

AMGA Foundation National Diabetes Campaign

©2020 All rights reserved



Monthly Campaign Webinar April 2020

©2020 All rights reserved

Today's Webinar

- Together 2 Goal[®] Updates
 - Webinar Reminders
 - AMGA COVID-19 Resources
- Hypoglycemia Prevention
 Initiative



 Jeffrey Boord, M.D., MPH of Parkview Physicians' Group



Webinar Reminders

- This webinar was prerecorded and made available on April 16th
 - www.Together2Goal.org





AMGA COVID-19 Resources



AMGA COVID-19 Resources

Since the COVID-19 outbreak began, AMGA has worked closely with members, federal agencies, and other healthcare entities to respond to this challenge and to make sure our member medical groups and health systems have the most up-to-date information and resources.

Here are current tactics and tools from members, our latest advocacy efforts, updated federal policies, and resources from payers and others.





Today's Featured Presenter

Jeffrey Boord, M.D., MPH



Chief Quality and Safety Officer Parkview Physicians' Group

©2020 All rights reserved

Reducing the Incidence of Hypoglycemia

Jeffrey Boord, MD, MPH Chair, Hypoglycemia Prevention Initiative Steering Committee

April 2020





Key Messages

- ASK about hypoglycemia
 - Ask about hypoglycemia events and the "why" behind them
- **SET** appropriate glycemic targets
 - Engage with your patient, individualize goals
- **MODIFY** therapy where appropriate
- EDUCATE your patients
 - Regarding recognition, monitoring, treatment, and prevention
- MONITOR clinically and reassess at future visits





Definition of Hypoglycemia



Standardizing Clinically Meaningful Outcome Measures Beyond HbA1c for Type 1 Diabetes: A Consensus Statement of the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the American Diabetes Association, the Endocrine Society, JDRF International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange

| Level | Glycemic Criteria/Description |
|---------|--|
| Level 1 | Glucose < 70 mg/dL (3.9 mmol/L) and Glucose \geq 54 mg/dL (3.0 mmol/L) |
| Level 2 | Glucose < 54 mg/dL (<3.0 mmol/L) |
| Level 3 | A severe event characterized by altered mental and/or physical status requiring assistance |





Definition of Hypoglycemia

| Level | Glycemic Criteria | Description | |
|--|----------------------------------|--|--|
| Hypoglycemia alert value (level 1) | ≤70 mg/dL (3.9 mmol/L) | Sufficiently low for treatment with fast-acting carbohydrate and dose adjustment of glucose- lowering therapy | |
| Clinically significant hypoglycemia (level 2) | < 54 mg/dL (3.0 mmol/L) | Sufficiently low to indicate serious, clinically important hypoglycemia | |
| Severe hypoglycemia (level 3) | No specific glucose threshold | Hypoglycemia associated with severe cognitive impairment requiring external assistance for recovery | |

International Hypoglycemia Study Group. Diabetes Care 2017;40:155-157





The Burden of Hypoglycemia

Hypoglycemia accounted for **300,000 ER** visits in 2009 among T1D and T2D patients Hypoglycemia is the largest single barrier to

achieving glycemic control in diabetes

The prevalence and impact of hypoglycemia is **substantially underappreciated**

- Incidence of hypoglycemia among patients with T2D on insulin is, on average, 23 mild or moderate events and 1 severe episode per year
- Patients with T1D have hypoglycemia about 2-3X more often than patients with T2D
- 4-10% of deaths in patients with T1D are caused by hypoglycemia
- Hospitalization as a result of hypoglycemia is associated with a 18.1% 30day readmission rate and a 5% 30-day mortality rate

Seaquist ER. et al. Hypoglycemia and diabetes: a report of a workgroup of the ADA and the Endocrine Society. Diabetes Care 23:1384-1395, 2013 Lash, RW, et al. Preventing hypoglycemia in type 2 diabetes. J Clin Endocrinol Metab 103:1-4, 2018





The Burden of Hypoglycemia

- Insulin and oral insulin secretagogues (sulfonylureas) are among the top 3 medication classes that cause emergent hospitalization due to adverse drug events
- Severe hypoglycemic episodes are associated with higher risk of CV events mortality in patients with diabetes
 - Relationships between hypoglycemia, CV events, and mortality are complex
- Hypoglycemia can contribute to cognitive dysfunction, arrhythmias, and autonomic dysfunction
- Hypoglycemia increases the risk of falls and automobile accidents
- Fear of hypoglycemia reduces quality of life, increases diabetes-related distress, and may impact productivity and work

Seaquist ER. et al. Hypoglycemia and diabetes: a report of a workgroup of the ADA and the Endocrine Society. Diabetes Care 23:1384-1395, 2013 Lash, RW, et al. Preventing hypoglycemia in type 2 diabetes. J Clin Endocrinol Metab 103:1-4, 2018 Standl, E. et al. Increased risk of severe hypoglycemic events before and after cardiovascular outcomes in TECOS suggests an at-risk type 2 diabetes frail patient phenotype





Hypoglycemia Unawareness and Hypoglycemia-Associated Autonomic Failure (HAAF)

- Physiologic response to hypoglycemia
 - Adrenergic response (sweating, tachycardia, tremor, hunger)
 - Suppression of insulin secretion
 - Stimulation of glucagon, epinephrine, GH, cortisol secretion
- HAAF Components
 - Defective glucose counterregulation attenuated glucagon/epinephrine response
 - Hypoglycemia unawareness attenuated sympathoadrenal activity and minimal or absent adrenergic response
- HAAF is functional and most often caused by antecedent recurrent iatrogenic hypoglycemia
- HAAF associated with 25-fold increase risk of severe hypoglycemia during intensive glycemic therapy





Risk Factors for Hypoglycemia

- Insulin, sulfonylurea, or meglitinide use
- Prior severe hypoglycemia episodes (esp. requiring ED visit or hospitalization)
- History of high glycemic variability / labile glucose
- Older age
- Longer duration of diabetes
- Stage 3-5 CKD
- Cirrhosis
- Dementia or cognitive impairment
- Recent hospitalization with acute kidney injury
- Very tight control (A1c <6%) or poor control (>9%)
- Food insufficiency/malnutrition

Hung A, et al. Diabetes Care 41:503–512, 2018 Lipska KJ, et al. Diabetes Care 36:3535-3542, 2013





Clinic Case Study

- 72 year old female with cognitive impairment, heart failure with preserved ejection fraction, afib on warfarin anticoagulation, prior stroke, hypertension, neuropathy, pulmonary hypertension on chronic O2 therapy, referred for type 2 diabetes management
- Lives in a group home and is on insulin therapy
- Has been on insulin at least 2 years
- A1c: 6.4%, creatinine: 0.7
- Current regimen: Glargine, 35 units, daily in the morning
- Caregiver monitors glucose 3x/day at breakfast, supper, and bedtime
- Eats 3 meals a day and reports good appetite





Hypoglycemia – History

- Self-monitoring of blood glucose
 - Frequency, timing
 - Recent values/log
- Episodes of hypoglycemia
 - Any <70 mg/dl?
 - Any severe hypoglycemia?
 - Context: Diet, activity, medication use, timing
- Hypoglycemia unawareness
 - Can you feel it when your blood sugar is low?
 - Have you had a low reading but no symptoms?
- Self-management
 - What do you do when your blood sugar is low?
 - Do you carry around glucose tablets? Do you have a glucagon kit?
- Nutrition
 - Diet history, weight trend
 - Issues with food insufficiency





Clinic Case Study, Pt. 2

- Caregiver reports patient has hypoglycemia at least 2 times a week during the day, usually before supper or in the morning
- She does not reliably note symptoms during episodes
- Patient has not had any recent hospitalizations or ED visits due to hypoglycemia





2020 ADA Standards: Hypoglycemia

- Individuals at risk for hypoglycemia should be asked about symptomatic and asymptomatic hypoglycemia at each encounter. C
- Glucose (15–20 g) is the preferred treatment for the conscious individual with blood glucose ≤70 mg/dL [3.9 mmol/L]), although any form of carbohydrate that contains glucose may be used. B
- Glucagon should be prescribed for all individuals at increased risk of level 2 hypoglycemia, defined as blood glucose <54 mg/dL (3.0 mmol/L), so it is available should it be needed. Caregivers, school personnel, or family members of these individuals should know where it is and when and how to administer it. Glucagon administration is not limited to health care professionals. E

ADA Standards of Medical Care in Diabetes. Diabetes Care 2020 Jan; 43(Supplement 1): S66-S76





2020 ADA Standards: Hypoglycemia

- Hypoglycemia unawareness or one or more episodes of level 3 hypoglycemia should trigger reevaluation of the treatment regimen. E
- Insulin-treated patients with hypoglycemia unawareness, one level 3 hypoglycemic event, or a pattern of unexplained level 2 hypoglycemia should be advised to raise their glycemic targets to strictly avoid hypoglycemia for at least several weeks in order to partially reverse hypoglycemia unawareness and reduce risk of future episodes. A
- Ongoing assessment of cognitive function is suggested with increased vigilance for hypoglycemia by the clinician, patient, and caregivers if low cognition or declining cognition is found. B

ADA Standards of Medical Care in Diabetes. Diabetes Care 2020 Jan; 43(Supplement 1): S66-S76





For a Patient at Risk for Hypoglycemia

Determine appropriate glycemic goals with patient / caregiver

- Glycemic targets: A1c, FSBG ranges
- Explicit goal to minimize/ prevent hypoglycemia

Determine appropriate pharmacotherapy

- Change medications
- Modify dosing

Educate patient / caregiver and monitor

- FSBG monitoring
- Prescribe glucagon, when appropriate
- Clinical follow up
- When to notify provider between visits





Approach to the Management of Hyperglycemia

REVENTION INITIATIVE





Olde<u>r Adults – Treatment G</u>oals

| Overall Health Category | | Group 1 | Group 2 | Group 3 |
|-------------------------|-----|--|--|---|
| | | Good health | Intermediate health | Poor health |
| Patient characteristics | | No comorbidities or 1-2 non-diabetes chronic illnesses* | 3 or more non- diabetes chronic illnesses* | Any one of the following: |
| | | and No ADL [€] impairments | and/or Any one of the following: | End-stage medical condition(s)** |
| | | impairment | mild cognitive | Moderate to severe |
| | | | impairment or early | dementia |
| | | | dementia | ≥2 ADL impairments |
| | | | ≥2 IADL | |
| | | | impairments | Residence in a long- term nursing facility |
| | | Reasonable g | lucose target ranges a | nd HbA1c by group |
| | | Shared decision- | making: individualized goal may | be lower or higher |
| | | | | |
| | No | Fasting: 90–130 mg/dL | Fasting: 90–150 mg/dL | Fasting: 100–180 mg/dL |
| Use of drugs that | | Bedtime: 90–150 | Bedtime: 100–180 | Bedtime: 110–200 |
| may cause | | mg/dL | mg/dL | mg/dL |
| insulin. | | | <8% | |
| sulfonylurea, | | <7.5% | | <8.5%¥ |
| glinides) | Yes | Fasting: 90–150 | Fasting: 100–150 | Fasting: 100–180 |
| | - | mg/dL | mg/dL | mg/dL |
| | | mg/dL | mg/dL | mg/dL |
| | | | >7 5 and <8 0% | |
| | | >7.0 and <7.5% | <u>- 1.5 unu (0.070</u> | >8.0 and <8.5% [¥] |



HYPOGLYCEMIA PREVENTION INITIATIVE LeRoith D, et al. Treatment of Diabetes in Older Adults. J Clin Endocrinol Metab, 104: 1520-1574, 2019

For a Patient at Risk for Hypoglycemia

Determine appropriate glycemic goals with patient / caregiver

- Glycemic targets: A1c, FSBG ranges
- Explicit goal to minimize/ prevent hypoglycemia

Determine appropriate pharmacotherapy

- Change medications
- Modify dosing

Educate patient / caregiver and monitor

- FSBG monitoring
- Prescribe glucagon, when appropriate
- Clinical follow up
- When to notify provider between visits







Diabetes Medications with Low Hypoglycemia Risk

- DPP-4 inhibitors
- GLP-1 Agonists
- Metformin
- SGLT-2 Inhibitors
- Thiazoladinediones (TZDs)
- Meglitinides (lower risk than SU)

Tapering Advice*

- Set blood glucose and A1c targets, plus thresholds for returning to previous dose, restarting drug, or maintaining dose
- Develop tapering plan with patient / caregiver
- Doses may be increased or medication restarted at any time if blood glucose persists above individual target or symptomatic hyperglycemia returns

*deprescribing.org- antihyperglycemics deprescribing algorithm: https://deprescribing.org/wp-content/uploads/2017/11/AHG-deprescribing-algorithms-2017-English.pdf





For a Patient at Risk for Hypoglycemia

Determine appropriate glycemic goals with patient / caregiver

- Glycemic targets: A1c, FSBG ranges
- Explicit goal to minimize/ prevent hypoglycemia

Determine appropriate pharmacotherapy

- Change medications
- Modify dosing

Educate patient / caregiver and monitor

- FSBG monitoring
- Prescribe glucagon, when appropriate
- Clinical follow up
- When to notify provider between visits





Patient & Caregiver Education

- Signs and symptoms of hypoglycemia
- Hypoglycemia unawareness
- Treatment of hypoglycemia with oral carbohydrates or glucagon
- Risk factors for hypoglycemia
- Dietary factors
 - Carbohydrates and blood glucose
- Understand diabetes medications
 - How they work, how to take them, when they may need adjustment
- Exercise management
- Glucose Monitoring

http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/hypoglycemia-low-blood.html?loc=lwd-slabnav http://clinical.diabetesjournals.org/content/30/1/38





Hypoglycemia Prevention Initiative





Endocrine Society Prioritizes Hypoglycemia Prevention

Objective: increase national awareness of hypoglycemia and facilitate joint action by stakeholders to reduce its incidence

Established the Hypoglycemia Quality Collaborative (HQC)

Coalition of diabetes stakeholders including medical specialty societies, payers, industry, patient advocates, diabetes educators, and research organizations

Developed the HQC Strategic Blueprint

Provides a comprehensive framework for reducing the incidence of hypoglycemia

Implementing Outpatient Quality Improvement Pilot

A project testing the impact of risk assessment and education on the incidence of hypoglycemia in patients with T2D on insulin or sulfonylureas in the primary care setting

Partnering with Federal Agencies

A collaborative of Federal agencies (FDA, CMS, VA, HHS), Endocrine Society, and quality improvement organizations for raising awareness, improving surveillance, and improving quality of care





Hypoglycemia Quality Collaborative

LAUNCHED JANUARY 2016 BY THE ENDOCRINE SOCIETY

Organizations Participate in the Hypoglycemia Quality Collaborative

- Abbott Diabetes Care Inc.
- Aetna
- American Association of Clinical Endocrinologists
- American Association of Diabetes Educators
- American College of Physicians
- American Diabetes Association
- AstraZeneca
- Close Concerns
- Dexcom



- Johnson & Johnson
- Joslin Diabetes Center
- Juvenile Diabetes Research Foundation
- Lilly
- Medtronic Diabetes
- Merck & Co
- Novo Nordisk
- Pharmacy Quality Alliance
- T1D Exchange



HQC Strategic Blueprint

HQC Strategic Blueprint to Reduce the Incidence of Hypoglycemia



ENDOCRINE

Avalere

HYPOGLYCEMIA PREVENTION INITIATIVE

Hypoglycemia Prevention Initiative Objectives

- 1. Increase Outpatient Hypoglycemia Surveillance & Risk Assessment
 - Integrate risk assessment into clinical workflow in primary care
 - Develop outpatient hypoglycemia quality measures
- 2. Improve Management of Patients on Insulin and Sulfonylureas
 - Provide clinical decision support tools to guide assessment of appropriate A1c goals and medication management options
 - Use shared decision making to set goals and modify treatment
 - Provide educational tools to help patients identify and manage hypoglycemia
- **3.** Align Provider Reimbursement to Promote Best Practices
 - Incorporate clinical improvement activities and quality measures into value-based reimbursement programs
 - Incentivize care teams that provide high-quality care





Environmental Scan Supports Development of the Initiative

- Clinicians have a general lack of awareness of resources to identify, assess, and manage patients at high risk for hypoglycemia
- A few risk assessment tools exist but are not systematically incorporated in clinical workflow
- Educational resources are available but rarely used
- There are no outpatient quality measures on hypoglycemia and there is a clinical need to develop them

Robert W Lash, Deborah O Lucas, Judit Illes; Preventing Hypoglycemia in Type 2 Diabetes, *The Journal of Clinical Endocrinology & Metabolism*, <u>https://doi.org/10.1210/jc.2017-02804</u>





Providers Face Challenges Managing Hypoglycemia

Individualized Goals

- I'm not convinced than an A1c less than 7% is good for everyone. The goal is to accomplish the best A1c possible without hypoglycemia, without too much cost, without too much finger pricking, and without too much weight gain.
- I used to believe that lower A1c was better. Last few years I have seen patients with hypoglycemia and changed my practice to decrease hypoglycemia. I don't push for an A1c goal less than 7% for elderly patients. Cost of medications is an issue. Push target A1c down less than 7% and cost of meds increases.

Medication Modification

- Protocols on how to manage polypharmacy and switch meds to avoid hypoglycemia would be nice. Biggest challenge is knowing how to safely reduce insulin intake while still controlling their condition
- Biggest challenges with elderly patients are managing polypharmacy and multiple comorbidities, patient concerns on cost of medication, and patient access to enough glucose testing strips for SMBG.

Educating Providers and Patients

- I think it would be helpful to have patient education materials for hypoglycemia because patients are conditioned to think that they need to be treated for everything.
- Physicians need to know what medicines patients are on, assess risk of hypo (age, renal function, medications), which insulins are better to reduce risk of hypo, and patient goals and expectations.





Patients Report Lack of Education on Hypoglycemia

Fear and Knowledge of Hypoglycemia and Patient Quality of Life

- It's very scary living alone and having hypoglycemia.
- I didn't really learn about hypo until getting involved in peer support groups.
- Hypoglycemia is not always about being below a certain number, but often relative.
- I quit my job years ago and am now in a job that allows me to eat every few hours.

Avoiding Episodes

- I don't find them [hypoglycemic episodes] always so predictable.
- I don't like to take instant sugar/soda. It [treatment] is a little more complicated than just having more carbs, sometimes it's a lack of protein.
- Most episodes happen in the middle of the night

Patient Experience with Medical Care

- I think PCPs believe that even with testing, most diabetics are not going to test their blood or be advocates.
- My PCP never asks about low blood sugar, my endocrinologist always does (and handles all my medications).

Response to Educational Materials

• When I saw these, I was jumping up and down saying "wow I didn't know that" though I consider myself very educated from Diabetes Sisters and self-education.





Hypoglycemia Prevention Study (HypoPrevent)





HypoPrevent is a Component of the Hypoglycemia Prevention Initiative

The **Hypoglycemia Prevention Study**, a central component of the Initiative, is designed to test a dual-pronged intervention in primary care practices to:

- 1. Identify at-risk patients
- 2. Assess methods that decrease risk
 - a) Individualizing A1c goals
 - b) Changing medications





Research Questions & End Points

- 1. Can the hypoglycemia reduction intervention be integrated into primary care workflow?
- 2. What is the impact of the use of the hypoglycemia reduction intervention on provider behavior and patient outcomes?
- 3. What is the impact of the use of the hypoglycemia reduction intervention on the size of the at-risk population?





HypoPrevent Will Evaluate a Two-Pronged Intervention

| Hypoglycemia | Identifies patients potentially at risk of medication-related |
|---|--|
| Risk Tool | hypoglycemia |
| Hypoglycemia Reduction Clinical Decision Support Tool | Supports providers in assessing patients, care planning, and monitoring and ongoing evaluation focusing on: Shared decision-making Individualization of A1c goals Medication management changes |





Study Workflow

- · Identify patients 65 years old and older with T2D
 - $\circ~$ Includes prescription for insulin and/or sulfonylureas
 - Includes A1c of < 7% in previous 6 months
 - Excludes patients on insulin less than 3 months and/or with limited life expectancy of < 12 months
- Invite patients to participate in the study via telephone outreach
- Obtain patient informed consent in-person during
 Baseline visit
- · At Baseline visit and subsequent follow-up visits:
 - Patients complete surveys assessing impact of hypoglycemia and self-efficacy
 - Providers use information on the Decision Support Tool for clinical decision-making
 - Patients and providers either engage in 1) shared decision-making discussion on an individualized A1c target and/or modifications to treatment to reduce risk of hypoglycemia or 2) assess progress to changes to reduce risk of hypoglycemia
- Recommended frequency of follow-up visits is every three months

Evaluate







HypoPrevent Recruitment & Interim Analysis





Overview of Study Site: Pottstown Medical Specialists, Inc.

Overview

PMSI is a physician-owned multispecialty group practice with offices in Berks and Montgomery Counties in Southeastern Pennsylvania. They are committed to delivering the highest quality medical healthcare through the coordination of properly planned, managed and utilized medical services. PMSI has accreditation as a Diabetes Self-Management Support and Education (DSMES) service through AADE and is a recognized provider of the CDC's National Diabetes Prevention Program.

A certified diabetes educator (CDE) coordinates the study across the participating PMSI practices. The office manager ("site coordinator") in each practice and each participating provider was trained on the conduct of the study using a "train the trainer" approach. After training was complete, the first step was to identify and enroll patients into the study.

1,063 Total Patients 65+ with T2D



Total Participating PMSI Providers

Total Participating Locations



PMSI: Pottstown Medical Specialists, Inc.; CDC: Centers Disease Control and Prevention; AADE: American Academy of Diabetes Educator; CDE: Certified Diabetes Educator; T2D: Type 2 Diabetes



Enrollment Period

The enrollment period was extended 3 times due to slower than expected enrollment



*Enrolled declined in September due to unforeseen loss of PMSI staff member (Avalere notified 9/23) ** Only patients enrolled prior to 11/8 are included in Interim Report (n=3 for November).





Demographic Data for Enrolled Patient Population*





Patient Sex

Race

- White: 95% (60/63)
- Black or African American: 3% (2/63)
- 2 or more races: 2% (1/63)

1 n reflects number of records reporting this data. * Based on patients enrolled prior to November 8, 2019



- Ethnicity
 - Non-Hispanic: 98% (60/61)
 - Hispanic: 2% (1/61)
- Preferred Language: 100% English (n=62)



Demographic Data for Enrolled Patient Population*

Insurance Coverage



Data reported by PMSI indicates that almost all (42/43) patients with Medicare reported having Part D coverage.



1 n reflects number of records reporting this data. * Based on patients enrolled prior to November 8, 2019



Demographic Data for Enrolled Patient Population



Comorbid Conditions

- 50/63 (79%) of patients reported at least 1 comorbid condition
- Of those reporting a comorbid condition, **25/50 (50%)** reported more than 1 comorbid condition

Duration of Diabetes

- 29 of 63 (46%) patients reported a value for duration of diabetes
- Values reported range from 4 to 27 years with the median duration being 10 years

*Other conditions include Parkinson's Disease, Breast Cancer, CAD/OSA





Baseline Visit: Shared Decision-Making, A1c Goal Setting, and Medication Changes

97% (61/63) of enrolled patients had an SDM discussion at their baseline visit.

Patients may have had their medications changed during different types of conversations with their provider.



While almost a third of patients with an SDM discussion (19/61) had a medication change made either during the visit or during a follow-up phone call or in office visit, many of them (11/19) did **not** have an individualized A1c goal set during the baseline visit. We will continue to explore the reasons for this care decision, including potential alternative metrics to A1c being used to measure successful treatment changes.



SDM: Shared Decision-Making



Outpatient Hypoglycemia Quality Measures





Outpatient Hypoglycemia QMs

- Proportion of Patients Who Were Assessed to be at Greater Risk for Hypoglycemia
- Educational Intervention for Patients at Greater Risk for Hypoglycemia
- Patient Reported Level 3 Hypoglycemic Event Requiring Assistance





Outpatient Hypoglycemia QMs

- Published in Journal of Clinical Endocrinology & Metabolism (April 2020)
 - o Available online
- Develop "instructions" for using measures in practice
 - Implementation manual is in development
- Dissemination of measures to primary care practices







How You Can Become Involved

Interested in learning about how your practice can become involved in HypoPrevent? Would you like to be alerted when the study tools and QM implementation guide is available?

> Contact Stephanie Kutler Director, Advocacy & Policy skutler@endocrine.org





Hypoglycemia Prevention Initiative Supporters







Abbott









Thank you!

www.endocrine.org/hypoglycemia-prevention-initiative



