

ISMP



2017

**ISMP Guidelines for  
Optimizing Safe Subcutaneous  
Insulin Use in Adults**

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*Cover photo taken by ISMP fellow Ghadeer Banasser.*

## Introduction

Diabetes mellitus is an increasingly common diagnosis encountered and managed in both the inpatient and outpatient settings. One of the primary goals in diabetes treatment is to reduce episodes of hyperglycemia while minimizing the risk of hypoglycemic episodes. While subcutaneous insulin therapy is the cornerstone of hyperglycemic treatment, insulin is a high-alert medication that can be associated with significant patient harm when used in error.



### *Insulin as a High-Alert Medication*

Medications that are associated with the highest risk of injury when used in error are known as high-alert medications. Insulin has long been identified as belonging to this group of medications.<sup>1</sup> According to a 2014 survey of pharmacists and nurses conducted by the Institute for Safe Medication Practices (ISMP), intravenous (IV) insulin ranked first, and subcutaneous insulin ranked ninth among nearly 40 drugs and drug classes identified as high-alert medications that concerned practitioners.<sup>2</sup> Yet, of all the high-alert medications, subcutaneous insulin came in last place when pharmacists and nurses were asked to rank how confident they were regarding the effectiveness of hospital-wide precautions to prevent serious errors. The survey findings suggest a consensus among pharmacists and nurses that hospitalized patients are vulnerable to errors with subcutaneous insulin, and that more must be done to prevent patient harm with this high-alert medication.

### *Incidence of Insulin Errors*

For many years, insulin has been shown to be associated with more medication errors than any other type or class of drugs. As early as 1998, insulin was associated with 11% of all harmful medication errors in hospitals.<sup>1</sup> More recent studies add evidence to the high frequency of insulin involvement in harmful medication errors. In 2004, a state reporting program established that 25% of all reported medication errors involved high-alert medications, and 16% involved insulin alone.<sup>3</sup> Data published in 2008 showed that insulin was the leading drug involved in harmful medication errors, representing 16% of all medication error events with reported harm.<sup>4</sup> A 2010 study found that the most common medical errors in critical care patients were insulin administration errors.<sup>5</sup>

### *Types and Causes of Insulin Errors*

A variety of error types have been associated with insulin therapy, including administration of the wrong insulin product, improper dosing (under-dosing and overdosing), dose omissions, incorrect use of insulin delivery devices, wrong route (intramuscular versus subcutaneous), and improper patient monitoring. Many errors result in serious hypoglycemia or hyperglycemia.

Hypoglycemia is often caused by a failure to adjust insulin therapy in response to a reduction in nutritional intake, or an excessive insulin dose stemming from a prescribing or dose measurement error.<sup>6-8</sup> Other factors that contribute to serious hypoglycemia include inappropriate timing of insulin doses with food intake, creatinine clearance, body weight, changes in medications that affect blood glucose levels, poor communication during patient transfer to different care teams, and poor coordination of blood glucose testing with insulin administration at meal times.<sup>9</sup>

Hyperglycemia commonly results from reliance on only sliding scale insulin to control blood glucose, a failure to optimize treatment by increasing the dose of insulin, dosing errors, and dose omissions.<sup>6,7</sup> Stress from an illness, injury, or surgery; lack of exercise; not following a diabetic diet plan; not injecting insulin properly; using expired insulin; using certain medications that affect blood glucose levels; or not taking insulin as prescribed due to fear of weight gain are additional factors that contribute to hyperglycemia.<sup>10</sup> Other system-based barriers to achieving glycemic control include communication failures during **TRANSITIONS OF CARE**, glucose testing that is not coordinated well with meals and drug therapy, knowledge deficits surrounding treatment, lack of automated clinical alert systems to track and trend glycemic control, and the amount of incremental nursing time needed for complex insulin management.<sup>11,12</sup> Suboptimal prescribing of insulin, which also leads to hyperglycemia, may be due to a lack of knowledge and expertise on the part of the prescriber or fear of causing hypoglycemia.<sup>6</sup>

## Risk Associated with Subcutaneous Insulin Use in Adults

Although insulin can be lifesaving, it can also cause life-threatening injuries or death when used inappropriately as both overdoses and under-doses of insulin can cause harm.<sup>7</sup> In an inpatient setting, manifestations of poor glycemic control—including severe hypoglycemia and hyperglycemia—are deemed hospital-acquired conditions by the Centers for Medicare and Medicaid Services (CMS). CMS notes that poor glycemic control can be reasonably prevented with implementation of evidence-based guidelines; thus, the Agency denies payment for diabetic ketoacidosis, hypoglycemic coma, and other serious conditions related to poor glycemic control.<sup>13</sup>

Hypoglycemia is associated with significant morbidity and mortality, particularly from cardiovascular, cerebrovascular, and patient fall events.<sup>9,14,15</sup> Insulin was implicated in 33% of medical errors that caused death within 48 hours of the error.<sup>16</sup> A review in 2011 of more than 16,000 patient safety incidents involving insulin showed that 24% resulted in patient harm.<sup>17</sup> A 2011 study of emergency hospitalizations for adverse drug events in older Americans reported that insulin was one of four medications implicated in 67% of all emergency admissions due to adverse drug events.<sup>18</sup>

A more recent 2014 study looked at national estimates of insulin-related hypoglycemia and errors leading to emergency department (ED) visits and hospitalizations.<sup>9</sup> This study found there were nearly 100,000 visits for insulin-related hypoglycemia annually, with one-third resulting in hospitalization. Severe neurological outcomes were documented in an estimated 61% of ED visits for insulin-related hypoglycemia, and blood glucose levels of 50 mg/dL or less were recorded in more than half of the cases. This study also found that patients 80 years old or older were twice as likely to visit an ED for evaluation of insulin-related hypoglycemia than those 45-79 years old, and patients in the oldest group were almost five times more likely to be hospitalized than those 45-64 years of age. Inpatient episodes of hypoglycemia have resulted in increased mortality (particularly in critically ill patients), longer length of stay (by 3 days) and subsequent higher inpatient charges (38.9%), and a greater risk of discharge to a skilled nursing facility rather than home.<sup>19-22</sup>

Hyperglycemia is also common in inpatients.<sup>23</sup> Managing inpatient hyperglycemia can be difficult if the patient experiences fluctuations in their nutritional status, or if they are prescribed medications or fluids that cause hyperglycemia (e.g., steroids or dextrose).<sup>11,12</sup> Ketoacidosis and hyperosmolar hyperglycemia are the two most serious metabolic complications in patients with diabetes.<sup>10</sup> The mortality rate in patients with diabetic ketoacidosis is about 5%, and for hyperosmolar hyperglycemic state is 15%. The prognosis is worse for the very young and the elderly, and in the presence of comorbid conditions such as hypotension.<sup>10</sup>

### **Targeted Priority Areas of Risk**

While many healthcare organizations have focused improvement activities on the safe prescribing, dispensing, preparation, and administration of subcutaneous insulin along with proper patient monitoring and education, insulin errors and unanticipated harmful consequences persist. ISMP has published numerous cases involving deadly and harmful insulin-related errors and has served as a safe practice authority on the use of this medication. During the past several years, ISMP, along with other healthcare organizations, has identified several specific categories of risk associated with subcutaneous insulin use that have been overlooked and inadequately addressed in healthcare organizations.

## RISK ASSOCIATED WITH PRESCRIBING SUBCUTANEOUS INSULIN

### *Errors and poor outcomes with sliding scale insulin dosing*

Studies demonstrate, and experts agree, that there is little evidence for using only sliding scale insulin to control blood glucose.<sup>10,24,25</sup> A number of published articles have also focused on the problems associated with sliding scale insulin, primarily related to the heightened risk of errors with this dosing method and the “roller coaster” effect on blood glucose levels that often results.<sup>10,24,26,27</sup> Authors of a literature review concluded that fluctuating glucose levels are more harmful physiologically than levels that are continuously elevated.<sup>28</sup> Yet, sliding scale insulin using multiple complex or non-standard insulin algorithms remains a treatment strategy at some US hospitals, leading to confusion, wrong dose errors, and untoward patient outcomes.<sup>24,27,29</sup>

According to the 2017 American Diabetes Association (ADA) guidelines, non-critically ill, diabetic patients who are hospitalized should be managed with scheduled subcutaneous insulin doses that include **BASAL, NUTRITIONAL**, and **CORRECTIONAL** components as the preferred method for achieving and maintaining glucose control.<sup>10</sup>

### *Variable or absent insulin standard order sets*

Authoritative guidelines and consensus statements from the Endocrine Society, ADA, American Association of Endocrinologists (AAE), and American College of Endocrinology (ACE) recommend a defined format for prescribing all insulin orders (e.g., preprinted order forms, computerized order sets in electronic prescribing systems).<sup>10,30-32</sup> Yet, some organizations function without standardized insulin orders and therefore are prone to variability and misinterpretation given the number of look-alike insulin products (e.g., Huma**LOG**, Humu**LIN**, Novo**LOG**, Novo**LIN**) and potential use of the error-prone abbreviation “U” for units in either uppercase (U) or lowercase (u), which can be confused as a “zero” or the number “four.”<sup>33</sup> In addition, the abbreviation IU for “international units” is commonly seen on labeling outside the US and is also considered error prone. (See Statement 1.7.)

Use of standard order sets can also help prescribers and other clinicians consider important factors when ordering insulin doses, including nutritional status, weight, concomitant medications, severity of illness, and renal impairment. The order sets can suggest when an endocrinologist or other specialist trained in insulin management should be consulted for complex insulin issues. They can also provide guidelines for calculating **BASAL, NUTRITIONAL**, and **CORRECTIONAL** insulin doses, specify treatment options for hypo- and hyperglycemia, and suggest routine monitoring and blood glucose goals.<sup>34,35</sup>

## RISK ASSOCIATED WITH DISPENSING SUBCUTANEOUS INSULIN

### *Intermediate and long-acting subcutaneous insulin doses not dispensed in the most ready-to-use form in inpatient settings*

ISMP has an expanding volume of error reports associated with selecting the wrong vial of insulin from unit stock and measuring the wrong dose of insulin when withdrawing it from a vial into a syringe.<sup>33,36-38</sup> Many of the wrong drug errors are due to name similarity, name confusion, or labeling and packaging similarities. Examples include mix-ups between Huma**LOG** and Humu**LIN**, Huma**LOG** Mix 75/25 and Humu**LIN** 70/30, or Novo**LOG** Mix 70/30 and Novo**LIN** 70/30. In a 2009 review of statewide insulin error reports associated with the wrong insulin product or wrong dose, about a quarter occurred when obtaining the insulin for administration from stock or an automated dispensing cabinet (ADC). Specifically,

about a third of these reports noted that the wrong insulin product was obtained via an ADC using an override feature. About one-fifth of the wrong insulin errors involved mix-ups between a rapid-acting and short-acting insulin. Another quarter of the errors involved omissions of insulin doses, and about 13% involved an overdose. One in 10 of these dosing errors involved a tenfold overdose of insulin.<sup>29</sup>

Not all, but many of these wrong drug—wrong dose insulin errors could be avoided if pharmacists provided clinicians working in patient care units with patient-specific doses of intermediate- or long-acting insulin in properly labeled syringes.

## RISK ASSOCIATED WITH THE PREPARATION AND ADMINISTRATION OF SUBCUTANEOUS INSULIN

### *Errors with communicating and measuring doses of CONCENTRATED INSULIN*

ISMP has received a number of regular insulin U-500-related medication error reports.<sup>39</sup> Most of the reports have been related to dosing confusion caused by the previous unavailability of a syringe with a U-500 scale. This required practitioners to measure U-500 doses with a U-100 syringe or tuberculin syringe, and to teach the patient how to communicate their doses in “syringe units.” For example, 200 units of U-500 insulin would be measured by drawing up 40 “syringe units” on the U-100 syringe. But too often, patients do not understand the difference between U-100 and U-500, so they inaccurately state the volume of insulin they draw up in the U-100 syringe as their actual dose of U-500, or healthcare practitioners confuse the two concentrations, which can lead to five-fold dosing errors and possible life-threatening hypoglycemia or hyperglycemia.



### *Poor coordination of insulin with meals and glucose monitoring in inpatient settings*

Coordinating glucose monitoring, meal delivery, and insulin administration within the ideal time frame for rapid-acting insulin is a significant challenge often not being met in inpatient settings. Studies suggest that glucose monitoring and insulin administration occur within an acceptable range less than half of the time in hospitalized patients prescribed insulin.<sup>40,41</sup> In two studies, less than half of patients met the goal of receiving a rapid-acting insulin within 10-15 minutes of a meal, and 35% received glucose monitoring within one hour prior to insulin administration. Timing for meals, blood glucose testing, and rapid-acting insulin administration varied significantly and was not well synchronized among the various facilities.<sup>40,41</sup>

### *Lack of protocols to guide insulin administration*

Institutionally-developed protocols addressing the administration of subcutaneous insulin for patients who are receiving enteral or parenteral nutrition, transitioning from intravenous insulin, or designated to receive nothing by mouth (NPO) have been shown to decrease the incidence of hyperglycemia and hypoglycemia.<sup>23,35</sup> One type of error seen in the absence of such protocols is the withholding of a **BASAL** dose of insulin when a patient's glucose is within normal limits at the time a dose is due.<sup>42</sup> A standardized process should be established for alerting physicians, pharmacists, and nurses as to when insulin doses must be adjusted, held, or discontinued based on changes in the patient's carbohydrate intake (e.g., changes in enteral feedings, parenteral nutrition, NPO status).

### ***Lack of prospective risk assessment to identify patients at high risk for hypoglycemia***

Establishing and maintaining clinically appropriate glycemic targets in both the inpatient and outpatient settings has been difficult because the risk of hypoglycemia increases with tighter glycemic control.<sup>9</sup> A study identified the characteristics below as increasing the patient's risk of a hypoglycemic episode:<sup>9</sup>

- Body weight less than 69 kg
- Creatinine clearance less than 48 mL/min
- **BASAL INSULIN** doses greater than 0.25 units/kg
- Dosing of **BASAL INSULIN** without meal-time insulin (**BASAL**-only dosing)
- Nonstandard insulin therapy (e.g., 70/30 mix insulins)
- Concomitant use of a sulfonylurea

Despite this knowledge, few healthcare providers conduct a prospective risk assessment of insulin-dependent patients to identify those who are at high risk for developing hypoglycemia and then specifically target those patients for preventive interventions. A multifaceted approach aimed at improving clinician awareness of these risk factors and conducting real-time risk assessments would help improve patient safety.

### ***Lack of prospective risk assessment to identify patients at high risk for hyperglycemia***

The widespread use of insulin among inpatients and outpatients, many of whom have high-risk characteristics, creates an environment favorable to both hypo- and hyperglycemia. For example, high-risk characteristics associated with hyperglycemic crises include:<sup>10</sup>

- Infection
- Cerebrovascular accident
- Pancreatitis
- Myocardial infarction
- Trauma
- Alcohol abuse
- Concomitant therapy with drugs that affect carbohydrate metabolism (e.g., corticosteroids, thiazide diuretics, sympathomimetic agents)
- Eating disorder
- Factors that lead to insulin omission (e.g., fear of weight gain or hypoglycemia)

Few healthcare providers conduct a prospective risk assessment of insulin-dependent patients to identify those who are at high risk for developing hyperglycemia and then specifically target those patients for preventive interventions.



## RISK ASSOCIATED WITH THE USE OF INSULIN PENS AND VIALS

### *Misuse of insulin pen devices*

Insulin pens offer a method of insulin delivery that has the potential to provide greater dosing accuracy and ease of use, and a lower risk of hypoglycemia in ambulatory care settings, when used in comparison to conventional insulin vials and syringes.<sup>11,43-45</sup> Insulin pens are portable and discreet so they are convenient to use, and they save time since an insulin dose does not need to be drawn up from a vial with a syringe and needle. Also, some diabetic patients who have difficulty with self-injection can successfully self-administer doses when using a pen.<sup>46</sup> Patients tend to prefer insulin pens based on patient satisfaction scores and ease of use.<sup>47</sup> While lower overall healthcare utilization rates and costs have been associated with insulin pen use, they may be more expensive initially than vials of insulin.<sup>11,43-45</sup> Also, patients cannot mix two types of compatible insulin together in a pen to reduce the number of injections required, as they can do using a vial and syringe/needle.



ISMP has also received reports of errors associated with self-administration of insulin using pens. Most of the errors have been related to pen design flaws,<sup>48</sup> not inverting and rolling insulin pens to properly mix the insulin, injection technique errors (e.g., not keeping pen needle under the skin for 6 seconds to prevent leakage from the injection site), misreading the dose, and measurement errors, such as twisting the dosing dial back down to zero instead of pressing the injection button on a pen to administer a dose.<sup>49,50</sup>

Intended initially to facilitate safe and accurate self-administration of insulin in the ambulatory setting, insulin pens are often used in inpatient settings. In the inpatient setting, pens offer several advantages over vials beyond dosing accuracy, convenience, and ease of use:<sup>48</sup>

- Each pen is already labeled by the manufacturer with the product name and product barcode (whereas syringes of insulin prepared on the patient care unit from vials run the risk of being unlabeled)
- Each pen can be individually labeled with the patient's name (and ideally with a patient-specific barcode).
- The pen provides the patient's insulin in a form ready for administration.
- The pen lessens nursing time needed to prepare and administer insulin.
- Insulin pens reduce medication waste that can occur when dispensing 10 mL-sized insulin vials for each patient.

There are also anecdotal reports plus published literature that needlestick injuries may be less common with pen use.<sup>51</sup>

The design of some pens can predispose healthcare practitioners to error, and issues with injection technique have been reported. For example, nurses have reported seeing a "wet spot" on the skin post injection due to insulin leaking from the injection site because the needle was not left in place for 5-10 seconds after injection.<sup>7,48,52</sup> Needlestick injuries have also been reported after misaligning the angle of the injection, which allows the needle to travel through the patient's skin and into a nurse's finger.<sup>48</sup>

Insulin cartridges within pens have been misused as multiple-dose vials when staff who preferred to administer insulin using a conventional syringe attempted to withdraw an insulin dose from the pen's cartridge.<sup>7</sup> This practice could introduce air into the cartridge or reservoir, leading to subsequent insulin under-doses and subcutaneous injection of air.

Also, improper sharing of insulin pens among multiple patients has exposed patients to bloodborne pathogens.<sup>53,54</sup> Between 2009 and 2013, close to 7,000 patients may have been exposed to human immunodeficiency virus (HIV), hepatitis B, or hepatitis C because insulin pens were reused for multiple patients after only changing the needle.<sup>55</sup> The problem continues, and in 2014, another 4,200 patients in March and 3,100 in May were potentially exposed to bloodborne pathogens after receiving insulin doses that might have come from an insulin pen used for multiple patients.<sup>54</sup> Studies have demonstrated that retrograde travel of blood and tissue back into the insulin pen cartridge can occur, which can lead to disease transmission even when the needle is changed between patients.<sup>56,57</sup>

In October 2014, ISMP published an article about a hospital that continued to have “wrong patient” insulin pen injections despite full compliance with barcode scanning and other strategies to prevent the sharing of insulin pens. Even though nurses knew not to share pens, the barcode scanning system revealed that nurses had picked up the wrong insulin pen 400 times in three months, and without an alert might have administered those doses. Even with barcode scanning, seven patients received an insulin dose from another patient’s pen during that time, due in part to mixing up different patients’ pens, retrieving the wrong patient’s pen from a proximal medication bin, using a pen left over from one patient for another patient in the same room and bed, and failure to follow up when the barcode scanning system signaled the wrong patient’s insulin pen.<sup>55</sup>

### ***Misuse of insulin syringes, needles, and vials***

Improper injection techniques can contribute to poor glycemic control, transmission of infections, medication errors, and other adverse effects. For example, during subcutaneous insulin therapy, inadvertent intramuscular injections may increase pain and/or adversely affect glucose control by impacting the pharmacokinetics/pharmacodynamics of insulin.<sup>58</sup> This can happen if the length of the needle used for injection is too long. The evidence suggests that a 4-6 mm needle is effective for subcutaneous insulin injections in the adult population, including obese adults.<sup>58,59</sup> However, not all manufacturers provide needles in this size.

When compared to insulin pens, insulin vials have several advantages and disadvantages. The advantages of using insulin vials in an inpatient setting include the following:

- The sharing of syringes and needles used for the administration of insulin from vials is less likely than with pens.
- Compatible insulins can be mixed in a syringe for a single injection.
- Insulin doses removed from vials may be less costly than doses using insulin pens, and there may be less waste.

The disadvantages of using insulin vials instead of pens include the risk of inaccurate dosing when using an insulin syringe for measurement, as units have been mistaken as milliliters, and the U-100 designation on insulin vials has been misunderstood to represent 100 units per vial.<sup>60</sup> There can also be confusion and mix-ups between look-alike vials of various types or concentrations of insulin, or mix-ups with other drugs that are packaged in similar-looking vials.

There is also a small risk of contamination when using insulin vials, given common lapses in basic infection control practices.<sup>61</sup>

It should also be noted that labels on clinician-prepared insulin syringes are more likely to be limited or absent compared to pharmacy-prepared syringes. An American Nurses Association (ANA) survey concluded that only about one-third of nurses always label the syringes of medications they prepare, and one in four nurses never label the syringes.<sup>62</sup>

## RISK ASSOCIATED WITH MONITORING PATIENTS ON SUBCUTANEOUS INSULIN

### *Miscommunication of blood glucose values in inpatient settings*

Blood glucose monitoring and the ability to maintain blood glucose levels within a targeted range are key components of diabetes care. The measurements obtained with a point-of-care glucose monitor are intended to be timed appropriately, communicated to responsible caregivers, and acted upon in accordance with orders from a patient's healthcare provider. Unfortunately, ISMP and the Pennsylvania Patient Safety Authority have received many reports regarding miscommunication of glucose testing values, which has led to the administration of incorrect insulin doses and subsequent hypo- or hyperglycemia.<sup>29</sup>



In an annual review of insulin errors occurring just in inpatient settings, more than 1 in 10 wrong dose errors involved breakdowns with receiving or communicating patients' blood glucose values, particularly values obtained with bedside monitors.<sup>29</sup> Specific problems reported include communicating an incorrect value, confusing the patient's weight for his or her blood glucose level, and communicating the wrong patient's value, as well as simply documenting the wrong result.<sup>29</sup> For example, both licensed professionals and support staff have misunderstood room numbers on scraps of paper as glucose values, transposed numerals when reading the values, misheard verbal reports of values, mistaken documented weights as a glucose value, and mistaken weights communicated verbally as glucose values.<sup>29</sup> A standardized process which includes automated, interfaced blood glucose testing devices is paramount to safety.

## RISK ASSOCIATED WITH EDUCATING PATIENTS ON SUBCUTANEOUS INSULIN

### *Lack of patient education*

Studies and surveillance systems in the US continue to indicate that many patients with diabetes receive limited diabetes education.<sup>63</sup> To cite one example, a study published in 2013 suggests that many insulin-dependent patients may not be taught something as basic as proper injection site rotation, leading to a high rate (63%) of lipohypertrophy.<sup>64</sup> Medication non-adherence is also prevalent in patients with diabetes and is associated with increased hospitalizations and mortality.<sup>65</sup>

A study involving insulin-related hypoglycemia and errors leading to ED visits and hospitalizations uncovered similar deficiencies in basic understanding.<sup>8</sup> For example, almost half of all ED visits involved meal-related misadventures, such as neglecting to eat after taking rapid-acting insulin. One of many examples involved a young female driver who hit a tree and brick wall after taking insulin 2 hours before and having "no time to eat." Almost one-quarter of ED visits involved taking the wrong insulin product—most often intending to take long-acting insulin but taking short-acting insulin instead.

Annual calls to poison centers regarding insulin have increased by 279% between 2000-2009.<sup>66</sup> Most of the increase was caused by unintentional errors in dosing; 70% of the cases in the study were treated without having to go to a healthcare facility, thus avoiding an unnecessary expense.

In healthcare facilities where quality diabetes management is a priority, education may be readily available and roles may be clear. But in most cases, it is not obvious exactly which healthcare practitioners are responsible for meeting the educational needs of diabetic patients in the hospital.<sup>63</sup> The transition from the hospital to home for a diabetic patient is fraught with risks associated with self-administration of insulin and blood glucose monitoring; errors with either could be life-threatening.

## Developing Consensus Guidelines for Safe Subcutaneous Insulin Use

To begin addressing the numerous and varied subcutaneous insulin errors reported to ISMP's National Medication Errors Reporting Program (ISMP MERP), as well as those described in several ISMP practitioner surveys, in a systematic and standardized fashion, ISMP obtained an educational grant from BD to host a national summit of expert stakeholders. The purpose of this meeting was to establish a compendium of consensus-based best practices for the safe use of subcutaneous insulin. First-hand knowledge of unsafe practices and at-risk behaviors in acute care settings and outpatient locations across the US helped participants contribute to the extensive list of safety concerns. The summit, entitled ***Optimizing Safe Subcutaneous Insulin Delivery Across the Continuum of Care***, was guided by the following objectives:

1. Facilitate interdisciplinary communication among key stakeholders about the scope, causes, and prevention of subcutaneous insulin errors in the hospital and during **TRANSITIONS OF CARE**, and other preventable adverse outcomes associated with subcutaneous insulin delivery.
2. Gain consensus regarding common risks associated with subcutaneous insulin delivery in the facility and during **TRANSITIONS OF CARE**.
3. Identify safe practices and evolving equipment and technology that aim to optimize and standardize the delivery of subcutaneous insulin, including but not limited to:
  - Standard order sets
  - Insulin administration protocols
  - Use of **CONCENTRATED INSULIN**
  - Coordination of insulin delivery, meals, and blood glucose monitoring
  - Communication and documentation of blood glucose results
  - Use of insulin pen devices
  - Use of insulin vials and syringes
  - Patient education to improve **TRANSITIONS OF CARE** and safe insulin administration at home
4. Develop and communicate expert- and evidence-based guidelines for the healthcare community involving all aspects of subcutaneous insulin delivery, the equipment and technology associated with insulin use, as well as patient education.

Fifty-two participants, representing a range of frontline practitioners, professional organizations, regulatory bodies, and insulin product vendors from across the US, attended the two-day facilitated summit in November 2015. A framework of recommended safe subcutaneous insulin practices based on historic study by ISMP was established by summit staff, and then a pre-meeting survey of participants was conducted to identify early consensus on these practices. From this listing, top safety challenges were identified for discussion. Breakout sessions focused on the challenges with prescribing and dispensing insulin, challenges with preparation and administration of insulin (including vials, pens, pumps, and self-administration), challenges with monitoring, and challenges with education and transitions to home.

Consensus was reached on a variety of safe practices, which are presented in the statements below. Evidence-based research was used, as available, to support the development of the guidance statements; however, as with many patient safety or medication safety-related issues, controlled clinical trials have rarely, if ever, been done for a specific safe practice, nor would they be ethical in many cases. As such, this guidance document relies on the synthesis of the best evidence available at the time of publication, including clinical articles and other published literature, along with expert consensus. Regulatory evidence is also acknowledged and included as appropriate. Additional topics for further research and inquiry were developed based on group discussion and ISMP staff insight, and are listed in the section entitled *Future Inquiry*.

## Safe Practice Guidelines for Subcutaneous Insulin Use in Adults

### 1. PRESCRIBING OF SUBCUTANEOUS INSULIN

#### 1.1 An endocrinologist or practitioner trained in insulin management, as determined by the organization (e.g., physician, nurse practitioner, physician assistant, or pharmacist), is consulted for patients with hospital-defined uncontrolled hyperglycemia or hypoglycemia.

Discussion: A diagnosis of diabetes is associated with a longer hospital length of stay and increased healthcare costs.<sup>67</sup> Optimization of glycemic values is highly cost-effective and associated with a reduction in morbidity and mortality.<sup>68</sup> In a report analyzing the 39.9 million hospital discharges in the US in 2008, patients with diabetes had an average length of stay of 5.3 days versus 4.4 days for patients without diabetes.<sup>67</sup> Inpatient glycemic management is complex, and as such all inpatient providers may not have the expertise to effectively manage a patient's blood glucose values.<sup>68</sup> For this reason, it is recommended that consultation with a practitioner who has expertise in insulin management occurs for patients presenting with uncontrolled hyper- or hypoglycemia.

#### 1.2 The indication for insulin use is clearly documented in the health record and is readily accessible and visible to all clinicians during insulin order entry, verification, and administration.

Discussion: A diagnosis of diabetes or hyperglycemia should be confirmed prior to ordering, dispensing, or administering subcutaneous insulin.<sup>69</sup> Knowledge of the purpose of the medication may help differentiate between two medications that look or sound alike, detect insulin orders that are entered into the wrong patient's profile, or capture errors due to mental mix-ups between medications.<sup>69,70</sup> One way to facilitate documentation of the diagnosis is to provide a prompt within the insulin order set for the prescriber to indicate the appropriate diagnosis.<sup>71</sup>

#### 1.3 Organizations develop and utilize evidence-based insulin protocols and/or evidence-based insulin order sets with decision support capabilities when appropriate. These guide:

- a. Transitions from intravenous to subcutaneous insulin
- b. Calculations and communication of BASAL, NUTRITIONAL, and CORRECTIONAL INSULIN doses
- c. Management of insulin during planned and unplanned interruptions of oral, enteral, and parenteral nutrition
- d. Management of CONCENTRATED INSULIN
- e. Management of pregnant and postpartum patients with pre-existing type 1 or type 2 diabetes
- f. Management of patients receiving glucocorticoid therapy
- g. Management of patients with clinically significant episodes of hypoglycemia
- h. Defined laboratory testing, point-of-care (bedside) glucose monitoring (including frequency), and other clinical monitoring practices
- i. Identification, communication, and management of critical blood glucose values
- j. Management of inconsistencies between the patient's symptoms and blood glucose values
- k. When clinicians, other than the prescriber, may adjust or hold an ordered dose of insulin
- l. Post-discharge insulin management

Discussion: Standardized order sets and protocols, developed using evidence-based guidelines, can optimize the treatment of inpatient hyperglycemia.<sup>34,71</sup> Suboptimal care results when providers are inconsistent in their management of hyperglycemia, which can occur due to the complexity of maintaining euglycemia in the inpatient setting.<sup>71</sup> Protocols and order sets, when designed intuitively, enhance efficiency of workflow and prevent medication errors by reducing variability, which can lead to unintentional oversight.<sup>72</sup> Protocols targeting subcutaneous insulin prescribing and subsequent patient monitoring should

be developed by the facility to reduce the variability in patient care.<sup>34,71</sup> The order sets should contain appropriate glucose monitoring, glycemic targets, and instructions for how to treat episodes of hypoglycemia or how to manage insulin therapy when a patient's nutritional status changes.<sup>34,71,73</sup>

**1.4 Organizational policies are in place to guide the care of patients with a personal subcutaneous insulin pump. An endocrinologist or practitioner trained in insulin management, as determined by the organization (e.g., physician, nurse practitioner, physician assistant, or pharmacist), is consulted when a patient with a personal insulin pump is admitted or presents for other organizationally-defined episodes of care.**

Discussion: More patients are using ambulatory insulin infusion pumps than ever before. While they are convenient for the patient, many inpatient practitioners are unfamiliar with their functionality and the safest way to care for such patients in an inpatient setting. In a recent survey by ISMP, 75% of respondents did not have a policy, procedure, or guideline in place in their organization regarding the management of patients who present for care with an insulin pump.<sup>74</sup> Policies should be created to guide practitioners on appropriate continuation, discontinuation, and re-starting of an insulin pump.<sup>75</sup> Discontinuing an insulin pump without understanding its purpose or contents could lead to serious, even fatal, events. However, it is equally unsafe to continue the use of an ambulatory infusion device without knowing how to manage the pump, especially if the patient is not well enough to assist with managing the device. Even allowing a very capable patient to manage his or her own ambulatory medication pump can be risky in an inpatient setting and should require due consideration.<sup>74</sup>

With insulin pumps, for example, errors have been reported in which a patient self-administered a dose of insulin via an ambulatory pump without telling the nurse, and the nurse administered the same insulin dose via a subcutaneous injection. Also, a change in the patient's condition requires reassessment of the use of the device. For example, if the patient must undergo surgery, or if the patient suddenly becomes unconscious and is unable to manage his/her own device, the ambulatory pump may need to be managed by clinicians or turned off temporarily.<sup>74</sup> For additional recommendations on the safe use of an insulin pump, see: <https://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=125> and <https://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=1151>.

**1.5 The prescriber identifies the target glucose range in the patient's health record.**

Discussion: By identifying and communicating a target blood glucose range, the healthcare team understands the goal for therapy and can assist in the early identification of hyper- and hypoglycemia.<sup>71</sup> Identification of the target range can be accomplished as part of an order set for insulin management or included in the prescriber's admission documentation.

**1.6 Eliminate the use of sliding scale insulin doses based on blood glucose values as the only strategy for managing hyperglycemia.**

Discussion: The American Association of Clinical Endocrinologists (AACE), the American Diabetes Association (ADA), and the Endocrine Society all discourage the use of sliding scale insulin alone as the sole method for controlling inpatient blood glucose levels. "Scheduled subcutaneous administration of insulin is the preferred method for achieving and maintaining glucose control in non-critically ill patients with diabetes or stress hyperglycemia."<sup>71</sup> In fact, prolonged use of **CORRECTIONAL** sliding scale insulin without a scheduled dose is ineffective for most patients with diabetes and can be dangerous in patients with type 1 diabetes.<sup>34</sup> Subcutaneous insulin should be dosed based on the guidance from the ADA, AACE, and the Endocrine Society.<sup>71</sup>

**1.7 Insulin orders are free of error-prone abbreviations and dose expressions.**

Discussion: For decades, ISMP has reported on the danger associated with using the letter "u" as an abbreviation for the word "units." Serious mistakes, ten-fold overdoses, and even fatal events have occurred with insulin use when the

abbreviation associated with the dose was misread as a zero, a four, a seven, or “cc.” Errors have occurred not only with handwritten doses, but also when typed or displayed on computer screens. The Joint Commission also prohibits the use of “u” as an abbreviation for units due to its error-prone nature. Manufacturers have been asked to limit its use on product labeling. Internationally, the abbreviation IU for international units has also been used, and has been mistaken for the term IV or intravenous. This abbreviation also should not be used. In addition, practitioners are strongly encouraged to avoid the use of “SC,” “sub q,” or “SQ” to express the subcutaneous route of administration. Errors have been reported when “SC” was mistaken as SL (sublingual) or when “SQ” was mistaken as “5 every” or the “q” in “sub q” was mistaken as “every” (e.g., a medication ordered “sub q 2 hours before surgery” was misunderstood as every 2 hours before surgery). ISMP recommends to spell out the term subcutaneously, or if it must be abbreviated, use “subcut.”<sup>76</sup> ISMP also recommends to avoid the use of a decimal point and a zero after a whole number (e.g., 10.0), as this dose expression has repeatedly led to ten-fold overdoses.

**1.8 Strategies such as tall man lettering with bolded text for the unique letter characters are used on computer and device screens, pharmacy labels, order forms, storage bins, medication administration records, and drug information references to help distinguish look-alike insulin names (e.g., HumaLOG and HumuLIN; NovoLOG and NovoLIN).**

Discussion: Due to repeated wrong drug errors associated with similar names, several design techniques have been explored for differentiating look-alike drug names. Tall man lettering is one such technique. Tall man lettering describes a method for differentiating the unique letter characters of similar drug names known to be confused with one another. Accentuating a unique portion of a drug name with uppercase letters along with other differentiation strategies, such as color, bolding, or contrast, can draw attention to the dissimilarities between look-alike drug names, as well as alert healthcare providers that the drug they are selecting is one that is often confused with another drug name.

While numerous studies between 2000 and 2016 have demonstrated the ability of tall man letters alone or in conjunction with other text enhancements to improve the accuracy of drug name perception and reduce errors due to drug name similarity,<sup>77-79</sup> some studies have suggested that the strategy is ineffective.<sup>80,81</sup> The evidence is mixed due in large part to methodological differences and significant study limitations. Nevertheless, while gaps still exist in our full understanding of the role of tall man lettering in the clinical setting, ISMP believes there is sufficient evidence to suggest that this simple and straightforward technique is worth implementing as one of numerous strategies to mitigate the risk of errors due to similar drug names. To await irrefutable, scientific proof of effectiveness minimizes and undervalues the study findings and anecdotal evidence available today that support this important risk-reduction strategy.<sup>82</sup> As such, the use of tall man lettering has been endorsed by The Joint Commission (recommended, not required), the US Food and Drug Administration (FDA) (as part of its Name Differentiation Project), as well as other national and international organizations, including the World Health Organization (WHO) and the International Medication Safety Network (IMSN).<sup>83</sup>

While some technology systems are currently unable to provide the ability to program tall man lettering, including bolded text, ISMP encourages all health information system vendors to modify their system’s functionality in the future by adding methods of differentiation, such as the ability to use bold text, to differentiate unique letter characters.

**1.9 Communicate all patient-specific information related to diabetes care in one designated place in the health record.**

Discussion: All practitioners should have easy access to essential patient information in order to provide safe care for patients receiving insulin. Ideally, this information could be available as a single electronic record or dashboard which is available to all practitioners participating in the patient’s care. A typical dashboard might include administration times of all antidiabetic medications, blood glucose monitoring results (bedside and laboratory), episodes when hypoglycemia was treated, nutritional intake, and other pertinent information related to diabetes.

## 2. PHARMACY MANAGEMENT AND DISTRIBUTION OF SUBCUTANEOUS INSULIN

### 2.1 US manufacturers, regulatory agencies, drug information content providers, and healthcare facilities are encouraged to work concurrently to remove irrelevant information from insulin labeling.

Discussion: Terms such as human recombinant, rDNA, and recombinant DNA origin are no longer needed to describe the origin of the insulin products. This information takes up valuable space on electronic displays and product labeling and is not needed for product selection. When included on the label, it becomes more cluttered, and important dose or concentration information becomes more difficult to locate. The FDA has agreed and has removed this requirement for the nonproprietary name.<sup>84</sup> Drug information vendors and electronic health record (EHR) vendors should also aim to remove irrelevant information from their display for the same reason.

### 2.2 Processes are in place to differentiate insulin products of different types and concentrations wherever they are stored.

Discussion: Confusion between rapid-acting, short-acting, intermediate-acting, and long-acting insulin products have been known to contribute to medication errors. In addition, there are currently four different concentrations of insulin on the market (U-100, U-200, U-300, and U-500), with the potential for additional concentrations in the future. If an institution has different types or multiple concentrations of insulin on their formulary, risk-reduction strategies such as storage in separate, labeled (and possibly lidded) bins should be implemented to prevent inadvertent mix-ups of the various strengths and types. ISMP recommends that U-500 insulin be stored separately, segregated from other insulins, and stored only in the pharmacy. Auxiliary warning labels can be useful to differentiate products, and barcode technology can assist pharmacy personnel in drug selection and validation.

### 2.3 Pharmacists confirm the indication before verifying initial insulin orders.

Discussion: Nationally, there have been numerous error reports describing patients who have received a subcutaneous dose of insulin in error, despite not having diabetes or other clinically relevant indications requiring insulin. This happens most often at the time of order entry when an order is entered by mistake into the wrong patient's record. If done consistently, pharmacist confirmation of the indication for subcutaneous insulin use during order verification will support error capture before the active insulin order appears on the patient's medication administration record or the insulin is dispensed to the clinical unit. This expectation for pharmacist validation is supported in The Joint Commission (TJC) Standard MM.05.01.01: "A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the hospital."<sup>85</sup>

### 2.4 Insulin vials are removed from the manufacturer's carton prior to dispensing to patient care areas.

Discussion: Errors have occurred when insulin vials are used and then returned to the wrong insulin carton. To prevent patients from getting the wrong type of insulin product, do not dispense or store insulin vials in cartons on patient care units. This will also eliminate the opportunity for staff to scan the barcode on the carton instead of the actual insulin vial before administration, which has also contributed to wrong insulin errors.

### 2.5 When insulin vials are dispensed (unit-stock or patient-specific) and stored in patient care areas (excluding the patient room), ready-to-apply barcoded labels are available to apply to clinician-prepared syringes.

Discussion: When a subcutaneous insulin dose is prepared at an ADC or in other clinical storage locations, organizations can support safe labeling practices by providing preprinted, barcoded labels to apply to the insulin syringe immediately after preparation. Organizations should help staff recognize that scanning insulin labels not applied to the actual insulin syringe is considered a workaround and an at-risk behavior, leaving the patient and themselves vulnerable to a serious insulin event.



**2.6 The pharmacy prepares and dispenses BASAL INSULIN doses in patient-specific prefilled syringes (if stability permits) for patients who are not using a patient-specific insulin pen or insulin pump in the inpatient setting.**

Discussion: Having access to a variety of insulin types on the clinical unit carries the risk of wrong drug/dose errors, as well as infection control challenges. For example, when nurses are expected to prepare **BASAL, NUTRITIONAL, and CORRECTIONAL** subcutaneous insulin doses, there can be times when some of these doses will be prepared simultaneously, risking confusion of insulin types which may contribute to a hypoglycemic event. If a **BASAL** dose is always dispensed in a pharmacy-prepared, patient-specific barcoded syringe or pen device, and the only insulin vials that are available on patient care areas are rapid-acting insulin products, then the chance of mix-up is less likely. In addition, the pharmacy department can readily recognize if a basal dose of insulin was omitted if a dispensed basal syringe is later returned to pharmacy, unadministered.

**2.7 CONCENTRATED INSULINS are dispensed in patient-specific, labeled pen devices or in patient-specific, pharmacy-prepared syringes. U-500 insulin vials are only stored in the pharmacy.**

Discussion: As mentioned above, having access to a number of insulin products in a variety of concentrations outside of the pharmacy may pose a particular risk to the clinician selecting the ordered insulin type. Having pharmacy dispense **CONCENTRATED INSULINS** with a patient-specific label reduces the likelihood of a selection error and allows pharmacy to apply a barcoded label.

Fortunately, U-200 and U-300 products are available only in pens. However, if a hospital chooses to use U-500 vials instead of U-500 pen devices for subcutaneous insulin doses, access to the vials should be limited to the pharmacy to avoid serious dosing errors. Although a U-500 vial is larger in size than a U-100 vial (20 mL vs. 10 mL or 3 mL), and the package label is different, staff may be unaware that concentrations beyond U-100 are available and may prepare and administer a U-100 dose from a U-500 insulin vial by mistake. An error of this nature would result in a five-fold overdose of insulin and likely severe hypoglycemia. If U-500 syringes are not used in the inpatient setting due to the lack of a safety needle, standardized preparation protocols in the pharmacy using a U-100 or tuberculin syringe should be instituted.<sup>39</sup>

**2.8 Ideally, insulin pens are dispensed to the clinical units with a patient-specific, barcode label (that has been applied in the pharmacy, using a barcode verification process that confirms the correct pen type has been selected based on the patient's order) AND steps have been taken to ensure that only the correct patient-specific label can be scanned at the bedside.**

Discussion: To reduce the risk of an insulin pen being used on more than one patient, ISMP and other researchers recommend that a process exists for pharmacy to scan the insulin product to identify the proper insulin type and then place a patient-specific barcode label onto the insulin pen device being dispensed to a clinical location.<sup>55</sup> In addition, it is recommended that a tamper-evident seal be placed over both the cap and the barrel of the pen, to determine which insulin pens have been used if they are returned to the pharmacy.

**2.9 A patient-specific label is affixed on the body of the insulin pen (not on the removable cap), without obscuring important information on manufacturer labeling or the dose counter/dose window.**

Discussion: Insulin pen mix-ups between patients have been reported to ISMP when patient-specific labels were stuck to (or placed on) the pen caps rather than to the barrel of the pen and the caps of two different pens were inadvertently switched. Thus, patients were at high risk for receiving insulin from another patient's pen device as well as exposure to bloodborne pathogens or even the wrong insulin. All patient-specific labels should be applied to the barrel of the pen in a manner as not to obstruct manufacturer drug information.<sup>86</sup> Some organizations may purposely choose to have pharmacy apply a patient-specific

label to cover the manufacturer's barcode so that nurses are forced to scan the pharmacy-applied barcode that encodes both the patient identification and the drug product. Special "flag labels" are available that do not obstruct readability of the pen label. Additionally, it is also recommended that organizations apply tamper-evident tape between the cap and the barrel of the pen device prior to dispensing to the clinical unit.

### 3. ADMINISTRATION AND MONITORING OF SUBCUTANEOUS INSULIN

#### 3.1 Patient-specific insulin pens are stored on clinical units in a manner that prevents their inadvertent use on more than one patient.

Discussion: If an institution chooses to use insulin pen devices, each should contain a patient-specific label and be stored in a patient-specific bin/drawer on the clinical unit to prevent contamination from inadvertent misuse on another patient. Insulin pens should be returned to the patient's specific storage location immediately after administration, and nurses should not have more than one patient's pen in their possession at a time. At the time of internal transfer or discharge, a patient's insulin pen should be removed from the patient-specific bin/drawer along with any other remaining medications and transferred with the patient to the next unit of care, or returned to pharmacy/discarded as per organizational protocol.

#### 3.2 Organizations should develop a coordinated process to ensure timely blood glucose checks and administration of NUTRITIONAL INSULIN in conjunction with meal delivery.

Discussion: A lack of coordination between meals, glucose checks, and insulin administration can have a significant impact on the effectiveness of diabetes management and the prevention of hyper- and hypoglycemia. Variability in the timing of any of these segments of care can lead to harmful outcomes for the patient. Clear organizational guidance and standardization is key to success in this practice.<sup>70</sup> Prescribers should provide clear instructions on insulin administration when the patient's nutritional status changes (e.g., when the patient is NPO), as well as how to adjust insulin doses when carbohydrate intake or snacks and supplements are modified.

#### 3.3 Verbal communication of point-of-care blood glucose value results are avoided as much as possible and are NEVER routinely used as the only source of information when determining insulin doses.

Discussion: Verbally reported glucose values can easily be misheard or transposed. ISMP has received error reports in which room numbers and blood glucose values have been confused when temporarily transcribed and/or verbally reported. For example, a nursing assistant who performed bedside glucose testing advised a nurse that the patient's blood sugar was 217 mg/dL. Unfortunately, the nurse thought the assistant was talking about a different patient and she administered a sliding scale dose of insulin to a patient whose blood sugar was 116 mg/dL. The error was soon recognized, and the patient was fed and monitored. With the ability for electronic documentation of point-of-care testing results directly to the patient's EHR, verbal communication of glucose values should be eliminated.

#### 3.4 The insulin concentration (e.g., U-100, U-200, U-300) does not follow the name of the insulin on the medication administration record (MAR) or other medication lists, with the exception of regular insulin U-500 (HumuLIN U-500).

Discussion: ISMP has received errors where the strength of the insulin was mistaken for the dose when listed following the drug name on the MAR or other lists where insulin doses are recorded (e.g., medication history and discharge summary lists).<sup>87</sup>

### **3.5 Appropriately label all clinician-prepared syringes of subcutaneous insulin, unless the medication is prepared at the patient's bedside and is immediately administered to the patient without any break in the process.**

Discussion: It is a fundamental safety practice that whenever a drug is removed from its original container and placed in another, unless it is immediately administered, it should be appropriately labeled. While clinicians may think that a recently prepared insulin syringe will never leave their hands, errors reported to ISMP for subcutaneous insulin and other parenteral products consistently reinforce that interruptions and distractions will inevitably occur. The risk of an error increases if the unlabeled syringe is put down or placed in a pocket temporarily. The contents of a syringe should never be assumed, even if the same person is preparing and administering the product. Also, see statement 2.5.

### **3.6 Prior to subcutaneous insulin administration, the practitioner:**

- a. Confirms that there is an appropriate indication**
- b. Assesses the patient's most current blood glucose value**
- c. Assesses the patient for symptoms of hypoglycemia**
- d. Informs the patient of their most current blood glucose level**
- e. Informs the patient of their dose, the full name of the product, and the insulin's intended action**

Discussion: The practitioner who administers the medication is the last line of defense against errors, and as such, performing a series of validating steps helps to ensure that an accurate subcutaneous insulin dose is administered. An independent double check (IDC) of every subcutaneous insulin dose is not an optimal strategy for detecting errors, especially when used in isolation of other safety measures. Confirming the indication can help to detect when an insulin order may have been placed on the wrong patient's medical record. Organizations must define the optimal timing for meals, blood glucose values, insulin administration, and their relationship to one another.<sup>34</sup> As with any medication, staff should first assess the patient for untoward reactions (in this case symptoms of hypoglycemia), and be aware of the timing of the last dose of subcutaneous insulin and last meal consumed. Encourage patients to participate in their care by informing them of their blood glucose level and the subcutaneous insulin dose to be administered. Errors can be intercepted if patients have an active role in their care. By discussing the dose and product with the patient, the patient has an opportunity to ask questions and sometimes may correct a mistake (e.g., when the nurse tells the patient "I am giving you 80 units of regular insulin" and the patient is able to reply, "wait I only get 8 units"). A similar exchange has been known on more than one occasion to prevent errors with subcutaneous insulin. This step also allows the opportunity to assess the patient's knowledge in managing their disease state.

### **3.7 An individual insulin pen is never used for more than one patient.**

Discussion: Insulin pens are designed to be used multiple times for a single patient, using a new needle with each injection. Regurgitation of blood into the insulin cartridge can occur after a single injection creating a risk of pathogen transmission if the pen is then used for another individual, even if a new needle is used. ISMP has chronicled large-scale potential patient exposures to bloodborne pathogens when insulin pens were used for multiple patients. The Centers for Disease Control and Prevention's (CDC) Safe Injection Practices Coalition (SIPC), FDA, and the American Society of Health-System Pharmacists (ASHP) have all created campaigns to promote the use of one insulin pen for only one person. Organizations using insulin pen devices for subcutaneous insulin doses should understand and plan for this risk and actively take steps, other than staff education (e.g., barcode scanning of a pharmacy-applied patient-specific label), to ensure single patient use.<sup>86</sup> In addition, patients should be taught about the risk associated with insulin pen sharing during home use.<sup>88</sup>

### **3.8 An insulin pen cartridge is never used as a vial.**

Discussion: Using an insulin pen cartridge in an unintended manner as a single or multi-dose vial can lead to contamination, as well as dosing errors, drug mix-ups, and other types of medication errors. Using an insulin cartridge as a vial is also not supported by the ASHP guidance document on safe insulin use in the hospital.<sup>34</sup>

### **3.9 Barcode scanning is used to verify that a patient-specific pen is used to administer the correct insulin to the correct patient.**

Discussion: If an institution chooses to use insulin pen devices, it is essential that steps are taken to reduce the chance that an insulin pen may be used on more than one patient. Institutions should adopt necessary technology solutions and processes (e.g., barcode scanning technology in the pharmacy to verify application of the patient-specific label to the correct pen, followed by bedside barcode scanning of the pharmacy-applied label) to support single patient use. Barcode scanning introduces a layer of protection beyond what is possible with a manual check to protect the patient from wrong drug and wrong patient errors.

## **4. SAFE TRANSITIONS OF CARE FOR PATIENTS RECEIVING SUBCUTANEOUS INSULIN**

### **4.1 Prior to TRANSITIONS OF CARE, a process is in place to ensure that patients will have the necessary prescriptions, supplies, a follow-up care plan, and printed instructions for all prescribed insulin and blood glucose monitoring.**

Discussion: Often providers forget to prescribe lancets, needles, syringes, a glucometer, or other supplies needed to appropriately and safely manage the care of a patient with diabetes. This oversight often leaves the patient unprepared to care for themselves, reduces the likelihood of insulin adherence, and increases the chance of error. Organizations can assist by creating a process to ensure that patients have all the necessary supplies to administer insulin after discharge. A standardized checklist of items should include insulin, insulin syringes or pen devices, pen needles, blood glucose monitoring equipment including lancing devices or lancets, test strips, and emergency glucagon kits/oral glucose tablets or gel (as appropriate).

Other times, patients arrive to pick up their insulin and supplies, only to find out they are unable to afford them. This potentially leaves patients without their insulin until a new prescription can be obtained. Early assessment and intervention by a social worker, pharmacist, or certified diabetic educator are important to ensure the patient's prescription will be covered by insurance and to identify patients in need of financial support before they leave the hospital setting. Additional support and referral to home care or similar post-discharge services should be routinely provided for all patients identified as at-risk for adherence issues, regardless of the reason.

### **4.2 During TRANSITIONS OF CARE, a coordinated process is in place to identify which patients on insulin therapy require additional intervention by an endocrinologist or practitioner trained in insulin management, as determined by the organization (e.g., physician, nurse practitioner, physician assistant, or pharmacist).**

Discussion: **TRANSITIONS OF CARE** pose a high-risk situation for patients on insulin therapy. It may be useful to engage an endocrinologist or other designated practitioner to assist in the care of the patient (e.g., scheduling patient visits with a certified diabetic educator [CDE]).

### **4.3 Healthcare providers primarily prescribe insulin pen devices for outpatients to increase dosing accuracy and promote self-care and adherence with their insulin therapy regimen.**

Discussion: The use of insulin pen devices in the outpatient setting has been shown to promote patients' self-care and adherence to an insulin regimen. While insurance companies may require a higher copay for insulin pen devices, many patients prefer insulin pens because of their ease of use.<sup>88,89</sup> It is important to understand that such devices may not be appropriate for all patients, in all circumstances, so prescribers should consider which delivery method would promote safety and adherence to drug therapy. Regardless of whether a pen device or traditional vial with syringes is prescribed for insulin

administration, standardized education and support need to be provided in all settings and at all **TRANSITIONS OF CARE** to maximize insulin adherence and promote safety with insulin administration.<sup>89</sup>

#### **4.4 Patients discharged on insulin are assessed for understanding of their self-management, including:**

- a. Demonstration of proper dose measurement and self-administration using the same administration device that will be used at home (e.g., vial and syringe, pen, pump)**
- b. How to monitor blood glucose values**
- c. The signs and symptoms of hyper- and hypoglycemia and how to respond if these symptoms occur**
- d. Common types of errors possible with their insulin therapy and how to prevent or detect these errors**
- e. The importance of regular follow-up with their primary care provider/specialist, including the date of their next appointment**

Discussion: Education of the patient and/or their direct caregiver regarding subcutaneous insulin use and diabetes self-care is a crucial step in the overall management of diabetes across the continuum of care.<sup>35</sup> While the goal of such education is focused on self-management, it is foundational to the delay or prevention of the myriad of complications associated with diabetes.<sup>47</sup> Ideally, certified diabetic educators (CDEs) or others trained in diabetes education should be available in all settings to support patients during error-prone **TRANSITIONS OF CARE**. Notably, pharmacists can play an important role on both the inpatient team and during outpatient care transitions to support the continuing educational needs of the patient receiving subcutaneous insulin.<sup>90</sup> Organizations are encouraged to delineate staff roles and responsibilities for providing diabetes education to ensure completion of this vital task.

Practitioners must begin by assessing patients for their current level of knowledge and understanding of diabetes and subcutaneous insulin use, as well as their level of cognition and overall willingness to learn. Insulin injection assessment tools produced by the American Association of Diabetes Educators (AADE) can be found on their website at: <https://www.diabeteseducator.org/practice/educator-tools/insulin-injection-resources2>.

Once a baseline assessment of the patient's level of knowledge and understanding is complete, a standardized list of essential topics and skills should be shared with patients so they will gain the knowledge needed to manage their diabetes once they leave the inpatient facility.<sup>47,71,90</sup> A number of resources exist to assist healthcare providers, including those provided by the AADE at: <https://www.diabeteseducator.org/practice/educator-tools>. In addition, practitioners should educate patients on the potential for error with subcutaneous insulin use. A unique collection of materials to assist in this goal can be found on ISMP's consumer medication safety website, located at: <http://www.consumermedsafety.org/tools-and-resources/insulin-safety-center>.

#### **4.5 Patients who self-administer U-500 insulin using a vial and syringe are taught to use only a U-500 syringe and communicate their doses in terms of the name and concentration of the insulin and the actual dose in units using only the U-500 syringe.**

Discussion: Until recently, patients using vials to administer U-500 insulin had to use either a tuberculin or U-100 syringe to measure and administer their dose. This process is extremely complex and frequently results in miscommunication and wrong doses. Patients should be taught the difference between U-100 and U-500 syringes, and be able to articulate why they should not be used interchangeably. In addition, it is vitally important to understand on admission how the patient is measuring their U-500 insulin at home.

## Future Inquiry

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The topics below represent several unresolved safety issues from ISMP's *Optimizing Safe Subcutaneous Insulin Delivery Across the Continuum of Care* Summit. Many of these topics were briefly discussed, but not in enough detail in the time allotted to gain consensus on the risks and associated safe practices. The following statements are provided to encourage future studies and further discussion when looking to enhance the safety of subcutaneous insulin use.

- Steps to ensure the use of proper needle length for insulin administration
- Technology enhancements to ensure that an insulin pen device is never used for more than one patient
- Safe management of insulin in pregnancy
- Management of patients with diabetes who also have concomitant psychiatric or behavioral issues that impact insulin management
- Standardized post-discharge follow-up steps when an elevated hemoglobin A1C is identified
- Criteria to determine when vials and syringes should be used versus pen devices
- Safe insulin management in the home
- Safe subcutaneous insulin use in the pediatric population
- Use of the outpatient pharmacist in continuum of care management
- A predictive model to identify patients/circumstances prone to hypoglycemia
- How to measure harm from hyperglycemia
- Standardization of vocabulary (e.g., **NUTRITIONAL** versus mealtime versus prandial insulin)

## Conclusion

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Errors with subcutaneous insulin use continue to be one of the most frequent and often significant medication safety issues faced by practitioners today. While important advances in diabetes care have been made over the last few decades, insulin management, due to its complexity for both inpatients and outpatients, needs to remain a top priority for healthcare providers. Efforts to standardize best practices throughout the inpatient process, as well as during **TRANSITIONS OF CARE**, can serve as a foundation for better outcomes across the continuum of care. To ensure optimization occurs with safety in mind, the healthcare community must always monitor for adverse hypoglycemic and hyperglycemic events with subcutaneous insulin use, as well as identify and report insulin-related errors, wherever they may occur during the medication use process. Through this shared knowledge of our challenges, continued research, and the development of improved technology and product design to enhance insulin use, the healthcare community will continue to improve outcomes for patients with diabetes.

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## Definitions

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**BASAL (INSULIN)** – Insulin administered on a scheduled basis to maintain constant blood glucose levels during periods of fasting and between meals; long-acting insulin analogs, such as glargine, degludec, or detemir, are preferred because they provide relatively peakless levels of insulin; differs from intermediate-acting insulin, specifically NPH, which has pronounced and variable peaks.

**CONCENTRATED (INSULIN)** – For the purpose of the summit and these guidelines, ISMP considers any insulin with a concentration greater than 100 units/mL as “concentrated.”

**CORRECTIONAL (INSULIN)** – Insulin administered to lower elevated glucose levels, not to cover nutritional intake; correctional doses may be combined with **NUTRITIONAL** doses and administered simultaneously before a meal; rapid-acting insulin analogs, such as glulisine, lispro, and aspart, are preferred due to their prompt onset of action after dosing.

**NUTRITIONAL (PRANDIAL INSULIN)** – Insulin administered ideally 0-15 minutes before a meal to prevent the predicted postprandial rise in glucose levels; rapid-acting insulin analogs, such as glulisine, lispro, and aspart, are preferred due to their prompt onset of action and short duration of action after dosing; nutritional doses should be withheld when patients are NPO.

**TRANSITIONS OF CARE** – Transfer from an inpatient to an outpatient setting or vice versa; does not refer to levels of care within a facility (e.g., ICU to Med/Surg; Med/Surg to Radiology & return).

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Sanofi

## Appendix A

# Safe Practice Guidelines for Subcutaneous Insulin Use in Adults

### 1. PRESCRIBING OF SUBCUTANEOUS INSULIN

- 1.1** An endocrinologist or practitioner trained in insulin management, as determined by the organization (e.g., physician, nurse practitioner, physician assistant, or pharmacist), is consulted for patients with hospital-defined uncontrolled hyperglycemia or hypoglycemia.
- 1.2** The indication for insulin use is clearly documented in the health record and is readily accessible and visible to all clinicians during insulin order entry, verification, and administration.
- 1.3** Organizations develop and utilize evidence-based insulin protocols and/or evidence-based insulin order sets with decision support capabilities when appropriate. These guide:
  - a. Transitions from intravenous to subcutaneous insulin
  - b. Calculations and communication of **BASAL, NUTRITIONAL, and CORRECTIONAL INSULIN** doses
  - c. Management of insulin during planned and unplanned interruptions of oral, enteral, and parenteral nutrition
  - d. Management of **CONCENTRATED INSULIN**
  - e. Management of pregnant and postpartum patients with pre-existing type 1 or type 2 diabetes
  - f. Management of patients receiving glucocorticoid therapy
  - g. Management of patients with clinically significant episodes of hypoglycemia
  - h. Defined laboratory testing, point-of-care (bedside) glucose monitoring (including frequency), and other clinical monitoring practices
  - i. Identification, communication, and management of critical blood glucose values
  - j. Management of inconsistencies between the patient's symptoms and blood glucose values
  - k. When clinicians, other than the prescriber, may adjust or hold an ordered dose of insulin
  - l. Post-discharge insulin management
- 1.4** Organizational policies are in place to guide the care of patients with a personal subcutaneous insulin pump. An endocrinologist or practitioner trained in insulin management, as determined by the organization (e.g., physician, nurse practitioner, physician assistant, or pharmacist), is consulted when a patient with a personal insulin pump is admitted or presents for other organizationally-defined episodes of care.
- 1.5** The prescriber identifies the target glucose range in the patient's health record.
- 1.6** Eliminate the use of sliding scale insulin doses based on blood glucose values as the only strategy for managing hyperglycemia.
- 1.7** Insulin orders are free of error-prone abbreviations and dose expressions.
- 1.8** Strategies such as tall man lettering with bolded text for the unique letter characters are used on computer and device screens, pharmacy labels, order forms, storage bins, medication administration records, and drug information references to help distinguish look-alike insulin names (e.g., HumaLOG and HumuLIN; NovoLOG and NovoLIN).
- 1.9** Communicate all patient-specific information related to diabetes care in one designated place in the health record.

## 2. PHARMACY MANAGEMENT AND DISTRIBUTION OF SUBCUTANEOUS INSULIN

- 2.1 US manufacturers, regulatory agencies, drug information content providers, and healthcare facilities are encouraged to work concurrently to remove irrelevant information from insulin labeling.
- 2.2 Processes are in place to differentiate insulin products of different types and concentrations wherever they are stored.
- 2.3 Pharmacists confirm the indication before verifying initial insulin orders.
- 2.4 Insulin vials are removed from the manufacturer's carton prior to dispensing to patient care areas.
- 2.5 When insulin vials are dispensed (unit-stock or patient-specific) and stored in patient care areas (excluding the patient room), ready-to-apply barcoded labels are available to apply to clinician-prepared syringes.
- 2.6 The pharmacy prepares and dispenses **BASAL INSULIN** doses in patient-specific prefilled syringes (if stability permits) for patients who are not using a patient-specific insulin pen or insulin pump in the inpatient setting.
- 2.7 **CONCENTRATED INSULINS** are dispensed in patient-specific, labeled pen devices or in patient-specific, pharmacy-prepared syringes. U-500 insulin vials are only stored in the pharmacy.
- 2.8 Ideally, insulin pens are dispensed to the clinical units with a patient-specific, barcode label (that has been applied in the pharmacy, using a barcode verification process that confirms the correct pen type has been selected based on the patient's order) **AND** steps have been taken to ensure that only the correct patient-specific label can be scanned at the bedside.
- 2.9 A patient-specific label is affixed on the body of the insulin pen (not on the removable cap), without obscuring important information on manufacturer labeling or the dose counter/dose window.

## 3. ADMINISTRATION AND MONITORING OF SUBCUTANEOUS INSULIN

- 3.1 Patient-specific insulin pens are stored on clinical units in a manner that prevents their inadvertent use on more than one patient.
- 3.2 Organizations should develop a coordinated process to ensure timely blood glucose checks and administration of **NUTRITIONAL INSULIN** in conjunction with meal delivery.
- 3.3 Verbal communication of point-of-care blood glucose value results are avoided as much as possible and are **NEVER** routinely used as the only source of information when determining insulin doses.
- 3.4 The insulin concentration (e.g., U-100, U-200, U-300) does not follow the name of the insulin on the medication administration record (MAR) or other medication lists, with the exception of regular insulin U-500 (HumuLIN U-500).
- 3.5 Appropriately label all clinician-prepared syringes of subcutaneous insulin, unless the medication is prepared at the patient's bedside and is immediately administered to the patient without any break in the process.
- 3.6 Prior to subcutaneous insulin administration, the practitioner:
  - a. Confirms that there is an appropriate indication
  - b. Assesses the patient's most current blood glucose value
  - c. Assesses the patient for symptoms of hypoglycemia
  - d. Informs the patient of their most current blood glucose level
  - e. Informs the patient of their dose, the full name of the product, and the insulin's intended action



- 3.7 An individual insulin pen is never used for more than one patient.**
- 3.8 An insulin pen cartridge is never used as a vial.**
- 3.9 Barcode scanning is used to verify that a patient-specific pen is used to administer the correct insulin to the correct patient.**

#### **4. SAFE TRANSITIONS OF CARE FOR PATIENTS RECEIVING SUBCUTANEOUS INSULIN**

- 4.1 Prior to TRANSITIONS OF CARE, a process is in place to ensure that patients will have the necessary prescriptions, supplies, a follow-up care plan, and printed instructions for all prescribed insulin and blood glucose monitoring.**
- 4.2 During TRANSITIONS OF CARE, a coordinated process is in place to identify which patients on insulin therapy require additional intervention by an endocrinologist or practitioner trained in insulin management, as determined by the organization (e.g., physician, nurse practitioner, physician assistant, or pharmacist).**
- 4.3 Healthcare providers primarily prescribe insulin pen devices for outpatients to increase dosing accuracy and promote self-care and adherence with their insulin therapy regimen.**
- 4.4 Patients discharged on insulin are assessed for understanding of their self-management, including:**
  - a. Demonstration of proper dose measurement and self-administration using the same administration device that will be used at home (e.g., vial and syringe, pen, pump)**
  - b. How to monitor blood glucose values**
  - c. The signs and symptoms of hyper- and hypoglycemia and how to respond if these symptoms occur**
  - d. Common types of errors possible with their insulin therapy and how to prevent or detect these errors**
  - e. The importance of regular follow-up with their primary care provider/specialist, including the date of their next appointment**
- 4.5 Patients who self-administer U-500 insulin using a vial and syringe are taught to use only a U-500 syringe and communicate their doses in terms of the name and concentration of the insulin and the actual dose in units using only the U-500 syringe.**

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## About ISMP

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The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide timely investigation, analysis, and education about medication errors and their prevention. ISMP represents 40 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. ISMP is a federally certified patient safety organization (PSO).

For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit [www.ismp.org](http://www.ismp.org).



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