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Therapeutic Inertia in the Pharmacologic Treatment of Type 2 Diabetes Mellitus: Investigation of Causes and Recommendations for Change

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Diabetes mellitus (DM) is a pervasive chronic condition and a serious global health issue. Type 2 diabetes mellitus (T2DM) comprises approximately 90-95% of all DM cases (Centers for Disease Control and Prevention [CDC], 2022). The prevalence of T2DM has risen rapidly over time; in fact, the number of adults diagnosed with T2DM over the past 20 years has more than doubled (CDC, 2022). T2DM currently affects an estimated 462 million people globally (equal to 6.28% of the world's population), including more than one out of every 10 Americans (American Diabetes Association [ADA], 2018; CDC, 2022; Khan et al., 2020). In Washington state specifically, DM is the seventh leading cause of death (Washington State Department of Health [WADOH], 2018). As of 2018, one out of every 11 Washington adults have DM, and an estimated 33.7% of Washington's adult population have prediabetes (CDC, 2018; WADOH, 2018).

Systemic injustices cause disparities in the socioeconomic determinants of health that result in T2DM being most prevalent in low-income individuals and people of color (Cunningham et al., 2018; Han et al., 2019; Leung et al., 2016). According to a 2018 systematic review and meta-analysis, people of color — particularly Black Americans — were consistently found to be disproportionately affected by social risk factors for diabetes, including "poverty, poorer quality housing, lack of neighborhood spaces for physical activity, and limited access to healthy food" (Cunningham et al., 2018, Background, para. 3). The same study found that "patient-provider racial discordance, perceived racial bias in medical encounters, and resulting patient mistrust in healthcare providers and systems" were additional factors that contributed to poorer DM-related health outcomes for racial minority populations (Cunningham et al., 2018,

Background, para. 3). These disparities culminate in an increased prevalence of T2DM in underserved patient populations. On a national scale, 12.1% of non-Hispanic Black Americans have diagnosed DM, as well as 14.5% of American Indians/Alaska Natives, and 11.8% Latinx individuals (CDC, 2022). In comparison, only 7.4% of non-Hispanic white Americans have diagnosed DM (CDC, 2022). Non-Hispanic whites also have the lowest age-adjusted prevalence of DM in Washington state, while the proportion of Native Hawaiian/Pacific Islanders with DM is almost twice as large (WADOH, 2018).

T2DM can decrease quality of life and functional capacity, and the progressive nature of the disease leads to microvascular and macrovascular complications which have a significant negative impact on morbidity and mortality (Angier et al., 2019; Chudasama et al., 2021; Cunningham et al., 2018; Gabbay et al., 2020; Karam et al., 2020; Khunti et al., 2019; Powell et al., 2021; Selvin et al., 2018). T2DM is associated with a 60% higher risk of premature death and is the number one leading cause of kidney failure, adult blindness, and lower limb amputations (CDC, 2022). Additionally, 32% of individuals with T2DM also have cardiovascular disease, and 50% experience peripheral neuropathy (Gabbay et al., 2020). In Washington state specifically, adults with DM are 4.6 times more likely to have kidney disease, 3.3 times more likely to have a stroke, and 2.7 times more likely to have heart disease compared to adults without DM (Kemple et al., 2019).

The disparity observed in the prevalence of T2DM for low-income individuals and people of color translates to disproportionately high rates of DM-related morbidity and mortality in these same populations (Cunningham et al., 2018; Han et al., 2019; Leung et al., 2016). Black Americans appear to be particularly affected by this disparity. According to a 2018 systematic review, “African-Americans are less likely to have controlled A1c than non-Hispanic whites, are

more likely to develop retinopathy and nephropathy, and more likely to be hospitalized with diabetes-related complications" (Cunningham et al., 2018, Background, para. 2). Furthermore, recent studies have found that both Black adults and low-income adults are more than twice as likely to die from T2DM compared to their white and high-income counterparts (Han et al., 2019; Hill-Briggs et al., 2021).

Considering the prevalence, progressive nature, and complications associated with T2DM, a diagnosis of T2DM often results in significant healthcare costs. An investigation into the cost of DM by the ADA in 2017 found that T2DM management consumes one out of every four dollars spent on healthcare (ADA, 2018). This same study estimated the total annual cost of diagnosed T2DM in the United States at $327 billion, which included $237 billion in direct medical costs and $90 billion in costs related to reduced productivity (ADA, 2018). Washington state's T2DM-related healthcare expenditures comprised $6.7 billion of this total cost (WADOH, 2018). The ADA (2018) also found that people with T2DM in the United States had healthcare expenditures that were 2.3 times higher than people without T2DM. This disparity is even more pronounced in Washington state, where adults with T2DM spend greater than five times as much on both medications and total healthcare costs compared to adults without T2DM (WADOH, 2018).

Considering the impact of T2DM on long-term health and related expenses, strategies aimed at improving T2DM prevention and management would likely result in improved patient outcomes and decreased healthcare costs. Current research demonstrates that development of such strategies is of particular importance for addressing T2DM-related disparities experienced by underserved populations.

Background

There is a repository of strong evidence to support that individualized approaches targeting a glycated hemoglobin (A1c) level of less than 7% for most adults with T2DM are associated with objectively better long-term health outcomes, including decreased symptomatic burden, improved quality of life, and decreased incidence of DM-related complications (ADA, 2022; Chudasama et al., 2021; Karam et al., 2020; Khunti et al., 2017; Khunti et al., 2019; Powell et al., 2021; Selvin et al., 2018; Wrzal et al., 2021). Evidence also suggests that achieving glycemic targets during the first 12 months after diagnosis establishes a "legacy effect" in which long-term health outcomes are significantly improved (Chudasama et al., 2021; Gabbay et al., 2020; Karam et al., 2020; Khunti et al., 2019; Powell et al., 2021; Selvin et al., 2018). In contrast, failure to achieve early glycemic control results in increased morbidity, mortality, and a 60% increase in outpatient healthcare costs (Laiteerapong et al., 2018; Mehta et al., 2020).

Pharmacologic therapy is a mainstay of treatment for T2DM, and there have been marked advancements in glucose-lowering therapies over the past decade (ADA, 2021). Due to the progressive nature of T2DM, treatment intensification (i.e., adding or changing medications to an individual's regimen) is frequently required over time for long-term glycemic control, meaning that most patients will eventually be prescribed more than one medication (ADA, 2022). More specifically, current joint guidelines published by the American Diabetes Association and European Association for the Study of Diabetes (EASD) recommend that therapy be changed or intensified if glycemic targets are not achieved after three months (Davies et al., 2022). Despite these well-established and widely disseminated clinical practice guidelines, availability of a variety of efficacious glucose-lowering agents, and clear benefits to achieving glycemic control, evidence shows that the proportion of patients meeting glycemic targets has steadily declined since the early 2000s (Chudasama et al., 2021; Fang et al., 2021; Gabbay et al., 2020; Karam et

al., 2020; Khunti et al., 2017; Powell et al., 2021; Selvin et al., 2018; Wrzal et al., 2021). The achievement of individualized A1c targets decreased from 69% to 63% between 2007 and 2014; during this same time period, the proportion of people with an A1c >9% increased from 12% to 15.5% (Gabbay et al., 2020). Although the etiology of this trend is certainly multifaceted, a phenomenon called "therapeutic inertia" appears to be a significant contributor.

Therapeutic inertia is defined as "the failure to initiate or intensify therapy in a timely manner according to evidence-based clinical guidelines in individuals who are likely to benefit from such intensification" (Gabbay et al., 2020). It is a phenomenon that was first described in the early 2000s and has been principally observed in the management of chronic illnesses such as DM and hypertension (Philips et al., 2001). In terms of T2DM specifically, therapeutic inertia is a key reason for prolonged, uncontrolled hyperglycemia in many patients (Chudasama et al., 2021; Gabbay et al., 2020; Karam et al., 2020; Khunti et al., 2017; Khunti et al., 2019; Polonsky et al., 2017; Powell et al., 2021; Wrzal et al., 2021). A 2017 systematic review found that the median time to treatment intensification, after an above-target A1c measurement, was greater than one year (Khunti et al., 2017). Such delays in treatment intensification and concomitant prolonged hyperglycemia are associated with increased symptomatic burden and risk of complications, which in turn result in decreased quality of life and increased use of healthcare resources (Chudasama et al., 2021; Gabbay et al., 2020; Karam et al., 2020; Khunti et al., 2017; Khunti et al., 2019; Polonsky et al., 2017; Powell et al., 2021; Wrzal et al., 2021).

Similar to T2DM itself, the etiology of therapeutic inertia is multifactorial, arising from interrelated components at the level of the patient, the provider, and overhead systems (Chudasama et al., 2021; Gabbay et al., 2020; Karam et al., 2020; Khunti et al., 2017; Khunti et al., 2019; Polonsky et al., 2017; Powell et al., 2021; Wrzal et al., 2021). Commonly-cited factors

that underlie therapeutic inertia include disparities in the determinants of health (e.g., access to care, socioeconomic status, housing status, food security, insurance coverage, etc.), limited understanding of the progressive disease course, fear of unpleasant medication side effects, provider time constraints, lack of an effective interprofessional/team approach to care, and medication formulary restrictions (Karam et al., 2020; Khunti et al., 2019; Polonsky et al., 2017; Powell et al., 2021; Wrzal et al., 2021). Factors contributing to therapeutic inertia may also vary based on a healthcare organization's geographic location, level of access to necessary resources, patient population, and provider preparedness/comfort with managing T2DM (Karam et al., 2020; Khunti et al., 2019; Wrzal et al., 2021).

Identification of the unique set of factors that contribute to therapeutic inertia is an essential foundational step to develop and implement strategies to overcome this phenomenon. To that end, this project sought to answer the following clinical question: From the perspective of primary care providers (PCPs) at a Seattle-based community health organization, what are the commonly identified causes of therapeutic inertia in the pharmacologic treatment of adult patients with type 2 diabetes mellitus and how can this information be applied to targeted quality improvement initiatives?

The rationale behind focusing on the perspective of primary care providers is their involvement in multiple levels of T2DM management (including both direct patient care and interdisciplinary/team strategies) which renders them well-positioned to identify causes of therapeutic inertia that might be present at each level. Community health was chosen as the most appropriate project setting in order to maximize the downstream impact for the most-affected patients. As of 2019, 92% of patients receiving care at CHCs were low-income, and 62% were

from racial/ethnic minorities — the same patient populations that are the most affected by T2DM (Angier et al., 2019; Han et al., 2019).

The purpose of this project was twofold: to gain insight into why indicated, timely treatment intensification for adult patients with T2DM is commonly delayed, and to use this information to provide quality improvement recommendations with the long-term goal of decreasing T2DM-related disparities for the most affected patients. The project had four major aims: (1) to identify patient demographic trends associated with increased risk for therapeutic inertia (i.e., A1c >9% or no A1c monitoring in 6 or more months); (2) to identify commonly-cited causes of therapeutic inertia from the perspective of PCPs at the level of the patient, the provider, and overhead systems; (3) to identify specific resources or skills that PCPs feel are needed to reduce therapeutic inertia; and (4) to compare the prevalence of therapeutic inertia at different steps in the T2DM treatment pathway.

Theoretical Framework

The social-ecological model of health (SEMH) was used as a framework to provide theoretical structure for this project. The SEMH was adapted from the Ecological Systems Theory and was first popularized by the World Health Organization (WHO) in the 1940s (CDC Agency for Toxic Substances and Disease Registry [ATSDR], 2015). It is rooted in the principle that each person's health status and behaviors are influenced by complex, reciprocal interactions between the individual, their personal attributes, their physical and social environments, and the systemic structures in which they exist (ATSDR, 2015).

The SEMH describes four levels of factors that influence a person's health: the individual (personal biological and socioeconomic factors such as genetics, age, income, and education);

relationships (the individual's close friends and family); community (the physical environment in which a person's relationships exist); and society (systemic structures, public policy, societal norms; ATSDR, 2015). Understanding the multi-level factors that influence health translates to an enhanced ability to enact primary prevention at each level. Implementation of primary prevention strategies are more likely to result in sustainable improvements compared to interventions that are implemented at downstream (secondary or tertiary) levels of prevention (ATSDR, 2015). The CDC has frequently employed the SEMH for the development of community health promotion and disease prevention interventions (ATSDR, 2015).

Given that the SEMH has demonstrated use for improving primary prevention through the identification of multi-level factors that influence health, this framework was deemed appropriate for use in this project. The SEMH provided both a theoretical foundation and a structural framework for identification and categorization of multi-level factors that contribute to therapeutic inertia in the treatment of T2DM. Use of this framework was intended to enable stakeholders to identify areas within their scope of management that might be most impactful for future quality improvement strategies.

Project Design & Methods

This was a qualitative research project that was intended to provide a foundation for future quality improvement efforts. There were two major ethical considerations for this project: (1) maintaining the confidentiality of participants and any utilized patient demographic data, and (2) minimizing the introduction of bias. Management of confidentiality and bias is discussed throughout subsequent sections of this document. The Seattle University Institutional Review Board (IRB) determined that this project does not meet the federal regulatory definition for human participant research, and therefore does not require further IRB review.

The project was implemented at a Seattle-based Federally-Qualified Health Center (FQHC). This FQHC serves over 70,000 patients in the Seattle area and is the largest local provider of primary medical care for low-income, uninsured, and unhoused individuals and families (Neighborcare Health Development Office [NCHDO], 2021). Sixty-three percent of this FQHC's patients are adults between the ages of 18-65; 69% of patients are from racial/ethnic minorities; 80% have an income that is below the federal poverty level; 44% have insurance through Medicaid; and 29% are uninsured (NCHDO, 2021). As of 2021, 12.9% of this FQHC's patients have T2DM (NCHDO, 2021). Considering these demographics in the context of the purpose and aims of this project, this FQHC was determined to be well-suited to address the project's clinical question.

The first aim of this project was to identify whether there were patient demographic trends (such as age, race/ethnicity, income level, or level of insurance coverage) associated with prolonged hyperglycemia. This was based on the SEMH principle that individual factors or characteristics may increase the probability that a person experiences therapeutic inertia (ATSDR, 2015). Demographic data was collected in May 2023 from the most up-to-date reports generated by: (1) the organization's electronic health record, and (2) the organization's internal data visualization tool. To ensure privacy, data collected from these sources were only accessed through the organization's internal network, on private, secure, organization-owned computers. Data were aggregated and de-identified prior to its export for use in this project. All exported demographic data were prepared and approved by the organization's director of quality management in order to guarantee patient confidentiality.

In order to address the second and third aims of this project (identifying the causes of therapeutic inertia and recommendations for change), individual, semi-structured, voice-recorded

interviews with primary care providers were conducted at the Seattle-based FQHC described above. Interviews took place from March 1-25, 2023. Eligible participants were medical doctors, doctors of osteopathic medicine, nurse practitioners, and physician assistants employed through the organization's medical primary care clinics and who treat at least five adult patients with T2DM. The desired sample size for this project was at least 10 participants. Participants were recruited from February 14-28, 2023 through a non-random, purposive sampling method in which the investigator reached out to eligible participants through the organization's internal email system. The email invitation included basic information about the purpose of the project, the voluntary nature of participation, and a link to schedule a 30-minute interview within the date range at a time of the participant's choosing. The investigator offered 30-minute interview time slots from 08:00-18:00 every Monday through Saturday during the interview date range.

Seven eligible providers voluntarily agreed to participate in this project. The principal investigator conducted all seven interviews. Three interviews were conducted in person and four interviews were conducted over the phone (based on provider availability and preference). Participating providers were emailed an informed consent document three days prior to their scheduled interview. Verbal informed consent was obtained from all seven providers at the beginning of each interview; additionally, signed informed consent documents were collected from the three providers who chose to interview in person. Signed documents were stored in a locked filing cabinet that was only accessible to the principal investigator.

Interviews lasted 19-39 minutes, with a median interview duration of 28 minutes. The development of interview questions was informed by feedback from both the implementation site's medical director and the supervisor of the organization's nutriton and diabetes care and education team. To maintain the confidentiality of participants, no direct or indirect identifiers

were collected or recorded. Voice recordings of each interview were stored on a private, secured computer that was only accessible to the principal investigator.

Following a semi-structured interview format, participants were asked the same questions in the same order but were allowed to expand/digress from the question in order to capture as much relevant information as possible. Interview questions were open-ended for this same purpose. In order to maximize the reliability of the data, questions were clear and unambiguous, yes/no questions and leading questions were avoided, and participants were given time to completely answer a question before progressing to the next question. For reference, a copy of the investigator's interview guide has been included at the end of this document (Appendix A).

Raw interview data was analyzed qualitatively during the month of April 2023. First, recorded interviews were transcribed using NVivo 12 transcription software. The investigator reviewed each transcription for accuracy and manually corrected errors (such as incorrect transcriptions, typing errors, and incorrect syntax). Cleaned data were then analyzed through the process of inductive coding and thematic analysis. NVivo 12 software was used for data coding, categorization, and theme identification. In order to minimize introduction of bias from thematic analysis, the principal investigator practiced reflexivity (the continual process of acknowledging one's own preconceptions and motivations, while recognizing how they might affect the process and outcomes of the project) throughout the data analysis process. Following the conclusion of data analysis, descriptive statistics were used to visually display trends and identified themes. Results were delivered to the implementation agency in the form of a visual presentation developed and given by the principal investigator.

Results

Data Analysis

Seven primary care providers agreed to participate in this project and were subsequently interviewed individually as described above. Following the completion of interviews, audio recordings were transcribed and cleaned as outlined above, and were then imported into NVivo 12 for further analysis. The first step in the qualitative data analysis process involved becoming familiar with the data by reading through each transcription three times and taking notes on preliminary patterns and trends across the seven interviews.

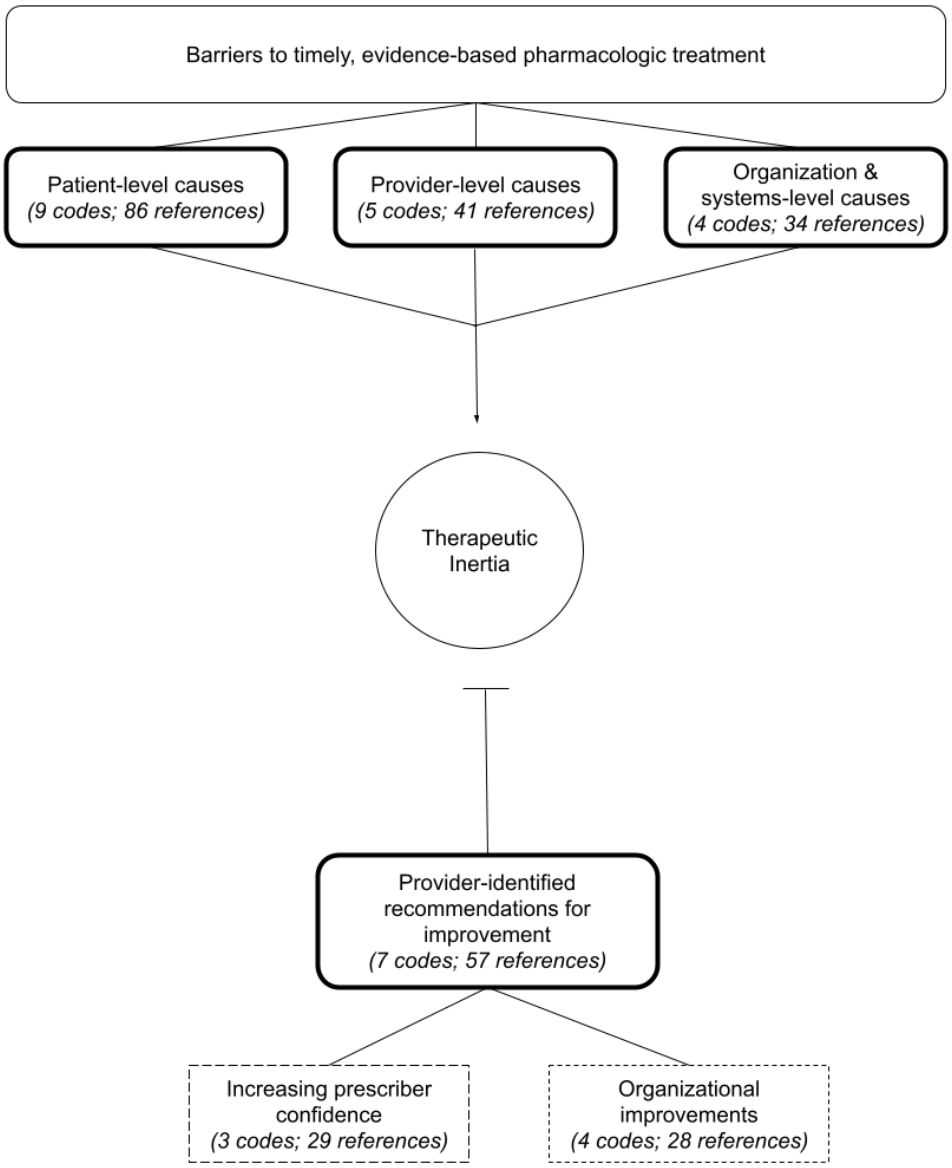
Next, the transcripts were coded inductively. Beginning with the first interview (chronologically), the transcript was separated into six subsections based on corresponding sections of the interview guide: (1) introductory questions; (2) general initial management; (3) initiating medication; (4) treatment intensification; (5) insulin therapy; and (6) wrap-up. Starting with the first subsection ("introductory questions"), the investigator utilized patterns and trends in participant responses to assign codes to the data. Existing codes were then applied to relevant data in subsequent subsections, and new codes were assigned based on emerging patterns and trends in each subsection. This iterative process was repeated until all transcripts were coded. Next, initial codes were reviewed for consistency in interpretation and fidelity of the data to its corresponding code. Codes with similar meanings were combined. This process resulted in 32 distinct codes.

Next, preliminary themes and subthemes were identified based on similarities and differences among codes, the relevance of each code to the aims of this project, frequency of a potential theme within the data, and conceptual distinctness of potential themes. Preliminary themes and subthemes were subsequently reviewed for fidelity to corresponding codes/reference

data. As a result, codes were categorized into four themes and two subthemes which are displayed in Figure 1 below.

Figure 1

Identified Themes and Subthemes Related to Therapeutic Inertia



Note. This diagram shows the relationship between identified themes and subthemes to the topic of therapeutic inertia. Themes are outlined with bolded borders; subthemes are outlined with dashed borders. Each theme and subtheme contain its corresponding number of codes and references from source interview data.

Project Results

Aim 1: Identification of Demographic Trends Associated with Prolonged Hyperglycemia

Aggregated, deidentified patient data was collected through reports from the organization's electronic health record and from an internal data visualization tool. Collected data was current through April 30, 2023. According to these reports, there were 4076 adult patients with T2DM who were seen in the organization's primary care department over the preceding 12 months. Of those patients, 18% had a most recent A1c >9%, and 12.4% had a most recent A1c 8-9%. Seven percent of these patients had no A1c level on file in the 12-month reporting period, and 32% had no A1c monitoring in at least 6 months.

Demographics that were available for review in the same timeframe included race/ethnicity; insurance coverage; housing status; and age. Reports were generated based on each demographic for patients with a most recent A1c >9%. These results are displayed in Table 1 below. Note that Native Hawaiian and Alaska Native were excluded from racial/ethnic data based on low sample size (n= 5 or less).

Table 1

Proportion of Patients With T2DM with A1c >9% By Demographic

Demographic	Proportion (%)
Race/Ethnicity	

American Indian	31%
Latinx	33%
Pacific Islander	33%
Black	30%
White	28%
Asian	22%
Level of Insurance	
Insured	28%
Uninsured	42%
Housing Status	
Homeless	42%
Not homeless	27%
Age	
Age <45	39%
Age >45	27%

Note. Percentages reflect the proportion of all patients with T2DM with an A1c level >9% in the past 12 months. Data were generated based on available patient demographics; this is not a comprehensive sample. Sample size varies based on demographic.

Aim 2: Identification of Common Causes of Therapeutic Inertia

The second aim of this project was to identify commonly cited causes of therapeutic inertia from the perspective of PCPs at the level of the patient, the provider, and overhead systems. There are three themes that contain results relevant to this aim: barriers to timely, evidence-based pharmacologic treatment at the (1) patient level; (2) provider level; and (3) systems-level. For clarity, results are subsequently reported according to theme.

Patient-Level Barriers. This theme consists of nine codes and 86 references from across the seven provider interviews. Providers identified a total of nine causes of therapeutic inertia at the level of the patient, including: cost; lack of understanding of the disease process; fear of/resistance to injection; medication side effects; low health literacy; stigma; time

commitment/competing priorities; self-management burnout; and pill burden. A breakdown of the frequency of patient-level barriers is provided in Table 2.

Table 2

Patient-Level Barriers By Frequency of Reference

Barrier	Frequency (%)
Cost	17.2%
Lack of understanding of disease process	17.2%
Fear/resistance to injection	16.4%
Medication side effects	11.2%
Low health literacy	10.3%
Stigma	10.3%
Time commitments/competing priorities	9.5%
Self management burnout	4.3%
Pill burden	3.4%

Note. Percentages were calculated based on the number of references to each individual barrier over the total number of references for all barriers.

Patients' low health literacy and lack of understanding of the progressive nature of T2DM, including the need for medical therapy to change over time, were identified as significant barriers to initiating and intensifying medication for both newly-diagnosed patients and those with an established diagnosis. Four providers explained that because the onset of T2DM is often slow, many patients are well-compensated at the time of diagnosis and therefore may feel asymptomatic which renders them reluctant to begin medication. One provider explained:

> The thing that I encounter the most, I think, is skepticism. Because, you know, they come in with an A1C of like 12, but they felt fine for years and years because their body's

> learned to. And they're like 40, so they haven't had all the significant side effects yet. But yeah, that's the biggest one, really.

Similarly, providers discussed patients' overconfidence in lifestyle modifications; not understanding the need for diabetes-only visits; or believing that medications are only temporary. One provider stated:

> Sometimes it's "my refill ran out." And the reason it might have run out is because they needed to come in for an appointment, but they don't make that connect. So it's just "you didn't give me more." You know, like not getting that they were supposed to have been coming back on a regular basis, and we're supposed to be monitoring, and just it suddenly ran out. And they don't understand. That's kind of the majority of them.

All seven providers identified cost as a patient-level barrier to initiating and intensifying medical therapy, particularly for newer antidiabetic agents such as glucagon-like peptide-1 receptor agonists (GLP-1 RAs) and sodium-glucose co-transporter-2 inhibitors (SGLT2Is).

Six providers identified medication side effects as a cause of nonadherence to prescribed medication regimens. Specific side effects that were mentioned included diarrhea with metformin; nausea and injection site reactions with GLP-1 RAs; urinary tract infections, vulvovaginal yeast infections, balanitis, and hyperkalemia with SGLT2Is; and hypoglycemia with sulfonylureas and insulin. Four providers discussed pill burden as a patient-level barrier to treatment intensification, including additional medications, medication bottles, and associated costs.

Five providers discussed patients' time commitments and competing priorities as causes of therapeutic inertia. Providers explained that many of their patients work multiple jobs and take

care of families; therefore, they are often unable to commit to the many appointments needed for optimal diabetes management – particularly for newly-diagnosed patients. One provider explained this barrier in the context of patients learning how to self-inject:

> The extra appointment is a barrier. Especially from the nursing side here, it's been easier if they say, "go to the pharmacy, pick it up and then come back and have it on you so we can do your first injection." But a lot of times they've got to go to work, they've got to go pick up a kid, and so we lost that momentum. So getting them to get their prescription and then make the appointment is another one, right? Like it's multiple pieces. It's a lot of time, it's a lot of appointments.

Stigma, fear, and psychological resistance to injection were identified by all seven providers as patient-level barriers to insulin initiation. One provider explained:

> I feel like another barrier will sometimes be that they had a friend or a family member who had insulin and died, or that they had that medicine and had side effects, or it didn't work for them, or just kind of information from other sources which competes with the information I have. I feel like sometimes also it's just that "if I'm taking insulin or I'm taking an injection, then I'm really diabetic" versus "I'm just taking this pill. It's no big deal."

Provider-Level Barriers. This theme consists of 5 codes and 41 references from across the seven provider interviews. Providers identified five causes of therapeutic inertia at the level of the provider: lack of confidence prescribing newer antidiabetic agents; prescribing sulfonylureas long-term; time constraints and competing priorities; lack of confidence initiating

or managing insulin; and failure to set or maintain clear glycemic targets. A breakdown of the frequency of provider-level barriers is provided in Table 3.

Table 3

Provider-Level Barriers By Frequency of Reference

Barrier	Frequency (%)
Lack of confidence prescribing newer agents	41.5%
Inappropriate sulfonylurea use	22%
Time constraints/competing priorities	19.5%
Lack of confidence initiating/managing insulin	9.8%
Failure to set clear glycemic targets	7.3%

Note. Percentages were calculated based on the number of references to each individual barrier over the total number of references for all barriers.

In discussion of the provider's process for setting glycemic targets with patients, three providers described rarely setting or maintaining these goals. One provider explained: "I'll cover it a little bit. Often I'll have a nurse try to talk to them, especially if I can get them on that same day. Otherwise, it's kind of piecemeal." Another provider stated:

> Many of my patients seem to have been diabetic for so long, so I will admit that sometimes I kind of -- I think that I can fall into the trap of making an assumption that they know what their goal is.

In terms of initiating and intensifying pharmacologic therapy, the most commonly cited cause of therapeutic inertia at the provider level was lack of confidence prescribing newer antidiabetic agents such as GLP-1 RAs or SGLT2Is. One provider explained:

> The newer agents came in like in the last few years, so I haven't had a ton of education on them. I think part of it is just like, I've been doing this for like 20 years now, and they're just not as natural for me to jump into. So I always have to kind of rethink and figure out like which ones I can use together. So it is a bit of a barrier, and I feel like it should be easier. It's just hard.

Similarly, four providers described having a lack of confidence with initiating and managing insulin. Three providers described the need for more education and experience prescribing insulin, while one provider expressed the desire for a more standardized dosing, titration, and follow-up schedule.

Four providers described challenges with patients' long-term use of sulfonylureas as a barrier to more appropriate T2DM medical management. One provider explained:

> A lot of patients are on a sulfonylurea. And even if they've gone on insulin, I find they don't really want to get rid of it sometimes, even though I've explained it to them. So yeah, though they're not really the first choice, I do prescribe them more frequently than I would think I should. Because that's what the patients want me to do.

Providers' time constraints and competing priorities were also frequently mentioned as a barrier to optimal T2DM management. Three providers described having difficulty getting patients to focus exclusively on diabetes during diabetes-only visits. For example:

> Like, as a provider, we have so little time. And it's never just diabetes, right? It's like six problems in 15 minutes. That's just the part. I prioritize that, but they're on like the foot pain or whatever, right? I think somehow we need to help patients figure out that like one appointment for one chronic disease is actually necessary. Because, you know, whether

it's time of appointment or cost of copays, whatever it is, they don't understand to come in just for the diabetes.

Three providers also expressed that they lacked time to sufficiently educate a patient with T2DM – particularly someone with a new diagnosis – about complex topics such as the progressive nature of T2DM, self-monitoring of blood glucose, or medication benefits and side effects.

Organization & Systems-Level Barriers. This theme consists of four codes and 34 references from the seven provider interviews. Providers identified three causes of therapeutic inertia at the organization & systems level: insurance & formulary restrictions (53.6%); varying access to the determinants of health (28.6%); and decreased access to certified diabetes care and education specialists (CDCES; 17.9%).

Four providers mentioned decreased patient access to CDCES as a significant barrier to optimal patient education. Because providers typically rely heavily on clinic-employed nurses and CDCES for detailed T2DM self-management education, decreased access to these resources often translates to a delay in patients receiving crucial education on self-monitoring and self-management techniques, which in turn delays indicated treatment intensification. One provider explained, “I mean, we're down a diabetic specialist, so to get in for a patient to have an appointment can sometimes be a month or so out. And especially with newly-diagnosed patients, that can be really hard.”

Four providers cited patients’ varying access to the determinants of health as a barrier to optimal T2DM medical management. Lack of health insurance, homelessness, low socioeconomic status, lack of access to fresh/high quality food, and lack of reliable

transportation were all mentioned as systemic contributors to therapeutic inertia in T2DM. One provider explained:

> I had a patient recently, actually, who mentioned that he's homeless and doesn't have a place to keep it – the insulin – to keep it cold. He also told me he has no place to put his bottles because everything's in storage. So like just physical space to keep some of these things. And then, you know, the other part of that is – if they're homeless – is food access. Whether they're even eating, or if they are, then the quality of food they're getting. Which then makes them need more insulin.

Insurance coverage and formulary restrictions were the most frequently mentioned systems-level barrier to optimal T2DM medical management. Five providers identified a lack of transparency/accuracy in formulary options when attempting to prescribe antidiabetic medications as a significant contributor to therapeutic inertia. As one provider explained:

> There can be a large disconnect, and especially with the formulary changes – like when they're changed from glargine over to like detemir – a lot of times the connect doesn't happen. It got changed, and they don't always get it. Or they do, and they don't like it. That's another reason that they'll self-discontinue. If they didn't like the one they were moved to and they didn't know why it was moved to a different one. And for some of them, it's gone back and forth a couple of times. And it seems there's easier ways, but you have to follow the formulary, right?

Aim 3: Identify Resources to Reduce Therapeutic Inertia

The third aim of this project was to identify specific resources or skills that PCPs feel are needed to reduce the incidence of therapeutic inertia. Results relevant to this aim are contained

within the theme "provider-identified recommendations for improvement." This theme contains 7 codes with a total of 57 references from the seven provider interviews. There are two subthemes within this parent theme: (1) increasing prescriber confidence, and (2) proposed organizational improvements. For clarity, results are subsequently reported by subtheme.

Increasing Prescriber Confidence. All seven providers endorsed varying degrees of lack of confidence prescribing newer antidiabetic agents, such as GLP-1 RAs and SGLT2Is. When asked to identify what would increase confidence prescribing these agents, four providers expressed a desire for more education on these medications. Specifically, providers requested free/easy access to continuing education modules and case studies; having more opportunities to collaborate with the interprofessional care team (e.g. CDCES, behavioral health specialists, case managers, and social workers); having access to more practice devices in order to better understand the various mechanisms; and having clearer guidelines regarding use of these medications in patients with common comorbidities (such as chronic kidney disease). One provider explained:

> I think continuing to have like, CME or more case discussions with our diabetes educators would be really helpful. We used to do, like, "Diabetes Day." We used to have meetings with our most challenging diabetes patients where we'd meet with the provider, the diabetes educator, a social worker, and behavioral health. And they took that away, obviously. But that would be huge. Like if we could get that back and do it, even if it's once every three months, it would make a big, big difference.

Three providers felt that they were already well-educated and prepared to prescribe newer antidiabetic agents, but they required more time and experience to feel confident making these prescriptive choices. One provider explained:

> It's literally just time. It's understanding cost, it's understanding... I feel like I'm still a little bit weak on the counseling. And I have to sometimes look up dosing. I also just feel like I'm still learning from my patients exactly how it feels to be on these medicines. So that's what's holding me back.

Five out of seven providers also expressed a lack of confidence initiating and managing insulin. Two providers felt they could benefit from further education regarding how to appropriately prescribe insulin. Two different providers felt that time and experience would increase their confidence. As one provider stated:

> It's just time. I feel like with insulin comes a lot of nuanced feedback from patients – like whether they're eating, how often they're checking their sugars. And, you know, getting good information back on when they're getting their lows, when they're getting their highs, are they checking their sugars every day, etc.

Four providers felt that increased clarity/accuracy with medication formulary would result in fewer delays for patients starting medications. One provider stated:

> I think troubleshooting some of the pharmacy issues – because it can really ping pong back and forth when you're starting these agents and then the patient goes to the pharmacy and either it's not covered or the co-pay is too high; those are kind of barriers. So if there's a way to make that easier, that would be helpful.

Proposed Organizational Changes. Providers recommended a variety of potential organizational changes in order to reduce the future incidence of therapeutic inertia in the management of T2DM. Two providers suggested bringing back semi-regular interprofessional meetings in order to increase outreach to patients from multiple touchpoints:

> At one point we got, like every three months we got a printout of all our diabetic patients - each of us. And we had meetings upstairs that would be like the dietitian and all the providers. You know, it was kind of helpful to see the list of all the patients because it trained us to target those ones that needed the most help.

Another common recommendation was for clinic-sponsored group activities focused on lifestyle modifications such as healthy diet and regular exercise. Two providers recommended hosting a cooking class for patients with T2DM. One provider explained:

> Cooking classes, to encourage and teach patients things that they really just don't know. And, you know, sometimes I'm telling a patient like "a cup of rice." And they need to see a cup of rice. I don't have the resources to show them what a cup of rice looks like or how to cook something else that doesn't have sugar. So I think those lifestyle management pieces, I think we miss a lot on that. Like we say how important it is, but we don't have the resources to really hone in on that.

A third provider recommended hosting group visits for T2DM patients in order to encourage community connections:

> I know in the past we used to do group visits for diabetes. I think that was very helpful. So I think doing those where we get together – you know, we might get a group of Vietnamese patients with diabetes and we'd have an interpreter and just kind of go over things as a group visit. And so I think that was helpful.

Finally, four providers felt that increased patient access to CDCES would reduce therapeutic inertia by improving patients' ability to self-monitor and self-manage their disease. One provider stated:

> I will try to get patients to see a diabetes educator, although their access has been... it used to be better. And it's really been down. So by the time patients get to them, it's already been months. We could definitely use more support in that department.

Another provider similarly stated: “Our diabetic educator right now is booking out six-to-eight weeks. I would like another diabetic educator. I think that would really help our patients.”

Discussion

This project helps illuminate the multifactorial risk factors and causes of therapeutic inertia in the pharmacologic treatment of adult patients with T2DM from the perspective of primary care providers in an urban community health setting. Specific recommendations for quality improvement strategies are provided based on project findings. Results from this project can be used to develop and prioritize quality improvement initiatives to overcome therapeutic inertia in community health.

1. Risk for Therapeutic Inertia

According to the ADA (n.d.), patients are considered to be at high-risk for therapeutic inertia if they have not had an A1c level in 6 or more months, or if their most recent A1c level was greater than 9%. Based on this definition, the following demographics were found to be associated with high risk for therapeutic inertia: being less than 45 years old; having no medical insurance; experiencing homelessness; and being from American Indian, Pacific Islander, or Latinx descent. Individuals from Asian or white backgrounds, as well as those with housing and medical insurance, were least likely to have an A1c >9%. These results agree with those in recent literature (CDC, 2022; Cunningham et al., 2018; Han et al., 2019; Leung et al., 2016). These findings should be disseminated to members of this FQHC’s diabetes care team (e.g., PCPs,

nurses, diabetes educators) to facilitate the prompt recognition of high-risk patients. Identification and monitoring high-risk patients allows for increased care planning and outreach.

2. Causes of Therapeutic Inertia

Patient-level Causes. This project identified nine patient-level causes of therapeutic inertia, six of which are consistent with literature findings: cost and availability of medications; limited understanding of the progressive nature of T2DM and need for treatment to change over time; medication side effects; fear and anxiety around self-injection; stigma, particularly related to insulin; and frustration/burnout from self-management burden and/or lack of progress. Project results suggest that prohibitive medication costs, limited understanding of the progressive nature of T2DM, and psychological resistance to insulin are the three most significant patient-level causes of therapeutic inertia at this FQHC.

Importantly, this FQHC primarily serves populations that are classically underserved. As such, many patients may have an inherent mistrust of the healthcare system, as well as a poor understanding of how to navigate complex healthcare and insurance systems. There may also be a significant social/emotional disconnect between providers and the patients they serve (Angier et al., 2019; Han et al., 2019). Further, disparities and adversities that patients endure may create additional challenges to understanding the course of T2DM and the role of medical therapy (Han et al., 2019). These factors suggest that building trust in the provider-patient relationship may be particularly important for overcoming therapeutic inertia in the community health setting.

Psychological resistance – including fear, anxiety, and stigma – was identified both by this project and by recent literature as a significant barrier to insulin initiation (Karam et al., 2020; Khunti et al., 2019; Polonsky et al., 2017). Patients commonly cite fear of needles, anxiety

over self-injection, lack of confidence with self-monitoring, and stigmatic anecdotes as reasons for being resistant to begin using insulin (Karam et al., 2020; Khunti et al., 2019; Polonsky et al., 2017). Additionally, although feelings of personal guilt or failure may be present at any step of the treatment pathway, these emotions appear to be particularly prevalent when insulin is first recommended (Karam et al., 2020; Khunti et al., 2019; Polonsky et al., 2017). Evidence shows that the most significant delay in treatment intensification occurs when there is an indication for insulin initiation (Khunti et al., 2017; Polonsky et al., 2017). These factors indicate that initiatives aimed at reducing patients' psychological resistance to insulin may be among the most impactful in reducing therapeutic inertia.

There were three patient-level causes identified by this project that were not explicitly identified as patient-level causes in the literature: (1) low health literacy; (2) patient's competing priorities; and (3) pill burden. Because this project was based on interviews with primary care providers in community health clinics, it's possible that these results may indicate new knowledge of these barriers in this particular setting. However, there is evidence in recent literature to support that providers commonly have a perception that patients will not be amenable or adherent to medication changes, and that providers tend to underestimate the ability of patients to self-manage their disease (Edelman et al., 2020; Karam et al., 2020; Khunti et al., 2019; Polonsky et al., 2017). As such, it is possible that these results actually reflect provider-level barriers rather than patient-level barriers.

Provider-Level Causes. According to Khunti et al. (2019), provider-level causes are the most significant contributors to therapeutic inertia, accounting for approximately 50% of the overall therapeutic inertia burden. This suggests that quality improvement initiatives targeted at the provider level may have the largest impact in overcoming therapeutic inertia. There were five

provider-level causes of therapeutic inertia identified by this project; four of which are supported in the literature: provider time constraints and competing priorities; failure to set and maintain clear glycemic targets; lack of confidence prescribing or managing insulin; and lack of confidence prescribing newer T2DM agents.

According to recent literature, time constraints and competing demands during primary care visits are the most commonly reported provider-level barriers to timely treatment intensification (Karam et al., 2020; Khunti et al., 2019; Polonsky et al., 2017; Powell et al., 2021; Wrzal et al., 2021). This includes patients redirecting "diabetes-only" visits toward alternative clinical concerns, which decreases the already limited time that providers have for effective T2DM care (Karam et al., 2020). Providers who participated in this project frequently endorsed similar concerns around lack of time for proper T2DM patient education; competing priorities based on patient comorbidities/complexity; and difficulty getting patients to focus on T2DM during diabetes-only visits. These results suggest that quality improvement initiatives should include efforts to reduce provider time burdens (likely through more effective interdisciplinary T2DM management).

Current clinical practice guidelines recommend that providers set clear glycemic targets with patients, and subsequently titrate medical therapy as needed to reach those targets (ADA, 2022). Consequently, a failure to set and use glycemic targets to initiate, evaluate, or intensify treatment results in therapeutic inertia and prolonged hyperglycemia (ADA, 2022). Although all providers in this project endorsed a "treat to target" approach to T2DM medical management, three of the seven providers felt that their patients were not aware of their glycemic targets. Patients who are not aware of their targets are less likely to understand the indication for both initial medication and subsequent intensification, rendering them less likely to agree and adhere

to prescribed regimens (ADA, 2022). This represents an opportunity for provider education and resetting expectations around appropriate T2DM care.

Another significant provider-level barrier identified in the literature is lack of knowledge, experience, or confidence prescribing and managing T2DM medications – particularly insulin (Karam et al., 2020; Khunti et al., 2019; Polonsky et al., 2017; Powell et al., 2021; Wrzal et al., 2021). This barrier has been attributed to provider overconfidence in adherence to clinical guidelines, lack of awareness of guideline changes causing a delay in adoption of new guidelines, variance in guideline recommendations, and lack of familiarity or inexperience prescribing T2DM medications (Karam et al., 2020; Khunti et al., 2019; Polonsky et al., 2017; Powell et al., 2021; Wrzal et al., 2021). In this project, providers endorsed an understanding of current clinical practice guidelines, yet a lack of education and experience prescribing newer T2DM agents. This indicates that guideline awareness alone may not be sufficient for providers to feel comfortable and confident changing their prescribing habits.

In addition to the provider-level causes already described, this project also identified the long-term use of sulfonylurea medications as a cause of therapeutic inertia. Specifically, providers reported that patients were frequently unwilling to discontinue sulfonylurea use despite the availability of more appropriate oral medications, and even upon insulin initiation. In the literature, sulfonylureas are not recommended for long-term use given that their effectiveness appears to wane over time (Viberti et al., 2002). Guidelines also recommend avoiding use of sulfonylureas with concomitant insulin therapy based on increased risk for hypoglycemia (ADA, 2022). Despite this evidence, this particular barrier has not been explicitly linked to therapeutic inertia in the literature. It is therefore possible that this may represent an opportunity for further

investigation. However, it is also possible that this barrier could be addressed by improvements in patient education, shared decision-making, and strength of the provider-patient relationship.

Systems-Level Causes. This project identified three causes of therapeutic inertia at the systems level: (1) insurance & formulary restrictions; (2) decreased access to CDCES; and (3) variable access to the determinants of health. All three of these barriers have also been identified in recent literature. Of these barriers, "insurance & formulary restrictions" was most frequently mentioned by providers who participated in this project. Preferred medications vary based on insurance coverage. This information tends to change frequently, and these changes do not always carry over into the electronic prescribing system. Furthermore, "non-medical switching" (NMS) adds a layer of difficulty to patients receiving and adhering to their medications. According to Karam et al. (2020), NMS describes "the change in a patient's prescribed medication to an alternative (not a generic) medication for reasons related to price, insurance coverage, formulary changes, and other administrative reasons." Patients may not understand why their medication was switched to an alternative option and may experience side effects or suboptimal responses based on these changes (Karam et al., 2020; Khunti et al., 2019; Powell et al., 2021; Wrzal et al., 2021). As a result, patients may choose to stop taking the new medication altogether (Karam et al., 2020; Khunti et al., 2019; Powell et al., 2021; Wrzal et al., 2021).

Decreased access to CDCES was another frequently mentioned barrier to evidence-based T2DM treatment. Nationally, the demand for diabetes self-management education and support (DSMES) exceeds supply – particularly in metropolitan areas where the concentration of people with diabetes is higher (Karam et al., 2020). Moreover, patients with T2DM may not be aware of these services, may have inadequate insurance coverage, or may be unable/unwilling to devote the necessary time to these programs (Karam et al., 2020). For this project, more than half of the

participating providers described a desire for more CDCES within the organization. Providers explained that patients routinely wait more than a month for an initial appointment with a member of the CDCES team, meaning that self-monitoring (and therefore medication titration) is also delayed.

According to the U.S. Department of Health and Human Services (DHHS, n.d.), each person's unique access to the social determinants of health (SDOH) profoundly impacts their health status, as well as their ability to interact with/navigate the healthcare system (DHHS, n.d.). There were several pertinent examples of this mentioned by providers in this project. First, individuals with low socioeconomic status and limited access or time to prepare fresh, healthy food may find it difficult or impossible to make the recommended dietary modifications for optimal T2DM management. Similarly, unhoused patients may not have the ability to safely store their insulin or GLP-1 RA medications. Patients who work one or more full-time jobs during business hours may find it difficult to come to the clinic with competing work or family related responsibilities. Likewise, patients without reliable transportation may face additional challenges attending in-person appointments. Because these factors have been shown to contribute to therapeutic inertia, clinicians should consider each patient's unique SDOH profile in the shared decision-making process for setting glycemic targets and choosing medications (Karam et al., 2020; Khunti et al., 2019; Powell et al., 2021; Wrzal et al., 2021).

3. Recommendations for Overcoming Therapeutic Inertia

According to the principles of the SEMH, identification of the causes of therapeutic inertia enables the facilitation of strategies to reduce its occurrence (ATSDR, 2015). Recommendations for overcoming therapeutic inertia should be directed at each hierarchical level (patient, provider, and systems) based on corresponding causes (ATSDR, 2015).

Patient-Level Recommendations. The results of this project suggest that patient-level interventions should focus on empowering patients to become better self-managers, reducing psychological resistance to insulin, and reducing medication costs. Literature shows that educated patients are empowered patients: early and frequent patient education regarding the progressive T2DM disease course and the role that insulin plays in glucose management teaches patients to expect treatment intensification over time without internalizing feelings of failure (ADA, n.d.). This is associated with increased buy-in and improved ability to self-manage T2DM (ADA, n.d.). Empowered patients are also better prepared to self-manage insulin. A 2019 systematic review and meta-analysis found that teaching patients to titrate their own insulin using a simple algorithm resulted in significantly greater A1c reductions compared to physician-led titration (Khunti et al., 2019). Improving patient access to mental/behavioral health specialists also appears to be an effective measure for overcoming fear and anxiety related to T2DM treatment, particularly in patients who are nonadherent to prescribed regimens, and for patients who are starting insulin and GLP-1 RA self-injection therapy (ADA, n.d.; Khunti et al., 2019).

In addition to the above measures, evidence shows that interventions that incorporated technology into care management strategies (e.g., reminder-recall systems; telehealth-based blood glucose monitoring; self-management education through text messaging and mobile apps) resulted in significantly greater A1c reductions compared to those without a technological component (Khunti et al., 2019). Thus, the most effective quality improvement initiatives should include technological components that increase the frequency of communication with patients and prevent delays in medication titration. Given that this project was implemented at a

federally-qualified health center, patient access to technological resources is likely variable. Therefore, this strategy may not be the most impactful in this particular setting.

Provider-Level Recommendations. Given that provider-level causes comprise approximately 50% of therapeutic inertia, provider-level interventions may be most impactful for overcoming therapeutic inertia (Khunti et al., 2019). Results of this project suggest that provider-level quality improvement initiatives should include education regarding glycemic targets, education and decision-making aids for newer antidiabetic medications and insulin, and efforts to reduce providers' time commitments and competing priorities.

Avoiding therapeutic inertia in T2DM begins with setting clear glycemic goals with patients, and then using those goals to guide therapeutic choices (ADA, n.d.; ADA, 2022; Khunti et al., 2019; Powell et al., 2021). Based on the results of this project, the organization should consider: (1) resetting this expectation with providers; and (2) investing in training providers about the shared decision-making process, specifically as it relates to setting glycemic targets. Shared decision-making allows patients the chance to be equal partners in their care; it gives patients the opportunity to verbalize their needs based on their unique circumstances; and it facilitates trust-building in the provider-patient relationship (Serrano et al., 2016). Evidence shows that patients respond better when they believe they are contributing to a positive outcome, therefore, shared decision-making may be especially important (Polonsky & Henry, 2016).

Because early glycemic control is critical for optimization of long-term health outcomes, providers should set clear follow-up timelines and engage interdisciplinary team members such as nurses and CDCES in patient education (ADA, n.d.; Khunti et al., 2019; Powell et al., 2021). It is recommended that the care team educate patients early and often about the progressive nature of T2DM and the need for treatment to change and intensify over time (ADA, n.d., Khunti

et al., 2019; Powell et al., 2021). Early, routine discussion of insulin's role in normal glucose metabolism may assuage patients' feelings of anxiety and resistance in the case that insulin eventually becomes necessary (ADA, n.d., Khunti et al., 2019; Polonsky et al., 2017).

Interdisciplinary collaboration appears to be a key strategy in mitigating therapeutic inertia: a 2021 systematic review and meta-analysis found that the most effective care management interventions were those that empowered non-physician team members to provide in-depth patient education and to independently initiate and intensify medications based on current guidelines (Powell et al., 2021). This process increases the frequency of outreach to patients during critical titration periods, and allows patients more opportunities to ask questions and become better self-managers (Khunti et al., 2019; Powell et al., 2021). Reliance on non-physician team members for patient outreach also reduces providers' care burden, allowing providers more time to focus on competing priorities. To facilitate independent T2DM management by the nurse team, it is recommended that titration algorithms and/or decision-making aids be built into the electronic health system (ADA, n.d.; Khunti et al., 2019). For this strategy to be effective, the organization would first need a fully-staffed team of nurses and diabetes educators who were prepared to independently manage T2DM medications. This was identified as a barrier by providers who participated in this project, and thus would likely be a logical first step toward sustainable change.

Frequent follow-up is crucial in effective T2DM care. In order to avoid therapeutic inertia, it is recommended that providers schedule "diabetes only" visits with patients as often as necessary for patients to meet their glycemic targets (ADA, n.d.). Specifically, patients with an A1c 9% or above should be seen in 6-8 weeks; those with an A1c 7.1-8.9% should be seen in 2-3 months; and those with an A1c 7 or below (or are otherwise at goal) should be seen in 3-6

months (ADA, 2022). In order to address the anxiety and depression that can complicate and delay T2DM treatment, providers should regularly screen patients for social/emotional barriers to care, and be prepared to recommend referrals or community support services as appropriate (ADA, n.d.; Khunti et al., 2019; Powell et al., 2021).

Finally, the organization should consider providing clinicians with easy access to free education modules, case studies, and simulated scenarios regarding T2DM medications to increase prescriber confidence (ADA, n.d.). Based on the results of this project, the most impactful modules would be focused on appropriately prescribing newer antidiabetic agents (such as GLP-1 RAs and SGLT2Is) as well as initiating and managing the various types of insulin.

Systems-Level Recommendations. Results of this project suggest that systems-level interventions should focus on identifying, monitoring, and increasing outreach to patients at high-risk for therapeutic inertia; increasing access to diabetes educators; addressing disparities in the social determinants of health; and addressing the insurance and formulary restrictions that complicate the process of both prescribing and receiving medications.

First, high-risk patients (e.g., A1c >9%; no A1c check in the last 6-12 months; patients from previously described high-risk demographics) should be identified from within the patient database (ADA, n.d.). These patient registries should be shared with their corresponding interdisciplinary T2DM care teams, including providers, nurses, diabetes educators, behavioral health specialists, and social workers. Care teams should meet regularly to plan outreach to these patients from multiple touchpoints. Interdisciplinary engagement with high-risk patients creates opportunities for therapeutic inertia to be avoided (ADA, n.d.). An additional metric that the organization should consider monitoring is the time from diagnosis to glycemic control,

recognizing that early glycemic control (i.e., within 6-12 months of diagnosis) is critical for optimization of long-term health outcomes (ADA, n.d.; Khunti et al., 2019; Powell et al., 2021).

As previously mentioned, the organization should make a concerted effort to fully staff interdisciplinary teams (such as nurses, diabetes educators, social workers, and behavioral health specialists) to enable success of the aforementioned interventions. A fully-staffed team of diabetes educators may be particularly important, as diabetes educators are critical for patients to become empowered self-managers (ADA, n.d.). Given the importance of diabetes educators, the organization should ensure that patients are seen by a diabetes educator under the following ADA-recommended circumstances: (1) at the time of diagnosis; (2) annually; (3) when complicating life factors develop; and (4) when transitions in life occur (ADA, 2022).

Addressing disparities in the SDOH and restrictions in insurance and formulary are important topics that are outside the scope of this project. These topics should be addressed in future systems-level investigations and quality improvement initiatives.

Conclusions & Implications for Advanced Practice Nursing

Type 2 diabetes mellitus is a prevalent chronic condition that increases morbidity, mortality, and healthcare costs for affected patients (ADA, 2018; CDC, 2018; WADOH, 2018). Systemic injustices and differences in access to the social determinants of health have led to low-income individuals and people of color to experience the highest T2DM prevalence and the worst associated outcomes (Cunningham et al., 2018; Han et al., 2019; Leung et al., 2016). Therapeutic inertia is a key reason for prolonged hyperglycemia in T2DM, leading to increased rates of T2DM-related complications and concomitantly increased healthcare costs (Chudasama

et al., 2021; Gabbay et al., 2020; Karam et al., 2020; Khunti et al., 2017; Khunti et al., 2019; Polonsky et al., 2017; Powell et al., 2021; Wrzal et al., 2021).

This project identified causes of therapeutic inertia at the level of the patient, provider, and overhead systems from the perspective of primary care providers at a federally-qualified health center in Seattle, WA. Patient demographic trends associated with increased risk for therapeutic inertia were also identified. Based on these findings, recommendations were provided for future initiatives targeted at overcoming therapeutic inertia in the community health setting.

Results of this project support current literature regarding the multifaceted causes of therapeutic inertia and provide insight into both causes and risk factors for therapeutic inertia specifically in an urban community health setting. These results can be applied to the development and prioritization of quality improvement initiatives targeted at overcoming therapeutic inertia for adult patients with T2DM who receive care at urban community health centers. Such initiatives are essential in order to improve health outcomes for the underserved patient populations that are most affected by T2DM.

Limitations, Lessons Learned, & Future Directions

This project was limited by several factors. First, the results are not generalizable on a large scale because the investigator utilized a non-random sampling method, and because the desired sample size was not met. Next, there is the issue of bias. The use of non-random sampling introduces selection bias. The use of qualitative, individual interviews does not control for participant response bias. In other words, participants may respond to interview questions in ways they perceive to be less harmful or more socially desirable. For example, it's possible that

the reason this project did not identify more provider-level causes of therapeutic inertia is because providers (rather than patients or administrators) were chosen to be interviewed, and they may be less likely to attribute causes to themselves. Qualitative data analysis provided a further opportunity for the introduction of bias: despite the investigator's practice of reflexivity, it is possible that confirmation bias occurred during the data analysis process.

There were also limitations to the patient demographic data that was used for this project. Specifically, racial/ethnic data pertaining to Native Hawaiian and Alaska Native populations were excluded due to low sample size; 348 patients were missing from racial/ethnic data (due to unspecified race/ethnicity); demographic sample sizes were highly variable (ranging from n=32 to n=1094); and no data pertaining to income or education level was available for review.

A final limitation for this project was that the fourth project aim (to compare the prevalence of therapeutic inertia at different steps in the T2DM treatment pathway) was not met. The FQHC that hosted this project does not currently have metrics or reports that track the time to treatment intensification after an above-target A1c. This offers a lesson in more effective project planning, as well as an opportunity for future quality-focused investigation.

Additional opportunities for future directions include quality improvement projects based on the results of this project; further exploration into the effects of the SDOH on therapeutic inertia in diabetes care and initiatives to reduce those effects; and systems-level quality improvement projects focused on reducing formulary restrictions and NMS.

Sustainability Plan

This qualitative research project created a foundation for future quality improvement initiatives to be implemented by this FQHC based on prioritized needs. These initiatives will be

aimed at reducing the prevalence of therapeutic inertia in the pharmacologic treatment of T2DM in the community health setting at the level of the patient, the provider, and/or overhead systems. The results of this project are currently being used to develop a quality improvement DNP project that will be implemented by a DNP student at this FQHC in the first quarter of 2024.

Quality improvement initiatives based on the results of this project are intended to sustainably improve the long-term quality of care and health outcomes for the underserved patient populations that are most affected by T2DM, thereby reducing a prevalent health disparity and improving the equity of community healthcare.

References

Agency for Toxic Substances and Disease Registry. (2015, June 25). *Models and frameworks for the practice of community engagement.* https://www.atsdr.cdc.gov/communityengagement/pce_models.html

American Diabetes Association. (2018). Economic cost of diabetes in the U.S. in 2017. *Diabetes Care, 41*(5): 917-928. https://doi.org/10.2337/dci18-0007

American Diabetes Association (2021). Pharmacologic approaches to glycemic treatment: Standards of medical care in diabetes—2022. *Diabetes Care, 45*(Supplement 1): S125-S143. https://doi.org/10.2337/dc22-S009

American Diabetes Association (2022). Standards of medical care in diabetes—2022 abridged for primary care providers. *Clinical Diabetes, 40*(1): 10-38. https://doi.org/10.2337/cd22-as01

American Diabetes Association (n.d.). *Practice improvement resources.* Overcoming therapeutic inertia. https://www.therapeuticinertia.diabetes.org/practice-improvement-resources

Angier, H., Ezekiel-Herrera, D., & Marino, M. (2019). Racial/ethnic disparities in health insurance and differences in visit type for a population of patients with diabetes after Medicaid expansion. *Journal of Health Care for the Poor and Underserved, 30*(1): 116-130. DOI: 10.1353/hpu.2019.0011

Centers for Disease Control and Prevention. (2021, December 16). *Type 2 diabetes.* Diabetes basics. https://www.cdc.gov/diabetes/basics/type2.html

Centers for Disease Control and Prevention. (2022, March 28). *By the numbers: Diabetes in America.* Advancing health equity. https://www.cdc.gov/diabetes/health-equity/diabetes-by-the-numbers.html

Centers for Disease Control and Prevention. (2022, July 7). *What is diabetes?* Diabetes basics. https://www.cdc.gov/diabetes/basics/diabetes.html#:~:text=Diabetes%20is%20the%20seventh%20leading,diabetes%20has%20more%20than%20doubled

Chudasama, Y.V., Zaccardi, F., Coles, B., Gillies, C.L., Hvid, C., Seidu, S., Davies, M.J., & Khunti, K. (2021). Ethnic, social and multimorbidity disparities in therapeutic inertia: A UK primary care observational study in patients newly diagnosed with type 2 diabetes. *Diabetes, Obesity & Metabolism, 23*(11): 2437-2445. https://doi.org/10.1111/dom.14482

Cunningham, A.T., Crittendon, D.R., White, N., Mills, G.D., Diaz, V., & LaNoue, M.D. (2018). The effect of diabetes self-management education on HbA1c and quality of life in African-Americans: A systematic review and meta-analysis. *BMC Health Services Research, 18*: 367. https://doi.org/10.1186%2Fs12913-018-3186-7

Davies, M.J., Aroda, V.R., Collins, B.S., Gabbay, R.A., Green, J., Maruthur, N.M., Rosas, S.E., Del Prato, S., Mathieu, C., Mingrone, G., Rossing, P., Tankova, T., Tsapas, A., & Buse, J.B. (2022). Management of hyperglycemia in type 2 diabetes, 2022. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care:* dci220034. https://doi.org/10.2337/dci22-0034

Edelman, S.V., Wood, R., Roberts, M., & Shubrook, J.H. (2020). Patients with type 2 diabetes are willing to do more to overcome therapeutic inertia: Results from a double-blind survey. *Clinical Diabetes, 38*(3): 222-229. doi: 10.2337/cd19-0067

Fang, M., Wang, D., Coresh, J., & Selvin, E. (2021). Trends in diabetes treatment and control in U.S. adults, 1999–2018. *The New England Journal of Medicine, 384:* 2219-2228. DOI: 10.1056/NEJMsa2032271

Gabbay, R.A., Kendall, D., Beebe, C., Cuddeback, J., Hobbs, T., Khan, N.D., Leal, S., Miller, E., Novak, L.M., Rajpathak, S.N., Scribner, P., Meneghini, L., & Khunti, K. (2020). Addressing therapeutic inertia in 2020 and beyond: A 3-year initiative of the American Diabetes Association. *Clinical Diabetes, 38*(4): 371-381. https://doi.org/10.2337/cd20-0053

Han, H.R., McKenna, S., Nkimbeng, M., Wilson, P., Rives, S., Ajomagberin, O., Alkawaldeh, M., Grunstra, K., Maruthur, N., & Sharps, P. (2019). A systematic review of community health center based interventions for people with diabetes. *Journal of Community Health, 44*: 1253-1280. https://doi.org/10.1007/s10900-019-00693-y

Hill-Briggs, F., Adler, N.E., Berkowitz, S.A., Chin, M.H., Gary-Webb, T.L., Navas-Acien, A., Thornton, P.L., & Haire-Joshu, D. (2021). Social determinants of health and diabetes: A scientific review. *Diabetes Care, 44*(1): 258-279. https://doi.org/10.2337/dci20-0053

Karam, S.L., Dendy, J., Polu, S., & Blonde, L. (2020). Overview of therapeutic inertia in diabetes: Prevalence, causes, and consequences. *Diabetes Spectrum, 33*(1): 8-15. https://doi.org/10.2337%2Fds19-0029

Kemple, A., Court, B., Xing, J., Bolton, D., Singh, D., McDermot, D., & Stahre, M. (2019, December). *Diabetes data supplement: December 2019.*

Khan, M.A.B., Hashim, M.J., King, J.K., Govender, R.D., Mustafa, H., & Kaabi, J.A. (2020). Epidemiology of type 2 diabetes – Global burden of disease and forecasted trends. *Journal of Epidemiology and Global Health, 10*(1): 107-111. DOI: 10.2991/jegh.k.191028.001

Khunti, K., Gomes, M.B., Pocock, S., Shestakova, M.V., Pintat, S., Fenici, P., Hammar, N., & Medina, J. (2017). Therapeutic inertia in the treatment of hyperglycaemia in patients with type 2 diabetes: A systematic review. *Diabetes, Obesity & Metabolism, 20*(2): 427-437. https://doi.org/10.1111/dom.13088

Khunti, S., Khunti, K., & Seidu, S. (2019). Therapeutic inertia in type 2 diabetes: Prevalence, causes, consequences and methods to overcome inertia. *Therapeutic Advances in Endocrinology and Metabolism, 10*: 2042018819844694. https://doi.org/10.1177%2F2042018819844694

Laiteerapong, N., Ham, S.A., Gao, Y., Moffet, H.H., Liu, J.Y., Huang, E.S., & Karter, A.J. (2018). The legacy effect in type 2 diabetes: Impact of early glycemic control on future complications (the diabetes & aging study). *Diabetes Care, 42*(3): 416-426. https://doi.org/10.2337/dc17-1144

Leung, L.B., Vargas-Bustamante, A., Martinez, A.E., Chen, X., & Rodriguez, H.P. (2016). Disparities in diabetes care quality by English language preference in community health centers. *Health Services Research, 53*(1): 509-531. https://doi.org/10.1111/1475-6773.12590

McKenzie, J.F., Neiger, B.L., & Thackeray, R. (2017). *Planning, implementing, and evaluating health promotion programs: A primer* (7th ed.). Pearson.

Mehta, R.R., Edwards, A.M., Rajpathak, S., Sharma, A., Snow, K.J., & Iglay, K. Effects of conformance to type 2 diabetes guidelines on health care resource utilization, clinical outcomes, and cost: A retrospective claims analysis. *Journal of Clinical & Translational Endocrinology, 19:* 100215. DOI: 10.1016/j.jcte.2020.100215

Neighborcare Health Development Office. (2021). *Report to the community for the year 2021.* https://neighborcare.org/about-us/annual-reports/

Philips, L.S., Branch, W.T., Cook, C.B., Doyle, J.P., El-Kebbi, M., Gallina, D.L., Miller, C.D., Ziemer, D.C., & Barnes, C.S. (2001). Clinical inertia. *Annals of Internal Medicine, 135*(9): 825-834. DOI: 10.7326/0003-4819-135-9-200111060-00012

Polonsky, W.H. & Henry, R.R. (2016). Poor medication adherence in type 2 diabetes: Recognizing the scope of the problem and its key contributors. *Patient Preference and Adherence, 10*: 1299-1307. DOI: 10.2147/PPA.S106821.

Polonsky, W.H., Arsenault, J., Fisher, L., Kushner, P., Miller, E.M., Pearson, T.L., Tracz, M., Harris, S., Hermanns, N., Scholz, B.M., Pollom, R.K., Perez-Nieves, M., Pollom, R.D., & Hadjiyianni, I. (2017). Initiating insulin: How to help people with type 2 diabetes start and continue insulin successfully. *International Journal of Clinical Practice, 71*(8): e12973. https://doi.org/10.1111%2Fijcp.12973

Powell, R.E., Zaccardi, F., Beebe, C., Chen, X.M., Crawford, A., Cuddeback, J., Gabbay, R.A., Kissela, L., Litchman, M.L., Mehta, R., Meneghini, L., Pantalone, K.M., Rajpathak, S., Scribner, P., Skelley, J.W., & Khunti, K. (2021). Strategies for overcoming therapeutic

inertia in type 2 diabetes: A systematic review and meta-analysis. *Diabetes, Obesity & Metabolism, 23*(9): 2137-2154. https://doi.org/10.1111/dom.14455

Selvin, E., Narayan, K.M.V., & Huang, E.S. (2018). Quality of care in people with diabetes. In: C.C. Cowie., S.S. Casagrande, & A. Menke (Eds.), *Diabetes in America* (3rd ed., chapter 41). Bethesda (MD): National Institute of Diabetes and Digestive and Kidney Diseases (US).

Serrano, V., Rodriguez-Gutierrez, R., Hargraves, I., Gionfriddo, M.R., Tamhane, S., & Montori, V.M. (2016). Shared decision-making in the care of individuals with diabetes. *Diabetic Medicine, 33*(6): 742-751. https://doi.org/10.1111/dme.13143

United States Department of Health and Human Services. (n.d.). *Social determinants of health.* Healthy People 2030. https://health.gov/healthypeople/priority-areas/social-determinants-health

Viberti, G., Kahn, S.E., Greene, D.A., Herman, W.H., Zinman, B., Holman, R.R., Haffner, S.M., Levy, D., Lachin, J.M., Berry, R.A., Heise, M.A., Jones, N.P., & Freed, M.I. (2002). A diabetes outcome progression trial (ADOPT): An international multicenter study of the comparative efficacy of rosiglitazone, glyburide, and metformin in recently diagnosed type 2 diabetes. *Diabetes Care, 25*(10): 1737-43. DOI: 10.2337/diacare.25.10.1737.

Washington State Department of Health (2018). *Washington state health assessment.* https://doh.wa.gov/data-statistical-reports/state-health-assessment

Wrzal, P.K., Bunko, A., Myageri, V., Kukaswadia, A., Neish, C.S., & Ivers, N.M. (2021). Strategies to overcome therapeutic inertia in type 2 diabetes mellitus: A scoping review. *Canadian Journal of Diabetes, 45*(3): 273-281. https://doi.org/10.1016/j.jcjd.2020.08.109

Appendix A

Interview Guide

INTRODUCTORY QUESTIONS
How is the management of your adult patients with type 2 diabetes going for you?
Thinking broadly, do you feel that patients with type 2 diabetes generally meet their clinical goals?
GENERAL INITIAL MANAGEMENT
How do you approach a patient with a new diagnosis of type 2 diabetes?
What is your process for setting glycemic targets with patients? • In your experience, what might prevent patients from meeting their targets within their desired timeframe?
You and a patient have agreed on a glycemic target within a specific timeframe. What are your next steps for helping the patient meet their goal?
How frequently do you typically check A1c in patients with type 2 diabetes?
INITIATING MEDICATION
What is your process for choosing an initial medication for newly-diagnosed patients? • Do you use any algorithms or decision-making aids? Which one(s)?
What barriers have you experienced when attempting to initiate medication for newly-diagnosed patients?
On a scale from 1 to 5, where 1 is not at all comfortable or confident and 5 is very comfortable and confident, rate your comfort and confidence with choosing an appropriate initial medication for an adult with a new diagnosis of type 2 diabetes. • What, if anything, would increase your comfort and confidence with making these choices?
When do you prescribe sulfonylureas like glimepiride or glipizide? • What would cause you to discontinue a sulfonylurea?
When do you choose immediate-release vs. extended-release Metformin?
What is your process for choosing among the newer diabetes medications, like Victoza/ Trulicity/ Ozempic (GLP1-RAs), Januvia (DPP-4 inhibitors), or Jardiance/ Invokana (SGLT-2 inhibitors)?
What barriers have you experienced with initiating newer diabetes medications for patients?
On a scale from 1 to 5, where 1 is not at all comfortable or confident and 5 is very comfortable and confident, rate your comfort and confidence with prescribing these newer diabetes medications. • What, if anything, would increase your comfort and confidence with prescribing these medications?
TREATMENT INTENSIFICATION
When do you typically recommend treatment intensification (adding/increasing a med) for a person with type 2 diabetes?
In your experience, what are some barriers that can delay treatment intensification?
What is your process for choosing a medication to add to a patient's treatment regimen?

INSULIN THERAPY
When do you typically initiate insulin therapy for a patient with type 2 diabetes? • What barriers have you encountered when attempting to initiate insulin therapy?
In your opinion, why might patients be reluctant to start insulin therapy? • Why might patients decide to stop taking insulin after they've started it?
When a patient agrees to start insulin, what do you do next to ensure a successful start?
On a scale from 1 to 5, where 1 is not at all comfortable or confident and 5 is very comfortable and confident, rate your comfort and confidence with initiating insulin therapy for adult patients with type 2 diabetes. • What, if anything, would increase your comfort and confidence?
WRAP-UP
What resources would help you help more patients meet their diabetes treatment goals?