

2017

Actionable Patient Safety Solution (APSS) #3C: Improve Prevention of Severe Hypoglycemia

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Recommended Citation

Lam JT, Barker S, Ramsay M, et al. Actionable Patient Safety Solution (APSS) #3C: Improve Prevention of Severe Hypoglycemia. Patient Safety Movement Foundation. January 2017 (http://patientsafetymovement.org/wp-content/uploads/2016/02/APSS-3C_-_Improving-the-Prevention-of-Severe-Hypoglycemia.pdf).

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Comments

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**Actionable Patient Safety Solution (APSS) #3C:
IMPROVE PREVENTION OF SEVERE HYPOGLYCEMIA**

Executive Summary Checklist

Severe hypoglycemia (SH) causes significant morbidity and occasional mortality in hospitalized patients. The establishment of an effective program to reduce errors in the recognition and treatment of SH requires an implementation plan that includes the following actionable steps:

- Establish a commitment from hospital administration and medical leadership to reduce SH.
- Raise institutional awareness of the issue by comparing hospital and nursing units based on performance quality scorecards.
- Create a multidisciplinary team that includes physicians, pharmacists, nurses, diabetic educators, medication safety officers, case managers, and long-term healthcare professionals. This team will:
 - Develop a system to identify patients receiving anti-diabetic medications (sulfonylureas, insulins, etc.) in the Electronic Health Record (EHR).
 - Implement real-time surveillance methods, analysis tools, and point-of-care blood glucose (BG) monitoring and reporting systems.
 - Create insulin order sets that could 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.
 - Develop a systematic approach to reduce SH and implement universal best practices.
- Continuously monitor the incidence of SH in the hospital, and use the results of this monitoring in medical staff education sessions as a part of Continuous Quality Improvement (CQI).

The Performance Gap

Hypoglycemia is a common problem for many patients with diabetes, and it can also occur in non-diabetics in a hospital setting. Mild episodes can cause unpleasant symptoms and disrupt daily activities. Severe hypoglycemia (SH) can result in disorientation and unusual behavior, and may be life-threatening. Frequent hypoglycemia is associated with increased morbidity, length of stay, and mortality. Hypoglycemia has been associated with mortality in the intensive care units.¹ Moderate and SH are strongly associated with increased risk of death, especially from distributive shock.² This is by means of impairment of autonomic function, alteration of blood flow and composition, white cell activation, vasoconstriction, and the release of inflammatory mediators and cytokines.^{3,4} The prevalence of hypoglycemia (serum glucose <70 mg/dL) was reported as 5.7% of all point-of-care blood glucose (BG) tests in a 2009 survey of 575 hospitals.⁵ The definition of SH (a low BG level that requires the assistance of another person for recovery), is a level <40 mg/dL, has been adopted as the level likely to cause harm in the hospital setting.⁶ SH is a preventable harm. Early therapeutic management of mild hypoglycemia can prevent more SH episodes. In addition, literature showed that clinicians do not consistently adjust their patient's anti-diabetic regimens appropriately following treatment of hypoglycemia, placing the patient at additional risk.^{7,8}

Causative factors that may lead to the development of hypoglycemia for inpatients may include excessive insulin dose, inappropriate timing of insulin or anti-diabetes therapy, unaddressed antecedent hypoglycemia or changes in the nutritional regimen, creatinine clearance changes, or steroid dose (9).⁹ Failure of effective BG monitoring and communication between physicians, pharmacists and nurses can also contribute to the problem. 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.

Closing the performance gap will require hospitals and healthcare systems to commit to action in the form of specific leadership, practice, and technology plans.

¹ Elliott, M. B., Schafers, S. J., McGill, J. B., & Tobin, G. S. (2012). Prediction and prevention of treatment-related inpatient hypoglycemia. *Journal of Diabetes Science and Technology*, 6(2), 302-309.

² NICE-Sugar Study Investigators. (2012). Hypoglycemia and risk of death in critically ill patients. *New England Journal of Medicine*, 2012(367), 1108-1118.

³ Adler, G. K., Bonyhay, I., Failing, H., Waring, E., Dotson, S., & Freeman, R. (2009). Antecedent hypoglycemia impairs autonomic cardiovascular function implications for rigorous glycemic control. *Diabetes*, 58(2), 360-366.

⁴ Wright, R. J., & Frier, B. M. (2008). Vascular disease and diabetes: is hypoglycaemia an aggravating factor?. *Diabetes/Metabolism Research and Reviews*, 24(5), 353-363

⁵ Swanson, C., Potter, D., Kongable, G., & Cook, C. (2011). Update on inpatient glycemic control in hospitals in the United States. *Endocrine Practice*.

⁶ Schwartz, A. V., Vittinghoff, E., Sellmeyer, D. E., Feingold, K. R., De Rekeneire, N., Strotmeyer, E. S., ... & Faulkner, K. A. (2008). Diabetes-related complications, glycemic control, and falls in older adults. *Diabetes Care*, 31(3), 391-396.

⁷ Boucai, L., Southern, W. N., & Zonszein, J. (2011). Hypoglycemia-associated mortality is not drug-associated but linked to comorbidities. *The American Journal of Medicine*, 124(11), 1028-1035.

⁸ DiNardo, M., Noschese, M., Korytkowski, M., & Freeman, S. (2006). The medical emergency team and rapid response system: Finding, treating, and preventing hypoglycemia. *Joint Commission Journal on Quality and Patient Safety/Joint Commission Resources*, 32(10), 591.

⁹ Deal, E. N., Liu, A., Wise, L. L., Honick, K. A., & Tobin, G. S. (2011). Inpatient insulin orders: Are patients getting what is prescribed?. *Journal of Hospital Medicine*, 6(9), 526-529.

Leadership Plan

- The plan must include the fundamentals of change outlined in the National Quality Forum safe practices, including awareness, accountability, ability, and action.¹⁰
- Hospital governance and senior administrative leadership (medical, pharmacy, and nursing) must fully understand the performance gaps in their own healthcare system.
- Hospital governance, senior administrative leadership, and clinical/safety leadership must close their own performance gaps by implementing a comprehensive approach.
- Hospitals should set a goal date for the implementation of the corrective plan, with measurable quality indicators and milestones.
- Specific budget allocations for the plan should be evaluated by governance boards and senior administrative leaders.
- Clinical/safety leadership should endorse the plan and ensure implementation across all providers and systems.

Practice Plan

- Each hospital should create a multidisciplinary team, which includes physicians, pharmacists, nurses, diabetic educators, medication safety officers, case managers, and long-term healthcare professionals).
- Develop a systematic approach to reducing severe hypoglycemia:
 - Identify events and prioritize
 - 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 a 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 known and assumed solutions to hypoglycemia (e.g., “STOP Hypoglycemia!”)
 - Kickoff reception for safety initiative
 - Frequent monitoring of glucose levels in patients who are at risk.
- Implement foundational Best Practices and “Just Do Its” (**Appendices A and B**)
 - Establish 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)
 - Implement “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**)
- Event investigation and collect causative factors
 - Causative Factors (to consider as part of analysis tool):
 - Insulin stacking
 - Wrong drug, dose, route, patient, or time
 - Insufficient glucose monitoring
 - Basal heavy regimen
 - Decreased nutritional intake
 - Event related to outpatient or emergency department drug administration
 - Event while treating elevated potassium
 - Glucose trend not recognized
 - High dose sliding scale insulin

¹⁰ National Quality Forum. (2010). Safe practices for better healthcare–2010 update. Retrieved from: http://www.qualityforum.org/publications/2010/04/safe_practices_for_better_healthcare_%E2%80%932010_update.aspx

- Home regimen continued as inpatient
 - Significant reduction in steroid dose
 - Sulfonylurea-related hypoglycemia
 - Insulin administration and food intake not synchronized
 - POC glucose reading not linked to insulin administration
 - POC glucose reading not synchronized with food intake
 - Analysis tool forms reviewed by either pharmacist and/or nurse in a timely manner (e.g., 72 hours) for causative factors; communicate findings with physician(s)
 - Results are collated and reported to Medication Safety Committee and the Pharmacy and Therapeutics Committee
 - Identify 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 an integrated results dashboard
 - Share best practices within hospital and to other hospitals
- Share strategies and implement informed interventions on target floors and patients.

Technology Plan

Suggested practices and technologies are limited to those proven to show benefit or are the only known technologies with a particular capability. As other options may exist, please send information on any additional technologies, along with appropriate evidence, to info@patientsafetymovement.org.

- Implement glycemic management clinical decision support for insulin therapy recommendation, based on individual responses to insulin and designed for mitigation of all types of hypoglycemia.
 - This would include all of the following bullet points with significant additional safety features.
- Implement real-time surveillance method for informatics alerts: “High-Risk Sulfonylurea Alert” and “Hypoglycemia Risk Alert”.
- Implement an automated hypoglycemia event analysis tool (to discover local causes of hypoglycemia and guide future interventions).
- Implement point-of-care BG monitoring and reporting systems, including quality assurance reports to audit compliance with hypoglycemia management goals and restriction of insulin utilization.
- Implement automated triggers for most common causative factors of hypoglycemia, an electronic tracking system for SH events, interventions used and clinical outcomes.
- Implement a results dashboard for each nursing unit within the hospital and Best Practices used to resolve the hypoglycemic event(s).
- Set restrictions for the prescribing of U-500 Regular Insulin to only specialists and under special circumstances in CPOE.

System or Practice	Available Technology
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: <ul style="list-style-type: none"> ● Computerized Physician Order Entry (CPOE) ● Drug-drug interaction check 	<i>The following EHR vendors have signed the Patient Safety Movement Open Data Pledge:¹¹</i> <ul style="list-style-type: none"> ● Cerner ● GE Healthcare

¹¹ Patient Safety Movement Foundation. Healthcare Technology Pledges. Retrieved from: <http://patientsafetymovement.org/challenges-solutions/commitments-pledges/healthcare-technology-pledges/>



Patient Safety

MOVEMENT

zero preventable deaths by 2020

<ul style="list-style-type: none"> • Drug-allergy interaction check • Clinical Decision Support tools (CDS) 	
FDA approved glycemic management clinical decision support for insulin therapy recommendation, based on individual patient's response to insulin and designed for mitigation of all types of hypoglycemia.	<ul style="list-style-type: none"> • Monarch Medical Technologies Endotool® Solutions
CPOE simulation tool to quantify the risk of serious ADEs with your current system CPOE ^{12,13}	<ul style="list-style-type: none"> • Leapfrog CPOE Evaluation Tool¹⁴
Drug Libraries	<ul style="list-style-type: none"> • Alaris® • Baxter® • Hospira® • Fresenius® • B.Braun® I.V. pumps • BD Intelliport™ Medication Management System for I.V. injectables, or • comparable systems.
Pharmacy Workflow Manager	<ul style="list-style-type: none"> • DoseEdge® from Baxter Healthcare®

¹² Leung, A. A., Keohane, C., Lipsitz, S., Zimlichman, E., Amato, M., Simon, S. R., ... & Seger, D. L. (2013). Relationship between medication event rates and the Leapfrog computerized physician order entry evaluation tool. *Journal of the American Medical Informatics Association*, 20(e1), e85-e90.

¹³ Metzger, J., Welebob, E., Bates, D. W., Lipsitz, S., & Classen, D. C. (2010). Mixed results in the safety performance of computerized physician order entry. *Health Affairs*, 29(4), 655-663.

¹⁴ The Leapfrog Group. (2016). CPOE evaluation tool. Retrieved from: http://www.leapfroggroup.org/sites/default/files/Files/CPOE_Instructions_20160624_1.pdf



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Revision History

Version	Primary Author(s)	Description of Version	Date Completed
Version 1	Jerika Lam, Ron Jordan	Initial Release	January 2016
Version 2	Steven Barker, Michael Ramsay, Joe Kiani, Jim Bialick, Ariana Longley	Executive Review	April 2016
Version 3	Jerika Lam, Steven Barker, Michael Ramsay, Ariana Longley, Joe Kiani	Workgroup and Executive Review	January 2017

Appendix A: Summary of Foundational Best Practices¹⁵

Intervention	Rationale
Elevate awareness of hypoglycemia	Best in class and individual hospital initiatives to elevate awareness on preventable harm have improved patient care.
Real time analysis (48 hours)	Pharmacy surveillance system provides information of when and where these events occur, but not why they occur. Many hospitals have had success lowering harm rate using this intervention.
Create and utilize diabetes management team	AACE/ADA (American Association of Clinical Endocrinologists/American Diabetes Association) noted creation of a multidisciplinary steering committee guided by local diabetic experts can establish 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 establish reasonable and achievable glycemic management goals with use of protocols and order sets.
Nursing education process	<ul style="list-style-type: none"> • AACE/ADA noted a lack of ownership in diabetes care may be due in part to insufficient knowledge or confidence in diabetes management. • Improvements in care can be achieved by ongoing education and training.
Insulin dose timing coincide with food intake	<ul style="list-style-type: none"> • AACE/ADA noted many hospitals are challenged by poor coordination of 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 POC 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 inpatients who are eating usual meals. • Important to avoid routine use of correction insulin at bedtime.
Utilize glucose management software	Collective evidence showed a reduction in hypoglycemic events through the use of glucose software management

¹⁵ 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.

Appendix B: Just Do Its! Recommendations¹⁶

Just Do It!	Modify insulin order set to hold insulin only with MD 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 MD 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 Project¹⁶

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

Preventable Harm: Risk potential and risk severity are both high

Resources: Pharmacist(s) and nurse(s)

Deliverable Goals:

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

Risks/Barriers:

- Hospitals that do not have the drug on formulary have not addressed patients using drug from home;
- Hospitals feel drug not on formulary will protect them from ADEs (Non-formulary does not equal no-risk of ADE)

¹⁶ 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>