

## QUESTION

**Should a structured program of patient education with follow up vs. unstructured advice be used for people receiving insulin therapy and who are at high risk of hypoglycemia?**

<b>POPULATION:</b>	outpatients receiving insulin therapy and who are at high risk of hypoglycemia
<b>INTERVENTION:</b>	a structured program of patient education with follow up
<b>COMPARISON:</b>	unstructured advice
<b>MAIN OUTCOMES:</b>	Hypoglycemia $\leq 70$ mg/dl; Severe hypoglycemia - patients; Hemoglobin A1C; Death; Myocardial Infarction; Stroke; Loss of consciousness/Seizure; Severe hypoglycemia - episodes; Time below range ( $< 54$ mg/dL); Time below range ( $< 70$ mg/dL); Time in range (70-180 mg/dL); Hemoglobin A1C;
<b>SETTING:</b>	Outpatient
<b>PERSPECTIVE:</b>	Clinical recommendation - Population perspective
<b>BACKGROUND:</b>	<p>Effective diabetes education is a critical aspect to ensure the safety of insulin treatment. Because hypoglycemia is common and education on how to reduce the risk of diabetes treated with insulin can be effective if done properly, structured counseling should be offered as a part of diabetes education. Despite these considerations such education is not delivered to most people on insulin therapy.</p> <p>The prevalence of serious hypoglycemia is now recognized as an imminent threat to most people with insulin-treated diabetes and unrecognized serious hypoglycemia is more common than was thought as CGM reveals its high likelihood. Recognizing and ameliorating the risk of hypoglycemia is an important priority as a part of diabetes education for most with insulin-treated diabetes.</p>
<b>CONFLICT OF INTERESTS:</b>	None

## ASSESSMENT

### Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	<p><b>The reduction of hypoglycemia is a high priority for patients with both type 1 and type 2 diabetes, and thus a structured diabetes education program involving hypoglycemia and its prevention is a priority, especially for people with diabetes using insulin.</b></p> <p>Hypoglycemia in diabetes is associated with substantial morbidity as well as an increase in risk of mortality for severe episodes (1, 2). Hypoglycemia unawareness is also a significant problem and hypoglycemia risk is increased in older adults with diabetes (3, 4). In a systematic review including 46 eligible studies with a total of 532,542 participants, the hypoglycemia prevalence in type 2 diabetes was 45% (95%CI: 0.34,0.57) for mild/moderate and 6% (95%CI: 0.05,0.07) for severe hypoglycemia. The incidence of hypoglycemic episodes per person-year for mild/moderate and for severe was 19 (95%CI: 0.00, 51.08) and 0.80 (95%CI: 0.00,2.15), respectively. Hypoglycemia was highly prevalent in those using insulin therapy, with a 50% prevalence for mild to moderate episodes and a 21% prevalence for severe episodes (5).</p> <p>Hypoglycemia also causes work productivity loss. Work productivity loss often consists of absenteeism and presenteeism. While absenteeism is to be absent from work due to health problems, presenteeism is defined as the health-related productivity loss at paid work (6).</p> <p>Presenteeism attributed to diabetes is caused by hypoglycemia, diabetic neuropathy, and mood disorders. In one of the studies evaluated, presenteeism was significantly associated with severity of hypoglycemia event (no hypoglycemia 17.7%, non-severe hypoglycemia 18.7%, and severe hypoglycemia 31.2%), and increasing costs based on hypoglycemia severity. Mean annualized costs due to presenteeism also increased with increasing severity of hypoglycemia (6).</p> <p>Some patients had insufficient knowledge of hypoglycemia, and those who had received knowledge training agreed that their concerns or fear levels were lower than before (7).</p>	

### Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE					ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li><input type="radio"/> Trivial</li> <li><input type="radio"/> Small</li> <li><input checked="" type="radio"/> Moderate</li> <li><input type="radio"/> Large</li> <li><input type="radio"/> Varies</li> <li><input type="radio"/> Don't know</li> </ul>	<b>Outcomes</b>	<b>N<sub>o</sub> of participants (studies) Follow up</b>	<b>Certainty of the evidence (GRADE)</b>	<b>Relative effect (95% CI)</b>	<b>Anticipated absolute effects* (95% CI)</b>	
					<b>Risk with unstructured advice</b>	<b>Risk difference with a structured program of patient education with follow up (with key elements identified)</b>
	Hypoglycemia ≤70 mg/dl follow up: range 6 months to 12 months	1182 (2 RCTs)	⊕○○○ VERY LOW <sup>a,b,c</sup>	<b>OR 0.57</b> (0.31 to 1.07)	Study population 543 per 1,000 <b>139 fewer per 1,000</b> (274 fewer to 17 more)	
	Severe hypoglycemia - patients follow up: range 3 months to 12 months	946 (4 RCTs)	⊕○○○ VERY LOW <sup>d,e</sup>	<b>OR 1.01</b> (0.47 to 2.41)	Study population 27 per 1,000 <b>0 fewer per 1,000</b> (14 fewer to 36 more)	
	Hemoglobin A1C follow up: range 6 months to 12 months	1631 (9 RCTs)	⊕⊕⊕○ MODERATE <sup>f</sup>	-	The mean hemoglobin A1C was <b>0</b> MD <b>0.34 lower</b> (0.5 lower to 0.2 lower)	
	Death	338 (2 RCTs)	⊕○○○ VERY LOW <sup>a,g</sup>	<b>OR 0.99</b> (0.10 to 9.68)	Study population 6 per 1,000 <b>0 fewer per 1,000</b> (5 fewer to 49 more)	
	Myocardial Infarction - not reported	-	-	-	-	
	Stroke - not reported	-	-	-	-	
	Loss of consciousness/Seizure - not reported	-	-	-	-	
	Severe hypoglycemia - episodes follow up: range 3 months to 12 months	0 (4 RCTs)	⊕⊕○○ LOW <sup>d</sup>	-	OR = 0.25; 95% CI: 0.13 to 0.47; I <sup>2</sup> = 0.00%	

The panel considered a 2.8% mean difference reduction in time below range for <54 mg/dL to be a moderate desirable effect. The panel considered there were better glycemic outcomes as reflected by time in range of 70-180 mg/dL with structured patient education. Fewer episodes <70 mg/dL were considered a substantial desirable effect as well. Overall, the panel viewed there were fewer episodes of hypoglycemia and better glycemic control with structured education.

It should also be noted that studies on the prevalence of serious hypoglycemia done using CGM find that for every glucose value below 54 mg/dL that is recognized there is roughly an equal number of values in this range that are unrecognized. This means that for people with type 1 diabetes there are double the number of serious hypoglycemia than are recognized.

Time below range (<54 mg/dL) assessed with: Change from baseline follow up: 6 months	100 (1 observational study)	⊕○○○ VERY LOW <sup>h</sup>	-	The mean time below range (<54 mg/dL) was <b>0</b> % of time spent in range	MD <b>2.8 % of time spent in range fewer</b> (2.4 fewer to 3.2 fewer)
Time below range (<70 mg/dL) follow up: 6 months	199 (1 RCT)	⊕⊕○○ LOW <sup>e,i</sup>	-	The mean time below range (<70 mg/dL) was <b>0</b> mean proportion (%) of glucose values in the range	MD <b>0.3 mean proportion (%) of glucose values in the range more</b> (1.44 fewer to 0.84 more)
Time in range (70-180 mg/dL)	199 (1 RCT)	⊕⊕○○ LOW <sup>i,j</sup>	-	The mean time in range (70-180 mg/dL) was <b>0</b> mean proportion (%) of glucose values in the range	MD <b>3.8 mean proportion (%) of glucose values in the range more</b> (0.17 fewer to 7.77 more)
Hemoglobin A1C follow up: range 6 months to 12 months	394 (3 observational studies)	⊕○○○ VERY LOW <sup>k</sup>	-	The mean hemoglobin A1C was <b>0</b>	MD <b>0.34 lower</b> (0.4 lower to 0.29 lower)

- a. Very serious concerns about risk of bias due to overall high risk of bias in both studies included in the analysis.
- b. Serious concerns about inconsistency due to poor overlap of CIs, and considerably large I squared statistic that is unlikely explained by chance (p=0.01)
- c. Serious concerns about imprecision due to wide CI crossing the clinical decision threshold of OR=1.
- d. Very serious concerns about risk of bias due to overall high risk of bias in all studies included in the analysis
- e. Very serious concerns about imprecision due to very wide CI that has appreciable benefits and harms
- f. Serious concerns about risk of bias due to 8 RCTs being at high risk of bias.
- g. Very serious concerns about imprecision due to very wide CI that has appreciable benefits and harms and a very small number of events (n=2).
- h. Very small sample size
- i. Serious concerns about risk of bias due to risk of selective reporting in the trial.
- j. Serious concerns about imprecision due to wide CI crossing the clinical decision threshold of OR=1.
- k. Serious concerns about risk of bias due to 2 nonrandomized studies being at high risk of bias.

## Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE					ADDITIONAL CONSIDERATIONS
<input type="radio"/> Large <input type="radio"/> Moderate <input type="radio"/> Small <input checked="" type="radio"/> Trivial <input type="radio"/> Varies <input type="radio"/> Don't know	<b>Outcomes</b>	<b>N<sub>o</sub> of participants (studies) Follow up</b>	<b>Certainty of the evidence (GRADE)</b>	<b>Relative effect (95% CI)</b>	<b>Anticipated absolute effects* (95% CI)</b>	
					<b>Risk with unstructured advice</b>	<b>Risk difference with a structured program of patient education with follow up (with key elements identified)</b>
	Hypoglycemia ≤70 mg/dl follow up: range 6	1182 (2 RCTs)	⊕○○○ VERY LOW <sup>a,b,c</sup>	<b>OR 0.57</b> (0.31 to 1.07)	Study population	

From the included studies, there were no undesirable effects across the outcomes considered important or critical, and all effects favored structured patient education.

months to 12 months				543 per 1,000	<b>139 fewer per 1,000</b> (274 fewer to 17 more)
Severe hypoglycemia - patients follow up: range 3 months to 12 months	946 (4 RCTs)	⊕○○○ VERY LOW <sup>d,e</sup>	<b>OR 1.01</b> (0.47 to 2.41)	Study population	
				27 per 1,000	<b>0 fewer per 1,000</b> (14 fewer to 36 more)
Hemoglobin A1C follow up: range 6 months to 12 months	1631 (9 RCTs)	⊕⊕⊕○ MODERATE <sup>f</sup>	-	The mean hemoglobin A1C was <b>0</b>	MD <b>0.34 lower</b> (0.5 lower to 0.2 lower)
Death	338 (2 RCTs)	⊕○○○ VERY LOW <sup>a,g</sup>	<b>OR 0.99</b> (0.10 to 9.68)	Study population	
				6 per 1,000	<b>0 fewer per 1,000</b> (5 fewer to 49 more)
Myocardial Infarction - not reported	-	-	-	-	-
Stroke - not reported	-	-	-	-	-
Loss of consciousness/Seizure - not reported	-	-	-	-	-
Severe hypoglycemia - episodes follow up: range 3 months to 12 months	0 (4 RCTs)	⊕⊕○○ LOW <sup>d</sup>	-	OR = 0.25; 95% CI: 0.13 to 0.47; I2 = 0.00%	
Time below range (<54 mg/dL) assessed with: Change from baseline follow up: 6 months	100 (1 observational study)	⊕○○○ VERY LOW <sup>h</sup>	-	The mean time below range (<54 mg/dL) was <b>0 %</b> of time spent in range	MD <b>2.8 % of time spent in range fewer</b> (2.4 fewer to 3.2 fewer)
Time below range (<70 mg/dL) follow up: 6 months	199 (1 RCT)	⊕⊕○○ LOW <sup>e,i</sup>	-	The mean time below range (<70 mg/dL) was <b>0</b> mean proportion (%) of glucose values in the range	MD <b>0.3 mean proportion (%) of glucose values in the range more</b> (1.44 fewer to 0.84 more)
Time in range (70-180 mg/dL)	199 (1 RCT)	⊕⊕○○ LOW <sup>i,j</sup>	-	The mean time in range (70-180 mg/dL) was <b>0</b> mean proportion (%) of glucose values in the range	MD <b>3.8 mean proportion (%) of glucose values in the range more</b> (0.17 fewer to 7.77 more)

Hemoglobin A1C follow up: range 6 months to 12 months	394 (3 observational studies)	⊕○○○ VERY LOW <sup>k</sup>	-	The mean hemoglobin A1C was <b>0</b>	MD <b>0.34 lower</b> (0.4 lower to 0.29 lower)
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- a. Very serious concerns about risk of bias due to overall high risk of bias in both studies included in the analysis.
- b. Serious concerns about inconsistency due to poor overlap of CIs, and considerably large I squared statistic that is unlikely explained by chance (p=0.01)
- c. Serious concerns about imprecision due to wide CI crossing the clinical decision threshold of OR=1.
- d. Very serious concerns about risk of bias due to overall high risk of bias in all studies included in the analysis
- e. Very serious concerns about imprecision due to very wide CI that has appreciable benefits and harms
- f. Serious concerns about risk of bias due to 8 RCTs being at high risk of bias.
- g. Very serious concerns about imprecision due to very wide CI that has appreciable benefits and harms and a very small number of events (n=2).
- h. Very small sample size
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- j. Serious concerns about imprecision due to wide CI crossing the clinical decision threshold of OR=1.
- k. Serious concerns about risk of bias due to 2 nonrandomized studies being at high risk of bias.

### Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> Very low <input checked="" type="radio"/> Low <input type="radio"/> Moderate <input type="radio"/> High <input type="radio"/> No included studies		<p>The certainty across the outcomes was considered moderate for HbA1c, but very low for the rest of the outcomes.</p> <p>There was no difference in death but there was a wide CI; however, this outcome was not considered as the most important one in relationship to the PICO question of structured education.</p> <p>Even though the body of evidence had very low certainty, the panel viewed that penalizing it was possibly not justified, since all the evidence for desirable effects was pointing to the same direction, with no apparent undesirable effects.</p> <p>The justification for upgrading from very low to low overall certainty was based on both hypoglycemia and severe hypoglycemia showing improvement with low certainty for severe hypoglycemia and time below/in range outcomes, on which the panel's decision-making was based.</p>

### Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
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<ul style="list-style-type: none"> <li><input type="radio"/> Important uncertainty or variability</li> <li><input type="radio"/> Possibly important uncertainty or variability</li> <li><input type="radio"/> Probably no important uncertainty or variability</li> <li><input checked="" type="radio"/> No important uncertainty or variability</li> </ul>	<p><b>Hypoglycemia affects all people with diabetes and is of value to them, given increased fear of hypoglycemia, increased diabetes distress and decreased quality of life.</b></p> <p>Intensive diabetes therapy with insulin increases the risk for hypoglycemia (8). Presence of hypoglycemia is associated with fear of hypoglycemia, which is common in patients with type 1 and type 2 diabetes. In a systematic review of 18 studies fear of hypoglycemia negatively impacted quality of life including psychosocial functioning, daily life and sleep quality. In addition, hypoglycemia worsens diabetes distress, already highly prevalent in people with diabetes, with a calculated prevalence of 36% as noted in a systematic review of 55 studies (and 36,998 participants with type 2 diabetes) (9).</p> <p>Structured diabetes education, particularly group-based education has been shown to decrease HbA1c, improve diabetes knowledge, and improve psychosocial outcomes. In a review of 47 studies (8533 participants), reduction of HbA1c was persistent even after 18 months. Of note, 5 of the 47 studies specifically included hypoglycemia as an end point of unwanted consequences and commonly feared acute complications of diabetes, and showed improvement in hypoglycemia (10).</p> <p>Structured diabetes education has been shown to reduce symptoms of depression in people with diabetes, as shown in a review of 11,884 subjects with both type 1 and type 2 diabetes (age range of 18-90 years) (11). Within this cohort, a highly interactive peer-led diabetes self-management program for type 2 DM participants, with emphasis on planning and problem solving, goal settings, demonstrated significant improvement in symptoms of hypoglycemia, depression, communication with physicians, healthy eating, and reading food labels at 6 months (<math>P &lt; 0.01</math>) (11).</p> <p>Of note, technological interventions with insulin pump therapy, continuous glucose monitoring, and sensor-augmented pump also reduced severe hypoglycemia, improved glycemic control, and restored hypoglycemia awareness when used in combination with structured education and frequent contact (12). Finally, in people with diabetes and high risk of hypoglycemia such as the patients on dialysis, educational programs improved, hypoglycemia, living with diabetes and coping with stress (13).</p>	<p>Hypoglycemia is a high value outcome and experiencing hypoglycemia results in distress (i.e. diabetes distress).</p> <p>The panel discussed that some people with diabetes may accept hypoglycemia as a “side effect” of glycemic management; people with impaired hypoglycemia awareness may not attribute their symptoms to hypoglycemia and in fact feel they are able to remain functional even at low glucose levels. However, hypoglycemia is always an unwanted outcome, and it should be avoided whenever possible in all people with diabetes even if there is great variability in how people prioritize hypoglycemia vs glycemic targets.</p> <p>In the presence of hypoglycemia, goals of glycemic targets are not in line with the side effect caused by hypoglycemia.</p>
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**Balance of effects**  
Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li><input type="radio"/> Favors the comparison</li> <li><input type="radio"/> Probably favors the comparison</li> <li><input type="radio"/> Does not favor either the intervention or the comparison</li> <li><input type="radio"/> Probably favors the intervention</li> <li><input checked="" type="radio"/> Favors the intervention</li> <li><input type="radio"/> Varies</li> <li><input type="radio"/> Don't know</li> </ul>		<p>The balance of effects is consistent with moderate desirable consequences, albeit with low overall certainty. No undesirable or trivial undesirable effects were noted, favoring the intervention of structured diabetes education.</p>

**Resources required**  
How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
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<ul style="list-style-type: none"> <li><input type="radio"/> Large costs</li> <li><input type="radio"/> Moderate costs</li> <li><input type="radio"/> Negligible costs and savings</li> <li><input checked="" type="radio"/> Moderate savings</li> <li><input type="radio"/> Large savings</li> <li><input type="radio"/> Varies</li> <li><input type="radio"/> Don't know</li> </ul>	<p><b>Diabetes education programs are not significantly costly, though not available to all patients (depending on where they live - rural vs urban setting, etc.)</b></p> <p>American Diabetes Association's Diabetes self-management education and support (DSMES) and AADE Self-Care Behaviors™ frameworks are established programs that provide people with diabetes content on multiple factors that contribute to hypoglycemia such as missed meals, activity changes without adjustment of insulin or food and suboptimal medication management (14).</p> <p>Medicare reimburses DSMES when the services meet the national standards and are recognized by the American Diabetes Association (ADA) or Association of Diabetes Care &amp; Education Specialists (ADCES)(15). DSMES is also covered by most health insurance plans.</p> <p>The cost for diabetes education estimated from a life-time model was less than US \$50,000 (16).</p>	<p>The panel considered the definition of structured education and which components of the program should be considered, whether virtual with real time question and answer time, or time spent by providers during their visits to apply structured education. Also, structured education should be provided on an annual basis.</p> <p>Group diabetes education sessions could be less costly than individual education sessions with specialists. The absence of a structured education program would result in the providers needing to utilize their time to provide education to the patients.</p> <p>Cost is also affected by the format of diabetes education; in -person vs. virtual. Structured education should not just follow a pre-packaged framework but be individualized as well. When considering the cost of structured diabetes education and comparing it to the cost related to Emergency Department visit and EMS visits for hypoglycemia, structured diabetes education provides probably savings through the reduction of hypoglycemia as well as the reduction of HbA1c.</p>
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**Certainty of evidence of required resources**  
 What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li><input type="radio"/> Very low</li> <li><input checked="" type="radio"/> Low</li> <li><input type="radio"/> Moderate</li> <li><input type="radio"/> High</li> <li><input type="radio"/> No included studies</li> </ul>	<p><b>No research evidence identified</b></p>	

**Cost effectiveness**  
 Does the cost-effectiveness of the intervention favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
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<ul style="list-style-type: none"> <li><input type="radio"/> Favors the comparison</li> <li><input type="radio"/> Probably favors the comparison</li> <li><input type="radio"/> Does not favor either the intervention or the comparison</li> <li><input type="radio"/> Probably favors the intervention</li> <li><input checked="" type="radio"/> Favors the intervention</li> <li><input type="radio"/> Varies</li> <li><input type="radio"/> No included studies</li> </ul>	<p><b>Structured diabetes self-management education programs have evidence of being cost-effective.</b></p> <p>Diabetes care is costly and so are the costs associated to complications of diabetes, especially hypoglycemia (1). Diabetes self-management education and support (DSMES) programs can be cost-effective for the practices and the patients.</p> <p>A systematic review showed that eight out of 12 programs included in their analysis, estimated costs. Among these eight, three studies showed a cost per unit reduction in clinical risk factors (HbA1c or BMI) of US\$491 to US\$7723 or cost per glycemically symptom day avoided of US\$39. Another review studied the evidence on the costs and cost-effectiveness of self-management support interventions for people with diabetes. In this analysis, 16 costing and 21 cost-effectiveness studies of a range of self-management support interventions were identified. Of these studies, 22 showed consistent evidence that DMES interventions are cost-effective or superior to usual care. Telemedicine-type interventions were more expensive than usual care and potentially not cost-effective. The quality of the evidence was limited (17).</p> <p>One particular challenge of diabetes self-management is in the avoidance of hypoglycemia during Ramadan, a prolonged religious fasting period that occurs yearly for individuals of Muslim faith. 17 studies identified in a systematic review revealed a significant reduction of hypoglycemia risk for fasting patients who took part in intervention groups with Ramadan-focused education compared to conventional care (OR 0.19, 95% CI: 0.08-0.46) (18).</p>	
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**Equity**  
What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <li><input type="radio"/> Reduced</li> <li><input type="radio"/> Probably reduced</li> <li><input type="radio"/> Probably no impact</li> <li><input checked="" type="radio"/> Probably increased</li> <li><input type="radio"/> Increased</li> <li><input type="radio"/> Varies</li> <li><input type="radio"/> Don't know</li> </ul>	<p><b>Diabetes education is open to people of all cultures and ethnicities; they all benefit from structured diabetes education.</b></p> <p>Diabetes self-management educational programs targeted to racial/ethnic minority groups can produce a positive effect on diabetes knowledge and self-management behavior. Studies that were conducted in the US with targeted programs to type 2 diabetes African American or Latino participants showed that most programs obtained some benefits, with HbA1c reduction of 0.31% (95% CI -0.48% to -0.14%) in a meta-analysis of 20 randomized controlled trials with 3,094 participants. In addition, 75% (15/20 studies) of the studies observed improvements in behavioral outcomes with education interventions (19). When analyzing the effects of DSME vs. usual care in a systematic review of studies including only African Americans, no significant differences were seen in HbA1c levels, but improvement in quality of life was seen in DSME participants vs. usual care (20).</p>	<p>Diabetes education impact on equity depends on the ability of people with diabetes to access structured programs, tailored to specific populations and ethnic-specific. Access depends greatly on the location where the programs are offered, the concern being that those who are in the most need to receive a structured diabetes education program to reduce hypoglycemia may be the ones that have the least access, whether because of distance or due to lack of computer and internet access for virtual programs.</p> <p>In order to enhance equity, structured diabetes education programs need to be offered in the language of the patients and with the cultural sensitivity of specific populations. When these parameters are met, equity is probably increased as long as the criteria are met and considered; in such settings, these personalized structured diabetes education programs would help with outcomes in affected populations.</p> <p>Telehealth and virtual education program can also improve access if people with diabetes have distance or transportation constraints. The availability of structured programs vs. lack of such programs, would probably increase health equity among all populations.</p>

**Acceptability**  
Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
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<input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	<p><b>Evidence suggests that intervention is acceptable to patients and caregivers, however it requires substantial time commitment and perceived benefit.</b></p> <p>Generally, patients with diabetes who attend structured programs for diabetes education, benefit from the experience with improvement of glycemic markers, and reduction of hypoglycemia (10, 11, 12, 13, 14)(15). However, there is evidence of patients referred to diabetes education who choose not to attend. A systematic review of 12 studies with quantitative and qualitative methodologies was conducted and two main overarching themes emerged: those who could not attend and those who will not attend. The first group included reasons due to logistical, medical, financial reasons that included lack of time, transport issues, inability to commit to the program duration due to family or work priorities, physical disabilities and insufficient health insurance coverage. The second group reported 4 reasons for not attending: no perceived benefit, i.e. felt diabetes education not to be a high priority or lack of enthusiasms shown by the healthcare professionals; knowledge, i.e. feeling of having received enough information elsewhere or lack of perceived problem with diabetes; emotional such as reporting negative feelings towards diabetes education and inability to cope with the thought of complications or being uncomfortable in a group setting; and cultural such as literacy, language and cultural issues (21).</p> <p>The national standards for diabetes self-management education and support recommend that all people with diabetes should participate in diabetes self-management education and receive the support needed to facilitate the knowledge, decision-making, and skills mastery necessary for diabetes self-care(15).</p>	<p>There was consensus among the panel that structured diabetes education program empowers patients with diabetes. Individual patients have different experiences in accepting diabetes education in their journey with diabetes.</p> <p>Whether they receive diabetes education in groups or individually, the attention of people with diabetes will be captured to make changes in their approach to diabetes.</p> <p>Studies show that some people with diabetes do not wish to attend diabetes education programs and are not focused on their glycemic management or improvement.</p> <p>Telehealth could be used as a method to improve acceptability of diabetes education and can improve access in the setting of transportation difficulties or schedule difficulty for in person attendance of classes.</p> <p>In the absence of a structured education program, clinicians would have reduced time for individual unstructured advice to patients during visits.</p>
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**Feasibility**  
Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know	<p><b>Evidence suggests that the intervention is feasible, and long-term results are consistent, and can be implemented both in person or using technology such as apps to enhance diabetes education.</b></p> <p>Patients with type 2 diabetes engaged in structured diabetes education programs (DSMES) benefit from statistically significant decreases in HbA1c. In a systematic review, modes of DSME delivery were classified into 1 of 4 categories: (1) individual education, (2) group education, (3) a combination of individual and group education, and (4) DSME primarily delivered by remote methods, with subject contact conducted online or by telephone. Several factors affected the likelihood of statistically significant and clinically meaningful improvement of the HbA1c, including the mode of delivery, the number of hours of engagement and baseline HbA1c. The combination group DSME was the most effective, as well as the greater the number of hours (more than 10). In addition, 78.1% of studies that enrolled participants with baseline A1C levels &gt;9.0 reported significant improvements in glycemic control in the intervention group compared with the control group.</p> <p>Similarly, the use of diabetes apps including delivery of education, has been found to improve glycemic control in type 1 and type 2 diabetes. A systematic review included 25 studies for analysis, where the use of mobile and secure messaging was evaluated. The technology-enabled self-management in the 25 studies utilized the AADE7 self-care behavior framework (14). Eighteen of the 25 studies reported significant HbA1c as an outcome measure. Four elements that contributed to the improvement in HbA1c were identified: 1) communication, 2) patient-generated health data, 3) education and 4) feedback (22). Crucial times for diabetes education are at diagnosis, at annual follow-up, during times of complications, and during care transitions, and these also have important implications as additional opportunities for education about risks for hypoglycemia. However, Diabetes self-management and education remains significantly underused in the United States and only 5% of eligible CMS beneficiaries are enrolled in these programs ((15, 14). Not all educational programs are the same and in order for patients to derive benefit there needs to be common terminology and content, as well as a similar duration for the program (number of sessions) and expertise with respect to those guiding/teaching the sessions.</p> <p>An absence of common hypoglycemia measures and terminology and suboptimal descriptions of DSMES programs for content, delivery, duration, practitioner types, and participants were identified as gaps in the literature.</p>	<p>Structured diabetes education programs are applicable to both type 1 and type 2 diabetes and in group settings. Peer support availability is of great utility.</p> <p>The panel felt that it is crucial that programs have trained staff and follow accredited curricula to deliver the program content. In the setting of commercialized program, the panel was concerned that the quality of the programs may be a challenge and would need to have the appropriate conditions to make them equitable. In this setting, insurance companies should provide discounts to support participation in programs.</p>

**SUMMARY OF JUDGEMENTS**

		JUDGEMENT					
PROBLEM	No	Probably no	Probably yes	Yes	Varies	Don't know	

<b>DESIRABLE EFFECTS</b>	Trivial	Small	<b>Moderate</b>	Large		Varies	Don't know
<b>UNDESIRABLE EFFECTS</b>	Large	Moderate	Small	<b>Trivial</b>		Varies	Don't know
<b>CERTAINTY OF EVIDENCE</b>	Very low	<b>Low</b>	Moderate	High			No included studies
<b>VALUES</b>	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	<b>No important uncertainty or variability</b>			
<b>BALANCE OF EFFECTS</b>	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	<b>Favors the intervention</b>	Varies	Don't know
<b>RESOURCES REQUIRED</b>	Large costs	Moderate costs	Negligible costs and savings	<b>Moderate savings</b>	Large savings	Varies	Don't know
<b>CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES</b>	Very low	<b>Low</b>	Moderate	High			No included studies
<b>COST EFFECTIVENESS</b>	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	<b>Favors the intervention</b>	Varies	No included studies
<b>EQUITY</b>	Reduced	Probably reduced	Probably no impact	<b>Probably increased</b>	Increased	Varies	Don't know
<b>ACCEPTABILITY</b>	No	Probably no	<b>Probably yes</b>	Yes		Varies	Don't know
<b>FEASIBILITY</b>	No	Probably no	Probably yes	<b>Yes</b>		Varies	Don't know

## TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ●
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## CONCLUSIONS

### Recommendation

We recommend a structured program of patient education over unstructured advice be used for adult or pediatric outpatients with type 1 or type 2 diabetes receiving insulin therapy. (Strong recommendation based, low certainty of evidence) (1⊕○○)

#### Remarks:

- Structured education on how to avoid repeated hypoglycemia is critical.
- Education should be performed by experienced diabetes clinicians.
- Insurance coverage for education should be available for all insulin-using patients.
- The recommendation is not intended to limit structured education only to those on insulin therapy, for example patients using sulfonylureas and meglitinides are also at risk for hypoglycemia and the recommendation may also apply to this patient population.

### Justification

The panel considered making a conditional vs. strong recommendation for structured program of patient education. Their decision for a strong recommendation was ultimately based on health benefits viewed as moderate, trivial or no undesirable effects, and severe hypoglycemia reduction as well as HbA1c reduction as the driving outcomes.

The panel agreed that severe hypoglycemia is a life-threatening situation in the person with diabetes which therefore fulfilled a paradigmatic situation for a strong recommendation in the presence of low certainty of evidence.

The panel also supported the use of structured diabetes education programs for pediatric population with a balance of desirable consequences in this population. The panel especially supported the use of structured diabetes education programs in specific populations such as people with diabetes with impaired hypoglycemia awareness.

### Subgroup considerations

Structured education programs are recommended for type 1 diabetes patients as well as type 2 diabetes.

Patients with type 1 diabetes, receiving insulin for their management, are at particular risk for hypoglycemia. In this setting, type 1 patients with hypoglycemia unawareness or with renal disease are at particular risk for hypoglycemia, as well as older adults with long standing type 1 diabetes.

Similarly, patients with type 2 diabetes that are not receiving insulin but taking medications that increase risk for hypoglycemia such as sulfonylureas would also be at high risk of hypoglycemia. For these patients, these recommendations also apply. However, this population was not specifically considered as a subgroup within this guideline question.

Therefore, the panel feels strongly that structured diabetes education programs should be recommended to all patients with diabetes, regardless of the type of diabetes or the diabetes management regimen.

### Implementation considerations

The panel considered important to identify settings where group education would be appropriate as well as individual training.

Similarly, the panel considered additional elements such as duration of the education programs, whether short vs. advanced or long version and these decisions should be made based on the patient's availability, their language barriers and cultural components of the education programs.

The panel debated on the possible unintentional consequence of people with diabetes not receiving sufficient education or the impact of cost or coverage limitations for these individuals. The panel emphasized that structured diabetes education programs should be a continuum and the patients' needs should be re-evaluated as their needs for education whether basic or advanced changes overtime for adult and pediatric age groups. This would include the education needed to initiate insulin or insulin pump therapy.

Additionally, the panel viewed the utilization of multiple formats as important, such as online tools, telehealth, on-demand tools or interactive apps as options for structured programs, in addition to in-person classes.

The panel felt it is particularly important to offer structured education during patient's various transitions of life, such as from pediatric to young adult care, or to older adult settings, or based on clinical conditions.

In particular, for the pediatric population, the panel felt that implementation of a structured education program should allow for re-educating at appropriate developmental steps and in transition from pediatric to adult care (continuum of education program).

In the US, accredited programs from the American Diabetes Association or the Association for Clinical Diabetes and Education Specialists allow institutions to receive reimbursement for the education services provided.

## Monitoring and evaluation

This recommendation should be monitored with respect to new data regarding diabetes education in specific patient populations (see below under 'research priorities'), as well as the types and effectiveness of structured diabetes education programs available (virtual vs. inperson, etc).

The panel noted the importance of accreditation of structured education programs and quality control.

## Research priorities

The panel highlighted the following research priorities:

- Studies on effects of programs in African American, Asian and South Asian American populations
- Studies assessing components of structured education (who provides education, how long is spent, group vs. individual, virtual vs. in-person and group-size, all at once vs. in segments, involvement of patient partners for structuring and tailoring a program) that are best and improve outcomes

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