



Devices for Self-management of Type 1 and Insulin-Dependent Type 2 Diabetes

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Disclosure for Dr. Sethu Reddy and Dr. Rifka Schulman-Rosenbaum

- No financial involvement with manufacturers (or their competitors) of any items or services being discussed.
- No relevant financial association—as consultant, research support, advisory board,
- No intellectual conflicts of interest
- American Association of Clinical Endocrinology also has no conflict of interest for this particular topic

AACE References of Relevance

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Summary Table of Surrogate markers and related Domains

Surrogate markers	Appropriateness	Duration (Length of Study)	MCID
· Number of hypoglycemic episodes (<70 mg/dL), especially episodes of Level 2 hypoglycemia (<54 mg/dL)	5	6 months	Reduction by 25% from baseline i.e. if baseline incidence is 4%, reduction to 3% is meaningful
· Percentage of time in level 2 hypoglycemia (<54 mg/dL)	4	3 months	Difference of 25%
· Impact on A1C (MCID = 0.5% change)*	4	3 months	Agree
· Percentage of time in acceptable glucose range (70-180 mg/dL)	5	3 months	5-10% difference – increase in time in range
· Percentage of time in hyperglycemia (>180 mg/dL)	4	3 months	5% reduction difference

Health Outcome		Duration	MCID
· Restoration of hypoglycemia awareness	3	3 months	Difficult to quantify
· Cognitive function changes	5	6 months	Greater than 20% decline in standard tests of cognition
· Diabetes-related emergency department visits	5	6 months	Greater than 50% reduction
· Diabetes-related hospitalizations	5	6-12 months	Greater than 50% reduction
· Complications of diabetes, e.g., kidney disease, major adverse cardiovascular events (MACE)	3	24-60 months	Greater than 15% reduction in incidence

Quality of Life		Duration	MCID
· Audit of Diabetes-Dependent Quality of Life (ADDQoL) questionnaire	4	3 months	Increase by 10%
· Diabetes Distress Scale	4	3 months	Improved by 10%
· Diabetes Impact Measurement Scales (DIMS)	3	3 months	Improved by 20%
· Diabetes Treatment Satisfaction Questionnaire	3	3 months	Improved by 20%
· Hypoglycemia Fear Survey	5	3 months	Improved by 25%
· Problem Areas in Diabetes	3	??	??

Device related Safety		Duration	MCID
· Hypoglycemia-related emergency department visits	4	6 months	Improved by 50%
· Harms such as tissue damage, if appropriate	2	??	??
· Device discontinuation rates	3	6 months	Reduced by 20%
· Patient preferences (comparing the device with conventional self-management) and adherence	4	3 months	Preferred by more than 25%

Suggestion

The questions of duration of study needed and the MCIDs for each metric will depend on the baseline values and the number of subjects in the study. For the MCIDs to be evaluated, a careful power analysis is needed to determine the length of study and the number.