Proposed Title

Improving the Insulin Experience in Patients With Diabetes

Goal

Educate health care providers about strategies to overcome psychological insulin resistance

Learning Objectives

After completing this activity, learners should be better prepared to:

1. Describe barriers to insulin initiation and adherence/persistence facing people with diabetes.
2. Discuss underlying causes of psychological insulin resistance that contribute to treatment delay.
3. Explain the effect of barriers to insulin initiation and adherence/persistence on patient outcomes.
4. Evaluate strategies to overcome barriers to insulin initiation and adherence/persistence.

Statement of Need

Needs assessment has identified the following practice gaps:

- Insulin therapy plays a central role in the management of diabetes,[1] with an estimated 6 million people with diabetes using insulin, either alone or in combination with oral medication.[2]
- Despite the strong evidence supporting the clinical and economic benefits of insulin therapy in achieving glycemic control and reducing diabetes-related complications,[3] treatment resistance remains common among patients and providers.[4,5]
- Insulin therapy continues to be underused, [6] with only 31% of US adults with diabetes using insulin either alone or in combination with oral medications.[7]
- Lack of adherence/persistence to insulin therapy has been shown to result in suboptimal patient outcomes.[8]
- Various patient, provider, and health care system factors contribute to barriers that impede insulin initiation and adherence/persistence.
- Patient barriers can result from the fear of needles and anxiety about pain from injections,[9-11] psychological beliefs and misconceptions about treatment,[12] and concerns about hypoglycemia and weight gain.[11,13,14]
- Provider barriers can result from clinical inertia, which can adversely affect timely diabetes management,[15-17] patient concerns about potential risks of insulin therapy,[11,13] and practical concerns that may increase the reluctance of clinicians to initiate insulin therapy.[18,19]
- System barriers can result from resource and time constraints that limit staff availability, systemic and financial barriers that limit treatment access, and the needs of special populations who require effective teaching techniques for patient education.[11,13,14]
- Once insulin therapy is initiated, patients often struggle with treatment adherence and persistence, leading to unfavorable outcomes, including inadequate glycemic control, increased risk for diabetes-related complications, and decreased quality of life (QoL).[5,9]
- Barriers to insulin adherence can be categorized using a similar approach to barriers to insulin initiation; these include patient factors, medication factors, and system factors.[1,2]

- Strategies to overcome barriers to insulin initiation and adherence/persistence should use patient-centered approaches for shared decision making that incorporate individual needs, preferences, and values.[19]

Identified gaps and barriers

- *Physician-related:* lack of familiarity with barriers to insulin initiation and adherence/persistence, the effect of barriers on patient outcomes, and strategies to overcome barriers to insulin initiation and adherence/persistence.
- *Systems-related:* lack of time to attend national conferences, resulting in failure to remain up-to-date with the current knowledge on the barriers to insulin initiation and adherence/persistence, the effect of barriers on patient outcomes, and strategies to overcome barriers to insulin initiation and adherence/persistence
- *Patient-related:* lack of familiarity with the barriers to insulin initiation and adherence/persistence, the effect of barriers on patient outcomes, and strategies to overcome barriers to insulin initiation and adherence/persistence
- *Disease-related:* lack of knowledge of the barriers to insulin initiation and adherence/persistence, the effect of barriers on patient outcomes, and strategies to overcome barriers to insulin initiation and adherence/persistence

Educational Gap Analysis

Gap	Learning Objective	Expected Outcome	ABMS Core Competencies
Clinicians may not be aware of barriers to insulin initiation and adherence/persistence, including the underlying causes of psychological insulin resistance	Describe barriers to insulin initiation and adherence/persistence facing people with diabetes Discuss underlying causes of psychological insulin resistance that contribute to treatment delay	Clinicians will exhibit awareness of the barriers to insulin initiation and adherence/persistence, including the underlying causes of psychological insulin resistance	▪ Medical knowledge ▪ Practice-based learning and improvement
Clinicians may not be familiar with the effect of barriers to insulin initiation and adherence/persistence on patient outcomes	Explain the effect of barriers to insulin initiation and adherence/persistence on patient outcomes	Clinicians will have increased awareness of the effect of barriers to insulin initiation and adherence/persistence on patient outcomes	▪ Medical knowledge ▪ Practice-based learning and improvement

Clinicians may be unaware of the strategies to overcome barriers to insulin initiation and adherence/persistence	Evaluate strategies to overcome barriers to insulin initiation and adherence/persistence	Clinicians will have increased awareness of strategies to overcome barriers to insulin initiation and adherence/persistence	▪ Medical knowledge ▪ Practice-based learning and improvement ▪ Patient care and procedural skills

National Quality Strategy

The National Quality Strategy (NQS) is a set of 3 general aims established by the Affordable Care Act with the goal of improving health and health care quality. The following table illustrates the ways in which the proposed educational initiative will support the aims of this effort.

NQS Aims	Proposed Education
Better care Improve the overall quality of care by making health care more patient-centered, reliable, accessible, and safe	● Describe barriers to insulin initiation and adherence/persistence facing people with diabetes ● Discuss underlying causes of psychological insulin resistance that contribute to treatment delay ● Explain the effect of barriers to insulin initiation and adherence/persistence on patient outcomes ● Evaluate strategies to overcome barriers to insulin initiation and adherence/persistence
Healthy People/Healthy Communities Improve the health of the US population by supporting proven interventions to address behavioral, social, and environmental determinants of health in addition to delivering higher-quality care	● Describe barriers to insulin initiation and adherence/persistence facing people with diabetes ● Discuss underlying causes of psychological insulin resistance that contribute to treatment delay ● Explain the effect of barriers to insulin initiation and adherence/persistence on patient outcomes ● Evaluate strategies to overcome barriers to insulin initiation and adherence/persistence
Affordable care Reduce the cost of quality health care for individuals, families, employers, and government	● Describe barriers to insulin initiation and adherence/persistence facing people with diabetes ● Discuss underlying causes of psychological insulin resistance that contribute to treatment delay ● Explain the effect of barriers to insulin initiation and adherence/persistence on patient outcomes ● Evaluate strategies to overcome barriers to insulin initiation and adherence/persistence

Literature Review

Introduction

Insulin therapy plays a central role in the management of diabetes. According to the American Diabetes Association (ADA) Standards of Care, people with type 1 diabetes should be treated with multiple daily

injections of prandial and basal insulin or continuous subcutaneous insulin infusion.[1] Insulin therapy may also be considered for the treatment of patients with type 2 diabetes who are unable to attain glycemic goals with oral antihyperglycemic agents. In the United States, an estimated 6 million people with diabetes use insulin, either alone or in combination with oral medication.[2]

Despite the availability of new therapies and technologies to treat diabetes, many patients are unable to achieve optimal glycemic control. Based on recent registry data from 25,529 participants in the TD1 Exchange, only 20% of patients with type 1 diabetes are meeting HbA1c goals.[20] Many patients with type 2 diabetes are also unable to achieve glycemic control. In a retrospective analysis of 39,074 patients from US claims data, it was reported that 50% to 73% of patients treated with basal insulin were still unable to meet recommended targets.[21]

Insulin is an important component of diabetes therapy to achieve glycemic control and reduce the risk for long-term complications, such as nephropathy and neuropathy.[5,22] Strong evidence supports the clinical and economic benefits of insulin therapy in achieving glycemic control and reducing diabetes-related complications.[3] Nonetheless, the failure to initiate and adhere to insulin therapy has been identified as a key factor that contributes to inadequate glycemic control.[23] Adherence is defined as the extent to which patients take their medications as prescribed by the health care provider.[24] Persistence is defined as the duration of time that patients adhere to the treatment plan.[25] Both adherence and persistence are required to achieve optimal outcomes.[26]

Patients and providers may show resistance in initiating and adhering to insulin therapy.[4] Due to barriers related to treatment initiation as well as obstacles that hinder treatment adherence,[5] insulin therapy remains underused,[6] with only 31% of US adults with diabetes using insulin either alone or in combination with oral medications.[7] Furthermore, many patients who receive insulin therapy have demonstrated patterns of poor persistence.

- In the Diabetes Attitudes, Wishes, and Needs (DAWN) study, one-fifth of respondents “often or sometimes” skipped insulin injections and 10% restricted daily insulin usage.[4]
- In a study by Asche and colleagues, rates of insulin persistence in the year after initiation of basal insulin were low, ranging from 26% to 52%.[27] These rates were even lower for bolus insulin, ranging from 19% to 42%.

Suboptimal patient outcomes have been documented with lack of adherence to insulin therapy.[8] Several studies have found nonadherence and decreased persistence lead to increased likelihood of treatment failure as well as higher overall health care costs.[5,26]

- In a study by Chandran and colleagues, lower adherence was associated with increased hospitalization costs (US $7,543 vs US $4,485).[28]
- In a pooled analysis from 3 US studies, patients with poor treatment persistence showed significantly higher HbA1c levels and significantly lower reductions in HbA1c at 1 year after initiation of basal insulin compared with persistent patients, with no significant difference in hypoglycemic events (HbA1c level: 8.46% vs 8.26%; *P*=0.0260; reduction in HbA1c: –0.86% vs –1.15%; *P*=0.0078).[29]

Factors impeding insulin initiation and adherence stem from a wide range of issues related to patients, providers, and health care systems.[9] It is important to identify and address these factors to improve the insulin experience for people with diabetes and promote strategies to overcome barriers to insulin initiation, adherence, and persistence.

Barriers to Insulin Initiation

The American Association of Diabetes Educators states that the identification of barriers is a critical step toward successful diabetes self-management.[9] Among both patients and providers, resistance to initiating or intensifying insulin therapy is common.[4]

Patient Barriers

A number of patient-related factors may contribute to treatment resistance.[1,13] Commonly recognized patient barriers are fear of needles and anxiety about pain from injections.[9-11]

- Clinicians can demonstrate the injection technique to the patient and show the insulin pen and small needle tips.
- Patients may prefer insulin pens, which have been found to be more discreet, less painful, and easier to use.
- Applying the principles of systematic desensitization may help to alleviate the fear of needles and anxieties about pain.

Patient reluctance to use insulin can be psychological and based on misconceptions about treatment.[12]

- A common misconception is the belief that the need for insulin reflects personal failure.[30,31] Clinicians should explain that diabetes is a progressive disease that eventually requires insulin during the course of treatment.[15]
- Patients may believe that insulin therapy will be complicated and inconvenient.[9] To address this, clinicians should explain how insulin is injected into subcutaneous tissue and educat3 on the correct administration of insulin.[13,32]
- Another misconception patients may have is the belief that insulin causes diabetes complications.[11,14] Clinicians should explain that insulin is a natural hormone necessary as a replacement therapy at some point for most patients with diabetes.[15] Patients should be informed that insulin will help achieve glycemic target and minimize the risk for complications. Clinicians can prescribe once-daily basal insulin that minimizes inconvenience and is easy to use.
- Some patients may believe that once started, insulin can never be stopped and will restrict their lifestyle.[11,13,14] Clinicians can offer a 3-month trial period with subsequent reassessment.[1,33] Patients may also feel a loss of control in reaction to treatment decisions, and by engaging them in shared decision making, patients can be empowered to facilitate improved outcomes.[11,18,19]

Patient concerns about hypoglycemia and weight gain may contribute to treatment resistance.[11,13,14]

- Patients should be reassured that most hypoglycemic episodes are mild and severe hypoglycemia is rare.[9,34] Clinicians should educate patients on how to recognize, treat, and avoid hypoglycemia. Patients should be aware of the importance of meal planning and know how to

respond to symptoms and self-adjust insulin (including slow dosage titration during treatment initiation).[9,35] Clinicians should also select insulins and regimens with lower rates of hypoglycemia.[36]

- Weight gain is a common patient concern that can interfere with treatment initiation.[9] Patients should be informed that weight gain with insulin therapy may be caused by excess calories retained due to improved glycemic control. Fluid retention and higher food intake to prevent hypoglycemia can also contribute to weight gain. Weight gain with basal insulin regimens, especially the newer basal insulin analogues, is typically small.[15] Patients should also be encouraged to exercise and have a healthy diet.

<u>Provider Barriers</u>

Several provider-related issues can contribute to treatment resistance.

- Clinical inertia, which is defined as the failure of the provider to advance therapy when required, can adversely affect the timely management of diabetes.[15-17] Findings from the DAWN study demonstrate a high level of clinical inertia among US clinicians who frequently delay insulin therapy until absolutely necessary.[4] As a result, insulin therapy is underused and initiated later than in most other countries. Clinicians need to recognize that treatment delay prevents patients from achieving HbA1c goals and increases the risk for diabetes-related complications.[30,37]
- Another provider concern may involve the potential risks to patients, which may include hypoglycemia and weight gain.[11,13] To address these concerns, clinicians should recognize the low risk for hypoglycemia and weight gain with earlier insulin use as well as with next generation basal insulin therapies.[36,38] Clinicians may also have assumptions regarding patient inability or refusal to use insulin. The benefits of initiating insulin therapy versus the risk should be discussed with the patient.[11,35] Clinicians should provide education and allied health support to increase patient awareness of managing treatment for optimal outcomes.
- Practical concerns may also increase the reluctance of clinicians to initiate insulin therapy.[18] These concerns, which are sometimes overestimated by clinicians,[19] include patient anxiety, complexity in training patients, and demands on the clinician to manage the patient's use of insulin.[18]

<u>System Barriers</u>

System-related factors may also affect treatment initiation.[11,13,14]

- There may be resource and time constraints that limit the availability of staff with the skills needed to support insulin initiation and ensure sufficient follow-up.
- Systemic barriers that limit treatment access may stem from socioeconomic factors, such as lack of family or social support.
- Drug costs and inadequate insurance coverage can also hinder treatment initiation.
- Effective teaching techniques may be needed for special populations, such as individuals with low literacy skills, or impaired hearing, vision, or dexterity.

Barriers to Insulin Adherence/Persistence

Once insulin therapy is initiated, patients often struggle with treatment adherence and persistence. This leads to unfavorable outcomes, including inadequate glycemic control, increased risk for diabetes-related complications, and decreased QoL.[5,9]

Adherence to insulin therapy is an important aspect of diabetes management.[39] The ADA categorizes barriers to adherence as either patient factors, medication factors, or system factors.[1,2]

- Examples of patient barriers are difficulty remembering to obtain refills from the clinician or pick them up from the pharmacy, difficulty remembering to take medications, fear of taking medications, depression, or health beliefs regarding medications.
- Potential medication factors include medication regimen complexity, multiple daily dosing of medications, cost, and side effects. In addition, patient preferences related to insulin delivery devices, treatment complexity and lifestyle may also influence insulin adherence.
- System factors may include insufficient follow-up or support;[22] or financial barriers.[40]

The proposed educational activity will provide information on the insulin experience in people with diabetes and barriers to insulin initiation and adherence/persistence.

Overcoming Barriers to Insulin Initiation and Adherence

Strategies to overcome barriers to insulin initiation and adherence require the use of different communication styles during patient counseling and education.[41] Clinicians should adopt patient-centered approaches for shared decision making that incorporate individual needs, preferences, and values. Important considerations that need to be taken into account are:[19]

- Patient knowledge about insulin therapy
- Main patient concerns and perceived problem areas
- Collaborative goal setting and problem solving
- Need for continued support

Described by Berard and colleagues, the 5-step "LEASE" approach to managing insulin therapy may help to enhance outcomes for patients with diabetes.[15]

- The first step ("Listen and ask") involves actively listening to the patient's fears and concerns. This includes normalizing these concerns before discussing alternatives, encouraging an open dialogue, and showing conviction of belief and supportive body language.
- The second step ("Educate") involves asking permission to educate about the benefits and importance of insulin therapy, the progressive nature of the disease, and how to self-manage their disease.
- The third step ("Address") involves proactively addressing patient concerns that may deter initiation and adherence to insulin. This includes asking questions, identifying barriers, and outlining goals.
- The fourth step ("Support") involves enlisting support of the diabetes management team. This includes providing continuous support and education through the course of treatment.
- The fifth step ("Empower") involves encouraging and educating the patient on self-management (eg, demonstrate how the insulin delivery device works and let them try it; explain how to take

medications, self-monitor blood glucose, and prevent and treat hypoglycemia; and reinforce healthy lifestyle and diet). This includes incorporating the principle of shaping—by using repetition and support for next step goals, self-efficacy in a new behavior can develop).

With a better understanding of the insulin experience for people with diabetes and improved knowledge of strategies to overcome barriers to insulin initiation and adherence, clinicians can work together with patients to improve the insulin experience and overall treatment outcomes.

The proposed educational activity will provide information on strategies to overcome barriers to insulin initiation and adherence/persistence.

Expert Opinion

"It is important to understand patients' beliefs about barriers to insulin initiation as early as possible in the disease process. By understanding these factors early, and using targeted, scientifically correct information to counter negative or incorrect impressions, health care practitioners may be able to appropriately influence patients to initiate insulin therapy sooner."[42]

—Luigi Meneghini, MD

"Many patients are reluctant to start insulin for a variety of reasons, and also may be reluctant to make daily decisions on dosing and matching insulin to meals and daily activities. Identifying and proactively addressing patients' concerns and barriers through assessment, education, and ongoing support is essential to engaging them in self-care to improve metabolic and quality of life outcomes."[23]

—Matthew Riddle, MD

Public Health Data

An estimated 6 million people with diabetes use insulin, either alone or in combination with oral medication.[2] Nonetheless, insulin therapy remains underused,[6] with only 31% of US adults with diabetes using insulin either alone or in combination with oral medications.[7] Large numbers of patients who receive insulin therapy have demonstrated patterns of poor adherence and persistence. Findings from the landmark DAWN study showed that one-fifth of respondents "often or sometimes" skipped insulin injections and 10% restricted daily insulin usage.[4] In addition, reported rates of insulin persistence in the year after initiation of basal insulin are low, ranging from 26% to 52%.[27] These rates are even lower for bolus insulin, ranging from 19% to 42%.

As reported in several studies, nonadherence and decreased persistence lead to increased likelihood of treatment failure as well as higher overall health care costs.[5,26] Chandran and colleagues found that lower adherence was associated with increases in hospitalization costs (US $7,543 vs US $4,485).[28] In a pooled analysis of 3 US studies, Wei and colleagues showed that patients with poor treatment persistence had significantly higher HbA1c levels and significantly lower reductions in HbA1c at 1 year after initiation of basal insulin compared with persistent patients.[29]

Observed Need

Health care professionals require additional education on the insulin experience and the barriers to insulin initiation and adherence/persistence facing people with diabetes. As new research unfolds, revealing an improved understanding of factors affecting insulin initiation and adherence/persistence, clinician education is needed. Insulin initiation, adherence, and persistence are suboptimal in people with diabetes, leading to unfavorable treatment outcomes, poor quality of life, and increasing health care costs.

Recent and ongoing clinical trials aim to improve the understanding of barriers to insulin initiation and adherence/persistence. A search of the National Institutes of Health's clinical trials database at www.ClinicalTrials.gov found 78 trials involving insulin adherence in diabetes, including 21 active trials (17 of which are currently recruiting). These clinical trials are investigating insulin adherence in patients with diabetes, both type 1 and type 2, and have the potential to change the way this disease is managed. Clinician education on this topic will raise awareness of, and potentially enrollment in, clinical trials, which will ultimately advance the understanding of the insulin experience, and allow for the creation of strategies to improve insulin initiation and adherence/persistence.

Target Learner Audiences

The intended audiences for these activities include endocrinologists, internal medicine physicians, family practice physicians, and advanced-level practitioners (nurse practitioners and physician assistants). Global and Applied Clinical Education expect to reach *** members of these professional communities with the proposed educational activity.

1. Direct beneficiaries from the project outcomes include practitioners in each of these specialties, as well as the patients they serve.
2. The overall population sizes are as follows:
    a. Endocrinologists: ~8,000; Global anticipates *** members of this audience to participate in the activity.
    b. Internists: ~93,000; Global anticipates *** members of this audience to participate in the activity.
    c. Family practice physicians: ~88,000; Global anticipates *** members of this audience to participate in the activity.
    d. Advanced-level practitioners (nurse practitioners and physician assistants): ~400,000; Global anticipates *** members of this audience to participate in the activity.
    e. Patients using insulin: 6 million Americans. Clinician participation in this activity will help improve care to these patients.

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