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# Getting Under the Skin of Clinical Inertia in Insulin Initiation: The Translating Research Into Action for Diabetes (TRIAD) Insulin Starts Project

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# Abstract

**Purpose**—The purpose of this cross-sectional study is to explore primary care providers' (PCPs) perceptions about barriers to initiating insulin among patients. Studies suggest that many patients with poorly controlled type 2 diabetes do not receive insulin initiation by PCPs.

**Methods**—As part of the TRIAD study, we conducted structured interviews in health systems in Indiana, New Jersey, and California, asking PCPs about the importance of insulin initiation and factors affecting this decision. We calculated proportions choosing each multiple-choice response option and listed the most frequently offered open-ended response categories.

**Results**—Among 83 PCPs, 45% were women, 60% were Caucasian, and they averaged 13.4 years in practice. Four-fifths of PCPs endorsed guideline-concordant glycemic targets, but 54% individualized targets based on patient age, life expectancy, medical co-morbidities, self-management capacity, and willingness. Most (64%) reported that many patients were resistant to new oral or insulin therapies due to fears about the therapy and what it meant about their disease progression. Two-thirds (64%) cited patient resistance as a barrier to insulin initiation, and 43% cited problems with patient self-management, including cognitive or mental health issues, dexterity, or ability to adhere.† Eighty percent felt that patient non-adherence would dissuade them from initiating insulin at least some of the time.

**Conclusions**—PCPs perceived that patient resistance and poor self-management skills were significant barriers to initiating insulin. Future studies should investigate whether systems-level interventions to improve patient-provider communication about insulin and enhance providers' perceptions of patient self-management capacity can increase guideline-concordant, patient-centered insulin initiation.

The authors have no conflicts of interest to disclose.

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#### Keywords

diabetes; insulin therapy; clinical inertia; clinical decision-making

Although guidelines recommend the early initiation of insulin therapy among type 2 diabetes who do not achieve adequate glycemic control on oral agents,<sup>1,2</sup> many primary care providers do not initiate insulin therapy even when their patients are not adequately controlled. In a retrospective study of 7208 patients, from time of diagnosis to the start of insulin therapy, the average patient spent nearly 5 years with their hemoglobin A1c >8% and 10 years with their hemoglobin A1c >7%.<sup>1,2</sup>

The decision to initiate insulin may be affected by patient-, provider-, and systems-level factors. For example, research suggests that patients resist initiating insulin – either by failing to fill a new prescription for insulin or to refill an existing prescription – because of fears about discomfort or harm from the therapy, limited understanding of its risks and benefits, or uncertainty about self-management.<sup>3,4</sup> Patients' perceptions about medication intensification or initiation may differ markedly from provider recommendations; patients may view the event as evidence of personal failure and a potentially health risk itself (rather than reducing future complication risk) and may consider de-escalation a primary goal.<sup>5</sup>

Other studies have examined potential provider reasons for clinical inertia – or failure to intensify medication therapies – including providers' overestimating the quality of care they provide, use of "soft" rationalizations to avoid intensification, and lack of organizational mechanisms to help providers track and achieve therapeutic goals.<sup>6</sup> Provider frustrations with their own inability to address patient or health system barriers may also play a role in deciding not to intensify therapy.<sup>7</sup> At the systems level, care facilities may lack the support mechanisms needed to assist providers in initiating more complex therapies such as insulin.

However, deferring insulin initiation based on the benefits and risks for individual patients may be appropriate patient-centered care. Recent studies have raised uncertainty about the cardiovascular benefit of tight glycemic control among type 2 diabetics and concerns about the risks and long-term consequences of hypoglycemia.<sup>8–10</sup> The American Geriatric Society and the American Diabetes Association clinical guidelines recommend an individualized approach to glucose-lowering for older patients, emphasizing the need to adjust glycemic targets based on life expectancy, geriatric syndromes, and quality of life.<sup>1,11</sup> As a result of these and other factors, providers may be left with clinical dilemmas when they need to decide whether to initiate insulin for individual type 2 patients.

We conducted this study to investigate primary care providers' beliefs regarding the importance of initiating insulin to achieve glycemic control targets and factors affecting their decision to initiate insulin therapy among patients with poorly controlled diabetes.

# Methods

#### Study Design and Sample Population

We conducted structured interviews with primary care providers in three states. Providers were drawn from the Indiana University Medical Group (IUMG), community-based primary care physicians in New Jersey, and the Kaiser Permanente Medical Group of Northern California (KPMG). This cross-sectional study was part of the *Insulin Starts Project*, which was in turn an ancillary study of a larger ongoing CDC and NIDDK-funded study of the quality of care and self-care for people with diabetes in U.S. managed care settings, The

*Translating Research Into Action for Diabetes (TRIAD).* The TRIAD study design and methods have been previously reported.<sup>12</sup>

Eligible participants were primary care providers (PCPs) – physicians or nurse practitioners – with at least two half-day clinic sessions per week and panels with at least 50 patients with type 2 diabetes, including patients who had a hemoglobin 8% on maximal doses of 2 oral hypoglycemic agents in the past 18 months (i.e., patients eligible for a separate study within TRIAD.<sup>3</sup> Physicians-in-training were excluded. Eligible providers were identified by the health plans.

#### **Data Collection**

Providers were recruited by TRIAD staff at each of three TRIAD translational research centers participating in this study. We mailed letters to providers who cared for patients deemed eligible for the patient survey asking for approval to recruit their patients and inviting them to participate in this provider study. Recruiters aimed to enroll 90 PCPs from the three health plans, and provider recruitment was concluded after reaching enrollment targets. Providers received \$100 for their participation.

Research assistants conducted one-hour structured telephone interviews at a time and date convenient for providers. The instrument contained open-ended questions and follow-up probes about the following topics: glycemic goals, factors contributing to insulin initiation, barriers to insulin initiation, choice of insulin once initiated, and barriers to insulin adherence. Questions were not linked to specific patients, but rather asked providers to consider an average patient in their panel with diabetes. Providers also reported their demographic characteristics. This analysis focuses on interview items assessing factors that affect PCPs' choice of glycemic targets, contribute to their decisions to initiate insulin therapy, and serve as barriers to their decisions to initiate insulin therapy. The Institutional Review Boards of all three TRIAD translational research centers approved this study.

#### Data Analysis

We calculated the proportions of participants choosing each response option. For openended response options, we listed the most frequently offered responses, as categorized by the authors. Respondents were allowed to respond to multiple items relevant to an individual question.

# Results

Eighty-three PCPs completed interviews. Their average age was 45.6 (SD 8.9) and average time in practice 13.4 years (SD 9.5). Half (45%) were women; 60% were white, 11% African-American, 10% of Asian descent. Twenty-seven percent were from California, 37% from Indiana, and 37% from New Jersey.

#### **Glycemic Goals**

Most PCPs endorsed a guideline-concordant glycemic target, with 69% choosing hemoglobin A1c under 7.0 as an ideal target for good control; 13% chose values between 6.0 and 6.9 and 18% chose values between 7.2 and 8.0. However, over half (54%) perceived a need to raise the target A1c value depending on patient factors. Providers most frequently chose the following patient factors as reasons to accept higher glycemic targets: advanced age or shortened life expectancy (54%), presence of co-morbidities (34%), poor selfmanagement capacity due to poor cognitive abilities (35%), low educational level or poor health literacy (34%), and patients' unwillingness to self-manage their diabetes (33%).

#### **Factors Contributing to Insulin Initiation**

When offered a list of potential factors that would lead to initiating insulin, 83% of PCPs chose failure to reach anti-hyperglycemic goals using other therapies, while some providers cited medication contraindications (27%) or side effects (23%) to oral agents. Only 7% felt that patients' requests for insulin were a factor.

#### **Barriers to Initiating Insulin**

When asked for the reasons that they decided not to initiate insulin therapy, 64% cited patient refusal or resistance and 43% cited concerns about patients' lack of self-management skills. PCPs indicated that it was somewhat or very common that patients will <u>not</u> try new therapies proposed by providers or adhere to these therapies once started. Two-thirds of PCPs (67%) felt that at least 10% of their patients would refuse insulin and that at least 10% who start insulin would decide not to continue. The primary reasons that PCPs thought patients refuse to initiate insulin included: fear of injections (97%), patients' beliefs that using insulin means they will get sicker (38%), and the inconvenience associated with injections and self-monitoring of glucose (22%). Similarly, PCPs reported that the most common reasons patients fail to adhere to insulin therapy were inconvenience (34%), fear of hypoglycemia (30%), injection discomfort (28%), and inability to self-manage with insulin (15%). Forty-one percent of PCPs felt that language barriers would be a challenge when starting a patient on insulin in their practice environment.

When asked for reasons that would lead them to deem a patient incapable of managing insulin therapy, 49% selected self-management skills, 35% blindness, 33% poor cognitive abilities, and 27% psychological issues. Finally, four-fifths of PCPs felt that, for patients with low levels of adherence to oral agents, they would not initiate insulin some of the time (43%), most of the time (34%), or ever (5%).

# Discussion

In this multi-site study, PCPs endorsed the importance of achieving glycemic goals and of initiating insulin to reach glycemic targets for those uncontrolled on oral agents. However, most believed that several factors would mitigate their ability to intensify therapy in general and to initiate insulin in particular. Most of the respondents identified patient factors as a prime contributor to decisions to not initiate insulin. The respondents reported that at least 10% of their patients would refuse starting or continuing insulin therapy due to fear of the injections, fear of insulin, or the inconvenience of self-management. For most providers, this perceived resistance or lack of self-management skills in their patients was a barrier to initiating insulin therapy, and prior non-adherence to oral agents would dissuade most PCPs from initiating insulin with some patients.

Provider decision-making about whether to initiate or intensify medication therapy is a complex process affected by multiple factors,<sup>6</sup> and clinical inertia is considered a major reason for inadequate metabolic control in diabetics.<sup>13–15</sup> In prior studies, rates of appropriate medication intensification for poorly controlled hemoglobin A1c have ranged from 46 to 66%.<sup>14,16,17</sup> However, these studies did not investigate the relative contribution of PCPs' attitudes to their clinical inertia.

Our results lend insights into how providers incorporate their beliefs about patients' prior adherence, preferences, and treatment risk and burden into their decision-making. Indeed, while most providers aimed for a hemoglobin A1c target of <7.0%, most also would adjust this target or refrain from starting insulin, a modification that is consistent with established guidelines.<sup>1,8,11</sup> Given recent studies highlighting the linkage between inadequate health literacy among insulin users and hypoglycemia risk, and the long-term and acute

consequences of hypoglycemia events,<sup>9,10,18</sup> providers' concerns about initiating insulin therapy may be both patient-centered and medically appropriate. With the potential for physical, psychological, and financial burdens of intensive therapy and monitoring, some have questioned the wisdom of applying quality indicators to promote tight glycemic control among all type 2 diabetics, arguing for more conservative prescribing practices.<sup>19,20</sup>

However, it is unclear how accurate PCPs are in their assessment of patients' preferences, concerns, and self-management capacity. A separate part of the TRIAD Insulin Starts Project assessed attitudes towards insulin among patients with poorly controlled diabetes who fail to fill their first insulin prescriptions and found similar barriers to insulin therapy reported from the patient perspective.<sup>3</sup> Fear of injections occurred for 30% of patients who failed to start insulin, and 97% of PCPs recognized that this is a major reason for patients' failure to initiate insulin therapy. Meanwhile, 55% of patients who did not fill their insulin prescription felt that medication risks and benefits were not adequately explained by their providers, with 51% reported difficulty learning about their condition because of problems understanding written information (i.e., inadequate health literacy). Among patients who did not fill their ability to give themselves shots (42%) and potential negative impact on their jobs (33%) and their social lives (38%).<sup>3</sup> This suggests that some of these potential barriers might be addressed by more patient education and counseling and more focus on the quality of providers' communication regarding insulin initiation.

Providers' assumptions about self-management capacity could also contribute to disparities in intensification in response to suboptimal glycemic control. In our study, PCPs considered limited health literacy and language issues to be barriers to self-management, which is itself a barrier to insulin initiation. A recent study did find that patients with limited health literacy were 30–40% more likely to experience hypoglycemia compared to those with adequate health literacy.<sup>9</sup> However, a patient's capacity for self-management is not a static factor, and health care systems interventions can enhance diabetes self-management among diverse patient populations.<sup>21,22</sup> For example, a randomized controlled trial of automated telephone self-management support among a low income population with limited English proficiency and poorly controlled diabetes demonstrated significant improvements in self-management behavior, including increased participation in self-management behaviors and physical activity.<sup>22</sup>

Providers' beliefs that some patients lack the willingness or capacity to take insulin may reflect a need for more resources to help providers engage patients in effective shared decision-making and enhance patients' capacity for self-management. In one study of older patients with diabetes, the higher patient ratings of their providers' provision of information and participatory decision-making style were significantly associated with self-management behaviors such as diet, exercise, glucose monitoring, and foot care, and patients' ratings of their self-management were associated with glycemic control.<sup>23</sup>

Our study highlights the prominence of perceived patient non-adherence in dissuading providers from initiating insulin. Consistent with our findings, another study suggested that academic general internal medicine physicians emphasized patient adherence, along with patient fear of injections and patient desire to prolong non-insulin therapy as major insulin barriers.<sup>24</sup> In one study examining pharmacy claims, 23% of poorly controlled hyperglycemic patients had evidence of poor adherence and lack of treatment intensification by providers.<sup>17</sup> Still, 30% of poorly controlled, hyperglycemic patients had no treatment intensification despite a lack of evidence of poor medication adherence, suggesting that providers may not accurately assess non-adherence in their patients or that this does not explain clinical inertia entirely.<sup>17</sup> Meanwhile, interventions focused on improving

medication adherence have been complex and marginal in effectiveness.<sup>25</sup> More strategies are needed to help providers assess and manage non-adherence and to determine whether maintaining, decreasing, or intensifying a regimen is the most effective or patient-centered recommendation.

This study is limited in that, although the providers were drawn from three different health systems caring for diverse patient populations, our findings may not be generalizable to providers in other systems caring for different populations. We did not assess formally validity or reliability of the interview instrument. Because we asked PCPs to reflect on patients in general, our results may be susceptible to recall bias by providers attempting to recall factors in past decision-making experiences with their patient panel. An interview conducted immediately following a specific decision regarding a specific patient – particularly if paired with an interview with the patient itself – might be less subject to recall bias, but might also yield different insights into the insulin initiation decision-making process. Finally, our limited sample size precludes us from determining whether PCP factors such as years in practice or clinic site are related to attitudes. the study methodology asked PCPs to reflect on their patients in general;

# Conclusions

In summary, although they believed in the importance of tight glycemic targets, these PCPs perceived that patient resistance and poor self-management skills were significant barriers to initiating insulin therapy. Consequently, many patients remain on less intensive therapies. Some of the factors identified may be amenable to education and counseling. However, PCPs may defer insulin therapy based on reasonable concerns about patients' capacity to use safely an intensive therapy that requires extensive self-management. Future studies should investigate whether systems-level interventions to improve patient-provider communication about insulin therapy and enhance patient self-management can decrease providers' perception of these barriers and increase the likelihood of guideline-concordant, patient-centered insulin initiation.

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# Implications / Relevance for Diabetes Educators

- In this study in three health systems, half of primary care providers believed in the need to individualize targets based on patient age, life expectancy, medical co-morbidities, self-management capacity, and willingness.
- Most primary care providers cited patient resistance, poor self-management skills, and non-adherence as barriers to insulin initiation
- To increase guideline-concordant, patient-centered insulin initiation, managed care leaders should consider strategies to improve patient-provider communication about insulin and enhance providers' perceptions of patient self-management capacity.

#### Table 1

Primary care providers' attitudes about intensifying anti-hyperglycemic therapy and initiating insulin among poorly controlled diabetics, from a telephone study in three health care systems (n=83)

Attitudes	%
Highest hemoglobin A1c for which patient would be in good control	
6.0 - 6.9	13
7.0	69
>7.0 - 8.0	18
Reasons to adjust glycemic targets *	
Age / life expectancy	54
Ability to self-manage due to cognitive abilities	35
Medical co-morbidities	34
Ability to self-manage due to education level / health literacy	34
Patient willingness to self-manage	33
Reasons to initiate insulin <sup>*</sup>	
Failure to reach glycemic goals using other therapies	83
Contraindications to oral agents	27
Side effects with oral agents	23
Proportion of patients failing to try oral medications $\dot{\tau}$	
<10%	41
10%	33
15–30%	24
33–50%	2
Proportion of patients trying but failing to continue or al medications ${}^{\acute{\mathcal{T}}}$	
<10%	23
10%	41
15–30%	28
33–50%	8
Proportion of patients failing to try insulin $\dot{\tau}$	
<10%	34
10%	23
15–30%	33
35–70%	Ģ
Proportion of patients trying but failing to continue insulin <sup><math>\dot{\tau}</math></sup>	
<10%	39
10%	28
15–30%	26
33–55%	7

Attitudes	%
Perceived reasons why patients refuse to initiate insulin *	
Fear of injections	97
Beliefs that insulin will mean they will get worse, go blind, die sooner, etc.	38
Inconvenience due to injections and self-monitoring blood glucose	22
Perceived reasons why patients refuse to continue or adhere poorly to insulin *	
Inconvenience due to injections and self-monitoring blood glucose	34
Fear of hypoglycemia	30
Discomfort from injections	28
Inability to self-manage with insulin.	15
Reasons for deciding NOT to initiate insulin therapy*	
Patient refusal or resistance	64
Concerns about patient's self-management skills	43
Discomfort from injections	28
Prior non-adherence would lead PCP to decide with this type of patient to	Ι
Never initiate insulin	5
Not initiate insulin most of the time	34
Not initiate insulin some of the time	43
Rarely not initiate insulin	17

\*Respondents were asked to select >1 response, so proportions do not add up to 100%

 $^{\dagger}$ Open-ended responses were solicited, then categorized into intervals during analysis based on the actual responses in those categories.