Hypoglycemia Prevention Initiative: Frequently Asked Questions

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HYPOGLYCEMIA PREVENTION INITIATIVE

A. Overview

1. What is the Hypoglycemia Prevention Initiative?

As an ongoing effort to reduce the frequency of diabetes-related hypoglycemia in patients with Type 2 diabetes (T2D), Endocrine Society and Avalere Health have been working collaboratively to develop and implement the Hypoglycemia Prevention Initiative. The Initiative engages in various opportunities to support research, advocacy, education, and quality of care. The Hypoglycemia Prevention Study, HypoPrevent, is a central component to the Initiative.

The goals of the Initiative are to:

- Support providers in adopting clinical guidance in practice
- Promote patients' confidence in managing hypoglycemia
- Test interventions for decreasing the risk of hypoglycemia in clinical settings
- Advance awareness of hypoglycemia in T2D through the dissemination of research findings and creation of multi-stakeholder partnerships
- Advance measure development and payment and delivery reform

2. Who is the Endocrine Society?

The Endocrine Society is the oldest and largest global professional membership organization representing the field of endocrinology with over 18,000 members in 122 countries. Our members care for patients and are dedicated to advancing hormone research and excellence in the clinical practice of endocrinology. These expert scientists and physicians shape the genesis and delivery of patient care from bench to bedside to well-being.

Since 2014, the Endocrine Society has made hypoglycemia a strategic priority, conducting a series of roundtables with key stakeholders from the federal government, provider community, patient advocates, and payers to determine a comprehensive approach to this problem. Endocrine Society, in collaboration with Avalere Health, has now embarked on a multi-year quality improvement project, the *Hypoglycemia Prevention Initiative.*

3. Who is Avalere Health?

Avalere Health is a healthcare advisory firm headquartered in Washington, D.C., specializing in strategy, policy, and data analysis across health sectors. Avalere delivers a comprehensive perspective, compelling substance, and creative solutions to help organizations make better business decisions. In 2016, Avalere partnered with the Endocrine Society to develop and initiate a multi-year quality improvement project, the *Hypoglycemia Prevention Initiative*.

4. What is the Hypoglycemia Prevention Study (HypoPrevent)?

HypoPrevent, a central component of the Initiative, is a quality improvement study designed to pilot a two-pronged intervention in primary care practice to identify patients at risk of hypoglycemia and assess methods to decrease their risk through the individualization of their A1c goals and/or changes to their medications. The target population is patients 65 years of age and older who are treated with insulin or sulfonylureas with a most recent A1c level of less than 7%.

a. What is the intervention being piloted in HypoPrevent?

HypoPrevent is piloting a two-pronged intervention, containing the following primary components:

i. **Hypoglycemia Risk Screening Tool**: an evidence-based algorithm to enable providers to identify patients with T2D aged 65 and older within their patient panel who are at risk for medication-related hypoglycemia based on risk factors: prescription for hypoglycemic agents including insulin and/or sulfonylureas and a most recent hemoglobin A1c (A1c) value of < 7.0%

ii. **Provider Hypoglycemia Reduction Clinical Decision Support Tool**: an evidence-based, point-of-care, decision support tool to guide providers in patient assessment, care planning, and monitoring and ongoing evaluation of patients through shared decision-making with a focus on reducing risk of hypoglycemia through the individualization of A1c goals and/or changes in medication management

b. What is the goal/purpose of HypoPrevent?

The goal of the HypoPrevent pilot study is to assess the feasibility of implementing the intervention in real-world clinical practice, assess clinician acceptability, and explore the impact of the interventions on patient outcomes and provider behaviors.

c. What is the duration and scope of HypoPrevent?

The anticipated practice participation requirements are outlined in the table below.

Expected Duration	9 months (baseline visit + two quarterly follow-up visits) + follow-up surveys and interviews
Size of participating practice	15-20 providers
Number of enrolled patients per provider	15-20 patients
Number of visits per patient	1 baseline visit and 2 follow up visits

5. Who should participate in HypoPrevent?

HypoPrevent is designed for primary care practices with experience in quality improvement that have an interest in a population management approach to identify patients at risk of hypoglycemia and to mitigate that risk on an individual patient basis. Practices with 15-20 primary care providers, a large number of older (65+) patients with T2D, and without a formal mechanism to identify those with hypoglycemia will have the greatest opportunity to make an impact on their patient population through participation in this pilot study. Please note that all providers in a practice will be expected to participate in the pilot study.

B. Benefits and Resources

6. What are the key benefits of participating in HypoPrevent?

There are numerous ways that you and your practice will benefit from HypoPrevent, including improved quality of care and safety for your patients, provider and patient focused resources related to hypoglycemia and shared decision-making, and the chance to have input on developing new quality measures. Additionally, practice-level compensation will be provided to cover study-related expenses. Some benefits include:

For Practices…

- Opportunity to be recognized as a leader and early adopter in hypoglycemia quality improvement
- Opportunities to publish and present on your practice's experience and results
- Obtain technical assistance with collection of performance data to track and monitor implementation progress

For Providers…

- Improve the safety of your patients with T2D in your busy clinical practice with an intervention that helps you better identify individuals at risk of hypoglycemia and help them mitigate their risk
- Improve your ability to effectively engage patients on the topic of hypoglycemia through easy to use resources
- Provider-focused resources to help facilitate shared-decision making and medication changes designed to maximize patient engagement and reduce the risk of hypoglycemia
- Patient-focused resources to help patients recognize, treat, and avoid hypoglycemia
- Access to educational resources and training to implement guidelines into practice related to setting individualized A1c goals for older patients
- Opportunities for educational activities that may include CME
- Potential opportunity to achieve MIPS Improvement Activities reporting requirements through the provision of glycemic management services
- Have input on developing new quality measures for diabetes to improve patient safety

7. Will a participating practice receive compensation?

Yes, compensation will be provided to help practices offset any resource and infrastructure costs associated with participation. Examples include the cost of the Practice Coordinator's time, and the data capture and transmission of various reports and surveys.

An initial payment of $15,000.00 will be made after receipt of the Patient Panel Report by the HypoPrevent team. After study completion, the practice will receive the following per patient payment based on the total number of visits for up to 160 patients for a total payment not to exceed $55,000:

- Baseline, follow-up visit one, and follow up visit 2: $250.00 per patient
- Baseline, one follow-up visit: $125.00 per patient
- Baseline visit only: no additional payment

8. *What support will I receive as a participating practice?*

Before participating in HypoPrevent, you will have the opportunity to engage in a series of onboarding and training sessions with experts in the field.

During HypoPrevent, participants will have access to individual technical assistance calls with HypoPrevent leaders, opportunities to informally engage with implementation experts, data collection guides, templates, and other resources to facilitate implementation of the Intervention. Finally, resources to support uptake of the interventions with providers and patients will be made available in the HypoPrevent Toolkit.

9. *What is the HypoPrevent Toolkit?*

The Toolkit is an exclusive HypoPrevent resource that contains provider and patient resources that are: an evidence-based, easily accessible, supportive of practice-based quality improvement, and aligned with the goals of the Hypoglycemia Prevention Initiative. The Toolkit provides both quality and clinical resources for members of a practice to use in implementing the intervention at every stage of the clinical workflow, in addition to providing resources aimed at patients and helping them better understand and manage their hypoglycemia risk.

C. Expectations and Responsibilities of Participation

10. *How will HypoPrevent's Intervention and resources be integrated into my practice's existing clinical workflow?*

HypoPrevent is designed to be integrated into a practice's existing workflow, occurring during regular recurring visits standard for the T2D population and requiring data that is for the most part already being collected. The Intervention is intended to assist primary care providers, who often face competing priorities and limited time with complex patients, to effectively manage this at-risk population by focusing their encounters on the areas in which they can have the greatest impact in reducing risk of hypoglycemia.

11. *How can I determine if my practice is ready?*

We will work with practices that are interested in participating in the study to determine whether they are ready to participate. We will use a combination of surveys and pre-enrollment screening calls to gather information about practices to identify an ideal practice for HypoPrevent who fits our eligibility criteria and is ready to implement a new quality improvement project in their practice.

In order to successfully participate in the pilot study, a practice must:

- Have experience in protocol-driven initiatives
- Systematically assign patients to a primary care provider's panel
- Be able to pull customized patient panel reports from their EHR based on specific patient information such as lab results, age, diagnoses, medication use, etc.

12. *What are the expectations of participating in HypoPrevent?*

Once selected, practice participants will be asked to complete the following tasks:

- Sign a Practice Participation Agreement and Business Associate Agreement (BAA) with HypoPrevent's Project Team
- Participate in practice onboarding activities, specifically, educational training sessions, and receiving the Practice Welcome Announcement
- Provide HypoPrevent's Project Team with a report of all patients in your panel, including characteristics used to determine risk
- Conduct outreach to patients identified as at risk for hypoglycemia regarding HypoPrevent participation
- Enroll patients into HypoPrevent and collect informed consent
- Commit to collecting and supporting analysis of data on all study endpoints
- Complete pre- and post-study assessments including a clinical acceptance survey to determine providers' acceptance of the study tools

13. What is the process for Internal Review Board (IRB) Approval and patient informed consent for HypoPrevent?

IRB Submission: HypoPrevent protocol will be submitted and approved by Quorum Review IRB, in anticipation that practices may not have access to their own IRB. Quorum is a nationally recognized central IRB whose boards comply fully with relevant U.S. and Canadian regulations and has full accreditation from the Association for the Accreditation of Human Research Protection Programs. A pilot practice will receive information necessary to register under Quorum. If a participating practice is required by its organization to obtain local IRB approval, it will receive materials to support its application to the local IRB.

Patient Informed Consent: Each patient will consent in writing to participation in HypoPrevent prior to any assessments and will be obtained by the provider or a designated member of a practice. The practice should safely store signed informed consent documents.

14. What are the data collection and submission requirements for HypoPrevent?

- A practice will be required to collect data from a variety of different sources for purposes of HypoPrevent, including: patient demographic information, A1c lab test results, patient surveys, provider surveys, and documentation of actions taken during the visit
- Submission requirements will utilize a combination of EHR data extraction, patient-reported surveys, and Adobe PDF forms.