

MEMOIRS OF A ROOT CANAL SALESMAN: THE SUCCESSFUL IMPLEMENTATION OF A HOSPITAL-WIDE INTRAVENOUS INSULIN INFUSION PROTOCOL

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ABSTRACT

Objective: To summarize key metabolic results from use of the Yale Insulin Infusion Protocols (IIPs), as well as the primary barriers to their implementation. To offer practical suggestions for overcoming these barriers, drawing from our experiences “selling root canals” during the successful implementation of our hospital-wide IIPs.

Methods: Since 2002, Yale IIPs have been employed to achieve strict glycemic control in our ICU patients. Barriers to protocol implementation were noted, and strategies were designed to overcome these barriers.

Results: In 2002, we implemented Version 1 of the Yale IIP, which purposefully targeted conservative blood glucose (BG) levels of 100 to 139 mg/dL. Following extensive hospital-wide experience with Version 1, Version 2 of the IIP (which debuted in 2004) successfully lowered BG targets to 90 to 119 mg/dL, with minimal impact on observed rates of hypoglycemia. These nurse-driven protocols safely and effectively controlled glucose levels in our ICU patients, without the need for ongoing physician supervision.

Conclusion: This work describes the successful implementation of an evolving hospital-wide IIP. To be successful, an IIP must account for the following essential elements: (1) the current BG level, (2) the velocity of glycemic change, and (3) the current insulin infusion rate. We have reviewed five “points of emphasis” to consider when implementing an IIP. (*Endocr Pract.* 2006;12[Suppl 3]:79-85)

Abbreviations:

AACE = American Association of Clinical Endocrinologists; **BG** = blood glucose; **CTICU** = cardiothoracic intensive care unit; **ICU** = intensive care unit; **IIP** = insulin infusion protocol; **IV** = intravenous; **MICU** = medical intensive care unit; **TTD** = total daily dose

INTRODUCTION

Across a wide variety of clinical settings, strict glycemic control improves outcomes in critically ill patients (1-6). In 2001, following the publication of a high-profile randomized controlled trial in the *New England Journal of Medicine* (5), we sought to improve the standard of care for hyperglycemic patients in our intensive care units (ICUs). At the time, published insulin infusion protocols (IIPs) (1,3,5) provided useful “guidelines” for managing intravenous (IV) insulin. However, these protocols could not effectively automate the insulin infusion process. In our ICUs, use of published IIPs required continuous expert supervision and produced a local “epidemic” of hypoglycemia (7).

To improve glycemic control in our ICU patients, we designed the Yale Insulin Infusion Protocol in 2002. Using this protocol, we safely and effectively lowered blood glucose (BG) levels to 100 to 139 mg/dL in our medical intensive care unit (MICU) (8). We then successfully employed the same protocol for patients undergoing cardiothoracic surgery (9). In 2004, following publication of the American College of Endocrinology (ACE) Position Statement on Inpatient Metabolic Control (10), we revised our protocol (Yale IIP Version 2), achieving lower BG targets of 90 to 119 mg/dL without significantly increasing risks for hypoglycemia (11). Implementing a hospital-wide IIP is an onerous task, during which a variety of barriers must be overcome. In the Winter 2005 issue of *Diabetes Spectrum* (7), we reviewed the practical lessons learned while implementing these protocols throughout our hospital. A summary of this work is provided herein.

This present report was prepared as part of the “Improving Diabetes Care: A Call to Action” conference, co-sponsored by the American College of Endocrinology (ACE) and the American Diabetes Association (ADA), which took place on January 30-31, 2006, in Washington, DC. The purpose of this article is threefold: (1) to review the necessary components of a successful IIP, (2) to summarize clinical data obtained using sequential versions of the Yale IIP, and (3) to summarize the practical lessons we learned (the hard way) during the difficult process of IIP

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implementation. Naturally, the content of this article draws largely from our previous publications (7-9,11).

DESIGNING AN EFFECTIVE INSULIN INFUSION PROTOCOL

During our initial efforts to implement published IIPs in 2002, we immediately experienced a local “epidemic” of hypoglycemia. We quickly surmised that existing IIPs, while providing valuable “guidelines” for insulin therapy, were unable to completely automate the insulin infusion process. For example, consider the following clinical scenario: a 62-year-old man with type 2 diabetes, acute pancreatitis (receiving total parenteral nutrition), and adult respiratory distress syndrome (receiving IV corticosteroids) is receiving 15 U/h of IV insulin. At 2:00 PM, his fingerstick BG is 360 mg/dL. One hour later, at 3:00 PM, his BG has declined to 160 mg/dL. How should this patient’s insulin infusion be adjusted?

Based on his rapid rate of BG decline (200 mg/dL/h), logic suggests that the insulin infusion must be slowed significantly, to prevent hypoglycemia. Indeed, should this patient’s glucose level continue to decrease at its current rate, severe hypoglycemia would be predicted within the hour. However, in accordance with the published IIPs available in 2002, this patient’s insulin drip rate would remain unadjusted (3), or might even be increased to 16 U/h (5). Such actions almost certainly would result in severe hypoglycemia. Based on medical record reviews from our ICUs, we learned that real-life scenarios such as these were responsible for most of our hypoglycemic events. Therefore, we concluded that clinical experience (guiding logical deviations from protocol) is a prerequisite for successfully employing published IIPs. At the time, our ICU physicians and nurses simply lacked the necessary experience to effectively manage IV insulin infusions.

Therefore, in 2002, we designed our own IIP, incorporating the 3 essential elements used by experienced endocrinologists to guide IV insulin therapy: (1) the current BG level, (2) the “velocity” of glycemic change, and (3) the current insulin infusion rate. Our goal was to create an automated protocol that could be safely and effectively implemented by our ICU nursing staff, with minimal need for ongoing physician supervision. Version 1 of our IIP was first published in the February 2004 issue of *Diabetes Care* (8). Version 2, with lower BG targets of 90 to 119 mg/dL (discussed below), has been reproduced here (Fig. 1) (11). This updated version of the IIP is currently in use throughout our institution and in many others.

RESULTS FROM THE YALE IIP, 2002-PRESENT

In 2004, we reported metabolic outcomes from Version 1 of our IIP, which was employed 69 times in 52 patients admitted to our MICU. (The IIP could be used more than once per patient.) Sixty-two percent of these patients were

male, and 63% were Caucasian. Their mean (\pm SD) age was 59 ± 18 years, mean body mass index (BMI) was 28.3 ± 8.3 kg/m², and mean APACHE II score was 23.9 ± 9.2 . Fifty-six percent had a known history of diabetes mellitus. Figure 2 shows our primary metabolic results (7). From a mean BG level of 299 ± 96 mg/dL at drip initiation, the median time required to achieve our narrow target BG range of 100 to 139 mg/dL was 9 hours. Once BG levels decreased to below 140 mg/dL, 52% of 5,808 subsequent values fell within our narrow target range, whereas 66% fell within a “clinically desirable” range of 80 to 139 mg/dL. Mean BG levels (by patient) were 123 mg/dL. Hypoglycemia, present in just 0.3% of BG levels (or 5.4% of patient days), produced no clinically significant events. Predictably, IIP results were unaffected by age, gender, severity of illness, or diabetes status.

Version 1 of the IIP worked equally well in the cardiothoracic intensive care unit (CTICU). In 2 such units (one at Yale, the other in a local community hospital), the IIP was employed 137 times in 118 patients. Sixty-three percent of these patients were male, and 94% were Caucasian. Their mean (\pm SD) age was 69 ± 12 years, mean BMI was 29.0 ± 6.3 kg/m², and mean APACHE II score was 17.0 ± 7.5 . Thirty-four percent had a known history of diabetes mellitus. From a mean BG level of 218 ± 53 mg/dL at drip initiation, the median time required to achieve target BG levels was 5 hours. Once BG levels declined into target range, 58% of 2,242 subsequent values fell between 100 and 139 mg/dL, whereas 73% fell within a “clinically desirable” range of 80 to 139 mg/dL. Mean BG levels (by patient) were 121 mg/dL. Hypoglycemia, occurring in just 0.2% of BG levels (or 2.9% of patient days), again produced no clinically significant events. In our CTICUs, as in the MICU, results were unaffected by age, gender, severity of illness, or diabetes status.

Following publication of the ACE position statement in 2004, and after familiarization with our IIP throughout our hospital, we chose to lower our BG target range to 90 to 119 mg/dL. Version 2 of the Yale IIP (Fig. 1) was then tested in 47 MICU patients and 54 CTICU patients. Metabolic results were published in the Summer 2005 issue of *Diabetes Spectrum*. Compared with Version 1, Version 2 effectively lowered mean BG levels (from 123 to 118 mg/dL in the MICU, and from 121 to 109 mg/dL in the CTICU) and increased the proportion of BG levels within the “desirable range” of 80 to 139 mg/dL (from 52% to 56% in the MICU, and from 58% to 66% in the CTICU), without significantly increasing the risk of hypoglycemia. In addition, by providing a larger initial IV insulin bolus, Version 2 achieved target BG levels more rapidly. Finally, Version 2 employs only JCAHO-compliant terminology.

We have been made aware that our IIP is being successfully employed by several institutions across the country. For example, at the AACE Consultants Course V in October 2005 (12), Dr Adam Kelman presented results using the Yale IIP at Valley Hospital in Ridgewood, New



THE NEW* YALE INSULIN DRIP PROTOCOL



The following insulin drip protocol is intended for use in hyperglycemic adult patients in an ICU setting, but is not specifically tailored for those individuals with diabetic emergencies, such as diabetic ketoacidosis (DKA) or hyperglycemic hyperosmolar syndrome (HHS). When these diagnoses are being considered, or if BG ≥ 500 mg/dL, an MD should be consulted for specific orders. Also, please notify an MD if the response to the insulin drip is unusual/unexpected, or if any situation arises that is not adequately addressed by these guidelines. The starting dose, adjustments, and glucose targets have been intensified.

Initiating an Insulin Drip

- 1) **INSULIN INFUSION:** Mix 1 unit of Regular Human Insulin per 1 cc 0.9% NaCl. Administer via infusion pump (in increments of 0.5 U/h).
- 2) **PRIMING:** Flush 50 cc of Insulin/NS drip through all IV tubing, before infusion begins (to saturate the insulin binding sites in the tubing)
- 3) **THRESHOLD:** IV insulin is indicated in any critically ill patient with persistent BG ≥ 140 mg/dL; consider use if BG ≥ 110 mg/dL.
- 4) **TARGET BLOOD GLUCOSE (BG) LEVELS:** **90-119 mg/dL***.
- 5) **BOLUS & INITIAL INSULIN DRIP RATE:** If initial BG ≥ 150 , divide initial BG level (mg/dL) by 70, then round to nearest 0.5 units for bolus AND initial drip rate. If initial BG < 150 mg/dL, divide by 70 for initial drip rate only (i.e., NO bolus)

Examples: (1) Initial BG = 335 mg/dL: $335 \div 70 = 4.78$, rounded \uparrow to 5: 5 units IV bolus + start drip @ 5 U/h.
 (2) Initial BG = 148 mg/dL: $148 \div 70 = 2.11$, rounded \downarrow to 2: start drip @ 2 U/h (NO bolus)

Fingerstick (FS) Blood Glucose Monitoring

- 1) Check FS hourly until stable (defined as 3 consecutive values in target range). In hypotensive patients, capillary blood glucose (i.e., fingersticks) may be inaccurate, and obtaining a blood sample from an indwelling vascular catheter may be preferable.
- 2) Once stable, check FS q 2 hours; once stable $\times 12-24$ hours, FS checks can be spaced to q 4 hours IF:
 - a) no significant change in clinical condition AND
 - b) no significant change in nutritional intake
- 3) If any of the following occur, consider the temporary resumption of hourly FS monitoring, until BG is again stable:
 - a) any change in insulin drip rate (i.e., BG out of target range)
 - b) significant changes in clinical condition
 - c) initiation or cessation of pressor or steroid therapy
 - d) initiation or cessation of dialysis or CVVH
 - e) initiation, cessation, or rate change of nutritional support (TPN, PPN, tube feedings, etc.)

Changing the Insulin Drip Rate

If BG < 50 mg/dL:

D/C INSULIN DRIP Give 1 Amp (25 g) D50 IV; recheck BG q 15 minutes

\Rightarrow When BG ≥ 90 mg/dL, wait 1 hour, recheck BG, then restart drip at 50% of most recent rate (if BG still ≥ 90 mg/dL).

If BG 50-69 mg/dL:

D/C INSULIN DRIP If symptomatic (or difficult to assess), give 1 Amp (25 g) D50 IV; recheck BG q 15 minutes

If asymptomatic, consider 1/2 Amp (12.5 g) D50 IV or 8 ounces juice PO; recheck BG q15-30 minutes

\Rightarrow When BG ≥ 90 mg/dL, wait 1 hour, recheck BG, then restart drip at 75% of most recent rate (if BG still ≥ 90 mg/dL).

Changing the Insulin Drip Rate (cont'd.)

If BG ≥ 70 mg/dL:

STEP 1: Determine the CURRENT BG LEVEL - identifies a COLUMN in the table:

BG 70-89 mg/dL	BG 90-119 mg/dL	BG 120-179 mg/dL	BG ≥ 180 mg/dL
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STEP 2: Determine the RATE OF CHANGE from the prior BG level - identifies a CELL in the table - Then move right for **INSTRUCTIONS:**

[Note: If the last BG was measured 2-4 hours before the current BG, calculate the hourly rate of change. Example: If the BG at 2PM was 150 mg/dL and the BG at 4PM is now 120 mg/dL, the total change over 2 hours is -30 mg/dL; however, the hourly change is $-30 \text{ mg/dL} \div 2 \text{ hours} = -15 \text{ mg/dL/h}$.]

BG 70-89 mg/dL	BG 90-119 mg/dL	BG 120-179 mg/dL	BG ≥ 180 mg/dL	INSTRUCTIONS*
		BG \uparrow by > 40 mg/dL/h	BG \uparrow	\uparrow DRIP by "2 Δ "
	BG \uparrow by > 20 mg/dL/h	BG \uparrow by 1-40 mg/dL/h OR BG UNCHANGED	BG UNCHANGED OR BG \downarrow by 1-40 mg/dL/h	\uparrow DRIP by " Δ "
BG \uparrow	BG \uparrow by 1-20 mg/dL/h, BG UNCHANGED, OR BG \downarrow by 1-20 mg/dL/h	BG \downarrow by 1-40 mg/dL/h	BG \downarrow by 41-80 mg/dL/h	NO DRIP CHANGE
BG UNCHANGED OR BG \downarrow by 1-20 mg/dL/h	BG \downarrow by 21-40 mg/dL/h	BG \downarrow by 41-80 mg/dL/h	BG \downarrow by 81-120 mg/dL/h	\downarrow DRIP by " Δ "
BG \downarrow by >20 mg/dL/h <i>see below</i> [†]	BG \downarrow by >40 mg/dL/h	BG \downarrow by >80 mg/dL/h	BG \downarrow by >120 mg/dL/h	HOLD DRIP x 30 min, then \downarrow DRIP by "2 Δ "

***CHANGES IN DRIP RATE** ("delta" or " Δ ") determined by the current drip rate:

Current Drip Rate (units/hour)	Δ = Rate Change (units/hour)	2 Δ = 2x Rate Change (units/hour)
<3	0.5	1
3-6	1	2
6.5-9.5	1.5	3
10-14.5	2	4
15-19.5	3	6
20-24.5	4	8
≥ 25	≥ 5	10 (& notify MD)

[†]D/C INSULIN DRIP;

^vBG q 30 min; when BG ≥ 90 mg/dL, restart drip @75% of most recent rate.

Goldberg PA & Inzucchi SE, Yale University 11/04

Fig. 1. Yale Insulin Infusion Protocol, Version 2. Reproduced with permission.

Jersey. Dr Kelman's results exceeded our own; at Valley Hospital, patients had an average BG level of 121 mg/dL and spent 71% of their time within the target BG range, with hypoglycemia being rare (and clinically insignificant). With minor modifications, Dr Kelman also converted our IIP into a computer-based algorithm. As a result, his ICU nurses no longer need to perform manual calculations, saving nursing time and reducing human errors (12). Computer-based programs such as these, once available nationally, certainly will advance the ACE/ADA cause of improving inpatient glycemic control.

“SELLING ROOT CANALS” – OVERCOMING BARRIERS TO THE SUCCESSFUL IMPLEMENTATION OF AN IIP

For a variety of reasons, including the “culture” of inpatient BG management, clinicians' fears of hypoglycemia, and staff unfamiliarity with intensive insulin therapy, implementing an intensive IIP is an onerous task, akin to “selling root canals.” Over the past 4 years, our institution has devoted significant time and efforts to improving patient care in this regard. As a result, we were asked to summarize the practical lessons we learned (the hard way) while implementing our IIP (7). In the Winter 2005 edition of *Diabetes Spectrum*, we reviewed 5 points of emphasis, which are summarized below:

1. Educate Your Nursing Allies

Intensive insulin therapy significantly increases workload for an ICU nursing staff. This fact must be openly acknowledged during initial “marketing” to ICU nurses. At Yale we found that, once our nurses understood the *purpose* and *potential benefits* of the IIP, they were quite eager to employ it, despite the extra work that it created. In fact, in

many cases we found that certain ICU nurses were instrumental in expediting the protocol's implementation. During our 45-minute in-service training sessions, we spent most of our time simply explaining the *value* of strict glycemic control—specifically by summarizing key clinical data from Leuven (5), Portland (3,4), and other studies. During oral and written feedback following these in-services, we found that our ICU nurses responded very favorably to this approach. Many nurses reported that they had not been aware of the value of strict glycemic control.

When implementing an IIP, special efforts must be devoted to helping the nursing staff adapt to the increased workload. For example, at our hospital, we quickly uncovered a significant shortage of glucose meters. With so many new patients on IV insulin, purchasing additional glucose meters for each ICU was necessary. Additionally, many nurses initially complained about the excessive time required to locate a glucose meter, perform the fingerstick, chart the results, and change the insulin drip rate. To address these issues, assigned duties performed by our ICU nurses' aides were expanded. Finally, to maximize efficiency and minimize unnecessary fingersticks, nurses were encouraged to use venous or arterial blood samples attained for other purposes. We recognized that, although glucose measurements from these sources may differ slightly, the magnitude of these differences was unlikely to be of clinical relevance.

Once these issues were addressed, the IIP was extremely well received throughout our institution. In our MICU, 73% of nurses rated our IIP as either “very easy” or “somewhat easy.” Seventy-five percent reported that the protocol was “an overall improvement” compared with the prior nonstandardized guidelines for insulin infusion. The IIP was equally well received by our other ICUs. By empowering nurses to take control of patients' BG levels, we

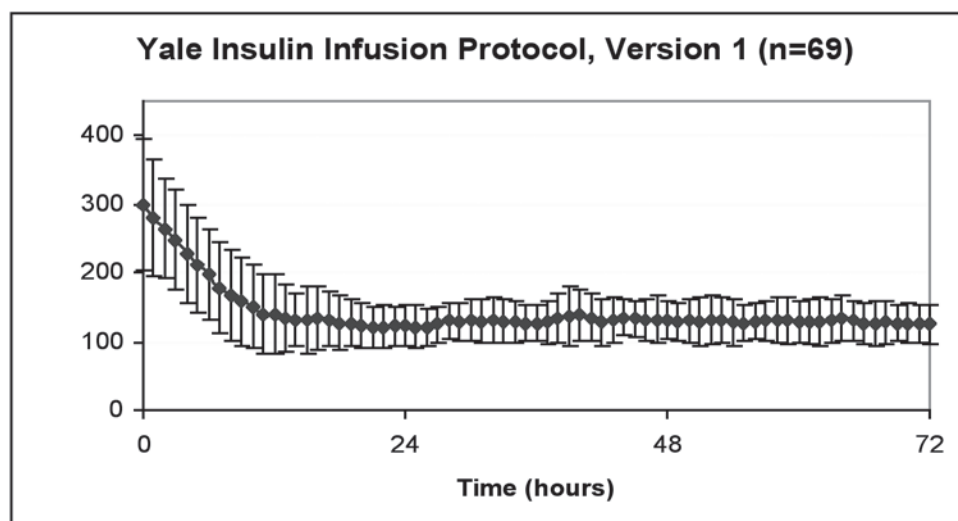


Fig. 2. Blood glucose (BG) results (mean \pm SD) obtained during initial implementation of the Yale Insulin Infusion Protocol (Version 1) in a medical intensive care unit.

discovered that the IIP actually could *reduce* some of the nursing time and effort spent on managing BG levels. For example, the IIP dramatically reduced the need for nurses to page physicians (and wait for the return call) for specific insulin orders.

2. Recruit and Educate Clinician Allies in Each Unit

For the most part, endocrinologists are poorly suited to provide continuous consultations for hospitalized patients. To ensure the success of an IIP, *local* (i.e., physically present) clinicians must be recruited and trained to serve as local “experts.” To get one’s foot in the door with ICU clinicians, data regarding the value of strict glycemic control should first be presented at medical/surgical grand rounds, or at a critical care conference. During this process, it must be remembered that, until recently, critical care physicians placed little (if any) emphasis on glycemic control. As a result, they may be completely unaware of the potential benefits of IV insulin therapy.

Physicians also should understand that IIPs actually would *reduce* their workload, by automating a process that otherwise would require the constant revision of insulin orders. Where possible, hospital administrators also should be involved with quality control in the ICUs, particularly if (or when) JCAHO begins to mandate national standards for inpatient BG management. Last, periodic meetings with hospital and nursing administration are helpful to identify and correct problems in real time.

3. Dispel the Myths of Hypoglycemia

Until recently, unrealistic fears of hypoglycemia were rampant in the vast majority of US hospitals. For decades, based largely on these unfounded fears, medical culture accepted moderate hyperglycemia as “normal,” altering the perceived definition of normal glucose levels for hospitalized patients. In 2001, when polled about “ideal” BG levels for their patients, most of our ICU nurses preferred BG levels in the high 100s, or even the low 200s, specifically to avoid hypoglycemia. Double-digit BG values, including normal levels between 70 and 99 mg/dL, typically were treated with oral carbohydrates or IV dextrose infusions. To our surprise, in 2002, many of our ICU nurses were unable to accurately report normal glucose ranges, probably because they encountered them so rarely.

During our in-services, when presented with strict BG targets, our ICU nurses immediately voiced their concerns about creating hypoglycemia in their patients. Many nurses, especially those from our surgical units, feared being “blamed” for these hypoglycemic events. From the clinician or hospital administration standpoint, hypoglycemia also is an important liability issue because it represents an “act of commission” that may be more challenging to defend in the courts (13). Fortunately, we and others now have generated sufficient data to demonstrate that clinically relevant hypoglycemia is exceedingly rare when imple-

menting successful IIPs (5,8-12). At our institution, even using IIP Version 2, BG levels below 60 mg/dL comprised just 0.3% of BG levels in the CTICU, and 0.4% of BG levels in the MICU. Stated another way, hypoglycemia occurred during just 3.0% of CTICU patient days and 7.1% of MICU patient days. Despite careful independent scrutiny, not a single episode of hypoglycemia in either unit was associated with adverse clinical sequelae.

4. Encourage Forethought and Troubleshooting

Although IIPs can essentially automate IV insulin infusions, nurses and clinicians must use their clinical skills to anticipate and prevent glycemic excursions. Several common clinical interventions, such as corticosteroids, vasopressors, enteral nutrition, and parenteral nutrition, have been clearly associated with hyperglycemia in ICU patients (14). Thus, when these interventions are started or stopped, insulin infusions should be adjusted empirically. Patient excursions from the ICU for diagnostic tests or procedures, or “field trips,” should be taken into consideration and planned for appropriately. For example, consider that a patient is receiving enteral feedings (containing 30 g of carbohydrates per 240-mL can) at 80 mL/h, representing 10g/h of carbohydrate intake. When the patient’s tube feedings are held in preparation for a computed tomography scan, substituting D10 (containing 10 g of dextrose per deciliter) at 100 mL/h would match the ongoing insulin infusion, allowing a stable drip to continue uninterrupted.

Finally, it is critical to recognize that each hospital and hospital unit possesses its own local culture and unique set of challenges. This may necessitate some “fine tuning” during IIP implementation. Although the underlying concepts remain constant, IIPs may not be “one size fits all” with regard to protocol details. To this end, close and constant collaboration with clinicians, nurses, pharmacists, and hospital administrators is key.

5. “Now What?” Address Transition to Subcutaneous Insulin Therapy

Once patients are placed on an IV insulin protocol, transition protocols to subcutaneous insulin therapy must be employed to facilitate patient transfer to subacute units. There are several rational approaches to this issue, the best of which employ a “basal-bolus” method of subcutaneous insulin therapy. For example, Bode et al (15) recommend calculating each patient’s 24-hour insulin requirements by extrapolating the last 6 to 8 hours of IV insulin infusion, then using 80% of this total as the total daily dose (TDD). Fifty percent of this TDD is then provided as basal insulin (usually glargine or NPH), and the other 50% is given as mealtime rapid-acting insulin analogs. An alternate method, advocated by Abern et al (16), employs the final hour’s insulin infusion rate to calculate subcutaneous NPH and regular insulin doses. At our institution, we currently add up the last 8 hours of IV insulin, then double this total

to obtain our TDD. This TDD is then split 50-50 between basal and bolus insulin preparations. Our method, although very similar to (and in fact derived from) that of Bode et al, employs slightly more conservative insulin doses (67% versus 80%) and is easier to calculate.

CONCLUSION

There are a number of successful published IIPs. To be successful, a protocol must account for the following 3 essential elements: (1) the current BG level, (2) the velocity of glycemic change, and (3) the current insulin infusion rate. In 2002, we effectively implemented Version 1 of the Yale IIP, which purposefully targeted conservative BG levels of 100 to 139 mg/dL. This nurse-driven protocol safely and effectively controlled glucose levels in our ICU patients, without the need for ongoing physician supervision. Following extensive hospital-wide experience with Version 1, Version 2 of the IIP (which debuted in 2004) successfully lowered BG targets to 90 to 119 mg/dL, with minimal impact on observed rates of hypoglycemia. This report summarizes the major results from our own IIPs, as well as the primary barriers to their implementation. Also provided are a number of practical suggestions for overcoming these barriers. It is hoped that this work will empower other institutions to better achieve strict glycemic control in their critically ill patients.

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