

## PATIENT SAFETY AND INPATIENT GLYCEMIC CONTROL: TRANSLATING CONCEPTS INTO ACTION

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### ABSTRACT

**Objective:** (1) To summarize current knowledge regarding patient safety issues and their impact on inpatient glycemic control and (2) to provide a systematic and practical approach to improving patient safety in this area.

**Methods:** Insulin delivery in inpatient settings is examined, as are the barriers to safe insulin therapy. A distinction is made between safety strategies of proven value and those that are less useful. Characteristics of safer insulin algorithms are discussed.

**Results:** Errors in insulin administration remain a common cause of injuries. Despite strong evidence of the dangers of sliding-scale insulin regimens in inpatient settings, sliding-scale insulin regimens remain a widely used but ineffective (and occasionally dangerous) method. To correctly analyze inpatient processes of care, a systems approach is needed, and the relationship between quality of care, latent medical errors, injurious patient errors, and patient safety must be understood. In complex systems such as hospitals, catastrophic error has complex roots involving many individuals, and the design of the system often has latent flaws that make human error likely, even predictable. The concept of the scope of awareness is useful in understanding why it is ineffective to focus only on those at the point of care, and how improvement is more apt to occur with a team approach and the evaluation of systemic factors, at the "blunt end" of care. Error-prone organizations are often very unsafe, and certain practices tend to be common among them. Data are now available showing the negative impact of poorly supervised trainees and the extent of the problem worldwide on patient safety.

**Conclusion:** Redesign of patient care provided in hospitals regarding glucose control is long overdue. Practical strategies are given that focus on improving patient safety for the patient needing inpatient glycemic control. Such techniques now have a sufficient evidentiary base.

Therefore, hospitals should move rapidly to make euglycemia a goal for all inpatients, and to make patient safety in glycemic control a reality, not just for a few, but for all patients in our care. (*Endocr Pract.* 2006;12[Suppl 3]49-55)

### Abbreviation:

CPOE = computerized physician order entry system

### INTRODUCTION

In the past few years, we have begun to understand that it is not enough to merely set quality-of-care targets in the care of hyperglycemic patients. We must also focus on the processes of care if we are to provide patient safety as well. In January 2005, the American College of Endocrinology convened a Consensus Conference to develop a consensus statement on the principles of patient safety in diabetes care (1). This consensus conference highlighted previous data that confirmed the high incidence of injurious medical errors worldwide, as well as data showing that errors in diabetes care are an important cause of poor outcomes (2-5). Moreover, evidence was presented demonstrating that insulin administration was a common cause of injurious errors (2). An important issue, on which consensus was achieved, is that the widespread use of sliding-scale insulin regimens in the inpatient setting is a mistake, because sliding-scale insulin regimens alone, without regularly scheduled insulin doses and basal insulin, often lead to an ineffective and dangerous set of rules that more often hinder than help in achieving glycemic control (6).

The Joint Committee on Accreditation of Healthcare Organizations considers insulin to be one of its 5 high-alert medications (7) because the consequences of errors with insulin therapy can be catastrophic. Because insulin is central to the care of hyperglycemic inpatients, appropriate administration of insulin is key and safer strategies must be developed. Fortunately, there are abundant data to support several evidence-based methods in use today (6). On the other hand, the limited usage of these methods is a genuine concern.

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Medical errors also remain a much-misunderstood problem (8,9). Most medical errors never cause harm, and are rapidly corrected by those who caused them. Examples of these are slips and lapses, almost ubiquitous events in the care of patients (10). On the other hand, most *injurious* errors are multifactorial, and a systems approach to analyzing these errors offers the best chance to prevent harm to patients (11). Inpatient systems of care are sufficiently complex that a systems approach to analyze hospital processes is necessary to begin to understand how best to make the care safer (12).

### SYSTEMS AND PATIENT SAFETY

A deeper understanding of the relationship between patient safety and the systemic analysis of medical care can begin by realizing the central relationship between quality-of-care issues and patient safety issues. Not all patient safety issues involve preventable causes. For instance, a patient may be injured because of a previously unknown complication to a new drug. Another example would be an accident during transportation of the patient to a site of care. However, apart from nonpreventable patient safety issues, nearly all of the other potentially preventable patient safety issues are part of a distinct subset of injurious medical errors, which in turn are a subset of latent medical errors and system issues. That subset is itself a subset of the quality-of-care issues. These subsets form a collection of nested sets, in the sense that each subset is contained within the previous set. Figure 1 shows the relationship between preventable patient safety issues, injurious medical errors, latent medical errors and systemic issues, and quality-of-care issues.

Although it would be tempting to consider patient safety issues merely a subset of quality-of-care issues, it is the difference between what is commonly studied as a quality-of-care issue and what is termed a patient safety issue that makes this distinction so important. For example, many processes used to count quality measures will not be as useful for patient safety issues because, especially in this litigious healthcare environment, few healthcare workers are comfortable disclosing their medical errors that have resulted in patient safety problems (13).

Furthermore, the remedies for patient safety issues also are quite different than for shortcomings in quality issues. It is one thing to ask that the target for glycemic control be a hemoglobin A1c level below 6.5%. It is quite another thing to identify which doctors are using insulin algorithms that are dangerous to patient care because of either unacceptable hypoglycemia or negligently high glucose levels, and then to effect changes in their behavior.

One useful method to visualize the relationship between systemic factors affecting medical errors and those that occur at the point of care is to contrast the “blunt end” of care with the “sharp end” at the point of care (10). A commonly used diagram is shown in Figure 2.

In the diagram, the apparent error is the nurse giving an incorrect dose of insulin to the patient, which leads to hypoglycemia and injury to the patient. This error may be related to factors under her control (such as her attention and her use of check-offs) as well as factors not under her control, which may have influenced her and increased the likelihood of error. One example of the latter would be the illegible handwriting of the physician, which may be considered a systems issue because it could be avoided with a computerized physician order entry system (CPOE). The

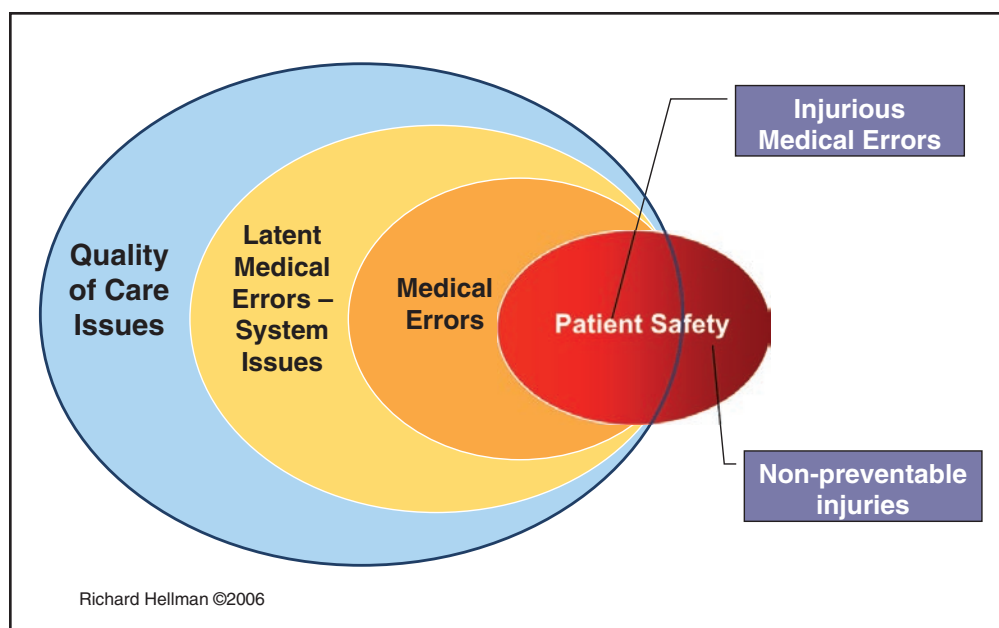


Fig. 1. Relationship between quality, errors, and safety.

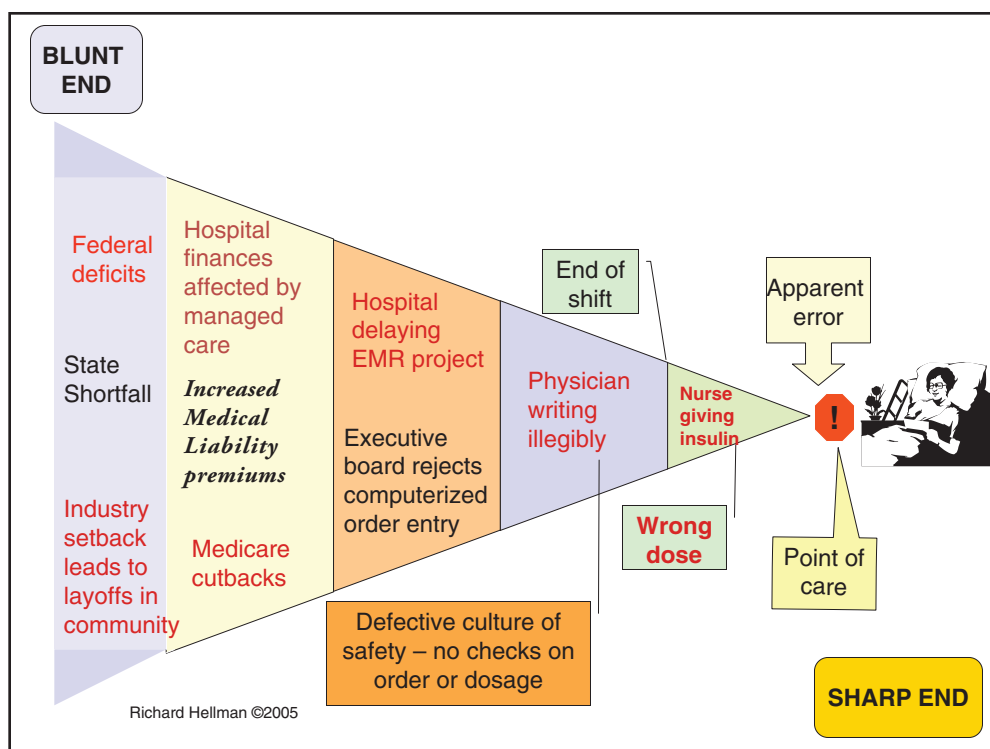


Fig. 2. Systems perspective for medical errors.

effects of forces at the blunt end of care, far away from the hapless nurse, may have profoundly affected the likelihood of her having the time, resources, and technology to easily see the correct dose of insulin for the patient.

The term “culture of safety” (11) refers to a system of care that establishes a collective point of view among its members and results in them working together as a team to protect the patient from accidental injury due to a medical error. Common characteristics of a culture of safety are the timely communication of important clinical information and the presence of “backup” checks in critical settings. One reason why a culture of safety is so important is that, even under the best conditions, excellent physicians and other healthcare providers have only a limited scope of awareness. The concept of “scope of awareness” and its importance in a culture of safety are illustrated in Figure 3.

When resources are stripped from the system of care and the culture of safety is defective, the healthcare system is put under stress (14). Examples of this can be found in many under-funded systems of care, where the race for the bottom line allows money managers to undervalue the importance of a coherent system of backups and clinical checks. An example of the consequence can be seen in Figure 4.

### ERROR-PRONE ORGANIZATIONS

Numerous workers in the field of patient safety have pointed out that error-prone organizations often have simi-

lar characteristics (11,15), such as discounting the importance of training, education, and supervised practice in their workforce (12). There is a real threat to patient safety from unsupervised or poorly educated trainees. In a study of 10,843 caregivers from 203 hospitals in 3 countries (including the United States), Pronovost et al (16) noted that only 58% of the care providers believed that their trainees were supervised adequately. These trainees, because of their inexperience, potentially have a greater risk of causing major medical errors. In the diabetes care setting, the tools we use, such as insulin, have a relatively high risk when misused.

There are other important factors common to error-prone organizations. They are more apt to fail to analyze their own errors carefully, instead focusing on punishment of their front-line personnel at the point of care. This strategy often is severely stressful to the staff. Those at the point of care rarely are in control of the many systemic factors at the “blunt end” of care that often are very powerful in increasing the risk of error. Another feature of error-prone organizations is the high frequency with which instructions to healthcare providers are ambiguous, and no effort is made to inspect the orders to determine what the authors intended or how the recipients are likely to interpret and understand them.

A very common trait of error-prone organizations is the nearly universal failure to spend any significant time designing a system that specifically has a goal of preventing injurious medical errors. Organizations often perceive

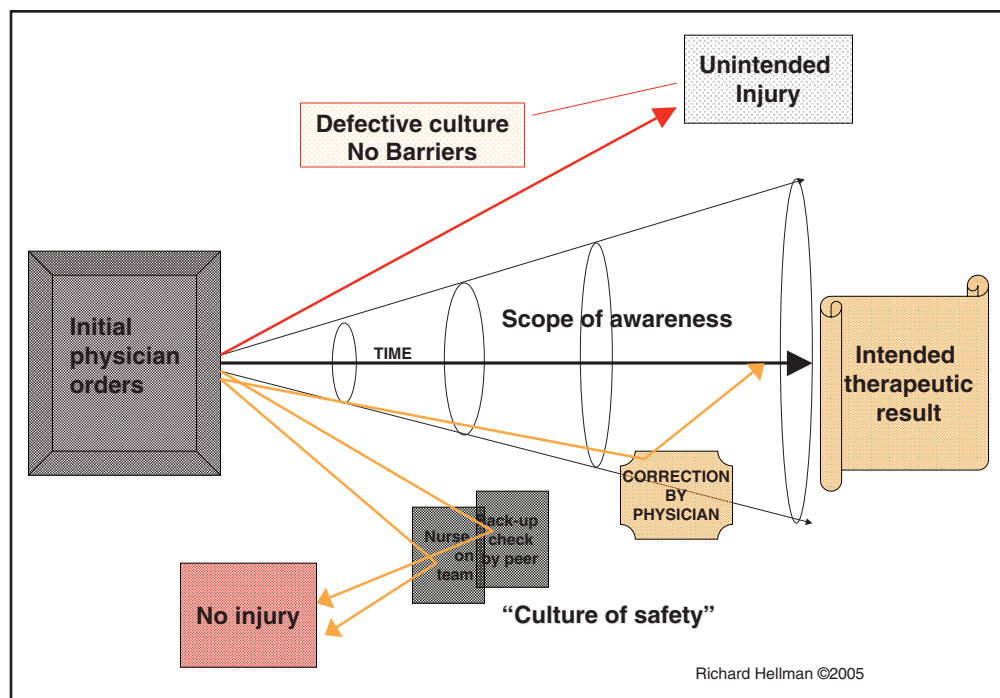


Fig. 3. Culture of safety and the scope of awareness.

medical errors as a moral failure and those who cause them as “bad apples.” The lack of understanding of the nature and ubiquity of medical errors leads to a faulty self-assessment of the system of care, a lack of interest in redesign, and may result in an inability to significantly improve patient safety (15).

### HYPOGLYCEMIA AND A DEFECTIVE CULTURE OF SAFETY

To illustrate how these systemic factors play a role in causing an organization to be error prone in the handling of glycemic control, a problem that often leads to frequent episodes of hypoglycemia, we will review some of the systemic factors commonly involved.

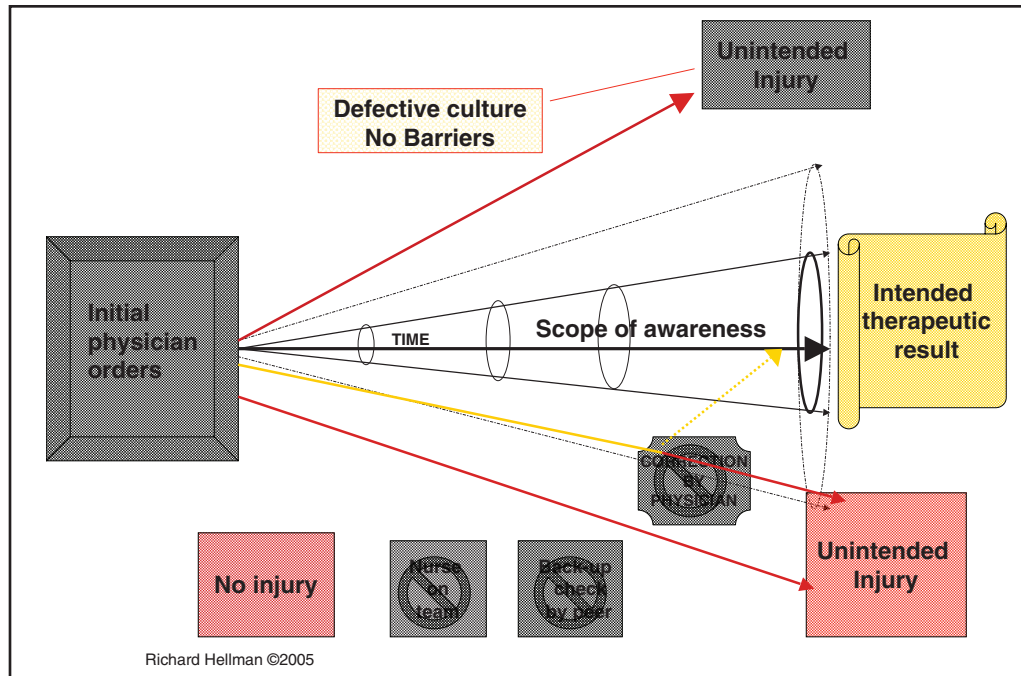
When there is lack of coordination between dietary and nursing departments, there often is resultant mistiming of insulin dosing with respect to food. Dr David Bates (17) reports that hypoglycemia due to this mistiming is extremely common in Boston, and it is widely reported elsewhere as well (2). A well-known latent error is inadequate glucose monitoring; in such cases, the insulin dose is given without any available data on the patient’s current blood glucose level (2). If the glucose level is much lower than anticipated, the dose of insulin may be far more than what would be safe, and hypoglycemia may occur.

The lack of coordination between hospital transportation workers and the nursing department commonly leads to problems similar to those between food and insulin coordination (2,5). If the patient is given the insulin dose on

time, but is transported to the radiology department before the food is given, then the patient may become hypoglycemic. This scenario is a common cause of hypoglycemia among inpatient settings, and is particularly common when the communication between different departments is not a hospital priority (2).

Another factor contributing to avoidable episodes of hypoglycemia in the hospital setting is the problem of undecipherable orders, leading to problems in properly and accurately transcribing the order and carrying it out. The more complex the insulin order, the higher the risk of the recipient not understanding it and thus not carrying it out accurately. This is often compounded by the lack of in-service education or clinical simulations to provide hands-on experience. Moreover, there is a widespread systemic lack of assessment as to how care providers involved with insulin administration are doing with respect to understanding what is being done and why it is being done. Often, only when there is an injurious medical error is there any attention to what the provider understood in the first place.

Other systemic issues that can be corrected are the lack of availability of electronic medical records and CPOEs (1). It should be expected that a well-designed CPOE should significantly reduce errors in ordering and promote safety (18). On the other hand, some data show that a poorly designed CPOE can generate errors (19), and it is probably not true that 50% of orders during transcribing could be eliminated by a CPOE alone. The dispute lies primarily in the estimates of the magnitude of improvements that can be achieved through CPOEs. There is little dispute that a



**Fig. 4.** Culture of safety and the scope of awareness in the system under stress. Note that the lack of backup help from peers, nurses, and other team members dramatically reduces the scope of awareness and inadvertently cause injuries.

well-designed CPOE should be expected to be helpful in error reduction and patient safety (1,18,20), but technology alone is not useful without acceptance by the end users.

There are other important issues that remain. Defective handoffs between clinicians remain a common source of serious errors (21). Defective communication between team members is more apt to occur when transitions occur quickly and with little structure. With respect to preventing hypoglycemia, there are complex clinical factors that must be considered. The effects of treatments and the disease process itself on the variation in insulin requirements may be very complex, and accurate assessment requires a high degree of expertise. In a study of insulin requirements in an intensive care setting with patients on insulin infusions, generic factors accounted for only a small fraction of the variance in insulin requirements (22,23). Expert and trained specialists in diabetes care have an important role in the many decisions made for the hyperglycemic inpatient (2).

Common features that increase the risk of hypoglycemia in the inpatient setting include advanced age, decreased oral intake, chronic renal failure or liver disease, and the use of beta blockers (24,25). The latent error of inappropriate, infrequent glucose monitoring is a common antecedent of hypoglycemia in the hospital setting.

#### INSULIN ALGORITHMS AND SAFETY

The key items needed to safely maintain euglycemia in critical inpatient settings include very frequent glucose monitoring, as often as hourly or more; excellent,

clear, safe algorithms for insulin infusion; trained teams to administer the algorithms correctly; and backup plans for large variances in glucose readings. Nearly all of the systems allow for expert override, so that clinical problems not previously noted or accounted for can be ascertained. It is an error to believe that just one algorithm can account for every conceivable glucose variation; especially because, almost always, the plan is based on assumptions that must be inspected periodically. Even the best algorithms will fail if the method of insulin delivery fails—for instance, if the pharmacist forgets to put the insulin in the infusion bag, or the patient becomes extremely insulin resistant because of a medical catastrophe. There is a need for expert input, in a timely manner, to protect the patient from unanticipated but serious events such as those described above.

Among the points to review when assessing the many available insulin algorithms are the characteristics of the algorithm itself. Is it clearly written, or is it difficult to comprehend for those who will be using it? Is the logic clear and unambiguous? Is it safe? Among the safety issues to consider are whether the intervals of glucose monitoring are sufficiently close together that the rate of decline of glucose levels will not cause hypoglycemia before the next scheduled glucose test. Moreover, the minimum concentration of insulin must be low enough so that the delivery system at its slowest rate does not deliver more than the patient's insulin needs.

An example of this common error is when the pump is only able to deliver fluid at a rate of  $\geq 1$  mL/h, the insulin concentration is 1 U/mL, and the patient's insulin require-

ment is only 0.3 U/h. The correct concentration of insulin should be less than 1 U/mL in this setting, and thus a concentration of 0.1 U of insulin per milliliter would be safer to use.

If the protocol is used for patients having oral intake, the algorithms should have orders for that contingency and for transition to and from the fed state. It is important to know if the protocol has been field tested and whether its performance has been analyzed independently. A common problem is that, without knowing the nature of the patient population on which the algorithm was tested and the conditions for which it was used, it is difficult to assess the utility of the algorithm for the conditions and patient base that it would be serving.

Training the team that will be using the algorithms is another key issue. Too often the hospital administrators are unaware that the training period is a necessity, and without a serious and continued effort to train those using the insulin infusion algorithms, nurses often have a higher rate of error and suboptimal results (2).

#### **PATIENT SAFETY IN HOSPITAL SETTINGS: A TEAM EFFORT**

Most authorities agree that after a physician orders a medication, anywhere from 14 to 40 individual steps must take place before the patient receives the medication. Although many of these steps are not under the control of a physician, they may be a source of serious error. Most safety issues are difficult to resolve without support and leadership of physicians, key administrations, and the hospital staff.

In any complex system—and few are as complex as hospitals—relatively subtle issues early in the sequence of events may have a profound effect. Many of these powerful but subtle issues that profoundly affect patient safety may be outside the physician's scope of awareness, but may be central issues of others. These individuals also need to be a part of the team that works to improve patient safety.

An example is the issue of hypoglycemia that occurs when a transportation worker takes a patient from his or her hospital room before the meal arrives but after the insulin dose is given. This common coordination error cannot be easily resolved without involving the transportation department of the hospital, a group not usually included in clinical discussions.

#### **CONCLUSION**

In January 2005, the American College of Endocrinology held a consensus conference on patient safety (1). Their recommendations are very relevant to achieving increased safety in the control of inpatient glucose levels in patients with diabetes or other causes of hyperglycemia. Their recommendations were:

- Create a culture of safety
- Implement electronic records and information-sharing systems
- Reduce medication errors through CPOEs
- Improve coordination of care
- Improve patient self-care through education and communication

To these recommendations we will add others. It is important to understand the relationship between quality measures and those regarding patient safety. Barriers exist in trying to ascertain the frequency of patient safety issues and in efforts to correct these problems. The concept of "scope of awareness" is useful in understanding why patient safety issues must be a team effort. The development of better algorithms for both intravenous and subcutaneous insulin use is necessary.

The damage that poorly trained persons can do in the care of diabetic inpatients cannot be underestimated, and the ubiquity of this problem is becoming evident. It is a global problem in healthcare. Unfortunately, resources for proper training are not always easily obtainable, but our goal should be to develop a consensus that training, education, and teamwork need to be an integral part of glucose control for inpatients.

Identifying error-prone organizations is important because these facilities may have a pedigree that proves to be a barrier to improving care for inpatients needing glycemic control. However, nearly all healthcare organizations may have flaws in their care system, and because normally there is inertia that resists change, even if improvements are made, they must be revisited and reinforced at regular intervals.

We have a long way to go to make the system of care safe for those with diabetes and other hyperglycemic conditions in the hospital setting. The stakes are too high for us to delay our efforts further. It is gratifying to see the progress being made currently in a wide variety of settings, both in the United States and abroad. Our goal should continue to be keeping our patients normoglycemic during their hospital stay. The tools are now available to make this happen—not just for a select few, but for nearly all patients under current care.

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