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HYPOGLYCEMIA QUALITY COLLABORATIVE STRATEGIC BLUEPRINT

A RESOURCE TO INCREASE AWARENESS OF HYPOGLYCEMIA
AND PROMOTE ACTIVITIES TO REDUCE ITS INCIDENCE

REPORT AND STRATEGIC RECOMMENDATIONS

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I. OVERVIEW OF THE STATE OF HYPOGLYCEMIA

Diabetes mellitus (DM) is a disease of two forms characterized by high blood glucose. Type 1 diabetes (T1D) results from insulin deficiency due to autoimmune destruction of pancreatic β -cells. Type 2 diabetes (T2D) is a consequence of either cellular insulin resistance or relative deficiencies in insulin productionⁱ. The Centers for Disease Control and Prevention (CDC) estimate that 9.3 percent (29.1 million people) of the US population is affected by DM and each year approximately 1.7 million new cases are diagnosed among adultsⁱⁱ.

Treatment to control blood glucose and reduce long-term microvascular, neurologic, and macrovascular complications includes exercise, dietary modifications, weight control and the use of medications. Blood glucose-lowering medications include: insulins, dipeptidyl peptidase-4 inhibitors (DPP-4), glucagon-like peptide-1 (GLP-1) analogues, sodium-glucose co-transporter 2 (SGLT2) inhibitors, and thiazolidinediones (TZDs) in combination with metformin and a sulfonylurea.

Following evidence from the landmark Diabetes Control and Complications Trialⁱⁱⁱ, clinical guidance^{iv} for blood glucose management was updated to recommend strict glycemic control targets using HbA1c values of <6.5 or <7.0 percent. More recent evidence has shown that the use of intensive glycemic control targets when treated with oral agents, insulin-based therapies, or SGLT-2 combined with insulin puts patients at greater risk for hypoglycemia. These findings are particularly pronounced for elderly^v and critically-ill^{vi} patients.

Hypoglycemia is associated with loss of consciousness and dementia leading to hospitalization, including nearly 300,000 emergency department (ED) visits in 2009^{vii}. For persons with DM, the threat and fear of hypoglycemia, whether spontaneous or therapy-associated, is one of the most significant barriers to glycemic control^{viii}.

Patients and providers including specialists, primary care physicians, and nurses are often undereducated and ill-equipped to prevent and manage therapy-associated or spontaneous hypoglycemia that may be caused by dietary or exercise pattern modifications. In addition, issues of access and health literacy among low socioeconomic status individuals contribute to poor outcomes^x. For example, the 30-day mortality for hypoglycemia admissions for Medicare beneficiaries in 2010 was 5.0 percent and the 30-day readmission rate was 18.1 percent^x. Further, the cost of hypoglycemia is significant. Between January 2007 and December 2011, ED visits for therapy-associated hypoglycemia resulted in spending of more than \$600 million^{xi}.

To prevent and manage hypoglycemia, current clinical guidance recommends the use of individualized HbA1c goals based upon patient characteristics such as health status and life expectancy^{xii}. Clinicians also have access to treatment algorithms, such as those developed by the American Association of Clinical Endocrinologists (AACE) and new technologies for continuous blood glucose monitoring that support the targeting of preventative interventions in real-time.

For patients, diabetes self-management education (DSME) that includes self-monitoring blood glucose (SMBG) instruction (e.g., evaluation of fasting, pre-meal, post-prandial and bedtime blood glucose), healthy eating choices, and physical activity is important for hypoglycemia prevention^{xiii}. However, low referral rates to DSME by clinicians, low completion rates by patients, and varying payer coverage of DSME result in poor glucose pattern and hypoglycemia symptom recognition. These factors cause delays in treatment and a high frequency of preventable hypoglycemic events^{xiv}.

For policymakers and payers, new policies for preventing and managing hypoglycemia are important, such as evidence-based reimbursement design that includes the use of quality measures to benchmark care.

Recently, because of the increasing prevalence and urgency of the problem, federal regulators and DM stakeholders have increased their focus on hypoglycemia. In October 2014, the Department of Health and Human Services (DHHS) National Action Plan for Adverse Drug Event (ADE) Prevention highlighted diabetes agent-associated hypoglycemia as a primary concern. This report cited the lack of a consensus definition for different levels of hypoglycemia severity as a major barrier to reducing the incidence of hypoglycemia^{xv}. Following release of the DHHS National Action Plan, the Endocrine Society convened a stakeholder roundtable to discuss opportunities to advance care related to hypoglycemia. In addition, beginning in April 2016, the Juvenile Diabetes Research Foundation (JDRF) launched a multi-stakeholder initiative to address gaps in care for T1D that includes efforts to develop consensus definitions for differing hypoglycemia severity.

Despite the availability of evidence-based prevention and management techniques, policy mechanisms, and digital health tools, hypoglycemia outcomes in individuals with DM remain poor and the incidence and effects of long-term and recurrent hypoglycemia are not fully understood. These facts necessitate joint action by DM stakeholders to increase national awareness and to execute tactics that improve the prevention and management of hypoglycemia in the United States.



II. INTRODUCTION TO THE HYPOGLYCEMIA QUALITY COLLABORATIVE (HQC) AND STRATEGIC BLUEPRINT

The Endocrine Society established the Hypoglycemia Quality Collaborative (HQC) to signal its continued commitment to improving care for individuals with DM. The HQC is a coalition of DM stakeholders including: medical specialty societies, payers, industry, patient advocates, diabetes educators, and research organizations with the goal to increase national awareness of hypoglycemia in persons with DM and to foster initiatives focused on reducing its incidence.

The HQC created the HQC Strategic Blueprint (“the Blueprint”). The Blueprint is designed as an actionable document and evergreen resource for DM stakeholders to identify and contextualize opportunities to work together to reduce the incidence of hypoglycemia.

The Blueprint contains six key domains that together create a comprehensive framework for reducing the incidence of hypoglycemia:

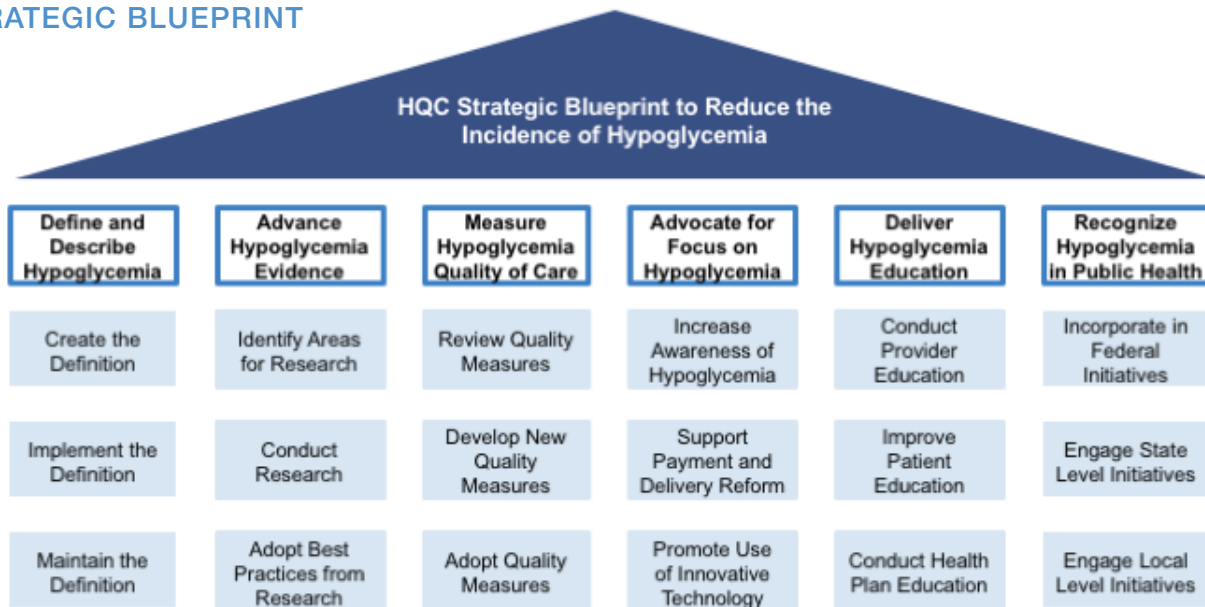
- Defining and Describing Hypoglycemia to Support Standards of Care;
- Advancing Hypoglycemia Evidence to Reduce Gaps in Care;
- Measuring and Improving Quality of Care for Patients who Experience Hypoglycemia;

- Advocating for Increased Focus on Hypoglycemia;
- Delivering Hypoglycemia Prevention and Management Education;
- Recognizing Hypoglycemia as a Public Health Issue

As shown below, each Blueprint domain contains three strategic areas. Using the expertise of its participants, the HQC has developed recommendations for DM stakeholders conducting efforts in a specific strategic area. Each of the domains and strategic areas, whether it be developing new quality measures or conducting hypoglycemia education, have been identified as absolutely necessary to improve national awareness of hypoglycemia and promote tactics to reduce its incidence.

Diabetes stakeholders should execute tactics in the strategic areas of the Blueprint individually or in partnership. In some areas, efforts are already underway. For example, by developing consensus definitions for differing hypoglycemia severity, the Juvenile Diabetes Research Foundation (JDRF) is currently leading efforts in the “Create a New Definition” strategy of the “Define and Describe Hypoglycemia to Support Standards of Care” domain (See Appendix A for efforts identified by the HQC). As such, over the next 12 months, DM stakeholders can determine how to complement the work of JDRF by pursuing efforts in the “Implement the Definition” strategy or focus their efforts in a different domain and strategy area.

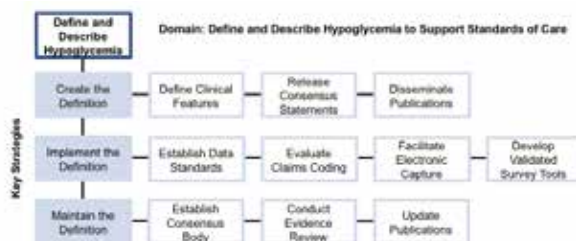
III. THE HYPOGLYCEMIA QUALITY COLLABORATIVE (HQC) STRATEGIC BLUEPRINT





DEFINING AND DESCRIBING HYPOGLYCEMIA TO SUPPORT STANDARDS OF CARE

The current definition of hypoglycemia does not support differentiation of hypoglycemic episodes by severity. The foundation for improving the prevention and management of hypoglycemia is an updated definition that accounts for differing hypoglycemia severity. A comprehensive and standardized definition can then be adopted in research, clinical guidance and decision support tools, and reimbursement models that reward quality.



Create a New Definition: A new definition of hypoglycemia must be created through a review of evidence and include both clinical values and descriptions of positive and negative symptoms. The definition should have consensus support and facilitate the recognition, tracking, and treatment of different hypoglycemia severity (Note: JDRF is currently leading efforts to develop a consensus definition for differing hypoglycemia severity).

- **HQC Recommendation:** A new definition should include both a symptom-complex and a biochemical definition since there are many factors that may affect whether a patient has symptoms.
- **HQC Recommendation:** To support prevention and management, a new definition should allow for capture of data related to pre- and post-hypoglycemia events in acute, post-acute, and community care settings (e.g., outpatient or home), including patient factors such as fears and beliefs of hypoglycemia.

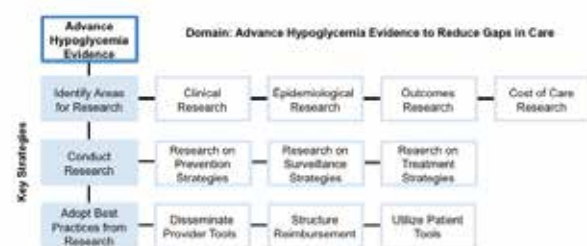
Implement the Definition: The new definition will require a technical expert panel to establish data standards and a set of standardized data elements for consistent electronic capture and transfer of hypoglycemia data by severity. Similarly, diagnostic and procedural coding (e.g., ICD, CPT) must be evaluated to support comprehensive capture of hypoglycemic episodes by severity. These steps provide the foundation for development of survey-based tools and testing of new hypoglycemia quality measures.

- **HQC Recommendation:** To accelerate the adoption of a new definition, large commercial payers and provider organizations should be engaged to adopt the consensus definition and disseminate it to members within their organizational network such as through the organization's DM standards of care.

Maintain the Definition: The definition of hypoglycemia will require a consensus body that periodically monitors and conducts targeted literature reviews to update the evidence base and support definition maintenance.

ADVANCING HYPOGLYCEMIA EVIDENCE TO REDUCE GAPS IN CARE

Current research related to glycemic control often focuses on the prevention and management of hyperglycemia. The federal government must increase funding for research at the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) to reduce gaps in evidence related to hypoglycemia prevention and management. This research should elucidate the short-term and long term effects of hypoglycemia on patient outcomes so that standards of care can be updated or newly developed.



Identify Areas for Research: Major gaps in hypoglycemia evidence should be identified so that research may be conducted to design prevention and management strategies that reduce gaps in care for hypoglycemia.

- **HQC Recommendation:** Major gaps in evidence include:
 - The pre-cursor clinical indicators of severe hypoglycemia such as frequent or protracted non-severe hypoglycemia;
 - The incidence of hypoglycemia by severity level including events in emergency and outpatient settings;
 - The short-term effects of hypoglycemia on outcomes (e.g., arrhythmias, cardiovascular events, and cerebrovascular events);
 - The long-term effects of hypoglycemia (e.g., quality of life, functional status);
 - The patient characteristics that increase hypoglycemia risk such as age, ethnicity, beliefs and fears of hypoglycemia, DSME status, and therapy choices (e.g., insulin, sulfonylurea, analog insulin, or bolus insulin);
 - The indirect costs of hypoglycemia (e.g., lost productivity/absenteeism);
 - The best practices for using continuous glucose monitor (CGM) data to inform appropriate medication or lifestyle modifications;
 - The best practices for standardized reporting of CGM data.



Conduct Research: Research that is conducted should have the objective of informing prevention, surveillance, and management approaches that account for differing hypoglycemia severity.

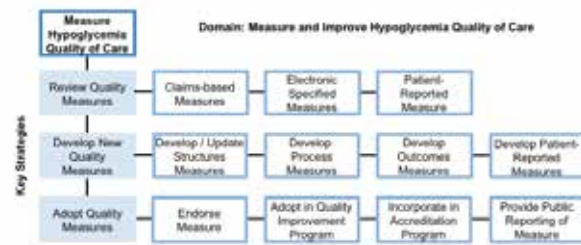
- **HQC Recommendation:** Research on patient beliefs and attitudes impacting behavior is a high priority in order to improve prevention and management strategies, especially for patients at risk for recurrent severe hypoglycemia.
- **HQC Recommendation:** Research to improve surveillance should focus on elucidating the incidence of hypoglycemia by severity and across settings of care such as the utilization of emergency medical and outpatient services related to hypoglycemia.

Adopt Best Practices from Research: Action by all stakeholders is needed for comprehensive adoption of best practices from research. Medical specialty societies must make timely updates to clinical guidance documents and educational materials; primary care teams must incorporate new surveillance strategies; diabetes educators and patient advocates must update educational materials; commercial and public payers must review and adjust reimbursement and benefit designs; and health information technology vendors and digital health manufacturers must provide tools that support new standards of care.

- **HQC Recommendation:** To encourage adoption of new best practices for prevention and management of hypoglycemia based on severity, medical specialty societies should develop a communication strategy with key messaging for engagement with regulators and payers.
- **HQC Recommendation:** Medical specialty societies should engage with primary care providers to identify opportunities to support primary care providers in adopting best practices for hypoglycemia prevention and management.
- **HQC Recommendation:** Payers and providers should actively consider ways to incorporate CGM data into clinical decision making for prevention and management of hypoglycemia in high risk individuals.

MEASURING AND IMPROVING HYPOGLYCEMIA QUALITY OF CARE

Quality measures for DM that specifically assess prevention and management of hypoglycemia are lacking. Evidence-based quality measures are needed that support coordinated, timely, and safe prevention and management of hypoglycemia. DM stakeholders must coordinate to develop and test hypoglycemia quality measures with appropriate risk adjustment to support improved hypoglycemia outcomes.



Review Current Quality Measures: Current claims, electronic, and patient-reported outcomes measures for DM should be reviewed and updated, if necessary, to improve alignment of the measures with current clinical guidance for preventing and managing severe hypoglycemia.

- **HQC Recommendation:** Current measures should be reviewed and updated to promote the use of individualized HbA1c target goals and SMBG targets (e.g., fasting, pre-meal, post prandial and bedtime blood glucose), distinguish differing hypoglycemia severity, and evaluate whether DSME was received/completed.

Develop New Quality Measures: New quality measures are needed that support surveillance of individuals at risk for hypoglycemia across settings of care, use of shared decision-making for medication selection, and evaluation of patient attitudes, fears, and behaviors related to blood glucose management.

- **HQC Recommendation:** Structural measures should be developed to support timely communication to notify a patient's primary care provider of a hypoglycemia-related emergency room visit or a medication switch following an inpatient admission.
- **HQC Recommendation:** Process measures should be developed to improve outpatient hypoglycemia risk evaluation, including less severe hypoglycemia, and use of individualized HbA1c targets goals.
- **HQC Recommendation:** Patient-reported outcomes measures are needed to evaluate fears of hypoglycemia, effect on quality of life, loss of productivity, and confidence with self-management.
- **HQC Recommendation:** Outcome measures that use clinical endpoints other than HbA1c are needed to better understand glycemic control. New measures could use multiple metrics including HbA1c, time-in-range, and hypoglycemia as potential endpoints for evaluating glycemic control.

Adopt Current and New Quality Measures:

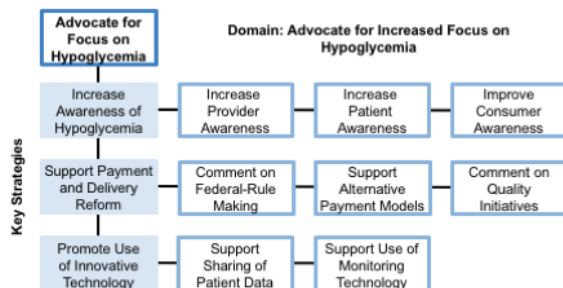
Evidence-based measures that are closely tied to outcomes and patient-centered interests must be adopted in national quality improvement, provider accreditation, and public reporting programs.



- **HQC Recommendation:** Physician Consortium for Practice Improvement (PCPI) measures for DSME^{xvi} should be submitted for adoption in Centers for Medicare & Medicaid Services (CMS) inpatient and outpatient quality improvement programs as well as for use by commercial payers.
 - These measures can be submitted to CMS for adoption in the Physician Quality Reporting System (PQRS) or future Merit-Based Incentive Payment System (MIPS) using mechanisms such as the Qualified Clinical Data Registry (QCDR) reporting option.
- **HQC Recommendation:** Quality measures such as NQF 2363: Glycemic Control should be submitted for adoption in the National Committee for Quality Assurance's (NCQA) Diabetes Recognition Program and The Joint Commission (TJC) disease specific certification programs.

ADVOCATING FOR INCREASED FOCUS ON HYPOGLYCEMIA

Advocacy is an effective tool to increase national focus on hypoglycemia. Through advocacy, DM stakeholders become more aware of the need to devote resources and attention towards preventing and managing hypoglycemia.



Increase Awareness of Hypoglycemia: Advocacy through the development of policy positions, educational events, and engagement with other DM stakeholders should improve awareness of the harm of hypoglycemia, describe methods for prevention and management, and promote increased funding of research that supports provider and patient clinical decision-making for hypoglycemia.

- **HQC Recommendation:** Patients/caregivers should be engaged by diabetes educators, patient advocacy groups, and social workers regarding self-management techniques as well as protective rights in the workplace.
- **HQC Recommendation:** Primary care providers/ organizations and advanced practice providers should be engaged to expand their role in both DM management and hypoglycemia prevention by referring patients to certified diabetes educators or patient education programs that are typically covered services.

- **HQC Recommendation:** Providers should be engaged regarding the impact of hypoglycemia relative to hyperglycemia and the importance of managing hypoglycemia by setting appropriate HbA1c and SMBG targets, using appropriate medications, educating on diet and exercise, and providing blood glucose monitoring education and tools.
- **HQC Recommendation:** Members of medical specialty societies should be engaged regarding the importance of legislative mechanisms for improving diabetes care such the Diabetes Clinical Care Commission Act.

Support Payment and Delivery Reform: Care models that incentivize coordinated, timely, safe, and accessible care for DM should be promoted through engagement with state health officials, federal rule-making, and outreach to commercial payers.

- **HQC Recommendation:** States with Diabetes Action Plans (Kentucky, Texas Illinois, Louisiana, New Jersey, North Carolina, North Dakota, Oregon and Washington) should be engaged to include explicit tactics for preventing and managing hypoglycemia.

- States without Diabetes Action Plans should be encouraged to develop action plans that specifically include tactics for preventing and managing hypoglycemia.

- **HQC Recommendation:** Public and commercial payers should be engaged regarding the value of reimbursement strategies that promote evidence-based care for hypoglycemia.
- **HQC Recommendation:** Policy makers should be engaged regarding the value of reimbursement that promotes evidence-based prevention and management for hypoglycemia to reduce the significant costs and poor outcomes of hypoglycemia.

Promote Use of Innovative Technology: Advocacy to federal regulators, commercial payers, and providers should promote patient access to glucose monitoring tools (e.g., CGMs, strip meters) and education to support providers to utilize data from these tools to inform prevention and management decisions.

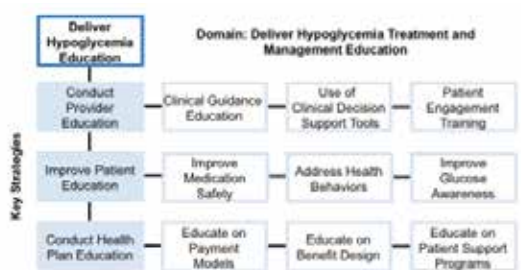
- **HQC Recommendation:** Public and commercial payers should be engaged regarding the importance of digital health and remote monitoring technologies for evaluating the burden of hypoglycemia, improving provider care coordination, and promoting shared decision-making.
- **HQC Recommendation:** Public and commercial payers should be engaged to promote access and use of active surveillance tools such as CGMs for patients at high risk for severe hypoglycemia.



- **HQC Recommendation:** Electronic medical record vendors should be engaged to integrate clinical decision support tools that allow for capture and transfer of hypoglycemia data by severity.

DELIVERING HYPOGLYCEMIA PREVENTION AND MANAGEMENT EDUCATION

Stakeholder education is a significant activity that is necessary to increase the use of evidence-based standards of care for prevention and management of hypoglycemia. Such education is important across settings of care and especially for patients and providers directly involved in the delivery of care.



Conduct Provider Education: All primary care healthcare professionals should receive hypoglycemia prevention and management education regardless of care setting. Hypoglycemia-specific education is needed to increase the use of individualized HbA1c and SMBG targets, referral of patients to DSME programs/diabetes educators, shared decision-making for management goals such as medication selections, discussion of barriers to medication adherence such as patient fears, and appropriate use of technology to prevent and manage hypoglycemia.

- **HQC Recommendation:** Initiatives to educate on new prevention and management approaches for hypoglycemia must be updated to include recommendations by hypoglycemia severity. These initiatives should also consider modifications to the provider's workflow.
- **HQC Recommendation:** Providers should receive education regarding the interpretation and use of CGM and SMBG tools, including use and definition of multiple basal rates.

Improve Patient Education: Patient education is vital for improving outcomes, however, referral rates to educational programs are too low^{xvii}. Patients should be referred to an accredited or recognized diabetes education program with the overall objective to support self-care behaviors, problem solving, and shared decision-making with the health care team.

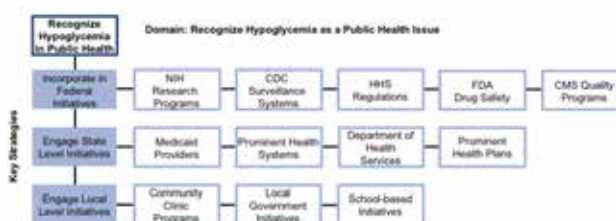
- **HQC Recommendation:** Patient education initiatives should meet the *National Standards for Diabetes Self-Management Education and Support*.
- **HQC Recommendation:** Hypoglycemia-specific education should be targeted by age and gender, sensitive to the number of hours a patient has available, and ideally include training from behaviorists, nurses, dietitians and exercise physiologists.
- **HQC Recommendation:** Hypoglycemia-specific training should include education on glucose pattern recognition and self-management actions, medication safety, fears of hypoglycemia, hypoglycemia unawareness, nutrition and lifestyle strategies, and strategies for appropriate glucose monitoring.
- **HQC Recommendation:** The use of telephonic / mobile patient education should be expanded with digital education targeted to those who will benefit most.
- **HQC Recommendation:** Patient-centered perspectives that encompass the experience of hypoglycemia, impact on quality of life, and strategies for self-management should be provided to patients.

Conduct Health Plan Education: Health plans have the ability directly influence provider and patient behavior based on reimbursement and benefit design. Education of both regional and national health plans on reimbursement and benefit design that improves hypoglycemia prevention and management is needed.

- **HQC Recommendation:** Regional payers and payers should be educated on the importance of reimbursement and benefit design that includes case management for individuals with DM from nurses or dietitians as mechanisms to reduce the frequency, impact, and incidence of severe hypoglycemia.

RECOGNIZING HYPOGLYCEMIA AS A PUBLIC HEALTH ISSUE

Many DM public health programs currently exist at federal, state, and local levels. Within these programs, the topic of hypoglycemia must become a point of emphasis. By elevating the topic of hypoglycemia as a public health issue, DM stakeholders have a mechanism to significantly improve national awareness of hypoglycemia and reduce its incidence for any severity.





Incorporate in Federal Initiatives: Federal agencies must ensure that hypoglycemia is consistently reflected in research programs, surveillance systems, regulation, drug safety, and quality programs.

- **HQC Recommendation:** DM stakeholders should engage with the agencies of the Department of Health and Human Services (HHS) to promote focus on hypoglycemia in federal programs and regulations.
- **HQC Recommendation:** The National Institutes of Health (NIH) should increase funding for research to improve prevention and management of hypoglycemia.
- **HQC Recommendation:** The programs of the Centers for Disease Control and Prevention (CDC) should supporting support national hypoglycemia surveillance.
- **HQC Recommendation:** Important topics such as hypoglycemia in a public health context should be submitted to the Diabetes Mellitus Interagency Coordinating Committee, a workgroup of federal agencies that coordinates government components to work together to address issues in diabetes.

Engage State Level Initiatives: Medicaid providers and state-level Departments of Health and Human Services (DHHS) should incorporate hypoglycemia awareness and risk reduction into public health initiatives.

- **HQC Recommendation:** To affect change at the state level, important topics in diabetes such as hypoglycemia awareness and risk reduction should be reflected in state-level Diabetes Action Plan legislation.^{xviii}
- **HQC Recommendation:** State-level initiatives should be delivered in a culturally sensitive format based upon the state's DM population and educate on the use of technology, health literacy, and numeracy.
- **HQC Recommendation:** State-level DHHS should coordinate with prominent health systems and health plans in the high-priority regions of the state.

Engage Local Level Initiatives: In collaboration with state agencies, local entities can promote hypoglycemia public health awareness and distribute educational resources through clinics, local government, and schools.

- **HQC Recommendation:** To effectively deliver information and educate communities on pediatric diabetes hypoglycemia prevention and management, programs should be developed in collaboration with school nursing organizations such as National Association of School Nurses.
- **HQC Recommendation:** DM and hypoglycemia public health resources should be culturally and linguistically appropriate to successfully engage an ethnically diverse DM patient population.

- **HQC Recommendation:** Community and socio-ethnic factors that contribute to hypoglycemia should be identified and targeted strategies must be used to prevent and manage hypoglycemia at a local level.

IV. CONCLUSION

The battle to improve the prevention and management of DM in the United States is critical given the high prevalence of the disease with more than 29.1 million people affected. In addition, an estimated 86 million people are living with prediabetes placing them at increased risk for developing type 2 diabetes^{xix}. Individuals affected by DM are at risk for a number of long-term microvascular, neurologic, and macrovascular complications as well as acute short-term complications such as hypoglycemia.

Prevention and management of hypoglycemia is complex. To reduce its incidence, explicit tactics are needed by all DM stakeholders whether they are involved in research, education, treatment, payment, or policy. The HQC Strategic Blueprint facilitates action by highlighting six domains and strategic areas to improve hypoglycemia prevention and management. By following the Blueprint, DM stakeholders can identify and engage potential partners to jointly pursue strategic efforts recommended in the domains of the HQC Blueprint.

Success in increasing awareness and reducing incidence will require the ability of the entire healthcare, medical, and patient community to elevate the issue of hypoglycemia in the national consciousness and work together to design, implement, and evaluate initiatives to improve the prevention and management of hypoglycemia. This Blueprint provides a starting point.

The Hypoglycemia Quality Collaborative Blueprint is an initiative spearheaded by the Endocrine Society in conjunction with: Abbott Diabetes Care Inc., Aetna Inc., American Association of Clinical Endocrinologists, American Association of Diabetes Educators, American College of Physicians, American Diabetes Association, Astrazeneca LP, Close Concerns, Dexcom, Inc., Lilly USA, LLC, JDRF, Johnson & Johnson, Joslin Diabetes Center, Medtronic Diabetes, Merck & Co., Inc., Novo Nordisk Inc., PQA Alliance, and T1D Exchange.

Endocrine Society would like to thank Merck & Co. for their generous support of the Hypoglycemia Quality Collaborative Blueprint.



V. APPENDIX

A. Current Efforts Identified Through Development of the HQC Strategic Blueprint

Efforts to Define and Describe Hypoglycemia to Support Standards of Care:

1. The Juvenile Diabetes Research Foundation (JDRF) is developing definitions for hypoglycemia that account for differing severity levels. JDRF will publish the final definitions in June 2017.
2. The International Hypoglycemia Study Group has previously classified severe, symptomatic, and asymptomatic hypoglycemia and presented the classification at the 76th ADA Scientific Session in June 2016.

Efforts to Advance Hypoglycemia Evidence to Reduce Gaps in Care:

1. The American Association of Clinical Endocrinologists (AACE) recently updated its Comprehensive T2D Treatment Algorithm that includes algorithms for glycemic control and intensifying insulin use^{xx}.
2. Linda Gonder-Frederick of the University of Virginia has numerous publications on the fear of hypoglycemia and adherence to self-management training.
3. William Polonsky of the Behavioral Diabetes Institute has developed the 14-item Hypoglycemic Attitudes and Behavior Scale (HABS), finding significant hypoglycemic concerns in T2D adults that are associated with emotional distress and HbA1c.
4. The Joslin Diabetes Center is conducting a national study to evaluate the association between hypoglycemia and motor-vehicle-accidents.

Efforts to Measure and Improve Hypoglycemia Quality of Care:

1. The Pharmacy Quality Alliance (PQA) is testing new measures such as Serious Hypoglycemic Events Requiring Hospital Admission or ED Visit Associated with Anti-Diabetic Medications.
2. The T1D Exchange Enhanced Registry is currently developing measures that incorporate data from continuous glucose monitoring (CGM) technologies. This program is working to develop standards for data elements that receive data from CGMs.
3. The University of Virginia uses the low blood glucose index and average daily range index as methods for measurement of hypoglycemia risk.
4. Measures related to hypoglycemia were proposed by the Centers for Medicare & Medicaid Services (CMS)

for Meaningful Use Stage 3, including (1) Percentage of patients on sulfonylurea / insulin therapy with out-of-range HbA1c, (2) Alert to potential risk for hypoglycemic events, (3) Shared-decision making for hypoglycemic events, (4) Hypoglycemic event, serious, (5) Hypoglycemia, mild, (6) Recurrent Hypoglycemia, (7) Documentation of etiology of hypoglycemic event, (8) Alert to potential risks for hypoglycemic event.

Efforts to Advocate for Increased Focus on Hypoglycemia:

1. The National Diabetes Clinical Care Commission Act^{xxi} is proposed legislation to establish a commission of DM experts including healthcare professionals, patient advocates, and leaders from federal agencies who are responsible for streamlining federal activities related to DM.
2. The Medicare CGM Access Act^{xxii} is proposed legislation that would expand Medicare beneficiary access to continuous glucose monitors^{xxiii}.

Efforts to Deliver Hypoglycemia Prevention and Management Education:

1. The University of Virginia's Blood Glucose Awareness Training pilot-program has been translated by the Joslin Diabetes Center into a condensed half or full day patient education program on hypoglycemia prevention^{xxiv} that includes training from behaviorists, nurses, dietitians and exercise physiologists.
2. Organizations such as the National Diabetes Education Initiative provide a centralized place to access evidence-based provider^{xxv} and patient education^{xxvi} resources for DM.
3. CMS recently launched the Everyone with Diabetes Counts program^{xxvii} that offers evidence-based self-management training using the Diabetes Self-Management Education curriculum^{xxviii}.
4. The NIDDK's National Diabetes Education Program^{xxix} facilitates the adoption of DM management approaches at federal, state, and local levels for healthcare professionals, patients, and payers.
5. Project Endo Echo^{xxx} is a recently launched collaborative educational program that includes endocrinologists and primary care physicians who conduct case rounds via teleconference.

Efforts to Recognize Hypoglycemia as a Public Health Issue:

1. The Centers for Disease Control and Prevention (CDC) funds the Diabetes Prevention Program^{xxxi} in every state. These programs monitor DM prevalence and implement interventions to increase access to care and identify high risk populations.



2. Prevent Diabetes STAT^{xxxii} is a national effort of the CDC and the American Medical Association to prevent diabetes through surveillance for pre-diabetes.
3. The National Diabetes Education Program^{xxxiii} is a federally funded program that includes over 200 federal, state, and local level partners with the goal of improving treatment of DM.

B. Glossary of Terms

Clinical Data Standards: Data standards are an established set of terms and definitions that support consistent capture and sharing of healthcare data among different healthcare stakeholders and information systems.^{xxxiv}

Current Procedural Terminology (CPT): CPT codes are used by public and private health insurance plans as the consensus nomenclature to document medical procedures and services. The CPT codes are maintained by the American Medical Association.^{xxxv}

Diabetes Self-management Education (DSME): The process of providing patients and caregivers with the knowledge, skill, and techniques for diabetes self-care.^{xxxvi}

International Statistical Classification of Diseases and Related Health Problems (ICD): The ICD is used to code diseases, signs and symptoms, abnormal findings, complaints, social circumstances and external causes of injury or diseases. The ICD is classified by the World Health Organization (WHO). The current iteration is the ICD-10 version.^{xxxvii}

Patient-reported Outcome Measure^{xxxviii}: a measure that aggregates information that has been shared by a patient as a reliable measure of health system performance.

Process Measure^{xxxviii}: A measure for a process of care that is a health care-related activity performed by the patient, caregiver or provider.

Outcome Measure^{xxxviii}: A measure that evaluates the state of health of a patient following health care that is provided.

State Diabetes Action Plan: The Diabetes Action Plans are legislative documents that provide an overview of a state's steps to reduce the prevalence of diabetes in their state. States with a Diabetes Action Plan include: Kentucky, Texas, Illinois, Louisiana, New Jersey, North Carolina, North Dakota, Oregon and Washington.^{xxxix}

Structure Measure^{xxxviii}: A measure of a health care organization or clinician related to the capacity to provide high quality health care.

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