

Actionable Patient Safety Solutions (APSS) #3C: **Severe hypoglycemia**

How to use this guide

This guide gives actions and resources for creating and sustaining safe practices for severe hypoglycemia. In it, you'll find:

Executive summary checklist.....	120
What we know about severe hypoglycemia	121
Leadership plan	122
Action plan	122
Technology plan	124
Conflicts of interest disclosure	125
Workgroup	125
References	126
Appendix A: Summary of Foundational Best Practices (Moghissi et al., 2009)	127
Appendix B: Just Do Its! recommendations (Milligan et al., 2014)	128
Appendix C: Start Now: U-500 regular insulin project	128

APSS #3C: Severe hypoglycemia

Executive summary checklist

Severe hypoglycemia (SH) is defined as having a low blood glucose level of less than 40 mg/dL and is likely to cause harm to the patient in an inpatients setting (Schwartz *et al.*, 2007). SH causes significant morbidity and occasional mortality in hospitalized patients.

Create an action plan

- Get commitment to reduce SH from hospital administration and medical leadership
- Create a multidisciplinary team that includes physicians, pharmacists, nurses, diabetic educators, medication safety officers, case managers, and long-term healthcare professionals
- Create a systematic approach to reduce SH and use universal best practices

Ensure best patient care

- Educate staff, patients, and caregivers about the early warning signs and symptoms of SH
- Create a system to identify patients taking anti-diabetic medications (sulfonylureas, insulins, etc.) in the Electronic Health Record (EHR)
- Create insulin order sets that can be modified to reduce risks of hypoglycemia
- Coordinate glucose monitoring, automate insulin dose calculations, insulin administration, and meal delivery during changes of shift and times of patient transfer from one unit to another

Engage staff and use data to find areas for improvement

- Use real-time surveillance methods, analysis tools, and point-of-care blood glucose (BG) monitoring and reporting systems
- Continuously monitor the incidence of SH in the hospital, long-term care and skilled nursing facility settings
- Use the results of this monitoring in staff education as a part of Continuous Quality Improvement (CQI)
- Raise institutional awareness of issues through a system that compares the healthcare facilities and nursing units based on performance quality scorecards

What we know about severe hypoglycemia

SH can cause cardiac arrhythmias, seizures, brain damage and death (Griffing, 2016). It is a preventable harm, and addressing it can help create a safety culture, which is a culture that promotes patient safety and quality of care while reducing preventable risks and harm.

While hypoglycemia (low blood sugar) is a common problem for many patients with diabetes, it can also occur in non-diabetics in a health care setting. In a 2009 survey of 575 hospitals, 5.7% of all point-of-care BG tests showed hypoglycemia (<70 mg/dL) tests (Swanson et al., 2011).

Causes of hypoglycemia for patients include:

- Too much insulin dose
- Inappropriate timing of insulin or anti-diabetes therapy
- Unaddressed previous hypoglycemia
- Changes in nutritional status and regimen
- Renal and hepatic function changes
- Steroid dose (Deal et al., 2011)
- Failure to monitor BG
- Ineffective communication between physicians, pharmacists, and nurses and other healthcare providers

The diverse nature of potential errors in the treatment of inpatients with SH supports the need for a decision-making model that can be used to predict and prevent SH episodes and improve overall patient safety and outcomes. Research has found that:

- Frequent hypoglycemia is related to increased disease, length of stay, and death, especially in the intensive care units (Elliott, Schafers, McGill and Tobin, 2012)
- Moderate and SH are strongly linked to increased risk of death, especially from distributive shock (NICE-SUGAR Study, 2012) through:
 - Impairment of autonomic function
 - Changes in blood flow and composition
 - White cell activation
 - Vasoconstriction
 - Release of inflammatory mediators and cytokines (Adler et al., 2008; Wright and Frier, 2008)
- Clinicians do not consistently adjust their patient's anti-diabetic regimens after treatment of hypoglycemia (Boucai, Southern, and Zonszein, 2011; DiNardo, Noschese, Korytkowski, and Freeman, 2006)

Preventing SH

Early recognition and management of mild hypoglycemia can prevent SH. For example, adjusting the patient's anti-diabetic regimens after treatment of hypoglycemia, or place the anti-diabetic medication on hold if the patient is not eating.

Leadership plan

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce SH.

To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions.

Show leadership's commitment to preventing SH

- Create a plan to prevent SH that includes the areas of change outlined in the National Quality Forum Safe Practices for Better Healthcare, including awareness, accountability, ability, and action (National Quality Forum, 2010)
- Clinical and safety leadership should endorse the plan and ensure use across all providers and systems
- Hospital governance and senior administrative leadership (medical, pharmacy, and nursing) must fully understand the safety issue in their own healthcare system

Create the infrastructure needed to make changes

- Hospital governance, senior administrative leadership, and clinical/safety leadership must address SH by implementing a comprehensive approach
- Hospitals should set a goal date for the start of the corrective plan, with measurable quality indicators and milestones
- Governance boards and senior administrative leaders should evaluate specific budget allocations for the plan

Engage staff

- Use patient stories - in written and video form - to teach and inspire change in your staff
 - Find The Patient Safety Movement Foundation stories here:
<http://patient.sm/2XvRoX>

Action plan

Ensure accountability

- Create a multidisciplinary team that includes:
 - Physicians
 - Pharmacists
 - Nurses
 - Diabetic educators
 - Medication safety officers
 - Case managers
 - Long-term care professionals

Create protocols and provide staff training

- Create a systematic approach to prevent SH and optimize glycemic management:
 - Identify and prioritize events
 - Raise institutional awareness
 - Compare hospitals and nursing units based on performance quality scorecards

(use harm rate for at-risk patient days: [# of events]/[# of patient days during hospital stay when an anti-diabetic agent is ordered at any time])

- Encourage nurses to enter hypoglycemia into safety event self-reporting site
- Communicate to the hospital leadership board
- Send letters to physicians and providers (from case managers)
- Educate hospital staff, providers, and patients - hospital newsletter and posters made for each hospital/nursing unit listing common risks of hypoglycemia, safer medication alternatives, and solutions to prevent hypoglycemia (e.g., "STOP Hypoglycemia!")
- Conduct a kick-off reception for SH safety initiative
- Perform frequent monitoring of glucose levels in patients who are at risk
- Use foundational Best Practices and "Just Do Its" (**Appendices A and B**)
 - Create a Hypoglycemia Task Force for the hospital
 - Propose multidisciplinary diabetes safety team at each hospital
 - Adopt foundational best practices (literature-based recommendations for all hospitals)
 - Start "Just Do Its!" (or "Start Nows") - these should be safe and reasonable interventions tested internally
 - Adopt ISMP recommendations for U-500 insulin precautions (**Appendix C**)
- Set restrictions for the prescribing of U-500 Regular Insulin to only specialists and under special circumstances in CPOE
- Create a checklist of precipitating and contributory factors that could lead to hypoglycemia and SH
- Develop a protocol that provides proactive carbohydrates by a standardized process (e.g., IV dextrose), with scheduled reassessment of BG and nurse-driven adjustments to prevent recurrent hypoglycemia (Griffing, 2016)

Track and analyze your progress

- Investigate SH events and collect causative factors to consider as part of the analysis tool, such as:
 - Insulin stacking
 - Wrong drug, dose, route, patient, or time of administration
 - Insufficient glucose monitoring
 - Basal or long-acting insulin regimen
 - Decreased nutritional intake
 - Event related to outpatient or emergency department medicine administration
 - Event while treating elevated potassium level
 - Glucose trend not recognized
 - High dose sliding scale insulin
 - Home regimen continued during hospitalization
 - Much lower steroid dose
 - Sulfonylurea-related hypoglycemia
 - Insulin administration and food intake not in sync

- o Point-of-care BG reading not linked to insulin administration
- o Point-of-care BG reading not in sync with food intake
- A pharmacist and/or nurse reviews analysis tool forms in a timely manner (e.g., at least within 72 hours) for causative factors and communicates findings with physicians
- Collate and report results to Medication Safety Committee and the Pharmacy and Therapeutics Committee
- Identify the interventions (evidence-based and expert opinion) that are used to resolve the most common or most harmful causative factors
- Track the interventions and create customized action plans based on the results

Report outcomes inside your organization and share best practices outside your organization

- Share best practices within hospital and to other hospitals and healthcare facilities
- Share strategies and use informed interventions on targeted floors and at-risk patients

Technology plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider:

<https://patientsafetymovement.org/actionable-solutions/apss-workgroups/technology-vetting/>

System or practice	Available technology
<p>ONC Meaningful Use Certified Electronic Health Record (EHR) System with the following capabilities:</p> <ul style="list-style-type: none"> • Computerized Provider Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Clinical Decision Support (CDS) tools • Restriction settings for the prescribing of U-500 Regular Insulin to only specialists and under special circumstances in CPOE 	
<p>Glycemic management CDS for insulin therapy recommendations, based on individual responses to insulin and designed for mitigation of all types of hypoglycemia</p>	<ul style="list-style-type: none"> • Includes all of the following bullet points with significant additional safety features
<p>Real-time surveillance method for informatics alerts and triggers for initiation of hypoglycemia prevention protocol</p>	<ul style="list-style-type: none"> • “High-Risk Sulfonylurea Alert” • “Hypoglycemia Risk Alert”

An automated hypoglycemia event analysis tool (to discover local causes of hypoglycemia and guide future interventions)	
Point-of-care BG monitoring and reporting systems	<ul style="list-style-type: none"> • Quality assurance reports to audit compliance with hypoglycemia • management goals and restriction of insulin use
Automated triggers for most common precipitating or contributory factors of hypoglycemia; and an electronic tracking system for SH events, interventions used, and clinical outcomes	
A results dashboard for each nursing unit within the hospital and Best Practices used to resolve the hypoglycemic event(s)	
FDA approved glycemic management CDS for insulin therapy recommendation, based on individual patient's response to insulin and designed for relief of all types of hypoglycemia	
CPOE simulation tool to quantify the risk of serious ADEs with your current system CPOE	
Drug libraries in EHR systems	<ul style="list-style-type: none"> • Injectables, or comparable systems
Pharmacy Workflow Manager	

Measuring outcomes

Topic 1 - Glycemic control of severe hypoglycemia Rate of SH events (<40 mg/dL) within 12 hours of administration of insulin, or within 24 hours of administration of an anti-diabetic medication other than insulin, and no subsequent glucose value >80 mg/dL within five minutes of the low glucose event.

Outcome Measure Formula:

Harm rate for at-risk patient days: (# of events) / (# of patient days during hospital stay when an anti-diabetic medication is ordered at any time)

Numerator: Number of reported adverse drug events with harm, (as defined above) - (by class or medication)

Denominator: Number of doses administered (by medication or class of medication)

Metric recommendations

Indirect Impact (preventable rate): All patients

Direct Impact (non-preventable rate): All patients prescribed medications that could cause hypoglycemia

Lives Spared Harm:

Lives Spared Harm = (ADE Rate *baseline* - ADE Rate *measurement*) X (Doses or Adjusted Patient Days at *baseline*)

Lives Saved:

Lives Saved = (Lives Spared Harm) x (Mortality Rate)

Notes:

Top medication classes and triggers:

1. Insulins
2. Sulfonylureas
3. Fluoroquinolones
4. Beta blockers
5. Inappropriate timing of insulin or anti-diabetes therapy
6. Unaddressed previous hypoglycemia
7. Changes in nutritional status and regimen
8. Renal and hepatic functionCreatinine clearance changes
9. Steroid dose (Deal et al., 2011)
10. Failure to monitor BG

Failure to monitor BGDData Collection

SH reporting information is based on volunteer reporting and accuracy of people verifying reports, (preferably from pharmacy and thea medication errors reporting and prevention (MERP) program, MERP).

Anti-diabetic medication usage information is usually collected from billing information rather than medication orders (more accurate if patient received the dose or not).

Conflicts of interest disclosure

The Patient Safety Movement Foundation partners with as many stakeholders as possible to focus on how to address patient safety challenges. The recommendations in the APSS are developed by workgroups that may include patient safety experts, healthcare technology professionals, hospital leaders, patient advocates, and medical technology industry volunteers. Some of the APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Co-Chairs:

Ron Jordan

Chapman University School of Pharmacy

Jerika Lam

Chapman University School of Pharmacy

Christopher Jerry

The Emily Jerry Foundation

Members:

This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Hania Alim	Patient Safety Movement Foundation
Peter Antevy	Handtevy
Steven Barker	Masimo; Patient Safety Movement Foundation
*Linda Benezé	Monarch Medical Technologies
Michel Bennett	Patient Safety Movement Foundation (formerly)
Laressa Bethishou	Chapman University School of Pharmacy
Jim Broselow	eBroselow
John Burnam	Louise H. Batz Patient Safety Foundation
Mitchell Goldstein	Loma Linda Medical Center
Kari Hamlin	Hackensack Medical Center
Helen Haskell	Mothers Against Medical Error
Soojin Jun	Quorum Health
Edwin Loftin	Parrish Medical Center
Ariana Longley	Patient Safety Movement Foundation
Jacob Lopez	Patient Safety Movement Foundation (formerly)
Olivia Lounsbury	Patient Safety Movement Foundation
Anne Lyren	Children's Hospitals' Solutions for Patient Safety
Brendan Miney	Talis Clinical
Sidney Morice	Lee Health
Lisa Morrise	Consumers Advancing Patient Safety
Steve Mullenix	National Council for Prescription Drug Programs
*Flannery Nangle	Monarch Medical Technologies
Robert Nickell	Enovachem
Donna Prosser	Patient Safety Movement Foundation
Talia Puzantian	Keck Graduate Institute
Judith Reiss	Advocate
Claire Roy	Patient Safety Movement Foundation
Rochelle Sandell	Patient Advocate
Enrique Seoane-Vasquez	Chapman University School of Pharmacy
Alex Shaffer	Advocate
David Shane Lowry	Rosalind Franklin University of Medicine and Science
Robin Shannon	The T System
Deeba Siddiqui	Hackensack Medical Center
Charles Simmons	Cedars-Sinai Medical Center
Nat Sims	Massachusetts General Hospital

Robert Stein	Keck Graduate Institute
Laura Townsend	Louise H. Batz Patient Safety Foundation
Kimberly Won	Chapman University School of Pharmacy
Jason Yamaki	Chapman University School of Pharmacy
Sun Yang	Chapman University School of Pharmacy

Metrics Integrity:

Robin Betts Kaiser Permanente, Northern California Region

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

References

- Adler, G. K., Bonyhay, I., Failing, H., Waring, E., Dotson, S. and Freeman, R. (2008). Antecedent Hypoglycemia Impairs Autonomic Cardiovascular Function: Implications for Rigorous Glycemic Control. *Diabetes*, 58(2), 360-366. doi:10.2337/db08-1153
- Boucai, L., Southern, W. N. and Zonszein, J. (2011). Hypoglycemia-associated Mortality Is Not Drug-associated but Linked to Comorbidities. *The American Journal of Medicine*, 124(11), 1028-1035. doi:10.1016/j.amjmed.2011.07.011
- Deal, E. N., Liu, A., Wise, L. L., Honick, K. A. and Tobin, G. S. (2011). Inpatient Insulin Orders: Are Patients Getting What is Prescribed?. *Journal of Hospital Medicine*, 6(9), 526-529. doi:10.1002/jhm.938
- DiNardo, M., Noschese, M., Korytkowski, M. and Freeman, S. (2006). The Medical Emergency Team and Rapid Response System: Finding Treating, and Preventing Hypoglycemia. *The Joint Commission Journal on Quality and Patient Safety*, 32(10), 591-595. doi:10.1016/s1553-7250(06)32077-6
- Elliott, M. B., Schafers, S. J., McGill, J. B. and Tobin, G. S. (2012). Prediction and Prevention of Treatment-Related Inpatient Hypoglycemia. *Journal of Diabetes Science and Technology*, 6(2), 302-309. doi:10.1177/193229681200600213
- Griffing, K.L. (2016). Hypoglycemia Prevention in Hospital Patients: A Quality Improvement Project to Prevent Severe and Recurrent Hypoglycemia. *Clinical Diabetes*, 34(4), 193-199. doi:10.2337/cd15-0055
- Milligan, P. E., Blackburn, M. C., Dachroeden, R. R. (2014). Multi-faceted Improvement Initiative to Detect and Improve Prevention of Severe Hypoglycemia. Retrieved from: <http://www.ashp.org/DocLibrary/Abstract-Archive/SM14-Session-Abstracts.pdf>
- Moghissi, E. S., Korytkowski, M. T., DiNardo, M., Einhorn, D., Hellman, R., Hirsch, I. B., ... & Umpierrez, G. E. (2009). American Association of Clinical Endocrinologists and American Diabetes Association Consensus Statement on Inpatient Glycemic Control. *Diabetes Care*, 32(6), 1119-1131.
- National Quality Forum Forum, N. Q. (2010). Safe Practices for Better Healthcare-2010 update. Retrieved from [http:// patient.sm/nqm-safe-practices](http://patient.sm/nqm-safe-practices)
- NICE-SUGAR Study Investigators. (2012). Hypoglycemia and risk of death in critically ill patients. *New England Journal of Medicine*, 367(12), 1108-1118. doi: 10.1056/NEJMoa1204942
- Schwartz, A. V., Vittinghoff, E., Sellmeyer, D. E., Feingold, K. R., Rekeneire, N. D., Strotmeyer, E. S., ... Harris, T. B. (2007). Diabetes-Related Complications, Glycemic Control, and Falls in Older

Swanson, C., Potter, D., Kongable, G. and Cook, C. (2011). Update on Inpatient Glycemic Control in Hospitals in the United States. *Endocrine Practice*, 17(6), 853–861. doi:10.4158/ep11042.or

Wright, R. J. and Frier, B. M. (2008). Vascular Disease and Diabetes: Is Hypoglycaemia an Aggravating Factor?. *Diabetes/Metabolism Research and Reviews*, 24(5), 353–363. doi:10.1002/dmrr.865

Appendix A: Summary of Foundational Best Practices (Moghissi et al., 2009)

Intervention	Rationale
Raise awareness of hypoglycemia	Initiatives to raise awareness on preventable harm have improved patient care
Real time analysis (48 hours)	<ul style="list-style-type: none"> Pharmacy surveillance system provides information of when and where these events occur, but not why they occur Many hospitals have lowered harm rate using real time analysis
Create and use diabetes management team	AACE/ADA (American Association of Clinical Endocrinologists/American Diabetes Association) noted that a multidisciplinary steering committee of local diabetic experts can create reasonable and achievable glycemic management goals
Provide prescriber with tools to use as a dosing guide	<ul style="list-style-type: none"> AACE/ADA suggests a systems approach for management of inpatient glycemic control Can create reasonable and achievable glycemic management goals
Nursing education process	<ul style="list-style-type: none"> AACE/ADA noted a lack of ownership in diabetes care due to insufficient knowledge or confidence in diabetes management Ongoing education and training can improve care

Insulin dose timing coincide with food intake	<ul style="list-style-type: none"> • AACE/ADA noted many hospitals don't coordinate meal delivery and prandial insulin administration • A systems approach can promote the coordination of glucose monitoring, insulin administration, and meal delivery, particularly during change of shifts and times of patient transfer
Improve point-of-care BG testing glucose testing with the insulin administration time	<ul style="list-style-type: none"> • AACE/ADA stated that bedside BG monitoring with use of POC glucose meters should be performed before meals and at bedtime in most in-patients who are eating usual meals • Avoids routine use of correction insulin at bedtime
Use glucose management software	<ul style="list-style-type: none"> • Reduces hypoglycemic events

Appendix B: Just Do Its! recommendations (Milligan et al., 2014)

Just Do It!	Modify insulin order set to hold insulin only with physician order
	Modify insulin order set to match pending electronic order set to reduce doses of bedtime sliding scale (30% reduction)
	Modify insulin order set to avoid routine correction insulin at specific times (e.g., 0200 and 0400)
	Modify insulin order set to match pending electronic order set to state: Notify physician when hypoglycemic event occurs (2 levels <70 mg/dL or 1 level <50 mg/dL, or >300 mg/dL)
	Add Pharmacist and Endocrinologist on diabetes management team

Appendix C: Start Now: U-500 regular insulin project

Scope

Create guidelines for injectable U-500 insulin to reduce ADE preventable harm. U-500 insulin is an uncommon concentration, which can cause serious harm if given with syringes designed for U-100 insulin.

Preventable Harm

Risk potential and risk severity are both high

Resources

Pharmacist(s) and nurse(s)

Goals:

- Create standard “High Alert” or “High Hazard Medication” or restrictions for U-500 insulin at all hospitals to prevent improper dosing and harm related to hypoglycemia
- Create policy that will safeguard or restrict the use of U-500 to specialists and special circumstances

Risks and barriers

- Hospitals that do not have the medication on their formulary have not addressed patients who may use it from home
- Hospitals feel that the medication not on their formulary will protect them from ADEs - but non-formulary medications do not equal to no-risk of ADE