

INPATIENT MEDICAL ERRORS INVOLVING GLUCOSE-LOWERING MEDICATIONS AND THEIR IMPACT ON PATIENTS: REVIEW OF 2,598 INCIDENTS FROM A VOLUNTARY ELECTRONIC ERROR-REPORTING DATABASE

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ABSTRACT

Objective: To describe characteristics of inpatient medical errors involving hypoglycemic medications and their impact on patient care.

Methods: We conducted a cross-sectional analysis of medical errors and associated adverse events voluntarily reported by hospital employees and staff in 21 nonprofit, nonfederal health-care organizations in the United States that implemented a Web-based electronic error-reporting system (e-ERS) between August 1, 2000, and December 31, 2005. Persons reporting the errors determined the level of impact on patient care.

Results: The median duration of e-ERS use was 3.1 years, and 2,598 inpatient error reports involved insulin or orally administered hypoglycemic agents. Nursing staff provided 59% of the reports; physicians reported <2%. Approximately two-thirds of the errors (1,693 of 2,598) reached the patient. Errors that caused temporary harm necessitating major treatment or that caused permanent harm accounted for 1.5% of reports (40 of 2,598). Insulin was involved in 82% of reports, and orally administered hypoglycemic agents were involved in 18% of all reports (473 of 2,598). Sulfonylureas were implicated in 51.8% of reports involving oral hypoglycemic agents (9.4% of all reports).

Conclusion: An e-ERS provides an accessible venue for reporting and tracking inpatient medical errors involving glucose-lowering medications. Results are limited by

potential underreporting of events, particularly by physicians, and variations in the reporter perception of patient harm. (*Endocr Pract.* 2008;14:535-542)

Abbreviations:

e-ERS = electronic error-reporting system; LOI = level of impact; OHAs = orally administered hypoglycemic agents

INTRODUCTION

On the basis of recent evidence that improved inpatient glycemic control may enhance patient-related outcomes (1-3), national organizations have recommended stricter glycemic goals for inpatients (4). Nevertheless, increased use of glucose-lowering medications to achieve these goals without implementation of evidence-based and expert-guided approaches may actually increase medication-related errors, which may not only have a negative impact on patient care but also increase health-care costs (5,6).

Recognizing medical errors and identifying their causes usually necessitate a manual review of medical records. This process is impractical, costly, time-consuming, and often delayed. Increased emphasis on quality improvement demands that this process be made more efficient. The development of computer-based event reporting and surveillance databases allows the review of these data in a cost-efficient and timely manner. There is a growing body of literature reflecting the usefulness in tracking medical error reports electronically, with use of both automated and voluntary reporting systems (7-10). Information from such databases can be used to improve communication, raise awareness of patient risk among members of the health-care team, and prevent future errors.

The Joint Commission on Accreditation of Healthcare Organizations has labeled insulin as one of the top 5 "high-risk medications" (11). Insulin alone accounted for

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3.5% of medication-related errors in the United States Pharmacopeia Medication Errors Reporting Program in 2002 (12), which is higher than errors involving other commonly used medications, such as heparin (2.3%) and morphine (2.5%).

Our objective was to report the incidence and impact on patient care of inpatient errors related to specific glucose-lowering medications self-reported by members of health-care organizations that use a commercially available, voluntary, electronic error-reporting system (e-ERS).

RESEARCH DESIGN AND METHODS

The electronic reporting system has been described previously (9). It consists of a secure, Web-based portal available on all computers at participating organizations. Any clinical staff member or employee could submit a report. A series of standardized screens with pull-down response menus prompt the reporter to enter information about the medical error, such as time, location, service, personnel involved, and impact on patient care. Reporting was not anonymous but was peer-review protected and accessible only to prespecified hospital administrators. Reports could be accessed immediately after entry and could be amended to reflect information obtained from subsequent investigation, verification, and patient follow-up. Managers and executive leaders could edit reports for improved accuracy during final review. Data entry required approximately 10 minutes for each event. Reporters designated a "level of impact" (LOI) on patient care, as shown in Table 1. For this analysis, we grouped

the errors depending on whether they reached the patient (LOI 3 through 8) or not (LOI 0 through 2). Levels 7 and 8 had the fewest reports and were also combined for purposes of this analysis. We further analyzed the reports and impact on patient care by type of glucose-lowering medication.

We evaluated errors reported by 21 nonprofit, non-federal health-care organizations located throughout the United States. Eight organizations had more than one facility contributing data, for a total of 44 acute care facilities contributing data. For this analysis, we included data from inpatient wards, critical care units, postoperative care units, emergency departments, and acute rehabilitation facilities located within hospitals. Errors reported from outpatient practices, outpatient pharmacies, home health services, long-term skilled nursing facilities, and nursing homes were excluded. Each organization voluntarily implemented and used the same commercial e-ERS product as a component of quality improvement. Multiple reports of the same error were combined manually at each hospital site. All errors were merged in a single database and were deidentified to study investigators.

Seven organizations were major teaching hospitals and served as primary sites for residency programs in multiple specialties. Nine organizations were located primarily in urban settings; 2 were exclusively pediatric hospitals. Specialty hospitals for orthopedics, oncology, and obstetrics were included as part of their respective organizations. Hospital admission rates were obtained from publicly available American Hospital Association admission data (13). The most recent year available was used to extrapo-

Table 1
Levels of Impact of Inpatient Medical Errors and Associated Definitions^a

e-ERS-related definitions		
Level of impact	Description	Analysis-defined definitions
0	Unknown	Did not reach patient
1	Safety or environment (unsafe practices or conditions [or both] in the institution)	Did not reach patient
2	Near miss (error or adverse event corrected or averted before it reached the patient)	Did not reach patient
3	No harm to patient; no increase in monitoring	Reached patient
4	No harm to patient; monitoring was increased	Reached patient
5	Temporary harm to patient; no treatment instituted	Reached patient
6	Temporary harm to patient; minimal treatment initiated	Reached patient
7	Temporary harm to patient; major treatment instituted	Reached patient
8	Permanent harm to patient or death	Reached patient

^a e-ERS = electronic error-reporting system.

late admission data for each year that a hospital reported to the database during the period reviewed. The reporting rate for each organization was evaluated by a C chart analysis (14). The first facility implemented the e-ERS in August 2000. All organizations had implemented the e-ERS by 2004.

Implementation of an e-ERS requires time for staff to become aware of its availability, to receive training in its use, and to be consistent with reporting. Patient populations also vary among the organizations. To account for these variables, we used a time-between-event analysis to identify when error reporting stabilized (15,16). An analysis of each patient-care unit generated a date after which the time-between-event reporting was statistically stable for our events of interest. Reports from each patient-care unit that occurred before this date were excluded. For example, unit 1 had 50 reports involving glucose-lowering medications. A time-between-event analysis revealed that it took 2 months for its rate of reporting to stabilize. If 3 reports occurred before this date, they were removed, and unit 1 would contribute 47 reports to the final analysis. Approximately 100 data points were excluded from analysis by this method.

Reporting staff designated their own job title or role. We grouped these roles into the following categories: *nursing*, *pharmacy*, *physician*, or *other*. The “nursing” category included any titles (such as registered nurses and clinical nurse managers) or degrees (RN, LPN, and so forth) denoting nursing staff but excluded nurse-practitioners. Pharmacists and pharmacy technicians comprised the “pharmacy” category. The “physician” category included all titles (attending physician, house staff physician, and so forth) and degrees (MD, DO) that designated a physician. The category of “other” included nurse-practitioners, midlevel providers, administrative staff, or reporters not specifying a title or degree.

Glucose-lowering medications were defined and identified by using both generic and trade names (Table 2). Orally administered hypoglycemic agents (OHAs) included sulfonylureas, meglitinides, biguanides, thiazolidinediones, and formulations that combined 2 OHAs. Human insulin and insulin analogues were identified, and both subcutaneously and intravenously administered insulins were included. The long-acting category included glargine, Lente, Ultralente, and isophane, whereas the intermediate-acting category consisted of NPH insulin. The rapid-acting category included aspart, lispro, and regular insulin. “Combination insulin” included commercially available premixed insulin and, where specified, custom mixed insulin. “Insulin, other” included intravenously administered regular insulin, inhaled insulin, pork insulin, and zinc insulin and errors attributed to insulin but without a specified insulin type.

RESULTS

The median duration of e-ERS use was 3.1 years (range, 1 to 5.1). The 21 health-care organizations contributed 258,027 reports to the database from August 1, 2000, through December 31, 2005. Medication-related errors accounted for approximately 29% (74,733) of all reports. After the time-between-event analysis, 2,598 reports involving glucose-lowering medications, representing 3.5% of medication-related errors, were reviewed. The mean reporting rate for glucose-lowering medications was 5.6 events per 1,000 admissions (range among the various organizations, 0.1 to 40 events). There was no association between errors reported and number of admissions.

Among the 73% of errors (1,907 of 2,598) that reported patient age, 4% (77 of 1,907) occurred in patients younger than 18 years, 49% (929 of 1,907) occurred in patients 18 to 65 years old, and 47% (901 of 1,907) occurred in patients older than 65 years. Patient sex was included in 68% of reports (1,772 of 2,598), and 53.4% of these inpatient errors occurred in women. For all reported errors, the distribution of reporting staff categories was as follows: nursing category, 59%; pharmacy category, 26.7%; physician category, 1.5%; and other, 13%.

The overall LOI for inpatient errors related to glucose-lowering medications is shown in Figure 1. Of errors reaching the patient, 26% caused no harm (LOI 3), whereas 21.2% caused no harm but necessitated increased patient monitoring (LOI 4), 2.8% caused temporary harm but without requiring treatment (LOI 5), and 13.6% involved temporary harm resulting in treatment (LOI 6). Errors that caused major or permanent patient harm (LOI 7 and 8) accounted for 1.5% of reports. Type of treatment was not specified.

Overall, OHAs accounted for 18% of reported inpatient errors (473 of 2,598). Of these, sulfonylureas were the most commonly reported OHAs (51.8%), followed by metformin (30.4%), thiazolidinediones (11.8%), meglitinides (3.2%), and combination OHAs (2.7%) (Fig. 2). The last-mentioned category consisted of commercially available agents that combined sulfonylurea and metformin (12 events) or rosiglitazone and metformin (1 event) in a single formulation. On review of the 3 most severe categories (LOI 6, 7, and 8), we found that OHAs were involved in 13.5% of reports (53 of 394). In this assessment, sulfonylureas were the most common class of OHAs involved, constituting 66% of the reported errors (35 of 53).

The majority of the glucose-lowering inpatient errors (82%) involved insulin (Fig. 3). “Insulin, other” accounted for 43.7% of insulin-related reports (929 of 2,125), followed by rapid-acting insulin (35.4%), long-acting insulin

Table 2
Glucose-Lowering Medications Searched

Class	Drug name (trade name)	
Sulfonylureas	Glyburide (DiaBeta, Micronase)	
	Glipizide (Glucotrol)	
	Glipizide XL (Glucotrol XL)	
	Glimepiride (Amaryl)	
	Acetohexamide (Dymelor)	
	Chlorpropamide (Diabinese)	
	Tolazamide (Tolinase)	
	Tolbutamide (Orinase)	
Meglitinides	Repaglinide (Prandin)	
	Nateglinide (Starlix)	
Biguanides	Metformin (Glucophage)	
Thiazolidinediones	Pioglitazone (Actos)	
	Rosiglitazone (Avandia)	
Oral combinations	Glyburide-metformin (Glucovance)	
	Glipizide-metformin (Metaglip)	
	Rosiglitazone-metformin (Avandamet)	
	Pioglitazone-metformin (Actoplus Met)	
	Rosiglitazone-glimepiride (Avandaryl)	
Insulins		
	Rapid-acting	Aspart (NovoLog)
		Lispro (Humalog)
		Regular (Novolin R or Humulin R)
	Long-acting	NPH (Novolin N or Humulin N) ^a
		Isophane
		Glargine (Lantus)
		Lente
		Ultralente
	Combination	Novolin 70/30
		Humalog 75/25
		NovoLog 70/30
		Isophane-regular
	Other	Insulin, type not specified
Intravenously administered regular insulin		
Inhaled insulin		
Pork insulin		
Zinc insulin		

^a This intermediate-acting insulin was included in the long-acting category only for the purposes of our analysis.

(16.4%), and combination insulin (4.5%). On review of the LOI 6, 7, and 8 events, the “Insulin, other” category accounted for 37.8% (149 of 394), 25.4% involved rapid-acting insulin, 17.7% involved long-acting insulin, and 5.6% involved combination insulin.

DISCUSSION

Our results show that insulin is associated with the largest number of inpatient errors related to glucose-lowering medications (82% of reports), but OHAs are also a

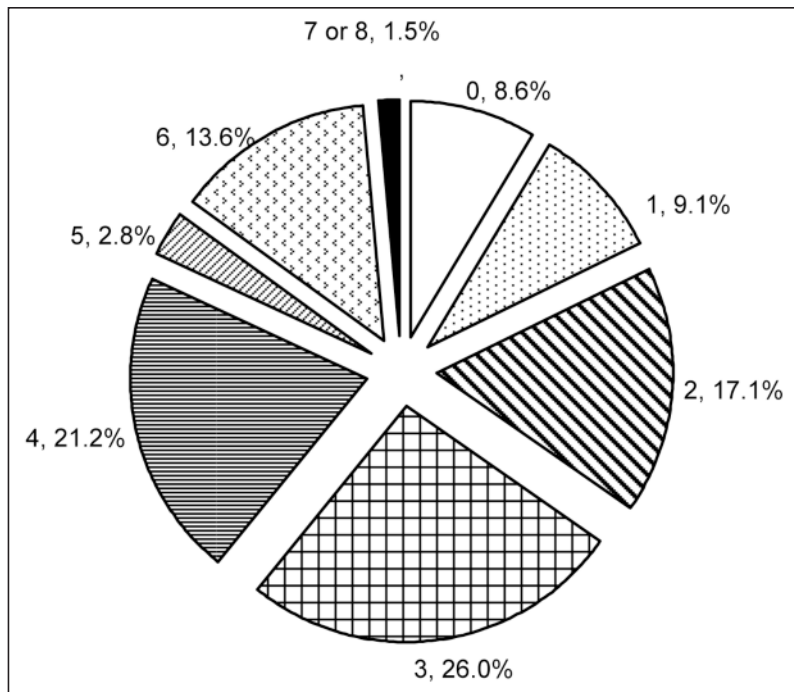


Fig. 1. Overall frequency of levels of impact of inpatient medical errors. See Table 1 for definitions of the 8 levels.

source of medication-related errors in the inpatient setting. Approximately two-thirds of all errors related to glucose-lowering medications reached the patient, and 39% resulted in alterations in care, through either increased monitoring or institution of a treatment. A voluntary e-ERS was effective in capturing inpatient errors involving glucose-lowering medications. Knowing overall event rates is the first step in attempting to implement system-wide improvements.

Our analysis is in general agreement with previous reports (8,10,17,18) in finding that glucose-lowering medications are a source of medication-related errors in the inpatient setting; however, the incidence of errors involving these medications in our study is in the lower range of the rates published previously. This result may be partially due to the different definitions used between previous studies and our study. Previous publications on medical errors have used the terms “antidiabetes agents” or “glu-

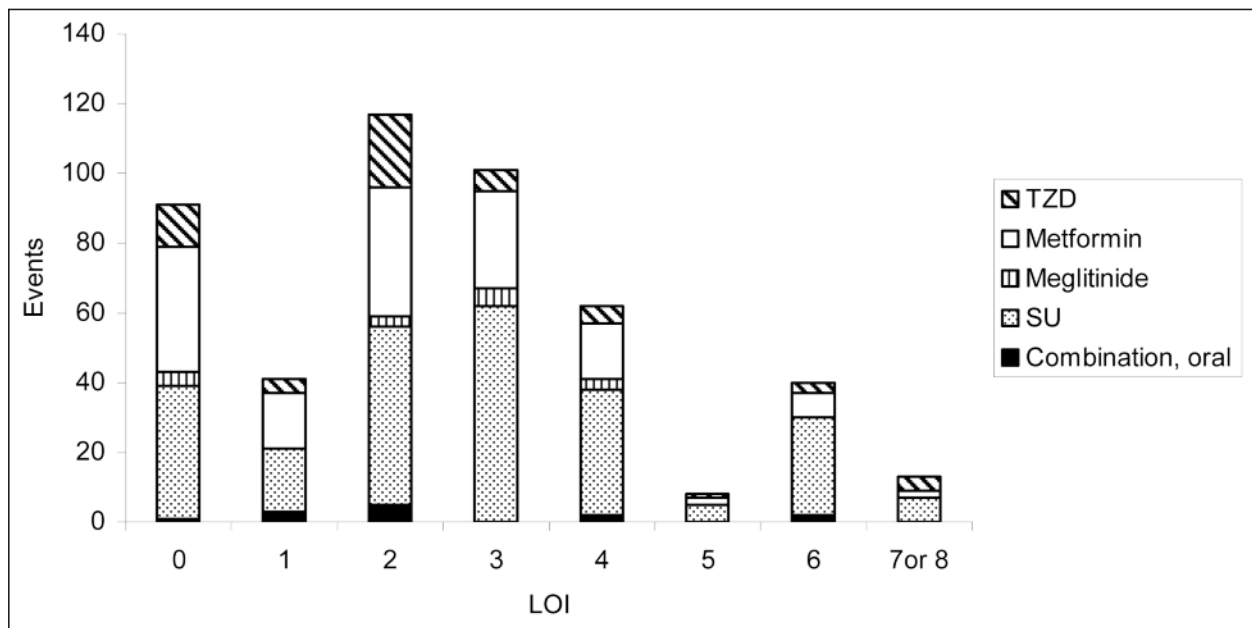


Fig. 2. Levels of impact (LOI) of inpatient medical errors, stratified by orally administered hypoglycemic agents. *SU* = sulfonylureas; *TZD* = thiazolidinediones.

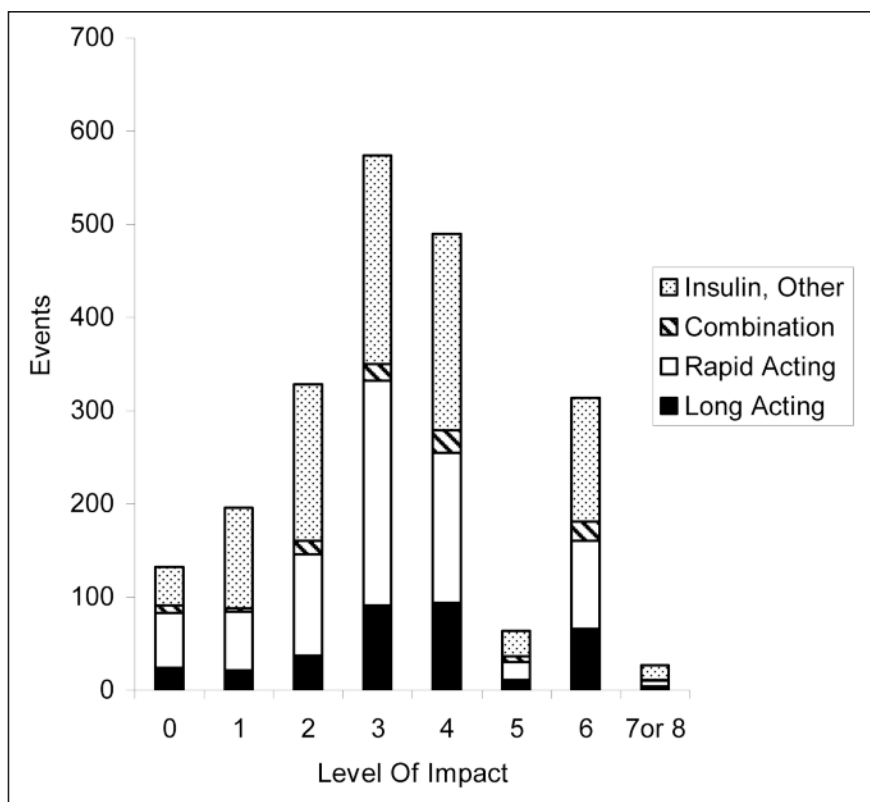


Fig. 3. Levels of impact of inpatient medical errors, stratified by insulin formulations. See Table 2 for components of the “Insulin, Other” category.

cose regulators” (8,10,19) and have reported that these drugs account for 5% to 25% of all medication-related errors. Other authors describe preventable events, at a rate of 6% to 7%, related to antidiabetic agents or insulin (17,18). Some reports do not list agents at all but simply refer to an “endocrinology” drug class (20). The relatively low rate we report may also be attributable to underreporting by some of the involved health-care organizations.

Errors were reported from every level of the patient-care team. The nursing staff spends the majority of time in direct patient care and, as expected, reported the largest number of errors. The pharmacy staff scrutinizes medication orders and also are well positioned to monitor medication errors. We found that physicians at any level of training are unlikely to document inpatient errors, reporting only 1.5% of errors. There are several potential explanations. A cultural bias exists among physicians against reporting errors, by either oneself or a colleague. Physicians may fear retribution from their colleagues, embarrassment at being considered a “failure” in comparison with their peers, or medicolegal consequences of such errors. Physicians could also fail to appreciate the significance of temporary harm to a patient or may be unaware of their important role in the actual reporting process. Moreover, the time required for reporting such an event (approximately 10 minutes) may also be a deterrent for a physician feeling pressured for time. For such a system to

be useful, physicians should be encouraged to assume an active role in monitoring patient safety.

In the current study, a large proportion of reported events (34.8%) occurred before involvement of the patient. Events necessitating treatment accounted for 15.1% of reports, whereas increased monitoring without additional treatment accounted for 24% of errors. Staff members may interpret the absence of treatment to mean that errors involving glucose-lowering medications are less concerning than those events involving narcotics or cardiovascular medications. Nevertheless, by increasing the level of monitoring, costs associated with laboratory orders, medication orders, point-of-care glucose testing, and time spent with the patient increase. Depending on the timing of the event, a discharge may even be delayed so that the patient can remain under observation. Thus, additional monitoring alone may lead to longer hospital stays and increased costs.

Insulin remains the medication of choice for control of blood glucose during hospitalization, and its use should increase in light of the increasing prevalence of diabetes and the current emphasis on inpatient glycemic control. Frequently (but not invariably), OHAs are discontinued during hospitalization, and occasionally they are resumed before dismissal from the hospital and continued despite discharges being delayed. This analysis reveals that OHAs were involved in 18% of inpatient errors, with sulfonyl-

ureas being most frequently reported. Practitioners have used sulfonylureas for many years, are comfortable with them, and may view them as “safe” medications. Our results show, however, that sulfonylureas are associated with medical errors in the hospital setting. Therefore, it is prudent that sulfonylureas be withheld during a hospitalization because a rapid change in a patient’s condition can make the glucose-lowering effects of these agents unpredictable.

Although technology can help decrease certain errors, clinicians must still exercise sound judgment and evidence-based practices when writing medication orders. In the United States, inpatient glycemic control remains reliant on insulin regimens passed along from generations of physician and nursing staff members. Patients continue to receive “sliding scale” insulin orders despite evidence that this is an ineffective method of glycemic control (21-24). Errors associated with traditional insulin orders may be compounded unless effort is invested to standardize the system and reeducate all staff members.

Reports to the current database encompassed many areas within the hospital, including order entry and transcription, dispensing of medications, and patient monitoring. In several areas, technologic advances can potentially reduce or eliminate medication-related errors (25). Electronic physician ordering systems may be especially useful in eliminating use of unapproved abbreviations, errors of order transcription due to illegible handwriting, and confusion between medications with similar names. Patient identifiers with bar codes can help prevent the dispensing of medications to the wrong patient. Error-reporting databases can then be used to compile these events and provide individualized feedback to all members of the health-care team. Consequently, individual behaviors can be changed, and the quality of health care can be improved.

Our data have certain limitations. For example, a voluntary e-ERS can miss some events and potentially result in underreporting. Such missing events should diminish as organizations and their staff members recognize the benefits that voluntary reporting has on the quality of patient care. In addition, a large number of reports in the “Insulin, other” category did not specify the type of insulin, which certainly is useful information for practitioners. Moreover, personal interpretation of LOI varies considerably between reporters. In particular, the “unknown” LOI designation, found in 8.6% of reports, may lead to misclassification bias. Perception of what constitutes “major” or “minor” harm also varies, and reporters did not always add details about the outcome of an event.

Furthermore, the database analyzed is designed to collect information from every aspect of health-care delivery. Although it is sensitive enough to collect a large variety of events, many of our reports had a lack of detail relative to the type of event and the harm to the patient. A lack of knowledge about diabetes, its management, and the usefulness of framing events in the context of either

hyperglycemia or hypoglycemia limits a reporter’s ability to describe an event accurately. Another major barrier is the lack of a standardized language for describing adverse events (26). Encouraging the reporter to provide as detailed a report as possible should help to improve communication and the quality of the feedback given to the health-care team.

CONCLUSION

We found that both insulin and OHAs are sources of medication-related errors in the inpatient setting. Lower glycemic targets during a hospitalization should translate into an increase in ordering and dosage of glucose-lowering medications. Accordingly, we expect that medical errors involving glucose-lowering medications and their negative impact on patient care will increase in the future. For effective glucose management, a well-educated health-care team and a strong commitment to evidence-based care are important. A multidisciplinary approach with nursing, pharmacy, and physician staff is necessary to deliver high-quality patient care while minimizing harm to the patients. Finally, a voluntary e-ERS can be a useful tool in tracking these errors, particularly when trends related to changes in protocols or technology are evaluated.

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DISCLOSURE

The commercial entity from which the data were obtained assisted in the analysis but not the interpretation of results and did not provide financial support for this report. Dr. Kumar is the President and Chief Medical Officer of and Mr. Chen and Mr. Karnam are employed by Quantros Inc., Milpitas, California. The other authors have no conflicts of interest to disclose.

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