

Integration of Around-the-Clock Clinical Pharmacy Specialists Into the Critical Care Team Can Increase Safety of Hyperglycemic Crisis Management

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■ IN BRIEF “Quality Improvement Success Stories” are published by the American Diabetes Association in collaboration with the American College of Physicians, Inc., and the National Diabetes Education Program. This series is intended to highlight best practices and strategies from programs and clinics that have successfully improved the quality of care for people with diabetes or related conditions. Each article in the series is reviewed and follows a standard format developed by the editors of *Clinical Diabetes*. The following article describes an effort to improve the safety of hyperglycemic crisis management at a Veterans Affairs Medical Center by making clinical pharmacy specialists available to the critical care team 24 hours/day.

Describe your practice setting and location.

The Malcom Randall Veterans Affairs Medical Center is a 289-bed academic, tertiary care medical center in Gainesville, Fla. The hospital has 26 medical and surgical intensive care unit (ICU) beds. The 12-bed medical intensive care unit (MICU) was the primary practice setting involved in this initiative.

The MICU physician staff includes an attending intensivist, a critical care fellow, and resident physicians. Second- and third-year internal medicine resident physicians staff the MICU around the clock. The medical residents, on average, complete 8–10 weeks of critical care rotations per year during their internal medicine program. No formal curriculum on the management of hyperglycemic crises is mandated during the internal medicine residency program. Attending or fellow physicians are in the hospital during overnight hours on a part-time basis and are otherwise available on call.

The nursing ratio for the MICU is a maximum of two patients to one

nurse. Additional core staff includes a clinical nurse leader, a clinical nurse educator, respiratory therapists, dietitians, and clinical pharmacy specialists.

Describe the specific quality gap addressed through the initiative.

This initiative focused on improving safety around the management of diabetic ketoacidosis (DKA) and hyperglycemic hyperosmolar state (HHS)—collectively known as hyperglycemic crises. Treatment of hyperglycemic crises is complex, typically involves use of high-risk medications such as intravenous (IV) insulin, and is commonly complicated by hypoglycemia (1,2). Due to the frequency of complications, health care systems are increasingly implementing standardized clinical protocols to help guide staff in the management of hyperglycemic crises (3–7). Despite implementation of a standardized protocol, our institution continued to experience a high incidence of complications.

An informal survey of the resident physicians and nursing staff demonstrated a need for additional expertise

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to assist with the management of hyperglycemic crises and the use of our institution's protocols. Our pharmacists were identified as experts who could help bridge the quality gap.

Clinical pharmacists have been shown to improve safety in the ICU setting and to improve the quality of care in the treatment of diabetes and its associated complications (8,9). In our institution, most patients with hyperglycemic crises were admitted to the MICU and treated during the hours in which there was no clinical pharmacy specialist present (i.e., evening and overnight hours). During these hours, pharmacy services were centralized, meaning all in-house pharmacists were in the pharmacy focused on operational activities, including IV medication compounding, prescription order verification, and medication distribution. Our existing clinical pharmacy specialists provided comprehensive clinical services in the ICUs during daytime hours only. These clinical services included, but were not limited to, rounding with the interdisciplinary medical team, therapeutic drug monitoring, nutrition support management, pharmacokinetic monitoring, participation on emergency response teams, management of drug interactions/adverse effects/allergies, and medication prescribing. Thus, we considered our clinical pharmacy specialists to be underutilized.

This quality improvement (QI) initiative focused on the impact of 24-hour clinical pharmacy specialists on complications associated with the management of hyperglycemic crises.

How did you identify this quality gap? In other words, where did you get your baseline data?

Our first attempt at improving the safety of hyperglycemic crisis management included developing a standardized clinical protocol to assist the medical and nursing staff. The protocol was for management of both DKA and HHS and included a

computerized order menu and graphic flow diagram with recommended management algorithm. The protocol provided guidance but allowed for alterations to the protocol based on providers' clinical judgment. Guidance included initial IV insulin dosing, IV insulin dose adjustments, IV fluid composition, IV fluid infusion rates, electrolyte replacement doses, frequency of glucose monitoring, direction for addition of dextrose to IV fluids when blood glucose reached a correction threshold, and parameters for holding IV insulin.

After implementing this clinical protocol, we conducted a quality assurance project to identify the impact of the intervention. Our analysis found that, compared to pre-protocol implementation, safety did not significantly improve, and patients treated post-protocol implementation continued to have a high occurrence of complications.

Summarize the initial data for your practice (before the improvement initiative).

Over the course of the 28 months before our initiative, we found that 14 of 59 patients (23.7%) experienced hypoglycemia (defined as a point-of-care blood glucose measurement <70 mg/dL) while on the hyperglycemic crisis protocol. Of the 59 patients treated under the protocol, 24 were diagnosed with type 1 diabetes, and 35 were diagnosed with type 2 diabetes. Forty-six patients were treated for DKA, and 13 patients were treated for HHS. Six patients developed mild hypoglycemia (blood glucose 60–69 mg/dL), eight developed moderate hypoglycemia (blood glucose 40–59 mg/dL), and none developed severe hypoglycemia (blood glucose <40 mg/dL).

After resolution of hyperglycemic crisis and transition to a subcutaneous insulin regimen, 10 of the 59 patients (16.9%) experienced hypoglycemia within 24 hours. Of these, 5 had mild hypoglycemia, 3 had moderate hypoglycemia, and 2 had severe hypo-

glycemia. Information regarding the specific causes of hypoglycemia was not available for mild and moderate cases; however, the causes of severe hypoglycemia were evaluated and documented at the time of each event. Both cases of severe hypoglycemia were caused by restarting the patient's home dose of subcutaneous insulin—one prescribed by the General Medicine team after transfer from the MICU and one prescribed by the Endocrinology consultant service.

What was the timeframe from initiation of your QI initiative to its completion?

This evaluation was conducted as part of a continuous quality assurance program, in which we monitor the safety of our ICU protocols, including the standardized hyperglycemic crisis protocol. For the evaluation, we compared a 28-month period after our initiative to a 28-month period before the implementation of our initiative. This timeframe for evaluation was selected because the standardized hyperglycemic crisis protocol was in use for this period before the QI initiative.

Describe your core QI team. Who served as project leader, and why was this person selected? Who else served on the team?

The core team for this project included the clinical pharmacy specialists, the clinical nurse educator, and the medical director for the MICU. The project leader was a clinical pharmacy specialist for the MICU who was selected due to his familiarity with hyperglycemic crises management, protocol development, and staff training.

Describe the structural changes you made to your practice through this initiative.

The major structural change made to our practice was the integration of clinical pharmacy specialists into the ICU team during the times when most patients with hyperglycemic crises are admitted (i.e., evening and overnight hours). This allowed for

disease co-management by the pharmacists, physicians, and nursing staff. Clinical pharmacy specialists trained in critical care were physically present in the ICU around the clock and were not required to perform drug distribution activities from the pharmacy.

Describe the most important changes you made to your process of care delivery.

We allowed our clinical pharmacy specialists to prescribe necessary treatments and monitoring parameters per protocol for patients with hyperglycemic crises as part of their scope of practice. Before the initiative, all prescribing was performed by the resident physicians. The clinical pharmacy specialists also adjusted our standardized hyperglycemic crises protocol to simplify treatment and improve accordance with expert consensus recommendations.

The primary simplification made in the protocol was the elimination of routine insulin dose titration. We used fixed dosing that was only adjusted when blood glucose reached 250 mg/dL and upon resolution of DKA or HHS. Once blood glucose reached 250 mg/dL, dose adjustments were made by nursing staff at bedside based on current blood glucose, previous blood glucose, and insulin infusion rate. Insulin rate adjustments were provided by an Excel (Microsoft, Seattle, WA) calculator on the nurse's bedside computers using a validated dose adjustment protocol.

Despite protocol simplification, the pharmacists' role in hyperglycemic crisis management was essential. The pharmacists provided guidance to resident physicians on protocol ordering, deviations from the protocol if necessary, IV insulin dosing, IV fluid selection and dosing, and electrolyte supplementation. The pharmacists assisted the nurses with protocol orders, including IV insulin administration and IV fluid adjustments. The pharmacists often wrote or clarified the orders for IV fluids, IV insulin, electrolyte replacement, laboratory

monitoring, and nursing instructions under their scope of practice.

Summarize your final outcome data (at the end of the improvement initiative) and how it compared to your baseline data.

We compared the pre- and post-initiative rates of hypoglycemia in patients admitted to the ICU for management of hyperglycemic crises. Patients were excluded from analysis if complete data regarding diagnoses and treatments were not available. For inferential statistical analysis, we used the χ^2 or Fisher's exact test, as appropriate. An alpha of 0.05 was set for statistical significance.

We found that, during the 28 months after implementing around-the-clock clinical pharmacy specialist coverage, hypoglycemia occurred in 4 of 74 patients (5.4%)—a decrease of 18.3% from the pre-initiative cohort. This difference was statistically significant ($P < 0.01$). Nineteen patients were diagnosed with type 1 diabetes, and 55 patients were diagnosed with type 2 diabetes. Fifty-two patients were treated for DKA, and 22 were treated for HHS. Of the four patients who developed hypoglycemia, one had mild hypoglycemia, two had hypoglycemia, and one had severe hypoglycemia. As above, information on the specific cause of hypoglycemia was only available for severe cases. The one case of severe hypoglycemia was caused by a medication error in which dextrose-containing IV fluids were prescribed, but IV fluids without dextrose were mistakenly administered.

Upon resolution of hyperglycemic crisis and transition to subcutaneous insulin, hypoglycemia occurred within 24 hours in 9 of 74 patients (12.2%). This was a decrease of 4.7% from the pre-initiative cohort, a difference that was not statistically significant ($P > 0.05$). Of the nine patients who developed hypoglycemia with subcutaneous insulin, five had mild hypoglycemia, two had moderate hypoglycemia, and two had severe

hypoglycemia. Both cases of severe hypoglycemia were caused by restarting the patient's home subcutaneous insulin regimen, one by the General Medicine team after transfer from the MICU and one by the Endocrinology consultant service.

Due to the small sample size, this study may have been underpowered to detect a difference between groups for this measure. Both before and after the intervention, we found that subcutaneous insulin dosing after hyperglycemic crisis resolution was not standardized and involved prescribers from the ICU, General Medicine, and Endocrinology. Although recommended doses were provided in the updated protocol after the intervention, adherence to these recommendations was inconsistent. These findings may also explain the lack of a significant difference between the pre- and post-intervention groups.

We could not determine whether the adjustments made to our hyperglycemic crises protocol had an impact on the occurrence of hypoglycemia independently of the pharmacists' intervention.

What are your next steps?

We believe our results are generalizable to many other health systems. Having clinical pharmacy specialists available during evening and overnight hours in ICUs is rare. We hope to encourage others to follow our example. We plan to start by encouraging leadership within Veterans Affairs health systems to optimize their critical care pharmacy services.

We were unable to determine whether the intervention affected other outcomes such as mortality, lengths of stay, or costs. However, we hope to evaluate this further to help define the relative value of additional clinical pharmacy specialists in the ICU. We should note that the clinical pharmacy specialists involved in this intervention had many responsibilities that were not described in this report. These responsibilities were similar to those of the daytime clinical

pharmacy staff, including pharmacokinetic consultation, emergency response, and drug therapy monitoring for all critically ill patients. We plan to conduct evaluations on the overall impact of around-the-clock critical care clinical pharmacy specialists.

We also plan to incorporate our results into strategies to reduce the incidence of electrolyte abnormalities during the treatment of hyperglycemic crises. Additionally, we hope to expand the scope of improved diabetes management after hyperglycemic crises resolution, including prevention of subsequent hypoglycemia with subcutaneous insulin. We plan on engaging with practitioners from the ICU, General Medicine, and Endocrinology to develop tools to assist with the transition from IV insulin to subcutaneous insulin after resolution of hyperglycemic crises.

What lessons did you learn through your QI process that you would like to share with others?

Implementing practice changes involving reallocating staff can have a significant impact on the health system and can be difficult to justify. Having champions from multiple disciplines to support the initiative is essential. There may be members of the health care team who can improve the quality of care but are underuti-

lized. It is important to encourage all team members to contribute to QI initiatives.

Standardized protocols are created with a goal to guide staff in the management of complex disease states; nevertheless, complications still occur, and appropriate management requires providers trained in treating complex disease states such as hyperglycemic crises. Hyperglycemic crisis protocols have shown mixed results regarding the incidence of hypoglycemia after implementation, with higher, lower, and unchanged occurrence being reported (4–7). Additionally, when surveyed, most nurses found a hyperglycemic crisis protocol difficult to follow (5). Therefore, our opinion is that QI efforts to supplement institutional protocols and health care provider education are warranted. Our results suggest that implementation of around-the-clock critical care pharmacy services, through which clinical pharmacy specialists are able to co-manage hyperglycemic crises, can improve care.

Duality of Interest

No potential conflicts of interest relevant to this article were reported.

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