Impact of Medicaid Health Home on Patients With Diabetes in New York City
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PROTOCOL
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1) Objectives

We plan to examine the effects of New York State's (NYS) Medicaid Health Home (HHs) program (a population-targeted intervention at the state level) on the process of care, outcomes, and racial/ethnic disparities among low-income residents of New York City (NYC) with Type II diabetes mellitus. In 2012, NYS Medicaid initiated HHs with the "triple aim" of 1) improving quality, 2) improving outcomes, and 3) reducing costs of care for high-need patients with chronic diseases. The program was designed to enhance care and outcomes for patients with two or more chronic conditions, such as diabetes and coronary disease, HIV, and/or a serious mental health condition. HHs provide these patients with coordination of care, by promoting collaboration among health care providers, social service agencies, community-based organizations, and health insurance plans. Taken together, the roll-out, timing, scope of the program, which currently serves over 60,000 patients in NYC, and the availability of both Medicaid data and unique clinical data in NYC through the NYC-Clinical Data Research Network and the Health Evaluation and Analytics Lab provides an opportunity to evaluate the impact of HHs on diabetes management, complications, and health disparities, using quasi-experimental methods.

Similar care management programs have been shown, in studies of limited scope, to improve intermediate outcomes for patients with diabetes. However, the impact of HHs on processes of care and outcomes among low-income patients with diabetes mellitus in large, diverse, and complex urban settings remains largely unexplored. Additionally, current research on the impact of HHs, both in NYS and elsewhere, does not incorporate individual-level clinical data on chronic disease management. As a result, whether the Medicaid HHs program has impacted the health of patients with diabetes has not been examined. It is also not known how interventions of this scope will affect long-standing racial and ethnic disparities in the quality of care and outcomes of individuals with diabetes. Since similar programs are being implemented nationally, it now is critically important to evaluate the effects of HHs on the process and outcomes among patients with diabetes, a condition with multiple complications, which are disproportionately prevalent among racial and ethnic minorities and low-income populations in the United States.

We plan to use two complementary sources of longitudinal individual-level data: 1) NYS Medicaid administrative and claims data and 2) the New York City-Clinical Data Research Network (NYC-CDRN), funded by the Patient-Centered Outcomes Research Institute (PCORI). The NYC-CDRN has identified a cohort of patients with diabetes (approximately 90,700 Medicaid enrollees with diabetes) from 7 large health systems based on electronic health record data; and it has developed a common data model that includes clinical variables related to the process and outcomes of care of patients with diabetes. Using information available from the two complementary data sources and quasi-experimental methods, we will assess the impact of Medicaid HHs in NYC.

Among adult Medicaid patients with diabetes in NYC, we propose:

Aim 1: To assess the impact of HHs on the process of care for patients with diabetes.
Aim 2: To assess the impact of HHs on the health outcomes of patients with diabetes.

Aim 3: To assess the impact of HHs on racial and ethnic disparities in the process of care and outcomes among Medicaid patients with diabetes.

Our sample will include Medicaid enrollees with diabetes who are seen at NYC-CDRN sites and in HHs (estimated 6,500-20,000) and a matched comparison group of Medicaid enrollees with diabetes who are part of the NYC-CDRN, but not HHs. We plan to develop a set of propensity score matched controls, based on a set of patient, practice, and market-level (zip-code) characteristics. We will use quasi-experimental methods to investigate the magnitude of the effects of the HHs program between 2010 and 2017. This secondary data analysis is referred to as **Activity 1** in this protocol. In addition, we will gather information regarding the patient experience of HHs through interviews (**Activity 2**). We will also utilize interviews with HH leaders and care managers from NYC HHs to further characterize these entities (**Activity 3**). Columbia University will participate in only **Activity 1**.

8/20/20 update: Apart from evaluating the impact of the NYS Medicaid HH program on the process and outcomes of care for low-income NYC residents with diabetes, compared to non-enrolled residents with similar conditions and utilization histories, we have received funding to extend this work to examine the impacts of the COVID-19 pandemic on this vulnerable population, a majority of which is Black or Latinx. We hypothesize that HH participation will reduce pandemic-related disruptions in access to health care and social services and improve health outcomes among patients with diabetes in NYC. Using a quasi-experimental difference-in-differences design, we will contrast access and utilization of health care and social services and health outcomes among HH enrollees and non-enrollees during a baseline period prior to the pandemic (CY2019) with each month of the pandemic time period (2020).

Aim 4: Using Medicaid claims data, we will estimate the impact of HH enrollment compared to usual care among Medicaid-insured patients with diabetes and other chronic conditions on access to health care and social services and COVID-19 and non-COVID-19 clinical outcomes, as well as racial/ethnic disparities in these outcomes, before and during the pandemic in NYC.

Using Medicaid claims only, we will identify HH participants with diabetes living in NYC in 2019, and use matching and weighting methods to develop a non-HH comparison group who were similar to HH enrollees in their demographics, comorbidities and utilization histories. We will then conduct difference-in-differences analyses using an "event study" framework to compare the pre-COVID time period (CY2019) to each month of the post-COVID period (2020) in terms of access, utilization, and clinical outcomes between the HH and matched non-HH group, overall and stratified by race/ethnicity (Activity 4).

2) Background

Diabetes Prevalence

Type II diabetes mellitus is a common chronic disease, with an overall prevalence of 9.3% in the US (1). In New York City (NYC), the overall prevalence of diabetes is somewhat higher, 10.8%; and, the prevalence of diabetes are higher among racial and ethnic minorities, compared to Whites (2): among Hispanics, the prevalence is 15.2%; among non-Hispanic Blacks 12.8%; and, among non-Hispanic Whites 7.1%.(3) The prevalence of diabetes also is higher among those of lower socioeconomic status (SES),

compared to those of higher SES: among those living at <100% of the Federal Poverty Level (FPL) the prevalence is 14.8%; and, among the highest income group (>/=600% FPL) 4.7%.(3)

Diabetes Complications

The complications of diabetes impact health and well-being. In addition to the direct metabolic consequences, diabetes increases the long-term risk of cardio-renal diseases, including coronary heart disease, stroke, heart failure, renal disease, retinopathy and blindness; and these complications contribute to health disparities. In NYC, mortality related to diabetes is significantly higher among non-Hispanic Blacks and Hispanics and among individuals living in high-poverty neighborhoods, compared to non-Hispanic Whites and those living in low-poverty neighborhoods respectively.(4) Individuals living in high-poverty neighborhoods also have higher rates of hospitalizations for diabetes-related complications.(5)

Diabetes care

In order to improve health care and outcomes, reduce costs, and address health disparities related to diabetes, a number of health care interventions have been implemented by health systems and insurance providers, many focused on care management and care coordination. Increasingly, as health systems are incentivized to address health on a population level, interventions are also designed to address health determinants outside of the health care system, such as social and environmental factors and health behavior, through collaboration with community-based organizations (CBOs). Prior research among racially and ethnically diverse populations has shown that care management interventions delivered by primary care providers, registered nurses, community health workers, and endocrinologists can improve intermediate outcomes, such as hemoglobin A1c (HbA1c).(6-9) However, evidence does not presently exist on the long-term outcomes of care management and care coordination for patients with diabetes. Peek et al. describe many interventions that involve community-health system partnerships. Examples include clinics working with community-health workers, physician-referrals to community-based education, food “prescription” programs, and the integration of community-based resources into broad quality improvement initiatives.(10) While evaluations of some of these have shown promising effects on intermediate outcomes, there is little data about the overall effects of such interventions to date, especially in large, diverse, urban settings.

Medical homes

Care management and community-health system partnerships commonly exist within the patient-centered medical home (PCMH) model. The Agency for Healthcare Research and Quality (AHRQ) defines the PCMH as a model of care that offers comprehensive care of each patient’s physical and mental health through a team of providers, is patient-centered, coordinates care across the health system, provides accessible services, and engages in continual quality and safety improvement evaluation and activities.(11) Consensus principles of the PCMH, building on the backdrop of 40 years of primary-care practice redesign, were established in 2007 by the American College of Physicians, the American Academy of Family Physicians, the American Academy of Pediatrics, and the American Osteopathic Association.(12) A growing number of providers are part of PCMHs, serving several million patients.(13, 14) However, there are large variations in the definition, and implementation of the PCMH.(15) This variation has made it difficult to assess the impact of the PCMH on quality of care and clinical outcomes.

Affordable Care Act and Medicaid Health Homes

As part of the Patient Protection and Affordable Care Act (ACA) of 2010, "health homes" were authorized for care management and coordination for individuals enrolled in Medicaid. Under the ACA, six health home services are eligible for reimbursement: comprehensive care management, care coordination and health promotion, comprehensive transitional care, patient and family support, referral to community and social support services, and use of health information technology to link services.(16) As such, the Medicaid Health Home (HH) includes interventions previously tested among individuals with diabetes. However, the payment reforms associated with these new care delivery mechanisms add another aspect to the intervention. In addition, these types of interventions are now being expanded to include a larger patient population- those eligible for HHs. In order to be included in a HH, patients need to have chronic conditions, including serious mental illness, substance use disorders, or multiple chronic diseases, including diabetes. As of November 2014, 20 states had approved plans for HHs.(17)

New York State (NYS) established a Medicaid Health Home program in 2012, with the New York State Health Home State Plan Amendment (SPA). In New York State at the end of 2014, over 5 million low-income individuals were enrolled in Medicaid, including over 3 million of NYC's estimated 8.4 million residents.(18, 19) The State estimated in 2012 that approximately 1 million individuals would be eligible for the HH program, including 418,677 Medicaid recipients with mental health or substance use disorders, and 386,399 participants with other chronic conditions. HHs were rolled out in three phases during 2012, with Phase I in January (which included the Bronx and Kings (Brooklyn) Counties), Phase II in April (which included New York (Manhattan), Queens and Richmond (Staten Island), the remaining counties in NYC), and Phase III in July.(20) As of August 2014, 40,776 individuals were enrolled in NYC.(21, 22) Around 35,000 Medicaid enrollees across NYS were part of precursor care management programs (including the Office of Mental Health's Targeted Case Management Program (for those with severe mental illness), Managed Addiction Treatment Services Program, and the Comprehensive Medicaid Case Management Program (for people living with HIV/AIDS), which are all in the process of converting to HHs.(16)

The identification of individuals eligible for HHs is initiated by one of two processes: a NYS Department of Health (DOH) predictive algorithm utilizing Medicaid services data, which prioritizes individuals based on risk of future hospitalization; and community or "bottom up" referrals from healthcare providers, community-based care management providers, including harm reduction providers, and other agencies such as those who serve individuals re-entering the community from jail or prison. Enrollment in HHs has been slower than expected, and several challenges have been identified and are being addressed by the NYS DOH. These include inaccuracies in the lists of targeted individuals, challenges in the recruitment process, and individuals electing not to participate in the program.(16) The new program may put stress on already under-resourced facilities, by increasing the complexity of billing, the requirements around health information technology (HIT), the caseloads of facilities and case managers, and, in some cases, lowering reimbursement for care management services. Another significant change brought about by HHs is the expanded scope of health conditions of clients served by care management agencies that formerly provided case management for people living with HIV/AIDS, substance use disorders, or serious mental illness (P. Schafer, personal communication, March 9, 2015).

Medicaid Health Homes and Diabetes Management

HH-eligible patients with diabetes are likely to be an especially vulnerable population, and one where disparities in access and quality are starker. The prevalence of diabetes among patients with serious

mental illness (SMI) is higher than in the general population. Increased mortality among those with SMI is partially attributable to higher rates of cardio-metabolic disease.(23, 24) Patients with SMI and diabetes have been found to be less likely to receive indicated services and care, and more likely to be admitted to the hospital with ambulatory-care sensitive conditions when compared to those without SMI.(23, 25) Over half of patients with diabetes have at least one other chronic condition, and a large proportion of these have two or more.(26, 27) Suffering from multiple chronic diseases puts individuals at greater risk of preventable hospitalizations, poor functional status, higher cost care, and increased mortality.(26, 28)

HH enrollment would ideally improve the processes and the outcomes of care; and it would reduce health disparities (related to the process and outcomes of care) for individuals with diabetes. Through coordination of care, intensive case management, and attention to social needs, individuals with diabetes could develop better disease self-management, receive proper specialist evaluation and evidence-based regimens, and work with a team that identifies opportunities to bolster social support. As the HH intervention is applied differently at different facilities, these effects may vary across institutions. In NYS, evaluations are currently being conducted of the overall HHs program and of those participants with substance use disorders and those with HIV; however, by focusing on individuals with diabetes, the proposed research would add substantially to knowledge about the effect of HHs on patients on an important common chronic condition, diabetes.

Impact of COVID-19 on Medicaid Health Homes

In spring 2020, New York City (NYC) was the American epicenter of the COVID-19 pandemic. In addition to direct health effects, the pandemic also had major impacts on the delivery of health care and social services. Low-income patients with diabetes, especially among racial/ethnic minorities, are more vulnerable to the serious morbidity and mortality associated with COVID-19; and, they are more likely to experience a lack of access to health care and social services. Outpatient medical care essentially shut down for in-person visits during the pandemic, and access to primary care, disease management, and medications continue to be disrupted. Limited mobility and social determinants, such as access to transportation, employment, internet connectivity, and competing needs, also likely impacted access to health care and social services and clinical outcomes during the pandemic. In response, New York State (NYS) Medicaid adapted regulations to allow Health Homes (HHs) to bill for remote delivery of care management services. As a result, HH participants are likely to have higher rates of health care and social service utilization and better health outcomes, compared to similar HH non-participants.

The proposed study will be among the first to utilize the New York City Clinical Data Research Network (NYC-CDRN) data and infrastructure to examine the effects of a population-level health policy, the implementation of the Medicaid HH program, on the process, outcomes, and disparities of care for a common chronic condition, diabetes.

3) Setting of the Human Research

The primary research team is located at the Icahn School of Medicine at Mount Sinai. Other members of the team are located at Weill Cornell Medicine and the New York Academy of Medicine (NYAM) (Co-PI David Siscovick). NYAM is a non-profit center of interdisciplinary research, evaluation, policy, and

program initiatives focused on urban health. The study is a collaboration with the New York City Clinical Data Research Network and the HEAL at NYU School of Medicine.

The New York City Clinical Data Research Network (NYC-CDRN) was founded with support from the Patient-Centered Outcomes Research Institute (PCORI) to join its PCORnet program. The mission of the NYC-CDRN is to create an accessible, sustainable, scalable clinical data network to facilitate patient-centered research, learning healthcare systems and a national research network (PCORnet). Efforts are focused on five goals:

1. Creating thoughtful privacy policies that protect the identities of individual patients, clinicians, and health systems;
2. Establishing a de-identified database with clinical data on at least one million New Yorkers;
3. Engaging patients, caregivers, and clinicians in network governance and decision-making;
4. Embedding research activities in the delivery of healthcare to minimize the burden on patients, clinicians, and health systems; and
5. Developing a high-functioning, sustainable governance structure.

NYC-CDRN's program builds on the joint efforts of 22 organizations – including academic medical centers, associated Clinical and Translational Science Centers, federally qualified health centers, regional health information organizations (RHIOs), research institutions, consumer advocacy groups and government agencies - to develop a patient-centered, sustainable network for conducting research across New York City and the nation and facilitating a learning healthcare system.

The Health Evaluation and Analytics Lab (HEAL) promotes applied research to help health sector organizations evaluate initiatives that seek to improve health outcomes among populations and to improve health care delivery practices. HEAL has built a unique New York State Medicaid claims file. This large data system allows for a wide range of evaluative work focused on improving care and outcomes for the most vulnerable New Yorkers, who rely on Medicaid to pay for their medical care needs. The data set also allows providers to better track the services received by their patients. The effort to create the claims file analytical system was financially supported by the New York State Health Foundation and was done in close collaboration with the New York State Department of Health.

Participating organizations include:*

Health Systems/Facilities:

- **Clinical Directors Network**
- Columbia University
- New York-Presbyterian Hospital
- NYU Langone Medical Center
- **Montefiore Medical Center**
- **Mount Sinai Health System**
- **Weill Cornell Medical College**
- Charles B. Wang Community Health Center
- Community Healthcare Network

Infrastructure:

- Biomedical Research Alliance of NY (BRANY)
- Bronx RHIO (BRIC)
- Healthix RHIO
- A Weill Cornell approved vendor (NYC-CDRN Central Repository)
- Rockefeller

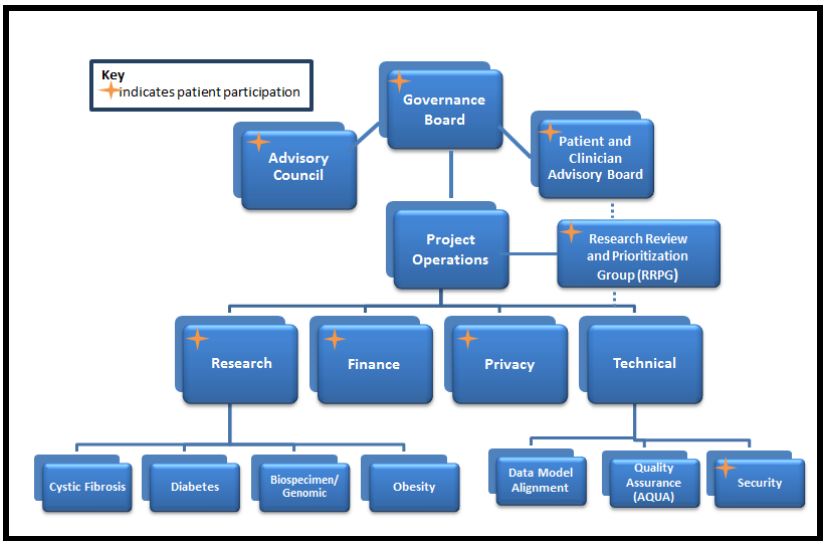
Other Partners:

- Center for Medical Consumers
- Cornell NYC Tech Campus
- NY Academy of Medicine
- NYS Department of Health
- Healthcore
- NYU School of Medicine HEAL

- Lutheran Family Health Center Network
- University

*All entities are involved in Activity 1.
Bolded entities are also a part of Activity 2.

Figure 1: NYC-CDRN Organizational Structure



4) Resources Available to Conduct the Human Research

Our study team includes multiple experienced investigators, a data analyst, experienced project management staff, and an experienced engagement manager. This team has the knowledge and resources needed to conduct the retrospective cohort analysis, focus groups, and HH leader interviews. ISMMS has robust data management and security protocols in place to safely store study data. For this study, we will be working with the NYC-CDRN, which, as described above, has the resources to combine data from multiple institutions and facilitate collaboration, and to ensure data security and quality.

Activity 2: The primary team at ISMMS will collaborate with partner institutions to conduct interviews. Investigators and stakeholders from the partner institutions will advise the primary team on reaching out to clinical providers, care management agencies, and HHs about contacting their patients. The primary team will reach out to and follow up with these providers. Then, the primary team will reach out to eligible participants. The primary team will conduct all interviews.

5) Study Design

a) Recruitment Methods

Activity 1: For this retrospective data analysis, we will not be recruiting any participants. The study will rely upon a distributed query of the participating healthcare systems in the NYC-CDRN. For a full description of query design, see section f for Activity 1. The protocol relies upon the NYC-CDRN infrastructure established under the BRANY IRB-approved protocol #14-02-95-380 (PI: Kaushal) to accomplish the data aggregation.

Activity 2:

Health Home patients will be recruited through referral from HH care managers. Care managers will share a flyer (created by the study team) describing the study with patients. If patients are interested, the care manager will add their contact information to an excel spreadsheet that will be shared with study staff. Study staff will follow up via phone. If the participant is reached via phone and interested in participating, study staff will provide further information about the interview process and content and will schedule the phone/virtual interview.

Activity 3: In order to identify leaders from HHs in NYC, we will utilize multiple sources including internet sites for each HH listing name and contact information for those in leadership positions, referrals from our Patient and Stakeholder Advisory Board (of which one member is a leader of a NYC HH and thus familiar with many of these individuals), from interviewees who have already participated, and HH forums. Study staff will reach out to individuals by phone or email and describe the study. If potential participants are interested, the study staff member will set up a telephone or video meeting, during which verbal consent will be obtained prior to any data collection.

Health Home directors that are study stakeholders and partners will assist with the identification of HH care managers and will share contact information of interested participants with the study staff in an excel spreadsheet. Study staff will follow up via email or via phone. If the participant is reached and interested in participating, study staff will provide further information about the interview process and content and will schedule the phone/virtual interview.

Activity 4: For this retrospective data analysis, we will not be recruiting any participants We plan to use NYS Medicaid administrative and claims data in the Medicaid Data Warehouse, available to researchers at HEAL at New York University.

b) Inclusion and Exclusion Criteria

Activity 1: For this analysis, the study cohort will consist of patients who: 1) have Type II diabetes, 2) are insured by Medicaid, and 3) are either part of a Health Home or meet criteria for Health Home enrollment, but are not enrolled in a Health Home.

1) In consultation with the Diabetes Subcommittee of the NYC-CDRN, this protocol will use the SUPREME-DM definition of diabetes, which has been previously validated.(29) This definition has been adopted as a standard across the three CDRNs that have diabetes as a disease focus (New York, Louisiana, and Oregon-Advance). It consists of the following algorithm (see Table 1), where any of the listed criteria are sufficient for inclusion for any patient with at least one outpatient visit at a participating CDRN site within the past year.

Table 1. Diabetes Definition

Criteria	Parameter	
ICD9/10 - Inpatient discharge diagnosis	1 or more of (250.x, 357.2, 366.41, 362.01–362.07)	
ICD9/10 - Outpatient diagnosis	2 or more of (250.x,357.2, 366.41, 362.01–362.07)	Visits must occur on separate days. Ambulatory visits only.

HbA1c	2 or more HbA1c's at >=6.5%	Tests must be on separate days no more than 2 years apart.
Fasting Plasma Glucose	2 or more at >= 126 mg/dL	Tests must be on separate days no more than 2 years apart.
Random Plasma Glucose	2 or more at >= 200 mg/dL	Tests must be on separate days no more than 2 years apart.
Random plasma plus fasting glucose	1 at => 200 mg/dL AND 1 at => 126 mg/dL	Tests must be on separate days no more than 2 years apart.
HbA1c plus fasting glucose	1 at >= 6.5% and 1 at >= 126 mg/dL	Tests can occur on same day but cannot be more than 2 years apart.
HbA1c plus random plasma glucose	1 at >= 6.5% and 1 at >= 200 mg/dL	Tests can occur on same day but cannot be more than 2 years apart.
2-h 75-g OGTT	1 at >= 200 mg/dL	Do NOT count if measured during pregnancy.
Medications	Sulfonylurea, insulin, biguanide, SGLT-2 inhibitors, thiazolidinedione, alpha-glucosidase inhibitor, incretin mimetic, meglitinide, amylin analog, or dipeptidyl peptidase inhibitor	>= 1 prescription. If dispense was for metformin, any thiazolidinedione, or exenatide, at least one lab test (HbA1c > 6.5%, random glucose >= 200 mg/dl, fasting glucose >= 126 mg/dl) is also required.

2) In order to be eligible for the cohort, subjects need to have been insured by Medicaid at some point during the years 2010-2016. This categorization will be available in the NYC-CDRN data set. Data will be gathered only from individuals who meet criteria for diabetes and have been insured by Medicaid.

3) Subjects who have participated in the HH program will be the treatment group in this study. Medicaid data contains a field that will identify those patients who were a part of this program during the study period. Our comparison group will consist of similar individuals who were not part of the HH program. The comparison group will be constructed of patients who have been propensity score matched to those in the treatment group, and are therefore similar on a number of characteristics.

Activity 2: For the focus group and interview aspect of this study, we will be conducting 2 rounds of data collection, in years 2 and 5. We aim to recruit 20-40 participants in year 5. Year 5 data collection will consist of only individual interviews. Inclusion criteria are as follows:

a. English-speaking
b. Are enrolled in a HH
c. 18 years old or older

All participants must be able to provide informed consent to participate, and must be able to speak with a study staff member over the phone/video call. All individuals must be able to communicate in English.

The ISMMS study team will coordinate with stakeholders who lead NYC HHs to engage HH members/patients who are potential participants.

Activity 3: HH leaders: In order to participate in this portion of the study, individuals must speak English and be in a leadership position at a HH entity in NYC or a NYC HH-affiliated Care Management Agency (CMA). Other than not meeting the inclusion criteria, there are no exclusion criteria.
Care managers: In order to participate in this portion of the study, individuals must speak English and be in care manager position with a NYC HH-affiliated Care Management Agency (CMA). Other than not meeting the inclusion criteria, there are no exclusion criteria.

Activity 4: For this analysis, the study cohort will consist of patients who: 1) have Type II diabetes, 2) are insured by Medicaid, and 3) are either part of a Health Home or meet criteria for Health Home enrollment, but are not enrolled in a Health Home. These criteria will be determined using only Medicaid claims data.

c) Number of Subjects
Activity 1: Estimated sample size of 51,000 patients.
Activity 2: 20-40 participants in year 5.
Activity 3: Approximately 10-30 participants (HH leadership and CMA leadership, care managers).
Activity 4: Estimated sample size of 60,000 patients

d) Study Timelines
Activity 1: This is a retrospective cohort analysis. We will examine two data sets: one with data from 2007-2014, and one with data from 2010-2017. The project has been funded from 3/1/2016-2/28/2021.
Activity 2: We completed our year 2 focus groups and interviews by 8/31/2018 and we anticipate completing year 5focus groups by 2/2021. Participation in the study will consist of being a part of an interview, and optional follow up activities (receiving study results). The project has been funded from 3/1/2016-2/28/2021.
Activity 3: We completed our first round of HH leadership interviews by 8/31/18. Year 5 interviews will be conducted by 2/2021. The project has been funded from 3/1/2016-2/28/2021.
Activity 4: We anticipated conducting primary analyses by 6/30/2021.

e) Variable and endpoints
Activity 1 and 4: For this aspect of the study, we will examine multiple endpoints related to process of care, outcomes, and racial/ethnic disparities. We will examine variable and endpoints in the following categories:

1) Individual level characteristics
Variables include gender, age, race/ethnicity, health insurance type, health care site, patient zip code, and tobacco use.

2) Health home indicators and patient co-morbidities

Indicators available include whether the individual was enrolled in the HH program, the date of joining the program, the name/location of the HH, patient-level co-morbidities and chronic conditions (additional diagnoses).

3) Process measures

In consultation with the Diabetes Subcommittee of the NYC-CDRN, the following process measures have been identified (see Table 2). Several organizations in the United States have developed sets of quality metrics that can be used to evaluate the adequacy and appropriateness of processes of care and outcomes for patients with diabetes. These include the Centers for Medicare and Medicaid Services (CMS), the Pharmacy Quality Alliance (PQA), the National Committee for Quality Assurance (NCQA)'s Healthcare Effectiveness Data and Information Set (HEDIS), and the Agency for Healthcare Research and Quality's (AHRQ) Prevention Quality Indicators (PQI) (which assess the quality of care for "ambulatory care sensitive conditions," also known as preventable admissions).(30-33)

Table 2. Process Measures

Metric	Component
Adherence to Chronic Medications (CMS)	At least two prescriptions for statins and a Proportion of Days Covered (PDC) of at least 0.8 during the measurement period (12 consecutive months)
Adherence to Chronic Medications (CMS)	At least two prescriptions for ACEIs/ARBs and a PDC of at least 0.8 during the measurement period (12 consecutive months).
Adherence to Chronic Medications (CMS)	At least two prescriptions for a single oral hypoglycemic agent or at least two prescriptions for multiple agents within an antidiabetic class and a PDC of at least 0.8 for at least 1 antidiabetic class during the measurement period (12 consecutive months).
Eye Exam (NCQA)	Received a retinal or dilated eye exam during the measurement year or a negative retinal or dilated eye exam in the year prior to the measurement year.
HbA1c testing (NCQA)	Received an HbA1c test during the measurement year.
LDL-C Screening (NCQA)	Received an LDL-C test during the measurement year.
Medical Attention for Nephropathy (NCQA)	Received a nephropathy screening test or had evidence of nephropathy during the measurement year.
Appropriate Treatment of Hypertension (PQA)	If dispensed a medication for diabetes and hypertension, are receiving an angiotensin-converting -enzyme-inhibitor (ACEI) or angiotensin receptor blocker (ARB) or direct renin inhibitor (DRI) renin-angiotensin-antagonist medication.
Foot exam (NCQA)	Received a foot exam (visual inspection with either a sensory exam or a pulse exam) during the measurement year.

4) Outcome measures

In consultation with the Diabetes Subcommittee of the NYC-CDRN, the following outcome measures have been identified (see table below). As with the identified process measures, these are metrics identified and developed by major quality reporting organizations, which means that results will be readily interpretable by policymakers and easily compared to other studies and datasets.(30)

In order to assess these metrics, and to perform individual-level longitudinal analyses, we will evaluate health system utilization and intermediate and long term outcomes. Outcomes will include:

1) Intermediate outcomes:HbA1c, blood pressure, LDL and renal function
2) Long-term outcomes: we will use validated ICD-9 code based-algorithms to assess
    a. macrovascular outcomes (stroke and myocardial infarction)
    b. microvascular outcomes (nephropathy, end-stage renal disease, neuropathy, amputation, retinopathy, and blindness)
3) Utilization outcomes:
    a. Number and diagnoses associated with diabetes-related preventable hospitalizations
        i. uncontrolled diabetes admissions
        ii. diabetes short-term complications admissions (diabetic ketoacidosis, hyperosmolarity, coma)
        iii. and long-term complications admissions (renal, eye, neurological, and circulatory disorders)
    b. ER visits
    c. Outpatient visits.

Table 3. Outcome measures
Metric
HbA1c Control (<8.0%) (NCQA)
HbA1c Poor Control (>9.0%) (NCQA)
Blood Pressure Control (<140/90 mm Hg) (NCQA)
Uncontrolled Diabetes Admissions Rate (PQI 14) (AHRQ)
Diabetes Short-Term Complications Admissions (PQI 1) (AHRQ)
Diabetes Long-Term Complications Admissions (PQI 3) (AHRQ)
Lower-Extremity Amputation Among Patients With Diabetes (PQI 16) (AHRQ)
Medical Attention for Nephropathy (NCQA)

Activity 2: For this qualitative research, we will identify cross-cutting themes from interviews.
Activity 3: Data collected through these interviews will be utilized to categorize HH, CMA, and care manager activities and experiences.

f) Procedures Involved in the Human Research

This is a mixed-methods study that will utilize a retrospective cohort design, as well as qualitative focus groups and interviews consisting of a combination of closed- and open-ended questions.

Activity 1: This part of the study will examine a merged data set that will include EHR data, Medicaid claims data, and HH-specific data. The study will rely upon a distributed query of the participating healthcare systems in the NYC-CDRN and HEAL at NYU School of Medicine will

extract the NY State Medicaid data. Our data flow is depicted in the figure and described below. The protocol relies upon the NYC-CDRN infrastructure established under the BRANY IRB-approved protocol #14-02-95-380 (PI: Kaushal) to accomplish the data aggregation.

1. The NYC-CDRN (New York City Clinical Data Research Network) conducts a query on centralized, de-identified electronic health record (EHR) data to select patients with diabetes.
2. A Weill Cornell approved vendor (NYC-CDRN Central Repository) identifies the patients selected in step 1 who were insured by Medicaid at some point during the study period (2007-2017) and provides a list of the relevant CDRN Master IDs and site-specific proxy IDs back to the NYC-CDRN.
3. The NYC-CDRN assigns site- and study-specific IDs (SS-IDs) to each patient. The SS-ID is unique to this study. The NYC-CDRN provides a list to:
4. 4a. The NYC-CDRN central data repository, which holds data from each of the NYC-CDRN clinical sites.

   4b. Health Evaluation and Analytics Lab (HEAL)- NYU School of Medicine

   4c. To Icahn School of Medicine at Mount Sinai (ISSMS) (in the form of a mapset, containing all linked SS-IDs).
5. HEAL utilizes SS-IDs to obtain the relevant Medicaid IDs.
6. HEAL provides Medicaid IDs to NYS Medicaid.
7. NYS Medicaid pulls HH data for the relevant Medicaid IDs.
8. NYS Medicaid sends HEAL HH data by Medicaid ID.
9. NYU HEAL creates a limited data set (containing 5-digit zip code and actual dates) including Medicaid claims data and HH data by SS-IDs.
10. HEAL sends limited data set to Mount Sinai.
11. The NYC-CDRN central data repository, which holds data from each NYC-CDRN clinical site, uses the SS-IDs provided to them in step 4a to perform a query of EHR data and creates a limited data set (containing 5-digit zip code and actual dates).
12. The NYC-CDRN central data repository, which holds data from each NYC-CDRN clinical site, provides limited data set with SS-IDs to ISMMS.
13. ISMSS merges Medicaid and HH data with EHR limited data sets using the map set of SS-IDs.

    This merged data set will then be used of analyses.

We will perform this process twice: once in 2017 for data 2007-2014 and once in 2019, for data 2010-2017.

We will perform this process twice: once in 2017 for data 2007-2014 and once in 2019, for data 2010-2017.

Activity 2: Interviews will be conducted with 20-40 participants in year 5. Given the COVID-19 pandemic, all interviews will be conducted remotely, either by phone or video call. One-two staff members will be present to obtain consent, conduct the interview, take notes, and facilitate recording. The interview guide was developed with the input of our study's investigators and Patient/Stakeholder Advisory Board (PSAB). The topics covered include: the experiences of HH members/clients/patients in NYC during the COVID-19 pandemic, particularly with regards to accessing care (for COVID-19 and non-COVID conditions) and accessing social services.

Based on experiences with initial interviews, we will iteratively modify the guide based on discussion flow and content.
No linkage with or examination of the participant's medical record will occur. Transcripts will be stripped of identifying information and not linked in any way to PHI.

Activity 3: One-on-one interviews will be conducted with leaders from NYC HHs and care managers. No other procedures will be performed with participants. The interviews will cover topics including: HH and Care Management Agency (CMA) structure, activities, reporting, quality measurement, quality improvement, challenges, areas of excellence, referral and enrollment processes, characteristics of the population served, and the experiences of New Yorkers working with the Health Home (care managers, program leaders) during the COVID-19 pandemic. The interview guide was developed in collaboration with our study's Patient/Stakeholder Advisory Board (PSAB). These interviews are low-risk: they do not touch on private or confidential information.

Activity 4: We plan to use NYS Medicaid administrative and claims data in the Medicaid Data Warehouse, available to researchers at HEAL at New York University. This is the same data set described in Activity 1.

g) Specimen Banking

Not applicable.

h) Data Management and Confidentiality

Activity 1: The NYC-CDRN has developed standardized protocols to transfer data securely between sites (including ISMMS), RHIOs, a Weill Cornell approved vendor (NYC-CDRN Central Repository), Project Ops of the NYC-CDRN. All data flows between parties will use established, secure methods of transmission. These currently include secure FTP and public key encryption protocol (for data transmission from sites to a Weill Cornell approved vendor); secure FTP (for data transmission from sites to the RHIOs); secure sockets layer (for data transmission from Healthix to a Weill Cornell approved vendor). The data flow was created to minimize any privacy and confidentiality risks through the use of Member IDs (proxy IDs) and of Site- and Study-Specific IDs (SS-IDs).
Dr. Mayer and her team have signed a contract committing them to comply with NYC-CDRN privacy and security policies and abide by applicable state and federal privacy and security legal requirements.
Dr. Mayer will upload all data received to a secured, password-protected, fire-walled local hard drive. Only Dr. Mayer and other authorized members of the analysis team will be able to access these files for the purpose of conducting analyses. All authorized members of the team will have completed any required CITI courses in biomedical research. After all analyses are complete, the files will be removed from the hard drive and deleted permanently.
Activity 2: Focus groups, telephone focus groups, and individual interviews will be audio recorded. Audio recordings will be securely shared with a HIPAA compliant transcription and translation company. Focus group and interview transcripts will be stripped of identifiers prior to storage on password-protected, hard-drives. Participant contact information will be stored separately so that data cannot be linked with the participant

(no study ID or other link will be used). Contact information will also be stored only on password-protected hard drives. Only authorized study staff who have completed research ethics training will have access to any data. Data will be stored for an additional year after all analyses have been completed.
Activity 3: Contact data for this aspect of the study is publicly available for HH and CMA leaders. All contact data for leaders and care managers will be stored on password-protected hard drives. Interviews will be audio recorded and transcribed and transcripts will be stripped of identifiers prior to storage on password-protected, hard-drives. Participant contact information will be stored separately so that data cannot be linked with the participant (no study ID or other link will be used). Only authorized study staff who have completed research ethics training will have access to any data. Data will be stored for an additional year after all analyses have been completed.

i) Provisions to Monitor the Data to Ensure the Safety of Subjects

This research involves no more than minimal risk to subjects. The PI, Dr. Mayer, will oversee data monitoring, focusing on the protection of the confidentiality of participant data. The Principal Investigator, Dr. Victoria Mayer, and the primary study team are located at the Icahn School of Medicine at Mount Sinai (ISMMS). The study will utilize the IRB of the Biomedical Research Alliance of New York (BRANY) and the Columbia University IRB (the only member of the New York City Clinical Data Research Network (NYC-CDRN) that does not rely on BRANY).

The PI, Dr. Mayer, will monitor the research study in close collaboration with and in concert with the regulations of the staff of the NYC-CDRN, NYS Medicaid's Data Warehouse Office of Health Insurance Programs Privacy Office, BRANY, the Columbia University IRB, and the ISMMS.

This study will utilize multiple data sources, including 1) data from the NYC-CDRN and data from New York State Medicaid (both retrospective), 2) focus groups and interviews, and 3) one-on-one interviews with Health Home leaders. All 3 aspects of this study present no more than minimal risk to study participants. The NYC-CDRN has developed a comprehensive set of privacy and security policies and procedures that include strong provisions to protect data security at rest and in motion in line with state and federal law and industry best practices. All sites have signed a master data use agreement, and investigators are required to sign individual data use agreements, agreeing to comply with those terms. Focus group data and interview data will be stored securely at ISMMS on password-protected, firewalled hard drives. The principle research-associated risk for the main retrospective cohort analysis is that of breach of confidential data. In order to minimize this risk, we will work with the NYC-CDRN and NYS Medicaid to ensure that all data transfer and storage protocols are consistent with best practices for data security. All data at ISMMS will be stored and accessed according to established regulations of ISMMS to ensure data privacy and security. Limited data sets will be constructed to contain the minimal amount of PHI needed to complete the study.

While we do not anticipate adverse events associated with our focus groups or interviews, in the case of an adverse event the study team would report this to BRANY for review. In the case of unanticipated problems, the study team will report this to BRANY a for review.

j) Withdrawal of Subjects

Activity 1 and 4: Researchers will not be able to identify subjects. Identifying subjects in order to withdraw them from the study would compromise confidentiality.

Activity 2: Subjects may withdraw from the study at any time by contacting the study PI or Engagement Manager. If subjects choose to withdraw from the study, we will not collect any further data, but will utilize already collected data as part of the focus group or individual interview.

Activity 3: Subjects may withdraw from the study at any time by contacting the study PI or Engagement Coordinator. If subjects choose to withdraw from the study, we will not collect any further data, but will utilize already collected data.

6) Risks to Subjects

Activity 1 and 4: The principal potential risks to subjects are confidentiality risks. We believe the risk is minimal because researchers, partner sites, and the a Weill Cornell approved vendor (NYC-CDRN Central Repository) must follow rigorous, established NYC-CDRN policies and procedures for privacy and security. NYC-CDRN project staff are trained in privacy and security, data transfer protocols are in place and data will be held on servers approved for holding PHI. The limited data sets that contain retrospective EHR data and Medicaid data, which will be given by the various NYC-CDRN partner sites to investigators at Mount Sinai will meet all applicable federal regulations and there is minimal risk to patient confidentiality. The merged limited data sets will be stored on servers approved for holding PHI. Only study staff trained in data privacy, security, and research ethics will be able to access this data.

Activity 2: The principal potential risks to subjects are non-physical privacy and confidentiality risks. As far as confidentiality, transcripts will be stripped of all identifying information during the transcription process. We will use a HIPAA compliant transcription service. Thus, transcripts used for analysis will not contain identifiable data. Any sharing of results will also not contain any identifiable information. In addition, participants may find it uncomfortable to answer certain questions that come up during the interviews. Moderators will make it clear that participants can stop sharing at any time, and that they do not need to answer any questions that make them feel uncomfortable- it is their choice.

Activity 3: There is a minimal confidentiality risk associated with the HH leader and care manager interviews. It is unlikely that any information shared in these interviews will be confidential; however, participants may share sensitive opinions/criticisms. When reporting results, we will therefore remove identifying information by which the interviewee could be surmised.

7) Provisions for Research Related Harm/Injury

This research involves no more than minimal risk to subjects.

8) Potential Benefits to Subjects

Activity 1 and 4: There will be no direct benefit to subjects whose data is a part of this study. The overall goal of the study is to evaluate the impact of the Health Home intervention on patients with diabetes. Identifying care management programs that are effective can offer benefit to the population of patients with diabetes and complex medical problems.

Activity 2: There will be no direct benefit to focus group or individual interview participants. As above, the overall study aims to benefit patients with diabetes.

Activity 3: There will be no direct benefit to HH leaders or care managers who participate in interviews. However, as key stakeholders in the HH program, they may benefit from knowledge eventually produced by the study.

9) Provisions to Protect the Privacy Interests of Subjects

Activity 1 and 4: This aspect of the research involves retrospective data analysis, with no contact with participants.

Activity 2: Interview recruitment: HH care managers will share the names and contact information of interested members/clients/patients with the recruitment team, or interested participants can reach out directly to team staff. The recruitment team will be trained in responsible research practices and will not reveal any private information via voicemail or message. No private information will be elicited by phone.

Interviews: We will let participants know that they may decline to answer any questions or refrain from participating in any discussions that are not comfortable or which raise privacy concerns for them. Any sharing of results will also not contain any identifiable information.

Follow up: As part of the study, we have proposed sharing overall study findings with participants from focus groups and interviews. Thus, we have included in the consent form that we would like to contact participants in the future regarding study findings. In addition, we will utilize address information to send gift cards to participants. Again, all outreach staff will not disclose private information as part of outreach efforts.

Activity 3: Information on the names and contact information of HH leaders is publicly available, and we will not be risking privacy by recruiting these participants. Care manager information will not be linked with responses. We will make it clear to those who choose to participate that data on their personal opinions/criticisms will not be linked with their identity/specific-HH.

10) Economic Impact on Subjects

Activity 1: no costs to subjects.
Activity 2: no costs to subjects.
Activity 3: no costs to subjects.
Activity 4: no costs to subjects.

11) Payments to Subjects

Activity 1 and 4: There will be no payments to subjects.

Activity 2: We will provide a $40 gift card to each participant in appreciation of their time, individuals who participate in individual phone interviews will receive their gift cards in the mail.

Activity 3: We will provide a $100 gift card to each participant in appreciation of their time.

12) Consent Process

Activity 1 and 4: For this analysis, we request a HIPAA waiver.

Activity 2: Prior to participation in an individual phone interview, study staff will read a script describing the research study, the risks and benefits of participating, and requesting verbal consent. Participants will be provided with written information describing the research. We are seeking a waiver of written consent in this case. The only purpose of an in-person interaction would be to obtain written consent. This aspect of the research presents no more than minimal risk of harm to subjects, and this research involves no procedures for which written consent is normally required outside of the research context.

Activity 3: We request a waiver of written documentation of the consent process. This aspect of the research presents no more than minimal risk of harm to subjects, and this research involves no procedures for which written consent is normally required outside of the research context. Study staff will read a script describing the research study, the risks and benefits of participating, and requesting verbal consent by phone. Participants will be provided with written information describing the research.

13) Process to Document Consent in Writing

Activity 1 and 4: For this analysis, we request a HIPAA waiver.

Activity 2: Any individuals who participate in individual phone interviews will provide verbal consent before the interview begins.

Activity 3: We request a waiver of written documentation of the consent process. This aspect of the research presents no more than minimal risk of harm to subjects, and this research involves no procedures for which written consent is normally required outside of the research context.

14) Vulnerable Populations

Activity 1 and 4: This retrospective data analysis will not specifically target vulnerable populations; however, vulnerable individuals may be a part of the cohort. For this arm of the research, we will not be asking participants to engage in research-related risk, and will have measures in place to protect the confidentiality of all individuals who are included in the research.

Activity 2: For the interviews, we will not recruit individuals from vulnerable populations. All participants will need to be able to give consent and be adults.

Activity 3: The HH-leader and care manager interviews will be carried out with individuals in leadership positions, and we will not recruit individuals from specific vulnerable populations.

15) Multi-Site Human Research (Coordinating Center)

This is a multi-site study with ISMMS as the lead entity. All data will be stored at ISMMS. Investigators from other institutions will have access only to data from analyses, but not to individual level data. They will participate in developing analysis plans and reviewing results.

16) Sharing of Results with Subjects

Results of all activities will be shared in aggregate through academic presentations and publications, lay talks, lay press communications. Results of overall study will be disseminated among focus group and interview participants.

17) Control of Drugs, Biologics, or Devices

Not applicable.

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