NIH Collaboratory Ethics and Regulatory Core: Planning Phase Consultation Call
Implementing Scalable, Patient-Centered Team-Based Care for Adults With Type 2 Diabetes and Health Disparities (iPATH)
December 18, 2023; 1:00-2:00 pm ET (via Zoom)

Attendees:

- Core, Coordinating Center, and NIH: Joe Ali (Johns Hopkins University), Stephanie Morain (Johns Hopkins University), Pearl O'Rourke (retired), Tammy Reece (Duke University), Kayte Spector-Bagdady (University of Michigan), Kevin Weinfurt (Duke University), Dave Wendler (NIH), Ben Wilfond (University of Washington)
- Study team: Emmilie Aveling (Harvard University), Sadie Chen (Ohio State University), Lucy Orr Ewing (Stanford Univesity), Alan Glaseroff (Stanford University), Amanda Gusovsky (Ohio State University), Maria Levis (Impactivo, LLC), Latha Palaniappan (Stanford University), Olivia Pardi (Ohio State University), Sara Singer (Stanford University), Kate Watkins (Stanford University)

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	OWNER
Brief review of the trial	Meeting attendees received the Research Strategy for iPATH with the meeting agenda (see supplementary material attached). Pearl O'Rourke facilitated introductions and the discussion. The iPATH team members present were Sara Singer (principal investigator) and several team members from Harvard University; Impactivo, LLC; Ohio State University; and Stanford University (see attendees list above). **Project overview**: Planning and implementation of iPATH are supported through an R01 grant award. The goal of iPATH is to refine and implement an approach to practice transformation that was originally conceived and pilot-tested to support federally qualified health centers (FQHCs) in their pursuit of National Committee for Quality Assurance recognition as patient-centered medical homes for patients with type 2 diabetes. The study will include extensive qualitative work to identify implementation factors in FQHCs that are diverse in terms of geography, race/ethnicity, and diabetes control performance; and to customize and comprehensively evaluate the implementation approach.		

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	Healthcare system partners: Multiclinic FQHCs identified through consultation with state and regional primary care associations **NIH Institute Providing Oversight**: National Institute on Minority Health and Health Disparities (NIMHD) **Study design**: In the first phase of the project, the study team will refine the iPATH practice transformation approach by conducting case studies with 12 FQHCs to identify organizational conditions and processes that promoted or impeded the effectiveness of type 2 diabetes care for NIH-designated health disparity populations before and after the COVID-19 public health emergency. The study team will use publicly available data on FQHCs to ensure diversity in representation, including data on diabetes control performance in the previous year. In the second phase of the project, the study team will conduct an effectiveness-implementation hybrid type 2 study, including a stepped-wedge cluster randomized trial in 8 multiclinic FQHCs in California, Massachusetts, Ohio, and Puerto Rico (with randomization at the clinic level), as well as formative, process, and summative evaluations of the implementation and effectiveness of the intervention. In response to questions about the stepped-wedge design, the study team replied that the design was selected to facilitate rollout of the complex intervention, to allow each participating practice site to ultimately receive the intervention, and to maximize statistical power. The intervention will be implemented over 3 years. In year 1, the intervention will be introduced at 1 practice site each in the first set of 4 FQHCs. In year 2, the intervention will be introduced at 1 practice site each in the second set of 4 FQHCs and at the remaining practice sites in the first set of FQHCs. In year 3, the intervention will be introduced at the remaining practice sites in the second set of FQHCs. In response to questions about the SMART PCMH Manager tool, the study team explained that the tool will be used to (1) better stratify patients and assign them to appropriate workflows, such as a diabetes collaborative or a session with a health educator or nutritionist; and (2) give providers better feedback on their practice via brief educational modules based on their performance in their clinic population. While the tool uses algorithms, it is not generative and it does involve patient		

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	interactions. The tool was designed for compatibility with the 2 largest electronic health record systems used by FQHCs. **Outcomes**: The primary outcome will be the percentage of patients with poorly controlled diabetes (hemoglobin A_{1c} greater than 9%) in the intervention arm vs the control arm. The study team will also evaluate a variety of implementation and process outcomes.		
Status of IRB approval	The single IRB of record is Advarra. IRB approval has been obtained for the first phase of the study.		
Risk (Does the project meet regulatory criteria for being considered minimal risk?); and consent (planned processes for relevant subjects)	The study team anticipates that the project will meet the regulatory criteria to be considered minimal risk. The study team will offer payment for participant interviews. Services offered through the iPATH approach to support clinics in their pursuit of recognition as patient-centered medical homes will be offered free of charge. For phase 1 of the study, the study team requested a waiver of documentation of consent. They would like to do the same for the intervention phase of the study. They are developing a summary information sheet for participating FQHCs to accompany the full regulatory documentation.		
Privacy (including HIPAA)	The study team requested guidance on the development of data use agreements (DUAs) that would enable the team to collaborate across institutions, including distributed analysis of qualitative data. Kayte Spector-Bagdady advised identifying a standard set of DUA stipulations that no site can reject, such as minimum standards for data access, data protection, and linking between sites and platforms. Kayte and others noted that regulations for qualitative data and development of standard approaches remain relatively immature but that sharing of deidentified transcripts across research sites has been uncontroversial. Stephanie Morain noted the distinction between (1) sharing data across research sites for the study and (2) placing data in a repository after the study to meet data sharing requirements. For the latter, Joe Ali shared the following resources:		

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	Qualitative Research Guide; University of California, San Francisco: https://guides.ucsf.edu/c.php?g=100971&p=9455584 • Managing Qualitative Social Science Data: An Interactive Online Course: https://managing-qualitative-data.org/ • DuBois et al. Exchanging words: Engaging the challenges of sharing qualitative research data. *Proc Natl Acad Sci U S A*. 2023 Oct 24;120(43):e2206981120. doi: 10.1073/pnas.2206981120. PMID: 37831745. And Kayte shared the following resource: • QDS: Qualitative Data Sharing Toolkit: https://qdstoolkit.org/ The study team also noted that the Stanford IRB has, to date, not permitted the use of automated transcription, such as by Zoom or other platforms, presumably out of concern for how the companies may use those data. Pearl O'Rourke encouraged the study team to revisit that determination with the Stanford IRB. Stephanie suggested that David Magnus could be helpful in making the case to the Stanford IRB. If the study team will not be permitted to use automated transcription services, Core members shared the following resources for transcription services: • Kayte – Landmark Associates, Inc: https://www.thelai.com/ • Stephanie – Production Transcripts: https://www.productiontranscripts.com/		
Monitoring and oversight	The study team has not yet determined whether a data and safety monitoring board will be used and will appreciate advice in the future about what issues to consider.		
Issues beyond this project (regulatory and ethics concerns raised by the project, if any)	None.		
Other matters			

RESEARCH STRATEGY: Implementing Scalable, PAtient-centered Team-based Care for Adults with Type 2 Diabetes and Health Disparities ("iPATH")

I. SIGNIFICANCE

1.1 Significant racial and socioeconomic health disparities persist in the U.S. and are particularly evident among patients diagnosed with type 2 diabetes. People living in low income and disadvantaged communities have a higher prevalence of type 2 diabetes than the general population.[20] Low socioeconomic status has been associated with almost twice the risk of diabetes-related mortality, and disparities remain even after controlling for other risk factors.[20] Diabetes risk is 77% higher among African Americans, 66% higher among Hispanics, and 18% higher among Asian Americans, as compared to non-Hispanic White adults.[21] These patients are not only at a higher risk for serious symptoms and complications, but also for poor health outcomes due to social determinants of health (SDOH) and disruption in the regular provision of care, including routine preventive, chronic, and acute care.[7] For patients with diabetes, preventive care includes screening services (e.g., A1c testing) that are critical for those with A1c>9% who are the most vulnerable to the adverse effects of preventable illness. Chronic care includes patient self-management, monitoring symptom progression, and adjusting care recommendations and medications. Acute care may be related to worsening chronic conditions (e.g., gastroparesis) or traumatic events (e.g., diabetic ketoacidosis, hyperglycemic hyperosmolar state). Access to care, especially for patients with poorly controlled diabetes, remains a priority.

1.2 The rapid evolution of the COVID-19 pandemic caused duress for historically underserved patients with diabetes who receive care at Federally Qualified Community Health Centers (FQHCs). COVID-19 profoundly impacted the ability of historically underserved patients with diabetes to seek and receive care. Pandemic-related delays in care for patients with diabetes and other chronic conditions have had deadly and life-altering consequences.[22] The disparity-related implications of COVID-19 are particularly pertinent for FQHCs, which serve more than 28 million people (8.6% of the U.S. population).[9,23] FQHCs constitute America's health care safety net. They serve a diverse (62% racial and ethnic minorities)[9] and significant number of uninsured (22%) and low income (47% Medicaid/CHIP enrollees) patients.[9] The number of patients seen at FQHCs decreased by 1.2 million patients from 2019 to 2020.[9] The rapid transition to remote care contributed to a reduction in A1c testing.[24] Anecdotal data suggests an increase in routine care visit cancellations with resultant care delays have led to undertreatment and exacerbation of medical conditions.[25]

FQHCs continue to evolve their healthcare delivery processes and technologies to address care issues related to COVID-19 and for ongoing chronic, preventive, and acute services.[26–30] COVID-19 revealed faults in the safety net and catalyzed a focus on building more resilient systems to ensure continuity of quality patient care. Because patients with diabetes often have appointments with multiple providers (e.g., primary care physicians, behavioral health providers, nutritionists, community health workers, peer-educators[31,32]), changes to a range of direct care and system-level processes (e.g., care coordination, care interactions, technology integration) can influence patient care experiences and outcomes.

1.3 FQHCs that adhere to American Diabetes Association (ADA) and National Committee for Quality Assurance (NCQA) Patient-centered Medical Home (PCMH) standards are well-positioned to improve outcomes for health disparity populations.[33] FQHCs, with their history of serving communities with high needs, must focus on SDOH.[34] Research shows that chronic disease is closely tied to SDOH, which impact 80% of a person's health outcomes.[35] At FQHCs, patients with multiple comorbidities and socio-economic complexities receive comprehensive care, regardless of ability to pay. FQHCs' holistic approach relies on cross-functional teams of professional, semi-professional and lay providers to meet individuals' needs. FQHC's have led on PCMH practice transformation efforts.[36] NCQA's emphasis on team-based, patient-centered, technology-enabled care is critical to providing effective diabetes care for NIH-designated U.S. health disparity populations. *Team-based care* is delivered by multidisciplinary professionals who work together and with patients, families, and caregivers. A meta-analysis of randomized controlled trials found "patients with diabetes who receive team-based care generally have better outcomes in diabetes, cardiovascular, and renal health."[37] Another review found interdisciplinary teams had consistently lower A1c levels.[38] Research also found team-based care was most effective for patients with "poorest diabetes management at baseline."[37] *Patient-centered care* is grounded in knowing and responding to patient need, preference, and capability. *Technology-enabled care* refers to an array of tools (e.g., electronic health records, telehealth, remote monitoring, analytics) that are critical for effective care management, coordination, and quality assurance.

1.4 iPATH will refine and test an innovative practice transformation strategy to improve type 2 diabetes for NIH-designated priority populations receiving care at FQHCs in 4 U.S. regions. A research synthesis on PCMH transformation efforts suggested that differences in the design and implementation approach may explain heterogeneity in patient outcomes.[27] Our approach draws on evidence from high

performing FQHCs, prior experience implementing practice transformation in FQHCs, and formative and process evaluations. Study teams from Harvard, The Ohio State University (OSU), Stanford, and Impactivo LLC will focus on FQHCs in Massachusetts, Ohio, California, and Puerto Rico (MA, OH, CA, PR), respectively.

We will refine an evidence-based, practice transformation strategy initially developed to support FQHCs' pursuit of ADA guidelines and NCQA PCMH status. Preliminary implementation across 7 FQHC clinics in Puerto Rico 2017-20 achieved an average 31% decrease in poorly controlled type 2 diabetes (A1c>9%). We will implement the refined practice transformation strategy in 8 FQHCs using our human-centered and design-based *iPATH implementation approach* (*see* **§2.1**), which is customizable for varied organizational readiness levels and patient needs, and supported by an innovative technology, the *SMART PCMH Manager* (*see* **§2.2**).

Features of iPATH are evidence-based. Supporting practice transformation has been shown to assist clinics in improving patient care.[39] A systematic review and meta-analysis of PCMH utilization in health care organizations that serve low-income populations found that PCMH transformation efforts and adherence to the NCQA standards were associated with better clinical outcomes for low-income patients.[29] One initiative reduced A1c poor control in FQHCs from 50.9% to 27.5% (46% relative improvement) in 1 year.[8] Technology-enabled remote care has been shown to optimize diabetes management for patients; remote, home-based care has been used to improve patient care access, convenience, and delivery from a multidisciplinary team.[40]

II. INNOVATION

2.1 Our iPATH implementation approach draws on a conceptual framework combining mass customization and organizational learning. *iPATH* incorporates a modularized approach to implementation that can be customized based on organizational readiness, population needs, and social contexts using human-centered design principles. Initiatives using modularized and customized approaches demonstrate positive health outcomes and greater improvements in outcomes compared to usual care and other approaches.[41–43] A systematic review of integration of SDOH at health centers found that further research into the effects of the customization of standardized tools is needed.[44] A systematic review of applications of design thinking in health care to address health outcomes and system processes found mixed success overall, but greater levels of satisfaction, usability, and effectiveness when compared to traditional interventions.[45]

iPATH applies principles of mass customization to tailor patient care practices (e.g., workflows) and address provider/staff knowledge gaps by combining, prioritizing, and adapting sets of learning modules (*see* **Table 1**) to both meet the specific needs of each FQHC and to respond to environmental changes.[17,18] How to adapt approaches that can meet individual needs but do so at scale is a core issue for efforts aiming to reduce disparities in diabetes care.

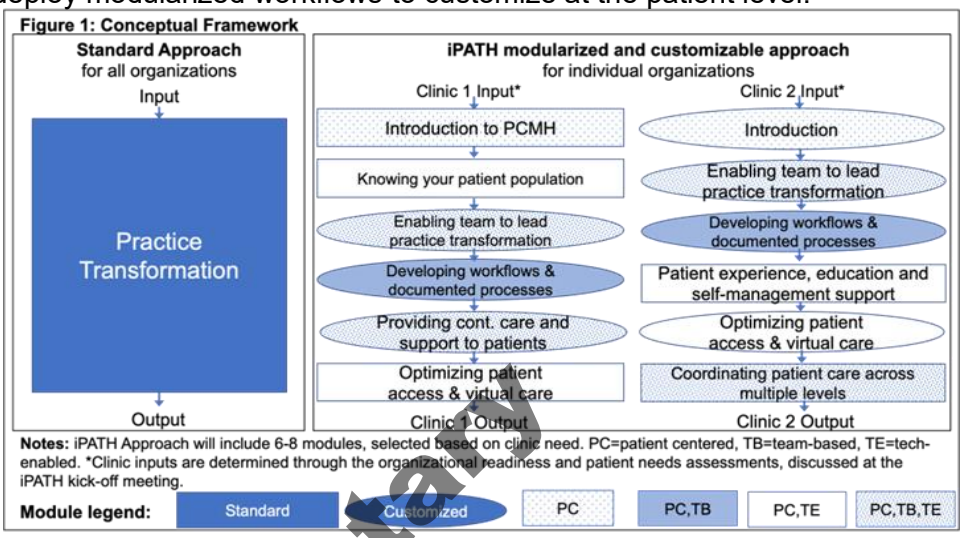
TABLE 1. IPATH PRACTICE TRANSFORMATION CUSTOMIZABLE MODULES		PCMH EMPHASIS
1	Introduction to the PCMH within the Context of Value Based Payments	PC
2	Continuously Improving the Quality of Care	PC, TE
3	Developing Workflows & Documented Processes	PC, TB
4	Knowing Your Patient Population	PC, TE
5	Enabling the Team to Lead Practice Transformation	PC, TB, TE
6	Leveraging Technology for Improved Decision Making & Reporting	PC, TE
7	Providing Continuous Care and Support to Patients (Before, During & Between Visits)	PC, TB, TE
8	Optimizing Patient Access & Virtual Care	PC, TE
9	Identifying Patient Care Gaps	PC, TE
10	Managing Care for Your Patient Population	PC, TB, TE
11	Coordinating Patient Care Across Multiple Levels of Care	PC, TB, TE
12	Patient Experience, Education and Self-management Support	PC, TE
13	Addressing the Needs of Medical/ Social Underserved or Complex Population	PC, TB, TE
14	Health Center Leadership Development and Resilience	PC, TB
Legend: PC=patient-centered, TB=team-based, TE=technology-enabled		

To inform this issue, we draw primarily from the manufacturing and service industries, in which the concept of "mass customization" has been developed over 20 years to describe the mass production of customized goods and services.[46] Attributed to Davis,[47] mass customization is a strategy that enables a relatively high volume of options for niche markets that demand customization, without tradeoffs in cost, delivery and quality.[48] Bohmer applied similar concepts to medical care[18] finding that performing "custom" and "standard" care simultaneously allowed clinicians to achieve good fit between patients' needs and processes for meeting them.[17] Our conceptual model builds on strategies for modularization and customization that can help FQHCs adapt and apply a research-based practice transformation strategy to their specific patient population, organization structure, and community context. We adapt Bohmer's concept whereby separating activities into discrete parts (modularization), FQHCs can select and tailor elements to their environment as needed and appropriate (customization).

iPATH will facilitate FQHCs to combine custom and standard care. Not all patients with diabetes and health disparities have equal needs. Customized healthcare could be crafted for each patient by linking a set of standard processes together that serve their individual needs. For example, FQHCs can use a modularized

approach to deploying patients to personalized workflows that support them according to their comfort level with telehealth by providing phone support or deploying a community health worker to the home as needed. FQHCs in the Puerto Rico pilot identified the need for workflow modularization to account for individual patient differences. We will use a patient needs assessment survey that considers socio-demographics (e.g., race, ethnicity, family composition); health and functional diversity; health insurance status; access to/satisfaction with health and social services; and SDOH (e.g., barriers to remote health, disparate impact of COVID-19, vulnerability to natural disasters) to deploy modularized workflows to customize at the patient level.

Applying the same logic, our conceptual framework reflects our approach to customization at the organizational level through combining standard and customized modules for *iPATH practice transformation*. As **Figure 1** shows, clinics may pursue modules in different sequences, and different clinics may require customization of different modules for their local culture (e.g., comfort with/capacity for telehealth) and clinic characteristics (e.g., organizational capacity, staffing characteristics). Our framework draws on theories of organizational learning,[49–56] recognizing that organizations are complex and situated within contexts that will affect them and evolve. Our approach includes monitoring conditions, learning from experience, and adapting to changing internal and external constraints.[57] An essential component of practice transformation is to model learning by adapting the *iPATH implementation approach* based on the past pilot, the high versus low performer comparison study, and FQHCs' own learning through the *iPATH practice transformation study*.



2.2 iPATH integrates the *SMART PCMH Manager*, an innovative machine learning tool that enables team-based, patient-centered primary care by changing the behavior of clinical providers and front-line patient care staff. Our Puerto Rico-based team developed and piloted the web-based software through National Science Foundation Small Business Innovation Research (NSF SBIR) phase 1 and phase 2 grants. It analyzes and stores specific electronic health record (EHR) data and user learning patterns in an MS SQL database where algorithms based on roles, rules, conditions, and variables develop personalized learning profiles for each user. User-tailored asynchronous e-learning instruction promotes inter-professional education and establishes collaborative practice support necessary for team-based practice transformation. Integration of patients' clinical and social characteristics are incorporated into suggested treatment paths, providing health professionals with recommended workflows based on gaps in care identified from patient data.[58] Using this capacity, patients can be deployed to different personalized care workflows based on clinical, social, and patient communication access; and preferences and skills (e.g., language, literacy, technology).

2.3 Our Rapid Data Collection and Reporting (RDCR) methodology will apply tools used with quantitative data to develop and apply a qualitative data capture and reporting system that allows for rapid, broad, and tailored dissemination of findings. Our project aims to identify processes and organizational conditions at FQHCs that promoted or impeded the effectiveness of team-based type 2 diabetes care over the course of the pandemic and strategies for strengthening treatment in these settings for this patient population. Investigators' ability to capture, illuminate, and respond to national variations in diabetes management is limited by the slow pace and small samples of standard qualitative research. Our novel methodology will speed data collection, analysis, and reporting by regional teams. We will apply semi-automated data analysis tools (e.g., R Markdown, which allows customized reports to be dynamically generated[59] to update results quickly as cases are entered into the dataset. Automation enables flexibly tailored reports for targeted audiences to highlight differences (e.g., region- or size-specific); and for comprehensive syntheses that draw from all case study data. This approach, familiar in quantitative data analysis, is not widely used with qualitative data; it will provide a model for future research and iPATH scale up.

2.4 Rigorous implementation and evaluation methods will combine a high versus low performer (H/L) comparison study and a hybrid type 2 effectiveness and implementation study of a multi-level, multi-component strategy. Our Aim 1 comparison of high performers (highest quartile, most improved) and

low performers (lowest quartile, not improved) for poor diabetes control will generate hypotheses, characterize differences, and come to actionable conclusions around how FQHCs and other healthcare organizations can more effectively implement high value diabetes management strategies that will inform refinement of our *iPATH implementation approach*. The hybrid type 2 effectiveness and implementation study[60] (Aims 2 & 3) will combine a stepped wedge cluster randomized trial (CRT) with formative, process, summative evaluations that will further inform the development, implementation, and analysis. The stepped wedge CRT is a novel pragmatic study design increasingly used in the evaluation of service delivery type interventions, but not yet used at this scale with FQHCs in this clinical area.[61–64] The design involves random and sequential crossover of clusters from control to practice transformation until all clusters are exposed. Advantages to this design include providing a rigorous scientific evaluation where, in the end, all study participants are exposed to iPATH. Also, compared to a traditional parallel cluster trial step wedge trials may overcome some logistical constraints given the sequential nature of implementing multiple elements of practice transformation.

Implementation outcomes will be guided by Proctor et al. (2011)[65] and include *acceptability, feasibility, fidelity,* and *penetration* of iPATH in diverse practice settings. This information will help define and refine the iPATH implementation approach in the formative and process phases and inform interpretation of observed effectiveness outcomes from the stepped wedge CRT in the summative phase. Data collection and interpretation will be informed through the Exploration-Preparation-Implementation-Sustainment (EPIS) model, given its focus on sustainment and ability to frame implementation factors across multiple levels (individual, organizational, network of organizations) within multiple phases of implementation.[19,66]

2.5 Our study will leverage FQHC progress on tracking patient data across multiple social contexts for racial and ethnic disparities to inform practical approaches for improvement. We will leverage the progress that FQHCs have made in tracking and reporting patient data by race and ethnicity to the Health Resources and Services Administration (HRSA).[9] Research indicates that even among organizations pursuing the collection and analysis of patient data by race and ethnicity, many struggle to shift from documenting disparities to intervening effectively to reduce them.[67] We will do so by refining the implementation approach that was piloted in Puerto Rico and collaboratively adapting and testing it in 8 FQHCs across the U.S. The *iPATH implementation approach* will draw upon and speak to, not only the unique operational challenges but also to the specific types of disparities and social issues that are pervasive in each FQHC's community and affect the quality and outcomes for diabetes care. This innovative approach emerges from the central tenet that not all people of color are the same, and nor should the health care programs be that serve their needs and preferences.[68,69] In drawing on pilot implementation within a Puerto Rico FQHC, rather than from a well-funded urban hospital system in the continental U.S., we build on the tradition in community health centers of innovation and learning across communities.[70,71] Scaling innovation that comes from a low-resourced setting in Puerto Rico to other low-resourced settings across the U.S. may help address the barriers to team-based care that have made models from high-resourced settings difficult to deploy in FQHCs. It also addresses the need to contextualize innovation according to the needs and reality faced by the population served.

III. APPROACH

3.1 (INVESTIGATORS) Our well-established transdisciplinary investigator team represents a broad range of expertise in social, behavioral, medical, and public health sciences; and has deep knowledge of primary care in the U.S. (see Biosketches and Budget Justifications).

Principal Investigator, Sara Singer, MBA PhD, Professor of Medicine and, by courtesy, Organizational Behavior at Stanford School of Medicine and Graduate School of Business. Dr. Singer's research focuses on how organizational leadership and culture influence efforts to implement health delivery innovations, integrate patient care, mitigate social determinants that undermine health, and improve safety of healthcare. She is faculty director of Stanford Primary Care and Population Health's Leadership, Organization, and Innovation Labs and associate director of the Clinical Excellence Research Center. As PI, she will lead the multi-state, interdisciplinary team to ensure effective communication and collaboration and will direct study activities in California. *Co-I Maria Levis-Peralta, MPA, MPH*, is founding director of Impactivo LLC, an established health care research and consulting firm focused on primary care transformation. A certified NCQA PCMH Content Expert, Ms. Levis-Peralta brings expertise in PCMH transformation and was PI for the preliminary NSF-funded Puerto Rico pilot that is the basis for iPATH. She will lead study activities in Puerto Rico for the H/L comparison study (Aim 1). She will lead facilitation for practice transformation activities for the 8 FQHC clinics in Aims 2 and 3. *Co-I Michaela Kerrissey, PhD,* is Assistant Professor in Health Care Management at Harvard Chan School of Public Health. She will lead study activities in Massachusetts. *Co-I Ann McAlearney, ScD, MS,* is Professor of Family Medicine, and *Co-I Daniel Walker, PhD, MPH*, is Associate Professor, both at OSU College of Medicine. They will co-lead study activities in Ohio. At Stanford School of Medicine, *Co-I, Latha*

Palaniappan, MD, Clinical Professor, is an internist and clinical researcher. She will provide expertise on type 2 diabetes, prevention, and diverse populations. *Co-I, Suzanne Tamang, PhD*, Instructor and Assistant Faculty Director, Data Science, Stanford Center for Population Health Science, is expert in utilizing Natural Language Processing for qualitative analysis. *Collaborator Alan Glaseroff, MD*, Adjunct Professor, Primary Care and Population Health, will provide expertise on FQHCs and primary care transformation and facilitation.

3.2 (PRELIMINARY STUDIES) iPATH's practice transformation and implementation approach are grounded in prior research focused on patient-centered primary care redesign for improved diabetes outcomes. iPATH will build upon projects conducted by Impactivo, LLC in Puerto Rico where Ms. Levis-Peralta has worked with FQHCs for more than a decade to address needs of low-income patients with chronic disease. She developed a patient and community health needs assessment methodology to understand SDOH in medically underserved communities and implemented it in more than 20 communities. Patient needs assessment findings informed the development of the *Healthcare Practice Transformation Series*,[16] an evidence-based modularized and customized practice transformation[72–74] to support FQHCs' pursuit of NCQA recognition as PCMHs. This "Puerto Rico pilot" guided FQHC PCMH teams through a series of trainings and exercises that established workflows, policies, and procedures focused on the FQHC's specific patient populations and practice realities. The 7 FQHC clinics that participated in the pilot improved poor diabetes control (52.4% to 36.4%) from 2017-20. Also, they improved high blood pressure control (57.2% to 63.1%), body mass index screening and follow up plan (70.8% to 89.8%), tobacco use screening and intervention (76.0% to 87.8%), depression screening and follow up plan (25.5% to 55.3%), aspirin or other antiplatelet use for ischemic vascular disease (49.0% to 76.3%) from 2017-18, and 6 clinics achieved PCMH recognition.

The Puerto Rico pilot demonstrated the viability of a hybrid model for practice transformation and yielded lessons that may be incorporated into iPATH practice transformation after validation through formative evaluation. Key lessons include (a) understand patient's clinical, social, and communication needs in order to deploy patients to modularized workflows and to anticipate demand for onsite and virtual care; (b) gather patient data before visits; (c) incorporate specialists to the care team in coordination with the primary care physician; (d) recognize patients view physicians as the most credible source of information; (e) determine health services that can or cannot be offered by telehealth; (f) address patient and provider limitations in electricity, equipment, and broadband access; (g) leverage community health workers using virtual tools to communicate with patients, coordinate social services, and enable telehealth; (h) address behavioral health and SDOH using virtual communication, safeguarding confidentiality for patients; (i) provide at-home patient-centered services including phlebotomy and medication delivery; (j) effectively train providers and care team members in standard operating procedures and workflows; (k) "flip the classroom" by circulating materials in advance to reduce the duration of face-to-face training sessions; (l) use social media and virtual education tools to educate and inform patients and staff; and (m) use videos for low literacy patients.

Patient needs assessment methodology. The Puerto Rico pilot used a 3-part community health needs assessment, including: secondary data analysis, a patient survey, and a key community informants survey and/or focus group. This information enabled FQHCs to better understand their population and to tailor the implementation to meet the community's needs in a more efficient and effective manner. The patient needs assessment amplifies the patient's voice, providing perspective on population health needs and other social, cultural, and economic factors, enabling FQHC's to culturally adapt and customize patient-care approaches.

SMART PCMH Manager. Preliminary research from the NSF SBIR awards used design-based approaches with FQHCs to develop SMART technology, which enables individualized assessment and workflow assignment to deliver personalized team-based care for patients with diabetes using machine learning. *SMART* will be a core component of the *iPATH implementation approach* (*see **§2.2)***.

3.3 (PRELIMINARY STUDIES) Study Investigators' prior research closely aligns with iPATH specific aims and methods. Investigators have (a) derived important insights from previous studies using mixed qualitative/quantitative methods (Aim 1); (b) developed and studied practice transformation and direct care interventions serving Hispanic, Black, and Asian patients with type 2 diabetes in low-resourced settings[75–82] (Aim 2); and (c) employed implementation science methods to improve care delivery (Aim 3).

3.3.1 High versus low performer comparison studies. *Drs. Singer and Kerrissey have* conducted studies for Commonwealth Fund,[83] CRICO, Harvard Primary Care,[84,85] and the Veterans Health Administration[86,87] to understand patient and provider experiences with integrated and team-based care. In the AHRQ-funded PROMISES grant, they studied mechanisms supporting implementation of processes to reduce malpractice claims at primary care clinics.[88] *Dr. Kerrissey* has used multiple methods and field data collection from H/L performing groups in studying efforts to collaborate for diabetes care management programs across clinical and social service organizations.[89] *Dr. Singer* led research comparing primary care practice settings that

achieve more/less value for high needs patients.[90] *Dr. McAlearney* has conducted national-level research using these methods across multiple studies, including AHRQ-funded studies to better understand specific strategies that can influence healthcare-related infection prevention.[91–105] An ongoing AHRQ-funded project with *Dr. Walker*, is developing measures of the higher-performing management practices applied to the prevention of central line-associated bloodstream infections and catheter-associated urinary tract infections.[106]

3.3.2 Primary (Diabetes) Care Clinical Redesign. *Dr. Palaniappan* has more than 150 peer reviewed studies in type 2 diabetes and chronic disease prevention. She is expert in observational study design and implementation using a variety of datasets. She recently completed 2 large randomized controlled trials of lifestyle interventions in type 2 diabetes. *Dr. Glaseroff* led the Humboldt Diabetes Project 2002-11, a county-wide implementation of the Chronic Care Model that lowered deaths from diabetes by 29% while deaths due to diabetes remained unchanged statewide. He later co-founded Stanford Coordinated Care, a service for patients with complex chronic illness (58% living with diabetes).[107] He served on the NCQA PCMH Advisory Committee 2009-10. *Dr. Singer* led evaluations of primary care clinical redesign initiatives and PCMH practice transformation initiatives,[72,108,109] including PROMISES,[110,111] the Academic Innovations Collaborative/CARES,[112–114] and the Engineering High Reliability Learning Lab.[115,116]

3.3.3 Implementation science and quality improvement (QI) practice transformation studies. *Dr. Singer* implemented such trials to test Leveraging Frontline Expertise, a program to drive hospital safety,[117] a QI initiative to reduce malpractice claims,[111] and the Safe Surgery South Carolina initiative to promote surgical checklist implementation.[118] She is advising a PCORI-funded stepped-wedge control trial of an intervention to promote clinician wellbeing. *Drs. McAlearney and Walker* conducted the national HEALing Communities Study using a stepped-wedge design to test an intervention to reduce opioid fatalities,[119,120] and an AHRQ-funded R01 to test use of a bedside patient portal to engage patients across the continuum of care.[121]

3.4 (AIM 1) Refine the *iPATH implementation approach*.

3.4.1 Study Design. We will conduct a multiple case study comparing a sample of high and low performing FQHCs for diabetes control. Our teams will conduct 12 in-depth case studies of FQHCs in MA, OH, CA, PR. Using consistent methods, teams will interview stakeholders (including patients) and compare trends and patterns in service utilization and quality to identify common themes, barriers, and actionable how-to processes and trends for this natural variation. Cases will include compelling provider/patient stories about effectively implementing ADA/NCQA guidelines of comprehensive clinical care for individuals with type 2 diabetes. Results will inform adaptation of the *iPATH implementation approach*.

3.4.2 Randomization and Study Sample. We will use a stratified randomization approach to select 2 high performing and 1 low performing FQHC in each region. A "high performer" will be (a) in the top quartile for diabetes control (lowest rate of poorly controlled diabetes (A1c > 9%) based on most recently available data, and (b) in the top half of FQHCs for change in diabetes control since 2019 (pre-pandemic); a "low performer" will be (a) in the fourth quartile for diabetes control and (b) in the bottom half for change in diabetes control.

Exclusion Criteria. We will exclude FQHCs that (a) have a patient population comprised of more than 80% children; (b) have a patient population multiplied by the FQHC's diabetes prevalence in the lowest 10% of all the clinics; or (c) have fewer than 5,000 or more than 50,000 patients. These exclusions will ensure the selected FQHCs have enough adult patients with diabetes for this population to be an organizational priority and are large enough to have organizational capacity for practice transformation but not so large as to make transformation untenable. HRSA Data System 2020 data indicates 71% of FQHCs fit the inclusion criteria.[9]

Problem/strategy. HRSA's measure of % poorly controlled diabetes lumps untested patients with patients whose A1c is >9%. A reduction in testing during the pandemic would appear as an increase in poor control. We include 2 criteria for selecting H/L performers and will confirm FQHC performance through interviews.

3.4.3 Recruitment. Our recruitment approach is informed by our experience successfully collaborating with FQHCs in prior and ongoing work. Study investigators will work with their state's FQHC member organization (see **Letters of Support**) to identify an administrative contact at each H/L comparison study clinic. We will schedule an initial informational call with the administrative contact to describe the study, review expectations for clinic participation, and confirm willingness to participate. If a clinic declines to participate, our contingency plan will be to randomly select a replacement FQHC within the region and quartile to engage them in the study.

3.4.4 Qualitative Data Collection and Analysis. We will apply our RDCR approach. We will gather data through individual and group interviews and archival data. Interviews will follow our *Rapid Case Study Interview Guide* (*see* **Appendix A**), and be tailored for each group of informants, pilot tested at a non-participating practice, and refined prior to deployment. We will work with the administrative contact at each clinic to characterize its "patient care teams" and to develop a key informant list, including (a) adult patients with type 2 diabetes, with preference for underrepresented groups (n=2-3); (b) FQHC clinic leaders (n=1-2); (c)

clinic transformation team members, if applicable (n=2-3); (d) "core" patient care team members (n=2-3); (e) "extended" patient care team members (n=2-3); and (f) community patient support team members (n=2-3), with core and extended defined by the clinic. Interviews and archival data sources will focus on barriers and facilitators to delivering high value and ADA/NCQA guideline concordant care, lessons learned, and COVID-19-related innovations, perceptions of best practices, and recommendations for practice transformation. We will summarize findings for each FQHC, then compare findings across all FQHCs to distill a set of promising practices for developing, implementing, and integrating practice transformation.

Site and Key Informant Consent. Site visits will begin with a preliminary phone interview with a designated site contact to collect general information and to identify potential key informants. Prior to site visits, we will request and review documents specifically related to the FQHCs diabetes outcomes and adherence to guidelines. Key informants will be recruited individually (*see* **Human Subjects**).

Rapid Case Study Data Collection. Regional study team members, trained in key informant interviewing, will conduct site visits. They will visit FQHC clinics to hold individual and group interviews, which will be audio recorded and transcribed. If in-person interviews are not feasible, we will use synchronous (phone/video) or asynchronous (secure email) methods. Our schedule will accommodate the FQHC's needs and circumstances.

Rapid Qualitative Data Analysis. Regional teams will synthesize each FQHC's data into a single narrative case report (5-7 pages) that follows a standard *Case Study Report Template*. Case report data will be entered into a shared data repository for rapid qualitative data analysis, conducted in small teams to enhance rigor.[122]

Qualitative Cross Case Comparisons. We will use the standardized case reports as the primary source of cross case analysis. This approach will enable us to complete a thematic analysis across cases, drawing both on semantic themes (common sense meanings arising from the reports) and latent themes (underlying meanings that give structure to the case narratives).[123] An overarching thematic analysis will identify themes related to serving patients with type 2 diabetes in each area of focus for the case study, including adherence to guidelines; implementation of process changes to improve care; clinical outcomes (e.g., diabetes control); implementation approach; and impacts on health disparities. Themes identified will inform development of audience-specific products for dissemination of the *iPATH implementation approach*.

Natural Language Processing (NLP). In addition to more traditional thematic analysis techniques used in the social sciences, we will analyze our case narrative data using Stanford CoreNLP tools,[124,125] an open source set of NLP tools that can use human language inputs and give back the base forms of words, their parts of speech, entity types such as people and organizations, interpret dates and other numerical information, and mark up the structure of sentences in terms of phrases or word dependencies. The Stanford CoreNLP tools python libraries include a variety of state-of-the-art models for core NLP challenges (e.g., named-entity recognition, relation-extractor, sentiment analysis).[126] We will use what is available in the core libraries but will customize them to capture terminology relevant to type 2 diabetes and health disparities concepts and to annotate health and biomedical terms. To ensure our NLP tools are extracting concepts accurately, we will validate our concept extraction techniques, based on comparison of 50 case narratives manually annotated by our clinical subject matter experts. Lastly, we will use the concepts extracted via NLP to perform "topic modeling," a machine learning technique to automatically detect hidden thematic structures in extensive collections of documents[127–129] without prior information about their theme and composition. We will adopt the commonly used topic model, latent Dirichlet allocation (LDA).[129] LDA is a widely used generative unsupervised statistical algorithm using Bayesian statistics. The LDA algorithm models each textual document as a mixture of topics, and each topic is represented as a probability distribution over all the words. LDA models a generative process of document generation. It is parameterized by 2 Dirichlet distributions, the first modeling the mixture of topics in documents, and the second modeling the mixture of words in topics. The model uses the expectation-maximization algorithm[130] to derive the optimized set of topics. We implemented the LDA topic model using the Python package gensim. The Stanford CoreNLP tools and the Python genism package are easily set up on a laptop or in the cloud; however, if we cannot use these tools, we will choose a comparable opensource product, such as AllenAI NLP[131] from the Allen Institute for AI.

Standard Qualitative Data Analysis. Given the semi-structured nature of our interview questions and our goal of exploring what has occurred with FQHC transitions to proactive outreach, telehealth, etc. during the pandemic, we will also use traditional thematic content analysis,[132] recognizing that this analytic approach may take longer than our RDCR. This iterative approach to analysis will include reading interview transcripts and discussing findings among our regional investigators as the study progresses. This process will enable us to explore emergent themes both within and across FQHCs. Cross-case comparisons will leverage our team-of-teams model and use Agile software (Slack or Microsoft Teams) to facilitate the constant comparative method across FQHCs, as currently used by the OSU team.[120] Analysis will prioritize the elucidation of key concepts

from individuals' statements made in interviews (extraction) and conceptual development based on constant comparative analysis. NVivo software will facilitate coding, data analyses, and merging data across FQHCs.[133] We will examine time required and findings from the NLP versus standard approach to compare and validate both; and we will apply Guba and Lincoln's 5 criteria for trustworthiness in qualitative research.[134–136]

3.4.5 Quantitative Data Collection. We will examine variation in adherence to guidelines, clinical outcomes, and disparities to explore the relationship between these indicators within the context of health disparities populations. We will request supplemental quantitative data to characterize process changes over time and to complement qualitative findings. We will provide FQHCs with a list of variables in 4 domains (process, outcome, disparities, patient/family experience), that are operationally important and typically collected and reported in standardized formats to both organizational and public stakeholders. For each of these measures, multiple timepoints will be requested to track change over time.

Process measures will include: (a) in-person visits, (b) telehealth visits (video), (c) telehealth visits (phone), (d) rate of cancellations, (e) no-shows for all visits, and (f) adherence to guidelines for type 2 diabetes.

Outcome measures will include commonly reported measures such as (a) HEDIS effectiveness of care for comprehensive diabetes prevention and management (e.g., BMI, tobacco use, depression screening, statin therapy for CVD, IVD Aspirin, or other treatment); (b) poor diabetes control (A1c>9%); (c) utilization measures (e.g., ER visits, acute hospital admissions); (d) adults' access to preventive/ambulatory health services; (e) health disparities; and (f) recently updated telehealth use measures.[137]

Disparities measures will include process and outcome measures by demographic characteristics of patients, including but not limited to race and ethnicity, depending on data availability.

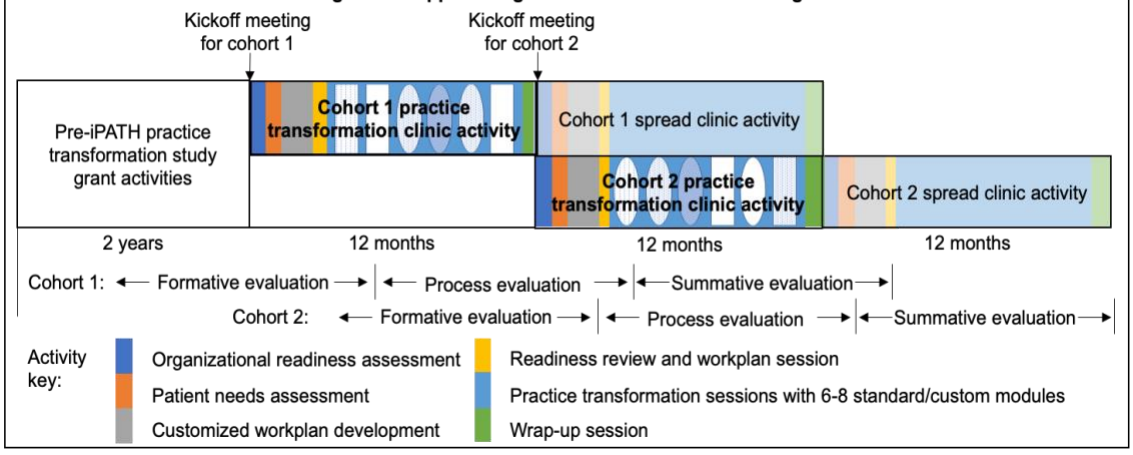
Patient-and-family experience measures will come from Press Ganey or Clinical and Group Consumer Assessment of Healthcare Providers and Systems surveys. The former provides a robust assessment of patient satisfaction with their care. The latter collects patient experience data about (a) timely appointments, care, and information; (b) quality of providers' communication with patients; (c) providers' use of information to coordinate patient care; (d) helpful, courteous, and respectful office staff; and (e) patient rating of provider.

Quantitative cross case comparisons will be based on data received from FQHCs. We will analyze trends in preventive/ambulatory visit type (in-person, video, telephone) by each FQHC over time. For process measures, we expect pandemic-related reductions in in-person visits partially offset by increases in telehealth visits with variability between practices depending on local disease burden, stay-at-home implementation, and clinic-specific characteristics. For outcome and disparities measures, we expect the FQHCs in the top quartile will consistently perform better than those in the bottom quartile. For the patient/family experience measures, we expect variable responses across practices due to variable responsiveness to the pandemic. Due to limited sample sizes, analysis will aim to benchmark practices to national FQHC averages. Where possible, we will assess trends over time using Cochran-Armitage trend tests. Further specification of our analytical approach may include regression discontinuity analysis as well as time-series models that include practice- and state-level fixed effects to control for variation within practices and states.

3.5 (AIM 2) Implement a multi-level, multi-component, technology-enabled practice transformation strategy.

3.5.1 Study Design. We will refine and customize the *iPATH implementation approach* to meet the needs of each FQHC and its patient population based upon findings from the Puerto Rico pilot; lessons from investigators' prior practice transformation implementation and evaluation studies; the H/L Comparison Study; and formative needs assessments. Led by Ms. Levis-Peralta and other practice transformation facilitators, we will implement the *iPATH practice transformation* (*see* **Table 2**) using a cluster-randomized, stepped-wedge design, involving 8 multi-site FQHC clinics, distributed across 4 regions (*see* **Figure 2**). Two cohorts of 4 FQHC clinics will pursue practice transformation in 2 waves (12-months each) followed by a

Figure 2. Stepped wedge cluster randomized trial design



second year during which FQHCs will spread practice transformation to their additional clinics.

3.5.2 Refining *iPATH Practice Transformation*. We will incorporate lessons from key FQHC stakeholders who participated in the Puerto Rico pilot. Study teams will review these lessons *vis-à-vis* published literature and personal experience with similar practice transformation initiatives. We will incorporate promising practices revealed in the H/L comparison study. Refinements will address findings from formative organizational readiness and patient needs assessments (*see* **§3.5.5**). Working with employees and patients at practice transformation clinics, we will use a learning-oriented, human-centered design-based research approach to identify cultural, historic, and linguistic conditions of our practice transformation clinics "...to discover an ensemble of tools, materials, tasks, organizational structures, and any other activities that are apt to set in motion a process of learning that improves on a focal problem of practice."[138] This approach has empirical support for its use across phases of practice transformation. Using QI methods, we will adapt to organizational conditions through iterative meetings with employees, stakeholders, and patients throughout the practice

Table 2. iPATH Practice Transformation

iPATH element	Actors	Description	Timeframe	EPIS Phases
MOU approval	• PTFs • Admin	• Agree on scope, timeline, and project deliverables	• Before cohort kickoff	**Explore**
Kickoff Meeting	• PTFs • Admin • TTs	• Set expectations & scope of work • Designate implementation leaders from process/clinical perspective • Set process meeting schedule; discuss next steps & preparations	• Within 1 month of Kickoff	
Organizational Readiness Assessment	• PTFs • TTs	• Review organizational barriers, expectations, and extent to which clinic currently meets PCMH standards.	• Hybrid • Completed within 8 weeks of kickoff	**Prepare**
Patient Needs Assessment	• TTs	• Collect patient needs assessment surveys via SMART PCMH Manager technology as part of regular patient "pre-visit" protocol • Review reports as input to ongoing practice transformation • Report quarterly to Governance Team	• Within 3 months of Kickoff • Ongoing	
Customized Workplan Development	• PTF • TT • Admin	• Analyze findings from assessments • Develop recommendations for a set/sequence of PCMH transformation modules—tailored based on patient population & organizational needs/strengths	• Hybrid • Over 1 month period after Org Readiness Assessment	
Readiness Review & Workplan Session	• PTF TT	• PTFs present results of organizational readiness & patient needs assessments; verify results reflect TT perceptions • Discuss proposed customization plan • Agree on priority, sequence, timeline, module customization & supports for Core and Extended team	• 2-hour in-person/ online session	
Practice Transformation Sessions (modules)	• PTF • TT • Core • Extended • Community	• Guide TT, Core, Extended, and Community teams through modules that include icebreakers (contextualized to learning objectives), PCMH content explanations, problem solving learning activities, implementation logistics, examples, resources, and references • Per workplan, PTFs "mix and match" from 14 modules to customize content to the clinic's specific needs and strengths • Engage Core and Extended patient care teams	• 1 session per month • 6-8 modules per cohort	**Implement**
QI sessions & Help desk	• PTFs • TT	• Regularly check in to ensure modules and module sequence are meeting Core and Extended team needs	• Ongoing • Kickoff to Wrap up	**Sustain**
Wrap-up session	• PTFs • TT • Admin	• Address any outstanding concerns and provide support to clinic • Discuss opportunities and plan for spread to remaining FQHC clinics	• 1 day	

PTF=practice transformation facilitators, Admin=FQHC Administration, TT=clinic transformation team, Core=core patient care team, Extended=extended patient care team, Community=community patient support team

transformation period, including preparation, design, implementation, and reflection. Reflection will consider whether solutions addressed problems and identify which parts of practice transformation were most effective.

3.5.3 Study Sample and Recruitment. Participants in the *iPATH practice transformation study* include 8 multi-clinic FQHCs in MA, OH, CA, PR (2 per). Included FQHCs will perform in the 3rd quartile with respect to the percentage of patients with poorly controlled diabetes (A1c >9%) based on most recently available data and not improved for change in diabetes control since 2019. FQHC practice transformation clinics in the control cohort will not receive practice transformation components while serving as controls. We will compare the first cohort of 4 practice transformation clinics to the second cohort and then both cohorts to similar clinics from participating FQHCs that were not selected for initial iPATH practice transformation ("non-cohorted clinics"). Our exclusion criteria and recruitment approach will mirror our approach in Aim 1 (*see* **§3.4**).

3.5.4 Randomization. We will use 1:1 stratified randomization at the clinic level. FQHCs will be stratified by state, and matched based on total size (# of patients served across multi-clinic FQHC). We will randomly select

1 clinic per FQHC for participation in practice transformation. Non-cohorted clinics will be eligible for spread activities. Our biostatistician will assist with randomization and be blinded to study assignment during analysis.

3.5.5 Formative Assessments. We will perform formative assessments at organization and patient levels. The organization readiness assessment (*see* **Appendices B** & **C**) uses an instrument based on the NCQA PCMH Standards and ADA Guidelines. We will administer the organizational readiness assessment to the members of the FQHC clinic transformation team (see **§3.5.6**) during a synchronous training session led by the practice transformation facilitator, who explains concepts before and answers questions during the survey. Findings are presented to the transformation team to verify results and discuss a customization plan based on what is learned, including priorities, sequence, and timeline, with the clinic team.

FQHC clinics participating in practice transformation will administer a patient needs assessment as part of their patient "pre-visit" protocols. If a clinic does not have a patient "pre-visit" protocol (a key part of the practice transformation strategy), this module will be prioritized to establish the mechanisms for patient outreach. The patient needs assessment methodology (see **§3.2**) has been used extensively in Puerto Rico and includes items from validated questionnaires including the CDC Behavioral Risk Factor Surveillance System (BRFSS);[139] Patient Health Questionnaire-2 (PHQ-2);[140] Generalized Anxiety Disorder Screening Tool (GAD-Q-IV);[141] Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE);[142] and the CDC Hurricane Katrina Response Community Health Needs Assessment.[143] We will add specific diabetes patient assessment tools: the Diabetes Distress Scale[144] and Problem Areas in Diabetes (PAID) questionnaire.[145] We will gather data on the SMART PCMH manager. Facilitators will use findings from the first month of patient survey data at practice transformation clinics to inform recommendations presented to clinic transformation teams at their Readiness Review and Workplan Session. The patient survey also serves as a practice transformation tool to deploy patients continuously to modularized workflows.

3.5.6 iPATH Implementation Approach (*see* **Table 2**). Thru 4 EPIS phases, iPATH covers project initiation and management; workflow and standard operating procedures redesign; provider training in data collection, QI, collaborative learning, change management, and evaluation activities to identify what is working, how to learn from failure and build on success. We employ a learning-oriented, design-based approach to adapt evidence-based practices to address FQHC's cultural, historical, and language factors, and enable spread.

iPATH practice transformation facilitators are trained and experienced in delivering iPATH and similar practice transformation strategies. Ms. Levis-Peralta will serve as lead facilitator, assisted by Dr. Glaseroff. Other study team members will contribute to specific modules based on their expertise.

FQHC clinic transformation team must include (a) FQHC clinic leader with decision-making authority, (b) clinician-champion, (c) information technologist capable of configuring reports, (d) person responsible for organizing documentation and standard operating procedures, (e) operations coordinator, and (f) one each: physician, nursing, administration. Where staff members work on QI, supplemental services, and behavioral health, these should also be represented. Teams may include more or other members.

3.6 (AIM 3) Comprehensively evaluate the *iPATH implementation approach*.

3.6.1 Study Design. To evaluate the *iPATH implementation approach*'s ability to spur transformation to patient-centered, team-based, technology-enabled diabetes care for NIH-designated U.S. health disparity populations, we will use multi-methods at 3 stages.[146] Evaluation will apply our RDCR. Formative evaluation will combine findings from the H/L comparison study (Aim 1) and formative assessments with stakeholder interviews from practice transformation clinics to understand early perceptions of *acceptability* and *feasibility* of proposed modifications. A midpoint process evaluation will include qualitative observations and interviews regarding *fidelity* within each FQHC clinic to intended iPATH modules and facilitators and barriers to iPATH implementation and sustainment following the EPIS framework.[19,66] Summative evaluation will combine quantitative assessment of impact including the stepped wedge trial, iPATH *penetration* within each FQHC clinic, and qualitative observations and interviews that explore the etiology of observed quantitative findings, including *acceptability* of implementation outcomes. Throughout iPATH practice transformation, facilitators will use registers to document measures of *penetration* and *fidelity* to the iPATH approach as part of iPATH delivery. As summative evaluation proceeds, we will work with practice transformation and control clinics to spread iPATH for achieving guideline-concordant care and improved outcomes across participating FQHCs.

3.6.2 Qualitative Interviews (formative, process, summative). We will work with the administrative contact at each clinic to characterize its "patient care teams" and to develop a key informant list similar to that in Aim 1 (n=11-17) (see **§3.4.4**). We will tailor interview guides to key informant roles. Individual or small group semi-structured interviews will explore external and internal factors affecting care delivery, satisfaction/burnout, and ability to address patient needs. Study teams will conduct interviews at practice transformation clinics for each evaluation (formative, process, summative), in their respective region, using standard guides. Where

feasible, we will interview the same respondents at each stage to highlight changes. Multiple disciplines will provide multiple perspectives on processes. Based on our prior work, such an approach achieves theoretical saturation.[84,85,147,148] Interviews (in-person and/or remote) will be audio-recorded and transcribed for rigorous analysis. Informants will receive a small honorarium for their participation in interviews.

3.6.3 Implementation activity registers. In the course of implementation, iPATH facilitators will document practice transformation, including the number, type, and sequence of activities and modules, numbers of participants, and facilitators and barriers identified.

3.6.4 Qualitative Analysis Methods. As in the H/L comparison study, we will combine and compare RDCR and standard approaches to qualitative analysis (see **§3.4.4**). We will use a deductive-dominant approach to thematic analysis.[149] Regional study teams will synthesize clinic's data, including interviews and implementation registers, into narrative case reports following a standard *Case Study Report Template*. We will develop an initial codebook drawing from the modules comprising iPATH and concepts from implementation science and learning theory. Using an iterative approach to analysis, we will read transcripts and discuss findings as the study progresses. This process will enable us to explore emergent themes and ensure saturation in data collection. Analysis will prioritize elucidation of key concepts from individuals' statements and conceptual development based on constant comparative analysis and the classification of data through code development.[150,151] We will use NLP tools[124,125] and Nvivo[133] to facilitate coding and data analyses (topic modeling). We will use tables and graphs to summarize and display measures of implementation. Findings from qualitative analyses will improve understanding of factors related to iPATH implementation and efficacy.

3.6.5 Quantitative Data Collection. Data collection from the 8 participating multi-clinic FQHCs will occur at baseline (practice transformation month 0) and at 12 and 24 months following the start of *iPATH practice transformation*. We will request patient-level EHR data for our primary analyses and clinic-level data for our secondary analyses. Data collection will include clinic reports of patient-level values for A1c, blood pressure, and lipid panels; clinic-level rates of poorly controlled A1c, blood pressure and lipids; and performance of ADA/NCQA recommended assessments, e.g., biannual A1c, annual fundoscopic exam, foot exams, annual urine protein/urine albumin-creatinine ratio test. Secondary measures include process, outcome, disparity, and patient experience measures reported in the HRSA Uniform Data System (see **§3.4.5**).

3.6.6 Quantitative Analysis Plan. We will use an intent-to-treat approach, analyzing participants in their randomly assigned study cohort. This approach fits the pragmatic nature of the *iPATH implementation approach* where uptake and translation may differ across clinics, increasing the generalizability of our findings.

Hypotheses: Our quantitative analysis will be designed to test the following primary hypotheses:

H1: There will be a greater reduction in the percent of patients with poorly controlled diabetes (e.g., A1c>9%) in the practice transformation arm compared to the control arm.

H2: The difference in reduction of percent of patients with A1c>9% in the practice transformation compared to the control arm will be greater for NIH-designated health disparity populations compared to other patients.

Our analysis will begin with examining balance in baseline demographic characteristics (e.g., age, gender, race, insurance status) and A1c values, between study arms, conservatively considering only Cohort 1 and Cohort 2 clinics, using standardized differences. Standardized differences larger than 10% are not expected given the randomized design and large sample size, but covariates that exhibit chance imbalance across study arms can be included as covariates in regression modeling for better precision of treatment effect.

Our primary approach to determining the effect of the trial on A1c (H1) at 12 (primary) and 24 (exploratory) months follow-up is to use a multilevel regression model (MLM) controlling for baseline A1c values and other sociodemographic variables. We will use a 3-level MLM, with random effects associated with (a) between-cluster random variation; (b) within-cluster and between-patient random variation: and (c) between time and within patient random variation. The model also will include a fixed effect for each step, and a fixed effect representing practice transformation status at a given step.[61] The primary test for differences between the study arms will be accomplished using Wald tests for significance of the appropriate linear combinations involving the fixed effects for the main independent variable representing practice transformation status, the main effects for the step/time point effect, and the interaction effect. Effect size will be measured by both standardized Cohen's d measure and by the difference in regression-adjusted mean percent of patients with poorly controlled diabetes between the practice transformation and control arms. Since the primary outcome is a binary indicator of whether or not a given patient had poorly controlled diabetes, we will use a linear logistic regression analysis. Residual plots will examine model assumptions, with transformation of the outcomes used as needed to satisfy modeling assumptions. Similar models will be used for other outcome variables. To evaluate H2 we will include interaction terms between the practice transformation indicator variable and a given race indicator variable. While we will not be powered to detect statistical significance of this effect, we will

estimate its effect size using Cohen's d and eta-squared measures. Problem/strategy: Our modularized, customized approach will both enhance the likelihood of impact and reduce our ability to identify a specific practice transformation strategy. Instead, our qualitative research will also highlight differences among modules. We will also identify patterns to sort modules into fewer buckets and test their effects.

3.6.7 Power Calculation. Our power and effect size calculations are based on our primary outcome measuring whether or not a patient has poorly controlled diabetes (A1c>9%). The stepped wedge CRT would involve randomization at the FQHC clinic level and analyses based on data gathered at the individual patient level. As a result, we expect observed outcomes on patients within the same clinic not to be independent. The amount of correlation between patients within clinics, measured by the intraclass correlation coefficient (ICC), is estimated based on the ICC used in a prior study, which used ICC=0.03.[152] Since the amount of correlation in the primary outcome for patients nested within clinics would be expected to be lower than at the smaller physician level, we used an ICC of 0.01. We calculated the minimum detectable effect size (MDES) given the sample size is fixed at 8 clinics for budgetary reasons, conservatively considering only Cohorted (not spread) clinics, in this pragmatic trial. Since this evaluation of the *iPATH implementation approach* uses a stepped wedge CRT design, the design effect (DE), which is needed to adjust the actual sample size to an effective sample size that appropriately accounts for the non-independence of individual observations, involves not only the ICC and cluster size but also the number of steps (2) and number of baseline measures (1).[153,154] The actual fixed sample size must be adjusted downward by a factor determined by the DE for such a study design.[153] Assuming observations on A1c are available on 1,000 patients with diabetes at each clinic, with 4 clusters, 1 baseline measure and 2 steps, the stepped wedge DE is 1.48, and the effective sample size, considering only Cohorted clinics, is 8,000/1.48= 5,405. Finally, assuming an average baseline percentage of patients with poorly controlled diabetes (A1c>9%) of 38%, then, with an effective sample size N(Eff)=5,405, and assuming a two-period decay correlation structure with cluster auto-correlation (CAC) of 0.9 (degree of waning of the similarity between patients in the same cluster [i.e., the ICC] with each measurement period) and individual auto-correlation (IAC) of 0.8 (strength of the correlation between any two observations on the same patient), we have 80.5% power to detect a decrease in the percentage of patients with A1c>9% from 38% to 34% (our *a priori* criterion for programmatic success) at alpha level of 0.05.

3.7 (SCIENTIFIC RIGOR). We will achieve study aims using a well-controlled design and comprehensive methods. The proposed research will achieve robust, unbiased, reproducible results through randomization and blinding of the statistician with *a priori* hypotheses and defined study outcomes. Our sample size was determined based on prior studies using the mean and standard deviation of A1c reduction. Parameter estimates, their standard errors, 95% confidence intervals, differences between groups, and p-values will be assessed with attention to modeling assumptions and goodness-of-fit, ensuring valid and reproducible comparisons. A 2-sided p-value < 0.05 will be considered statistically significant. EQUATOR guidelines[155] including SPIRIT standards[156] for describing clinical protocols and extended CONSORT guidelines[157] for reporting data from stepped wedge clinical trials will ensure results are reported in a rigorous manner. We will share deidentified study data with the scientific community upon request.

3.8 (DISSEMINATION) Research insights will be synthesized and reported proactively, engaging our target audiences as implementation and dissemination partners and using a variety of Knowledge Mobilization (KMb)[158] tools and outlets. We will conduct dissemination in accordance with the NIH Policy on the Dissemination of Clinical Trial Information. Products will range from traditional academic papers and presentations to lay-oriented webinars, podcasts, and social media communication. We will engage a professional writer who is skilled in health/ehealth literacy and a web communications designer. Our KMb strategy will emphasize tailored messages and actionable knowledge for target audiences (FQHCs, policymakers, professional associations, researchers, patient advocacy groups) to rapidly improve practice.

3.9 (IMPACT) Our innovative approach, strong regional research-practice partnerships, and leveraged resources will fuel our efforts to use knowledge and data to drive improvements in type 2 diabetes care for NIH-designated U.S. health disparity populations. Given clinical and financial pressures on FQHCs, public health officials and FQHC leaders seeking to address the care needs for patients with diabetes face 2 major challenges: they must understand how patient needs and organizational conditions affect team-based type 2 diabetes treatment, and they must support underperforming FQHCs in implementing evidence-informed solutions[159] toward patient-centered, team-based, technology-enabled practices. iPATH will build a research infrastructure and rapidly identify and disseminate information to enable FQHCs to provide safe, effective, equitable diabetes care. Findings will inform policymakers and directly benefit 20 case study and iPATH FQHCs. Our findings could benefit FQHCs and primary care practices across the U.S.—and the 37.3 million Americans with diabetes,[1] who account for $237 billion annually, 25% of healthcare costs.[160]

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