

III. Background/Needs Assessment

A. Physician Surveys and Expert Recommendations

B. Overall Statement of Need Based on Literature Review, Surveys, and Expert Interviews

Introduction

[Much of the text in this section was provided by the client. As it wasn't entirely my own work, I haven't included it in this sample].

C. Linkage Between Practice Gaps, Desired Outcomes, Learning Objectives

Practice Gap #1: Adherence to recommendations for optimal glycemic control in type 2 diabetes is less than optimal.

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Learning Objective #1: Describe consequences of inadequate glycemic control on long-term diabetic and cardiovascular complications.

Desired Outcome #1: Physicians are able to recommend an appropriate A1C goal and implement appropriate treatment regimens so that most patients under the physician's care meet their A1C goals.

Practice Gap #2: Physicians may be unfamiliar with emerging pharmacologic treatments for type 2 diabetes and their potential place in therapy.

Sodium-glucose cotransporter 2 (SGLT2) inhibitors are a new class of oral drugs under clinical investigation for treating type 2 diabetes. These agents limit glucose re-absorption in the renal tubules, thereby promoting urinary glucose excretion.¹

One such agent, dapagliflozin, is currently under review for approval by the US Food and Drug Administration (FDA). In one study, A1C levels decreased significantly compared to placebo, with reductions from baseline of 0.6 to 0.9% with dapagliflozin compared to 0.2% with placebo.² Furthermore, mean reductions in body weight of 2.5 to 3.4% were observed for dapagliflozin-treated patients. Although some weight loss was seen in the placebo and metformin groups, a greater proportion of patients treated with dapagliflozin than placebo achieved >5% reductions in body weight. Reductions in systolic blood pressure were also reported with dapagliflozin, which was consistent with the observed diuretic effect. However, there was no evidence of dehydration or effects on renal function.

In a second study, in which patients were concurrently treated with 50% of their daily insulin dose, dapagliflozin demonstrated improvements in A1C, fasting plasma and postprandial glucose, as well as greater reductions in weight, compared to placebo.³ Although hypoglycemia was more commonly reported with dapagliflozin than placebo (25-29% vs. 13% of patients), there were no major events of hypoglycemia in the dapagliflozin groups.

Another SGLT2 inhibitor, canagliflozin, is currently in phase 3 trials in the US and Europe.⁴

In summary, SGLT2 inhibitors represent a novel approach to the treatment of type 2 diabetes. These drugs lower glucose levels by inhibiting glucose re-absorption in the kidney and also appear to lead to negative energy balance.⁵

Learning Objective #2: Assess recent data on emerging pharmacologic agents for the treatment of type 2 diabetes.

Desired Outcome #2: Physicians are able to incorporate emerging treatments for type 2 diabetes once these enter into clinical practice.

Practice Gap #3: Many physicians are unfamiliar with recently-approved treatments for type 2 diabetes and may not be incorporating them where appropriate in clinical practice.

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Learning Objective #3: Incorporate knowledge of the mechanisms of action, indications, safety and efficacy of GLP-1 receptor agonists and DPP-IV inhibitors, and their use in combination with established drugs.

Desired Outcome #3: Physicians are able to incorporate newer treatments into clinical practice and identify the most appropriate treatment for a given patient.

Practice Gap #4: When clinical goals are not met, physicians are reluctant to intensify treatment by moving to combination therapy or initiating insulin.

[Much of the text in this section was provided by the client. As it wasn't entirely my own work, I haven't included it in this sample].

Learning Objective #4: Select suitable combination therapy and initiate insulin, when appropriate, for patients who are not meeting their A1C goals.

Desired Outcome #4: Physicians consider the use of all appropriate combinations and insulin to design a regimen that allows the patient to achieve A1C goals.

Needs Assessment Linkage Summary

Practice Gap	Learning Objective	Desired Outcome
Adherence to recommendations for optimal glycemic control in type 2 diabetes is less than optimal.	Describe consequences of inadequate glycemic control on long-term diabetic and cardiovascular complications.	Physicians are able to recommend an appropriate A1C goal and implement appropriate treatment regimens so that most patients under the physician's care meet their A1C goals.
Physicians may be unfamiliar with emerging pharmacologic treatments for type 2 diabetes and their potential place in therapy.	Assess recent data on emerging pharmacologic agents for the treatment of type 2 diabetes.	Physicians are able to incorporate emerging treatments for type 2 diabetes once these enter into clinical practice.
Many physicians are unfamiliar with recently-approved treatments for type 2 diabetes and may not be incorporating them where appropriate in clinical practice.	Incorporate knowledge of the mechanisms of action, indications, safety and efficacy of GLP-1 receptor agonists and DPP-IV inhibitors, and their use in combination with established drugs.	Physicians are able to incorporate newer treatments into clinical practice and identify the most appropriate treatment for a given patient.
When clinical goals are not met, physicians are reluctant to intensify treatment by moving to combination therapy or initiating insulin.	Select suitable combination therapy and initiate insulin, when appropriate, for patients who are not meeting their A1C goals.	Physicians consider the use of all appropriate combinations and insulin to design a regimen that allows the patient to achieve A1C goals.

References

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