



Emerging Challenges in Primary Care



NACE

LIVE CONFERENCE SERIES

Safely Achieving Goals in Type 2 Diabetes (T2D): The Role of Concentrated and Long-Acting Insulins



Final Outcomes Report Prepared for:

Lilly USA Grant ID: A-22822
October 22, 2018

Executive Summary

- ❖ This curriculum focused on the use of basal and concentrated insulins in the treatment of patients with type 2 diabetes, in addition to existing barriers to treatment.
- ❖ Substantial improvements were seen in learner awareness of barriers to insulin therapy initiation and intensification.



3,169*
Total Attendees



9 Cities

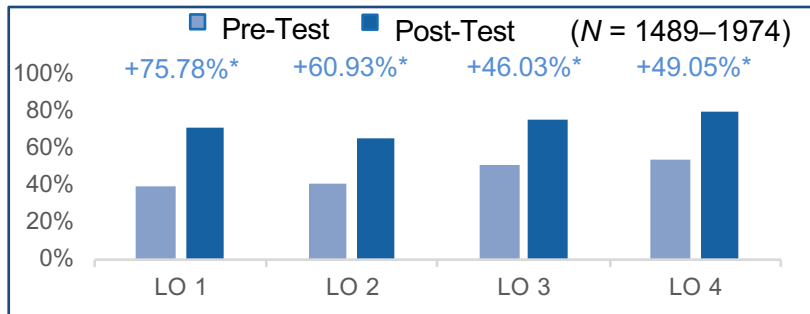


1,846*
On Site



1,323*
Simulcast / Virtual Symposium

Pre to Post Test Results By Learning Objective



- ❖ **76% Improvement:** Demonstrate greater awareness of clinician and patient barriers to initiation and intensification of insulin therapy.
- ❖ **61% Improvement:** Recognize the prevalence and clinical impact of hypoglycemia in special populations at risk.
- ❖ **46% Improvement:** Discuss the pharmacology and clinical differences between existing and new long-acting and concentrated insulins.
- ❖ **49% Improvement:** Incorporate new basal and concentrated insulins into clinical practice while minimizing the risk of adverse events.

Impact

- ❖ 3,169 attendees, mostly primary care providers, were reached via both online and live formats, with significant gains observed across cohorts and modalities.
- ❖ Learners remain challenged in their understanding of how the selection of insulin formulation can increase the risk of hypoglycemia, which reduces the ability of clinicians to optimally select insulin therapy.
- ❖ Learners demonstrated broad and significant retention on a 4-week Post Curriculum Assessment (PCA), though these scores were moderately reduced with respect to the Post-Test.

*These numbers represent the total number of attendees, irrespective of assessment participation



Curriculum Patient Impact

In the evaluation, learners (N = 3,169) were asked to report how many patients with type 2 diabetes they see in any clinical setting per week by selecting a range. The resulting distribution of learner responses was then extrapolated to reflect the total number of learners who participated in the onsite and online meetings.

The findings reveal that this education has the potential to impact

1,344,512

patients on an annual basis.

**22,624–29,088 patients
on a weekly basis**

22,624–
29,088



Emerging Challenges in Primary Care 2018

17th Annual Regional and Online CME Conference Series

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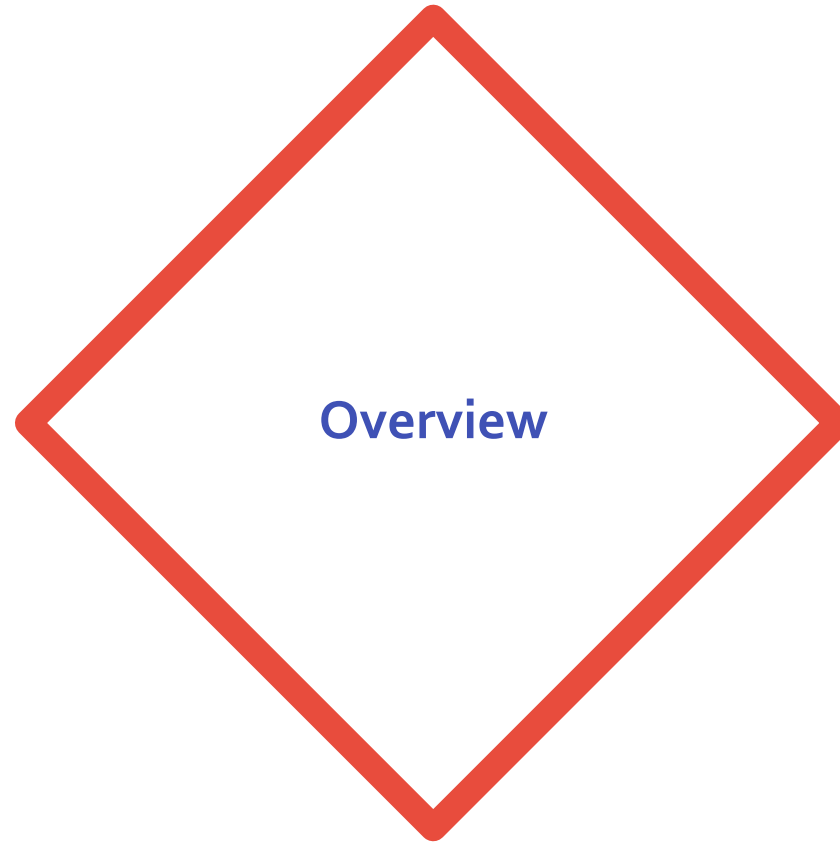
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Commercial Support

The Emerging Challenges in Primary Care: 2018 series of CME activities were supported through educational grants or donations from the following companies:

- ❖ Actelion Pharmaceuticals US, Inc
- ❖ AstraZeneca Pharmaceuticals LP
- ❖ ER/LA Opioid Analgesic REMS Program Companies
- ❖ Lilly USA
- ❖ Novo Nordisk Inc
- ❖ Sanofi Genzyme and Regeneron Pharmaceuticals



Curriculum Overview

9 Accredited Live Regional Symposia
April 28, 2018 – August 18, 2018



Enduring CME Symposium Webcast

Launch Date: August 15, 2018

End Date: August 14, 2019

Available at:

<http://bit.ly/naceconcentratedinsulins>



Speaker
Mark Stolar, MD
Associate Professor of Clinical Medicine
Feinberg School of Medicine
Northwestern University
Chicago, IL





1 Accredited Live Virtual Symposium:
June 23, 2018



Clinical Highlights eMonograph -

eMonograph containing key teaching points from the CME Activity was distributed 1 week after the meeting to all attendees.



Emerging Challenges in Primary Care

LIVE CONFERENCE SERIES

2018 Clinical Highlights

Safely Achieving Goals in Type 2 Diabetes (T2DM): The Role of Concentrated and Long-Acting Insulins

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- Adherence and efficacy of very high dose insulin therapy using standard insulin preparations has been suboptimal in intensifying management of hyperglycemia.
- Dysglycemia; i.e. hyper and hypoglycemia in the same patient is frustrating to patient and clinician and has adverse clinical implications
- Glycemic variability is a significant problem, even with standard basal insulins and undetected or unexplained hypoglycemia is a frequent occurrence
- As doses of basal insulin rise, the basal characteristics decline. Conversely the higher the dose of rapid acting, onset of action

Javier Morales, MD, FACP, FACE

Learning Objectives

- ❖ Demonstrate greater awareness of clinician and patient barriers to initiation and intensification of insulin therapy.
- ❖ Recognize the prevalence and clinical impact of hypoglycemia in special populations at risk.
- ❖ Discuss the pharmacology and clinical differences between existing and new long-acting and concentrated insulins.
- ❖ Incorporate new basal and concentrated insulins into clinical practice while minimizing the risk of adverse events.

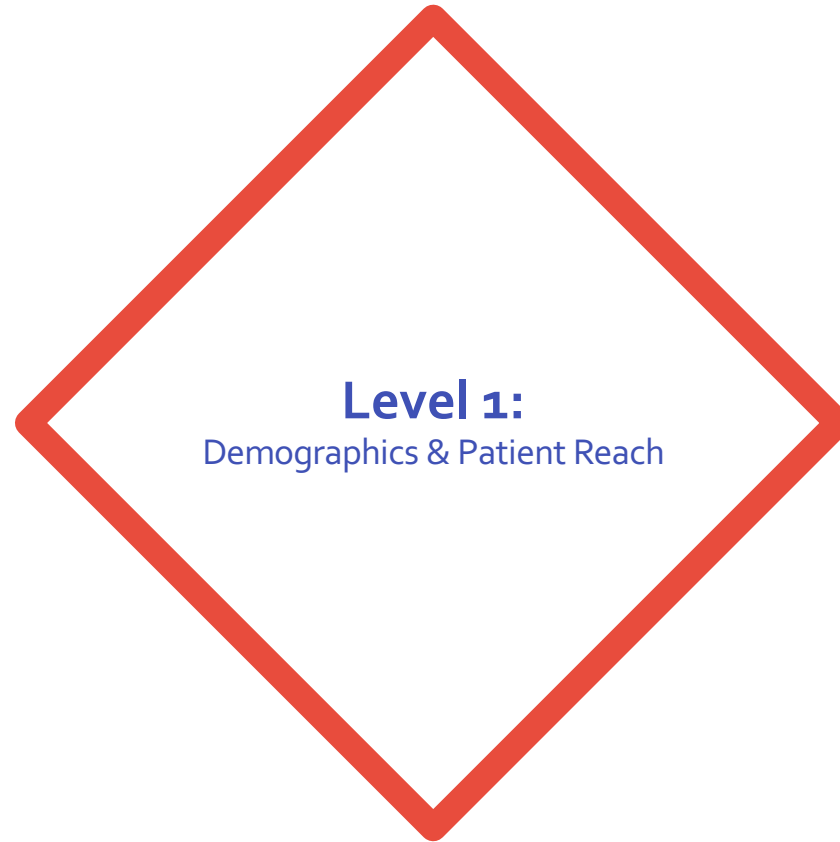
Outcomes Methodology

Learning outcomes were measured using matched Pre-Test and Post-Test scores for four learning domains (Knowledge, Competence, Confidence, and Practice Strategy) and across all of the curriculum's Learning Objectives.

Outcomes Metric	Definition	Application
Percentage change	This is how the score changes resulting from the education are measured. The change is analyzed as a relative percentage difference by taking into account the magnitude of the Pre-Test average.	Differences between Pre-Test, Post-Test, and PCA score averages
P value (p)	This is the measure of the statistical significance of a difference in scores. It is calculated using dependent or independent samples t-tests to assess the difference between scores, taking into account sample size and score dispersion. Differences are considered significant for when $p \leq .05$.	Significance of differences between Pre-Test, Post-Test, and PCA scores and among cohorts; significance of drivers in predictive modeling
Effect size (d)	This is a measure of the strength/magnitude of the change in scores (irrespective of sample size). It is calculated using Cohen's d formula, with the most common ranges of d from 0-1: $d < .2$ is a small effect, $d = .2-.8$ is a medium effect, and $d > .8$ is a large effect.	Differences between Pre-Test, Post-Test, and PCA score averages
Power	This is the probability (from 0 to 1) that the "null hypothesis" (no change) will be appropriately rejected. It is the probability of detecting a difference (not seeing a false negative) when there is an effect that is dependent on the significance (p), effect size (d), and sample size (N).	Differences between Pre-Test, Post-Test, and PCA score averages
Percentage non-overlap	This is the percentage of data points at the end of an intervention that surpass the highest scores prior to the intervention. In this report, it will reflect the percentage of learners at Post-Test who exceed the highest Pre-Test scores.	Differences between Pre-Test, Post-Test, and PCA score averages

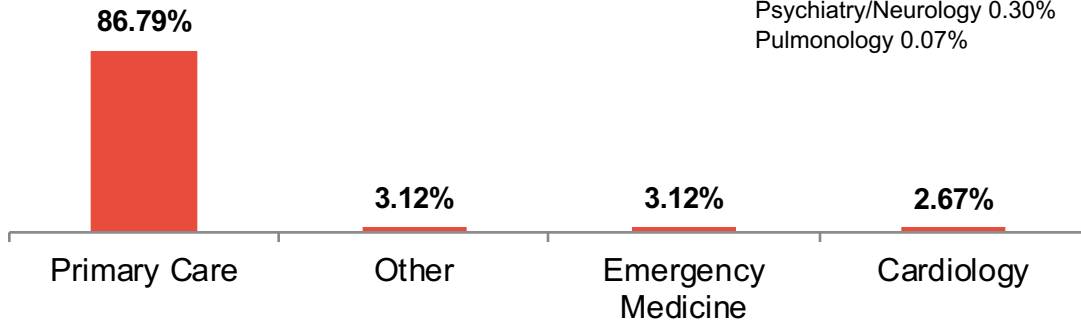
Participation

2018 Meeting/Simulcast	Date	Attendees
Miami, FL	4/28/18	179
Baltimore, MD	5/5/18	218
Baltimore, MD Simulcast	5/5/18	372
St. Louis, MO	5/12/18	129
Birmingham, AL	5/19/18	195
Atlanta, GA	6/2/18	233
Atlanta, GA Simulcast	6/2/18	296
Tampa, FL	6/9/18	275
Raleigh, NC	6/16/18	168
Virtual Symposium	6/23/18	655
Anaheim, CA	8/11/18	204
Houston, TX	8/18/18	245
	Total	3169



Level 1: Participation

Specialty

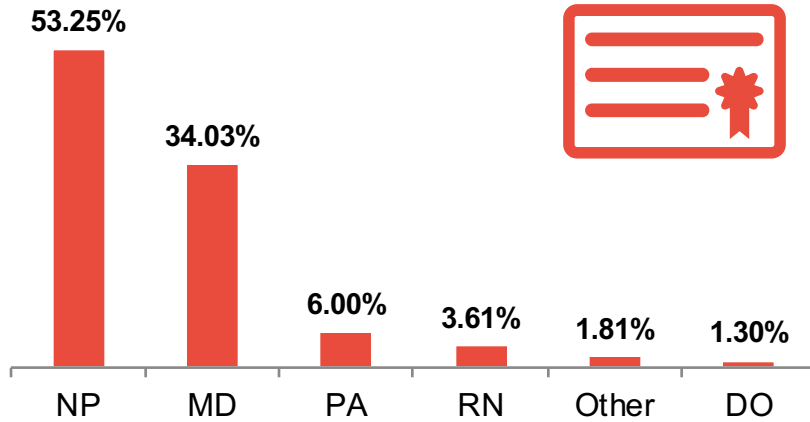


Specialists:

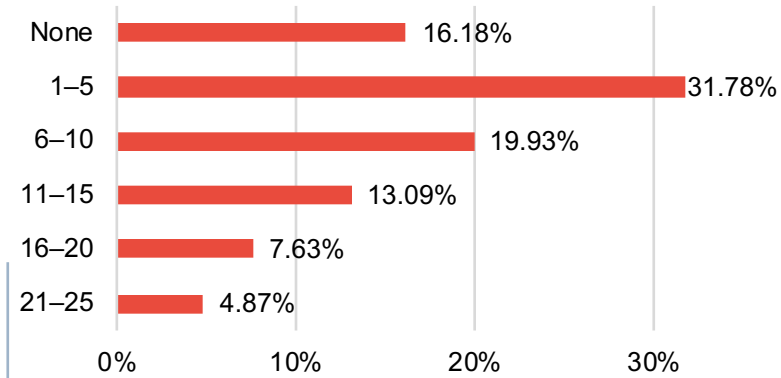
Endocrinology 1.48%
 Psychiatry/Neurology 0.30%
 Pulmonology 0.07%

Patient Care Focus: 94%

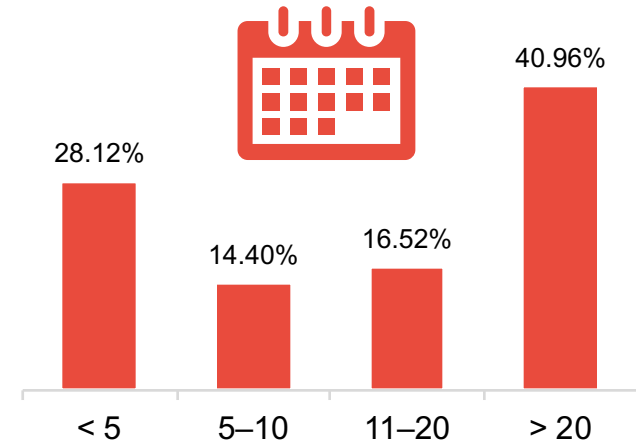
Profession



Patients with type 2 diabetes seen each week, in any clinical setting:



Years in Practice

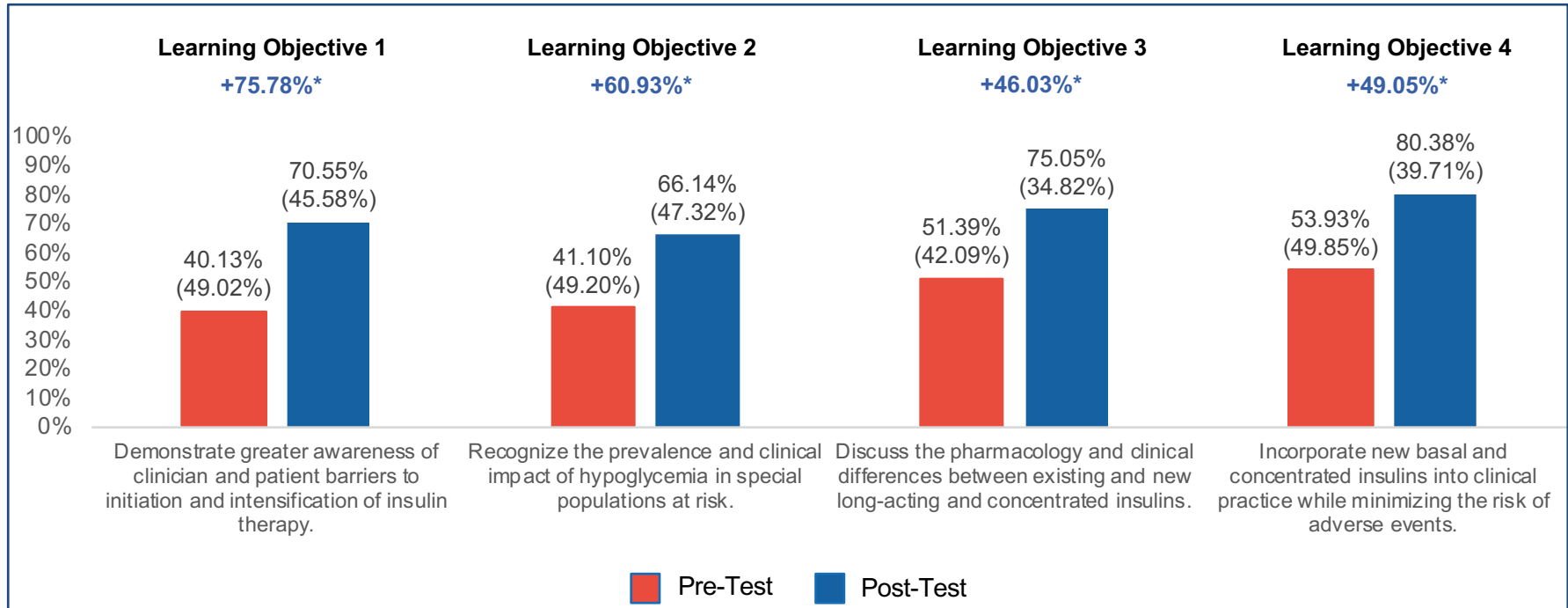




Level 2-5:
Outcomes Metrics

Learning Objectives Analysis

(N = 1489–1974)

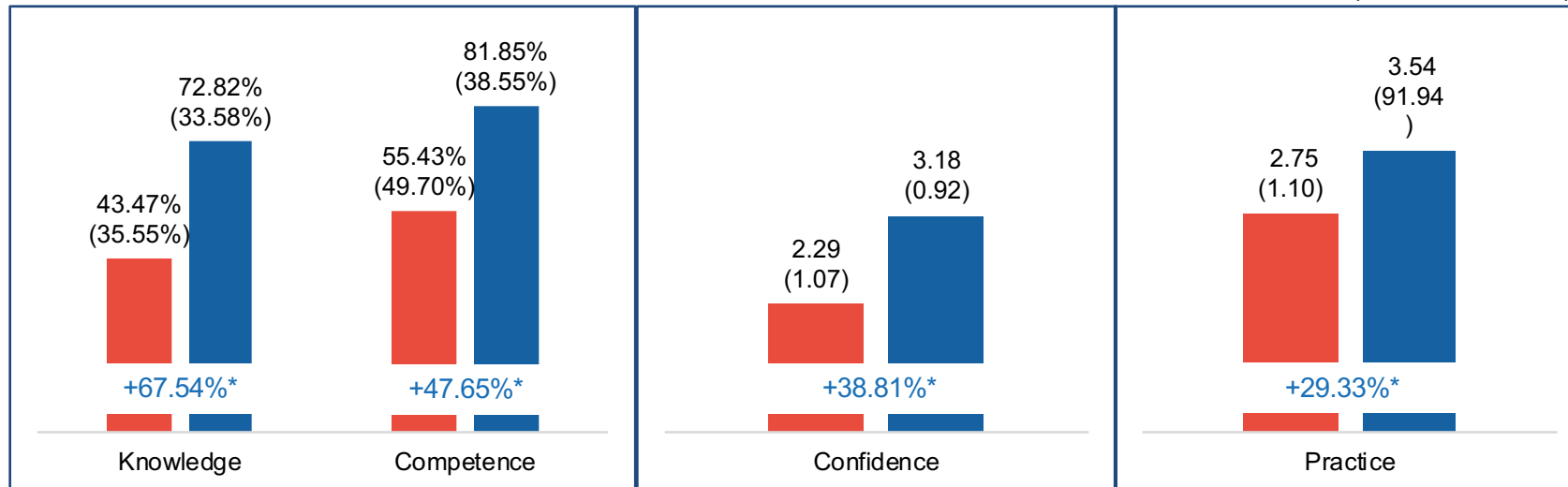


**significant at the $p \leq 0.05$ level*

- ❖ Substantial and significant gains (ranging from 46% to 76%) were achieved on all Learning Objectives.
- ❖ Learning Objective 2 demonstrated the lowest Post-Test score (66%).
 - Learners demonstrated difficulty on Knowledge questions that addressed insulin formulations that increase the risk of hypoglycemia.

Learning Domain Analysis

(N = 1183–1793)



Pre-Test Post-Test

**significant at the $p \leq 0.05$ level, matched data*

- ❖ Significant gains (29%–68%) were achieved in all learning domains.
- ❖ The increase in Knowledge from Pre- to Post-Test was due to increases ranging from 45% to 76% on individual Knowledge questions.
- ❖ Learners substantially (39%) increased their reported Confidence in their ability to utilize concentrated insulin therapy in patients with type 2 diabetes. The Post-Test rating, however, remained low (3.2).
- ❖ There was also a substantial (29%) increase in learners' reported intent to use concentrated insulin therapy in patients with type 2 diabetes who are not achieving treatment targets with standard insulin regimens. The Post-Test rating, however, again remained low (3.5).

Learning Domain by Professional Cohort

Learning Domain	Nurse Practitioner				Physician			
	N	Pre-Test	Post-Test	% Change	N	Pre-Test	Post-Test	% Change
Knowledge	588	44.50% (34.63%)	71.54% (32.99%)	+60.76%*	393	43.09% (35.14%)	73.62% (33.56%)	+70.87%*
Competence	435	58.16% (49.33%)	85.52% (35.19%)	+47.04%*	296	55.74% (49.67%)	81.76% (38.62%)	+46.67%*
Confidence	403	2.18 (1.05)	3.10 (0.90)	+42.16%*	296	2.50 (1.14)	3.34 (0.96)	+33.47%*
Practice	425	2.70 (1.07)	3.56 (0.93)	+32.08%*	296	2.82 (1.15)	3.57 (0.94)	+26.32%*

**significant at the $p \leq .05$ level*

- ❖ Nurse practitioners (NPs) and physicians demonstrated statistically significant gains in all learning domains.
- ❖ In all domains except Competence, physicians demonstrated moderately higher Post-Test averages compared to NPs. Physicians demonstrated the greater gain in Knowledge, but lower increase in all other domains.
- ❖ In Competence and practice strategy, Post-Test averages and score increases were comparable between the cohorts.

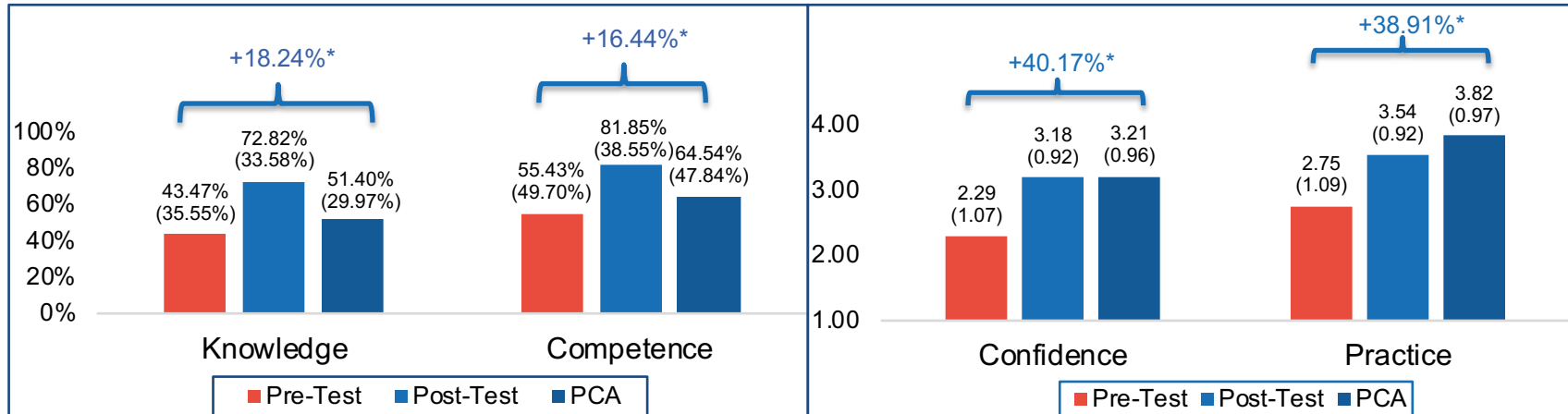
Curriculum/Activity Intervention Effect

Learning Domain	Effect Size*	% Non-Overlap
Knowledge	0.849	52.79%
Competence	0.385	31.80%

Effect Size Definition: This is a standardized measure of the strength/magnitude of the change in scores, irrespective of sample size. This metric quantifies the association between outcome and exposure to education, in a way which makes meta-analysis possible. There exist many types of effect size measures, each appropriate in different situations. We select Cohen's d for this analysis, which is a standardized difference in mean. Most commonly, d ranges from 0–1: $d < 0.2$ is a small effect, $d = 0.2–0.8$ is a medium effect, and $d > 0.8$ is a large effect.

4-Week Retention Analysis

(N = 670)



**significant at the $p \leq 0.05$ level*

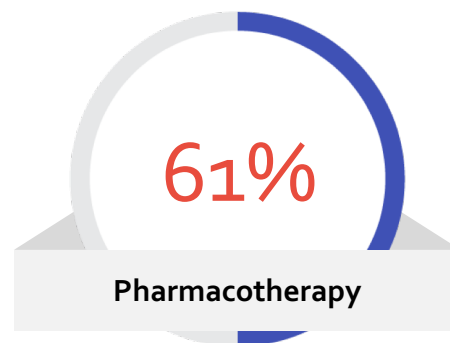
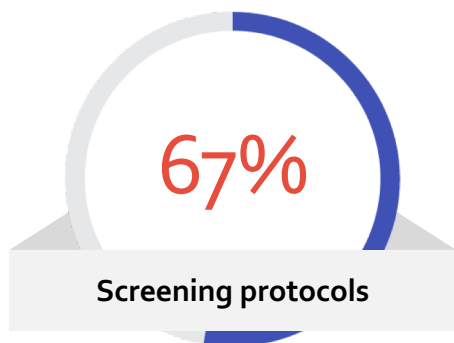
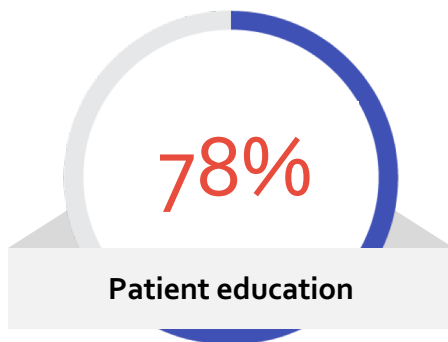
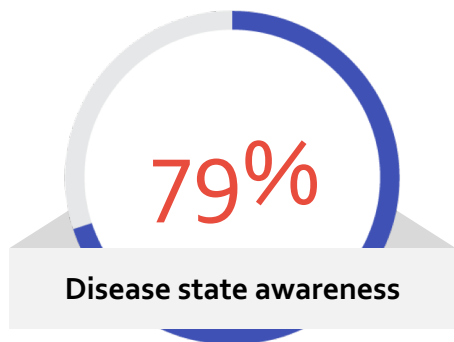
At follow-up:

- ❖ Statistically significant net gains were measured from Pre-Test to the Post Curriculum Assessment (PCA) in all learning domains.
- ❖ The greatest net increases (40% and 39%) were observed in Confidence and practice strategy, in part due to further score increases from Post-Test to the PCA.
- ❖ Although significant net gains were measured in Knowledge and Competence, the score slippage that was observed in these domains resulted in low PCA scores, reinforcing the need for continued education in this area.

(4-week Post Assessment)

Please select the specific areas of skills, or practice behaviors, you have improved regarding the treatment of patients with diabetes since this CME activity. (Select all that apply.)

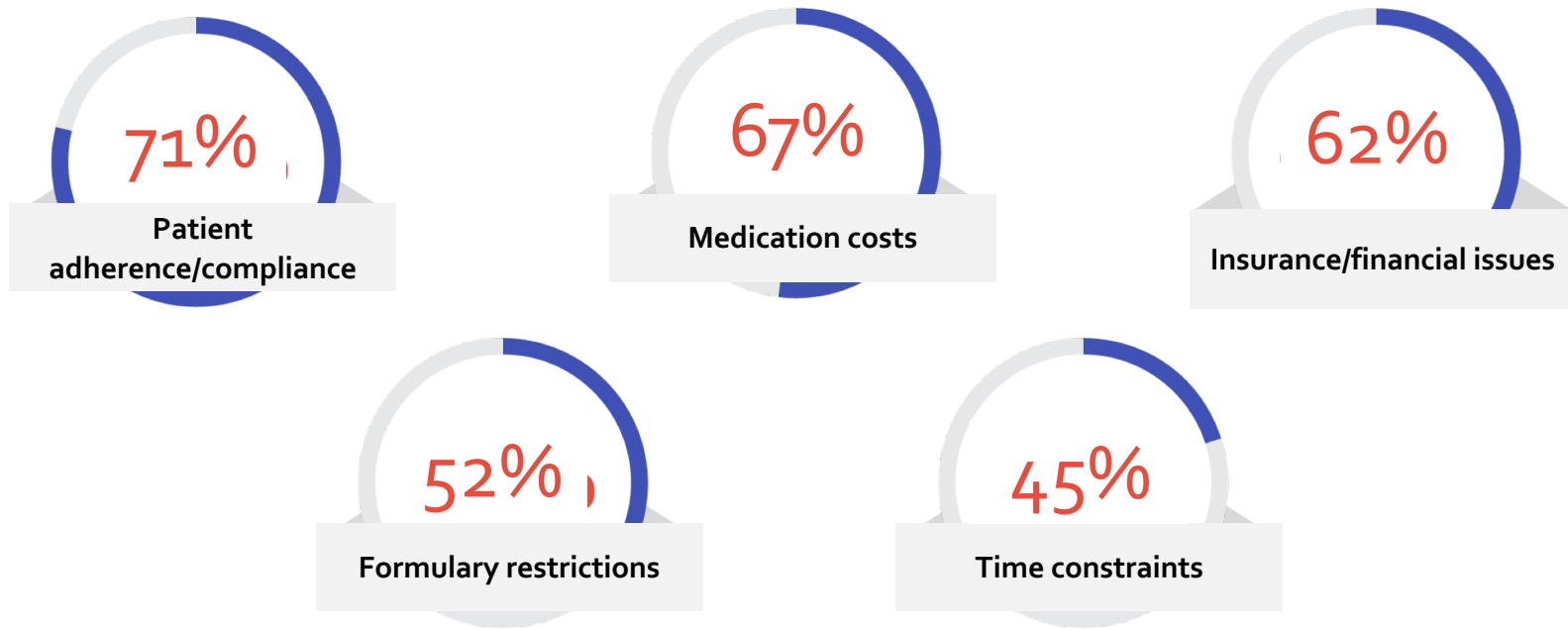
N=516



(4-week Post Assessment)

What specific barriers have you encountered that may have prevented you from successfully implementing strategies for patients with diabetes since this CME activity? (Select all that apply)

N=497



Identified Learning Gap:

Impact of insulin therapy on the risk of hypoglycemia

A low scoring question in the Knowledge domain addressed the increased risk of hypoglycemia caused by insulin formulations with a high coefficient of variability. A low score was also measured on a Knowledge question that addressed provider concern about initiating insulin, with a large proportion of learners incorrectly identifying the risk of hypoglycemia.

Knowledge Question:

Which of the following can increase risk of hypoglycemia and reduce adherence to insulin therapy?

Results:

- At Post-Test, 66% of learners correctly answered: “Insulin formulations with high coefficient of variability.”

Knowledge Question:

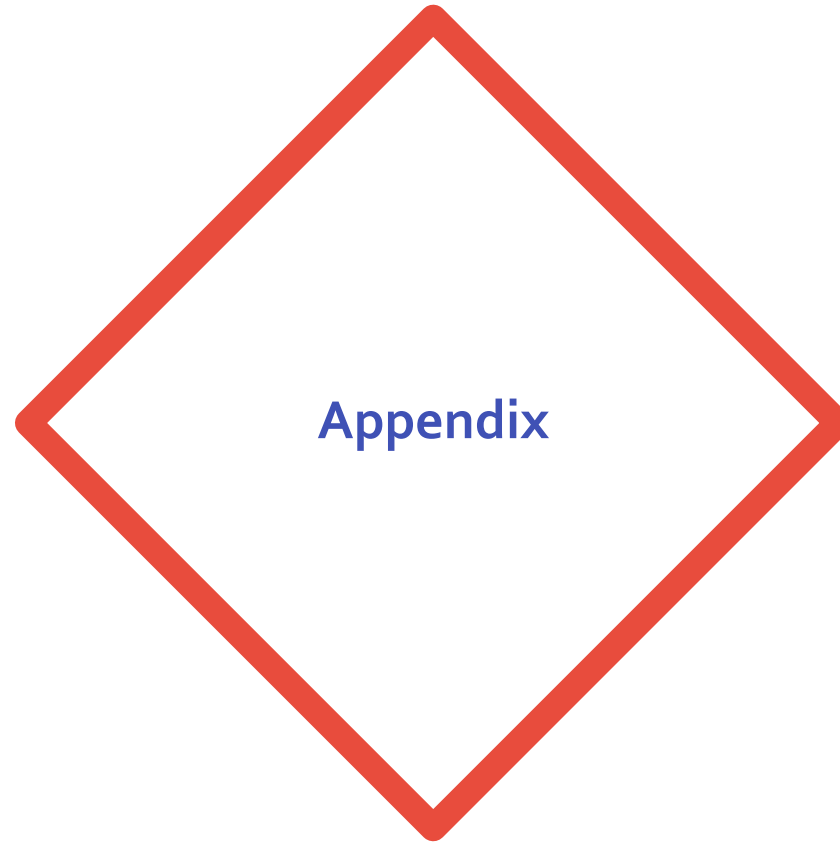
Which of the following is the leading health care provider concern about starting insulin therapy in a patient with T2D?

Results:

- At Post-Test, 71% of learners correctly answered: “Poor patient adherence to insulin.”

Overall Educational Impact

- ❖ This curriculum focused on the use of basal and concentrated insulins in the treatment of patients with type 2 diabetes, and on existing barriers to treatment.
- ❖ Significant improvements (ranging from 29% – 68%) were seen across all learning domains.
 - The cohort analysis of professions showed that physicians demonstrated higher scores than NPs in Knowledge and Confidence; comparable scores were measured in Competence and practice strategy.
 - Live onsite learners demonstrated higher averages than online participants on the Confidence and practice strategy ratings; comparable scores were measured in Knowledge and Competence.
- ❖ Significant improvements (ranging from 46% – 76%) were seen across all Learning Objectives.
 - Onsite learners demonstrated higher Post-Test averages than online learners on three of the four Learning Objectives; comparable scores were measured on the LO on barriers to the initiation and intensification of insulin therapy.
- ❖ The analysis of the Knowledge and Competence domains identified a **persistent learning gap related to the impact of insulin therapy on the risk of hypoglycemia.**
 - A low scoring Knowledge question (66% at Post-Test) addressed the increased risk of hypoglycemia caused by insulin formulations with a high coefficient of variability.
 - A relatively low score (71% at Post-Test) was also measured on a Knowledge question that addressed the leading provider concern about initiating insulin, with a large proportion of learners (25% at Post-Test) incorrectly identifying the risk of hypoglycemia.



Learning Objectives Analysis – Live Onsite vs. Live Online Audience

- “Live onsite learners” include only those attending in-person meetings.
- “Live online learners” include those from both the Simulcast and Virtual Symposium.

Learning Objective	Live Onsite Learners				Live Online Learners			
	N	Pre-Test	Post-Test	% Change	N	Pre-Test	Post-Test	% Change
Demonstrate greater awareness of clinician and patient barriers to initiation and intensification of insulin therapy.	1221	38.74% (48.72%)	69.21% (46.16%)	+78.67%*	431	44.08% (49.65%)	74.72% (43.46%)	+69.50%*
Recognize the prevalence and clinical impact of hypoglycemia in special populations at risk.	1135	40.88% (49.16%)	67.84% (46.71%)	+65.94%*	393	41.73% (49.31%)	61.04% (48.77%)	+46.26%*
Discuss the pharmacology and clinical differences between existing and new long-acting and concentrated insulins.	1372	51.46% (41.49%)	77.70% (33.00%)	+51.01%*	421	51.19% (43.98%)	67.86% (38.42%)	+32.57%*
Incorporate new basal and concentrated insulins into clinical practice while minimizing the risk of adverse events.	1117	54.97% (49.75%)	82.41% (38.08%)	+49.91%*	372	50.81% (49.99%)	74.69% (43.48%)	+47.00%*

**significant at the $p \leq 0.05$ level*

- ❖ Onsite learners demonstrated higher Post-Test averages on all Learning Objectives, with the exception of the LO on barriers to the initiation and intensification of insulin therapy, in which a comparable score with online learners was observed.

Learning Domain Analysis – Live Onsite vs. Live Online Audience

- “Live onsite learners” include only those attending in-person meetings.
- “Live online learners” include those from both the Simulcast and Virtual Symposium.

Learning Domain	Live Onsite Learners				Live Online Learners			
	N	Pre-Test	Post-Test	% Change	N	Pre-Test	Post-Test	% Change
Knowledge	1390	43.26% (34.93%)	72.24% (33.57%)	+66.99%*	403	44.17% (37.59%)	74.81% (33.53%)	+69.38%*
Competence	1024	56.35% (49.60%)	82.71% (37.81%)	+46.79%*	320	52.50% (49.94%)	79.06% (40.69%)	+50.60%*
Confidence	974	2.35 (1.11)	3.24 (0.92)	+37.76%*	209	2.00 (0.96)	2.89 (0.85)	+44.60%*
Practice	942	2.82 (1.12)	3.62 (0.93)	+28.47%*	321	2.58 (1.02)	3.32 (0.86)	+28.90%*

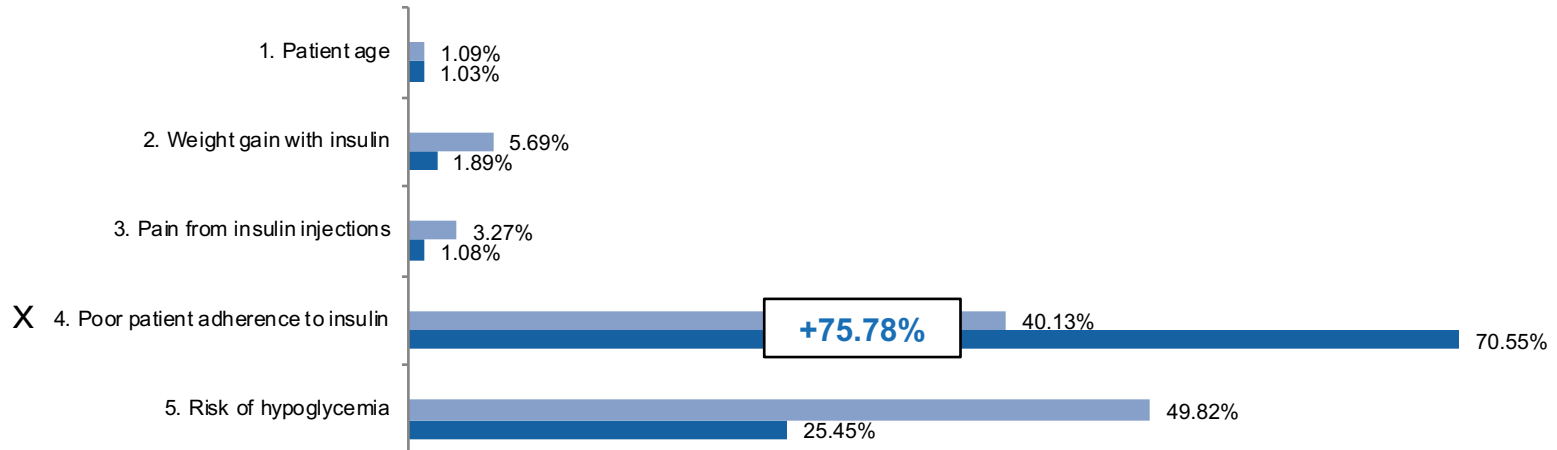
**significant at the $p \leq 0.05$ level*

- ❖ Live onsite learners demonstrated higher averages on the Confidence and practice strategy ratings.
- ❖ Comparable scores were measured in Knowledge and Competence.

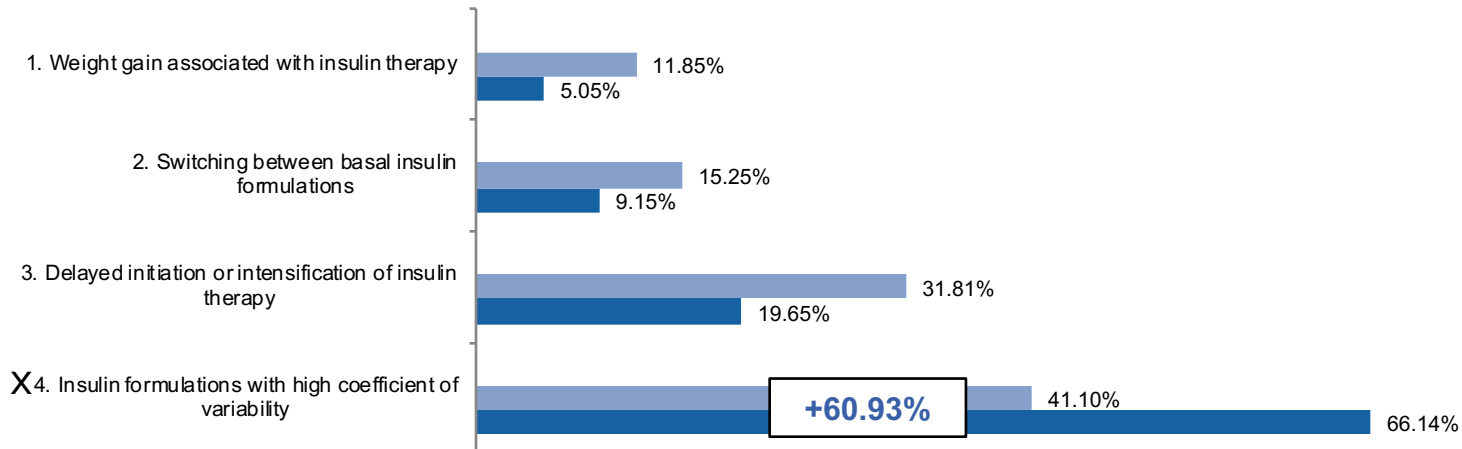
Knowledge Questions

N = (1528–1847)

Which of the following is the leading health care provider concern about starting insulin therapy in a patient with T2D?



Which of the following can increase risk of hypoglycemia and reduce adherence to insulin therapy?



Pre-Test Post-Test

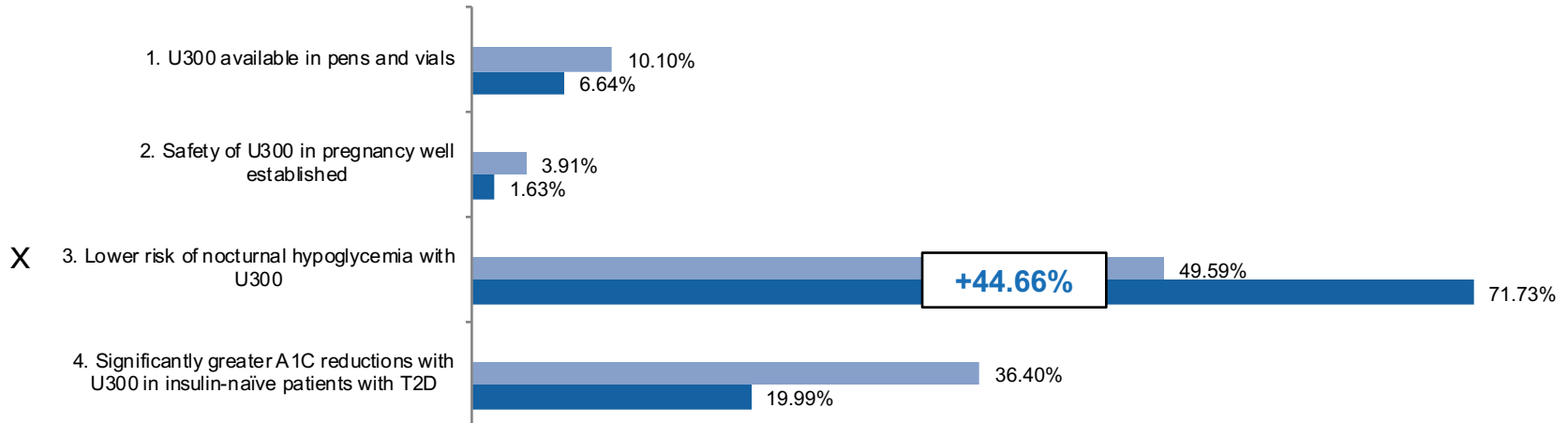
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Knowledge Questions

N = (1456–1776)

Which of the following is an advantage of glargine U300 compared to glargine U100?



Pre-Test Post-Test

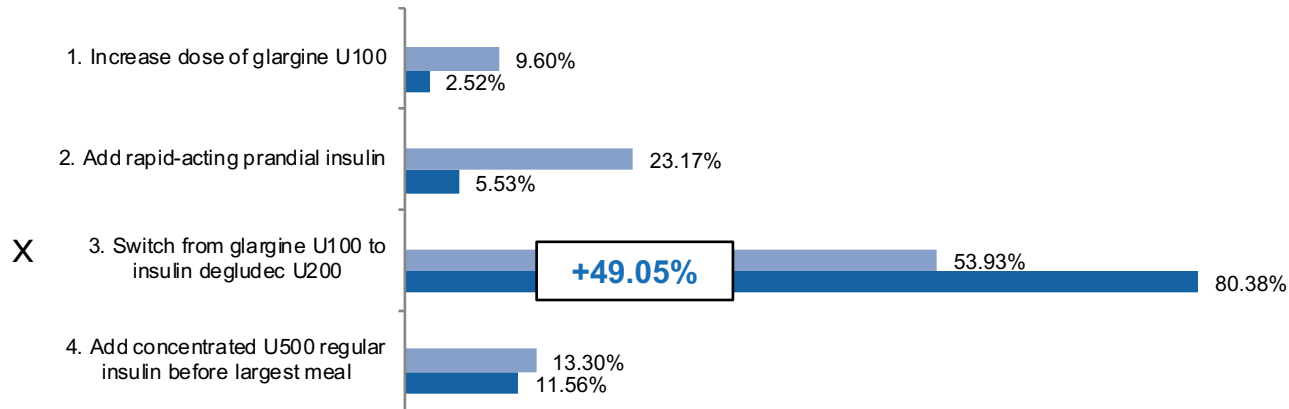
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Competence Questions

N = (1489–1825)

A 55-year-old obese man with 10-year history of T2D presents with A1C 8.8%. His fasting blood glucose levels are 150-210 mg/dL. Current medications include metformin 1000 mg bid, pioglitazone 15 mg qd, linagliptin 5 mg qd, and insulin glargine U100 70 units bid. He often forgets to take his evening dose of basal insulin, but says blood glucose readings don't seem much different on the following mornings. Which of the following might improve his glycemic control?



Pre-Test Post-Test

Note: Data is unmatched

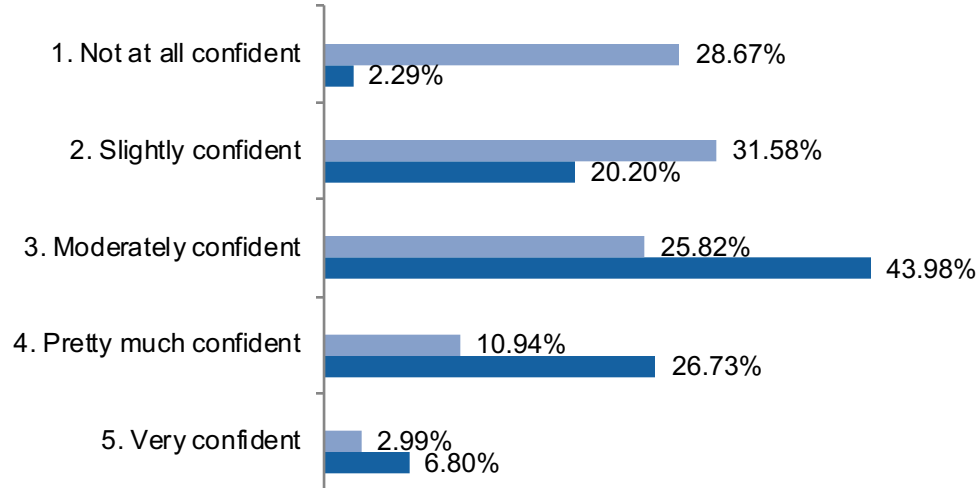


Confidence & Practice Questions

N = (1371–1837)

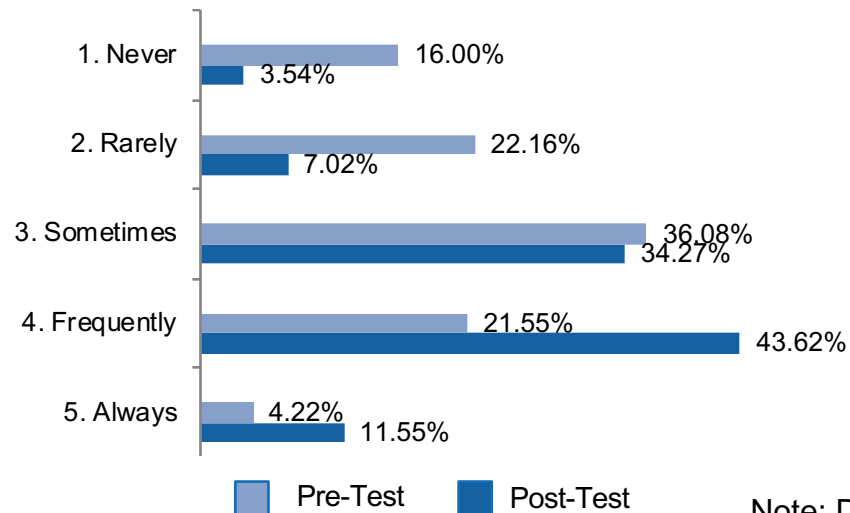
Confidence Question:

Please rate your confidence in your ability to utilize concentrated insulin therapy in patients with Type 2 Diabetes:



Practice Question:

How often do you consider using concentrated insulin therapy in patients with Type 2 Diabetes who are not achieving treatment targets with standard insulin regimens?



Pre-Test Post-Test

Note: Data is unmatched

