

# Overcoming Therapeutic Inertia: Accelerating the Pace of Advancing Diabetes Therapy

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## Abstract

Achieving glycemic targets and goals early in the treatment of a person with type 2 diabetes (PWT2D) is associated with maintaining lower A1C levels for longer periods of time. The corresponding reduced microvascular and macrovascular risk is a benefit that lasts for years, even if blood glucose targets achieved early are not sustained. Therapeutic inertia (TI), the failure to accelerate pharmacological therapy, when necessary, frequently prevents PWT2D and their providers from achieving glycemic goals. The registered dietitian nutritionist (RDN) with advanced practice skills in diabetes management has a right and an obligation to practice at the highest level their scope of practice allows if A1C levels in the US are to be improved.

## Introduction

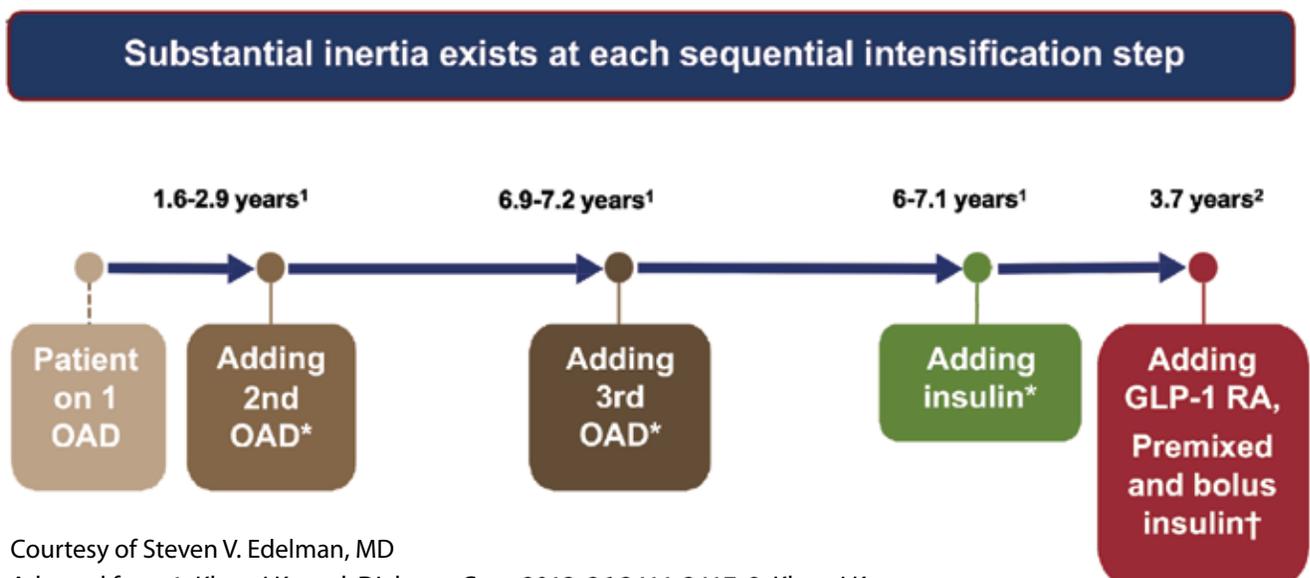
Three decades of landmark clinical trial research beginning with the UKPDS 10-year follow up, supports that achieving blood glucose targets at near normal levels early in the diagnosis of type 2 diabetes (T2D) establishes a “legacy” effect that leads to better outcomes and reduces risks of microvascular and macrovascular complications (1,2). Establishing this metabolic memory in the first year of treatment is associated with maintaining lower A1C levels for longer periods of time. These benefits last for years, even if initial blood glucose targets achieved are not sustained over time.

Yet, despite having a large armamentarium of diabetes medications and devices, we have

failed to move the national average A1C to optimal levels (3). The reason is thought to be therapeutic inertia (TI) — the failure to accelerate pharmacological therapy when necessary. TI is distinct from clinical inertia which is defined as the underuse of treatment interventions like failure to screen, perform risk assessments, initiate preventive measures, and make referrals such as nutrition therapy (2,4). Both therapeutic and clinical inertia result in delays in valuable treatment interventions and PWT2D not achieving goals.

American Diabetes Association (ADA) guidelines recommend treatment evaluation every 3-6 months and treatment escalation without delay for patients not achieving glycemic

**Figure: Documented delays in therapy intensification for people not meeting glycemic targets**



Courtesy of Steven V. Edelman, MD

Adapted from 1. Khunti K, et al. Diabetes Care. 2013; 36:3411-3417. 2. Khunti K, et al. Diabetes Obese Metab. 2016; 18:401-409

**Table 1: Promotors of Therapeutic Inertia Most Frequently Cited\***

<b>Clinician/Practice related</b>	<b>Patient related</b>	<b>System related</b>
Insufficient time	Cost and access to medications	Failing to identify patients at risk of therapeutic inertia (A1C>9%)
Failure to initiate, evaluate, coverage intensify therapy using glycemic targets and goals	Limited understanding of disease progression and need for therapy to change over time progression	Lack of point of care formulary information
Fear of aggressive therapy	Poor access or participation in Diabetes Self Management Education Support (DSMES)	Poor provision and promotion to team approach and DSMES
Lack of access to healthcare team	Poor communication and trust between physician and patient	Lack of education materials
Underestimating patient needs and abilities	Social determinants of health	

\*2020 Surveys of 608 Clinicians; Gabbay R, et al. Clinical Diabetes July 31, 2020

goals (5). Remarkably, however, studies highlight that more than two-thirds of PWT2D flounder with blood glucose levels above ideal targets for as long as 3 years before starting their first oral medication (Figure 2,6). It may then take another 3 to 6 years of elevated blood sugars before a second or third medication is added. Insulin therapy is often delayed for more than 7 years despite diabetes glucose targets not being met with oral agents. The resulting glycemic burden can be enormous.

It would be easy to attribute the problem of slow treatment to primary care providers (PCPs) who care for more than 90% of PWT2D. But as we know, diabetes management is complicated. Yes, clinicians are partially responsible for not intensifying therapy, but people with diabetes and the healthcare system can share equal responsibility. Factors perceived to be responsible for TI in these three critical realms have been identified through focus groups, surveys, and literature reviews, and are the subject of the ADA's Overcoming Therapeutic Inertia (OTI) initiative (Table 1) (3).

The focus of the OTI initiative is to adopt a framework that addresses

the primary contributors of TI in an effort to empower patients and providers, optimize care and treatment, and leverage tools and technology.

### **OTI: Empowering Clinicians to Work at the Top of Their Practice Scope**

A 2020 Kaiser Permanente study demonstrated that when PCPs took action to intensify therapy in the first year of treatment, patients with diabetes had fewer health problems and lower costs over the following 18 months (7). Additionally, a 2019 study of managed patients showed that PWT2D who did not achieve A1C goals in their first year of treatment had a 20-29% greater chance of developing diabetes related heart and kidney complications over 13 years compared to people who did achieve goals in the first year of treatment (8).

In 2021 the OTI steering committee initiated a meta-analysis and systematic review of research to examine strategies that accelerate and improve care in PWT2D (9). Thirty-six clinical trials conducted between 2004 and 2019 in more than 22,000 PWT2D met the

criteria. The results illustrate that the most effective approaches to mitigating TI and improving A1C are interventions where nurses, diabetes care and education specialists (DCES) including registered dietitian nutritionists (RDNs), or pharmacists have autonomy to address TI in partnership with PCPs (Table 2). A common and important characteristic identified was that team members independently initiated and intensified treatment using guidelines, protocols, and collaborative agreements. The authors concluded that effectiveness of these interventions may have depended less on the type of provider and more on delivery methods and frequency of communication. Indeed, studies that include RDNs using medication protocols have demonstrated similar findings (10,11). The important point is that PCPs will benefit from identifying team members available to them, developing partnerships, and referring patients to be managed by team members. The results can be improved patient outcomes and valuable clinical time saved so that PCPs can focus on other presenting health issues.

An OTI survey conducted at *Diabetes Is Primary CME* activities indicated that PCPs consult RDNs and certified diabetes care & education specialists (CDCEs) more frequently than any other group of clinicians (12). Nurse practitioners, physician assistants and pharmacists were more likely to do so than PCPs. The RDN with expertise in diabetes management is an important team member and may in some cases be the only available team member in a provider community. Working at the top of her/his abilities provides value and benefit to PCPs and their patients, and is an important opportunity for collaboration.

### OTI: Empowering Clinicians and PWT2D through Technology

Another key finding from the meta-analysis was that nearly all successful interventions utilized technology to support communication between PWT2D and team members (8). Telemonitoring, text messaging, virtual visits and mobile applications were used routinely by team members. More recently, cloud-based technology and diabetes management software with automated coaching were also used.

Recent advances in blood glucose monitoring and use of continuous blood glucose monitoring (CGM) devices provides real-time data to (PWD) people with diabetes and their clinicians. This technology is an amazing OTI tool as it facilitates rapid adjustment of medications, diet, and exercise plans long before and in between 3-month office visits (13).

While a 3-month A1C has been the primary feedback mechanism for PCPs to judge treatment success, it is now recognized as only one marker of glycemic control. Treatment

**Table 2: Percent A1C Reductions Compared to Control Arm, Grouped by Intervention\***

Intervention Type	% A1C Reduction
<b>Nurse or diabetes educators</b> using evidence-based protocols	<b>-1.62% to -0.40%</b>
<b>Care Management and Patient Education,</b> virtual coaching, telehealth SDM tools	<b>-1.2% to -0.30%</b>
<b>Pharmacist</b> providing medication therapy adjustments using guidelines	<b>-0.90% to -0.60%</b>
<b>Physician-based</b> Interventions influencing physician behavior via training and education and in-person support from clinical staff	<b>-0.40% to 0.26%</b>

\*Median range of intervention 1 year. Powell et al. Strategies for overcoming therapeutic inertia: A systematic review and meta-analysis. *Diabetes Obes Metab.* 2021

success and treatment decisions can now be based on daily blood glucose data and trends. The Association of Diabetes Care and Education Specialists (ADCES) has identified a framework for empowering DCEs to serve as technology champions for the PWD and the healthcare team (14). This framework, called ICC, involves identifying, configuring, and collaborating with patients on using technology to achieve glycemic goals. RDNs who are also DCEs would benefit their patients by using the ICC framework. (Please see the most recent *OTCE - New Frontiers* for an excellent article describing the ICC framework.)

RDNs evaluate daily glycemic profiles with regularity in PWT2D. For example, evaluating the need to add a medication to address basal or mealtime hyperglycemia is important to achieving timely glycemic targets. Assessing weight gain associated with a particular medication is clearly within the scope of the RDN's practice.

Since side effects can impact patient adherence to medications and can delay achieving goals quickly, RDNs are uniquely positioned to evaluate GI disturbances and hypoglycemia that may require de-intensifying

or modifying medication therapy. Fear of hypoglycemia keeps both providers and patients from using insulin or intensifying the dose. Next to cost, side effects like hypoglycemia are most frequently identified as the primary reasons PWD do not adhere to their treatment regimen (15).

### OTI: Empowering PWT2D to Actively Achieve Goals

Both PWT2D and their clinicians prioritized achieving their A1C goal quickly in a study examining TI from the perspective of both patients and physicians (13). Yet, providers sometimes fail to intensify diabetes therapy because they underestimate their patient's needs and abilities to carry out a treatment plan. Providers frequently identify patient denial, resistance, and lack of knowledge as barriers to becoming a self-manager of diabetes and contributing to TI. Yet patients in this study stated they were willing to do more than their physicians estimated they could or would do to achieve their goals; more than 80% wanted to get to goal quickly and were willing to make multiple changes to their treatment regimen to achieve goals. This represents an ineffective disconnect between patient and physician perceptions.

Frustration with not reaching A1C goals was common in these study patients and had a negative effect on emotional well-being. Poor communication and a lack of trust between patients and providers can influence the choice to follow a treatment plan (15). Good communication takes time and skill. RDNs have the skillset and the tools to assess patient knowledge, skills and capabilities.

RDNs often see and communicate with PWT2D as frequently as every week, and so have an opportunity to develop a trusting, caring relationship with the PWD that promotes sharing challenges such as social determinants of health or mental health issues that affect glycemic control. In turn, they can advocate for treatment regimen modification to achieve goals faster.

## OTI: Critical Conversations

An important patient knowledge gap identified through the OTI initiative is that PWT2D often do not understand the pathophysiology of the condition (Table 1). T2D is a progressive disease with multiple metabolic abnormalities contributing to elevated blood glucose levels. The ability to maintain blood glucose levels within a target range changes when the balance between insulin sensitivity and insulin production changes. By the time of onset of T2D, 50% of beta cell function may be lost and will continue to wane over time (16). It is critical that PWT2D understand this so they subsequently understand that medication management will change with time as well. Helping PWT2D share in the decision making regarding their medications represents a critical conversation all team members can and should have.

One of the most common myths is that the more diabetes medications someone takes, the sicker they are. I once had a patient who would delete one (different) pill each day because it helped her mentally feel less sick. While one medication may work initially for some, two or more may be required for others. Adding or changing medications is common and necessary (17).

PWT2D often believe that taking multiple medications or insulin indicates a personal failure—that they have done something wrong instead of recognizing the progressive nature of diabetes. Yet, more than 82% of PWD will take medications for glycemic management (3). Team members, including RDNs, can clarify misperceptions by assessing existing perceptions, attitudes, and beliefs regarding medications.

The diabetes team, including the RDN, can promote diabetes self-management education and support (DSMES). Patients want to do more to self-manage their diabetes but they need the knowledge and tools to do so (15). DSMES is a vital component of diabetes care and management as it provides PWT2D the knowledge, skill and confidence to become a self-manager of the disease. Sadly, DSMES is an underutilized benefit as less than 10% of eligible PWT2D participate (18). PCPs need to be informed of the value of DSMES and encourage PWT2D to attend. Healthcare professional recommendations and endorsements are valued by patients (15). Referral tools can help ease the burden of referring to DSMES. In turn, diabetes education needs to be accessible and interesting. Availability of individual education, telehealth and online options are currently expanding (18).

## Summary

Helping PWT2D achieve their glycemic goals effectively and in 3 - 6 months is critical to improving long-term health outcomes. The community of diabetes healthcare professional team members, including RDNs, has developed advanced practice skills in diabetes care and management. Each have a right and an obligation to practice at the highest level their scope of practice allows. The RDN, who is well positioned to integrate the pillars of diabetes management (food intake, physical activity, and medications), can aim to lead and support PWT2D, the multidisciplinary healthcare team, and healthcare systems to overcome TI.

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# Improving Diabetes Care: A Personal Journey

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## Abstract

A number of studies have shown that non-physician providers markedly improve diabetes control compared with usual care. Nurse practitioners (NPs) and physician assistants (PAs) accomplish this under their respective scopes of practice, while the clinical decisions of registered nurses (RNs), registered dietitian nutritionists (RDNs) and clinical pharmacists are based on either approved protocols or under the direct supervision of physicians. RDNs are in a unique position to improve diabetes control because they see patients for dietary intervention/nutrition counseling not only at diagnosis, but also frequently afterwards to gather glucose readings illustrating hypoglycemia or hyperglycemia that may warrant medication changes.

For the past 20 years the National Health and Nutrition Examination Survey has illustrated that glycemic control in people with diabetes has not improved. Stagnant A1C levels and fewer people achieving blood glucose targets in 2018 than 2007 is alarming (1,2). This lack of progress has occurred despite the introduction of new classes of non-insulin drugs, many new insulin analogues, and advanced diabetes-related technologies.

In 2009, I wrote an editorial decrying that “timely and appropriate clinical decisions are not being made in most patients under our current

medical care system” due to infrequent interactions with patients by providers not particularly knowledgeable or confident to treat diabetes (3). In that editorial, I pointed out that quality improvement studies had concluded that the only approach that was effective was using non-physician providers with advanced knowledge in diabetes care who were given the authority to make clinical decisions (4). This conclusion was supported by two randomized controlled studies in the same clinic system. The first was a diabetes case management study in which medication changes by nurse practitioners (NPs) required approval by primary care physicians (PCPs). Baseline A1C levels averaging >9.0% did not change over 18 months in either the intervention or control groups (5). The second study showed that baseline A1C levels averaging >10% fell by 2.1% in an intervention group treated by a clinical pharmacist with the authority to *independently* make clinical decisions compared to a 0.9% decrease in the usual care control group (6).

Unfortunately, the model of PCPs providing care that is infrequent and not team-based is still not working. I supervise two diabetes programs: one in a large county outpatient center and the other in a Federally Qualified Health Center (FQHC) that serves 27,000 patients. A large percentage of both populations are

poor, minority and under-resourced. I have documented that in the large county clinic more than 30% of the patients with diabetes have had A1C levels >9.0% for the past 3 years while in the FQHC, more than 20% have had these levels for the past 6 years (personal communication).

Years ago, I was given an opportunity to improve diabetes control in people with diabetes in a Health Maintenance Organization (HMO) where the hospital and physicians received a specific amount of money for each enrolled patient regardless of the services provided. This HMO (like most others) was losing money on their patients with diabetes and their medical director asked me to develop a Diabetes Management Program that would lower their costs. I decided to switch the outpatient diabetes care of these patients from

their PCPs, who provide care for 90% of people with diabetes (7), to nurses specially educated to give this care. To that end, Anne Peters, MD, and I developed detailed diabetes treatment protocols that Dr. Peters subsequently taught to nurses recruited for this program. Since that time, I have worked with 44 registered nurses (RNs), NPs, physician assistants (PAs) and clinical pharmacists to instruct them in the use of these detailed treatment protocols that have been progressively modified as new treatments were developed and approved.

These providers make independent clinical decisions including medication modifications. NPs and PAs do this under their scopes of practice while the clinical decisions of registered nurses and clinical

pharmacists are based on either approved protocols or under the supervision of physicians. These providers have uniformly and markedly improved diabetes control in poorly controlled patients receiving usual care as evident from at least eleven studies (see Table). The mean baseline A1C of 10.3% for these patients was reduced by 2.4% in these studies. Diabetes care directed by an RN following detailed treatment protocols reduced urgent care/emergency room visits by 51% and hospitalizations for preventable diabetes-related causes by 80% in 331 patients compared to their usual care the prior year (19).

Others have also shown that health care professionals other than physicians, using protocols, can improve diabetes control, as good as, or in some cases significantly

**Table – Effect of Non-Physician Clinicians Specially Trained in Diabetes Care on A1C Levels**

Reference	Type of Study	Treating Cohort	Duration (Months)	N	Baseline HbA1C (%)	Final HbA1C (%)	P Value Within Cohort	P Value Between Cohorts
8	Case Control	RN/PA	12	117	8.9	6.9	NA	<0.001
		Usual Care	12	88	8.3	9.1	NA	
9	Case Control	RNs	12	97	11.9	8.8	<0.001	NA
		Usual Care	12	67	10.0	9.9	NS	
10	Case Control	Clinical Pharmacists	12	89	8.8	8.0	NA	<0.03
		Usual Care	12	92	7.9	7.9	NA	
11	Pre-Post	RN	5	29*	8.4	7.7	<0.001	-
12	Case Control	RN/Clinical Pharmacist	6	120	13.3	9.8	<0.02	<0.001
		Usual Care		145	12.3	10.8	<0.01	
13	Pre-Post	RN	12	361	8.8	7.0	<0.001	-
14	Pre-Post	RN	9-12	178	11.1	7.2	<0.001	-
15	Pre-Post	NP	6	28*	10.0	8.0	<0.001	-
16	Pre-Post	Clinical Pharmacist	3	13†	11.5	8.3	<0.001	-
17	Pre-Post	NPs	12	451	>9.0	<7.5‡	NA	-
18	Pre-Post	NPs/PA	7	96	11.0	8.4	<0.001	-

NA – not available; NP – nurse practitioner; NS – not significant; PA – physician assistant; RN – registered nurse

\*Insulin-requiring using remote glucose monitoring; †Insulin-requiring using continuous glucose monitoring (CGM); ‡>90% of patients

more, than usual care (20-26). In 2021, a systematic review and meta-analysis was published summarizing interventions used to overcome therapeutic inertia (27). The range of changes in A1C levels for four different strategies were as follows: -1.62% to -0.4% for nurse or Certified Diabetes Care and Education Specialist interventions in five studies; -1.20% to +0.3% for case management and patient education interventions in 20 studies; -0.90% to -0.60% for pharmacist-based interventions in four studies; and -0.40% to +0.26% for physician-based interventions in seven studies. The authors concluded that “the most effective approaches to mitigating therapeutic inertia and improving A1C were those that empower non-physician providers such as pharmacists, nurses and diabetes educators to initiate and intensify treatment independently, supported by appropriate guidelines.”

Over the years, I have worked with RDNs who were given authority by supervising and collaborating physicians to change pharmacological therapy following approved protocols with effective results. Occasionally, organizational challenges have presented barriers to successfully implementing such a program. Yet, RDNs are in a unique position to fundamentally change clinical outcomes in people with diabetes for two reasons. First, many patients are referred to them soon after diabetes has been diagnosed. Second, they see patients frequently for dietary intervention and support and are thus positioned to gather important daily glucose readings illustrating hypoglycemia or hyperglycemia that may warrant medication changes—either

intensifying or de-intensifying drugs. Importantly, published findings support the role of RDNs in helping patients manage diabetes (24-26).

RDNs who have advanced certifications in diabetes – either board certified in advanced diabetes management (BC-ADM) or certified diabetes care and education specialist (CDCES) through Certification Board for Diabetes Care and Education (CBDCE) – are credentialed to manage complex patient needs including adjusting medications. Yet many other RDNs educated to provide pharmacological treatments using protocols can and should be given the authority to independently do so. This practice represents true team-based care and could have a marked beneficial effect on improving diabetes care and health outcomes.

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