. Evidence is mixed for the efficacy of EHR-based interventions in improving care for patients already diagnosed with diabetes (23,24). The use of EHR for diabetes screening and prevention may improve outcomes, because each primary care visit can be considered an opportunity for immediate intervention (25). If the outcomes of our analyses are positive, attribution of an EHR effect independent of other components of the intervention could be addressed in future studies.

Our study will be among the first to address whether it is possible to prevent diabetes in a large urban population by implementing an approach that is initiated during routine clinical practices and maintained over time by patients. A successful outcome could prompt health systems, health plans, and public insurers to adopt policies such as changes in reimbursement and reallocation of resources to facilitate prevention and early control of diabetes in primary care practices. In addition, it could prompt key players in the community (public agencies, business leaders, social organizations) to adopt and support policies aimed at developing and sustaining effective and affordable lifestyle intervention programs and at maintaining strong clinic–community linkages.

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## Appendix. Power and Statistical Analyses



### Primary Analysis

Our primary outcome is defined as percent reduction in HbA1c. Baseline is the HbA1c measurement collected at the patient's first visit, and we will obtain the baseline during the baseline period. This will be considered the pre-intervention measure. Final HbA1c will be the mean of all HbA1c measurements collected in the follow-up period. This will be considered the postintervention measure. This measurement must be made at least 12 months and no more than 24 months after the baseline measurement (Figure). The main “exposure” for our primary analysis will be receiving care from a provider in an enhanced diabetes management system site versus receiving care from a provider in a standard diabetes management system site. Other measures to adjust for potential noncomparability between groups include information on participant demographics, insurance coverage, clinical diagnoses, laboratory test results, use of laboratory services, and other measures of health services use collected on electronic medical records, including patient age, race, sex, zip code of residence, diabetes diagnosis, risk factor information, and other clinical data such as body mass index, blood pressure, blood lipids, and creatinine.

### Data Analysis

Our primary analysis will compare average change in participants' HbA1c levels at the enhanced and standard sites during a 12-month period. For these analyses, the dependent variables will be baseline HbA1c and final HbA1c as defined above. Mixed-effects models accounting for clustering of patients within clinics will be constructed to test whether the average change in HbA1c is greater in the enhanced than in the standard system during a 12-month period. The models will include the following fixed effects: intervention type (eg, enhanced vs standard), time (baseline vs follow-up), and interaction effect (intervention by time). The models will include clinic and patient random effects to account for potential clustering among participants in the same clinic and between repeated measures in the same patient.

Because this is a natural experiment, we anticipate some differences in the sociodemographic and clinical characteristics of patients across clinics. We will use propensity score matching to adjust for these differences, selecting from a wide array of measures, which will be downloaded from our electronic health records (EHRs) to develop appropriate scores.

### Missing Data

We anticipate few missing data points because our data will draw from an EHR system. However, when missing data occur, we will examine these data for potential bias in missingness and will apply 1 of several possible imputation methods on the basis of our initial evaluations of the nature and extent of missing data. Because we anticipate any missing data will follow a multivariate normal distribution, we will first consider a standard Markov Chain Monte Carlo method, and we will impute missing data multiple (at least 5) times to take into account the uncertainty of imputed values. On the basis of the nature and form of missing data, we will also consider the other 2 widely used imputation methods, the predictive method and the propensity score method.

### Loss to Follow-up

In this design, loss to follow-up would include participants who drop out of care at the designated site (eg, move out of New York City), who do not keep any follow-up appointments within 12 months of an initial screening that yields positive results, or who do not have an HbA1c test.

## Power Analyses

Data from our EHR and published data from prior research (1) provided estimates for the following sample size calculations. These calculations were based on the method published by Heo and Leon (2). We applied the following outcome measure assumptions: 1) the log-transformed HbA1c measure (or other appropriate transformation) is approximately normally distributed; 2) the intraclass correlation of repeated HbA1c measures within a 12-month period is approximately 0.62; 3) the total population variance of HbA1c measures is 3.63; 4) the expected difference between the enhanced and standard systems in HbA1c change over 12 months is 0.3; and 5) there will be at least 2 clinics per exposure group. We will allow an  $\alpha$ -error level of .05, and we anticipate a very conservative rate of loss to follow up of 15.0%. Given these assumptions, we have an 80.0% power to detect an average difference between the enhanced and standard group of 0.158 if we obtain a sample size of 568 patients assigned to each diabetes management system. Given the size of our health care system, we anticipate obtaining a sample size at least this large during our data collection period.

## Limitations

Because this is population-wide health services research, it is based on a nonrandomized design, leaving open the possibility of noncomparability between patients exposed to the enhanced system and those exposed to the standard system. Although we will consider this limitation as we conduct our analyses, biases and residual confounding are possible in this design. Participants at different practice sites are likely to differ in several ways. We will conduct subsequent analyses that examine each practice separately to make sure it is appropriate to combine these data. If not, separate results will be presented for each practice. However, this will reduce our power to detect a difference between the enhanced and standard systems.

## Secondary Analyses

In addition to the primary data analyses described above, we will conduct 2 secondary analyses.

1) We will examine whether observed improvements in the mean response profile of HbA1c of the enhanced diabetes management system is sustained after the first 12 months of follow-up. Because the enhanced system will be introduced to the 4 clinics using the standard system only at month 15, we will no longer have an unexposed concurrent control group. However, the available data will be useful for examining long-term trends over time for a large patient population. For example, we anticipate that the HbA1c outcomes for patients will continue to improve or remain stable over the longer-term observation period.

The measures and statistical models we will use for this analysis will be the same as those used for the primary analysis. In addition, we will consider using a combination of statistical techniques to compare the rate of change in participant HbA1c levels before and after implementation of the management systems, including lowess plots to assess the general shape of the curves, splining to account for nonpolynomial trends in the data, and linear mixed effects models. These findings will help us to draw conclusions about the overall effect of our diabetes management systems in our participant population.

2) We will also test whether patients in clinics adopting the enhanced system will be retained longer in the health care system and have greater adherence to recommended health care during the 12-month period following initiation of this system compared with those exposed to the standard system. For this analysis, our outcomes will include number of visits to a primary care physician, number of HbA1c measurements obtained, and number of community resources used. Prevention strategies can lead to unneeded medical care, that is, overuse of services. It will be important to monitor such unintended consequences and the cost of our enhanced diabetes management system. For example, we will closely monitor the number of HbA1c tests recorded for patients once their HbA1c levels are categorized as normal to determine whether unnecessary follow-up testing is being performed.

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## PREVENTING CHRONIC DISEASE

PUBLIC HEALTH RESEARCH, PRACTICE, AND POLICY

SPECIAL TOPIC

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# Designing a Natural Experiment to Evaluate a National Health Care–Community Partnership to Prevent Type 2 Diabetes

Ronald T. Ackermann, MD, MPH; Ann M. Holmes, PhD; Chandan Saha, PhD

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## Abstract

To address the growing incidence of type 2 diabetes in the United States, UnitedHealth Group, the YMCA of the USA, and the Centers for Disease Control and Prevention have partnered to bring a group-based adaptation of the Diabetes Prevention Program lifestyle intervention to a national scale. Researchers at Northwestern and Indiana universities are collaborating with these partners to design a robust evaluation of the reach, effectiveness, and costs of this natural experiment. We will employ a quasi-experimental, cluster-randomized study design and combine administrative, clinical, and programmatic data from existing sources to derive reliable, timely, and policy-relevant estimates of the program's impact and potential for sustainability. In this context, evaluation results will provide information about the unique role of a health care–community partnership to prevent type 2 diabetes.

## Introduction

An estimated 79 million Americans have prediabetes and are at high risk for developing type 2 diabetes in the next 5 to 10 years (1,2). Intensive population-based efforts are needed to reduce the development of type 2 diabetes, over a short time, among people who have prediabetes (3). To help address this issue, UnitedHealth Group (UHG), the YMCA of the USA (the Y), and the Centers for Disease Control and Prevention (CDC) have partnered to create a low-cost, group-based adaptation of the Diabetes Prevention Program's (DPP's) lifestyle intervention for implementation on a national scale.

The DPP clinical trial demonstrated the efficacy of a behavior-based lifestyle intervention to prevent or delay more than half of new cases of type 2 diabetes among adults at high risk (4). Because the DPP promotes healthful diet and moderate increases in physical activity to achieve modest weight loss, it also has benefits beyond diabetes prevention, such as improving other cardiovascular risk factors, reducing health care expenditures, and enhancing well-being (5–9). The DPP's high programmatic costs and the frequency of ongoing face-to-face visits have made it challenging to implement routinely in the real world (10).

Community delivery of adapted versions of the DPP have demonstrated promise for achieving weight losses consistent with the DPP trial for about one-eighth the cost of the original intervention design (11–13). In 2010, UHG partnered with the Y and CDC to develop 1) standards for recognition of community organizations that offer a program consistent with the DPP; 2) new infrastructures for the training of a nonclinical diabetes prevention workforce to deliver such a population-based program; 3) processes targeting employers, health professionals, and high-risk health plan enrollees to identify people with prediabetes in the general population; and 4) initiatives to encourage such high-risk people to enroll in a community-based DPP intervention. UHG and the Y also collaborated to develop a payment structure that encourages maximal attendance and achievement of at least a 5% weight loss goal for each participant. By combining new analytic and outreach procedures with performance-based payments for the DPP, UHG has constructed a novel preventive-health benefit design that aims to expand the reach and cost-effectiveness of the diabetes prevention programming that the Y offers nationally.

The success of this initiative depends on the efficient identification of high-risk adults in the population and the willingness of those adults to enroll and maintain participation in the program (13). However, the optimal mix of strategies to maximize program participation is unknown, and the potential for financial sustainability of the program depends on whether the health improvements achieved by greater participation in the DPP are associated with reductions in future health care expenditures. Learning whether the costs and benefits of the program are distributed equitably among all high-risk people in the population, regardless of age, race, culture, or economic context, is also important.

UHG, the Y, and researchers at Northwestern and Indiana universities have partnered to design an evaluation of this natural experiment that will be both pragmatic and rigorous. Our aims are to evaluate whether 1) UHG efforts to identify and engage high-risk adults can efficiently promote use of the Y program; 2) participation in this model for DPP delivery results in meaningful weight loss; 3) use of the program reduces the need for medications to treat diabetes, high blood pressure, or high cholesterol; and 4) DPP participants have lower overall health care use and costs.

## Evaluation Design

Our evaluation will focus on the combined elements of CDC workforce development, UHG engagement activities, and a Y model for DPP delivery that involve performance-based payments from UHG to maximize DPP participation and weight-loss effectiveness. This natural experiment will include more than 10,000 DPP participants in approximately 500 community-based DPP program sites in 44 cities throughout the United States.

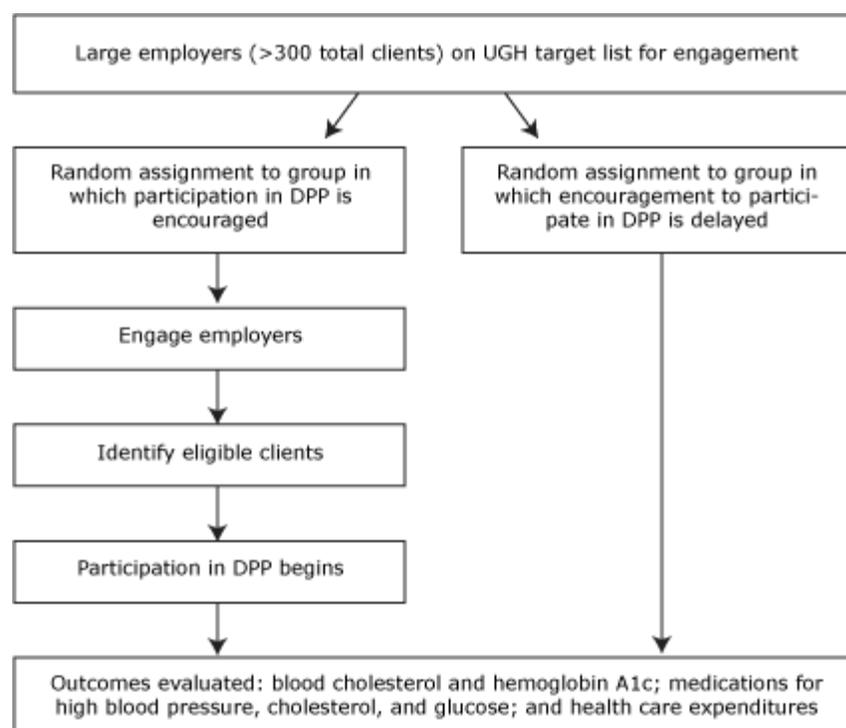
### Data sources and outcome metrics

Data from existing administrative, clinical, and Y sources will be evaluated. A dedicated electronic tracking and billing database, developed by UHG to help the Y administer the DPP, will allow us to analyze attendance and weight loss for program participants. Medical, pharmacy, and laboratory claims, available for all UHG enrollees, will allow us to compare changes in total and sector-specific (eg, inpatient) health care expenditures among different groups of enrollees regardless of DPP participation. Pharmacy claims will enable us to assess changes in treatment intensity for conditions linked to obesity and high metabolic risk (high blood pressure, high cholesterol, diabetes) (14). For subgroups of UHG enrollees with available test results associated with laboratory claims (approximately 20% of claims submitted nationally), we will evaluate changes in total cholesterol, low-density lipoprotein cholesterol, and hemoglobin A1c levels. Finally, data provided by the Y will enable us to explore whether regional variation in the structure and process of program implementation can help explain geographic differences in key program outcomes.

### Sampling and analysis plan

One strategy used by UHG to identify prediabetes and to enroll high-risk adults in a Y-based DPP intervention involves large-scale blood glucose or hemoglobin A1c testing as part of a workplace wellness or risk assessment initiative. Because these initiatives are deployed at an employer level, we have designed a cluster-randomized encouragement trial (CRET) as an innovative component of our research design (15,16). The CRET design will allow for comparisons with a randomized control group without interfering with the natural implementation of the program.

In select regions, UHG will provide the research team with a list of large employers whom it would aim to engage prospectively for on-site testing. We will randomly assign these employers to sequential waves of outreach and release them back to UHG to initiate encouragement procedures at a rate that matches the capacity of the UHG outreach team. As some employers are released into the active encouragement arm, others will remain in abeyance to serve as controls until being released at a future date (Figure). By using an intent-to-treat framework, clients who are actively encouraged (and far more likely to participate in the DPP) can be compared with clients who are not encouraged until a later time (17).



**Figure.** Cluster randomized encouragement design to be used in the Diabetes Prevention Program (DPP) by UnitedHealth Group (UHG). [A text description of this figure is also available.]

Although people cannot be randomized to attending the DPP, the CRET design will also enable us to analyze the treatment response among those who do elect to participate (18). Typically, comparisons of such self-selected subgroups can introduce selection bias. However, through the use of instrumental variables analysis (18–21), the CRET design will enable us to use the status of random assignment (ie, encouragement now vs encouragement later) as an instrumental variable to construct a robust estimate of the treatment effect of the program while minimizing the threat of selection bias.

The evaluation will focus on comparable samples of high-risk UHG clients who have prior claims-based evidence of diagnosed prediabetes (*International Classification of Diseases, Ninth Revision, Clinical Modification* [ICD-9-CM] code 790.21 or 790.22) or other indications of high metabolic risk (eg, diagnosed metabolic syndrome [ICD-9-CM code 277.7] or multiple metabolic traits such as overweight and obesity; high blood pressure; abnormal blood cholesterol). In this sample, the study will compare differences between randomized groups in the changes in laboratory tests for blood cholesterol and hemoglobin A1c, medication treatment intensities, and patterns and overall expenditures for health care. Total per-person-per-month (PPPM) health care expenditures will be compared by using 24 months of baseline and 12 month of follow-up data. We expect the cluster-randomization to yield a sample of approximately 60 employers and a minimum of 12,500 high-risk employees in each arm. Under reasonable assumptions that fewer than 30% of the observations may be missing (ie, as clients withdraw from the health plan) and that the intracluster correlation coefficient (ie, within employer) will be no more than 3%, we should have more than 80% power to detect mean differences in total health care costs as small as \$300 during the 12 months of follow-up.

One possible challenge of using a CRET design is that it may prove more powerful for evaluating the effects of UHG’s encouragement efforts than for evaluating direct effects of exposure to the DPP. If, for example, the number of employers randomized to the “active encouragement” arm exceeds the capacity of UHG to successfully engage them to identify high-risk employees, then the overall “dose” of DPP exposure in the active arm will be lower than anticipated, and statistical power of the study could be reduced.

## Conclusion

By using strong quasi-experimental methods mapped to the naturally occurring rollout plans of UHG and the Y, we aim to implement a robust study of this adaptation of the DPP program and to guide future policies about its role in the ongoing national fight against type 2 diabetes. In addition to informing UHG and the Y, our evaluation will provide information about how CDC and other public health and policy stakeholders can leverage natural experiments to build the knowledge base necessary for identifying effective policies to battle this and other population health challenges.

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## PREVENTING CHRONIC DISEASE

PUBLIC HEALTH RESEARCH, PRACTICE, AND POLICY

SPECIAL TOPIC

Volume 10 — January 31, 2013

# Impact of Emerging Health Insurance Arrangements on Diabetes Outcomes and Disparities: Rationale and Study Design

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## Abstract

Consumer-directed health plans combine lower premiums with high annual deductibles, Internet-based quality-of-care information, and health savings mechanisms. These plans may encourage members to seek better value for health expenditures but may also decrease essential care. The expansion of high-deductible health plans (HDHPs) represents a natural experiment of tremendous proportion. We designed a pre–post, longitudinal, quasi-experimental study to determine the effect of HDHPs on diabetes quality of care, outcomes, and disparities. We will use a 13-year rolling sample (2001–2013) of members of an HDHP and members of a control group. To reduce selection bias, we will limit participants to those whose employers mandate a single health insurance type. The study will measure rates of monthly hemoglobin A1c, lipid, and albuminuria testing; availability of blood glucose test strips; and rates of retinal examinations, high-severity emergency department visits, and preventable hospitalizations. Results could be used to design health plan features that promote high-quality care and better outcomes among people who have diabetes.

## Introduction

As discussed by Gregg et al in an accompanying article in this issue of *Preventing Chronic Disease* (1), diabetes is a growing threat to public health. In addition to its detrimental clinical impacts, diabetes creates an economic burden on both people and the health care system. Because type 2 diabetes and other chronic diseases are associated with both rising costs and modifiable lifestyle factors, consumer-directed health care advocates suggest that health systems should encourage greater patient cost-awareness and individual responsibility for health (2,3). They theorize that providing patients with information about health care quality while exposing them to full costs will create “activated health care consumers” (3). More than a decade ago, managed care organizations began to implement this theoretical framework in the form of “consumer-directed health plans” (4). These arrangements typically combine high-deductible health plans (HDHPs), Internet-based quality-of-care information, and mechanisms for saving money toward health expenses (5). Annual deductibles for the most rapidly growing HDHPs (health savings account–eligible plans [HSAs]) range from \$2,400 to \$12,100 per family (6,7). Advocates theorize that not only will HDHP members seek low-cost, high-quality care but they will also be more likely to adopt healthy behaviors to reduce future costs (2,3). For example, patients with diabetes may improve their diets, exercise regimens, and adherence to drugs and routine monitoring.

The expansion of HDHPs represents a natural experiment of tremendous proportion. Membership tripled between 2006 and 2012 (7), and 34% of US workers now have HDHPs (7). The rapid growth in HDHPs has been accompanied by concern — based on studies such as the RAND Health Insurance Experiment (8) — that high cost-sharing may reduce appropriate as well as inappropriate use. Recent evidence suggests that when necessary care such as essential medications (9–11) and screening tests (12,13) are subject to deductibles, use decreases. A newer school of thought has promoted “value-based insurance” designs as a remedy (14). These plans seek to broadly control costs using high deductibles while preserving evidence-based care through financial incentives. For example, plans may selectively

exempt preventive visits or hypoglycemic drugs from full cost sharing. Most HDHPs now have some value-based design features (7).

Despite their rapid expansion, the fundamental hypotheses of consumer-directed health plans with value-based features have largely been untested. Among diabetic populations, excluding secondary preventive services from cost sharing may either preserve use or lead to only small declines (15–18). One study found that both high- and low-income HDHP members with diabetes experienced small decreases in appropriate diabetes care (17). However, most studies have not controlled for member-level selection or examined adverse clinical outcomes. Furthermore, no studies have compared the effect of HDHPs with and without full prescription drug cost sharing on diabetes outcomes.

Our investigation seeks to determine the effect of HDHPs on diabetes quality of care, outcomes, and disparities. We are using a longitudinal, national data set that includes 2 million members with diabetes. We have 2 primary objectives:

1. To determine the effect of HDHPs on diabetes monitoring and clinical outcomes (including high-severity emergency department visits, preventable hospitalizations, and hospitalization days) in a national population and among people from vulnerable subgroups (blacks, Hispanics, those of low socioeconomic status, and high-morbidity patients with diabetes).
2. To determine the effect of HDHPs with and without full drug cost sharing on rates of medication adherence and related clinical outcomes, both overall and among high-risk subgroups.

## Study Design

We will identify a 13-year rolling sample (2001–2013) of HDHP members and members of a control group insured by a large national health plan. Preliminary analyses indicate that the pool of commercially insured persons from which we will select our sample is closely representative of the privately insured US population by age and sex (19). Our preliminary data set (2000–2009) includes 1.3 million members aged 18 to 64 years (2.5% aged 18–24, 31.0% aged 25–39, and 66.5% aged 40–64) with predominantly type 2 diabetes. Most members reside in the South (50.3%) and Midwest (28.8%), and 48% are women. Our data source can be linked to member-level sociodemographic variables, which provide self-reported information about disposable income, home ownership, and net worth. We will also use geocoded variables on socioeconomic status. Data on race/ethnicity, derived from a combination of surname analysis and geocoded census data, are provided in the preliminary data set. Approximately 1% have missing data in 2009 for education level, income, net worth, and race/ethnicity. Most members with reported race/ethnicity data are white (75.0%); 9.8% are black, and 11.5% are Hispanic. Overall, 40.0% of members are in health maintenance organizations (HMOs), 18.3% are in preferred-provider organizations (PPOs), and 29.1% are in point-of-service (POS) health plans; 15.5% were in an account-based HDHP at some point during their enrollment.

We will use a pre–post, longitudinal, quasi-experimental study design, a rigorous retrospective approach that we have used in previous HDHP studies (12,13,18,20). Our eligible cohort will consist of members enrolled in traditional plans (HMO, PPO, or POS) with low deductibles (\$250 or less individual deductible amount) for at least 1 year who experience an employer-mandated switch to an HDHP (ie, employees have no choice in selecting the type of health plan coverage). We will follow people for 1 year before and up to 3 years after the date of this mandated transition. Our comparison group will comprise contemporaneously enrolled members whose employers chose to remain in traditional low-deductible plans during the same period and who also were offered no choice of plan by employers. Including only members with mandated insurance coverage reduces the potential for bias resulting from individual self-selection into HDHPs. In selecting study groups, we will use employer-level propensity score matching to reduce differences between HDHP and traditional employers and member-level propensity score matching to reduce residual confounding. Propensity score matching is an established method for selecting a control group with a similar likelihood as the intervention group of selecting an intervention (in this case, choosing an HDHP) on the basis of observed characteristics when people have not been randomly allocated into study groups (21–23).

## Planned Study Outcomes

Our study will focus on the clinical effects of HDHPs. To assess changes in disease monitoring, we will measure rates of monthly hemoglobin A1c, lipid, and urine microalbumin testing (but not changes in test results because there is low completeness of lab value data); use of blood glucose test strips; and rates of retina examinations. We will graphically depict these outcomes using patient-level interrupted time series with comparison series plots. Using segmented longitudinal models (18), we will estimate changes in level and trend in use after the date of the switch to HDHPs, while controlling for autocorrelation and individual-level covariates using generalized estimating equations (24). Our clinical outcomes will include annual rates of high-severity emergency department visits, preventable hospitalizations, and inpatient hospital days. We will analyze these less frequent outcomes using a difference-in-differences approach with generalized linear models. Difference-in-differences calculations involve subtracting follow-up-minus-baseline

rates for the control group from follow-up-minus-baseline rates for the intervention group. Therefore, the effect of the intervention is adjusted both for the intervention group's baseline rates and the control group's change. This is the most rigorous retrospective approach available for estimating changes in low-frequency outcomes when time-series plots are unstable. For all analyses, we will stratify the population into vulnerable and less vulnerable groups when analyzing the effects of HDHPs on underserved populations, such as people who have low socioeconomic status.

To examine the effect of differential drug cost sharing, we will examine 2 measures of medication availability: the average number of oral hypoglycemic or antihypertensive medications available each month and the proportion of days that members have lipid-lowering or primary oral hypoglycemic medication available per month ("proportion of days covered") (18). We will use an interrupted time-series design to compare changes in level and trend of medication use between the study groups. We will subsequently stratify analyses to determine whether HDHPs that have more generous medication coverage are associated with more favorable emergency department and hospital outcomes.

## Methodological Decision Making and Limitations

A key design decision by our research team was to restrict the sample to health plan members who have no choice of health plan, which has the disadvantage of restricting the study to smaller employers who tend to not offer insurance choices. It also precludes the ability to examine different patterns of use between members who self-select HDHPs versus those who are required to enroll. However, removing members with a choice of plans has the substantial advantage of minimizing self-selection bias, a threat to validity in health insurance studies. We also recognize that employers may choose health plans on the basis of the characteristics of their workers, such as anticipated health needs or trends in costs; for this reason, we will use propensity score matching to reduce differences between HDHP members and traditional plan members and, when possible, use time-series plots and interrupted time-series analyses, which will demonstrate whether follow-up trends are different from baseline trends. A limitation of all health insurance claims-based studies is that members drop from the sample for reasons such as losing insurance, changing jobs, or changing insurer. We will choose only members who were continuously enrolled for a full 2 years. This approach removes bias due to differential dropout between groups, but there is also risk that members with longer continuous enrollment will have unusual characteristics, limiting generalizability. Preliminary calculations indicate that 49% of our sample will have 2 full years of continuous enrollment. Finally, some members in our cohort will be eligible to serve as either an HDHP member or a control, if, for example, they had 2 years of traditional plan enrollment followed by a year in an HDHP. We are therefore validating a method of randomizing such members to either the HDHP or control group.

## Implications for Policy Makers and Clinicians

In the context of continuing rapid growth of HDHPs, results from our study can be used to design health plans that promote high-quality care and better outcomes among diabetic populations (25). Policy makers could use findings to identify tests and therapies that should be exempt from full cost sharing, potentially informing changes to account-based HDHPs and facilitating extensions of value-based insurance design. Results also may affect the health plan arrangements that regulators include in emerging state-based health insurance exchanges. For example, evidence that exempting hypoglycemic drugs from full cost sharing preserves appropriate use may make this a standard or mandated arrangement.

We will present findings at research and policy conferences attended by policy makers and clinicians. We will also meet directly with public and private policy makers at the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality, and private insurance associations, among others, to discuss the implications of our research for policy decisions.

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