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# Advancing Health Policy and Program Research in Diabetes:Findings from the Natural EXperiments for Translation in Diabetes (NEXT-D) network

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Conflict of Interest

Mohammed K. Ali, Frank Wharam, O. Kenrik Duru, Julie Schmittdiel, Ronald T. Ackermann, Jeanine Albu, Dennis Ross-Degnan, Christine M. Hunter, Carol Mangione, and Edward W. Gregg declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent

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## Abstract

**Purpose of Review:** To advance our understanding of the impacts of policies and programs aimed at improving detection, engagement, prevention, and clinical diabetes management in the United States, we synthesized findings from a network of studies that used natural experiments to evaluate diabetes health policies and programs

**Findings:** Studies from the Natural EXperiments for Translation in Diabetes (NEXT-D) network used rigorous longitudinal quasi-experimental study designs (e.g., interrupted time series) and analytical methods (e.g., difference-in-differences) to augment causal inference. Investigators partnered with health system stakeholders to evaluate whether glucose testing rates changed from before-to-after clinic interventions (e.g., integrating electronic screening decision prompts in New York City) or employer programs (e.g., targeted messaging and waiving copayments for at-risk employees). Other studies examined participation and behavior change in low-(e.g., wellness coaching) or high-intensity lifestyle modification programs (e.g., Diabetes Prevention Program-like interventions) offered by payers or employers. Lastly, studies assessed how employer health insurance benefits impacted healthcare utilization, adherence, and outcomes among people with diabetes.

NEXT -D demonstrated that low-intensity interventions to facilitate glucose testing and enhance engagement in lifestyle modification were associated with small improvements in weight but large improvements in screening and testing when supported by electronic health record based decision-support. Regarding high-intensity Diabetes Prevention Program-like lifestyle programs offered by payers or employers, enrollment was modest and led to weight loss and marginally lower short-term health expenditures. Health plans that incentivize patient behaviors were associated with increases in medication adherence. Meanwhile, shifting patients to high-deductible health plans was associated with no change in medication use and preventive screenings, but patients with diabetes delayed accessing healthcare for acute complications (e.g., cellulitis). Findings were more pronounced among lower-income patients, who experienced increased rates and acuity of emergency department visits for diabetes complications and other high-severity conditions.

**Summary:** Findings from NEXT-D studies provide informative data that can guide programs and policies to facilitate detection, prevention, and treatment of diabetes in practice.



### Keywords

diabetes; policy; natural experiment; prevention; clinical management


## Introduction

Diabetes affects 30 million Americans, their families, and communities,(1) and is a leading contributor to rising healthcare costs in the United States (US).(2, 3) Over the past three decades, large randomized controlled trials (RCTs) have shown that individual-focused interventions can prevent or delay type 2 diabetes onset among adults with elevated blood glucose.(4–7) Studies have also shown that lifestyle modification and weight loss,(8) controlling glucose,(9–11) blood pressure,(12) lipids,(13) and avoiding tobacco (14) can all lower diabetes complications. In addition, enhanced care delivery strategies (e.g., team-

based care)(15, 16) have helped facilitate achievement of diabetes care goals nationally.(17, 18)

However, these successes must be viewed in context. Since 1990, the number of people with diabetes nationally has nearly tripled.(19) An estimated 84 million (or one in three American adults) have prediabetes, putting them at high risk of developing type 2 diabetes.(1) Consequently, while diabetes complication *rates* have fallen, absolute numbers with organ damage and healthcare use have increased.(20) Furthermore, though excess diabetes-related mortality has declined,(21) people with diabetes are living more years with disability and lower quality of life.(22)

Successfully addressing the diabetes epidemic will require efficiently translating, adopting, and sustaining evidence-based interventions to prevent type 2 diabetes and its complications in clinical and community venues -in the context of a socioecological milieu often unsupportive of protective, health related behaviors.(23) Translation of interventions into health gains ultimately depends on health programs and policies implemented by governments, payers, employers, health systems, and communities to facilitate efficiently reaching and affecting appropriate target populations. Despite this need, the science of large-scale dissemination and implementation is still nascent, due to a paucity of studies and infrequent use of rigorous research designs capable of inferring causation. In this report, we describe the efforts of the Natural Experiments for Translation in Diabetes (NEXT-D) network to advance the science of program and policy evaluation design in the area of diabetes, synthesize NEXT-D findings, and discuss their implications for practice and policy.

## Methods

In this narrative review, we summarize the major findings of NEXT-D studies between 2010 and 2016. Importantly, we provide a brief description of the natural experimental methods used for each evaluation because the choice of research designs greatly influences our ability to infer causal relationships between policies and outcomes. RCTs -and especially systematic reviews of multiple RCTs- are generally considered the strongest of research designs.(24) However, important practice-, institution-, organization-, system-, and payer-level interventions are often not amenable to RCTs nor to traditional observational epidemiological cohort studies. This reinforces the need for innovative evaluation methodologies (25, 26) and use of rigorous quasi-experimental approaches (Table 1). Natural experiment studies evaluate programs or policies that are not initiated or controlled by the researcher, such as those initiated by communities, governments, or commercial entities.(27)

The NEXT -D network consisted of five research centers and two funding agencies with expertise in clinical medicine, research design, epidemiology, behavioral science, economics, informatics, and statistics. From 2010–2016, NEXT-D studies sought to advance health program and policy research in diabetes, applying rigorous study designs and analytical methods to evaluate innovations, interventions, and policies in the broader landscape of diabetes care and prevention (Tables 2 and 3) (23, 28).

We interviewed NEXT-D evaluation teams to gather details regarding NEXT-D evaluation methods and findings to date, both published and unpublished. We then summarized these findings, organizing our review into 3 theme areas: 1) impacts on screening and outreach; facilitation of engagement and primary prevention; and 3) the influence of cost barriers on clinical diabetes management and outcomes. We then discuss NEXT-D findings as a whole, rather than simply individually, which enables broader conclusions to be made about the opportunities and challenges anticipated for policies and future national experiments in diabetes care and prevention.

## Screening and Outreach

Almost 9 in 10 people with prediabetes and 3 in 10 people with diabetes are unaware that they have elevated blood glucose levels, putting them at high risk for type 2 diabetes or diabetes complications, respectively.(29–31) Early detection is important and cost-effective, especially if screening is focused on identifying both prediabetes and type 2 diabetes, and connects people with proven interventions.(32, 33)

To promote targeted glucose testing, the American Diabetes Association (ADA)(34) and US Preventive Services Task Force (USPSTF)(35, 36) have each issued recommendations regarding whom to test and how often. However, a number of factors interfere with at-risk persons receiving testing, including system barriers such as financial access (e.g., insurance status and coverage for testing), provider practice variation (e.g., based on clinical judgement), and individual considerations (e.g., their perceived level of risk).(37)

To examine whether local implementation of primary care practice-based efforts to increase appropriate glucose testing aligned with screening guidelines at academic private and federally-qualified health centers (FQHC) serving 64,630 residents of New York City (NYC), NEXT-D investigators at Mount Sinai compiled electronic health record (EHR) data in 2010 and 2011.(38) Among 11,885 patients without known diabetes or recent testing, 75% were eligible for glucose testing based on ADA guidelines and 40–50% were eligible based on the previous USPSTF recommendations. Of note, however, only about one-fifth of those eligible by either guideline received a test.

NEXT -D researchers were then able to evaluate whether a NY C-wide program of training providers and integrating decision-support tools into EHRs could prompt higher screening rates for diabetes and prediabetes. The researchers used an interrupted time series study design and compared glucose test claims pre- and post-intervention at clinics with staggered intervention rollout (details in Table 2).(39) Among 40,456 adults without known diabetes or recent screening, the team noted an absolute 11 percentage point increase in the proportion of eligible individuals receiving screening (from a range of 7.4–10.4% screened monthly pre-intervention to 18.6–25.3% post-intervention). They also noted a 5 percentage point increase in screening among those not apparently eligible for screening.

To evaluate if lowering access barriers improved glucose testing, NEXT-D investigators at Kaiser Permanente Northern California (KPNC) partnered with two large employers to implement targeted outreach.(40) Using a combination of ADA and USPSTF guidelines,

employers identified employees who have not had a glucose test in the past 5 years and either were aged >45years or had BMI >25 kg/m2 or were in the KPNC hypertension registry. Employers identified 684 individuals with one of these high-risk profiles and invited and reminded them to obtain glucose testing at their usual health facility; copayments were waived. Compared with employees at three employers, matched on industry and employee characteristics but offering no intervention (n=1050), and adjusting for sociodemographic characteristics, comorbidities, and previous health utilization patterns, nearly three times more intervention (36%) than control (13%) employees completed testing in the 6 months after outreach. Of those tested, one-third had prediabetes-range glucose levels and 2–4% had diabetes.

### Implications

These findings highlight large gaps in identifying prediabetes and diabetes and suggest that provider-focused interventions such as training and EHR decision support as well as patient-focused reminders and copayment reductions can increase screening rates compared to no intervention. These interventions were also associated with some unnecessary diabetes screening among those that are ineligible. It remains unknown whether these low-intensity interventions to facilitate testing provide value for payers or health systems; but, identifying and engaging people at risk of type 2 diabetes remains a key component of addressing the high incidence of type 2 diabetes.

## Engagement and Primary Prevention

Several large RCTs (4, 5, 7) and other data (32, 41) show that, among people at high risk for developing type 2 diabetes, lifestyle modification can effectively and cost-effectively prevent or delay progression to type 2 diabetes. However, as delivered in the original trials, intensive behavior change programs for high-risk individuals are resource-intensive. This is especially concerning given that an estimated 84 million Americans have prediabetes-level blood glucose levels and potentially qualify for such interventions.(1) Studies replicating diabetes prevention trials in practical community settings have shown higher intensity programs and more contact with participants are associated with greater weight loss over 6 months to 2 years.(33, 41) This has led to efforts to scale up preventive services through community, clinical, and online programs for people at risk for type 2 diabetes.

Some programs are lower-intensity, such as brief, telephonic, health coaching. Other programs derive their curriculum and format from the original Diabetes Prevention Program (DPP) study such as those reporting data to the National Diabetes Prevention Program,(33, 42) which may demand a higher level of resource intensity as individuals or groups are tracked and offered ongoing support over months to years. In general, all focus on modest weight loss through healthful dietary changes, increases in physical activity, and behavior change strategies, but differ in frequency, intensity, duration, weight loss achieved, and sustainability of weight loss. More information is needed about the reach, uptake, costs, and satisfaction associated with these lower- and higher-intensity programs in broad, non-trial populations.

### Lower-intensity programs

Health systems and payers often implement different interventions “nudging” patients to engage in risk-lowering activities like exercising, modifying diets, and quitting smoking. NEXT-D investigators at KPNC evaluated several lower-intensity programs such as systematic documentation of exercise as a vital sign during healthcare encounters and targeted brief wellness coaching programs (details in Table 2).

The Exercise is a Vital Sign (43) initiative is an effort to motivate physicians to document patients’ physical activity levels and refer them to lifestyle programs. EVS involves an additional two questions posed by medical assistants in their clinical workflow and responses are entered into EHRs. Using difference-in-difference methods to compare four and seven clinics that had and had not yet implemented EV S, respectively, investigators at KPNC compiled data for 696,267 patients over 1.5 years.(44) The investigators adjusted for baseline differences in patient and practice characteristics. EVS implementation sites exhibited small but significantly higher rates of documentation of exercise (26.2% vs. 23.7% of visits) and slightly higher referrals to lifestyle programs (2.1% vs. 1.7%). From a random survey of 6,880 Medicare-insured patients, those who had encounters in EVS implementation practices were 14% more likely to receive exercise counseling than those attending non-EVS practices. At EVS sites, patients with obesity were nearly twice as likely to receive lifestyle referrals, patients who were overweight lost 0.2 pounds more body weight, and patients with poorly controlled diabetes experienced reductions in glycated hemoglobin that were 0.15 percentage points greater than matched patients at non-EVS sites.

Brief wellness coaching is a low-intensity program to encourage and support patients in adopting and sustaining healthy lifestyle behaviors. At KPNC, wellness coaching is a covered benefit, provided without additional charge. KPNC investigators used a randomized encouragement trial design to evaluate which outreach method (secure emails vs. mailed letters vs. no outreach) would lead to highest rates of participation (i.e. reach) among 14,584 adults with prediabetes.(45) Participation was defined as making an appointment for coaching within 6 weeks after being contacted. Average participation was low for all methods (1.9% overall), with highest participation (3.0%) among those receiving secure emails; notably, there was 0% participation among patients randomized to receive no outreach. Women, older adults, and individuals who were overweight or obesity, or gaining weight were more likely to engage.

KPNC investigators used an interrupted time series design to study the 12 months prior to and after enrollment in wellness coaching to evaluate health impacts of two telephonic coaching wellness programs - one aimed at weight control and another at tobacco cessation. Both programs used patient-centered motivational interviewing. KPNC investigators used individual-level segmented regression analysis to compare 954 adults in telephonic weight-related coaching to 19,080 propensity-matched non-participants.(46) Coaching program participants experienced an upward ($+1.78 kg/m^2$) and then a downward trend in BMI ($-1.79 kg/m^2$) prior to and after engaging in wellness coaching, respectively. Matched controls experienced smaller upward ($+0.87 kg/m^2$) then downward ($-0.26 kg/m^2$) changes in

BMI. Coaching participants had an overall 1.53 kg/m$^2$ greater reduction in BMI than matched controls.

To evaluate tobacco cessation coaching, researchers compared 241 adults enrolled in telephonic coaching, 4820 propensity-matched patients who did not enroll, and 4535 propensity-matched individuals who attended at least one in-person tobacco cessation class.(47) In the year following engagement, compared to non-participants, wellness coaching participants had significantly higher quit rates (31% vs. 23%) and tobacco cessation medication fill rates (47% vs. 6%). Those attending tobacco cessation classes had similar quit and medication fill rates as those in telephonic coaching.

The investigator team also evaluated satisfaction associated with free telephonic wellness coaching offered by the health system.(48) Survey participants were mostly women (83%), white (53%), and overweight or with obesity (82%). More than 60% reported a favorable impression of coaching and patient activation was correlated with satisfaction. However, the cross-sectional design limits inferences about whether activation preceded or resulted from the coaching.

### Higher-intensity programs

NEXT-D investigators at Northwestern University analyzed claims data to evaluate the largest community organization rollout (the YMCA of the USA) of a longitudinal, group-based, DPP-style program (YDPP)(details in Table 2).(49) From among 498,837 employees with health payer coverage through 759 participating employers, about 115,730 individuals were anticipated (using population estimates) to have elevated HbA1c tests in the range of 5.7 to 6.4%,(50) but health plan and employer outreach efforts only engaged 11,277 (9.7%) to complete a test to verify their high risk status. Of the 11,277 with documented prediabetes, 4554 (40.4%) attended at least one YDPP session, 3251 (28.8%) completed at least 9 core YDPP sessions, and 1302 (11.5%) lost 5% or more of baseline body weight.

To estimate the net costs of offering these high risk employees the YMCA's DPP, investigators used a difference-in-difference approach with pre- and post-exposure data comparing those attending at least one YDPP session (n=1725) during 2010–2013 with propensity-matched non-participants (n=1725) from the same worksites. Over 70% of participants were women, over 50% were aged 50 years or older, and approximately 50% and 25% were using blood pressure- and lipid-lowering medications, respectively. Based on observed session attendance, researchers estimated that payers reimbursed the YMCA an average of $213 for each YDPP participant. Over a two-year period, mean total healthcare expenditures for a YDPP participant was not statistically significantly different than matched non-participants. Thus, a strategy involving worksite-based HbA1c testing to identify prediabetes, followed by referral for free-of-charge access to the YDPP, is likely to yield 1) relatively low success in identifying high risk individuals; 2) modest YDPP enrollment by those who are identified; and 3) relatively high attendance and meaningful associated weight loss by those who do enroll. The approach has a relatively low intervention delivery cost for health payers and is likely to be cost neutral with respect to net healthcare expenditures over a 2 year time horizon.

## Metformin for Primary Prevention

In the DPP Study that was published in 2002, metformin was found to be a cost-effective method of reducing type 2 diabetes incidence by approximately 30% relative to no intervention among persons with impaired glucose tolerance.(4) The ADA recommends considering metformin -which remains unapproved by the Food and Drug Administration (FDA) for use in prediabetes- prescription as a complement to lifestyle intervention among people with prediabetes.(51) NEXT-D researchers at the University of California Los Angeles (UCLA) examined data from 17,352 continuously-insured employees with prediabetes, noting that only 3.7% were prescribed metformin over 2010–2012.(52)

## Implications

The NEXT -D findings, focused on engagement and primary prevention, highlight that employee engagement in employer-offered wellness programs is generally low. Despite being offered at no extra cost for enrolled KPNC members, uptake of wellness coaching was very low even with targeted outreach that encouraged participation. People with low participation may have other priorities (e.g., young children or busy jobs), prefer other approaches or intervention channels for increasing wellness, or may not yet recognize a need to address lifestyle risks; more targeted marketing may be needed to successfully engage these individuals. Worksite screening events to identify and enroll eligible commercially-insured employees with prediabetes resulted in relatively low yield. This may influence how employers and payers modify their biometric screening events, incentives for participation, and coverage. Indeed, further study of incentives and “nudges” may be of great value to payers and health systems seeking to shift the risk profile of populations they serve.(53, 54)

With regard to higher-intensity programs, to fully understand health and economic impacts, future research should also examine the added benefits of lifestyle programs, such as reductions in blood pressure and cholesterol,(33) and potentially fewer co-morbidities and improved quality of life that are often observed in participants of lifestyle programs.(55, 56) Additionally, future studies need to consider costs to engage and sustain participation. For example, the NEXT-D study of YDPP programs was not able to incorporate marketing and other outreach costs to engage employers and employees in screening that in YDPP participation. It is also hard to draw conclusions about costs in people who did and did not enroll without randomization because it is possible that the risk and health profile of people who did not enroll was different. Furthermore, financing the costs of program delivery (~ $200 per person per year in the YDPP program) may be different in other settings with different scale. That said, through interviews with human resource and senior executives from 21 employers across 7 industries, Northwestern investigators noted that company leaders were more focused on long-term value associated with prevention programs than on short-term returns on investment. They noted that value can include: employee satisfaction, increased productivity, decreased absenteeism and disability, improvement in clinical indicators, and preventing escalation in future healthcare costs. Even in the non-working population such as older adults, using actuarial estimates derived from YDPP data, the Centers for Medicare and Medicaid Services is paying for type 2 diabetes prevention services by CDC-recognized organizations because findings indicated that these programs will reduce costs over time.(57)

With regard to metformin, NEXT-D findings show that reach is currently low. This may be related to ongoing lack of approval from the FDA, patient or provider preferences, concerns over side effects, lack of studies among persons without IGT, and concerns about the feasibility of having patients with prediabetes adhere to metformin indefinitely.(58)

## Health Plan Influences on Clinical Diabetes Management

National data show improvements in diabetes care in the U.S. since the early 1990's.(17, 18) However, approximately half of all people with diagnosed diabetes still do not meet individual care goals and three-quarters do not achieve combined targets for glucose, blood pressure, lipid control, and avoiding tobacco.(31) Furthermore, costs associated with diabetes care continue to escalate.(59) To improve health and lower health care costs of patients with diabetes, employers and health insurers have included a variety of incentives and disincentives in their health plan offerings, such as specific covered benefits and care management programs.(23, 28, 60) However, little is known about if and how these employer-purchased arrangements influence health utilization and outcomes. NEXT-D investigators at UCLA and Harvard examined a range of outcomes associated with different health plan offerings (details in Table 2).

### Benefit Designs with Incentives

UCLA researchers examined whether employer adoption of a value-based insurance design, the Diabetes Health Plan (DHP), would influence medication adherence in employees with diabetes.(61) Specific DHP incentives offered by employers varied, but included some combination of: free or reduced copayments for oral glucose-, blood pressure-, and lipid-lowering medications used by patients with diabetes; free or reduced co-payments for primary care or endocrinology visits; and access to online or telephonic wellness coaching. Employees were required to engage in preventive services and health screenings to remain covered by the plan. The study compared employees at ten firms that offered the DHP with employees at 191 propensity-matched non-DHP firms over a three-year period. Employees in firms offering the DHP had an absolute 4–5 percentage point higher adherence to metformin, renin-angiotensin system modifiers, and statin medications. Of note, though the DHP was designed to lower copayments and increase prediabetes awareness, there was no evidence of differences in new metformin prescriptions between DHP and non-DHP patients with prediabetes (1.4 vs. 1.1%). It is possible that the economic incentives of the DHP were not effective for this goal given the generally low cost of metformin. Other barriers described above may also be related to low metformin use.

### Cost-sharing and Financial Disincentives

NEXT-D researchers at Harvard examined effects of employer-mandated changes from low-deductible (<=$500) to high-deductible health plans (HDHP: >=$1,000) on health utilization, outcomes, and costs among members with diabetes and matched controls.(62) HDHPs levy deductibles for most health care services, requiring out-of-pocket payments of approximately $1000 to $6000 per year. Preventive tests such as hemoglobin A1c and LDL cholesterol are often free or have low copayments, even under HDHPs. These arrangements are increasingly common, accounting for over 50% of employer-purchased health plans

nationwide.(63) Using national data from 12–64 year old patients with diabetes who were continuously insured for at least two to three years, Harvard researchers used an interrupted time series design to compare HDHP members to contemporaneous controls in low-deductible plans who were propensity-score- or coarsened-exact-matched on both employer and member characteristics including baseline levels and trends of key outcome measures.

Compared to controls, members with Health Savings Account-eligible HDHPs filled fewer oral glucose-, blood pressure-, and lipid-lowering medications in the first year after their switch, respectively. Reductions in medication use were more pronounced among poorer patients and those with less severe diabetes. By year two, these differences in medication use disappeared. HDHP members with diabetes experienced small or no changes in outpatient visits and disease monitoring measures such as HbA1c testing, though high-priority specialist visits declined to a moderate degree in the follow-up years. (62) In addition, HDHP members experienced delays in seeking outpatient care for acute complications such as cellulitis, urinary tract infections, or pneumonias. Notably, annual ED acute complication visits and episode costs among HDHP members increased substantially in the low-income and HSA-eligible groups.

A follow-up study found that, after the HDHP switch, ED visits declined to a small degree, while reductions in direct hospital admissions were more pronounced and total healthcare expenditures declined by approximately 4%.(64) Low-income members experienced major increases in high-severity ED visit expenditures and high-severity hospitalization days.

### Implications

Financial incentives and disincentives in insurance designs can have a wide range of effects on health seeking, behaviors and medication use, and health outcomes among people with diabetes, at least in the short term. Using large samples of employees nationwide, higher deductibles were associated with concerning patterns of ED visits and hospitalizations among low income, health savings account eligible, and high morbidity patients. HDHPs might be a viable option to reduce health insurance premiums for non-vulnerable patients with diabetes without causing harm, but, in comparison to low-deductible plans, they might result in increased adverse outcomes among vulnerable patients with diabetes.

Conversely, value-based insurance designs that incorporate appropriate incentives, especially in targeted subgroups, may be helpful in preserving or modestly improving health outcomes. Programs such as the DHP that address the motivations of patients may complement quality improvement efforts that focus on providers.

## Policy Implications

Over 2010–2016, NEXT-D studies addressed gaps in our understanding of programs and policies that can facilitate translation and sustained implementation of interventions to detect, prevent, and treat diabetes in real-life practice. Examining large populations, these studies affirmed that reach and adoption of evidence-based behavior change interventions within real-world health systems and insured populations is low (Figure 1). Coverage by payers or employers alone did not seem to encourage uptake, and the outreach and

engagement approaches that were evaluated generally achieved low yield. The effect sizes of employer-based, clinical, and policy changes observed were small on average, but larger in subgroups who were likely at higher risk (e.g., obese individuals) or most vulnerable (e.g., lower income individuals). More research is needed in this space to identify what engagement approaches are most appealing, for which population subgroups, whether they reduce or widen disparities, whether they lead to higher yield, better health, and greater value for employers and payers.

With regard to health benefits, health care providers should be aware that vulnerable HDHP members with diabetes might have an increased risk of adverse outcomes. Population-based management teams should be especially attentive to care patterns among low-income HDHP members with expensive chronic illnesses. Policymakers and employers hoping that benefit plans can reduce health costs among chronically ill patients might be disappointed, but might view the results as motivation to develop and encourage evidence-based, population-specific health insurance designs targeted to maintain or improve outcomes among vulnerable populations. For example, our findings show that the diabetes health plan for low-income workers (instead of a HDHP) may well have prevented the adverse outcomes we detected in that subgroup.

## Concluding Remarks

NEXT-D studies used rigorous quasi-experimental designs, aiming to advance the science and methodologies involved in natural experiment evaluations and highlighting design differences and elements of rigor, as compared to traditional epidemiological studies and clinical trial research (Table 1). Like most natural experiment evaluations, NEXT-D studies examined process and/or intermediate outcomes. This is partly a pragmatic reflection of what data are available in routine data systems. However, this is also reasonable given that relationships between process changes and clinical outcomes tend to be well-supported by traditional epidemiological studies. Furthermore, the fast-changing policy landscape is not always amenable to longer studies where the time horizon stretches to accrue sufficient numbers of measurable biological outcomes.

Policy evaluations must account for complex interplays between sociology, politics, and economics, and individuals' unique experiences of these interacting systems. Qualitative analyses may offer deep explorations of these nuances. For example, the Northwestern team's interviews with business leaders provided additional perspectives, showing that corporate executive respondents view employee wellness more broadly than financial returns on investment. Understanding the incremental costs -both fixed and variable- as well as the relative benefit(s) of investments in programs to prevent or manage type 2 diabetes could be valuable additions to decision-makers.

Collectively, NEXT-D's studies offer a window into effectiveness of population-focused interventions for diabetes and approaches for rigorous evaluation. Although they do not comprehensively examine all system-level interventions for diabetes, they offer evidence that natural experiment evaluations are feasible and can provide impactful policy guidance. Given the dynamic health policy landscape,(60, 65) there are many situations where natural

experiment evaluations can help policymakers understand the impact of current and future policy changes on the health of populations and further progress towards a higher value healthcare system.

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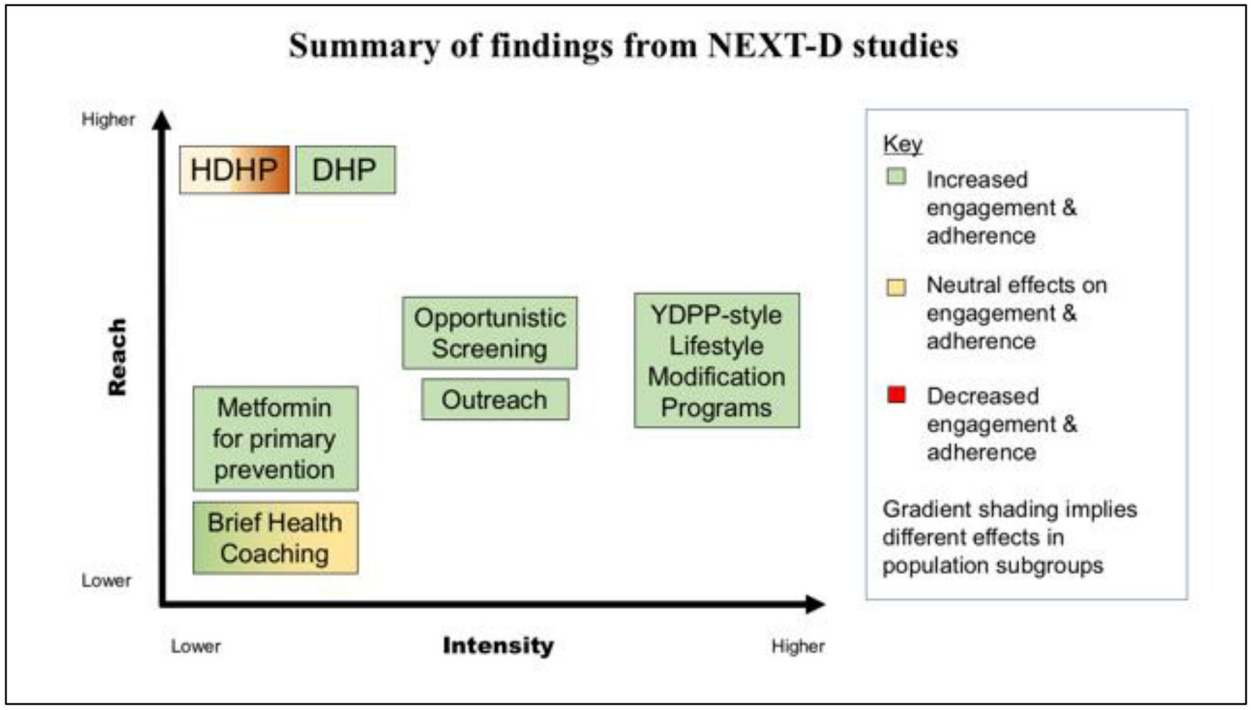


**Figure 1.**
Summarized findings from the Natural EXperiments for Translation in Diabetes (NEXT-D) studies

**Table 1.**

Comparison of traditional epidemiological, clinical trials, and natural experiment study features

| | Observational Studies | Controlled Trials | Natural Experiments |
|---|---|---|---|
| Populations | Representative or selected, depending on sampling | Usually selected, high risk volunteers | Mixed risk “general” populations for whom data is readily available |
| Purpose | Understanding burden (cross-sectional) or associations (longitudinal) | Understanding efficacy or safety of an intervention | Understanding effectiveness of a policy or program, in whom, and where |
| Interventions | Usually not focused on an intervention<br>Exposures can be compared as a proxy of interventions | Clearly-defined intervention<br>Investigator-directed intervention<br>Usually individual-focused | Clearly defined, but compliance or dose of intervention often unclear<br>Not investigator-initiated intervention<br>Local-, system-, state-, or federal-level policies |
| Outcomes | Depends on length of follow up | Usually intermediate and more end-organ disease events | Process, intermediate, or long-term event outcomes depending on length of follow-up |
| Magnitude of association or effect | Depends on intensity of behaviors initiated by participants | Usually large due to higher risk level of the population and intensity of the intervention | Usually small due to the low risk level of the population, low uptake, and low intensity of the intervention |
| Pitfalls | Costly<br>Difficult to achieve high response and retention<br>Reverse causation (i.e. the outcome may cause the exposure)<br>Confounding (observed and unobserved) | Costly<br>Difficult to extrapolate to “real-world” uptake and effects<br>Residual imbalance in covariates due to chance | Limited by scope of routine data and by the challenges of implementing programs in real world settings<br>Confounding<br>Selection by those most exposed or motivated by the policy or program |

**Table 2.**

Summary Descriptions of NEXT-D Studies

| | Population | | | Sample Size* | Intervention | Study Details | | | Outcomes | Other variables |
|---|---|---|---|---|---|---|---|---|---|---|
| | *Characteristics* | *Location* | *Insurance Status* | *Source and pool available* | *Description* | *Design* | *Duration* | *Comparator* | | |
| **Mount Sinai** | Adults aged ≥18 years | Adults attending 3 community clinics and 3 academic private practices | 34.6% uninsured; 56.4% public insurance; 7.1% Private; 1.9% other | 64,630 patients attending NYC clinics | EHR with built in screening and enhanced care prompts; plus physician training | Retrospective interrupted time series | 12 months | Clinics with delayed implementation of enhanced EHR | A1c testing<br>Change in A1c at 12 months | Stratified by screening eligibility<br>Other: BMI, lipids, BP |
| **KPNC** | Adults at high risk for diabetes<br>Primary care patients | Insured adults in integrated health system | 100% insured | EHR, claims, and pharmacy data for 3.8 million beneficiaries | Employer-based screening outreach<br>Telephonic wellness coaching<br>Exercise as a Vital Sign screening | Pre-post with control sites<br>Retrospective interrupted time series | Varies by analysis: most had 12 months pre- and 12 months postintervention data | Employers not providing outreach or wellness coaching | Glucose testing<br>Change in weight, physical activity, blood pressure, lipids | Patient surveys via phone and internet |
| **NU** | Adults with prediabetes | National data from large insurance company | 100% insured through employers | Claims and pharmacy records from ~500,000 adult employees | Group based lifestyle intervention delivered by YMCA and offered as covered benefit by employers | Retrospective difference in differences | 18 to 24 months pre- and postexposure to intervention | Propensity score matched control group without program as covered benefit | Reach, Adoption, Session attendance<br>Health care expenditures<br>Weight change | Employer-and employee-level matching |
| **Harvard Pilgrim Healthcare** | Members aged 12–64 years with type 1 and type 2 diabetes | National data from large insurance company | 100% insured through employers | Medical, inpatient and pharmacy claims from over 200,000 individuals | Employer-mandated switch to high-deductible health plans | Retrospective interrupted time series with control series | 1 year pre- and 1–2 years post-plan switch | Enrollees through companies offering only low deductible plans and matched on person- and employer-level characteristics | Disease monitoring<br>Drug adherence<br>Health service use<br>Acute diabetes complications; severe ED visits; inpatient days<br>Total health care costs | Stratified by income and morbidity levels |
| **UCLA** | Working age adults with prediabetes and diabetes | National data from large insurance company | 100% insured through employers | Claims and pharmacy records over 200 large and medium-sized employers | Employers purchased Diabetes Health Plan (DHP): insurance product with low or no cost sharing for | Retrospective difference in differences analyses | 3 years | Comparable employers and enrollees where DHP was not purchased | Adherence to medications and services<br>Adherence to preventive services | Employer-and enrollee-level matching |

| | Population | | | Sample Size* | Intervention | Study Details | | | Outcomes | Other variables |
|---|---|---|---|---|---|---|---|---|---|---|
| | *Characteristics* | *Location* | *Insurance Status* | *Source and pool available* | *Description* | *Design* | *Duration* | *Comparator* | | |
| | | | | | evidence-based treatments | | | | | |

* sample size varies by analysis; numbers show the source and size of potential data pool available

Abbreviations: KPNC, Kaiser Permanente Northern California; NU, Northwestern University; UCLA, University of California at Los Angeles; EHR, electronic health records; A1c, glycated hemoglobin; BP, blood pressure; BMI, body mass index; ED, emergency department

**Table 3.**

Interventions and outcomes studied in the Natural EXperiments for Translation in Diabetes (NEXT-D) network

| | Interventions | | | Outcomes | | | |
|---|---|---|---|---|---|---|---|
| | **Screening & Outreach** | **Lifestyle Modification Programs** | **Benefit Design Changes** | **Process Measures** | **Clinical Indicators / Outcomes** | **Health Utilization** | **Healthcare Costs** |
| **Mt. Sinai** | ■ (x) | | | ■ | | | |
| **KPNC** | ■ (x) | ■ | | ■ | ■ | | |
| **NU** | ■ | ■ | | ■ | ■ | | ■ |
| **UCLA** | | | ■ | ■ | | | |
| **Harvard** | | | ■ | ■ | ■ | ■ | ■ |

Abbreviations: KPNC, Kaiser Permanente Northern California; NU, Northwestern University; UCLA, University of California, Los Angeles

(x) Denotes that some outreach efforts were directed at providers and others at patients / plan members

Process measures included: enrollment in programs, receiving tests, adherence to medications

Clinical indicators included: weight, change in body mass index, or proxy measures such as medical visits and total costs for complications

Health utilization included: emergency room visits, inpatient stays