Reduction of Insulin Related Preventable Severe Hypoglycemic Events in Hospitalized Children

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OBJECTIVE: Insulin is a commonly used, high-risk medication in the inpatient setting. Incorrect insulin administration can lead to preventable hypoglycemic events, which are a significant morbidity in inpatient diabetes care. The goal of this intervention was to decrease preventable insulin-related hypoglycemic events in an inpatient setting in a tertiary care pediatric hospital.

METHODS: Methods included the institution of several interventions such as nursing and physician education, electronic medical record order sets, electronic communication note templates, and the development of new care guidelines.

RESULTS: After the institution of multiple interventions, the rate of preventable hypoglycemic events decreased from 1.4 preventable events per 100 insulin days to 0.4 preventable events per 100 insulin days.

CONCLUSIONS: Through the use of a multi-interventional approach with oversight of a multidisciplinary insulin safety committee, a sustained decreased rate of severe preventable hypoglycemic events in hospitalized pediatric patients receiving insulin was achieved.

Insulin therapy is used in the hospital setting to treat multiple conditions including diabetes, diabetic ketoacidosis (DKA), critical illness, and medication-induced hyperglycemia.^{1,2} Although the use of insulin is a necessary therapy in patients with these conditions,^{3,4} it is a high-risk medication and is frequently identified in medication errors in the inpatient hospital setting.^{5,6} Hypoglycemia is a common complication of insulin therapy, and if not recognized and treated appropriately, it can lead to adverse consequences: altered mental status, seizures, coma, and death. Inpatient hypoglycemia related to insulin therapy has been associated with an

increased risk of inpatient mortality and increased length of hospital stay in both pediatric and adult studies.^{7–10} Long-term sequelae of hypoglycemic events have been more difficult to analyze. Several clinical studies have shown that severe episodes of hypoglycemia in young children can cause deterioration in neurocognitive functions.^{11–13} A recent study identified a large number of hypoglycemic events in children hospitalized for diabetes management and critical illness and called for increased staff education to prevent these adverse events.¹⁴

In 2008, Children's Hospital Colorado (CHCO) joined 12 other pediatric hospitals in a collaborative effort

abstract

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Dr Poppy conceptualized and designed the study, designed the data collection instruments, collected data, carried out the initial analyses, drafted the initial manuscript, and revised the manuscript; Ms Retamal-Munoz and Drs Wood and Majidi contributed to the initial manuscript, participated in data collection and analysis of the data, and reviewed the manuscript; Drs Cree-Green and Davis contributed to the initial manuscript, participated in data collection and analysis of the data and critically reviewed the manuscript; Dr Clements contributed to the initial manuscript, participated in analysis of the data, and critically reviewed the manuscript; Drs Steck and Alonso participated in analysis of the data and critically reviewed the manuscript; Dr Chambers participated in data collection and analysis of the data and reviewed the manuscript; Dr Rewers participated in analysis of the data and critically reviewed the manuscript; and all authors approved the final manuscript as submitted.

DOI: 10.1542/peds.2015-1404

Accepted for publication Feb 19, 2016

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

To cite: Poppy A, Retamal-Munoz C, Cree-Green M, et al. Reduction of Insulin Related Preventable Severe Hypoglycemic Events in Hospitalized Children. *Pediatrics*. 2016;138(1):e20151404

to reduce adverse drug events focused on 4 high-risk medications, including insulin.¹⁵ CHCO created an insulin safety task force to address the insulin component of the collaborative. This performance-improvement collaborative was a 12-month effort, and at the end, none of the participating hospitals reported improvement in insulin-related adverse events.¹⁵ The efforts of the insulin safety task force at CHCO continued, and in 2011 a top-level organizational goal to reduce preventable severe hypoglycemic events was adopted. The insulin safety task force became the Insulin Safety Committee (ISC) and was formalized as part of the hospital's medication safety program.

The aim of this quality improvement (QI) effort by the newly formed ISC was to decrease the rate of preventable severe hypoglycemic events (defined as blood glucose less than 50 mg/dL^{16,17}) among patients receiving insulin in the hospital and emergency department by 10% in the first year with a 5-year goal of eliminating these events. Here we describe the efforts of our ISC to improve the safety of insulin treatment through a multi-interventional approach. This project was reviewed and approved by the Colorado Multi-Institutional Review Board.

METHODS

Setting

CHCO is a tertiary care teaching hospital with several satellite locations throughout the state of Colorado. Pediatric endocrinologists at the Barbara Davis Center for Childhood Diabetes provide diabetes consultations at CHCO. CHCO has a fully implemented, integrated electronic medical record (EMR). All insulin orders are placed, documentation completed, and laboratory values resulted in the EMR. Patients receive insulin by

subcutaneous injection, continuous subcutaneous insulin infusion, or by intravenous (IV) continuous infusion and may be admitted to 1 of many hospital services, including general medical, surgical, emergency, rehabilitation, oncology, psychiatry, and intensive care. Therefore, our efforts to reduce preventable hypoglycemic events were hospital-wide.

Project Design

The ISC is a multidisciplinary committee composed of physicians, nurses, pharmacists, and patient safety improvement staff. The committee meets monthly and reviews the data for severe hypoglycemic events to coordinate current projects and develop new initiatives for preventing severe hypoglycemic events.

Patients receiving insulin who had a blood glucose value <50 mg/dL were identified through a monthly trigger report from the EMR. Adapting the evaluation of triggers for adverse events from the Institute for Healthcare Improvement Global Trigger Tool methodology, the Medication Safety Specialist (MSS) evaluated the events in the report through retrospective chart review for preventability and the members of the ISC provided a second review and authentication of each event determined by the MSS to be preventable.¹⁷ Information evaluated includes blood glucose values before the hypoglycemic event, nutrition and fluid intake before and at the time of the event, orders for insulin and hypoglycemic treatment, insulin administrations before the event, provider and nursing notes, and patient symptoms and treatment administered in response to the hypoglycemic event. A hypoglycemic event was determined to be preventable if an error in insulin dosing or administration was made, a trend in decreasing blood glucose values was

not addressed by the clinical team, guideline-consistent treatment of less severe hypoglycemia was not provided resulting in subsequent severe hypoglycemia, or there was any other deviation from policies, procedures, guidelines, and protocols directing glycemia and insulin management at CHCO. Input from the endocrinologists consulting on the patient was also used to determine preventability. An event was determined to be a false-positive if the patient was not on insulin at the time of the event or if a repeat blood glucose value within 10 minutes, without intervention, was >50 mg/dL.

Members of the ISC further evaluated preventable events to determine contributing factors using apparent cause analysis. The most common contributing factors identified were communication failures, unclear policy, procedures, and guidelines for the management of patients receiving insulin, and gaps in knowledge of insulin and diabetes management.

Using informal plan-do-study-act cycles, interventions were developed by the ISC that include improving communication of insulin therapy through endocrinology consultation for patients receiving insulin; structured consultation notes, insulin order sets; development and refinement of policies, procedures, and guidelines; and education to improve knowledge for physicians, nurses, and pharmacists.

Interventions

Through apparent cause analysis the ISC identified 3 communication weaknesses as contributing factors in the development of severe hypoglycemia: verbal communication, unclear insulin orders, and lack of consistent endocrinology consultation. Before 2011, the endocrinology team was consulted by the primary team when questions arose regarding diabetes management or at time

A : DKA treatment recommendations

Recommendations:

1. Initial IV fluids: 3/4 NS + 20 K mEq/L K-Acetate + 20 mEq/L K-Phos at *** maintenance.
2. Insulin should be run at an infusion rate of 0.1 units/kg/hr.
3. Check blood glucose (BG) Q1 hour while on insulin drip. Check venous blood gas (VBG) and basic metabolic panel (BMP) Q2 hours, then can space to Q4 as patient stabilizes. Check Magnesium and Phosphorus at baseline, then in 6 or 8 hours. For new onset diabetics, please also draw TSH, total T4, and Hemoglobin A1C.
4. When BG is below 250 mg/dL change rehydration fluids to include dextrose.
5. Aim for target BG of 100-200 mg/dL; if BG drops below 100 mg/dL increase dextrose in fluids rather than decreasing insulin infusion rate. If more than 12.5% dextrose is required, reduce insulin infusion rate by 0.01 units/kg/hour to a minimum rate of 0.05 units/kg/hr until BG is greater than 100 mg/dL.
6. If BG falls below 70 mg/dL, stop insulin infusion, give 5 ml/kg bolus of 10% dextrose (max 150 ml) and recheck BG in 10 minutes. When BG is above 100 mg/dL, restart the insulin infusion at a lower rate.
7. Hypokalemia may complicate the treatment of DKA due to intracellular potassium shifts and total body potassium depletion.
8. (Patient name)'s age and degree of acidosis place her/him at significant risk for cerebral edema. Monitoring for this complication should consist of frequent neurological checks. Should there be any concern for cerebral edema such as changing mental status or bradycardia, please discuss with BDC immediately for consideration of treatment with mannitol.
9. When pH is greater than 7.30, serum bicarbonate is above 18 mmol/L, and (s)he is awake and ready to eat, a plan can be made to transition to subcutaneous insulin. Please call the BDC physician for advice and timing of the first dose.
10. Call BDC physician with any concerns (pager number).

B : Transition for IV insulin to Subcutaneous insulin recommendations

Assessment:

(Patient Name) is a (patient age) year old (patient gender) with (type 1/type2) diabetes, who has been receiving insulin drip therapy for (mild/moderate/severe) diabetic ketoacidosis. (S)he is now metabolically corrected, awake, alert, hungry, and ready to transition to subcutaneous insulin.

Recommendations:

1. Write all orders using the insulin order set (be sure hypoglycemia orders appear on the medication administration record (MAR)).
2. Have patient order a meal from the carb counting diet.
3. Give insulin glargine (Lantus) *** units now.
4. When food arrives, stop IV insulin drip, stop IV dextrose drip, and check blood glucose (BG).
5. (20 min before/20 min after) starting to eat:
 - Give lispro (Humalog) 1 unit for every *** grams of carbohydrates
 - Give lispro (Humalog) 1 unit for every *** mg/dl that BG is over *** mg/dl (this means at BG ***-*** mg/dL give 1 unit, ***-*** give 2 units, etc., until BG>400- then call house officer)
6. Discontinue frequent lab monitoring
7. Check BG qAC, qHS, and for symptoms of hypoglycemia
8. Call BDC physician with questions (pager number)

FIGURE 1

Samples of non-billable note templates. *** Are to be filled in by endocrinologist. BDC, Barbara Davis Center for Childhood Diabetes; BG, blood glucose; qAC, pre-meal; qHS, at bedtime.

of discharge. Other than billing notes, communication between the endocrinologist consultant and the primary medical team was primarily verbal, with no inclusion of the nursing or pharmacy staff. Documentation by the endocrinology team was not entered in the chart until after the consultant evaluated

the patient, often the morning after an overnight admission. The primary team placed all insulin orders, with choices based on the knowledge of the ordering provider, in most cases after phone consultation with an endocrinologist. To address these weaknesses, we implemented 3 communication-based solutions:

consultations, nonbillable medical record notes, and standard order sets.

In 2011, a policy was created requiring an endocrine consultation for admission of patients receiving insulin, regardless of cause for admission. The consulting physician verifies that insulin orders have been placed correctly and assists with dosing changes before medical procedures or during times of limited oral intake. To facilitate ease of consultation by the primary team, endocrinology implemented a dedicated consultation pager to access the endocrinology physician on call.

Note templates were created for admission of DKA (Fig 1A) and transition from IV to subcutaneous insulin dosing in the setting of DKA (Fig 1B). Both templates include detailed instructions on insulin dosing, IV fluid management and/or meal regimen, and timing of insulin administration in regard to meals. These notes are written by the endocrinologist and entered into the chart at time of verbal consultation with the primary team. Although these notes are not billable, they provide a reference for the primary medical team, nurses, and pharmacists.

Order sets that had previously been created were found to have inconsistent use through the evaluation of events by the ISC. The order sets addressed treatment of DKA in the emergency department, admission of a patient with DKA to the inpatient unit, and admission of patients requiring subcutaneous insulin for diabetes management to the inpatient unit. The order sets support the CHCO guidelines for treatment of diabetes, hyperglycemia, and insulin management through proper laboratory monitoring, insulin selection and dosing, IV fluid management, and hypoglycemia management. Improvements, such

as including an explanation of how to use the order sets, creating nursing communication orders for hypoglycemia management, and discrete insulin orders for carbohydrate coverage and glucose correction, were made to the order sets to make them less confusing to providers and increase the frequency of their use. In addition, to improve utilization, an alert, although not a hard stop, was implemented in the EMR when insulin was ordered without using the order set.

The ISC received feedback from staff that the policy and procedure (P&P) titled “Hypoglycemia: Treatment in Patients Requiring Insulin” was difficult to follow and implement. This P&P provides a standardized definition for hypoglycemia, outlines symptoms of hypoglycemia, and defines the “high-risk” population and assessment of the possible causes for a hypoglycemic episode. Most important, the P&P defines step-by-step treatment of hypoglycemic episodes and specifies parameters for hypoglycemic episode resolution. The ISC revised this P&P to simplify the hypoglycemia treatment protocol for inpatients by changing the amount of juice to administer to match a typical juice box, changing the IV concentration of dextrose for initial treatment from 20% to 10%, which was readily available on the inpatient nursing units, and eliminating low-dose glucagon, which required dilution before administration.

To further mitigate hypoglycemic events, the ISC targeted 3 additional P&Ps. The first was the “Insulin Administration/Subcutaneous Route Guidelines,” which was updated to provide a description and appropriate timing of administration of all subcutaneous insulin products on the hospital formulary, including proper administration of insulin for high blood sugar correction,

food coverage, and enteral feeds. Additional updates included outlining the standard insulin concentration and dosing (U-100, no smaller than 0.5-unit increments) and a procedure for use and administration of diluted insulin. Second, ISC worked with the critical care team to develop “Critical Care Glycemic Guidelines,” which outline the monitoring of patients over 6 months of age with hyperglycemia due to critical illness, implementation of IV insulin infusion therapy, and monitoring and adjustment parameters for IV insulin infusion therapy in the intensive care setting. Finally, an “Insulin Infusion Pump Guideline” was developed for the use of home insulin pumps during hospitalization. It is intended for patients who are capable of self-management or who can have a caregiver knowledgeable about the insulin pump at their bedside 24 hours per day. The guideline defines the expectations of the ordering provider, the nurse, and the family/patient for evaluation and adjustment of pump settings, witnessing of insulin administration, and order placement and documentation in the EMR. It also provides contraindications to pump use.

Education of health care practitioners has been identified as a critical component to improvement in diabetes and glycemic management. Important elements are use of and adherence to policies, procedures, protocols, order sets, equipment, and therapeutic targets.^{1,2,5,14,18–34} Several educational opportunities were identified, developed, and implemented by the ISC to improve knowledge of staff. Barbara Davis Center for Childhood Diabetes faculty, a certified diabetes educator, and clinical pharmacists developed education materials based on their expertise in insulin and diabetes management. All new graduate nurses receive a 1-hour presentation during orientation focusing on

diabetes treatment, policies, terminology, supplies, and hospital resources. A voluntary diabetes course is offered annually for nurses, providing a total of 12 hours of training over 3 days.¹⁹ During this course, nurses are able to wear an insulin pump, test their own blood glucose, and are encouraged to count their own meal carbohydrate content for 1 week to better understand the complexity of diabetes treatment. Knowledge of insulin pumps was assessed with a pre- and posttest. Six months after the course, a second test was sent to participants to assess for retained knowledge. Skills validation of the most commonly used pump is also completed. Finally, to supplement nurse education, posters displaying information about the hypoglycemia treatment P&P and cystic fibrosis-related diabetes were placed in areas frequented by nurses. Medical residents received formal education from endocrinologists annually on insulin action and DKA management in addition to existing ongoing education during patient care consultations with endocrinology. Additionally, the MSS created a lecture to address insulin safety for medical residents. Clinical pharmacists developed an online education module followed by a competency assessment test, which all pharmacists are required to complete annually.

Analysis

These multimodal approaches were proposed, implemented, evaluated, and revised throughout the project period. Preventable hypoglycemic rates from August 2011 through March 2014 were tracked to measure the impact and sustainability of interventions. Data were analyzed by using SPC, and an SPC chart (“u-chart”) was created by using QI Charts Version 2.0.22 (Scoville Associates, Austin, TX).^{35,36} The rate of preventable severe hypoglycemic

events was calculated by dividing the number of preventable severe hypoglycemic events by the number of insulin days and then normalizing to 100 insulin days. An insulin day is defined as each day that a patient receives at least 1 dose of insulin by any route of administration. Situations in which patients had >1 sequential blood glucose value <50 mg/dL with no intervention or repeat normal value were considered 1 episode and were not counted as discrete events.

RESULTS

Figure 2 represents the breakdown for the evaluation of 257 severe hypoglycemic events identified in the EMR trigger reports from August 2011 through March 2014. Of those, 99 were false positive and 158 were further evaluated through chart review to determine whether the severe hypoglycemic event was preventable. Forty-three severe hypoglycemic events were determined to be preventable, and 115 were determined to be nonpreventable. The 158 severe hypoglycemic events were evaluated in 86 patients. Patient characteristics are displayed in Table 1.

The SPC u-chart depicts the rate of preventable severe hypoglycemic events per 100 insulin days (Fig 3) with the timing of intervention implementation and demonstrates a significant decrease in the rate of preventable severe hypoglycemic events over the course of our continuous improvement efforts. From August 2011 to March 2012, there were 1.4 preventable severe hypoglycemic events per 100 insulin days, and from April 2012 to March 2014, there were 0.4 preventable severe hypoglycemic events per 100 insulin days, which represents a 28% decrease in preventable severe hypoglycemic events.

FIGURE 2

Severe hypoglycemic trigger evaluation, August 2011 through March 2014.

TABLE 1 Patient Characteristics, August 2011–March 2014

Characteristic	Result
Patients with severe hypoglycemic events evaluated, <i>n</i>	86
Gender, % male, (<i>n</i>)	52 (45)
Age at time of severe hypoglycemic event (y), median	14.6
Race/ethnicity, <i>n</i>	
Non-Hispanic white	56
African American	8
Hispanic	16
Other	6
Diagnosis, <i>n</i>	
Type 1 diabetes	55
Type 2 diabetes	5
Cystic fibrosis–related diabetes	6
Neoplasm: chemotherapy/bone marrow transplant	6
Critically ill	11
Other	3
Number of severe hypoglycemic events evaluated (may be >1 event per patient)	158
Insulin delivery route at time of event, <i>n</i> (%)	
Subcutaneous	96 (61)
Insulin drip	36 (23)
Subcutaneous continuous insulin infusion	18 (11)
Multiple routes	8 (5)
Number of insulin days	6478
Number of preventable severe hypoglycemic events	43
Number of nonpreventable severe hypoglycemic events	115

DISCUSSION

The aim of this QI effort was to reduce the rate of preventable severe hypoglycemic events in hospitalized pediatric patients receiving insulin therapy. Through continuous evaluation of severe hypoglycemic events, we achieved a 28% decrease in the rate of preventable severe hypoglycemic events by implementing interventions targeted at improving communication, policies, procedures and guidelines, and staff knowledge. The interventions

were not designed to be evaluated as independent variables; therefore, we attribute the decrease in the mean rate of preventable severe hypoglycemia to the combination of interventions with oversight from the ISC supported by an overarching organizational focus on patient safety. Our approach is unique compared with previous studies that have used single approaches to attempt to improve diabetes control and is in agreement with consensus statements that emphasize the need for a systems approach to improve safety

FIGURE 3

SPC u-chart of rate of preventable severe hypoglycemic events per 100 insulin days. UCL, upper control limit. Intervention annotations: 1, order set updates; 2, critical care glycemia guidelines >6 months old created; 3, P&P updates; 4, endocrine consult notes created; 5, education; 6, hypoglycemia guidelines updated; 7, critical care glycemia guidelines <6 months old created.

in insulin management.^{2,5,18,21,37–39}

The implementation of multiple interventions by the CHCO ISC aligns with recommendations from 3 consensus panels^{2,5,38} related specifically to our interventions:

- The development of protocols and order sets for different uses of insulin
- The use of EMRs for ordering including the use of order sets
- Standardized education and competency for all hospital-based health care professionals involved in the management and use of insulin
- Development of policies, procedures, and protocols to address insulin preparation, administration, and monitoring
- Real-time surveillance and management of patients with unexpected hypoglycemia

The use of protocols and order sets to improve glycemic management, decrease errors, and prevent hypoglycemia has been previously described.^{1,18,20,21,23–26,34,40–52}

Donihi et al described a decrease in insulin prescribing errors and adverse events 1 year

after the implementation of a standardized protocol and order set for sliding scale insulin.⁴⁰ Through the implementation of these interventions, they report a significant decrease in prescribing errors and a decrease in hyperglycemia with no significant change in incidence of hypoglycemia. This study demonstrates the positive impact that standardized protocols and order sets can have in decreasing adverse events.

A multidisciplinary team is a key element when implementing specific interventions or providing oversight of insulin use, diabetes care, or hyperglycemia management.^{1,18,20–23,40–42} Two groups specifically analyzed the impact of a committee focused on hypoglycemia and diabetes safety. Pasala et al described the impact of a hypoglycemia committee to decrease hypoglycemic events.¹⁸ They attribute their ability to design effective interventions to the systematic review and characterization of all hypoglycemic events by physicians, endocrinologists, or diabetes specialists. Their interventions included development of a hypoglycemia treatment protocol, standard insulin dosing, and physician education regarding

insulin prescribing and use of order sets. Korythkowski et al also described the development of a multidisciplinary diabetes inpatient safety committee to address glycemic control in the inpatient setting.²² They reported success in developing order sets, structured education for protocols, and QI measures to evaluate safety and effectiveness of protocols. These authors concluded that an effective multidisciplinary committee can improve glycemia management and decrease errors. The role of a committee and interventions described by these authors is similar to our experience.

Although the use of multiple interventions, the iterative nature to improve the interventions, and oversight by a multidisciplinary committee appears to have helped us exceed our goal of a 10% reduction in preventable severe hypoglycemic events, we believe that to achieve our 5-year goal of eliminating these events, we will need to improve the reliability of our processes and interventions.^{53–55} With turnover of staff, the observed gains may weaken over time unless there is maintenance of education and competency. Sustained effects in place include order sets, protocols, policies, and guidelines. The use of real-time triggers to improve evaluation of events may identify causes that previously were not detected. Tools such as failure-mode-and-effect-analysis and key driver diagrams, as well as use of improvement methodology such as Lean-Six-Sigma, may accelerate our improvement efforts.^{53–55}

A limitation of this project is the retrospective nature of the analysis of severe hypoglycemic events leading to the potential for missing documentation in the EMR. We do believe the involvement of the endocrinology fellows on the ISC, who were involved in the

care of the majority of the patients with hypoglycemic events, helps to mitigate the retrospective review when events are discussed to determine preventability. Because our interventions were conducted in a training hospital, generalizability to nontraining hospitals is unknown.

CONCLUSIONS

Through the use of a multi-interventional approach with oversight of a multidisciplinary insulin safety committee, a sustained decreased rate of severe preventable hypoglycemic events in hospitalized pediatric patients receiving insulin was achieved.

ABBREVIATIONS

CHCO: Children's Hospital Colorado
DKA: diabetic ketoacidosis
EMR: electronic medical record
ISC: insulin safety committee
IV: intravenous
P&P: policy and procedure
QI: quality improvement
SPC: statistical process control

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FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: Dr Alonso has received grants and revenue from Roche unrelated to the current study; the other authors have indicated they have no potential conflicts of interest to disclose.

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