Addressing Therapeutic Inertia in Diabetes Management:

A Quality Improvement Project

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Abstract

Background: Therapeutic inertia in diabetes management is the failure to initiate or intensify pharmacological treatment when a patient's glycated hemoglobin (HbA1c) goals are not met. Studies have shown that primary care providers (PCPs) overestimate how aggressive they are at titrating glucose-lowering therapy and that they underestimate how long their patients' HbA1c remain above goal. Early and more aggressive management of hyperglycemia reduces long term microvascular and macrovascular complications. Reducing therapeutic inertia leads to improved patient outcomes.

Aim: The primary aim of this quality improvement project was to decrease the percentage of patients age 18-75 years with HbA1c >9% who had no diabetic medication changes at their last visit by 10% at a primary care clinic in the Pacific Northwest

Methods: A chart review was performed that identified all paneled patients age 18-75 years with a last measured HbA1c >9%. For each patient, the last PCP note was reviewed and multiple data points were collected, including whether or not a medication was added or changed and the documented barriers to medication intensification. A ten-minute presentation that described therapeutic inertia, summarized the results from the chart review, and suggested solutions to barriers was presented to the PCPs of the clinic. They were also provided a "tip sheet" that summarized the details of the presentation.

Results: A total of 118 separate PCP visits were reviewed from July 2021 to February 2022. The median baseline percentage of patients who had no medication change at their last PCP visit was 54%. Post-intervention percentages were 36% in December, 30% in January, and 43% in February, but not enough post-intervention data points were present to determine if a true change occurred.

Conclusions: There is a high rate of therapeutic inertia at a primary care clinic in the Pacific Northwest. There is not enough data to determine if an educational intervention was successful. Future projects can focus on one of the seven identified barriers to initiating or intensifying glucose-lowering therapy.

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Introduction

Problem Description

In the United States (U.S.), over 1 in 10 people have diabetes, with the majority being classified as type 2 diabetes (Centers for Disease Control and Prevention [CDC], 2019). In Oregon, 9.4% of adults have been diagnosed with diabetes, but it is estimated that the number is closer to 12% when undiagnosed cases are included (Oregon Health Authority [OHA], 2015). Not only is diabetes the seventh leading cause of death in the U.S., but it also significantly increases the risk of other serious conditions such as cardiovascular disease, chronic kidney disease, and peripheral neuropathy (CDC, 2019; CDC, n.d.). Despite breakthroughs in newer pharmacological therapies, glycemic control for patients with diabetes has not improved; the percentage of people meeting their individualized glycated hemoglobin (HbA1c) goals declined from 69.8% to 63.8% between 2007 and 2014 and the proportion of people with a HbA1c >9% increased from 12.6% to 15.5% in the U.S. (Carls et al., 2017). Only 50% of people with diabetes obtain a HbA1c <7% (Edelman & Polonsky, 2017). Studies have shown that early and more aggressive management of hyperglycemia in people newly diagnosed with diabetes reduces long term microvascular and macrovascular complications (American Diabetes Association [ADA], 2021a). Therefore, in order to improve outcomes for people with diabetes, it is necessary to obtain individualized glycemic control quickly and to not delay treatment intensification.

Therapeutic inertia describes the phenomenon of failing to intensify or deescalate pharmacological treatment when a patient's therapeutic goals are not met (Gabbay et al., 2020). This project focused on the failure to advance treatment. A systematic review found that HbA1cs were above target for a median of over one year and up to seven years, before treatment was intensified (Khunti et al., 2018). The ADA recommends reassessing HbA1c every 3-6 months depending on the patient's current HbA1c and personalized HbA1c goal, and to use shared decision making to intensify therapy if the patient is still above goal at reassessment (ADA, 2021b). The gap in practice versus guidelines is an

opportunity to improve diabetes management and reduce the associated health risks. Factors that contribute to therapeutic inertia can be classified into provider factors, patient factors, and systemic factors (Gabbay et al., 2020). Successfully reducing therapeutic inertia will require interventions that address each of these aspects.

Available Knowledge

In April 2021 a literature search was performed in PubMed using the following query: ("therapeutic inertia" OR "treatment intensification" OR "treatment initiation" OR "clinical inertia") AND (type 2 diabetes) AND (intervention OR strategies OR methods OR overcom*). A five-year limit was placed on the search and resulted in 305 articles. The articles were manually reviewed to identify interventions that have been implemented to reduce therapeutic inertia in diabetes management. Additional articles were found from September 2021 through November 2021 using the same search terms and by reviewing references from resources of the ADA.

Most of the articles identified in the literature search had the purpose of establishing the existence of therapeutic inertia in diabetes management and identifying poor outcomes as a result (Paul et al., 2015; Desai et al., 2018; Boye et al., 2019; Nichols et al., 2019). Of the articles that focused on identifying barriers to initiating or intensifying glucose-lowering therapies and solutions to overcoming them, the focus of many was specifically on insulin therapy. While insulin can be an important component to diabetes management, many of the perceived barriers to initiation, such as fear of hypoglycemia, weight gain, or injections (Ng et al., 2015; Russell-Jones et al., 2018) do not apply to other glucose-lowering drugs. There is a lack of current research that addresses methods to overcome therapeutic inertia in the context of available therapies. However, several themes did emerge relating to both provider and patient factors that may be useful in addressing therapeutic inertia today.

The first intervention that has been shown to decrease therapeutic inertia at the provider level is simply measuring therapeutic inertia and making that information available to providers (Khunti et al.,

2019). Primary care providers (PCPs) often overestimate how aggressive they are at titrating diabetic therapies and underestimate how long it takes their patients to decrease their HbA1c (Edelman et al., 2020). Becoming aware of their actual statistics has been shown to change their prescribing habits (Khunti et al., 2019). Other than lack of awareness, a major barrier to initiating or intensifying therapy for PCPs is a lack of time (Okemah et al., 2018; Wrzal et al., 2021). Interventions that address this barrier are scheduling diabetes specific visits and utilizing other members of the healthcare team, such as pharmacists, nurses, nurse practitioners (NPs), or physician assistants (PAs) (Khunti et al., 2019; Wrzal et al., 2021).

There are not many proven strategies to reduce therapeutic inertia at the patient level. However, research centered around the importance of patient-provider communication on medication adherence can help shape future interventions. Patients often feel that starting or intensifying their diabetic medication regimen is a result of their own personal failure (Soto & Strain, 2018). There is also a common belief that medication is inherently unhealthy and dangerous; many people prefer traditional or herbal remedies (Brundisini et al., 2015). Education surrounding the progressive nature of diabetes and the need for both lifestyle interventions and medication can be beneficial (Soto et al., 2018; Khunti et al, 2019; Wrzal et al., 2021). However, when providers exclusively focus on medical problem solving and education, patients can feel like their disease is taking precedence, which fosters mistrust (Brundisini et al., 2015). Additionally, patients and providers often have different concerns. Patients are more likely to be worried about vision loss, hypoglycemia, and weight gain, while providers are more likely to be concerned with decreasing cardiovascular risk (Soto et al., 2018). Eliciting the patient's goals and using those as a reason for adherence not only makes the patient more invested in the outcome, but also illustrates that their values are being considered. Patients state that lack of collaboration and provider disinterest in their life contributes to poor medication adherence (Brundisini et al., 2015). These findings suggest that motivational interviewing and shared-decision making are important factors

in patient attitude and willingness to adhere to a medication regimen, which would decrease therapeutic inertia. More research is needed in this area.

Rationale

The Model for Improvement, developed by the Associates in Process Improvement, was used for this project. This model focuses on three questions: what are we trying to accomplish? How will we know that a change is an improvement? And what change can we make that will result in an improvement? (Langley et al., 2009). This model focuses on identifying clinical problems, developing measurable goals, implementing interventions, and evaluating outcomes.

Providing health care that is effective is one of the Institute of Medicine's (IOM) six aims for improving health care quality (2001). Under this framework, effort should be put into interventions that are known to work. It is known that initiating or intensifying glucose-lowering medications when HbA1c goals are not met lead to lower HbA1cs, which lead to lower rates of diabetic complications (Laiteerapong et al., 2017; ADA, 2021a). Current effective therapies are being underutilized (Khunti et al., 2018). Addressing therapeutic inertia increases the effectiveness of diabetes management and leads to improved outcomes for patients.

An HbA1c of >9% was used in this project because it is one of the quality measures set by the Centers for Medicare and Medicaid (CMS) (CMS, 2021).

Specific Aims

The aim of this improvement project was to decrease the percentage of patients at a primary care clinic in the Pacific Northwest with an HbA1c >9% who had no diabetic medication changes at their last PCP visit by 10%. The secondary aim was to decrease the percentage of patients at the same clinic with an HbA1c >9% by 10%. Only patients between the ages of 18-75 years were included. The original goal was to be met by February 1, 2022.

Methods

Context

The clinic participating in this improvement project is a primary care clinic in the Pacific Northwest that is affiliated with a larger academic health care organization. The clinic provides both family medicine and internal medicine services to approximately 7,500 patients in the community. Of these patients, approximately 23% use Medicaid, 10.5% use Medicare, and 3.5% are uninsured. The majority of the patients identify as White at 76%, followed by Asian at 9%, Multiracial at 4.5%, and Black at 2%. As of June 2021, 20-30% of visits occurred through telehealth. The PCPs at the clinic consist of nine physicians and three family nurse practitioners (FNPs). The PCPs frequently precept medical and FNP students. At the beginning of this project the clinic also started a new residency program consisting of three residents.

The pharmacist at the clinic has an ongoing project related to diabetes management. In October 2019, she initially reached out to patients with HbA1cs 9-10% and offered free consultations. During those consultations she counseled on lifestyle interventions and made medication changes to patients' diabetic therapy. She is no longer reaching out to patients specifically, but will still see those with a HbA1c >7% with their PCP's referral. There is no standard number of appointments that she has with them; it is individualized to the patient.

This project started about a year and a half after the COVID-19 pandemic began. The rate of cases and deaths fluctuated throughout data collection. In Oregon, the rate of cases steeply rose from the end of July 2021, peaking at over 4,500 new cases a day in September 2021, while the seven-day death average held steady around 35 through November 2021 (The New York Times, 2021). The effects of the pandemic are still not fully known. Many people avoided routine health care during this time (CDC, 2021) and preliminary research shows that many individuals experienced decreased physical activity, increased weight gain, and increased stress during the pandemic (Karatas et al., 2021; Biamonte et al., 2021). These factors are likely to affect glycemic control and healthcare priorities.

Interventions

An initial chart review was performed on October 1, 2021, that identified all paneled patients age 18-75 years with a last measured HbA1c >9%. Patients were identified based on National Quality Forum (NQF) measures, which exclude patients receiving hospice, patients age 66+ who live long term in an institution, and patients age 66+ with frailty (CMS, 2021). Patients managed by endocrinology were also omitted, which excluded all patients with type 1 diabetes at this clinic. Eighty patients fitting the above criteria were identified. For each patient, the last PCP note was reviewed and the following data was collected: type of visit (in-person, phone, or video), whether or not a glucose-lowering medication was initiated or intensified at the last visit, the patient's current glucose-lowering medications, the documented reason why medication was not initiated or intensified, and whether a resident or student was involved in the visit. Medication was counted as added or changed if it occurred at a visit within the past three months. The same data was also collected for every PCP visit where a patient had a HbA1c >9% by month, starting July 2021. This was done to better measure therapeutic inertia by visit, instead of by patient.

A ten-minute PowerPoint presentation aimed at the PCPs of the clinic was created. The presentation included: an explanation of therapeutic inertia and the poor outcomes associated with it, percentage of patients at the clinic with HbA1cs>9% who did not get a medication added or changed at their last PCP visit, the seven main barriers discovered in chart review, and five potential solutions to overcoming the barriers, see Appendix A. A "tip sheet" with the summarized solutions and the 2021 ADA Treatment Algorithms was created for distribution to the providers, see Appendix B. The presentation occurred December 8, 2021, by virtual meeting.

Study of the Interventions

The percentage of patients with HbA1cs >9% who were seen by residents or students was monitored, as well as type of visit, as these factors could influence medication changes. Barriers in

initiating or intensifying therapy was tracked by month, to determine if specific barriers became more prevalent during the improvement project.

Measures

The primary outcome measure is the percentage of clinic patients age 18-75 years with a HbA1c >9% who had no diabetic medication changes at their last PCP visit. This is one way to measure therapeutic inertia, because if the patient's HbA1c is >9% they are considered poorly controlled and a medication to decrease hyperglycemia should be added or increased (ADA, 2021a; ADA, 2021b). The secondary outcome measure is percentage of patients at the clinic with diabetes age 18-75 years with an HbA1c >9%. This is one of the quality measures at the clinic set by CMS. It is expected that the percentage of patients with HbA1c >9% should decrease over time as therapeutic inertia decreases, but this measure takes longer to improve since it is only measured every three months or less and patients who start with HbA1cs much higher than 9% may need multiple medication changes to get below 9%. Balancing measures include percentage of patients with HbA1c >9% that the pharmacist and residents are managing. Process measures include specific barriers to medication initiation or intensification.

Analysis

Data was recorded and analyzed in Microsoft Excel OneDrive. Run charts were used to track changes in percentage of patients with a HbA1c >9% who did not have a medication change at last visit and percentage of patients with diabetes with a HbA1c >9%. Run chart rules were used to determine true change. Barriers to medication changes were determined from the visit note and placed into one of seven identified categories.

Ethical Considerations

This project was submitted to the Oregon Health & Science University (OHSU) Investigational Review Board (IRB) and was determined to not be research. Patient health information was accessed

through chart review, but data collection did not include any patient identifiers. All data was stored in OHSU's approved secure storage site: Microsoft OneDrive. There are no conflicts of interest.

Results

Initial Chart Review

The initial chart review performed October 1, 2021 identified 80 patients with an HbA1c >9% who fit the previously mentioned NQF measures and were not already managed by endocrinology. Of these patients, 62% did not have a change in their diabetic medication regimen at their last PCP visit. If a glucose-lowering medication was added or increased within the three months prior to the PCP visit, it was counted as a medication change. The seven main barriers to adding or increasing a medication were identified as: a change was not initiated by the PCP (24%), the patient was referred to the pharmacist (22%), the patient did not adhere to their current medication regimen (20%), the patient declined a medication change (16%), the patient was lost to follow-up (12%), they were referred to endocrinology (4%), or an acute illness was a priority at the visit (2%).

The initial chart review also gathered three months of baseline data, starting July 2021. Fifty percent of patients did not have a medication change at their last PCP visit in July, 67% did not in August, and 62% did not in September.

Post Intervention

A total of 118 separate PCP visits were reviewed from July 2021 to February 2022. Of note, data from the month of February was only collected through the 22nd, and therefore does not contain a full month of data. The educational intervention occurred December 8, 2021, where baseline data through October 2021 was presented. The post-intervention percentage of patients who did not have a medication change at their last PCP visit was 36% in December, 30% in January, and 43% in February, which is below the baseline pre-intervention median of 54%. However, there is not enough post-

intervention data points at this time to determine if a true change has occurred (Institute for Healthcare Improvement [IHI], 2019). See Figure C1 for run chart.

There was also no change in the percentage of patients with an HbA1c >9%. Figure C2 shows both the percentage of patients who had a HbA1c >9% or no HbA1c measured within the past 12 months out of all patients with diabetes (CMS measure of "poor control") and the percentage of patients with a HbA1c >9% out of all patients who did have their HbA1c measured within the past year. This was expected, as only two months had passed since the intervention, which is not enough time for HbA1cs to be rechecked. Even if there had been a change in practice and results, HbA1cs would not yet reflect a change.

There were no significant changes in barriers to adding or intensifying glucose-lowering medications over time. The top three reasons for no change in medication from July 2021 to February 2022 (n=53) were that the patient was lost to follow-up (28%), the patient was referred to the pharmacist (28%), and that a medication change was not initiated by the PCP (15%). See Figure C3 and Figure C4.

The type of visit trended towards an increase of in-person visits over time (Figure C5). A very small percentage of all visits were managed by a resident (5%) or involved a student (4%). Out of all visits from July to February, only 26% of patients were prescribed a GLP-1 receptor agonist and 15% were prescribed an SGLT2 inhibitor, compared to 81% prescribed metformin and 35% prescribed a long-acting insulin. There may be a trend of increasing use of GLP-1 receptor agonists and SGLT2 inhibitors (see Figure C6), but again, there is not enough data to show a definitive change.

Discussion

Summary

This quality improvement project measured therapeutic inertia in diabetes management by calculating the percentage of patients with an HbA1c >9% who did not have a glucose-lowering

medication initiated or intensified at their last PCP visit. This metric was lower in the three months following an educational intervention to the providers at the clinic, but there is not enough data yet to determine if a true change in management has occurred. If the provider education did result in a reduction in therapeutic inertia, that is one step towards more effective diabetes management and will lead to improved patient outcomes.

Interpretation

A large percentage of patients with a HbA1c >9% did not have a glucose-lowering medication initiated or intensified at their last PCP visit, which shows that therapeutic inertia is a significant problem at this clinic. The initial chart review of all patients who fit the requirements showed that 62% did not have a medication change at their last PCP visit. The data collected by month starting July 2021 showed a slightly lower rate, with a median of 54%. This is comparable to other studies that have shown less than half of patients receive treatment intensification when it is indicated (Khunti et al., 2019). Rates were lower than the baseline median after the educational intervention, but without enough data to state that there has been a true change. Awareness is one of the proven interventions to decrease therapeutic inertia at the provider level (Khunti et al., 2019; Okemah et al., 2018). However, the percentage of patients who did not receive intensification decreased to 25% in November, the month before the intervention. The reason is unclear, but it is possible that an unknown factor caused the decrease in therapeutic inertia, and not the intervention. It is also possible that this is random variation and not a true change, which would become more apparent with more data points.

The top three reasons for no medication change from July 2021 to February 2022 were that the patient was referred to the pharmacist (28%), the patient was lost to follow-up (28%), and that a medication change was not initiated by the PCP (15%). This information can help determine directions for more focused interventions in the future. Referral to the pharmacist can actually decrease therapeutic inertia by off-loading some of the work from the PCP (Khunti et al., 2019; Wrzal et al., 2021).

This barrier may not be a true barrier. Important information to collect to determine the effectiveness of referral to the pharmacist would be what percentage of patients were able to meet with the pharmacist, how long it took them to get a visit, and whether medication was intensified at that visit. It may be of greater value to target patients lost to follow-up and reasons why the PCP did not initiate a medication change. There are many possible causes for both of these barriers that future quality improvement projects could focus on.

Out of all visits from July to February, only 26% of patients were prescribed a GLP-1 RA and 15% were prescribed an SGLT2i. This highlights the continued underutilization of these therapies, which has been shown in previous studies (Khunti et al., 2018). The ADA has recently increased the emphasis on using these classes of medications in their treatment algorithm as their effectiveness, cardiovascular benefits, and renal benefits have become more evident (ADA, 2022). Increasing the usage of these medications would be another method of decreasing therapeutic inertia.

Limitations

Limitations to this improvement project are a small sample size and lack of data points post intervention. Future projects may want to look at patients with an HbA1c >8%. While this is not the cut-off used for CMS, most patients have an individualized HbA1c goal of less than 8% (ADA, 2021a). This would allow for a greater sample size and it may be possible to track visits by week, which would make it easier to determine true changes and trends.

The educational intervention targeted primarily provider awareness and sense of urgency, but there are many reasons for therapeutic inertia. There were most likely too many solutions offered in the educational presentation, and each solution could have been an intervention in itself.

Finally, only one barrier was documented for each visit. Most likely there are many barriers to medication changes at each visit that are not being captured by reviewing visit notes. For example, cost

is one important and known barrier that was not documented in the charts. A survey of providers' and patients' perception of barriers could be helpful.

Conclusions

This quality improvement project illustrated the high rate of therapeutic inertia in diabetes management at a primary care clinic in the Pacific Northwest. An educational intervention was presented to the PCPs of the clinic to increase their awareness and urgency of the issue. While there was a decrease in the percentage of patients with an HbA1c >9% that did not have a medication change at their last PCP visit after the intervention, there is not currently enough data to determine whether a true change occurred. Future projects can focus on one of the seven barriers to initiating or intensifying glucose-lowering therapy that were identified during this project.

References

American Diabetes Association. (2021a). 6. Glycemic targets: Standards of medical care in diabetes 2021. *Diabetes Care*, *44*(Supplement 1), S73–S84. https://doi.org/10.2337/dc21-s006

American Diabetes Association. (2021b). 9. Pharmacologic approaches to glycemic treatment: Standards of medical care in diabetes—2021. *Diabetes Care*, *44*(Supplement 1), S111–S124. https://doi.org/10.2337/dc21-s009

American Diabetes Association. (2022). 9. Pharmacologic approaches to glycemic treatment: Standards of medical care in diabetes – 2022. *Diabetes Care, 45*(Supplement 1), S125-143. https://doi.org/10.2337/dc22-s009

Biamonte, E., Pegoraro, F., Carrone, F., Facchi, I., Favacchio, G., Lania, A. G., Mazziotti, G., & Mirani, M. (2021). Weight change and glycemic control in type 2 diabetes patients during COVID-19 pandemic: The lockdown effect. *Endocrine*, *72*(3), 604–610. https://doi-org.liboff.ohsu.edu/10.1007/s12020-021-02739-5

Boye, K. S., Stein, D., Matza, L. S., Jordan, J., Yu, R., Norrbacka, K., Hassan, S. W., & García-Pérez, L. E. (2019). Timing of GLP-1 receptor agonist initiation for treatment of type 2 diabetes in the UK. *Drugs in R&D*, *19*(2), 213–225. https://doi-org.liboff.ohsu.edu/10.1007/s40268-019-0273-0

Brundisini, F., Vanstone, M., Hulan, D., DeJean, D., & Giacomini, M. (2015). Type 2 diabetes patients' and providers' differing perspectives on medication nonadherence: A qualitative meta synthesis. *BMC Health Services Research*, *15*, 516. https://doi.org/10.1186/s12913-015-1174-8

Carls, G., Huynh, J., Tuttle, E., Yee, J., & Edelman, S. V. (2017). Achievement of glycated hemoglobin goals in the US remains unchanged through 2014. *Diabetes Therapy, 8*(4), 863–873. https://doi.org/10.1007/s13300-017-0280-5

Centers for Disease Control and Prevention. (n.d.). *A snapshot: Diabetes in the United States.* CDC.gov. https://www.cdc.gov/diabetes/library/socialmedia/infographics/diabetes.html

Centers for Disease Control and Prevention. (2019). *Diabetes.* CDC.gov. https://www.cdc.gov/nchs/fastats/diabetes.htm

Centers for Disease Control and Prevention (2021). *COVID data tracker weekly review*. CDC.gov. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html#ref02

Centers for Medicare & Medicaid Services. (2021, May 5). *Electronic clinical quality improvement (eCQI) resource center.* Retrieved October 6, 2021, from https://ecqi.healthit.gov/ecqm/ep/2021/cms122v9

Desai, U., Kirson, N. Y., Kim, J., Khunti, K., King, S., Trieschman, E., Hellstern, M., Hunt, P. R., & Mukherjee, J. (2018). Time to treatment Intensification after monotherapy failure and its association with subsequent glycemic control among 93,515 patients with type 2 diabetes. *Diabetes care*, *41*(10), 2096–2104. https://doi-org.liboff.ohsu.edu/10.2337/dc17-0662

Edelman, S. V., & Polonsky, W. H. (2017). Type 2 diabetes in the real world: The elusive nature of glycemic control. *Diabetes care*, *40*(11), 1425–1432. https://doi.org/10.2337/dc16-1974

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: A Publication of the American Diabetes Association*, *38*(3), 222–229. https://doiorg.liboff.ohsu.edu/10.2337/cd19-0067

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

Institute for Healthcare Improvement. (2019). *Run chart rules reference sheet.* http://www.ihi.org/education/IHIOpenSchool/Courses/Documents/11_RunChartRulesReferenceSheet.pdf

Institute of Medicine. (2001). *Crossing the quality chasm: A new health system for the 21st century*. The National Academies Press. https://doi.org/10.17226/10027

Karatas, S., Yesim, T., & Beysel, S. (2021). Impact of lockdown COVID-19 on metabolic control in type 2 diabetes mellitus and healthy people. *Primary care diabetes*, *15*(3), 424–427. https://doiorg.liboff.ohsu.edu/10.1016/j.pcd.2021.01.003

Khunti, K., Gomes, M. B., Pocock, S., Shestakova, M. V., Pintat, S., Fenici, P., Hammar, N., & Medina, J. (2018). Therapeutic inertia in the treatment of hyperglycaemia in patients with type 2 diabetes: A systematic review. *Diabetes, Obesity and 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*, 204201881984469. https://doi.org/10.1177/2042018819844694

Langley, G. J., Moen, R. D., Nolan, K. M., Nolan, T. W., Norman, C. L., & Provost, L. P. (2009) *The improvement guide: A practical guide to enhancing organizational performance* (2nd ed.). Jossey-Bass.

Laiteerapong, N., Ham, S. A., Gao, Y., Moffet, H. H., Liu, J. Y., Huang, E. S., & Karter, A. J. (2019). 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

Nichols, G. A., Romo-LeTourneau, V., Vupputuri, S., & Thomas, S. M. (2019). Delays in anti hyperglycaemic therapy initiation and intensification are associated with cardiovascular events, hospitalizations for heart failure and all-cause mortality. *Diabetes, obesity & metabolism*, *21*(7), 1551–1557. https://doi-org.liboff.ohsu.edu/10.1111/dom.13683

Okemah, J., Peng, J., & Quiñones, M. (2018). Addressing clinical inertia in type 2 diabetes mellitus: A review. *Advances in Therapy*, *35*(11), 1735–1745. https://doi.org/10.1007/s12325-018-0819-5

Oregon Health Authority. (2015). *Oregon diabetes report*. Oregon.gov. https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/CHRONICDISEASE/DIABETES/Documents/OregonDiabetesReport.pdf

Oregon Health Authority. (2021). *Tracking progress in Oregon to reach vaccination goals in the eligible population*. Public.Tableau. https://public.tableau.com/app/profile/oregon.health.authority.covid.19/viz/OregonVaccineMetricsGovernorsGoal/GovernorsGoal

Paul, S. K., Klein, K., Thorsted, B. L., Wolden, M. L., & Khunti, K. (2015). Delay in treatment intensification increases the risks of cardiovascular events in patients with type 2 diabetes. *Cardiovascular diabetology*, *14*, 100. https://doi-org.liboff.ohsu.edu/10.1186/s12933-015-0260-x

Soto, C., & Strain, W. D. (2018). Tackling clinical inertia: Use of coproduction to improve patient engagement. *Journal of Diabetes*, *10*(12), 942–947. https://doi.org/10.1111/1753-0407.12814

The New York Times. (2021, November 25). *Tracking coronavirus in Oregon: Latest map and case counts.* https://www.nytimes.com/interactive/2021/us/oregon-covid-cases.html

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.e13. https://doi-org.liboff.ohsu.edu/10.1016/j.jcjd.2020.08.109

Appendix A

PowerPoint Presented at Provider Meeting

2/27/2022

Therapeutic Inertia in Diabetes Management

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December 8, 2021

Clinical Problem

1 in 10 people have diabetes in the US

64% of people with diabetes reach their A1c goal

50% of people with diabetes have an A1c <7%

(CDC, 2019; Carls et al., 2017; Edelman & Polonsky, 2017)

1

Therapeutic Inertia

The failure to advance or deintensify the treatment regimen when a patient's therapeutic goals are not met

A systematic review found A1cs were above goal for a median of one year and up to seven years before treatment was intensified

(Khunti et al., 2018)

The Legacy Effect

Glucose control now improves outcomes over the next ten years

Early Glycemic Control

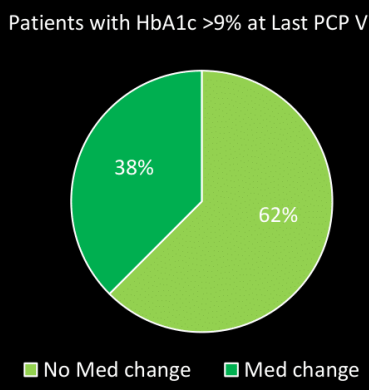
↓Risk of Macro & Microvascular Complications

↓Risk of all-cause mortality

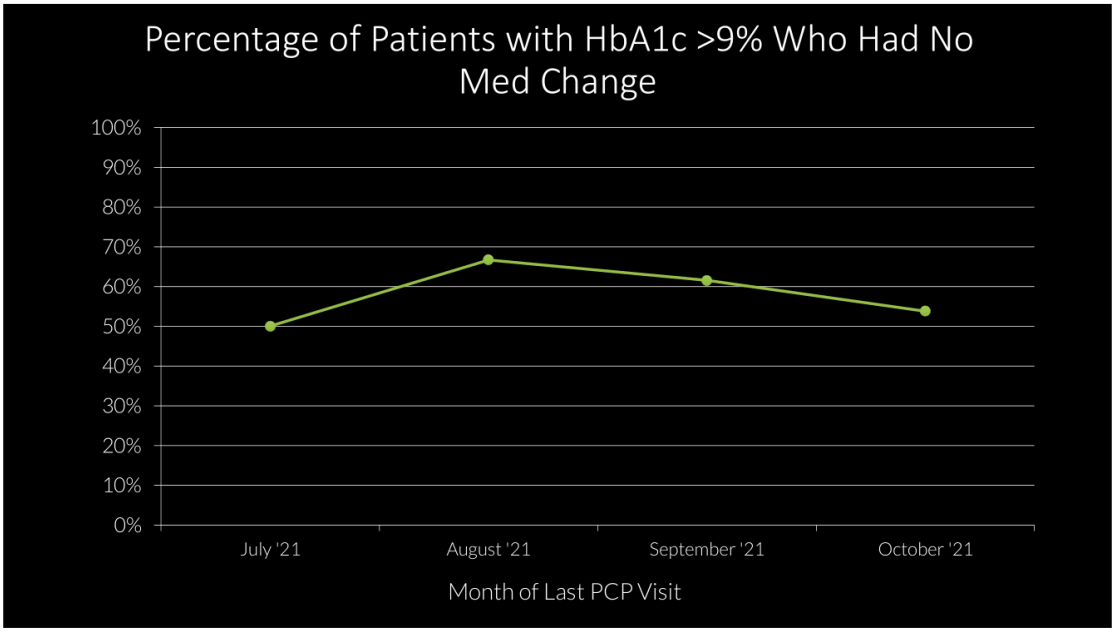
Longer maintenance of glucose control over time

(Abdul-Ghani et al., 2015; Laiteerapong et al., 2019)

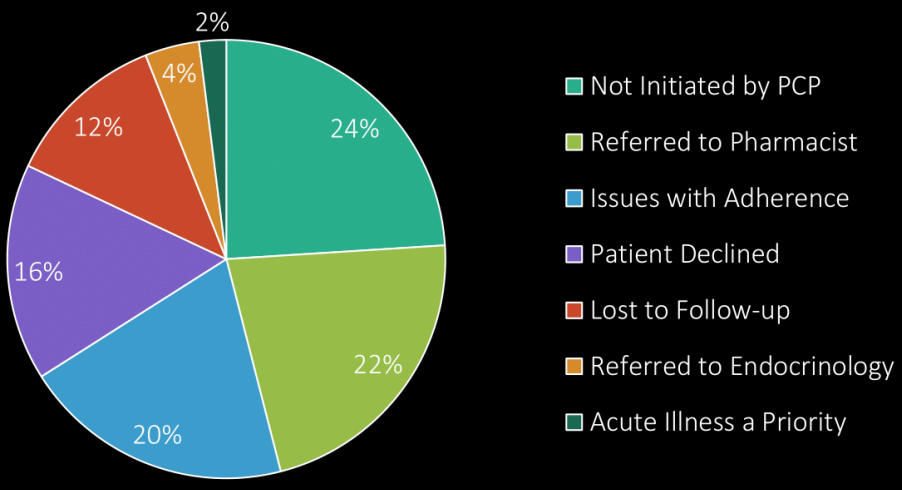
Therapeutic Inertia at this Clinic



3 out of 5 patients with a HbA1c >9% had no medication added or changed at their last PCP visit



Reasons for No Med Change



Potential Barriers

Lack of awareness
Lack of urgency
Lack of time
Unsure of next pharmacological step
HbA1c not current
Financial concerns

Solutions

Remember the Legacy Effect
Schedule diabetes specific visits
Utilize Telehealth
Use published guidelines
Place lab orders in advance, utilize POC HbA1c
Utilize resources

Patient Factors

Belief that medication is inherently unhealthy and dangerous

Feel that medication is a result of personal failure

Patients and providers often have different concerns

Motivational interviewing?

(Brudisini et al., 2015; Soto & Strain, 2018; Wrzal et al., 2021)

Cost Tips

- Prescribe under cardiac/renal indication if patient meets criteria
- Document previously tried therapies and rationale
- Manufacturer Copayment Reduction Cards
  - limited to commercial insurance, sometimes no prescription coverage
- Payment Assistance Programs

AACE Prescription Affordability Resource Center

ADCES Access & Affordability Resources

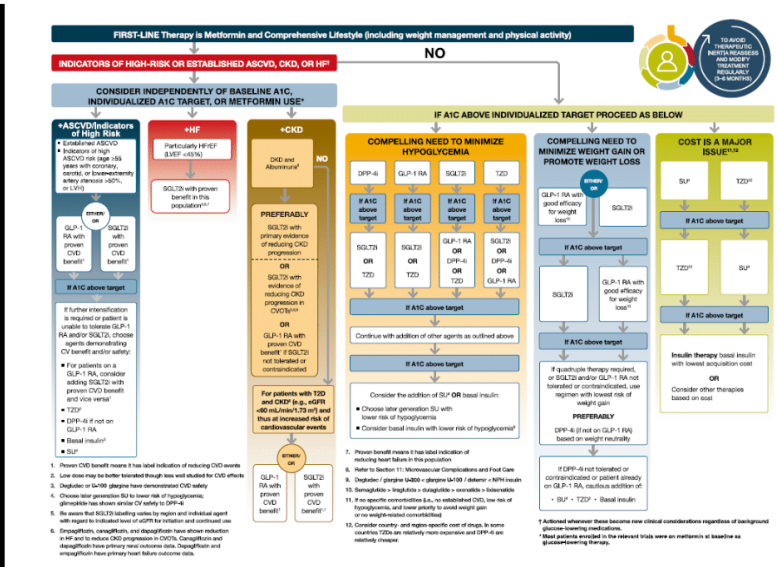


Figure 9.1—Glucose-lowering medication in type 2 diabetes: 2021 ADA Professional Practice Committee (PPC) adaptation of Davies et al. (35) and Buse et al. (36). For appropriate context, see **Fig. 4.1**. The 2021 ADA PPC adaptation of the **Fig. 9.1** "Indicators of high-risk or established ASCVD, CKD, or HF" pathway has been adapted based on trial populations studied. ASCVD, atherosclerotic cardiovascular disease; CKD, chronic kidney disease; CVD, cardiovascular disease; CVOTs, cardiovascular outcomes trials; DPP-4i, dipeptidyl peptidase 4 inhibitor; eGFR, estimated glomerular filtration rate; GLP-1 RA, glucagon-like peptide 1 receptor agonist; HF, heart failure; HFrEF, heart failure with reduced ejection fraction; LVEF, left ventricular ejection fraction; LVH, left ventricular hypertrophy; SGLT2i, sodium–glucose cotransporter 2 inhibitor; SU, sulfonylurea; T2D, type 2 diabetes; TZD, thiazolidinedione.

(ADA, 2021)

Table 9.1—Drug-specific and patient factors to consider when selecting antihyperglycemic treatment in adults with type 2 diabetes

	Efficacy	Hypoglycemia	Weight change	CV effects		Cost	Oral/SQ	Renal effects		Additional considerations
				ASCVD	HF			Progression of DKD	Dosing/use considerations*	
Metformin	High	No	Neutral (potential for modest loss)	Potential benefit	Neutral	Low	Oral	Neutral	▪ Contraindicated with eGFR <30 mL/min/1.73 m^2	▪ Gastrointestinal side effects common (diarrhea, nausea) ▪ Potential for B12 deficiency
SGLT-2 inhibitors	Intermediate	No	Loss	Benefit: empagliflozin†, canagliflozin	Benefit: empagliflozin†, canagliflozin, dapagliflozin‡	High	Oral	Benefit: canagliflozin§, empagliflozin, dapagliflozin	▪ Renal dose adjustment required (canagliflozin, dapagliflozin, empagliflozin, ertugliflozin)	▪ Should be discontinued before any scheduled surgery to avoid potential risk for DKA ▪ DKA risk (all agents, rare in T2D) ▪ Risk of bone fractures (canagliflozin) ▪ Genitourinary infections ▪ Risk of volume depletion, hypotension ▪ ↑LDL cholesterol ▪ Risk of Fournier's gangrene
GLP-1 RAs	High	No	Loss	Neutral: exenatide once weekly, lixisenatide Benefit: dulaglutide†, lraglutide†, semaglutide†	Neutral	High	SQ, oral (semaglutide)	Benefit on renal end points in CVOTs, driven by albuminuria outcomes: lraglutide, semaglutide, dulaglutide	▪ Exenatide, lixisenatide: avoid for eGFR <30 mL/min/1.73 m^2 ▪ No dose adjustment for dulaglutide, lraglutide, semaglutide ▪ Caution when initiating or increasing dose due to potential risk of nausea, vomiting, diarrhea, or dehydration. Monitor renal function in patients reporting severe adverse GI reactions when initiating or increasing dose of therapy.	▪ **FDA Black Box:** Risk of thyroid C-cell tumors in rodents; human relevance not determined (**lraglutide, albiglutide, dulaglutide, exenatide extended release, semaglutide**) ▪ GI side effects common (nausea, vomiting, diarrhea) ▪ Injection site reactions ▪ Pancreatitis has been reported in clinical trials but causality has not been established. Discontinue if pancreatitis is suspected.
DPP-4 inhibitors	Intermediate	No	Neutral	Neutral	Potential risk: saxagliptin	High	Oral	Neutral	▪ Renal dose adjustment required (sitagliptin, saxagliptin, alogliptin); can be used in renal impairment ▪ No dose adjustment required for linagliptin	▪ Pancreatitis has been reported in clinical trials but causality has not been established. Discontinue if pancreatitis is suspected. ▪ Joint pain
Thiazolidinediones	High	No	Gain	Potential benefit: pioglitazone	Increased risk	Low	Oral	Neutral	▪ No dose adjustment required ▪ Generally not recommended in renal impairment due to potential for fluid retention	▪ **FDA Black Box:** Congestive heart failure (**pioglitazone, rosiglitazone**) ▪ Fluid retention (edema; heart failure) ▪ Benefit in NASH ▪ Risk of bone fractures ▪ Bladder cancer (pioglitazone) ▪ ↑LDL cholesterol (rosiglitazone)
Sulfonylureas (2nd generation)	High	Yes	Gain	Neutral	Neutral	Low	Oral	Neutral	▪ Glyburide: not recommended ▪ Glipizide and glimepiride: initiate conservatively to avoid hypoglycemia	▪ FDA Special Warning on increased risk of cardiovascular mortality based on studies of an older sulfonylurea (tolbutamide)
Insulin — Human insulin	Highest	Yes	Gain	Neutral	Neutral	Low (SQ)	SQ, inhaled	Neutral	▪ Lower insulin doses required with a decrease in eGFR; titrate per clinical response	▪ Injection site reactions ▪ Higher risk of hypoglycemia with human insulin (NPH or premixed formulations) vs. analogs
Insulin — Analogs						High	SQ			

(ADA, 2021)

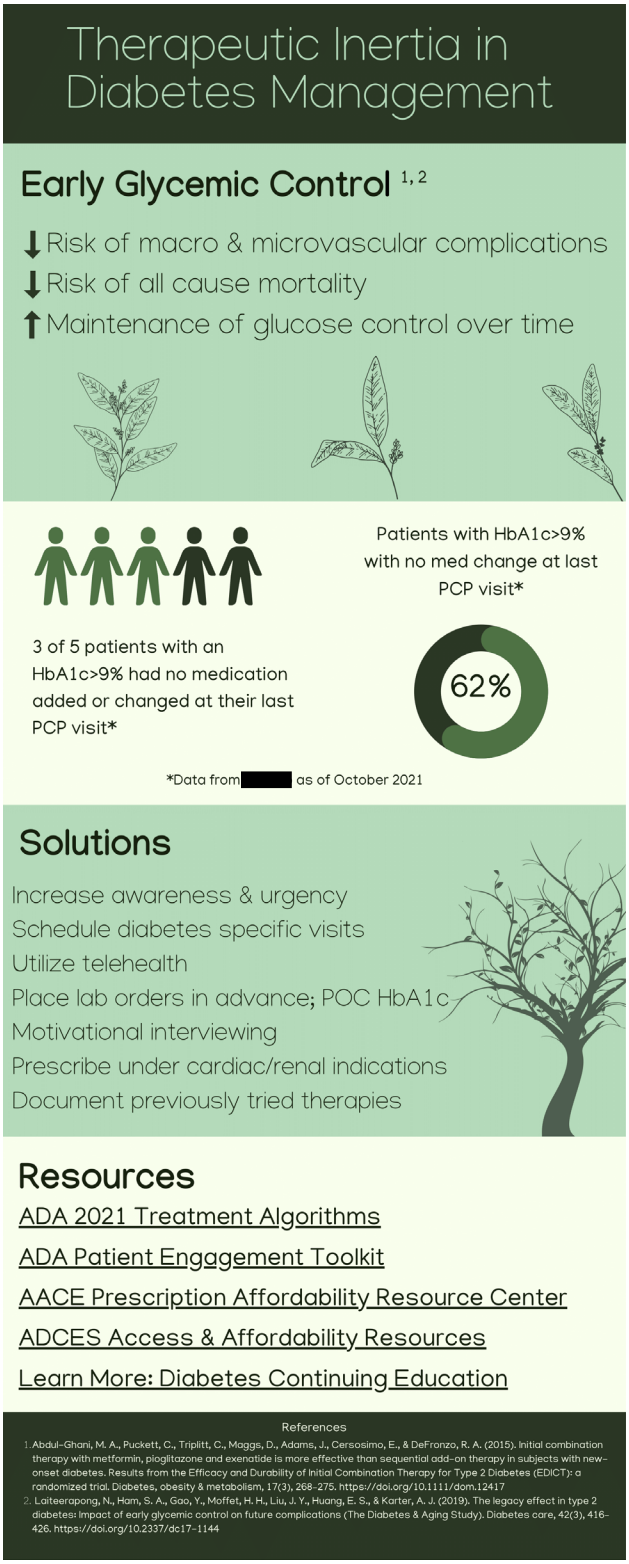
Thank you

References

- Abdul-Ghani, M. A., Puckett, C., Triplitt, C., Maggs, D., Adams, J., Cersosimo, E., & DeFronzo, R. A. (2015). Initial combination therapy with metformin, pioglitazone and exenatide is more effective than sequential add-on therapy in subjects with new-onset diabetes. Results from the Efficacy and Durability of Initial Combination Therapy for Type 2 Diabetes (EDICT): a randomized trial. *Diabetes, obesity & metabolism*, *17*(3), 268–275. https://doi.org/10.1111/dom.12417
- American Diabetes Association. (2021). 9. Pharmacologic approaches to glycemic treatment: Standards of medical care in diabetes—2021. *Diabetes Care*, *44*(Supplement 1), S111–S124. https://doi.org/10.2337/dc21-s009
- Brundisini, F., Vanstone, M., Hulan, D., DeJean, D., & Giacomini, M. (2015). Type 2 diabetes patients' and providers' differing perspectives on medication nonadherence: A qualitative meta synthesis. *BMC health services research*, *15*, 516. https://doi.org/10.1186/s12913-015-1174-8
- Carls, G., Huynh, J., Tuttle, E., Yee, J., & Edelman, S. V. (2017). Achievement of glycated hemoglobin goals in the US remains unchanged through 2014. *Diabetes Therapy, 8*(4), 863–873. https://doi.org/10.1007/s13300-017-0280-5
- Centers for Disease Control and Prevention. (2019). *Diabetes.* CDC.gov. https://www.cdc.gov/nchs/fastats/diabetes.htm
- Edelman, S. V., & Polonsky, W. H. (2017). Type 2 diabetes in the real world: The elusive nature of glycemic control. *Diabetes care*, *40*(11), 1425–1432. https://doi.org/10.2337/dc16-1974
- Khunti, K., Gomes, M. B., Pocock, S., Shestakova, M. V., Pintat, S., Fenici, P., Hammar, N., & Medina, J. (2018). Therapeutic inertia in the treatment of hyperglycaemia in patients with type 2 diabetes: A systematic review. *Diabetes, Obesity and Metabolism*, *20*(2), 427–437. https://doi.org/10.1111/dom.13088
- Laiteerapong, N., Ham, S. A., Gao, Y., Moffet, H. H., Liu, J. Y., Huang, E. S., & Karter, A. J. (2019). 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
- Soto, C., & Strain, W. D.. (2018). Tackling clinical inertia: Use of coproduction to improve patient engagement. *Journal of Diabetes*, *10*(12), 942–947. https://doi.org/10.1111/1753-0407.12814
- 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.e13. https://doi-org.liboff.ohsu.edu/10.1016/j.jcjd.2020.08.109

Appendix B

Tip Sheet for Providers



Appendix C

Figure C1

Percent of Patients with HbA1c >9% Who Had no Glucose-Lowering Medication Change by Month

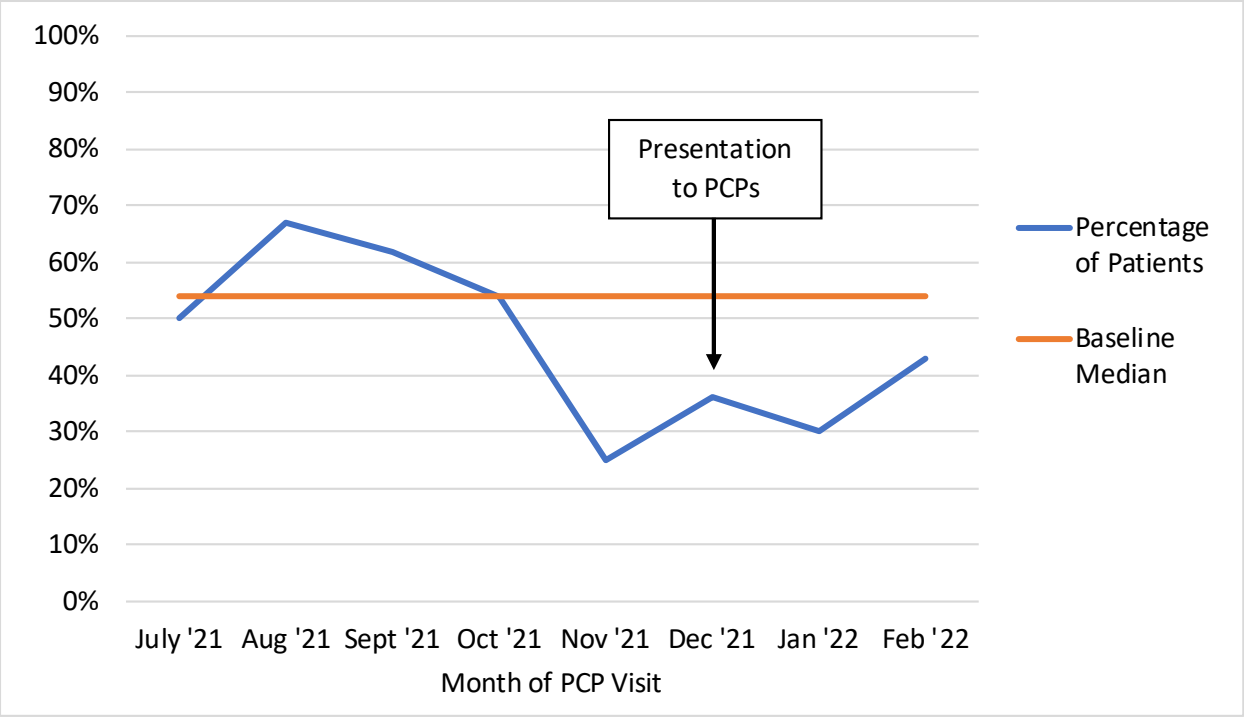
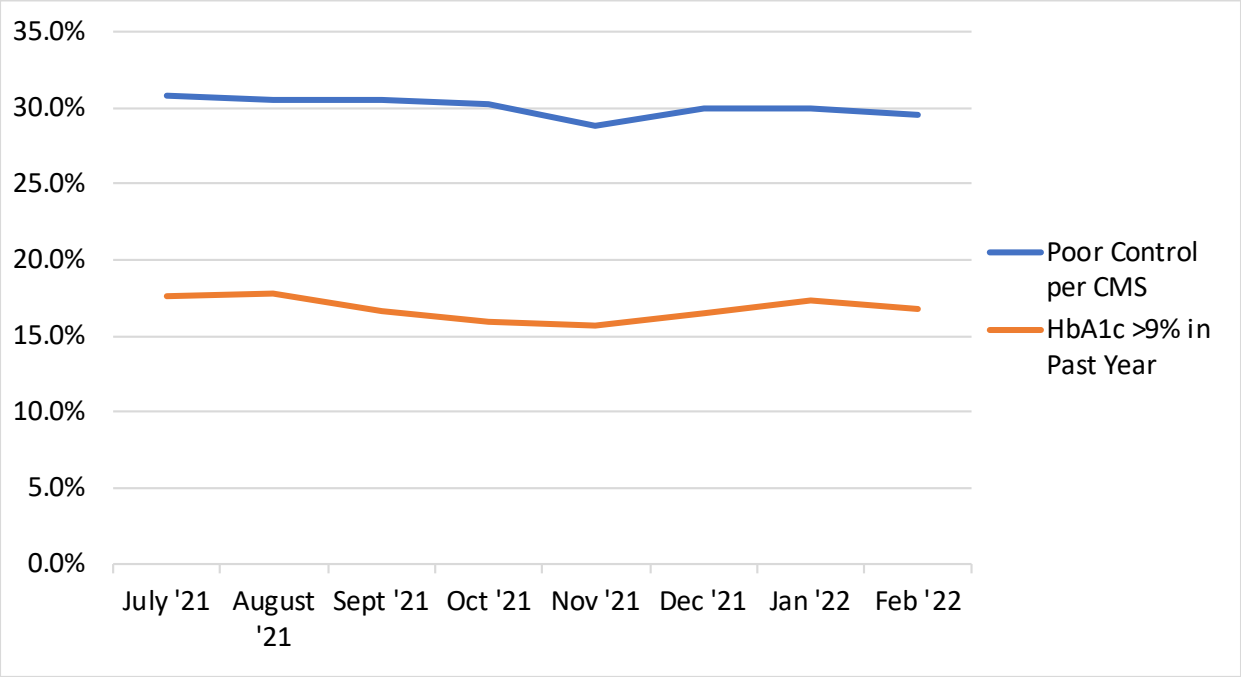


Figure C2

Percent of Patients with Diabetes Who Have a HbA1c >9%



Note. "Poor Control" is defined by CMS as percentage of patients who had a HbA1c >9% or no HbA1c measured within the past 12 months out of all patients with diabetes. The second orange line measures the percentage of patients with a HbA1c >9% out of all patients with diabetes who did have their HbA1c measured within the past year.

Figure C3

Barriers to Glucose-Lowering Medication Change by Month

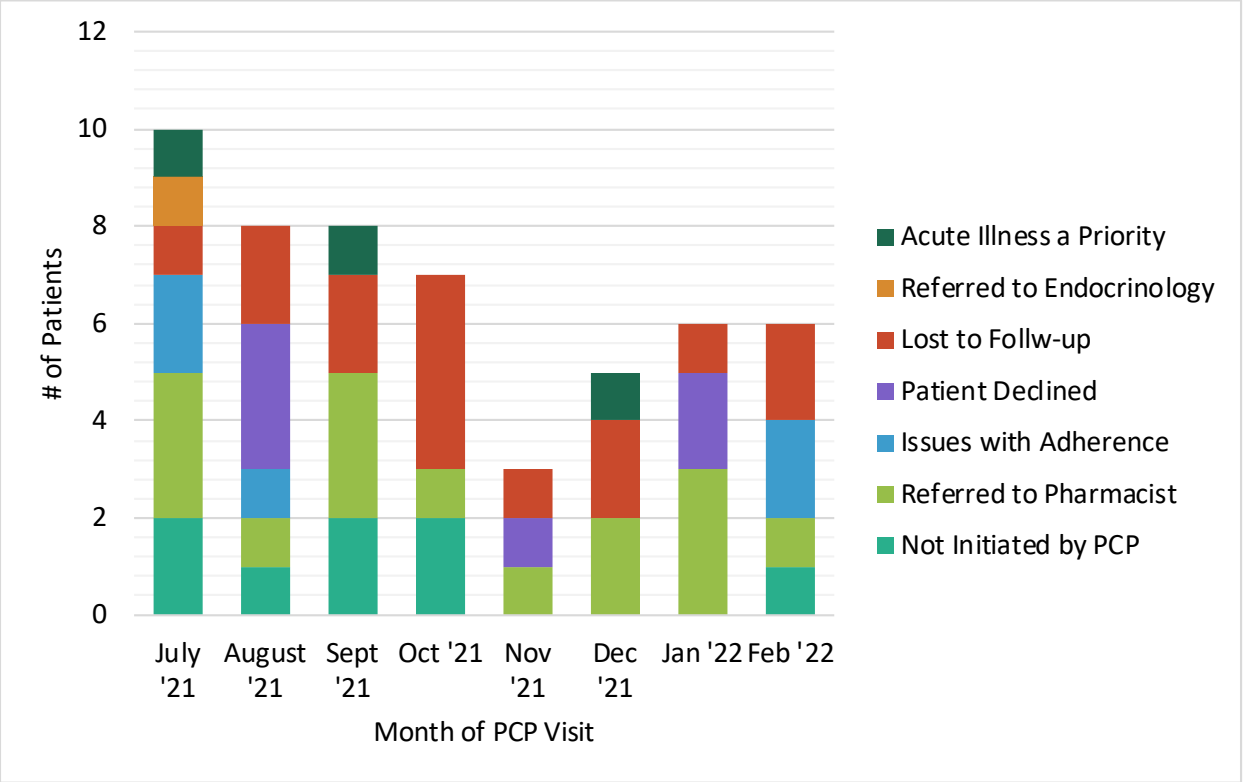


Figure C4

Barriers to Glucose-Lowering Medication Change from July 2021 – February 2022

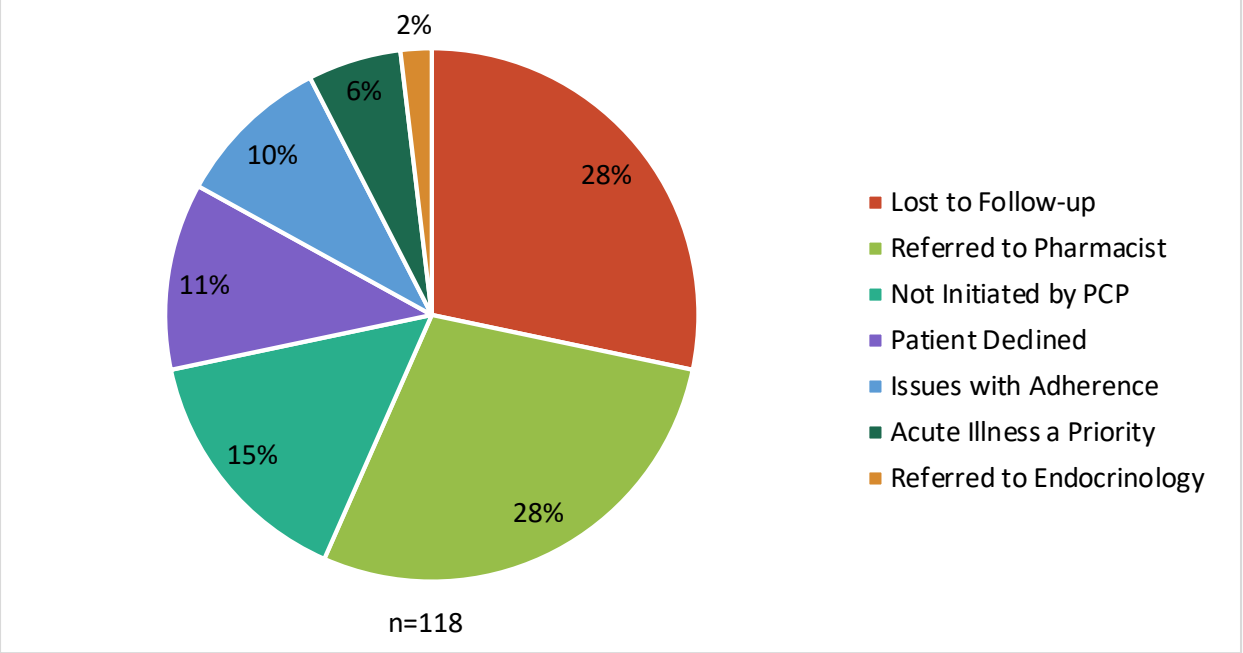


Figure C5

Type of Visit by Month

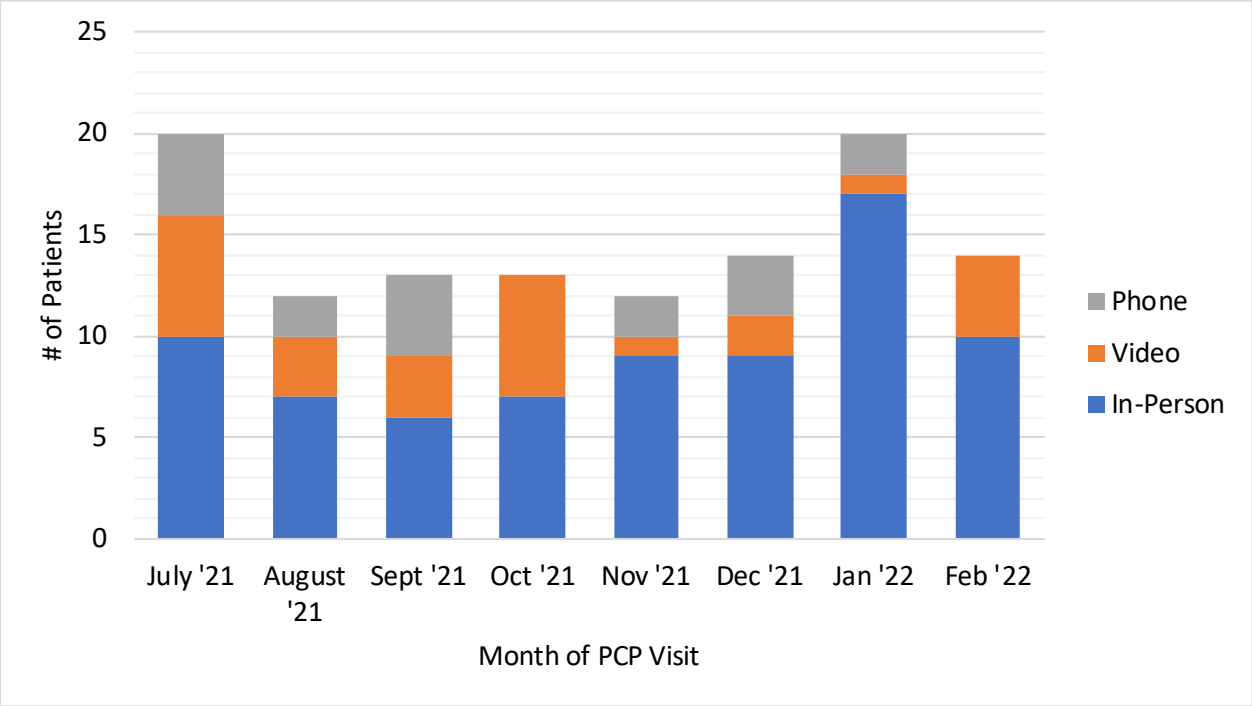
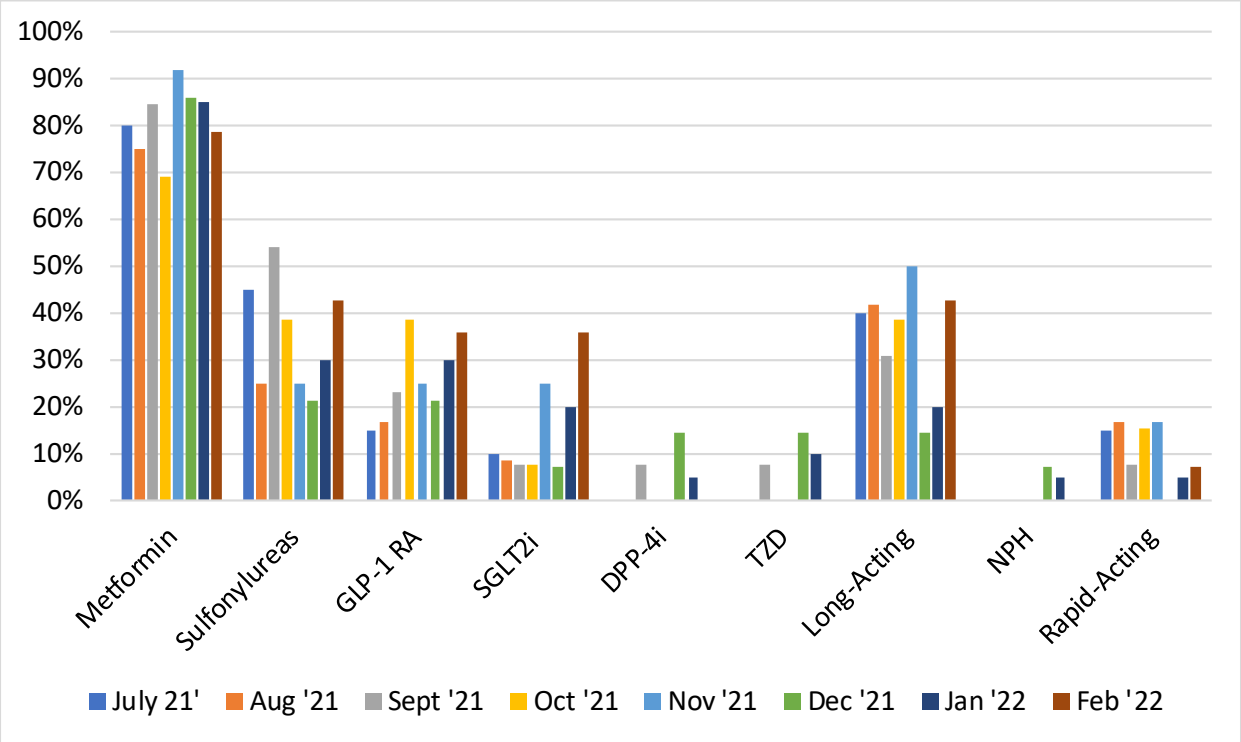


Figure C6

Percent of Patients Prescribed Different Glucose-Lowering Medication Classes by Month



Note. GLP-1 RA: glucagon-like peptide 1 receptor agonist, SGLT2i: sodium-glucose cotransporter 2 inhibitor, DPP-4i: dipeptidyl peptidase 4 inhibitor, TZD: thiazolidinedione; Long-Acting: Long-Acting Insulin, NPH: NPH Insulin, Rapid-Acting: Rapid-Acting Insulin.

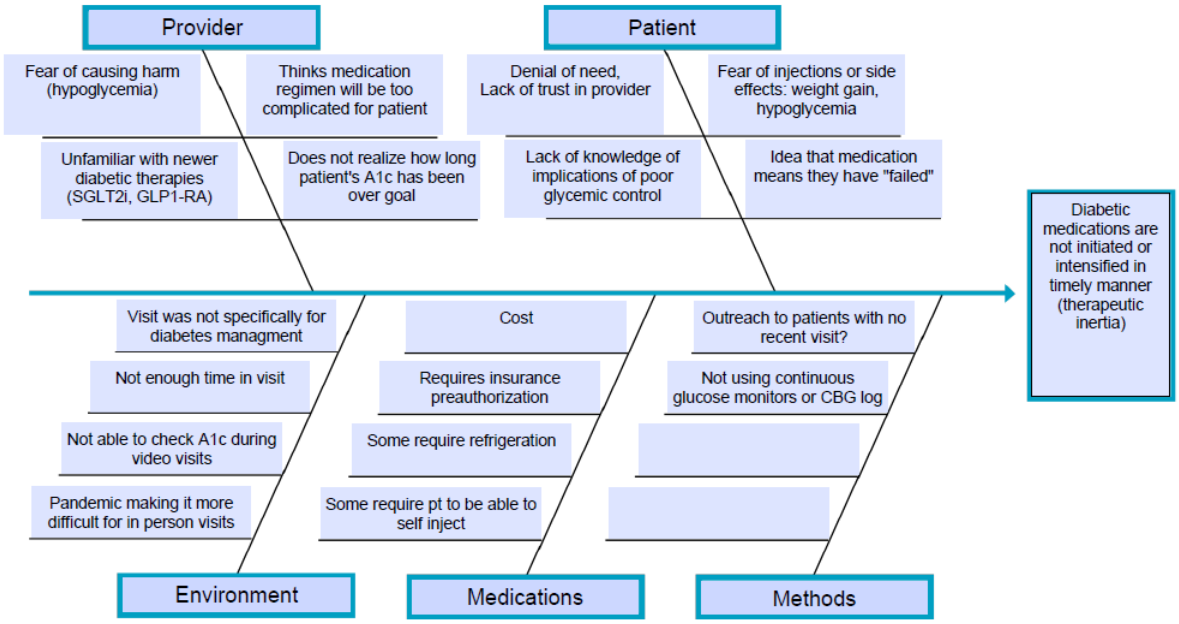
Appendix D

Project Timeline

	June	July	Aug	Sep	Oct	Nov	Dec	Jan-Mar
Finalize project design and approach (703A)	X							
Complete IRB determination or approval (703A)	X							
Initial chart review and baseline data collection		X						
Creation and dissemination of educational intervention (PDSA Cycle 1)		X						
Data collection and comparison to baseline data			X	X				
Continued data collection and dissemination to PCPs (PDSA Cycle 2?)				X	X	X		
Final data analysis (703B)							X	
Write sections 13-17 of final paper (703B)								X
Prepare for project dissemination (703B)								X

Appendix E

Cause and Effect



Appendix F

IRB Determination

IRB MEMO

Research Integrity Office
3181 SW Sam Jackson Park Road - L106RI
Portland, OR 97239-3098
(503)494-7887 irb@ohsu.edu

NOT HUMAN RESEARCH

July 6, 2021

Dear Investigator:

On 7/6/2021, the IRB reviewed the following submission:

Title of Study:	Addressing Therapeutic Inertia in Diabetes Management: A Quality Improvement Project
Investigator:	Jonathan Soffer
IRB ID:	STUDY00023177
Funding:	None

The IRB determined that the proposed activity is not research involving human subjects. IRB review and approval is not required.

Certain changes to the research plan may affect this determination. Contact the IRB Office if your project changes and you have questions regarding the need for IRB oversight.

If this project involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the HIPAA and Research website and the Information Privacy and Security website for more information.

Sincerely,

The OHSU IRB Office

Appendix G

Letter of Support

Date: May 25, 2021

Dear Anna Corson,

This letter confirms that I, Richard Kellis, allow Anna Corson (OHSU Doctor of Nursing Practice Student) access to complete his/her DNP Final Project at our clinical site. The project will take place from approximately June 2021 to December 2021.

This letter summarizes the core elements of the project proposal, already reviewed by the DNP Project Preceptor and clinical liaison (if applicable):

Project Site: OHSU Primary Care Clinic, Orenco Station. 6355 NE Cornell Rd Suite 100, Hillsboro, OR 97124

Project Plan:

- **Identified Clinical Problem:** Therapeutic inertia in diabetes management refers to failure to initiate or intensify antidiabetic medication when HbA1c goals are not met. A systematic review found that HbA1c was above goal for a median of over one year and up to seven years before therapy was intensified. Other studies have shown that primary care providers (PCPs) over estimate how aggressive they are at titrating antidiabetic therapy and under estimate how long their patients' HbA1c remains above goal. Early and more aggressive management of hyperglycemia in people with diabetes reduces long term microvascular and macrovascular complications. Therefore, reducing therapeutic inertia in diabetes management leads to improved patient outcomes.
- **Rationale:** Providing health care that is effective is one of the National Academy of Medicine's six aims for improving health care quality. It is known that initiating or intensifying antidiabetic medications when glycemic goals are not met lead to lower HbA1cs, which lead to lower rates of diabetic complications.
- **Specific Aims:** By the end of the project, the percentage of patients at OHSU Orenco with diabetes aged 18-75 with an HbA1c >9% who had no medication changes at their last visit will decrease by 10%. The secondary aim is to decrease the percentage of patients aged 18-75 with HbA1c >9% from 29% to 25%.
- **Methods/Interventions/Measures:** A chart review will be performed that identifies all patients with diabetes aged 18-75 at OHSU Orenco who have HbA1cs >9%. Main measures that will be collected include: length of time since last visit, whether or not a medication was initiated or intensified at that visit, and documented reason why medication was not initiated or intensified (if available). Other data collection will include percentage of patients managed by the clinical pharmacist and differences in prescribing between the pharmacist and PCPs. This data will be compiled into an educational intervention for the PCPs that provides possible solutions to the common barriers of initiating or intensifying antidiabetic medications. Data will be collected 1 month post educational intervention to determine if there is a reduction in percentage of patients who had changes to their diabetic medications at their last visit.
- **Data Management:** Data collection will not include any patient identifiers. All data will be stored on OHSU's approved secure storage site (currently Box).

During the project implementation and evaluation, Anna Corson will provide regular updates and communicate any necessary changes to the DNP Project Preceptor.

Our organization looks forward to working with this student to complete their DNP project. If we have any concerns related to this project, we will contact Anna Corson and Jon Soffer (student's DNP Project Chairperson).

Regards,

Richard Kellis — DNP Project Preceptor

Medical Director — Job Title

MD — Signature

5/25/21 — Date Signed