Second Edition

THE GLYCEMIC CONTROL IMPLEMENTATION GUIDE:

IMPROVING GLYCEMIC CONTROL, PREVENTING HYPOGLYCEMIA AND OPTIMIZING CARE OF THE INPATIENT WITH HYPERGLYCEMIA AND DIABETES

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Executive Summary

This *Glycemic Control Implementation Guide* is part of a continuing effort over the last decade by the Society of Hospital Medicine (SHM) to provide accurate guidance on best practices on glycemic control in the inpatient setting. This comprehensive *Guide* focuses not only on what should be done but also on how to do it. This is the fourth major revision of the *Glycemic Control Online Toolkit,* further illustrating SHM's dedication to meeting the needs of its members, continuous improvement and addressing major issues occurring in hospitals around the world.

The goal of this new version is to provide users with concise guidance and tips to help them assess their current state of care regarding glycemic control, gain institutional support, build an effective team, choose metrics to follow, implement proven interventions and continue to assess and improve over time. We have chosen to focus this edition less on the research and justification for these measures, though we will refer users to these resources, and instead to spend our time on clear, actionable guidance to help teams that are champions in their institutions to improve patient care regarding the prevention of hypoglycemia and appropriately preventing and treating hyperglycemia. We recognize that there are knowledge gaps about evidence surrounding some of these recommendations, and that research and guidelines are still evolving in this area. However, incomplete or imperfect evidence is not an excuse for inaction or unacceptable standards that have been shown to be ineffective and at times potentially dangerous to patients. Thus, we will make recommendations based on the best evidence available, making every effort to make this information clear. Please keep in mind from the outset that achieving safe and effective glycemic control for inpatients requires a multidisciplinary approach, from the team composition to the design and implementation of interventions; all levels of the hospital and staff must be actively involved. We must also remember that our goals do not end on discharge. In addition to preventing uncontrolled hyperglycemia and not causing hypoglycemia, we must also ensure safe and effective transitions into and out of the hospital and provide adequate education to set patients on the right path to controlling their disease for a lifetime.

Over the course of this *Guide* you will achieve the following essential elements to reach breakthrough levels of improvement in the care of patients with hyper- and hypoglycemia:

- **Gain institutional support** for and prioritization of this initiative, expressed as a meaningful investment in time, equipment, informatics and personnel in the effort
- **Create a multidisciplinary team or Steering Committee** that is focused on reaching glycemic targets and on many other aspects of the care of the inpatient with hyperglycemia and/or diabetes and that regularly reports to key medical staff committees
- **Develop specific aims, or goals, that are time defined, measurable and achievable**
- **Assess the current state of glycemic management in your facility** through an in-depth self-assessment utilizing tools such as process mapping
- **Review and identify best practices for the management of diabetes and hyperglycemia** for patients in your hospital
- **Choose reliable metrics and collect data** that, at a minimum, reflect glycemic control, hypoglycemia frequency and insulin use patterns. These data should be transformed into reports that inform the team and frontline workers of progress and problem areas to address

- **Deploy interventions and monitor impacts to decrease hyperglycemia** by drafting and approving algorithms, policies and protocols to ensure effective processes that are institution-specific and that support the order sets and promote their safest and most effective use. These tools must not merely exist; they must be widely disseminated and used and, in some cases, be embedded in CPOE order sets. A high-reliability design should be used to enhance effective implementation. These interventions include:
  1. Understanding the principles of effective implementation and high-reliability design
  2. Building effective and high-performing inpatient diabetes management teams
  3. Designing and implementing subcutaneous insulin order sets that promote the rational and evidence-based application of insulin in critical care and non-critical care settings
  4. Designing and implementing an insulin infusion order set
  5. Designing and implementing a DKA protocol
  6. Designing and implementing perioperative protocols and order sets
  7. Improving transitions of care for patients with hyperglycemia into the hospital, off insulin infusion and from the hospital to home
  8. Administering comprehensive education and certification programs for healthcare providers and patients, reinforcing both general and institution-specific information, including education about the items listed under algorithms, policies and protocols
- **Developing processes and structures to prevent hypoglycemia** through safe insulin management practices and a hypoglycemia reduction bundle; and improving processes around nutrition, insulin administration including consideration of use of insulin pens and policies around subcutaneous insulin pumps
- **Change and maintain a new culture of improvement** that will allow the institution to maintain gains made and to continue improving over time

How to Use This *Guide*

The *Guide* addresses each of the elements above in some detail. Although it is designed to assist leaders who are starting from scratch, the *Guide* can also benefit teams that have already made considerable progress, as it is unlikely that any institution is performing optimally in all areas. It is recommended that all users initially review Section I: Take First Steps, Section II: Identify Best Practices for Management of the Hospitalized Patient with Diabetes/Hyperglycemia and Section III: Assess Current State of Glycemic Management, which will help you assess your current status on all of the elements explained in these sections. Completing these sections first will put you in a position to proceed with good institutional support and to intelligently prioritize areas for intervention and allocation of resources.

Although we attempted to present the information in a logical order that mirrors a real-life approach, improvement teams should not feel obligated to adhere to every detail of every section or to follow the sections in the exact order they are presented. In fact, some will find it difficult to stay with one particular sequential order, as activities presented in different sections often occur in parallel in real life. However, over time, your team should eventually assess and attempt to improve the full range of quality issues involving care of the inpatient with diabetes/hyperglycemia.

The *Guide* incorporates sections of all the essential elements described above to achieve breakthrough improvement. In addition, it highlights important topics and improvement tools such as run charts, process mapping and methods to hold the gains and spread your improvement methods. Methods for demonstrating financial return on investment are also presented.

This *Guide* leverages resources within the SHM website, particularly the Glycemic Control Toolkit. The Online Toolkit provides links to guidelines, key references and examples of order sets, algorithms, protocols and educational materials that can be invaluable to your team. One special word of caution is in order, however. You are strongly discouraged from using these materials to build an order set or protocol without following the general improvement framework presented in the rest of the *Guide*. This framework calls for a multidisciplinary team effort, specific goals, reliable and practical metrics, and monitoring and learning from variation from your protocol. Ignoring these principles can lead to mediocre results and disillusionment.

Following these methods can enable you to demonstrate the value of quality improvement work to your medical center and insurers, both because of the outcomes obtained and because of the cost savings often inherent in higher-quality care. Demonstrating value in quality improvement and cost savings can lead to protected time for hospitalists and others to improve the quality and safety of the hospitalized patient.

Section 1: Take First Steps

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Section I: Take First Steps

Congratulations on beginning this journey to make your hospital safer and provide higher-quality care to your patients. Your first steps will involve forming your team, defining your goals, assessing at a high level the current state of your hospital and garnering the right resources and administrative support to help you achieve your goals for the project. However, it is first necessary to assess and recognize the existing factors for change in your institution. How did you get to the point that you are reading this *Guide*? Was this assigned to you? Are you just a concerned citizen? Are you a hospitalist starting a quality project? How invested is the institution, and how aware are others of the problem? The order in which you will take the steps below is dependent on these answers. If this endeavor already has strong administrative support, you may have the authority to form the necessary team and take these steps in order. If you are working alone, it may be important for you to identify other champions and spend some time getting a high-level assessment of the current state in order to get the administrative support you need to perform these steps thoroughly. As with any quality project, these steps do not have to be followed in a strict chronological order. They are often cyclic, achieving more with each cycle as we work toward our goals, but the basic principles are the same. Please keep the following in mind as you read this *Guide:*

Recognizing and Defining the General Quality Problem

Quality improvement projects should always develop from recognition of a gap between the level of care that is optimal and best supported by the evidence and the care that is actually being delivered to patients. The first issue is how you recognize the gaps that can be found within your institution. Each institution is unique, often excelling in some areas and lagging in others. It is imperative that you identify and work on the areas that need improvement within your facility, not just apply best practices randomly. What has worked at other institutions may not work in yours, as you likely have different processes and a different culture. You must have a good understanding of how things are done within your walls to have the greatest impact on the care of your patients.

Optimal Care for the Hyperglycemic Inpatient

Team leaders need to be thoroughly familiar with the evidence and principles of the management of diabetes and hyperglycemia in hospitals. Reviewing the appropriate sections in the *Glycemic Control Online Toolkit*, including important reviews, position papers and guidelines, and reviewing the annotated bibliography of key literature in the *Glycemic Control Online Toolkit* should bring you up to date quickly if you are not already well-versed in this literature. By understanding how things should be done, and knowing within your facility how things are done, you will begin to identify where the gaps exist between these, and be able to focus your efforts.

Looking into the Gap

Section III (Assess Current State) guides you to delve into the details of the care you currently provide and to recognize opportunities for improvement, while the metrics needed to accurately and reliably measure the quality of care your patients enjoy is fully outlined in Section IV (Metrics). A multidisciplinary approach and institutional support are needed to really complete these sections.

This section will focus on a high-level assessment.

A. Assess the Current State of Glycemic Management at a High Level

You may have already successfully used your own methods for convincing yourselves and your administration that inpatients with diabetes/hyperglycemia receive suboptimal care (either by anecdote or hard data) to such a degree that you have garnered full institutional support and a complete multidisciplinary team. If this is not the case, however, how are you to convince colleagues, staff and the administration that the care currently being delivered is suboptimal, and galvanize full participation in your cause?

Your first step should be to assess your hospital's glycemic performance not only to serve as a starting point, but also to use as evidence for the need to change. You will do much more in-depth analysis in the following sections, but a first step should be a global assessment of how patients with diabetes are doing in your hospital today. This is not research, so the data collection guidelines are much looser at this stage. The goal is for you to have situational awareness within your hospital of the current state and processes, then to use this data to motivate change. Some of the basic information-gathering activities at this point include the following:

1. Generate a Report of Glycemic Control with Benchmarking
2. Use a Small Sample to Identify Current Treatment Practices – e.g., sliding scale vs basal bolus
3. Be Aware of Any Sentinel Events – e.g., severe hypoglycemia or development of DKA in house
4. Assess Culture and Nursing/Physician Awareness of Glycemic Issues

The first two steps above are methods you should employ very early in this process to look at the current state at a high level – generating a report of outcomes level data, ideally with external benchmarking, to serve as a baseline, and using a small sample of patients to identify what current treatment practices are occurring in your hospital. Both of these processes should be able to be completed by a couple of people with a modest amount of effort, but will serve to help you enlist the larger team you will need to conduct the more in-depth analysis outlined in Section III. Let us go through each of these in more detail.

Generate a Report of Glycemic Control with Benchmarking

Generating a Glucometrics Report may sound daunting, but there are resources available to make this step less difficult. The goal is to determine the current rates of hyper- and hypoglycemia hospital-wide, and how you compare to other institutions. Without this information it will be very difficult to focus even your initial efforts. Do you have high rates of hypoglycemia with fairly good control of highs? Are you endangering patients both at the high and low end of the scales? Or, is your hospital so risk-averse to hypoglycemia that you allow permissive hyperglycemia but have all but eradicated low sugars? Each of these scenarios will lead to a different action plan.

We are not going to go into the science and mathematics of glucometrics at this point in the *Guide*; this will be covered in more depth in Section IV. The point here is to quickly generate a report that will give you a real-time assessment of care. It is highly unlikely that you will have the resources at this stage in your improvement work to generate these reports locally. Luckily, there are websites and services available with and without a cost to help you generate these reports. The legwork of this step will be getting access to the point-of-care (POC) glucose measurements from your hospital. You will first have to navigate the policies around getting access to data and then identify the resource to provide you with your (POC) glucose measurements. Your goal will be to obtain a file in Excel or CSV format with at least a month of data. This can be for the whole hospital or only the floors you are currently

working on. Within this file the only data points you need are a patient identifier, a time/date of test, a test result and the location of the test (all of which are always provided with each reading).

Most sites get this data directly from the POC lab, rather than out of their Electronic Medical Record (EMR). We would suggest that you start there. Either work with your quality department or contact the lab directly and find out who has access to the point-of-care (POC) glucose readings. Often this data exists in multiple areas; a local server where all POC readings are downloaded to proprietary software associated with the brand of glucometer being used, or an interface database where the EMR pulls this data from. You may even already have access to an analysis product, which is often included with the purchase of certain brands of glucose meters. Often it is finding the one person in the lab who manages this data or your quality outcomes department who is able to easily get access to this data. You will need to clear any processes of using this data with your internal policies, especially if you plan to upload it to an outside resource.

Once you have this data there are multiple options for analyzing it. It is recommended that you use the Society of Hospital Medicine's (SHM's) Glucometrics Benchmarking Report. This website will generate a report for you that will include commonly used measures with a comparison to other hospitals. It will generate graphics that you can use in your initial discussions when trying to gain support from your institution and will provide an overview of where the majority of your work will need to focus. The initial analysis is free and you can continue to use this site for an annual fee. Another option is the Yale Glucometrics website, available here. This will give you a robust glucometrics analysis, but does not have benchmarking and lacks some flexibility when building reports in the future. Whichever method you choose to use, this step is vital to your efforts – take the time to identify where to get this data (which you will need throughout this project) and use existing resources to analyze it.

Get these reports in a format that can be disseminated and that illustrate the points you find. Identify where the areas for improvement are and begin to prepare the case you will make below with this data.

Use a Small Sample to Identify Current Treatment Practices

We are presuming you don't yet have the capacity to collate large amounts of data from medical center databases. So this section mainly focuses on how to gather small amounts of data manually. Even a quick review of a small selection of patients with hyperglycemia can provide you with some numbers to convey the reality, size and scope of the problem to others and help you enlist members to a multidisciplinary team to address the rational and safe use of insulin in your medical center. In addition to these "glucometrics," you can get additional information about current processes in Section II (In-Depth Analysis/Assess Current State), which can be very useful when lobbying for support from your administration. Methodological rigor is not as important at this stage, as you are only trying to gather enough information to form a committed multidisciplinary team and gain enough institutional support to get started.

An extensive discussion of metrics is in Section IV; you will find it helpful to review this section, even before your first attempts at data collection.

Your goal is to design an audit tool that will give you insight and basic measures to define basic elements of care in your organization. Some examples of the data you will capture:

- Are the patients having hyper- or hypoglycemic events?
- What types of insulins are they ordered? Sliding scale, basal bolus, bolus or basal only?
- Are changes being made since admission if they are out of control?
- Are they written for oral agents as inpatients?

- Are the nurses giving the prescribed amounts of insulin or holding them?
- Are there differences in the above based on location, team or provider?

General suggestions for early data collection and analyses

- Do a separate evaluation of critical care units versus non–critical care areas.
- In early data collection, sampling active inpatients is the most efficient way to rapidly assess your current performance.
- Data collection should focus on three key areas: glycemic control, safety and patterns of insulin use. Collect all three parameters on the same chart reviews.
- Using analysis by patient-day gives you meaningful and robust numbers with small sample sizes.
- Follow a stepwise approach as outlined below.

Identify the target population: For example, you could target patients on general medical-surgical wards with monitoring of POC glucose or with insulin orders. Either target population can be identified by the nursing staff or by a quick scan of the chart, or pharmacists can identify patients on insulin.

Define your sampling strategy: Ideally, you will pick patients representative of the larger population. Random sampling with a random number generator is possible but probably not needed for early data collection. Options include picking consecutive patients who meet your criteria, or constructing a convenience sample from a selection of representative wards.

Define your exclusion criteria for patients, patient-days and glucose values: You might exclude patients with only a one- or two-day LOS, or decide to only collect data through the fifth hospital day, for example. Instead of collecting, recording and analyzing all patient glucose values, you can collect only some of the more representative ones. For patients on subcutaneous insulin, your analyses of glycemic control might be limited to those most representative of the routinely collected values in order to prevent oversampling around glycemic excursions. On the other hand, you can characterize overall glycemic control when limiting data to routinely collected glucose values, while still noting whether the patient has any hypoglycemic or extreme hyperglycemic readings for a given hospital day. For a critical care population, you might decide to only look at morning glucose values instead of all values collected over the entire day.

Decide on how you will characterize the key areas of glycemic control, safety and patterns of insulin use: The good news for a limited sample that is collected manually is that you can use sophisticated methods fairly easily. For example, analysis by patient-day and by day-weighted mean is fairly straightforward when collecting data by hand.

Build a data collection tool and pilot it with one or two patients: This will give you an idea of whether you can really get at the information you want with your construct.

Do not let the complexity of data collection dissuade you from collecting data at this stage. Use simple measurements if necessary, but the following example can be done by most sites with minimal expertise. The next two pages illustrate many of these principles. Data collection and a summary of just three patients on a non-critical care ward are shown. You will want to have a sample of more than three patients (perhaps 10-15), but the spreadsheet can be easily expanded to accommodate more patients.

Example of data collection/analysis

- Target population: Non-critical care medical-surgical pat

Be Aware of Any Sentinel Events

You may already be aware of an event that generated your current interest in improving glycemic management. Even if you are not, it is important for your team to be aware of issues that may be contributing to the culture you have locally and to provide evidence for a need for change. Anecdotes or incidents reflecting unsafe medication use and hypoglycemia in your setting can be powerful additions to make the case for support. Ask your current team members and other nursing or pharmacy level staff about any incidents regarding insulin use. Examples would be episodes of severe hypoglycemia or development of DKA in the hospital. Contact your risk management department or quality department to elicit other incidents. Learn as much as possible about these events, as these events create the stories you will tell that can motivate change. Learn about the patients as individuals and craft the story you will tell to help promote the changes you will be proposing.

Assess Culture and Nursing/Physician Awareness of Glycemic Issues

It is very essential to have an idea of how important and what the culture is at both a nursing and physician level. At this stage we are not talking about a full-blown survey or detailed interviews, but your team needs to be aware of staff perceptions around inpatient glycemic management. Ideally, many members on your interdisciplinary team will be able to help identify this.

1. Does nursing and physician staff recognize the importance of glycemic control?
2. Are staff aware of what the glycemic targets are during hospitalization?
3. Do staff feel this is an important issue within your organization?
4. Is there fear of hypoglycemia compared to importance of treating hyperglycemia?

During many of your initial meetings with stakeholders, getting access to data and forming your team, you will receive many clues as to the culture within your institution. Pay attention to these and do not assume that this issue is important to everyone. Once again, every hospital is different. You may find that the frontline nurses are champions for this cause, but the administration is unaware; or that a group of physicians are obstructing efforts due to not believing evidence on this issue. It is imperative to identify those in support, those who are ambivalent and those who oppose change. This often means asking the right questions to the right people and being aware of the perspective from their point of view. It may be necessary at a later date to perform a more in-depth analysis of culture and awareness, but at this stage, informally assess each time you meet with nurses, administration or physician groups. Ask your team members to be aware and report back.

B. Obtain Institutional Support

Your team needs support from both your medical center leadership and the frontline ranks to achieve your improvement effort. Getting institutional buy-in and administrative support is essential. Although you may not yet have robust data, the rationale for directing resources toward glycemic control efforts can be spelled out. You will now use the data you obtained above to generate a need for change. You want to garner support at both the frontline and the highest administration. We would recommend that you widely disseminate both data and stories to illustrate the need for change in your institution. Develop your 'elevator speech' and ask each person you have on your team to garner support in all venues for the project.

First, recognize who the existing stakeholders are in the institution. Who is this already important to? Is the quality department focused on Core Measures, is the intensive care unit (ICU) working on post-CABG patients, does pharmacy have projects around insulin drips or insulin pens? Identify and meet with anyone who may already be working on efforts in this area. Then identify where the gaps are and how high the support goes to begin to garner more support. You will do a more in-depth analysis of stakeholders when forming your team, below, but at this stage you want to know who is either strongly for or opposing these efforts.

Recognize that each audience has different perspectives and will respond to different information. For the senior leadership you must make the case that glycemic control efforts can be cost effective. You need to convince them of the bottom line and how investing time and effort into this project will benefit the institution. Without their support you are unlikely to get the administrative support you will need or the team members with time devoted to this effort. Projects are much more likely to be successful when they have a leadership champion, and you should make the efforts to identify this person. Ideally, this would be C-Suite level, the chief nursing officer or COO, but could also be the chief quality officer or an executive medical director. It is important to know your organization's structure to identify who may be best suited to support the project, and this may take some time. A direct line to administrative support for your effort, either by a direct reporting structure or by involving a senior administrator in the team, should be in place before you go any farther.

Meet with members of your administration and have prepared "talking points," and, ideally, some preliminary information you've collected demonstrating the need for the administration's attention. Talking points are listed in the online Glycemic Control Toolkit which can be used to make the economic and quality case and to help you convince your administrative leaders of the importance of supporting a program to improve glycemic control and reduce the incidence of hypoglycemia in the hospital. Include local data you have collected as you see appropriate, perhaps using ideas instead of data collection from your small sample size analysis

No effort will be successful without engaging the frontline, so part of institutional support is finding champions and changing sentiment at the frontline. This is sometimes easier once you have leadership support, but that is not sufficient. Use both your data and patient stories at the frontline to generate interest in this effort.

What does support look like at this stage? Support comes in many forms, but ideally what you are looking for is vocalized and real actions around the initiative that would include resources for data collection, administrative assistant or meeting support, project management resources, support to identify team members, financial support to purchase data analysis products, meeting space and refreshments, support to make changes to the EMR, or to change nursing or physician practices. You want to identify leaders who can help push initiatives through that may be met with resistance in the future. Ideally you will begin to see glycemic control show up on strategic plans or on unit and service line yearly goals. This search for support is an ongoing part of any quality project, and as you get more momentum and are proposing more drastic changes, you will need more support, so always have this in mind during the project.

C. Form an Interdisciplinary Team

To be effective in a quality project, you must have an effective interdisciplinary team. At the outset this might be you and one other person, but ideally it will grow to include all of the individuals you need to achieve the goals of this *Guide*. The first steps will be identifying other champions and building your team to begin this process. Once you have administrative support, some of these team members may be assigned, but it is also important to find those champions who already exist in the organization and enlist them to this cause.

The mundane task of arranging and facilitating meetings with a team lead to the the success or death of a project. Do not take these steps lightly. How large your team is, who is arranging the agenda, scheduling space and sending out minutes and action items is vitally important. A team too large may never find compatible meeting times, one too small may not have the appropriate individuals who can make proposed changes. Find this balance and learn about meeting management. Also advocate for administrative assistant support to help with these tasks during your administrative support meetings.

Identifying all the stakeholders and defining who needs to buy-in and be aware of your efforts is important to increase the likelihood of early adoption, to give you legal protection for information you uncover and to plan educational efforts. Typically, these groups include representation from:

1. Pharmacy and therapeutics committee
2. Pharmacists
3. Nursing groups (including leadership bodies, diabetes clinical specialists, frontline nurses and nursing education department members)
4. Physicians (including hospitalists, endocrinologists, intensivists, surgeons and other hospital physicians)
5. Diabetes educators (RN or RD-certified diabetes educators)
6. Quality and patient safety, performance improvement staff
7. OR or perioperative committees
8. Chief residents and/or residency program directors
9. Unit clerks/secretaries
10. Departmental committees
11. Nutritionist/dietitians
12. Lab and POC lab personnel
13. EHR, medical records and computerized physician order entry (CPOE) expertise
14. Forms committee
15. Patients

Each hospital team must decide who will be the key core members essential for the development and implementation of the team initiative. Other persons whose input will be required periodically may serve as ad hoc glycemic control team members, for example, representatives from billing/coding services and finance.

Please review the introduction about team members and how to approach the scope of your efforts. Have everyone on the team get some basic education on quality improvement, either through readings, online resources, or in person courses. SHM has resources to help with this. Efforts are often initiated by just a few thoughtful leaders who see a big gap between the current practice and the best-known practice and who then recruit others to their cause. Members of each glycemic control team for each major area of focus should include a team leader, content expert, team facilitator and process owners.

TEAM LEADER(S): This is usually a physician hospitalist leader, endocrinologist, critical care physician, surgeon or other physician leader. This leader, hopefully with some administrative help, is responsible for calling meetings and communicating directly with administrative and appropriate medical staff committees. If the team leader doesn't personally take the minutes, he or she should edit their content for presentation to senior leadership and should "own" them. The team leader should be a respected member of the medical staff with some topic expertise in insulin usage and inpatient diabetes and does not necessarily have to be a physician. Just as important, the team leader needs to have the commitment and perseverance to drive the entire process forward. There may actually be several leaders, whose involvement varies as the focus changes. For example, a surgeon may lead efforts on perioperative glycemic control, whereas a hospitalist may lead efforts to improve subcutaneous insulin use on the wards. Alternatively, an endocrinologist or other individual may lead the entire effort. In any case, a coordinated effort is required across the entire spectrum of care.

Another effective structure is to form teams with physician and nursing leader 'dyads'. This ensures engagement by both sides and avoiding this looking like a 'hospital' initiative or physician project. This structure also allows for responsibilities to be split, while maintaining buy-in from both sides where process changes are going to be required.

CONTENT EXPERT: An endocrinologist may not always be the team leader and may not always have the time or expertise to lead the effort to improve glycemic control at your institution. However, having an endocrinologist, hospitalist or other physician who is an expert in glycemic control to buy in and assist in reviewing and formulating insulin order sets, protocols and educational materials is essential and will lend authority to the team's recommendations and interventions. Approaching and enlisting as an active ally a prominent and respected endocrinologist at the onset of your efforts can be an important move to make in forming your team. When this is not possible, hospitalists are becoming the experts in glycemic control and may serve as the content expert where there is not an endocrinologist available.

TEAM FACILITATOR: The team facilitator's main duties are maintaining team rules, helping the team leader stay on track by calling on effective team techniques and introducing the appropriate quality improvement (QI) tools for practical use by the team. Mastery of QI tools at the onset of the project is not necessary. What is needed is a willingness to learn QI tools and introduce them to the team as necessary. Mastery of insulin/diabetes literature is not important for this position. Sometimes one person can be both team facilitator and team leader, but for more ambitious projects or for projects involving buy-in from disparate physician and nursing groups, a separate facilitator is very strongly recommended.

PROCESS OWNERS: Participation of frontline personnel (nurses and pharmacists, for example) is essential to having an effective team trying to optimize glycemic control and other aspects of care provided to the inpatient with hyperglycemia.

At your very first team meeting, the team rules need to be established and everyone needs to explicitly agree to them. The facilitator is usually given the task of gaining consensus on, and enforcing the team rules.

D. Establish Team Rules

Use the team rules below as a starting point. The team should modify the rules as needed, then officially record and acknowledge them. To some, these rules may appear a bit preachy. The key principle that must be maintained is this: everyone on the team must be encouraged to speak up, and their views must be respected. Traditional concepts of rank have to go "out the window." A unit clerk should feel comfortable telling the lead physician, "I don't think that will work because of [reason]. Why don't we try it this way?"

In addition to these rules, it should be made very clear that potential members should notify the leader quickly if they cannot devote the requisite time and effort so a suitable replacement can be found. Timely minutes as well as a quick turnaround for comments/corrections should be the rule.

Team Ground Rules

- All team members and opinions are equal.
- Team members will speak freely and in turn.
  - We will listen attentively to others.
  - Each must be heard.
  - No one may dominate.
- Problems will be discussed, analyzed or attacked (not people).
- All agreements are kept unless renegotiated.
- Once we agree, we will speak with "one voice" (especially after leaving the meeting).
- Honesty before cohesiveness.
- Consensus versus democracy: we each get our say, not our way.
- Silence equals agreement.
- Members will attend regularly.
- Meetings will start and end on time.

E. Define Scope, Priorities and General Goals of Your Efforts

Establishing good goals is essential for maintaining focus and motivating the team. Eventually your aims should be specific, measurable and time-defined and should specify the population or populations for whom you want to improve care. A "stretch" goal should be established that should be aggressive enough to mandate a change in the design of your current process in order to achieve it. Until you have reliable metrics and a baseline evaluation, however, team-supported general aims or goals can be important for galvanizing action and establishing clarity of purpose. While this may seem like an unnecessary step early in a QI project, putting into words what you are trying to accomplish and ensuring that all members of the team agree with these goals can be difficult, but can help solidify the team around this common stated goal.

One important task is to define the scope of your efforts. Do you want to focus on just one ward or service? Will you focus on critical care patients, ward patients, or both; medical patients, surgical patients, or both? Again, we encourage a broad view of the scope of your efforts as affecting all inpatients with hyperglycemia, but it may be reasonable to start small and then spread your improvement methods to other areas. On the other hand, even if the scope of your effort includes all patients in your hospital or system, the interventions you choose should be piloted on a small scale when possible. The bottom line is this: think BIG! Don't bite off more than you can chew initially, but serial testing and learning on a small scale can make even very large projects more manageable.

First develop general aims. These will help define the population you are trying to address and what aspect of care you are trying to improve. This will help focus the efforts of everyone on the team as they may each come with their own agendas. You can always refer back to these aims when changes are made to see if they are in line with one of the general aims.

Examples of general aims:

1. General aim: Substantially improve glycemic control of inpatients in critical care units.
2. General aim: Substantially improve glycemic control of all adult inpatients in non-critical care units.
3. General aim: Reduce the incidence of hypoglycemic events in non-critical care inpatients.
4. General aim: Improve the knowledge and education of patients and healthcare providers on diabetes and hyperglycemia management.

Under each of these general aims, you will develop specific aims:

1. General aim 1: Substantially improve glycemic control of inpatients in critical care units.
   - Specific Aim 1: Decrease severe hypoglycemia by 50 percent within one year.
   - Specific Aim 2: Develop and implement an insulin transition protocol within CPOE and have it used in 90 percent of transitions from IV insulin to subcutaneous insulin.

As your team develops, your challenge will be to define many of the terms in your general aim, which will entail developing defined metrics and more mature, specific, time-defined aims. For example, how will you define/summarize/report glycemic control in the critical care setting? How will you define and quantify hypoglycemic event incidence in your institution? How do you define an evidence-based protocol or insulin regimen? How will you know if a variation in hypoglycemic rates or glycemic control is a result of "noise" and random variability or whether it is a real and meaningful change? These and many other issues are addressed in later sections, so don't get nervous if you don't know the answers right now.

F. Review the Framework for QI and QI Tools

Any team that wants to effectively improve glycemic control at its institution should understand the basics of effective implementation and improvement. Having an identified improvement framework will dramatically enhance a team's chances of realizing breakthrough improvement. At least one or two hospitalists in your group should become very familiar with the general framework for improvement and with proven QI tools. Medical center resources — such as a patient safety officer, a QI leader or a QI facilitator — may be available at your institution. You should identify these individuals and enroll them in your cause in the earliest stages.

There are many tools for QI. Each tool has particular strengths for use at different points in the improvement process. A few are particularly important and are useful in almost every project. Process flow mapping is an important step in designing or redesigning a process to make it more efficient and reliable. Process flow mapping also lends itself to producing protocols and clinical algorithms and is essential to identifying where things can go wrong, either informally or more formally by failure modes effect analysis (FMEA). We also consider run charts as nearly essential because they help the team follow and communicate progress toward its goals. We recommend having a working familiarity with these tools, either by the in-house expert or by the hospitalists who are (or will become) your improvement team resources.

- The **Institute for Healthcare Improvement** has an excellent website that reviews a model for improvement, as well as provides QI tools that you can actually download. Although registration is needed to download the tools, this is a quick and free resource.
- The **American Society for Quality** has an excellent, user-friendly site with overviews of the major quality improvement tools. Explore this section with particular attention to run charts, SPC charts, process flow diagrams and FMEA.
- The **Society of Hospital Medicine** has resources that can support an entire QI effort, from full mentored implementation programs, to QI/Leadership course offerings and online QI courses. Through the SHM online discussion forums at HMX, there is opportunity for discussions with experts.
- **Intermountain Healthcare** is a recognized leader in the performance-improvement field and in integrating performance improvement with all of its key clinical endeavors. The Institute for Healthcare Delivery Research, led by Dr. Brent James, has a wealth of presentations and other information available at no charge.

G. Conclusion

If you have completed all of the steps above you should have a good understanding of the care being provided in your hospital and where the needed areas for improvement are. You now have some initial data that shows your glycemic control outcomes, and you have sample data to show you the patterns that most physicians use in your hospital to treat hyperglycemia. You are aware of the culture that exists in both the providers and nursing staff. You have generated both administrative and frontline support and you have a team formed with regularly set meetings. You have already met and developed initial general aims and perhaps a few specific aims. You are now ready to do a much more in-depth analysis of your current practices and begin the work of changing the care you provide. You will be identifying best practices, analyzing current processes, selecting metrics and finally designing and deploying interventions. You will ensure you have processes to combat hypoglycemia, and then you will build a structure to continue to improve over time and not to lose the ground you will gain. This is an ambitious project and you should be off to a good start.

Section II: Identify Best Practices for Management of the Hospitalized Patient with Diabetes/Hyperglycemia

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A. Background

Uncontrolled hyperglycemia in hospitalized patients with or without a previous diagnosis of diabetes is associated with adverse outcomes and affects a large number of patients. In the United States alone, there are approximately 1.6 million new cases of diabetes each year, an overall prevalence of 29.1 million (9.3% of the population), and another one-fourth of the cases still remain undiagnosed.[1] In addition, many patients without pre-existing diabetes experience stress-related hyperglycemia during hospitalization resulting in a total of approximately one-third of hospitalized patients experiencing significant hyperglycemia.[2] The average length of stay for patients with diabetes is approximately one day longer, and the costs to care for them have been estimated to be double that of those without diabetes.[3,4] In 2015, these costs may increase, as Medicare is scheduled to reduce payments for all diagnosis-related groups by one percent for hospitals in the top quartile of healthcare-acquired condition rates including DKA and hypoglycemia.[5]

Overtreatment and undertreatment of hyperglycemia represent major safety issues in hospitalized patients with and without diabetes.[6,7] In a review of point-of-care (POC) data from 126 U.S. hospitals, blood glucose values exceeded the target of 180 mg/dL in 45% of the readings in the intensive care unit (ICU) and 31% of all readings in non-ICU areas.[8] While less prevalent, hypoglycemia also affects a large number of hospitalized patients with 2.9% and 5.1% for ICU and non-ICU settings, respectively, in the same study and 6.7 and 5.7% of patient days.[9] In a large cohort of hospitals that had implemented various interventions to improve inpatient glycemic control through the Society of Hospital Medicine (SHM), a mean of 5% of non-ICU patients per day experienced a blood glucose (BG) less than 70 mg/dL, 0.6% had a BG less than 40 mg/dL during their hospital stay, a mean of 34% had a recurrent episode of hypoglycemia after the index event and the mean time to resolution of hypoglycemia was 127 minutes.[10]

Inpatient hyperglycemia is associated with adverse patient outcomes — but acute illness, inconsistent caloric intake, changes from home medications, fear of hypoglycemia, clinical inertia and limitations regarding the timing of glucose monitoring and insulin administration are all significant obstacles to managing inpatient hyperglycemia. Recent guidelines for optimal glucose control and safety in hospitalized patients have been developed by the American Association of Clinical Endocrinologists (AACE), the American Diabetes Association (ADA) and The Endocrine Society.[11,12,13] These call for moderate glycemic targets; the use of basal, nutritional and correctional components of insulin; and discourage the use of oral agents and sliding scale alone. This recommended insulin regimen has also been supported by recent randomized controlled trials.[14,15,16] However, controlling glucose and avoiding hypoglycemia is challenging even for experienced clinicians and ongoing education, order sets and systems of care that incorporate the principles of physiological insulin delivery are essential to overcoming these obstacles and safely achieving glycemic goals.

B. Monitoring Glucose Levels and HbA1c

The HbA1c is an important tool to incorporate into the inpatient evaluation. It is now accepted as a diagnostic test for diabetes, and values can supplement patient clinical history in determining the effectiveness of pre-hospitalization treatment regimens. The test can help to identify some of the 25 percent of patients with diabetes mellitus (DM) that had previously been undiagnosed and recognition of DM while inpatient may reduce their risk of readmission.[1,17] Since it is relatively easy and inexpensive, it has become an “opt out” test on many order sets, is recommended in some guidelines and testing it on all patients with hyperglycemia without a value documented within the last 60 days is a required component for Joint Commission Certification in Advanced Inpatient Diabetes Care.[13]

Guidelines recommend that all patients have blood glucose testing upon admission and those with a BG value >140mg/dL have ongoing testing for at least 24-48 h.[13] POC glucose meters are currently the method most widely used for monitoring glucose because of the rapid turnaround and need to make timely adjustments to therapy. However, there are a wide number of potential issues (shock, hypoxia, dehydration, extremes in hematocrit, elevated bilirubin and triglycerides) impacting the accuracy.[18,19] Additionally, issues with some monitors and lack of Food and Drug Administration (FDA) approval for critical care or hospital use have also been raised.[20,21] Outside of these analytical issues, pre-analytical issues with site selection and interface with results for the correct patient being available to caregivers are important influencers on the quality of care being provided. Incorporating meter quality control and the processes for testing and recording values are important components for multidisciplinary committees to consider. Procedures aligned with The Joint Commission (TJC) must be established to assure ongoing quality control of the monitors, process of patient testing and recording the results. Additionally, with such threats to valid POC test results, clinical condition should guide treatment with the use of confirmatory venous samples when in question. Hospitalized patients require frequent testing due to the fluctuations and many variables influencing blood glucose. Testing is generally recommended to be performed before meals and at bedtime in patients who are eating or receiving bolus tube feeds[13] although recent studies have called into question the value of the bedtime value.[22] In patients who are NPO or receiving continuous enteral or parenteral nutrition, glucose monitoring is performed every four to six hours depending on whether short-acting or rapid-acting analog insulin is used. For patients on intravenous insulin, the ADA and AACE recommend hourly blood glucose monitoring except for patients with stable blood glucose within the target range, for whom monitoring can be performed up to every two hours.

C. Glycemic Targets

Critically Ill

In 2001, van den Berghe published results demonstrating significant improvements in mortality in surgical ICU patients treated with IV insulin therapy targeted at normalizing blood glucose.[23] Following this, numerous specialty organizations published recommendations targeting "very tight" glycemic control and many hospitals implemented infusion protocols to normalize blood glucose values in their critically ill patients.[24,25] However, subsequent trials had mixed results and finally NICE SUGAR ultimately demonstrated increased mortality and hypoglycemia with "very tight"/normalized blood glucose versus moderate control.[26, 27] Revised guidelines now recommend that insulin therapy be initiated if the blood glucose is ≥180 mg/dL and then maintained between 140 and 180 mg/dL in critically ill patients. Glucose targets somewhat lower than these may be appropriate in selected patients although strong evidence is lacking. The Society of Critical Care Medicine guidelines continue to recommend a target of 100-150 mg/dL but emphasize avoiding hypoglycemia.[28] For these purposes, critical illness generally refers to patients requiring invasive mechanical ventilation, those requiring pressor support and patients with multisystem organ failure.

Special Populations

For post-operative cardiovascular surgery, The Joint Commission's Surgical Care Improvement Project (SCIP) updates from January 2014 set targets of blood glucose levels in the 18-24 hour window after anesthesia end time of <180mg/dL but these SCIP glycemic metrics are currently on hold as of early 2015 with new metrics still to be determined at the time of this publication.[29]

Non-Critically Ill

With very few prospective, RCT data for establishing specific guidelines in non-critically ill patients, the ADA/AACE recommendations in 2009 are based on clinical experience and judgment.[13]

Hypoglycemia

Hypoglycemia has associated risks demonstrated in various studies, and strategies are necessary to avoid it. Studies have used variable definitions for hypoglycemia but the ADA has defined hypoglycemia as a blood glucose level <70 mg/dL and severe hypoglycemia as <40 mg/dL.[30]

D. Methods to Achieve Control

Inpatient hyperglycemia is best managed with insulin only. Insulin works reliably, and doses can be rapidly adjusted depending on changes in glucose levels and food intake. Oral agents should be discontinued during acute illness in most circumstances.[13] Most are associated with some risks and are limited in their ability to be rapidly adjusted to achieve goals.[31, 32]

1. **Subcutaneous insulin:** 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. The recommended components of inpatient subcutaneous insulin regimens are a basal, a nutritional and a correctional element. Prolonged therapy with sliding-scale insulin (correction only without scheduled insulin) as the sole regimen is ineffective in the majority of patients (and dangerous in those with type 1 diabetes). However, initial therapy with correction insulin only may be appropriate in patients with type 2 diabetes who:

- are well controlled (HbA1c <7% or normal BG values) with only diet or a low dose-oral agent
- have mild hyperglycemia and
  - are NPO on no nutritional replacement
  - are on new or tapering steroids
  - hypoglycemic risk factors including but not limited to end-stage liver or kidney disease, elderly patients or those with an unknown drug overdose

The general recommendations for dosing subcutaneous insulin are derived from published studies and current ADA/AACE and Endocrine Society guidelines. They generally involve:

1. Estimating patients' total daily insulin requirement, or total daily dose (TDD)
2. Dividing the TDD into approximately 50 percent basal insulin and 50 percent nutritional
3. Adding a correction scale based on the patient's estimated insulin sensitivity and then
4. Adjusting the doses daily

2. **Insulin infusion and transition to subcutaneous:** On the basis of the available evidence, insulin infusion should be used to control hyperglycemia in the majority of critically ill patients or post-operative patients in the ICU setting, specifically patients requiring invasive positive pressure ventilation and moderate to high dose vasopressor support.[33] In addition to critically ill patients, some patients may have improved control with insulin infusion including but not limited to those with uncontrolled hyperglycemia on glucocorticoids, TPN, hyperglycemic crisis and labor and delivery. Many hospitals have been able to safely administer insulin infusions outside of the critical care setting by providing staff education and adjusting nurse-to-patient ratios to allow continued frequent blood glucose monitoring and adjustments.[34]

   Following resolution of their indication for insulin infusion, patients will need to be transitioned to subcutaneous insulin. Patients with type 1 DM, on insulin prior to admission to the hospital and those requiring insulin infusion rates more than two units/hour, will need to be transitioned to basal/bolus insulin regimens. The average infusion rate over the preceding six to eight hours is then multiplied by 24 to determine the predicted requirement for the next day. Given that patients are likely to be continuing to improve and have reduced insulin requirements, that daily estimate is further reduced to 60-80 percent. This value can be used as the total daily requirement if they were receiving significant nutritional support in the ICU (TPN or tube feeds) or the basal amount with nutritional layered over time as oral intake increases.[35-40]

E. Transition to the Outpatient Setting

Preparation for transition to the outpatient setting is an important goal of inpatient diabetes management and begins with the hospital admission. The HbA1C is an important laboratory test that should be ordered in nondiabetic hyperglycemic patients and diabetic patients who have not had a recent test. An HbA1c value >6.5% is diagnostic of diabetes, 5.7-6.4% is "pre-diabetes" and one over 9 percent has been recommended by some to indicate the need for newly aggressive treatment strategies.[41] Modification of the outpatient regimen should be done with careful planning and assessment of patient and facility-specific resources as well as with communication with the outpatient provider.[42] There are several published algorithms for diabetes treatment that can be used to guide such decisions but it is most important to factor in individual patient needs.[47] All patients with diabetes should receive teaching in diabetes self-management education focused on survival skills.[13]

Communication to the outpatient provider regarding the education provided, relevant lab values including the HbA1c and medication changes is essential for patient safety and a requirement of The Joint Commission's Inpatient Diabetes Disease Certification.

F. Conclusion

High-quality inpatient glycemic management involves systematic improvements and standardization of processes while also paying close attention to patient-specific factors. However, focusing on all of these areas and working to implement best practices can lead to improvements not only in hyperglycemia but also in reductions in hypoglycemia.[43,44] The details in each of these aspects of patient care are further detailed throughout this *Implementation Guide.*

References

[1]Centers for Disease Control and Prevention 2014 National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States. Atlanta: U.S. Department of Health and Human Services. Available at http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf Accessed on May 20, 2015.

[2]Umpierrez GE, Isaacs SD, Bazargan N, You X, Thaler LM, Kitabchi AE. Hyperglycemia: an independent marker of in-hospital mortality in patients with undiagnosed diabetes. *J Clin Endocrinol Metab.* 2002 Mar; 87:978–982.

[3]Fraze T, Jiang HJ, Burgess J. Hospital stays for patients with diabetes, 2008. AHRQ Healthcare Cost and Utilization Project. Statistical Brief #93. August 2010. Available from http://www.hcup-us.ahrq.gov/reports/statbriefs/sb93.pdf. Accessed May 15, 2015.

[4]Newton CA, Young S. Financial implications of glycemic control: results of an inpatient diabetes management program. *Endocr Pract. 2006;*12(Suppl 3).43–48

[5]Center for Medicare and Medicaid Services Hospital-Acquired Condition (HAC) Reduction Program. Available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program.html. Accessed May 2015.

[6]Hellman R. A systems approach to reducing errors in insulin therapy in the inpatient setting. *Endocr Pract.* 2004;10(suppl 2):100–108.

[7]Hellman R. Patient safety and inpatient glycemic control: translating concepts into action. *Endocr Pract.* 2006; 12(suppl 3):49–55.

[8]Bersoux S, Cook CB, Kongable GL, Shu J. Trends in glycemic control over a 2-year period in 126 U.S. hospitals. *J Hosp Med. 2013;*8:121–125.

[9]Swanson CM, Potter DJ, Kongable GL, Cook CB. Update on inpatient glycemic control in hospitals in the United States. *Endocr. 2011; Pract* 17:853–861.

[10]Maynard G, Ramos P, Kulasa K, Rogers KM, Messler J, Schnipper JL, How Sweet Is It? The Use of Benchmarking to Optimize Inpatient Glycemic Control, *Diabetes Spectrum*. Volume 27, Number 3, 2014.

[11]Qaseem A, Humphrey L, Chou R, Snow V, Shekelle P. Use of Intensive Insulin Therapy for the Management of Glycemic Control in Hospitalized Patients: A Clinical Practice Guideline from the American College of Physicians. *Ann Intern Med. 2011;* 154:260–267.

[12]Moghissi ES, Korytkowski MT, DiNardo M, Einhorn D, Hellman R, Hirsch IB, Inzucchi SE, Ismail-Beigi F, Kirkman MS, Umpierrez GE. American Association of Clinical Endocrinologists, American Diabetes Association: American Association of Clinical Endocrinologists and American Diabetes Association consensus statement on inpatient glycemic control. *Diabetes Care. 2009;* 32:1119–1131.

[13]Umpierrez GE, Hellman R, Korytkowski MT, Kosiborod M, Maynard GA, Montori VM, Seley JJ, van den Berghe G, Endocrine Society. Management of hyperglycemia in hospitalized patients in non-critical care setting: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab* 97:16–38.

[14]Umpierrez GE, Smiley D, Zisman A, Prieto LM, Palacio A, Ceron M, Puig A, Mejia R. Randomized study of basal-bolus insulin therapy in the inpatient management of patients with type 2 diabetes (RABBIT 2 trial). *Diabetes Care.* 2007; 30(9):2181–2186.

[15]Umpierrez GE, Hor T, Smiley D, Temponi A, Umpierrez D, Ceron M, Munoz C, Newton C, Peng L, Baldwin D. Comparison of inpatient insulin regimens with detemir plus aspart versus neutral protamine hagedorn plus regular in medical patients with type 2 diabetes. *J Clin Endocrinol Metab.* 2009; 94:564–569.

[16]Umpierrez GE, Hor T, Smiley D, Temponi A, Umpierrez D, Ceron M, Munoz C, Newton C, Peng L, Baldwin D. Comparison of inpatient insulin regimens with detemir plus aspart versus neutral protamine hagedorn plus regular in medical patients with type 2 diabetes. *J Clin Endocrinol Metab.* 2009; 94:564–569.

[17]Robbins JM, Webb DA. Diagnosing diabetes and preventing rehospitalizations: the urban diabetes study. 2006; 44:292–296.

[18]Inoue S, Egi M, Kotani J, Morita K: Accuracy of blood-glucose measurements using glucose meters and arterial blood gas analyzers in critically ill adult patients: systematic review. *Crit Care. 2013;* 17:R48.

[19]Slater-MacLean L, Cembrowski G, Chin D, Shalapay C, Binette T, Hegadoren K, Newburn-Cook C. Accuracy of glycemic measurements in the critically ill. *Diabetes Technol Ther.* 2008; 10:169–177.

[20]Food and Drug Administration: Blood glucose monitoring test systems for prescription point-of-care use. Available from http:// DeviceRegulationandGuidance/GuidanceDocuments/UCM380325.pdf. Accessed May 20, 2015.

[21]Food and Drug Administration: Self-monitoring blood glucose test systems for over-the-counter use draft guidance for industry and Food and Drug Administration staff. Available from http://www.fda.gov/downloads/ MedicalDevices/DeviceRegulationandGuidance/ GuidanceDocuments/UCM380327.pdf. Accessed May 20, 2015.

[22]Vellanki P, Bean R, Oyedokun FA, Pasquel FJ, Smiley D, Farrokhi F, Newton C, Peng L, Umpierrez GE. Randomized controlled trial of insulin supplementation for correction of bedtime hyperglycemia in hospitalized patients with type 2 diabetes. *Diabetes Care. 2015;* Apr;38(4):568–74.

[23]Van den Berghe G, Wouters P, Weekers F, Verwaest C, Bruyninckx F, Schetz M, Vlasselaers D, Ferdinande P, Lauwers P, Bouillon R. Intensive Insulin Therapy in Critically Ill Patients, *N Engl J Med. 2001;* 345:1359–1367.

[24]Clement S, Braithwaite SS, Magee MF, Ahmann A, Smith EP, Schafer RG, Hirsch IB. American Diabetes Association Diabetes in Hospitals Writing Committee: Management of diabetes and hyperglycemia in hospitals. *Diabetes Care. 2004;* 27:553–591.

[25]Garber AJ, Moghissi ES, Bransome ED Jr, Clark NG, Clement S, Cobin RH, Furnary AP, Hirsch IB, Levy P, Roberts R, Van den Berghe G, Zamudio V; American College of Endocrinology Task Force on Inpatient Diabetes Metabolic Control: American College of Endocrinology position statement on inpatient diabetes and metabolic control. 2004; *Endocr Pract.* 10:77–82.

[26]Griesdale DE, de Souza RJ, van Dam RM, Heyland DK, Cook DJ, Malhotra A, Dhaliwal R, Henderson WR, Chittock DR, Finfer S, Talmor D. Intensive insulin therapy and mortality among critically ill patients: a meta-analysis including NICE-SUGAR study data. *CMAJ. 2009;* 180:821–827.

[27]The NICE-SUGAR Study Investigators. Intensive versus Conventional Glucose Control in Critically Ill Patients. *N Engl J Med. 2009;* 360:1283–1297.

[28]Jacobi J, Bircher N, Krinsley J, Agus M, Braithwaite SS, Deutschman C, Freire AX, Geehan D, Kohl B, Nasraway SA, Rigby M, Sands K, Schallom L, Taylor B, Umpierrez G, Mazuski J, Schunemann H. Guidelines for the use of an insulin infusion for the management of hyperglycemia in critically ill patients. *Crit Care Med . 2012;* 40:3251–3276.

[29]Surgical Care Improvement Project. Available at at http://www.jointcommission.org/assets/1/6/2w_SCIP-Inf-4.pdf. Accessed May 2015.

[30]Seaquist ER, Anderson J, Childs B, et al. Hypoglycemia and diabetes: a report of a workgroup of the American Diabetes Association and The Endocrine Society. *Diabetes Care.* 2013 May; 36(5):1384–1395.

[31]Deusenberry CM, Coley KC, Korytkowski MT, Donihi AC. Hypoglycemia in hospitalized patients treated with sulfonylureas. *Pharmacotherapy. 2012;* 32:613– 617.

[32]Salpeter SR, Greyber E, Pasternak GA, Salpeter Posthumous EE. Risk of fatal and nonfatal lactic acidosis with metformin use in type 2 diabetes mellitus. *Cochrane Database Syst Rev. 2010;* 1:CD002967.

[33]Kavanagh BP, McCowen KC. Clinical practice: glycemic control in the ICU. *N Engl J Med. 2010;* 363:2540–2546.

[34]Ku SY, Sayre CA, Hirsch IB, Kelly JL. New insulin infusion protocol improves blood glucose control in hospitalized patients without increasing hypoglycemia. *Jt Comm J Qual Patient Saf. 2005;* 31:141–147.

[35]Bode BW, Braithwaite SS, Steed RD, Davidson PC. Intravenous insulin infusion therapy: indications, methods, and transition to subcutaneous insulin therapy. *Endocr Pract. 2004; 10* (Suppl. 2):71–80.

[36]Furnary AP, Braithwaite SS. Effects of outcome on in-hospital transition from intravenous insulin infusion to subcutaneous therapy. *Am J Cardiol. 2006;* 98:557–564.

[37]Olansky L, Sam S, Lober C, Yared JP, Hoogwerf B: Cleveland Clinic cardiovascular intensive care unit insulin conversion protocol. *J Diabetes Sci Technol* 3:478– 486.

[38]Schmeltz LR, DeSantis AJ, Schmidt K, O'Shea-Mahler E, Rhee C, Brandt S, Peterson S, Molitch ME. Conversion of intravenous insulin infusions to subcutaneously administered insulin glargine in patients with hyperglycemia. *Endocr Pract. 2006;* 12:641– 650.

[39]Larsen J, Goldner W. Approach to the hospitalized patient with severe insulin resistance. *J Clin Endocrinol Metab. 2011;* 96:2652–2662.

[40]Kelly JL. Ensuring optimal insulin utilization in the hospital setting: role of the pharmacist. *Am J Health Syst Pharm. 2010;* 67:S9–S16.

[41]American Diabetes Association. *Standards of Medical Care in Diabetes.* vol. 37, Supplement 1 S14–S80.

[42]Inzucchi SE, Bergenstal RM, Buse JB, Diamant M, Ferrannini E, Nauck M, Peters AL, Tsapas, A, Wender R, Matthews DR, American Diabetes Association (ADA), European Association for the Study of Diabetes (EASD): Management of hyperglycemia in type 2 diabetes: a patient-centered approach: position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care.* 2012;35:1364–1379.

[43]Maynard G, Lee J, Phillips G, Fink E, Renvall M. Improved inpatient use of basal insulin, reduced hypoglycemia, and improved glycemic control: effect of structured subcutaneous insulin orders and an insulin management algorithm. *J Hosp Med. 2009;4:3-15.*

[44]Pietras SM, Hanrahan P, Arnold LM, Sternthal E, McDonnell ME. State-of-the-art inpatient diabetes care: the evolution of an academic hospital. *Endocr Pract. 2010;16:512–521.*

Section III: Assess Current State of Glycemic Management

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A. Performing a Comprehensive Local Assessment of Current Care Processes

The first step to any improvement effort is having a complete understanding of your current processes. As outlined in Section I, you should have already performed a high-level assessment of your outcomes and some basics on your process measures. This should help you target your improvement efforts and those processes you must begin to investigate in more detail. In Section IV, you will be choosing your metrics and spending more time on outcomes measures. This section will focus on understanding the processes around the care you currently provide to help you plan your interventions. We will briefly describe tools to help you make this assessment and then give some specifics around certain aspects of glycemic management as examples of the level of detail you should understand within your institution. It cannot be emphasized enough how important this step is in your improvement efforts. Any quality project that skips this step and tries to institute 'best practices' from another institution or a guideline without assessing its need locally may disrupt what is working well in their organization and miss improving the processes that are most in need.

B. Current Glycemic Performance

Outcomes Measures

As discussed in Section I and to be covered in much more depth in Section IV, the first step should be using an established means to assess your current performance on hypo- and hyperglycemic measures. We will briefly review that again here. We would recommend using the Society of Hospital Medicine (SHM) Glucometrics website to upload your hospital's point-of-care glucose readings to receive a report that will show you what your percentages are for glycemic control and will compare you to benchmarks.

To do this you need to get access to your point-of-care glucose measurements. As described in more detail in Section I, this is usually easiest to achieve through the lab rather than trying to pull the data from your electronic health record (EHR). Please refer to the instructions on the SHM website for how to format this data for analysis. We would recommend that you use at least three months of data to have an accurate report.

By evaluating this report, you will be able to compare to internal benchmarks like other floors and past performance as well as external benchmarks like published outcomes or public or private reports. This will allow you to identify the areas that your team needs to focus on first, as well as identify which units or services are the most in need of interventions. It is important not to assume what the issues are before having an accurate unbiased assessment. Many hospitals have had isolated events and have chosen to focus on hypoglycemia for example, when this intervention could worsen the real issues of the hospital being permissive with hyperglycemia, and a predominance of sliding-scale treatment modalities. After a critical event, if the root causes are not explored, the intervention at best will not work and has the risk of actually making things worse.

In reviewing these reports, identify how often you are achieving good glycemic control. Look at different floors and how they compare — are there specific problem areas? What priorities can you set: are there very high rates of severe hypoglycemia in certain locations or severe hyperglycemia? What is your performance responding to hypoglycemia and how do these relate to your existing policies? Provide these reports to each of these floors and allow for a whole hospital comparison (and hopefully competition). Review your rates of hypoglycemia and use the comparisons to other hospitals. Then carefully select how you will use these metrics and how you will report them. The goal at this stage is to identify those areas where you will focus your improvement. You may want to group reports in different ways to identify problem areas (for instance all medicine floors, or all ICUs), you may also want to look at performance over time to see if there are trends toward improvement or if things are getting worse. Compare this to things you know about the hospital — did you recently transition to CPOE, was there a change in staff?

Section IV will discuss these metrics in more detail. Please refer there for a better understanding of how these are derived and the meaning behind the different glucometric measures. After choosing your intervention areas, you will be choosing metrics to follow. This will require a better understanding of how these metrics are derived, but at this point you are using this preliminary data to get a global sense of current performance to plan interventions that will have the greatest likelihood of benefiting your organization.

Process Measures

The next step is having a basic understanding of how your organization is currently approaching glycemic control and identifying their specific processes and practices. This data can be more difficult to pull in automated reports. Many projects can get bogged down in how exactly to pull research quality metrics in this area. Please avoid this trap. At this stage in your project you are trying to get information on performance to help focus your efforts and to have data to motivate change. This does not require sophisticated research analysis. You should investigate both physician and nursing practices. At a minimum, we would suggest that regardless of the methods selected you have a process in place to address the following questions:

- What percentage of patients are prescribed basal bolus regimens versus sliding scale?
- Are changes being made to insulin orders after admission for uncontrolled patients?
- Are there any nursing processes routinely occurring that interfere with glycemic control?

Other questions that can yield helpful information are: what services or floors are performing well versus not? For nursing practices, are nurses routinely holding insulin that is prescribed and, if so, for what reasons? For instance, many institutions may find out that basal insulin is routinely being held if a patient is NPO, which may be against your policy; or that nursing has arbitrary conditions to hold nutritional insulin. These facts may not be apparent to the treating medical team.

While it would be ideal to have an assessment of how every diabetic has received their care over the last six months in your hospital, what you need to know right now is a basic 'how are we doing?' There are a number of options to achieve this:

1. Periodic chart audits evaluating insulin use connected with individual patient results

The periodic audits can be done by a small team randomly selecting charts of patients receiving insulin and using a basic spreadsheet to identify how they are being treated. We have developed a tool to help you with this that is available on the SHM Glycemic Control Toolkit website in a brief chart review, you will identify the percent of patients achieving glycemic control, what types of insulin they are prescribed and if changes are being made when uncontrolled. By entering data into the spreadsheet table, graphs will be produced that will show you the percentage of patients being treated with sliding scale only, and the percentage of patients on 'appropriate therapy.'

2. Pharmacy reports of the frequency of insulin use

You may be able to work with your data team to generate reports from pharmacy that can show you the percentage of patients prescribed basal + bolus regimens vs. correction scale only. Explore these options if you have those resources available.

3. Audits of outliers — hypoglycemic or hyperglycemic events

Lastly, we suggest that you select patients who are uncontrolled and look into the factors that have resulted in this. This is similar to a mini root cause analysis (RCA). Were patients prescribed the appropriate regimen in the appropriate doses; were doses held? Are there other factors involved? Even looking at a handful of patients will give your team a much better understanding of current state. This process will hopefully evolve into your glycemic control intervention team that will perform these analyses in real time and improve care for these patients as soon as they are identified. This is described in more detail in Section V.

C. Electronic Medical Record (EMR) Review

The other important step that you have likely already been involved in, is understanding the current capacity of your EMR and how it is impacting these processes. You need to understand both possible functionality and what your current builds are. For instance, do you have order sets already built and, if so, is there clinical decision support built in? What views do nurses and physicians see when ordering or administering insulin? Is there a single view where providers can see all of the data they need to make decisions on a daily basis regarding diabetic patients? Does nursing have forms to fill out during events of hypoglycemia?

You will also need to explore if there is functionality available within your EMR that you are not currently utilizing both for process as well as for data collection and reports. Is there a module that will show you if patients are out of control in real time? Are there more sophisticated dashboards that are available both on a population and individual patient basis? Lastly, be aware that there are third-party products that help manage insulin — do you have any of these currently available in your system and is this something being considered?

An inevitable part of your quality project will be making changes to an existing EMR or interacting with it to get necessary data. Knowing who within this department can help you make these changes or get you this data will be vitally important. You will also need team members who are acutely aware of what is and what is not possible within your system as you propose changes.

Focusing Your Efforts

At this stage you should have a much better sense of your current outcomes and what processes may be contributing to this. The next step is selecting processes to perform a more detailed assessment with the intention of implementing changes.

D. Process Flow Mapping: A Critical QI Tool

Achieving your quality improvement goals will almost certainly require that substantial changes be made to whichever process you target. Although you may think that you understand the gaps between your current process and the best practice, formally mapping the process will almost certainly reveal gaps that would otherwise be overlooked. It will also provide your team with a better understanding of the workflow in general. Process mapping is really nothing more than diagramming everything that happens in a given process. The Institute for Healthcare Improvement (IHI) and the American Society for Quality websites provide more in-depth information. The major steps of the process are defined first, and then each step is analyzed in detail below.

Common pitfalls during process mapping include describing how things are ‘supposed’ to be done rather than how they are actually done, and not getting enough input from stakeholders. Strategies to address this are to interview leadership

as well as frontline workers and to complete it with the multidisciplinary team. In many circumstances it is necessary to actually go and directly observe the process being mapped to identify all of the steps and variations that may be taking place. Finally, even after what appears to be a well-thought-out process map is completed, we would recommend taking it and observing at the frontline if it is accurate in the majority of cases.

Once the process is mapped, the gaps between the current process and the best practice will become apparent. The members of the team with the most detailed understanding of the best practice will be able to recognize the gaps and highlight them for the team. The assessment questions, presented later in this section, can also help team members recognize the gaps that need to be addressed in order to achieve the team's goals, and this list will be used to create interventions.

(Provided by Mark V. Williams, MD and Janet Nagamine, MD)

Insulin Drip: Macro- and Subprocesses

1	2	3	4
Prescribe & Transcribe	**Prepare & Dispense**	**Administer Insulin Drip**	**Monitor Insulin Drip**
1A: MD writes order	**2A:** RN checks order	**3A:** RN places tubing in infusion pump	**4A:** Blood obtained for glucose level per MD order
1B: Order faxed to pharmacy	**2B:** RN obtains insulin from refrigerator	**3B:** RN connects tubing to patient	**4B:** RN documents glucose in care record
1C: Order entered into pharmacy profile	**2C:** RN obtains NS bag	**3C:** RN programs pump	**4C:** RN titrates insulin drip per MD range
1D: MAR is generated	**2D:** RN draws insulin, verifies dose with RN2	**3D:** RN verifies patient's identification	**4D:** RN calls MD if glucose outside parameters
	2E: RN places insulin in bag	**3E:** RN titrates insulin according to MD order	
	2F: RN labels bag		
	2G: RN primes tubing		

Example template for mapping subprocesses related to ordering and delivery of subcutaneous insulin

***Write what happens in each subprocess, as shown for* subprocess 1.**

1. Insulin order is written (along with other insulin-related orders, e.g., diet, glucose monitoring) ⇨	**2.** Orders are removed/ processed/delivered (clerical or via computer) ⇨	**3.** Orders are processed in the pharmacy/ MAR generated ⇨	**4.** Nurse is made aware of the order and prioritizes it ⇨
Who: Usually the intern, sometimes the resident, occasionally the attending	**Who:**	**Who:**	**Who:**
What: No protocol in place, dosing and strategy left to the intern's discretion, sliding-scale insulin alone commonly used, diet order and glucose monitoring not always matched to the insulin order	**What:**	**What:**	**What:**
Where/When/Why: No guidelines about when insulin should be used or goals of therapy, left to intern's discretion	**Where/when/why:**	**Where/when/why:**	**Where/when/why:**
How: Written as strip order in the chart	**How:**	**How:**	**How:**
Other questions/observations: Not clear how often the order is written by someone other than the intern	**Other questions/ observations:**	**Other questions/ observations:**	**Other questions/ observations:**

5. Insulin pre-administration assessment: the patient and clinical circumstances (glucose level, diet) are assessed ⇨	**6.** Food tray or other nutrition is delivered to patient (if appropriate) ⇨	**7.** Patient communication ⇨	**8.** Insulin is administered to the patient ⇨
Who:	**Who:**	**Who:**	**Who:**
What:	**What:**	**What:**	**What:**
Where/when/why:	**Where/when/why:**	**Where/when/why:**	**Where/when/why:**
How:	**How:**	**How:**	**How:**
Other questions/ observations:	**Other questions/ observations:**	**Other questions/ observations:**	**Other questions/ observations:**

E. Individual Glycemic Control Process Assessment Items

Early in your improvement effort you should perform a thorough survey of your current care environment, order sets, methods for assessing and tracking glycemic control and a variety of other factors. This section provides a framework for such an assessment. This list may seem daunting at first, but having a basic idea of how you would answer these questions may also help you recognize your strength and focus on your weaknesses. Again, you may wish to focus on selected portions of the assessment at first, but eventually, essentially all these items need to be assessed and improved on in order to achieve optimal care.

Assessment Item 1: Institutional Support

- Are buy-in from administration and a communication/medical staff committee reporting structure defined and in place? Do you have the resources available for forming a team and supporting its efforts in formulating order sets, protocols, educational programs and metrics to optimize the care of the inpatient with hyperglycemia? Do you have an executive staff sponsor?
- A team working on an improvement effort this large is doomed to fail without the recognition by hospital administration and medical staff committees of the importance of glycemic control and prevention of hypoglycemia. If you haven't already done so, Section I will assist you in enrolling the administration in your cause and in defining the medical staff entities your team needs to report to.
- Presence of a multidisciplinary team to address issues.
- Have you formed a truly multidisciplinary team or Steering Committee that works on the front lines of healthcare delivery, as outlined in Section I. If not, do so now. You will not be able to complete the survey without the knowledge of representatives from all disciplines.

Assessment Item 2: Reliable Data Flow and Metrics

Point-of-care (POC) glucose testing, recording and storage and retrieval issues (separate assessments may be needed for critical care and non-critical care areas).

- Does your institution have a robust bedside glucose monitoring quality control program with the parameters outlined here?
- Is the methodology for acquiring and recording POC glucose tests standardized and reliable across different wards?
- Are POC glucose test results recorded and quickly available to the prescribing physician across all wards?
- Is POC glucose information available electronically, or is it recorded on paper? Is it recorded in the medication administration record, the bedside record, the permanent record or lab data?
- Do your bedside glucose devices allow for identification of provider and patient via barcoding?
- Are your POC glucose results downloaded in a timely manner to the centralized lab database?
- Does your institution have any reports summarizing glycemic control or hypoglycemic event rates for all populations of inpatients (critical care, wards, perioperative settings)? Are the metrics reliable enough and descriptive enough to be actionable?
- Do you have metrics and reports describing the frequency and severity of hypoglycemic events that are based on glucose testing, not just incident reporting and D50 use?

Help on data flow, formulating metrics and presenting data is available in Section IV.

Assessment Item 3: Standardized Order Sets for Insulin (Subcutaneous and Infusion)

An institution will frequently have dozens of order sets of varying quality. At times, order sets designed to facilitate the care of the perioperative patient, the stroke patient or other special populations will have sliding-scale insulin orders embedded in them. To truly standardize and optimize insulin usage, all insulin orders should be created using your standardized forms. Understanding what is already in place and who "owns" each order set/protocol will enable you to approach the stakeholders and register their support.

- What order sets/protocols for insulin administration and glucose monitoring already exist?
- Does your subcutaneous order form specifically encourage the use of scheduled basal, long-acting, or intermediate-acting insulins?
- Does your order form specifically encourage the use of scheduled nutritional (prandial) insulin?
- Does your order form standardize the administration of correction dose insulin?
- Is there a choice of standard scales to use based on insulin sensitivity?
- If on paper, does you form conform to National Patient Safety Goals (making it compliant with The Joint Commission (TJC) spelling out units and eliminating trailing zeros?
- Does your form provide specific guidance for the timing of insulin administration with regard to tray/nutritional delivery?
- Does your form include or refer to a standardized hypoglycemia protocol?

Intensive insulin infusion order set/protocol

- Is there a standardized intensive insulin infusion regimen used in your critical care units? Is it standardized and used throughout the institution, or is it at least standardized for each type of unit and patient?

  If YES:

  - Is it in computerized physician order entry (CPOE) or handwritten form?
  - Are calculations and application of mathematical rules automated or translated into tabular form and algorithmic, or are the nurses expected to make these calculations?
- Does your insulin infusion order set clearly state the glycemic target?
- Are general guidelines for when to start and stop an insulin infusion embedded in the order set?
- Are general guidelines for dosing insulin infusions embedded in the order set?
- Does your insulin infusion order set include instructions for standard insulin infusion concentrations?
- Does your insulin infusion order set allow for differing sensitivity to insulin, making adjustments based on both current glucose value and the rate of change (dynamic scale) of the glucose values?
- If on paper, does you form conform to National Patient Safety Goals (rendering them TJC compliant), spelling out units and eliminating trailing zeros?
- Does your form include or refer to a standardized hypoglycemia protocol?
- What is the level of nursing and physician acceptance of and enthusiasm for the order set? How do you know?
- Do you have "smart" insulin infusion pumps applied with insulin infusions?
- Are guidelines for the transition from infusion to subcutaneous insulin regimens embedded in the insulin infusion order set?
- Are insulin infusion solutions labeled and prepared in the centralized medical center pharmacy?

Several examples of subcutaneous and infusion insulin order sets/protocols, along with guidelines for successful implementation, are provided on the SHM Glycemic Control Toolkit website.

Assessment Item 4: Nutritional Dietary System

What is the status of the nutritional/dietary system for hyperglycemic patients at your institution?

- Is there a routine process for addressing the special needs of inpatients with diabetes?
- Is there an accepted way of ordering a diabetic diet?
- Do meals delivered to all patients on insulin have consistent carbohydrate content?
- Is the timing of tray delivery/administration reliable and linked appropriately to POC glucose testing and insulin administration?
- Are there safeguards in place to prevent patients from being deprived of food/nutrition after receiving nutritional insulin (such as being sent for dialysis or testing) or from holding nutritional insulin for unexpected cessation of nutritional calories? Are nighttime snacks available?

Assessment Item 5: Diabetes Self-Management

- Does your institution have a program that allows carefully selected patients to self-manage their diabetes in the hospital?
- Does your hospital have a policy around insulin pump usage while hospitalized?

Assessment Item 6: Hypoglycemia, Insulin Safety and Cultural Issues

- Does your institution have a standardized hypoglycemia protocol? Is this protocol directed at the prevention of hypoglycemia and the recognition of risk factors for hypoglycemia in addition to the treatment for hypoglycemia?
- Does your hypoglycemia protocol address when to repeat the finger stick to measure blood glucose (BG), when to send a blood glucose specimen to the laboratory and when to call the doctor/nurse practitioner/physician assistant?
- How does your organization define hypoglycemia? How does it define severe hypoglycemia?
- How often do patients who have had an episode of hypoglycemia suffer repeat episodes?
- Has your hospital evaluated and worked on its “culture of safety”? Would nurses be comfortable questioning an insulin dose or regimen they believed might be dangerous, or for that matter, would they feel comfortable pushing physicians for more aggressive insulin therapy in poorly controlled patients? Do physicians respond appropriately to questions and concerns from nurses? Does the culture vary in different parts of the hospital? How do you know?
- Are endocrinologists readily available? If so, how interested are they in aggressive consultation for hyperglycemic inpatients? Are hospitalists capable and willing to fill this role?
- Does your institution have bar coding to assist in preventing errors in the administration of insulin?
- Are pharmacists participating in physician rounds or surveillance of insulin-prescribing patterns?
- Is CPOE available at your institution?
- Are there mechanisms to trigger action/investigation for severe hypoglycemia, sustained hyperglycemia or inpatient development of ketoacidosis or hyperglycemic hyperosmolar states?

Assessment Item 7: Algorithms, Protocols and Policies

Do you have algorithms, protocols and policies available to assist caregivers in managing special situations and ordering appropriate insulin regimens for each situation? (All these items are covered in this *Guide*, so don't panic if you do not have most of them in place now.)

Calculating insulin dosages

- Do you provide widespread guidance in estimating the total daily dose of subcutaneous insulin a patient needs or assistance in adjusting insulin?
- Recommended insulin regimens for patients with different forms of nutritional intake
- Do you have institutional guidelines for preferred specific insulin regimens for the:
  - NPO patient?
  - Patient eating meals or on bolus tube feedings?
  - Patient on TPN? Nocturnal TPN?
  - Patient on continuous or nocturnal enteral tube feedings?
- Are your institutional guidelines for these scenarios available at the point-of-care, or are they embedded in your order sets?
- Do nurses understand and embrace their role in coordinating bedside glucose testing, delivering nutrition and administering insulin?
- Does your nursing staff have guidance/protocols for managing common bedside issues such as what to do when the nutritional source is interrupted or a patient is unable to eat a meal?
- Is there pharmacy oversight or standardization of insulin orders in patients receiving TPN?
- Do you monitor the quality of glycemic control in any of these patients?
- Transitioning from an infusion to a subcutaneous insulin regimen
- Do you have guidance/protocols for transitioning patients from an infusion insulin regimen to a subcutaneous insulin regimen? Are they embedded in the order set?
- Patients in other special situations: caring for perioperative patients and patients receiving high-dose steroids

Periprocedural Care

- How does your institution address glycemic control in patients undergoing procedures and operations?
- Do your insulin order sets or perioperative order sets encourage basal insulin throughout the perioperative period?
- Are insulin infusions encouraged or mandated for hyperglycemic patients whose perioperative NPO status is expected to be prolonged?
- Are dextrose-containing solutions routinely provided for NPO perioperative patients?
- How aware are your surgeons and anesthesiologists of the need for good glycemic control?
- Do you have any methods for assessing the quality of glycemic control in the perioperative setting?
- Who does peri-op orders (pre-op, in OR, post-op, back to floor)?

Glucocorticoids

- Has your medical center developed guidelines for hyperglycemic patients receiving large doses of steroids (chemotherapy regimens and post-transplant regimens, for example)?
- Are these guidelines incorporated into order sets for chemotherapy/transplant regimens that include large steroid boluses?
- Do you have any data/reports assessing the glycemic control of post-transplant or chemotherapy patients receiving large steroid boluses?

HbA1c values and prompts for monitoring glucose

- Are HbA1c values routinely obtained (if none from the previous 30 days) to help guide insulin therapy? Is there a prompt for ordering HbA1c in insulin order sets?
- Are all patients admitted screened for hyperglycemia by laboratory test or bedside glucose monitoring? Is glucose monitoring routine for perioperative patients and patients entering critical care areas?

Assessment Item 8: Discharge

- Patients move quickly through the spectrum of healthcare environments. The care process, resources and personnel often differ dramatically between the home, the emergency department, the general medical/surgical ward and the OR and post-op environments, and each transition in care presents a challenge to provide patients with consistent, high-quality, safe therapy and education tailored to their individual needs.
- Is there diabetes teaching before discharge?
- Is there assurance that the medical regimen on discharge is tailored to the patient, that the patient can afford and understand it, that bedside glucose meter machines/strips are covered by the patient's insurance and that the patient has defined follow-up?
- Are patients without diabetes dx who have random high BG/stress-induced hyperglycemia known/followed up?
- Is there communication with the PCP?
- How do you identify patients who need translation of verbal and written instructions?
- How is med reconciliation handled at these interfaces?

Assessment Item 9: Educational Issues

- Do you have a comprehensive patient diabetes education process in place?
- Is there a template in place for ordering diabetes self-management education (DSME) materials for patients?
- Is CDE available and what is its role?
- Do you have weekend teaching?
- Does your program utilize the general principles of diabetes self-management education outlined in "Management of diabetes and hyperglycemia in hospitals," by Clement et al.?
- Do you routinely assess the learner as part of the educational process?
- Do you include information on community resources and further outpatient education if needed?
- Is up-to-date and comprehensive written information provided as appropriate?
- Do you have a reliable method to educate the patient whose primary language is not English?
- Is there a certification/training program for nurses providing DSME?
- Have you considered implementing a diabetes resource nurse program to help extend the reach of diabetes education in your hospital?
- Implementation strategies and further resources for DSME are provided in this Section V.8.

Staff education and certification

- Do you have a complete educational/certification program in place for care of the inpatient with hyperglycemia, rational insulin therapy and prevention/treatment of hyperglycemia?
- Is it widely available via intra- or Internet access?
- Is it interactive in the form of learner-based modules?
- Are the modules tailored to the nurses? Tailored to physicians and other providers?
- If yours is a teaching institution, is education appropriately targeted at house staff?
- Does your program address institution-specific order sets as well as general principles?
- Is there mandatory participation by key providers?
- Is the educational program case based?
- Is there any method for tracking participation or competence/understanding of the most important concepts?

Pharmacy issues

- Do pharmacists critically review all insulin orders? Do pharmacists call physicians when insulin orders are irrational or deviate from the protocol? Does the MAR distinguish basal, nutritional and corrective insulin and give instructions that assist the providers in delivering each of these appropriately?
- Have steps been taken to ensure that insulin nomenclature and abbreviations don't cause medical errors? (N might represent NPH or Novolog, for example, and L might represent Lantus or lispro.) What steps have been taken to avoid improper mixing of insulin types? (Lantus, for example, should not be mixed with other types of insulin.)

Section V.8 is designed to assist you in successfully building, implementing and tracking the results of a comprehensive educational program.

Performing an institutional assessment can be daunting at first. Remember, you don't have to fix or assess everything at once.

F. External Assessment Tools

Lastly, there are other methods to help with assessments of current state as well. For instance The Joint Commission has criteria to achieve "Advanced Certification in Inpatient Diabetes" and their assessment tool is available here (http://www.jointcommission.org/certification/inpatient_diabetes.aspx). Even if your organization does not plan to apply for this distinction, using the self-assessment tools they have can be very useful to assess your current performance and target interventions.

Section IV: Choose Metrics and Develop a Data Collection Plan for Your Glycemic Control Program

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shm

Section IV: Choose Metrics and Develop a Data Collection Plan for Your Glycemic Control Program

A. Introduction

Data collection, analysis and presentation are keys to the success of any hospital glycemic control initiative. Measurement should inform and motivate change. To be more specific, measurement allows the improvement team to:

- Assess baseline performance
- Assure the team and medical staff that protocols being introduced are safe and effective
- Track performance over time
- Compare like units in the hospital to each other
- Prioritize efforts
- Assess trade-offs between glycemic control and hypoglycemia

In addition, local measurement can set the stage for benchmarking and for comparing your hospital's performance to others.

Process measures (e.g., insulin use patterns, rates of adherence to protocol) are much more sensitive to change than outcomes measures, and should reflect nursing and physician practice. Outcomes measures include general parameters like length of hospital stay, mortality and infection rates that could be influenced by glycemic control. ''Glucometrics'' may be defined as the systematic analysis of blood glucose (BG) data — a phrase initially coined specifically for the inpatient setting.[1] Glucometric outcomes like the prevalence of hypoglycemia and uncontrolled hyperglycemia are often considered intermediate outcomes. Every Glycemic Improvement Team should collect some process measures locally, while glucometrics, which are more complicated and labor intensive, are often outsourced.

B. Process Measures

Process measures should provide insight into how well your organization performs important aspects of care for the hyperglycemic patient, which are linked in some way to better glycemic control, hypoglycemia prevention or improved patient outcomes. Although it is often difficult to pull this information in automated reports, small sample observations and simple analysis is all that is required to inform the team and motivate change.

For ICU and perioperative settings, the major process measure should include the proportion of patients meeting criteria for insulin infusion that are on the insulin infusion order set. Designation of BG levels that trigger insulin infusion in these settings should be agreed upon in advance. The number of patients who meet the predefined glycemic criteria would make up the denominator, and the number of patients on the insulin infusion order set would make up the numerator.

On non-critical care units, measuring the percentage of subcutaneous insulin regimens that contain a basal insulin (versus a 'sliding scale regimen') is a useful way to monitor the penetration of protocol-driven subcutaneous insulin order sets. A more detailed analysis could examine the percentage of patients on simultaneous basal and nutritional insulin (if applicable), or look at the percentage of patients over glycemic target on a basal/bolus regimen. An important measure of clinical inertia is to track the percentage of patients who had changes in their insulin regimens on days after hypoglycemic or hyperglycemic excursions. Another important measure is the frequency with which the standardized order set is being used, analogous to the measure of insulin infusion use in the ICU. Rates of basal insulin being held inappropriately for brief NPO status can provide useful insights into nursing practice. A final process measure, indirectly related to insulin use, is the frequency of use of oral diabetes agents. Some practical tips and tools to collect process measures are presented in Section III.

C. Other Measures

Examples of other process measures that can be used to track the success of quality improvement efforts include:

1. Glucose measurement within eight hours of hospital admission.
2. Glycated hemoglobin (HbA1c) measurement obtained or available within 60-90 days of admission to help guide inpatient and especially discharge management.
3. Appropriate glucose testing in patients with diabetes or hyperglycemia (e.g., four times per day in patients not on insulin infusion protocols, at least until 24 hours of euglycemia is documented).
4. The percentage of patients on insulin with on-time tray delivery.
5. The timing of subcutaneous insulin administration in relation to glucose testing and nutrition delivery.
6. Documentation of carbohydrate intake among patients who are eating.
7. Appropriate transitions from IV to subcutaneous insulin regimens (e.g., starting basal insulin prior to discontinuing infusion in patients who have been on an insulin infusion of at least units/hour or who have a known diagnosis of diabetes or HbA1c>7).
8. Nursing and physician education/certification in insulin prescribing, insulin administration and other diabetes care issues.
9. Satisfaction of physicians and nurses with order sets or protocols, using standard surveys.
10. Physician and nurse knowledge, attitudes and beliefs about insulin administration, fear of hypoglycemia, treatment of hypoglycemia and glycemic control in the hospital.
11. Patient satisfaction with their diabetes care in the hospital, including the education they received.

D. Outcome Measures and Glucometrics Introduction

Patient outcomes strongly associated with glycemic control (e.g., surgical wound infections, ICU LOS, catheter-related bloodstream infections, as well as readmission and mortality rates in inpatients with diabetes/hyperglycemia) can be important to justify glycemic control efforts and track the impact of interventions. Root cause analyses of hypoglycemic events reported in hospital reporting systems can be used to understand and prevent future events. Voluntary reporting systems, however, will not provide reliable data on hypoglycemia rates, as full reporting is not guaranteed and there is no denominator in these reports.

As stated above, a good glucometrics reporting system is necessary to optimize glycemic control efforts, motivate change, track performance and prioritize efforts. Hypoglycemia metrics must be especially convincing because fear of hypoglycemia remains a major source of clinical inertia, impeding efforts to improve glucose control, and insulin-related hypoglycemia is one of the top three sources of inpatient adverse drug events (ADEs).[2] The Endocrine Society recommends that each institution establish a uniform method of collecting and evaluating point-of-care (POC) glucose data and insulin use information as a way of monitoring the safety and efficacy of the glycemic control program.[3] A recent consensus panel for safe inpatient insulin management echoed these recommendations, and also endorsed real-time active surveillance for glycemic outliers and monitoring of the coordination of insulin administration, glucose testing and nutrition delivery.[2] Unfortunately, the gap between these recommendations and reality is very large. A recent survey of 269 U.S. hospitals showed that about one-third of hospitals had no metrics to track the quality of inpatient diabetes/glycemic control, and 59 percent did not have a reliable method to extract and analyze their glucose data.[4] The reasons for this "implementation gap" are many.

Lack of institutional prioritization and the sheer volume of data points are barriers to building local glucometrics. There are currently no consensus standards on formulating metrics on the quality of inpatient glycemic control, contributing to local inertia.[4,5] In 2008, the Society of Hospital Medicine (SHM) Glycemic Control Task Force published practical recommendations for assessing the impact of glycemic control efforts,[5] drawing on the expertise of task force members[6-9] and building on previously published work from the Yale group.[1,10] Unfortunately, clear guidance was not enough to spur formulation of local glucometrics in many centers. Design and upkeep of a comprehensive glucometrics reporting system is technically challenging and fairly labor intensive. Furthermore, institutions constructing their own unique set of glucometrics remain unable to compare and contrast their performance to other hospitals. External sources providing glucometrics have been devised to address these challenges, including SHM sources, and these will be described in more detail later in this section. These powerful tools can accelerate change and allow for benchmarking. The glycemic reports from external sources, however, do not include information about demographics medications, service or other diagnoses. Sites performing research or desiring to link glucometrics to these parameters must therefore do at least some of their glucometrics locally.

E. Measuring Glycemic Control: Glucometrics

This section provides detailed descriptions of glucometrics as a point of reference, most suitable for researchers and those vested in building local reports. Institutions that use SHM or other external sources may wish to skim these details, or skip directly to the discussion of the external glucometrics options later in this section.

There are numerous ways to do these analyses, depending on which patients and glucose values are considered, the definitions used for hypoglycemia and hyperglycemia, the glycemic range targeted as desirable, the unit of measurement (e.g., patient, patient-day, individual glucose value) and the measure of control (e.g., mean, median, percent of glucose readings within a certain range). While there is no consensus about the best methods, we provide some guidance on our preferred methods. The discussion includes optimal measures assuming diagnostic codes, patient demographics, and exposure to hypoglycemic agents are available. This data may not be available to you, and is not available for glucometrics generated by external sources, so the recommendations must be adjusted by local institutional capabilities.

1. Defining the Target Patient Population

The first decision to be made is which patients to include in your analysis. Choices include the following:

1. Patients with a discharge diagnosis of diabetes: this group has face validity and intuitive appeal, is easy to identify retrospectively and may capture some untested/untreated diabetics, but will miss patients with otherwise undiagnosed diabetes and stress hyperglycemia. It is also subject to the variable accuracy of billing codes.
2. Patients with a certain number of POC glucose measurements: this group is also easy to identify, easy to measure and will include patients with hyperglycemia without a previous diagnosis of diabetes, but will miss patients with untested/untreated hyperglycemia. Also, if glucose levels are checked on normoglycemic, nondiabetic patients, these values may ‘‘dilute’’ the overall assessment of glycemic control. In spite of these limitations, this practical method is used by external reporting vendors.
3. Patients treated with insulin in the hospital: this is a good choice if the purpose is mainly drug safety and avoidance of hypoglycemia, but by definition excludes most untreated patients.

4. Patients meeting criteria for inpatient hyperglycemia, e.g., those with two or more fasting BG values (laboratory and/or POC) over 140 mg/dL or any BG over a certain threshold (e.g., >180 mg/dL or 200mg/dL). This will likely capture more patients with inpatient hyperglycemia, whether or not detected by the medical team, but is subject to wide variations in the frequency and timing of laboratory glucose testing, including whether or not the values are pre-prandial (note that even pre-prandial POC glucose measurements are not always in fact fasting values).

5. For sites creating local reports, in general, we favor an approach that includes patients with a critical mass of tested values, and who have either a diagnosis of diabetes OR have demonstrated hyperglycemia during their stay. Do not limit analyses to only those patients with a diagnosis of diabetes or only those on insulin, which will lead to biased results.
   - For non-critical care patients, we recommend a combined approach: adult patients with a diagnosis of diabetes (e.g., using diagnosis-related group [DRG] codes 294 or 295 or International Classification of Diseases 9th edition [ICD9] codes 250.xx) or with hyperglycemia (e.g., laboratory and/or POC BG values >180 mg/dL or two or more fasting BG values >140 mg/dL), excluding patients with DKA or hyperglycemic hyperosmolar state (HHS) or who are pregnant. Excluding patients with only one day of readings and fewer than four to five readings is reasonable.
   - For critical care units, we recommend either all patients, or patients with at least mild hyperglycemia (e.g., two random glucose levels >140 mg/dL or any glucose >180 mg/dL). Critical care patients with DKA, HHS and pregnancy should be evaluated separately if possible. For analysis of whether or not your infusion protocol is effective, include only those who get infusion insulin, but for analysis of glycemic control in a given critical care unit, include all patients.

Exclusion criteria to consider for those creating local reports, if possible

- Patients with a diagnosis of DKA or HHS, which should be analyzed separately
- Palliative care/comfort care patients
- Patients with too few readings to reflect care given in the hospital
- Pregnant patients/OB population should be analyzed separately from general adult medical/surgical populations, as different treatment regimens and glycemic targets are in place

Critical care and non-ICU populations should be assessed separately.

2. Which Glucose Values to Include and Exclude

To answer this question, we first need to decide which method to use for BG measurement. There are several ways to measure BG, including the type of sample collected (capillary [''fingerstick''], arterial and venous) and the technique used (central laboratory analyzing plasma, central laboratory analyzing whole blood [e.g., from an arterial blood gas sample], glucose meter [usually calibrated to plasma], etc.). The POC (e.g., capillary, glucose meter) glucose measurements alone are often preferred in the non-ICU setting because laboratory plasma values generally provide little additional information and typically lower the mean glucose by including redundant fasting values.[1,10]

In critical care units, several different methods are often used together, and inclusion of glucose values from sources other than POC BG values deserves consideration for locally built glucometrics. POC BG readings can be inaccurate compared to reference clinical laboratory results, and this problem can be more pronounced in the critically ill patient. Interfering substances like high levels of bilirubin, uric acid and toxic acetaminophen levels can contribute to

inaccuracy. Patients on pressors or with poor peripheral perfusion are prone to inaccurate results.[4] Accuracy issues with blood glucose meters led to closer scrutiny from the Food and Drug Administration (FDA) about their use in the critical care setting. The FDA has been considering more stringent requirements under the Clinical Laboratory Improvement Amendments (CLIA) to hospitals using BG meters in the critical care setting. This would classify BG monitoring systems as "high complexity" testing, which would mandate extra training and increased local validation of accuracy to reference standards. At least one meter is now FDA-approved for use in the ICU without high complexity requirements,[11] but it is not approved for capillary BG samples in critically ill patients with potentially decreased peripheral blood flow. This highly controversial area will likely continue to evolve over the next few years.

POC BG readings remain the most practical method to direct clinical practice in the critical care arena, but special efforts must be made to ensure proper sample collection, and to use alternate methods in situations known to cause inaccuracies by this method. The inherent differences in calibration between the methods do not generally require separate analyses, especially given the frequency of testing in the ICU setting.

The next question is which values to include in analyses. In some situations, it may be most useful to focus on a certain period of hospitalization, such as the day of a procedure and the next two days in assessing the impact of the quality of perioperative care. Some exclude data after the first 14 days of a non-critical care stay to keep outliers for length of stay (LOS) from skewing the data, while others exclude data from the first hospital day, with thought that early BG control is impacted by multiple variables beyond direct control of the clinician (e.g., glucose control prior to admission, severity of presenting illness) and may not realistically reflect your interventions. On the other hand, the impact of these maneuvers on the overall analysis is small, and external benchmarking sources include this data.

By the same token, some hospitals select only the regularly scheduled (before each meal [qAC] and at bedtime [qHS], or every six hours [q6h]) glucose readings for inclusion in the summary data of glycemic control in the non-ICU setting, in an attempt to reduce bias caused by repeated measurements around extremes of glycemic excursions. On the other hand, this method could lose valuable information on hypoglycemic or other outlier events. ASHM recommends an alternative method of censoring glucose readings within 5-10 minutes of a previous reading to eliminate reflexive repeat testing after a hypo- or hyperglycemic value.

Recommendations

- *In the non-ICU setting, we recommend using POC BG values. Excluding values after hospital day 15 or hospital 1 are reasonable, but this can be labor intensive and is not done by external benchmarking and analysis sites. Exclusion of reflex testing values (repeat values obtained within 5-10 minutes of a prior value) is recommended, especially in hypoglycemia metrics.*
- *In critical care units, analysis of POC BG testing is generally acceptable, but other values sometimes drive care, and these other sources can be included if available.*
- *Appropriate care should be taken in the inpatient setting (especially for the critically ill patient) to ensure POC BG sampling and testing techniques are optimized, and alternative methods used in situations associated with inaccurate POC BG testing.*

3. Units of Analysis

There are several different units of analysis, each with its own advantages and disadvantages:

1. ***Glucose value:*** This is the simplest measure. All glucose values for all patients of interest comprise the denominator. A report might say, for example, that one percent of the 1,000 glucose values were <70 mg/dL during a certain period or that the mean of all glucose values collected for the month from patients in non-critical care areas was 160 mg/dL.

The disadvantages of this approach are that these analyses are less clinically relevant than patient-level analyses, and that patients with many glucose readings and long hospitalizations may skew the data. The variable frequency of testing during hospitalization, and between hospitals, make this a less desirable unit of analysis and we recommend against using it.

2. ***Patient-stay:*** All patients who meet the inclusion criteria make up the denominator. The numerator may be the percentage of patients with any hypoglycemia during their hospital stay or the percentage of patients achieving a certain mean glucose during their hospitalization, for example. This is inherently more clinically meaningful than using glucose value as a unit of analysis. A major disadvantage is not controlling for LOS effects. For example, a hospitalized patient with a long LOS is much more likely to be characterized as having at least one hypoglycemic value than is a patient with a shorter LOS. Glycemic control and hypoglycemia rates for hospitals with a different mean LOS would be difficult to compare. Another shortcoming is that this approach does not correct for uneven distribution of testing. A patient's mean glucose might be calculated on the basis of eight glucose values on the first day of hospitalization, four on the second day, and one on the third day. Despite all these shortcomings, reporting by patient remains a popular and valid method of presenting glycemic control results, particularly when complemented by other views and refined to control for the number of readings per day. Also, SHM glucometrics adjust for the variable testing frequency throughout a patient-stay by calculating a mean BG for each hospital stay, summing these means and calculating a day-weighted mean for each patient's hospital stay.

Note that we advocate for separate analyses of critical care and non-ICU stays, yet individuals frequently spend some hospital days in each of these settings. For this reason, the patient-stay in glucometrics is often calculated as the consecutive hospital days monitored on like units, and one patient may generate more than one patient-stay as result.

3. ***Monitored patient-day:*** The denominator in this setting is the total number of days a patient glucose level is monitored. The benefits of this method have been described and advocated in the literature.[1,5] As with patient-level analyses, this measure will be more rigorous and meaningful if the BG measures to be evaluated have been standardized. Typical reports might include percentage of monitored days with any hypoglycemia, or percentage of monitored days with all glucose values in the desired range. This unit of analysis may be considered more difficult to generate and to interpret. On the other hand, it is clinically relevant, less biased by LOS effects and may be considered the most actionable metric by clinicians. This method provides a good balance when presented with data organized by patient. SHM also expresses patient-day glycemic exposure as a weighted mean for the population. A mean glucose is calculated for each patient-day, and then the mean is calculated across all patient-days in the population, weighting each hospital day equally and correcting for variation in the number of glucose readings each day.

   The following example uses all three units of measurement, in this case to determine the rate of hypoglycemia, demonstrating the different but complementary information that each method provides:

   In one month, 3,900 POC glucose measurements were obtained from 286 patients representing 986 monitored patient-days. With hypoglycemia defined as POC BG <70 mg/dL, the results showed the following:

   - 52 of 3,900 measurements (1.3 percent) were hypoglycemic
   - 22 of 286 patients (7.7 percent) had at least one hypoglycemic episode over their stay
   - 40 of 986 monitored days (4.4 percent) had at least one hypoglycemic episode

The metric based on the number of glucose readings could be considered the least clinically relevant because it is unclear how many patients were affected; moreover, it may be based on variable testing patterns among patients, and could be influenced disproportionately by one patient with frequent hypoglycemia, many glucose readings, and/or a long LOS. One could argue that the patient-stay metric is artificially elevated because a single hypoglycemic episode characterizes the entire stay as hypoglycemic. On the other hand, at least it acknowledges the number of patients affected by hypoglycemia. The patient-day unit of analysis likely provides the most balanced view, one that is clinically relevant and measured over a standard period of time, and less biased by LOS and frequency of testing.

Recommendations

- *We recommend a combination of patient-day and patient-stay measures.*
- *We recommend against using the glucose value as the unit of analysis in most situations.*

4. Glucometric Measures

- **Glucometrics can be summarized in multiple ways:**
  - Glycemic Exposure:
    - Patient-day weighted mean
    - Patient-stay weighted mean
    - Three-day post-op mean
    - Hyperglycemic index
  - Glycemic Control
    - Percent of reading in goal range
    - Percent of patient-days with all readings in range
    - Percent of patient-days with a mean BG above the desired range (e.g., ≥180 mg/dL).
    - Percent of patient-stays with a mean BG above the desired range (e.g., ≥180 mg/dL)
  - Glycemic Safety/Adverse Events
    - Patient-days with severe hyperglycemia
    - Patient-days with hypoglycemia
    - Patient-stays with severe hypoglycemia
  - Hypoglycemia Management – Timeliness and Effectiveness
    - Mean/median time interval to the next documented reading
    - Mean/median time to documented resolution
    - Percent of hypoglycemic events with repeat testing within 30 minutes
  - Regulatory Measures:
    - SCIP
    - NQF

Glycemic exposure metrics are generally expressed as a mean and median composite glucose value over time. As discussed above, mean glucose values with the glucose test as a unit of analysis is simple, but not recommended. Patient-day and patient-stay units are both commonly used.

Patient-day method: Glycemic exposure for a population is expressed as a patient-day mean for the population. A mean glucose value is calculated for each individual patient-day. All individual patient-day means for patients included in the query are then averaged to calculate the patient-day mean for the population.

Patient-stay method: The mean glucose over each patient's stay is calculated. The means of the stay are then analyzed and presented as average, median and range of patient-stay means. SHM goes one step further, and uses a day-weighted mean for each patient, to reduce bias for varied testing over the course of the patient stay.

Other methods: In critical care and perioperative settings, interest in glycemic exposure is often more intense around the time of a particular event such as major surgery or after admission to the ICU. For example, the Portland group uses the mean glucose of each patient for the period that includes the day of coronary artery bypass graft (CABG) surgery and the following two days. The three-day BG average (3-BG) correlates very well with patient outcomes and can serve as a well-defined target.[12] Assessing the efficacy of an infusion insulin protocol might also look at the mean/median glucose over the infusion period.

Measuring the hyperglycemic index (HGI) is a validated method of summarizing glycemic control of ICU patients.[13] It is designed to take into account the sometimes uneven distribution of patient testing. Time is plotted on the x-axis and glucose values on the y-axis. The HGI is calculated as the area under the curve of glycemic values but above the upper limit of normal (e.g., 180 mg/dL). Glucose values in the normal or hypoglycemic range are not included in the AUC. This sophisticated and somewhat complicated method was not as predictive as patient-stay mean glucose metrics in some studies, however, and this method is not in common use.[14]

Glycemic Control assessment typically measures the percent of readings in a given range (e.g., 71-179 mg/dL on non-ICU wards for example). Again, the unit of analysis comes into play, and metrics can be expressed as the percent of patient-days with all readings in the desired range, or the average percent of readings per stay in the desired range. Some hospitals have used the percent of patient-stays with all readings in range, but this has the disadvantage of reflecting outpatient pre-admission glycemic control as much as inpatient management, and we discourage that method.

Another way to express glycemic control is the percent of patient-days or patient-stays with a mean BG above the desired range (e.g. ≥180 mg/dL). In our experience, this metric is more sensitive to improvement efforts than other markers of glycemic control.

Glycemic Safety/Adverse Events measures are variants of glycemic control measures that summarize the probability of more extreme glycemic excursions. These include the percent of patient-days or patient-stays with hypoglycemia, severe hypoglycemia or more extreme hyperglycemia.

Uncontrolled hyperglycemia and hypoglycemia varies, making it difficult at times to compare results across studies or institutions. Although many centers define hypoglycemia as <60 mg/dL, we prefer to use the ADA definition, based on physiologic changes that may take place, which defines hypoglycemia as BG <70 mg/dL. Severe hypoglycemia, with any BG <40 mg/dL, is a useful marker of unambiguously dangerous hypoglycemia. Not all hypoglycemia represents an adverse drug event, as hypoglycemia can occur spontaneously in patients with severe sepsis, liver failure and other conditions. If feasible to do so, including only patients exposed to insulin or oral hypoglycemic agents capable of contributing to hypoglycemia preceding the hypoglycemic event (e.g., within 12-24 hours), can further refine the metric.

The definition of uncontrolled and potentially dangerous hyperglycemia also has various definitions. SHM metrics define severe hyperglycemia as a BG >299 mg/dL, and track the percent of patient-days with severe hyperglycemia as a prominent safety metric that is sensitive to improvement efforts.

Hypoglycemia Management – Timeliness and Effectiveness - Multiple reports have shown that hypoglycemia management is often neither timely nor effective in preventing potentially avoidable recurrent hypoglycemic events, and that the mere presence of a hypoglycemia management protocol does not imply that it is being followed in clinical practice.[8,15,16]

SHM incorporated mean/median times to repeat glucose testing and times to documented resolution after a hypoglycemic event. Metrics are summarized as the mean/median time interval to the next documented reading, and to documented resolution with a repeat normal BG (excluding reflexive testing values, as described above), and as the percent of hypoglycemic events with repeat testing within 30 minutes.[17,18] These intervals at most medical centers are surprisingly long and demonstrate a wide range.

Another metric summarizes the percent of hypoglycemic patients who have more than one hypoglycemic day during their hospital stay. The rationale is that patients with appropriate assessment and management of their index hypoglycemic event will be much less likely to suffer recurrent hypoglycemia. In our experience, this metric is amenable to improvement, and often improves in tandem with the timeliness of hypoglycemia management. This is discussed more in the hypoglycemia section.

Recommendations

- *We recommend selecting a variety of complementary glucometric measures that capture glycemic exposure, glycemic control, safety/adverse events and efficiency/efficacy of hypoglycemia management.*
- *We recommend defining hypoglycemia as BG <70 mg/dL and severe hypoglycemia as BG <40 mg/dL.*
- *In the absence of definitive data or consensus, we recommend a threshold of a BG >299 to define severe hyperglycemia, and 180-200 mg/dL as the upper limit of the desirable BG range.*

5. Regulatory Measures

SCIP-Inf-4: There is only one publicly reported measure of inpatient glycemic control. The Surgical Care Improvement Project (SCIP) measure ID SCIP-Inf-4 is an NQF-endorsed measure focused on cardiac surgery patients.[19] The denominator consists of adult cardiac surgery patients with no evidence of prior infection, and the denominator is the subset of those patients with a postoperative BG <180 mg/dL in the time frame of 18 to 24 hours after anesthesia end time. The measure is consistent with a cardiothoracic surgery guideline[20] but has stirred controversy regarding its validity, and is rumored to have unintended consequences of withheld feedings in order to meet the metric.

NQF measures: Two measures have been submitted to the National Quality Forum (NQF) and have received recommendations for endorsement. They are NQF 2362: Glycemic Control – Hyperglycemia, and NQF 2363: Glycemic Control – Severe Hypoglycemia.

The NQF 2363 draft measure will attempt to measure the frequency of severe hypoglycemic events (<40 mg/dL) induced by hypoglycemic agents per patient-day of exposure to hypoglycemic agents, excluding metformin, which does not induce hypoglycemia.

The balancing measure NQF 2362 attempts to assess the percent of patient-days with hyperglycemia (two or more BG levels >200 mg/dL at least six hours apart, or a single value >200 mg/dL if only one value obtained) in admissions with a diagnosis of diabetes, hyperglycemia >200 mg/dL during their stay or receiving hypoglycemic agents.

These measures have great potential to raise awareness and establish baseline and benchmarking performance for inpatient glycemic control and hypoglycemia. Unfortunately, the summary sentences above are gross simplifications of the actual measures. They will be labor intensive to capture, and only partially amenable to automated retrieval at most medical centers. In addition, with only two metrics, institutions will need several more metrics to assess their glycemic control efforts. Full specifications of the draft measures are available.[21]

F. External Sources to Obtain Glucometrics and Benchmarking

Introduction and comparison of external resources and benchmarking

External sources providing glucometrics have been devised to address the barriers of complexity, expense, reproducibility and comparability of local measures. The most prominent external sources capable of providing glucometric reports are the Remote Automated Laboratory Systems[22] (RALS® Medical Automation Systems, Charlottesville, Virginia) application, the Yale Web-based system[23] and the SHM Glucometrics Web-based system.[17,18,24,25]

Large benchmarking studies with RALS data repositories have been published using metrics similar to those recommended here, but the reports available to hospitals are more limited in nature.[26-28] The Yale Glucometrics site offers free, on-demand reporting with high-quality glucometrics, but lacks benchmarking or quality improvement resources, and uploading data requires serial uploads for each unit on a month-to-month basis and is somewhat time-consuming and tedious.[1,10,23]

The SHM Data Center offers both flexible on-demand reporting and robust benchmarking. Table 1 compares and contrasts the SHM Data Center with the RALS and Yale systems. These authors have an obvious bias, but believe a thoughtful review will support our assertion that the SHM Glucometrics product is the best available. We present a brief summary of capabilities and major features here, and direct the reader to available literature and webinars for more detailed descriptions of the SHM glucometrics on-demand reports and benchmarking features.[17,18,24,25]

SHM on-demand reporting center

Medical centers upload POC blood BG data in a secure and de-identified process. BG values, date, time, patient unit and an encrypted numeric patient encounter identifier are uploaded in a standardized format. Data from multiple months and units can be uploaded in a single session. Patients with fewer than four BG readings or with only one hospital day are excluded, and data are “scrubbed” for erroneous or questionable values. Each hospital unit is defined on the first upload as being critical care vs non-ICU vs other, and further defined as being medical, surgical, mixed medical-surgical, orthopedic, obstetrics, etc., allowing for on-demand reporting for a group of like units or care types. Metrics summarizing rates of hyperglycemia, hypoglycemia, recurrent hypoglycemia and the timeliness of hypoglycemia management and resolution are all available on-demand. Significant customization of the reports (down to the level of an individual unit or month if desired) facilitates comparison of performance between similar units for any time period.

Table 1. Comparison of Glucometrics Tools

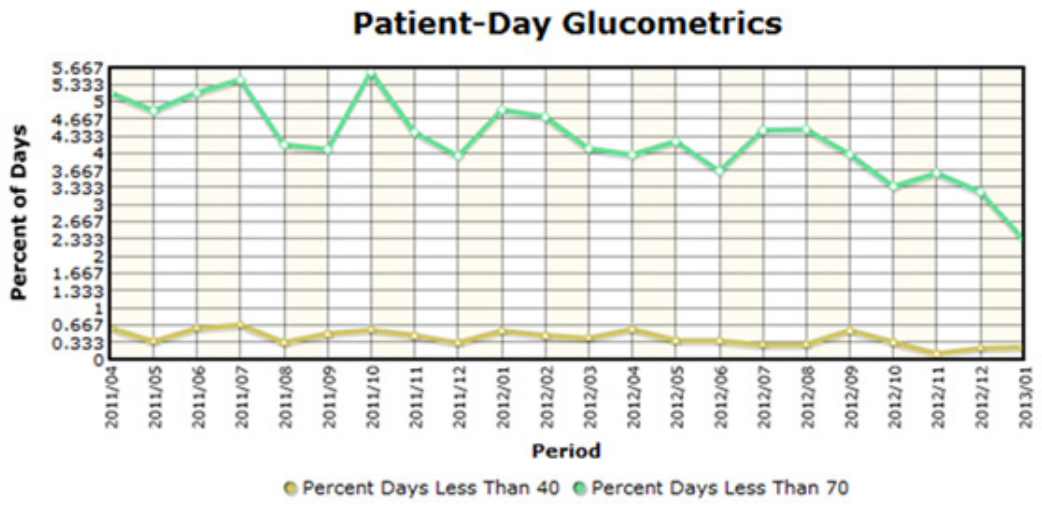
	RALS®-TGCM RALS®-Report	Yale	Society of Hospital Medicine
Cost	Proprietary – Must use RALS software system to manage point of care BG values. Variable cost, depending on modules and products hospital uses.	Free	$2,500/year tuition model. Free trials frequently available. Free for sites when grant funding for the Glycemic Control Mentored Implementation Program available.
Bundled Resources to support improvement	Not provided	Not provided	Live and on-demand webinars, community, multiple other resources
Data upload	Those paying for RALS are connected automatically, no active uploading required.	Requires each unit to be uploaded separately, month by month. Data spanning monthly boundaries considered separate patient-stays.	Data files for the entire hospital, spanning multiple months or years, can be uploaded in a single session. Patient-stays remain continuous across monthly upload boundaries.
Patient-day and patient-stay metrics	No. Patient-day metrics reported in literature from the database, but not available for users. Reports based on means of all values.	Yes	Yes
Benchmarking	Annual BG mean/median glucose, and percent of values with hypo-/hyper- glycemia available for ICU and non-ICU, limited graphics.	Not currently available	At least annual benchmarking with wide range of glucometrics and robust graphic presentation of data. Top quartile constitutes achievable benchmark. Scatterplot juxtaposes hypoglycemia and glycemic control parameters on one plot. Top performers achieve top quartile in both hypoglycemia and glycemic control.
On-demand reporting	RALS®-TGCM hospital level reports can depict selected glucose results by hospital, comparison by unit and comparison by date/time period.	User generated reports available on-demand. Limited flexibility in report construction.	Flexible user generated reports with available export into various file formats. Wide variety of reports.
Run charts for unit or hospital performance	Not available	Not available	Several run charts accompany each of the three month-to-month reports available.
Hypoglycemia reports	Limited to mean/median of percent with hypoglycemia	Limited to mean/median of per-cent with hypoglycemia	Also offers reports for recurrent hypoglycemic-days and time intervals for hypoglycemia re-testing and resolution.
Glucose value expressed as:	Mg/dL only	Mg/dL only	Mg/dL or mmol/L at user discretion

RALS – Remote Automated Laboratory Systems BG - Blood Glucose Modified from the Journal of Diabetes Science and Technology, Article reference 18. For actual table and article visit http://www.ncbi.nlm.nih.gov/pubmed/24876426.

All measures can be presented as a summary table for any time period the user designates, or as month-to-month results with accompanying run charts (Figure 1).

The SHM glucometrics reporting engine also provides access to a robust community, webinars, slide decks, print materials and other resources to assist the Improvement Team in addressing the full range of inpatient glycemic control issues. The option to upload and view reports and benchmarking in international units is now available.

Figure 1. Hypoglycemia run chart for non-ICU patients. The run chart depicts the percent of patient-days for the selected units with any hypoglycemic event (<70 mg/dL, in green) and any severe hypoglycemic event (<40 mg/dL,in gold). A variety of other metrics are depicted in both tabular form and run charts in the SHM glucometrics reporting engine.

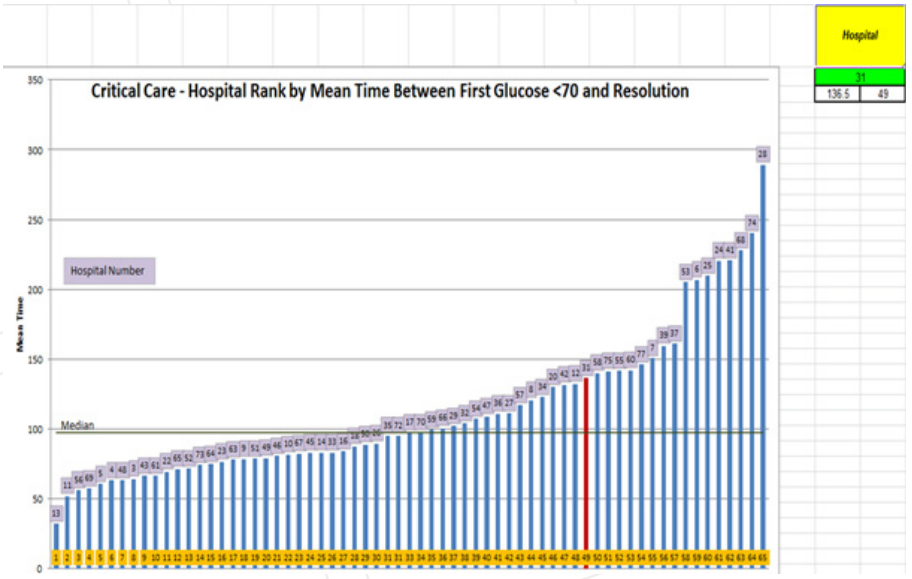


SHM benchmarking reports-

In response to repeated requests from hospitals, SHM developed benchmarking tools, allowing hospitals to set realistic goals and gain perspective on their performance.[17,18] Participating hospitals are assigned a confidential numeric code, and performance on a wide variety of metrics is summarized and placed in rank order, with separate analyses for ICU and non-ICU units. Each hospital can compare its performance to the mean, median and top-quartile performance for every parameter. Two types of graphic displays are available for multiple metrics.

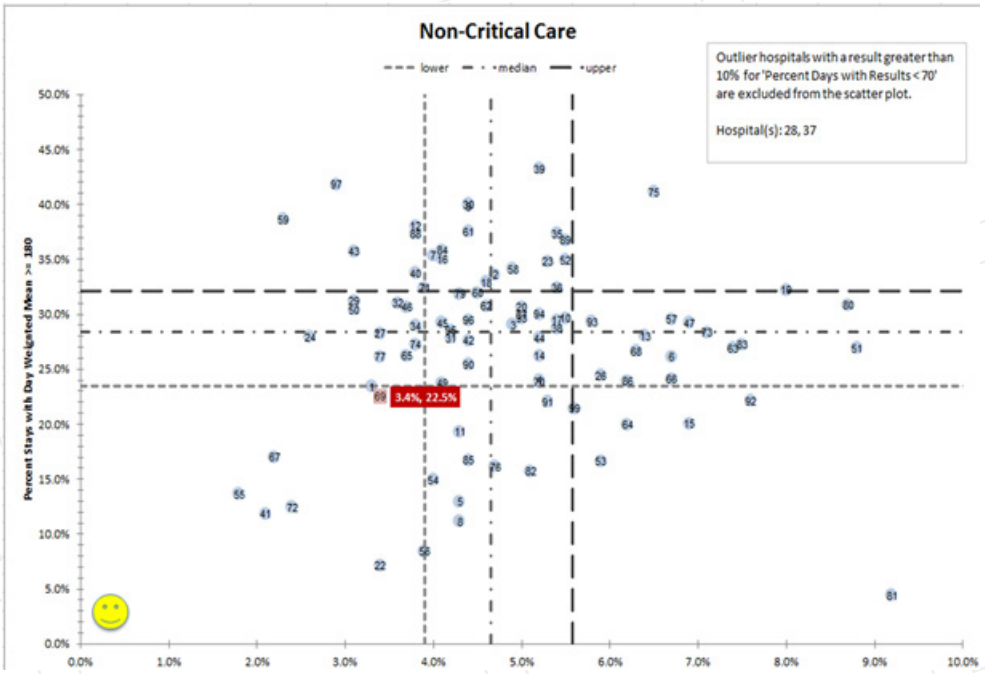
A rank order bar chart plots absolute performance on the y-axis and consecutive relative performance on the x-axis. Figure 2 provides an example of a rank order bar chart, in this case, for the metric of the mean time interval (in minutes) it takes each hospital to document resolution of a hypoglycemic event. Each hospital can distinguish itself from others in the cohort by entering their hospital numeric identifier in the benchmarking report, which highlights its hospital's symbol in red (see next page).

Figure 2. Rank-order bar chart of mean time interval between a hypoglycemic event and its documented resolution. In the example shown, the hospital with a numeric identifier #31 has a mean time of 136.5 minutes to documented resolution in critical care units, giving it a rank of 49 out of 65 hospitals. Note the wide spread of performance.



Perhaps the most important and informative graphic presentations are benchmarking scatterplots. As in the rank order bar charts, entering their numeric identifier highlights their hospital in red. Each hospital's performance on a glycemic control parameter is depicted on the y-axis, while a hypoglycemic parameter is depicted on the x-axis. Lower, median and upper quartile boundaries are clearly marked (Figure 3).

Figure 3. Benchmarking scatterplot for non-ICU units. Each hospital is depicted by its numeric ID and its position, defined by its performance for glycemic control (in this case, the percent of stays with a day-weighted mean ≥ 180 mg/dL) on the y-axis, and hypoglycemia rates per patient-day on the x-axis. The left lower quadrant contains hospitals with top quartile performance in both glycemic control and hypoglycemia parameters. The red color highlights an individual hospital's performance (hospital 69 has a hypoglycemic event in 3.4 percent of monitored days, and has uncontrolled hyperglycemia in 22.5 percent of patient-stays).



The scatter plot makes the trade offs between glycemic control and hypoglycemia very transparent, allowing intelligent prioritization of efforts. Ideally, this kind of report would inform the team of priorities early in their efforts.

All external reporting systems lack access to medications, comorbidities, diagnostic codes and demographics. While analysis by care type and unit are available, service and provider specific data are not. These limitations, and the need for other metrics relating to glycemic control programs, mandate that medical centers devise some metrics beyond what external providers can supply. Nonetheless, high-quality glucometrics, and especially benchmarking comparisons, are not available to most centers internally.

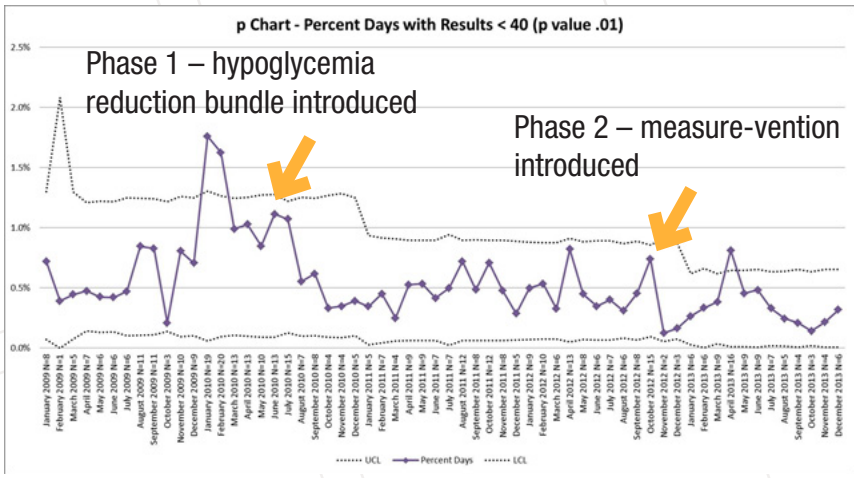
Recommendations

- *A variety of process and outcome measures should be tracked by improvement teams in addition to metrics with glucose values*
- *We recommend that hospitals should seek comparison/benchmarking data, either from within their system or via external benchmarking glycemic monitoring systems.*
- *Uni-dimensional benchmarking, focusing solely on hypoglycemia rates in isolation, or glycemic control in isolation, can be misleading. We recommend reviewing performance on glycemic control within the context of concurrent performance on hypoglycemia rates.*
- *External sources should not be the sole source of information for glycemic control teams. Active surveillance, insulin use patterns and a host of other measures (described below) are needed to complement the glucometrics described above.*

G. Effective Presentation of Data

Graphic displays of data often have more impact and are more easily understood by medical staff committees and other stakeholders. Run-charts are a common and effective method to present results over time. Figure 1 is a run-chart generated via the SHM glucometrics data and reporting engine. In a run chart, the x-axis is time and the y-axis the desired metric, such as patient-day weighted mean glucose. Points in time when interventions were introduced or modified can be highlighted. Run charts have several advantages over before-and-after summaries: they do not require interventions remaining fixed and are more compatible with continuous quality improvement methods, it is easier to see the effect of different aspects of the interventions as they occur, one can get a quicker picture of whether something is working and it is easier to separate out the impact of the intervention from secular trends. Finally, the use of run charts does not imply the absence of statistical rigor. Run charts with statistical process control (SPC) limits can easily convey when the observed time trend is unlikely to be due to chance using pre-specified P values. Pre-specified signals (e.g. seven to nine consecutive points on one side of the center line, four out of five consecutive points falling beyond on SD on the same side of the center line) help identify “special cause” variation from natural variation that can occur in a stable process.[29] Figure 4 is an example of an SPC chart (in this case, a p chart) depicting reduction in severe hypoglycemic days over time, as interventions were serially introduced.

Figure 4. Annotated SPC chart for severe hypoglycemia at UC San Diego



Presentation of data on a unit-by-unit basis in a graphic format can also be very helpful, to allow staff to compare their performance to other like units, and to foster a healthy competition. Figure 5 is an example of just such a graphic, which depicts progress on hypoglycemia rates over time, and also compares their performance to other units.

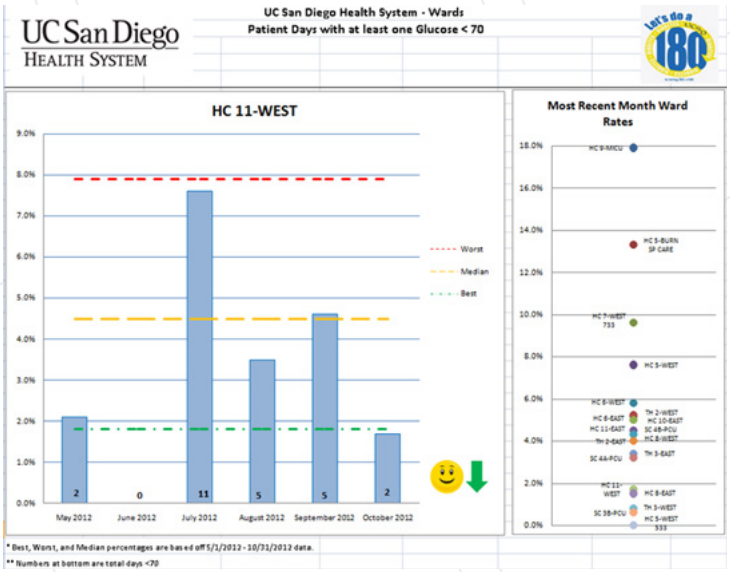


Figure 5. Graphic presentation on hypoglycemic events on an individual unit over time, with a display of rates from similar units to provide context.

Active surveillance with real-time measures (measure-vention)

Another important form of glycemic measurement is real-time measurement to identify outliers or patients who may require concurrent intervention. This active surveillance or measure-vention can be used to accelerate improvement and reach high levels of performance. Measure-vention is discussed in more detail in Section V.1 Principles of Effective Implementation and High-Reliability Design and Section VI.1 (Implement Safe Use of Insulin Management Practices and a Hypoglycemia Reduction Bundle).[31,32]

H. Conclusion

Like the field of inpatient glycemic management itself, the field of devising metrics to measure the quality of inpatient glycemic control is also in its infancy and quickly evolving. One should not be paralyzed by the lack of consensus regarding measurement — the important point is to pick a few metrics and begin the process locally. External sources of glucometrics reporting and benchmarking should be strongly considered as a complement to locally formulated measures, as they accelerate obtaining access to data, allow for comparison with other hospitals and help prioritize efforts intelligently. As your institution gains experience with measurement and the field evolves, your metrics may change. We recommend keeping all process and outcome data in its raw form so that it can be summarized in different ways over time. Once measures are established, specific and measurable, time-limited goals can be set. Only with a valid measurement process can institutions hope to know whether their changes are resulting in improved care for patients.

References

[1]Goldberg PA, Bozzo JE, Thomas PG, et al. ''Glucometrics''— assessing the quality of inpatient glucose management. *Diabetes Technol Ther.* 2006;8:560–569.

[2]Cobaugh DJ, Maynard G, Cooper L, Kienle PC, Vigersky R, Childers D, Weber R, Carson SL, Mabrey ME, Roderman N, Blum F, Burkholder R, Dortch M, Grunberger G, Hays D, Henderson R, Ketz J, Lemke T, Varma SK, Cohen M. Enhancing insulin-use safety in hospitals: Practical recommendations from an ASHP Foundation expert consensus panel. *Am J Health Syst Pharm.* 2013 Aug 15;70(16):1404-1413. PubMed PMID: 23903479.

[3]Umpierrez GE, Hellman R, Korytkowski MT, Kosibrod M, Maynard GA, Montori VM, Seley JJ, Van den Berghe G. Management of Hyperglycemia in Hospitalized Patients in the Non-critical Care Setting: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metabol.* . 2012; 97:16-38.

[4]Cook CB, Elias B, Kongable GL, Potter DJ, Shepherd KM, McMahon D. Diabetes and hyperglycemia quality improvement efforts in hospitals in the United States: current status and barriers to implementation. *Endocr Pract.* 2010;16(2):219–230.

[5]Schnipper JL, Magee MF, Inzucchi SE, Magee MF, Larsen K, Maynard G. SHM Glycemic Control Task Force Summary: Practical Recommendations for Assessing the Impact of Glycemic Control Efforts. *J Hosp Med.* 2008 Sept/Oct ;3(S5):66-75.

[6]Maynard G, Lee J, Phillips GW, et al. Improved Inpatient Use of Basal Insulin, Reduced Hypoglycemia, and Improved Glycemic Control: Effect of Structured Subcutaneous Insulin Orders and an Insulin Management Algorithm. *J Hosp Med.* 2009 Jan;4(1):3-15.

[7]Lee J, Clay B, Ziband Z, Clay B, Maynard G. Indication Based Ordering: A New Paradigm for Glycemic Control in Hospitalized Inpatients. *J Diabetes Science Tech. 2008;2(3):340-356.*

[8]Maynard GA, Huynh MP, Renvall M. Iatrogenic Inpatient Hypoglycemia: Risk Factors, Treatment, and Prevention: Analysis of Current Practice at an Academic Medical Center With Implications for Improvement Efforts. *Diabetes Spectr.* 2008;21: 241–247.

[9]Schnipper JL, Ndumele CD, Liang CL, Pendergrass ML Effects of a subcutaneous insulin protocol, clinical education, and computerized order set on the quality of inpatient management of hyperglycemia: results of a clinical trial. *J Hosp Med. 2009;*4(1):16–27.

[10]Thomas P, Inzucchi SE. An Internet Service Supporting Quality Assessment of Inpatient Glycemic Control. *J Diabetes Sci Technol.* 2008;2(3):402–408.

[11]FDA Press release, available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm416144.htm Last reviewed November 14, 2014.

[12]Furnary AP, Wu Y, Bookin SO. Effect of hyperglycemia and continuous intravenous insulin infusions on outcomes of cardiac surgical procedures: the Portland Diabetic Project. *Endocr Pract.* 2004;10(suppl 2):21–33.

[13]Vogelzang M, van der Horst IC, Nijsten MW. Hyperglycaemic index as a tool to assess glucose control: a retrospective study. *Crit Care.* 2004;8:R122–R127.

[14]Kosiborod M, Inzucchi SE, Krumholz HM, et al. Glucometrics in patients hospitalized with acute myocardial infarction:defining the optimal outcomes-based measure of risk. *Circulation.* 2008;117:1018–1027.

[15]Varghese P, Gleason V, Sorokin R, Senholzi C, Jabbour S, Gottlieb JE. Hypoglycemia in hospitalized patients treated with antihyperglycemic agents. *J Hosp Med.* 2007;2(4):234–240.

[16]Garg R, Bhutani H, Jarry A, Pendergrass M. Provider response to insulin-induced hypoglycemia in hospitalized patients. *J Hosp Med.* 2007;2(4):258–260.

[17]Maynard G, Ramos P, Kulasa K, Rogers KM, Messler J, Schnipper JL. How Sweet is It? The Use of Benchmarking to Optimize Inpatient Glycemic Control. *Diabetes Spectrum* 2014:27(3):212–217.

[18]Maynard G, Schnipper JL, Messler J, Ramos P, Kulasa K, Nolan A, Rogers K. Design and Implementation of a Web-Based Reporting and Benchmarking Center for Inpatient Glucometrics. *J Diabetes Science Tech.* 2014:published online May 12, 2014. doi: 10.1177/1932296814532237.

[19]Specifications Manual for National Hospital Inpatient Quality Measures (including SCIP-Inf-4). Available at http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx. Accessed November 11, 2014.

[20]Lazar H, McDonnell M, Chipkin S, Furnary A, Engelman R, Sadhu A, Bridges C, Haan C, Svedjeholm R, Taegtmeyer H, Shemin R. The Society of Thoracic Surgeons practice guideline series: Blood glucose management during adult cardiac surgery. *Ann Thorac Surg.* 2009;87;663–669.

[21]Specifications proposed glycemic measures. Available online at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/index.html?redirect=/qualitymeasures/03_electronicspecifications.asp. Accessed November 13, 2014.

[22]Alere™ Informatics Website for Remote Automated Laboratory Systems (RALS®): http://www.rals.com/index.html. Accessed February 14, 2014.

[23]Yale Glucometrics Website: http://metrics.med.yale.edu. Accessed January 2, 2014.

[24]Rogers K, Childers D, Messler J, Nolan A, Nickel WK, Maynard G. Glycemic Control Mentored Implementation: Creating a National Network of Shared Information. *Joint Commission J Qual and Patient Safety.* 2014,40(3):111–118.

[25]SHM Glycemic Control Webinar – Introducing the new Web-Based Reporting Engine for Glucometrics. http://www.hospitalmedicine.org/AM/Template.cfm?Section=Quality_Improvement&template=/CustomSource/ondemand/12052012_SHM_Glycemic_Control_Program_Informational_Webinar.cfm. Accessed January 16, 2014.

[26]Cook CB, Moghissi E, Joshi R, Kongable GL, Abad VJ. Inpatient point-of-care bedside glucose testing: preliminary data on use of connectivity informatics to measure hospital glycemic control. *Diabetes Technol Ther.* 2007; 9(6):493–500.

[27]Anderson M, Zito D, Kongable G. Benchmarking Glucose Results through Automation: The 2009 Remote Automated Laboratory System Report. *J Diabetes Sci Technol. 2010;*4(6): 1507-1513.

[28]Cook CB, Kongable GL, Potter DJ, Abad VJ, Leija DE, Anderson M. Inpatient glucose control: a glycemic survey of 126 U.S. hospitals. *J Hosp Med. 2009;*4(9) E7-E14.

[29]Benneyan JC, Lloyd RC, Plsek PE. Statistical process control as a tool for research and healthcare improvement. *Qual Saf Health Care.* 2003;12:458–464.

[30]Maynard et al Section V.1 Section A. Five Key Principles for Effective Implementation and Clinical Decision Support

[31]Maynard G et al. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. *Endocr Pract.* published online Dec 22, 2014 ahead of print, 1-34. doi:10.4158/EP14367.OR.

Section V:

1. Designing and Implementing Protocols for Optimal Inpatient Glycemic Control
   Authored by: Kristen Kulasa, MD, Greg Maynard, MD, MSc, SFHM (Lead Editor)
2. Inpatient Glycemic Management Teams — Traits of High-Performing Teams
   Authored by: Kristen Kulasa, MD, Greg Maynard, MD, MSc, SFHM (Lead Editor)
3. Subcutaneous Insulin Order Sets and Protocols: Effective Design and Implementation Strategies
   Authored by: Kristen Kulasa, MD, Greg Maynard, MD, MSc, SFHM (Lead Editor)
4. Designing and Implementing Insulin Infusion Protocols and Order Sets
   Authored by: Kristen Kulasa, MD, Greg Maynard, MD, MSc, SFHM (Lead Editor)
5. Design and Implement a DKA Protocol and Order Set
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6. Perioperative Management of Diabetes
   Authored by: Karrie Berg, DO
7. Improving Reliability of Care across Transitions: Into, Within and From the Hospital
   Authored by: Cheryl O'Malley, MD, FACP, FHM
8. Building and Implementing a Comprehensive Educational Program
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Section V.1: Designing and Implementing Protocols for Optimal Inpatient Glycemic Control

In this section, we cover a wide range of important interventions to optimize the management of subcutaneous insulin, insulin infusions, transitions, DKA, perioperative glycemic control, hypoglycemia management and prevention and education. In essence, the team is creating a series of linked protocols and order sets, reinforced by education, active monitoring and feedback, checklists, alerts and other methods.

In each case, the approach to implementation has common elements and is part of the larger QI framework as covered in Section I. This framework brings together common elements reported in the literature such as the "Turning Research Into Practice" ("TRIP") model,[1,2] the "Plan Do Study Act" model popularized by the *Institute for Healthcare Improvement,*[3] Society of Hospital Medicine Improvement Programs[4-7] and other successful glycemic control efforts.[8-10]

1. Review the evidence and best practices from guidelines, regulatory agencies and other sources. These sources provide general standards for insulin management, monitoring and safety for several different groups and special populations. This *Guide* and surrounding resources should allow your team to do this efficiently.
2. Distill the most important best practices from guidelines and other sources down to the most important ones you will reinforce. This filtering or distillation of the guidelines is essential. From thousands of pages derived from a score of sources, you must identify the most important ones you want to reinforce in protocols.
3. Identify and address potential barriers to implementation.
4. Translate the most important best practices from the guidelines and other sources into protocols, order sets and policies.
5. Pilot on a small scale, revise as needed and implement the protocol.
6. Continue to monitor and revise the protocol as needed.
7. Deploy multiple layered interventions to enhance the reliability of carrying out the best practices. Leverage the electronic health record (EHR) and other tools as much as possible to reinforce the protocol, manage patients efficiently and capture data for day-to-day management and ongoing programmatic assessment.

This quote typifies the approach of selecting the most important practices and then working toward reliably carrying them out.

"Excellence is best described as doing the right things right — selecting the most important things to be done and then accomplishing them 100% correctly." —Author Unknown

What is a protocol?

Protocols provide specific guidance for management of groups of patients, in an algorithmic structure that facilitates clinical decision-making, tailored to the local environment.[11] Protocols embody the local definition of acceptable practice. Protocols should have operational definitions that are detailed enough for staff to follow and to remove ambiguity about best practice standards. For example, a hypoglycemia management protocol must define hypoglycemia, dosing and route of treatment modalities, timing of retesting, documentation standards and roles and responsibilities of each step.

Medical center policies add another layer of definition and reinforcement to local standards. Policies often require medical center committee/medical staff votes to alter them. These policies have a longer review and revision cycle. Policies will ideally state acceptable standards in more general terms, while protocols are more specific and easier to revise.

Why a protocol?

The key concept is routine. Doing a complex activity the same way each time is the best way to make sure nothing is left out. In the hospital, protocols serve that purpose. They standardize and structure care delivered by a group of providers.

Why is routine important? Across a population of patients, one of the most common sources of suboptimal care arises from provider inconsistency. For a variety of reasons, providers inevitably vary care inappropriately, whether compared to each other or compared to themselves. In fact, a graph that depicts improved system performance over time almost always shows a progressive narrowing of the range of performance data points. In a powerful way, protocols improve care by specifically reducing this unnecessary variation in performance, from medical decision-making to ordering.

The best protocols, however, preserve our ability to customize care for special patient situations or circumstances. In contrast to variation that arises from provider behavior, variation from the protocol because of special patient situations is always acceptable. The protocol should make that clear.

As always, the devil is in the details. An order set/protocol will usually fail unless the team pays attention to these details. Details of the protocol will drive the design of order sets, measurement tools and educational efforts.

A. Five Key Principles for Effective Implementation and Clinical Decision Support

Protocol-driven order sets are ideally easy to use, provide the necessary guidance and are positioned in such a way that the embedded guidance should affect virtually all patients at key junctures such as on admission, post-operatively and on transfer from one level of care to another.[5-7] Effective implementation with provision of clinical decision support is enhanced by adhering to the following principles:

Principle 1

Keep it simple for the end user. It may be tempting to create an order set that provides comprehensive guidance and outlines the best management for the entire spectrum of patient situations. Improvement teams must strike a fine balance between providing guidance for the majority of the hyperglycemic inpatient population, yet keeping the process simple and efficient for the end user. Almost always, simpler is better, and less is more. Usability is immensely important, and success or failure may hinge on it.[12]

Excessively long or complicated order sets might provide excellent guidance if used properly, but they generally end up being bypassed. Having links or PDF documents within the ordering process might be desirable, but in reality, those links are rarely used. It is far more effective to provide less guidance that is used reliably, than to provide copious guidance that is bypassed. Providing extensive guidance detailing exceptions to the general rules within the ordering process itself may be counterproductive, and it is generally better to focus the protocol on patients who demonstrate the rule, rather than the exception. For substantial minority populations with special needs (obstetric patients, patients on TPN), a dedicated order set and protocol tailored to them is likely a better approach than inserting details about those populations into a general medicine or surgery insulin order set.

Minimize calculations and data entry the end user has to make, or automate that process for them. Look for opportunities to assist the end user by auto-populating some of the data elements they might need from elsewhere in the record, such as weight, BMI, creatinine clearance and the most recent HbA1c level. In some cases, there are several acceptable insulin management options for a given situation. Improvement teams can simplify the work for the end user and reinforce standardization by streamlining those choices.

Principle 2

Do not interrupt workflow. Don't become shortsighted about the importance of this particular intervention to enhance glycemic control and insulin administration in your medical center. Remember that this is rarely the primary focus of members of a caregiving team, and they are likely to be attending to dozens of other tasks per patient. Involve frontline workers to make sure your plans are feasible and that your order sets/protocols are easy to use. Check boxes and pre-written scales can encourage rapid acceptance because they make the work easier. Get their input on how to make implementation go smoothly. Clinicians should want to use your order sets if they are constructed properly.

Principle 3

Design reliability into the process. Human beings are incapable of doing anything reliably 100 percent of the time in the complicated healthcare setting. Part of your team's job is to engineer higher reliability into the process of getting rational insulin dosages to hyperglycemic patients. If the glycemic management protocol relies solely on traditional methods — personal checklists, working harder next time, education and the like — you will be disappointed with the results.

These traditional methods are helpful (and some are necessary), but they are not sufficient for achieving breakthrough improvement. You must design at least one of the following methods into your interventions to enhance the probability that each patient will receive the correct kind of therapy for his or her particular situation.

High-Reliability Strategies

Desired action is the ***default*** action (not doing the desired action requires opting out).
Desired action is ***prompted*** by a reminder or a decision aid.
Desired actions are ***standardized*** into a process (take advantage of work habits or patterns of behavior so that deviation feels weird).
Desired action is ***scheduled*** to occur at known intervals.
Responsibilities for desired action are ***redundant.***
Algorithms and reminders are incorporated into the order sets.

Examples of these methods as they apply to insulin administration:

- Incorporate glycemic targets and HbA1c orders into the subcutaneous insulin order set.
- Integrate default actions on appropriate glucose monitoring and insulin dosing into your order sets.
- Integrate guidance on what changes to make in the insulin regimen when caloric intake is interrupted.
- Make subcutaneous insulin regimens with scheduled basal insulin the default.
- Strip out all other insulin order sets of your institution. A review of post-op, transfer and admission order sets that all services use will probably reveal a half-dozen or more embedded sliding-scale insulin order sets that need to be eliminated. This will help to make your order set the only easy way to order insulin. Of course, correction insulin alone may be appropriate for a minority of patients, so your orders need to preserve this as an option while still encouraging basal insulin for most patients.

Examples of these and much more are presented in later sections, along with specific tips on how to integrate high-reliability design features.

Principle 4

Pilot your protocol/order set on a small scale before attempting wide implementation. No plan survives its first contact with reality. Inevitably there will be glitches with a first pass at anything new. It's best to "fail faster" by piloting on a small scale, so you can get the glitches out of the way before you implement your protocol more broadly. Piloting in a live version of CPOE, limiting the order set to one ward or service, can be difficult or impossible in some centers. However, small-scale pilots can be as simple as a five-minute focus group where five physicians give feedback on several versions of an order set. Taking an order set out for a "test drive" is far more effective when the pilot order set is applied to patient case scenarios, as ease of use and issues of ambiguity become so much more apparent than they are in a clinical vacuum. The pilot can be as simple as a paper algorithm you ask three to four doctors to use or trying the order set on one ward.

Principle 5

Monitor the use of your protocol and order set (and plan for measurement/monitoring). Rolling out the protocol is only a beginning. The team must have a plan that ensures the glycemic protocol is followed and the CDS embedded in order sets is actually used reliably for the appropriate patients.

A central challenge of standardization is to construct protocols that work for the great majority of patients, while allowing for individualization of treatment. Monitoring these justifiable variations from the protocol can instruct refinement that increases acceptance of standardization, while remaining flexible for the variable populations seen. When providers bypass the protocol altogether, reasons might derive from logistics and deviations from normal work flow rather than resistance to the concept of standardization. The team should anticipate variations from the protocol but should capture those instances, learn from them and take steps to reduce them. The team should ask:

- Why is the order set not used in some areas?
- Can it be integrated into other heavily used order sets?
- Which types of admissions are inadvertently bypassing the protocol?
- Which patients just do not fit the protocol?
- Can the protocol be changed so it fits more patients and situations?
- Which providers would benefit from focused educational efforts?
- Is the protocol stocked and re-stocked (if on paper) or in the work flow in all the key areas in the hospital?

Meet with your CPOE and/or IT team early and often about order set design, and about the potential to make measurement an integral part of the process. Information stored as discrete data elements can be recalled and organized into meaningful reports more easily than free text. Automating measures is easier if planned into the process at inception. As you design your glycemic control order sets and documentation tools, think ahead to how you would audit a patient, and determine whether or not they meet protocol-directed best practice standards (see Section IV for details).[13] The importance of ease of use applies to the measurement tools your team will need to deploy, as well as the ordering process.

A properly designed order set, when well-positioned and implemented, will prevent errors in hyperglycemia and hypoglycemia management and monitoring. Monitoring order set use, and designing some ongoing process that identifies patients who have "fallen between the cracks" can spur mitigation of the lapse in care concurrently. Finally, redesign of the process and order sets should continue to improve the system.

B. Layering Interventions to Reinforce the Protocol and the Hierarchy of Reliability

Consider the following hierarchy of reliability in implementing programs to enhance glycemic control and reduce hypoglycemia with physiologic subcutaneous insulin prescribing, intravenous insulin infusion regimens and safe-use practices. The hierarchy of reliability, first validated in VTE prevention efforts,[5-7] has also proven useful as an improvement concept and a way to predict reliability of care delivery in glycemic control efforts.[10] Keep in mind that you are creating several linked protocols and order sets and that these levels pertain to each protocol and order set and to the transitions you build into them to go from one protocol to the next. Focusing on only one aspect (such as IV insulin infusion protocols) will result in suboptimal care, as patients flow from one setting to the next.

Level 1 *State of nature (sometimes chaos)*

The institution has no standardized order sets or protocols. Reliance on individual expertise and experience is the only strategy to achieve quality care. Expect:

- More than 30 percent of your patients in non-critical care areas to have a mean glucose >200 mg/dL
- Only 30 percent of subcutaneous insulin regimens have a basal insulin component
- Uneven training/knowledge by providers
- High rates of preventable hypoglycemia
- Dissatisfaction of patients with the care they receive for their diabetes/hyperglycemia
- Poor coordination of tray delivery/glucose testing/insulin administration

Level 2 *Average: incomplete order sets/protocols*

Standardized order sets with basal, nutrition and correction dose terminology and/or standardized orders for insulin infusion may exist, but guidance for managing the myriad challenges of inpatient glycemic control at the point of care is incomplete and suboptimal; or detailed guidance is available in stand-alone protocols, but these protocols are not well integrated into the order sets or work flow.

Level 3 *Integrated order sets/protocols*

Level 3 is the entry point for most serious QI efforts; some would term this method “indication-based order sets,” meaning each order set is for a specific purpose (order subcutaneous insulin or administer intravenous insulin, for example), and some guidance for proper ordering, administration and monitoring is integrated into it. Both elements in level 2 are combined into a paper order set or CPOE that also has instructions endorsing the preferred options for different situations. This visual link enables providers to “back into” appropriate treatment choices. Aids for decision making, created by the multidisciplinary team, are available to support decision making at the point of care or in the order sets.

Remember that providers should always retain the freedom to deviate from the protocol specifically to meet the needs of a given patient. Eventually, with successive refinements, the protocol should drive management choices for the great majority of patients.

Level 4

All Level 3 conditions are in place, but the general order sets and protocols are supported by more detailed, comprehensive, institution-specific algorithms and protocols that promote a standardized approach and additional performance-improvement strategies are used.

For example, subcutaneous insulin orders would lead the ordering provider to follow the institutional protocol for:

- Patient who is eating
- Patient who is NPO
- Patient who is receiving enteral nutrition, continuous or intermittent bolus
- Patient who is receiving TPN
- Patient who is perioperative (brief or longer duration of expected NPO status)
- Patient who is on steroids
- Patient who needs insulin infusion
- Patient who is transitioning from infusion insulin to subcutaneous insulin
- Patient who is being transitioned from the hospital regimen to a home regimen

Guidance from your local algorithms and protocols are reinforced at the point-of-care whenever possible. Remember, some trade-offs are inherent to this more guided and algorithmic methodology. As you integrate more and more of your preferred algorithm and regimens into your order set, you reduce not only variability in ordering but also the choices available to your prescribers and patients. For example, if your team decides all hyperglycemic patients who are eating should be on insulin glargine as a basal insulin and a rapid-acting analog insulin as a nutritional insulin, you can eliminate the other choices from your order set for that type of patient. So, what is the downside? The loss of choice may irritate both physicians and patients, and extra efforts must be taken to ensure the patient is informed about why these changes are being made.

At Level 4, tools like glucose management pages provide a graphic depiction of glycemic control trends, and pull together information related to glycemic control (such as HbA1c, insulin dosing, glucose values, carbohydrate intake, weight, creatinine and BMI) into one location.

Extra care must be taken to ensure the diabetes regimen the patient receives on discharge is appropriate to that patient's level of understanding, motivation, finances, insurance plan and other considerations. This is discussed in more detail in Section V.[14] Also, education must continue, as always, because healthcare providers must understand the rationale for the protocol in order to know when to wisely deviate from it.

The table on the next page outlines several quality improvement strategies to consider. Most of these other strategies leverage the glycemic control and insulin protocols you have in place. Providers, nurses, pharmacists, even patients can refer back to the glycemic control protocols for clarity, confidence or advocacy. ***With any additional layer(s) to the overall glycemic control effort, include at least one high-reliability mechanism in the design.***

Level 5 *Oversights identified-and-mitigated in real time. Measure-vention and active surveillance*

Level 5 represents a profound leap in quality. At this level you will improve care by a whole order of magnitude, a rare achievement in healthcare. All the conditions of Level 4 exist, plus there is now a strategy to identify and address the management oversights that inevitably occur. We have termed this form of active surveillance measure-vention, coupling real-time measurement and identification of quality outliers to spur concurrent intervention. Identifying and addressing quality outliers in real time (as opposed to relying solely on month-to-month metrics) was first found to be successful

in thrombo-prophylaxis,[5-7] but has since been successfully utilized in a number of other improvement efforts, including glycemic control and hypoglycemia reduction.[10]

In addition to addressing the individual lapse in care, the root cause of failure is analyzed and appropriate changes in the system are made to improve care even further. At Level 4, 70-80 percent of your patients on subcutaneous insulin will have a scheduled basal insulin in their regimen. Will your team be satisfied with that considerable gain? It depends on whether you are merely pursuing excellence (relative to "industry standards") or whether you are actually pursuing perfection. There will always be instances when the optimal insulin strategy is not used or an HbA1c level is not ordered, or a patient suffers from a preventable hypoglycemic episode. Strategies that "identify-and-mitigate" these oversights are critical for achieving breakthrough improvement.[3] Level 5 is made more practical and sustainable with an electronic reporting mechanism and proper metrics, which we reviewed in Section IV.

Armamentarium of QI Strategies

QI Strategies	Specific Ideas for Glycemic Control
Provider education	• Didactic sessions on insulin use (e.g., noon conference, Grand Rounds, etc.) or, better yet, comprehensive educational programs with mandatory participation and performance (certification). • Distributed educational materials (e.g., pocket cards, handbooks, etc.). • Intranet- or Web-based educational programs.
Provider reminder systems	• Prompts nested within paper admission/transfer/post-op order sets supported by guides for insulin ordering (insulin protocol). • Prompts within CPOE to follow insulin protocol. • Stickers on charts or posters in order-writing areas.
Facilitated relay of clinical data to providers	• Alerts to physicians by means other than the medical record (e.g., page, electronic alert, phone call, email to provider about patients with poor glycemic control or patients not on recommended therapies).
Audit and feedback on performance to providers	• Feedback of glycemic control or insulin usage performance to individual providers or groups of providers (with or without benchmarking top performers).
Patient education	• Programs dedicated to assessing the learner, teaching "survival skills" and other materials (e.g., pamphlets, physician or nurse teaching patient or caregiver closed-circuit TV program in patient rooms, etc.).
Organizational or operational change	• Administrative support personnel dedicated to ensuring constant stocking of insulin protocols and order set in needed areas. • Clinical support personnel dedicated to collecting data and creating useful reports on glycemic control (see Metrics section). • Hospital-wide (or unit- or service-specific) teams or individuals with regular responsibility to focus on glycemic control (e.g., physician, nurse, pharmacist, etc.), also known as the "glycemic control hit squad"/ Glycemic Management Team.
Incentives, regulation and policy	• Provider-directed: • Honor recognition of highest performers each month or quarter. • Financial incentives based on achievement of glycemic control performance goals. • Punitive actions for failure to meet minimum performance or to cooperate with improvement efforts (suspension of privileges, stockade in town square, etc.) • Health System directed: • Enforced policy mandating use of insulin protocols (e.g., "hard stops" in processing of a pre-op patient to make sure the patient is assessed for hyperglycemia and, if present, treated via the protocol).

Source: adapted from reference 15. Shojania KG, McDonald KM, Wachter RM, Owens DK. Series Overview and Methodology. 2004. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies; vol 1. Available at: http://www.ahrq.gov/downloads/pub/evidence/pdf/qualgap1/qualgap1.pdf.

C. Action-Oriented Learning: Plan–Do–Study–Act

In a complex environment like a hospital there will always be unforeseen problems when trying something new. But you can start small and scale quickly by using rapid cycles of action-oriented learning. A great way to do this is by using the popular "Plan–Do–Study–Act" (PDSA) model.

Start by planning (plan) your intervention, and then test (do) it. The next step (study) is critical. Observe the test yourself, paying close attention to competing demands and physical space. Most important, ask those involved in the test what worked, what did not, and listen carefully. Ask them for alternative ideas, pitch your own and talk it out. The idea is to get a read on what could or should be done differently from how your team originally planned it. The last step is to set things up to do better next time (act).

The following table highlights the advantages of PDSA and provides principles for doing it well.

Advantages of PDSA and Principles for Success

Advantages of PDSA
Allows valuable modifications to improve effectiveness or preserve productivity.
Allows "failures" to come to light without undermining performance and momentum.
Identifies areas of resistance that might undermine spread to other units.
Allows costs and side effects of the change to be assessed.
Increases certainty that change will result in improvement.
Allows for detailed documentation of improvement.
Principles for Success
Start new changes on the smallest possible scale, such as one patient, one nurse, one doctor.
Run just as many PDSA cycles as necessary to gain confidence in a change, then spread incrementally.
Spread incrementally to more patients, then more nurses, then doctors and finally units.
Balance changes within the overall system to ensure other processes are not adversely stressed.
Pay special attention to preserving productivity and work flow.

Whoever observes and studies the test should record lessons and the suggested tweaks. These should be shared at the next multidisciplinary team meeting.
The IHI has a preprinted PDSA Worksheet you may find helpful to download.

Plan–Do–Study–Act Worksheet for Testing Changes

Aim — Describe the aim of this project
- — Every aim will require multiple smaller tests of change
- — Describe your first (or next) test of change
- — Person Responsible
- — When to be done
- — Where to be done

Plan — List the tasks needed to set up this test of change
- — Person Responsible
- — When to be done
- — Where to be done
- — Predict what will happen when the test is carried out
- — Measures to determine if prediction succeeds

Do — Describe what actually happened when you ran the test

Study — Describe the measured results and how they compared to the predictions

Act — Describe what modifications to the plan will be made for the next cycle from what you learned

On to Specific Interventions

As we continue this section, we will assist you in constructing a series of algorithms and protocols for your institution, addressing subcutaneous insulin regimens, IV insulin infusion, transitions, perioperative settings, monitoring programs and educational programs that will support your efforts. Return to these introductory sections on interventions periodically to make sure you are leveraging the algorithms and protocols to the fullest extent possible.

On the next several pages, we will start picking a preferred subcutaneous insulin strategy for several different situations and begin building an algorithm for your institution.

References

[1]Pronvost P, Berenholz S, Needham D. Translating evidence into practice: a model for large scale knowledge translation. *BMJ*. 2008;337:a1714. doi: 10.1136/bmj.a1714.

[2]Munoz M, Pronovost P, Dintzis J, Kemmerer T, Wang N, Chang Y, Efird L, Berenholz SM, Golden SH. Implementing and Evaluating a Multicomponent Inpatient Diabetes Management Program: Putting Research into Practice. *Joint Commission J Qual and Patient Safety*. 2012;38(5):195-206.

[3]Nolan T, Resar R, Haraden C, Griffin FA. Improving the Reliability of Health Care. IHI Innovation Series white paper. Boston: Institute for Healthcare Improvement; 2004. Available at http://www.ihi.org/IHI/Results/WhitePapers/ImprovingtheReliabilityofHealthCare.htm. Last accessed Nov 8, 2014.

[4]Rogers K, Childers D, Messler J, Nolan A, Nickel WK, Maynard G. Glycemic Control Mentored Implementation: Creating a National Network of Shared Information. *Joint Commission J Qual and Patient Safety*. 2014;40(3):111–118.

[5]Maynard G, Stein J. Preventing Hospital-Acquired Venous Thromboembolism: A *Guide* for Effective Quality Improvement. Prepared by the Society of Hospital Medicine. AHRQ Publication No. 08-0075. Rockville, MD: *Agency for Healthcare Research and Quality*. August 2008.

[6]Maynard G, Stein J. Implementation *Guide*- Optimize Prevention of Venous Thromboembolism at your Medical Center. Society of Hospital Medicine website, VTE Quality Improvement Resource Room. http://www.hospitalmedicine.org. last Accessed July 8, 2010.

[7]Maynard G, Stein J. Designing and Implementing Effective VTE Prevention Protocols: Lessons from Collaboratives. *J Thromb Thrombolysis*. 2010 Feb;29(2):159-166.

[8]Maynard G, Lee J, Phillips GW, et al. Improved Inpatient Use of Basal Insulin, Reduced Hypoglycemia, and Improved Glycemic Control: Effect of Structured Subcutaneous Insulin Orders and an Insulin Management Algorithm. *J Hosp Med* Jan. 2009;4(1)3-15.

[9]Ramos P, Childers D, Maynard G, Box K, Namba, J, Stadalman,K. and Renvall M. Maintaining glycemic control when transitioning from infusion insulin: A protocol-driven, multidisciplinary approach. *J Hosp Med*. 2010:5(8):446–451. doi: 10.1002/jhm.810.

[10]Maynard G, Kulasa K, Ramos P, Childers D, Clay B, Sebasky M, Fink E, Field A, Renvall M, Juang PS, Choe C, Pearson D, Serences B, Lohnes S. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. *Endocr Pract*. published online Dec 22, 2014 ahead of print, 1-34. doi:10.4158/EP14367.OR.

[11]Streiff BM, Carolan HT, Hobson DV, Kraus PS, Holzmueller CG, Lau BD, Biscup Horn P, Pronvost PJ, Haut ER. Lessons from the Johns Hopkins Multi-Disciplinary Venous Thromboembolism (VTE) *Prevention Collaborative*. BMJ 2012;344:e3935. doi: 10.1136/bmj.e3935.

[12]Bates DW, Kuperman GJ, Wang S, Gandhi T. et al. Ten Commandments for Effective Clinical Decision Support: Making the Practice of Evidence-based Medicine a Reality. *J Am Med Inform Assoc*. 2003;10:523–30.

[13]Maynard G (and others). Choose Metrics and Develop a Data Collection Plan for Your Glycemic Control Program. Reference old toolkit.

[14]O'Malley CW (and others). Improve Transitions of Care for Patients with Hyperglycemia. Reference old toolkit.

[15]Shojania KG, McDonald KM, Wachter RM, Owens DK. Series Overview and Methodology 2004. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies; vol 1. Available at: http://www.ahrq.gov/research/findings/evidence-based-reports/qualgap1.pdf.

Section V.2: Inpatient Glycemic Management Teams — Traits of High-Performing Teams

Once institutional support has been obtained, protocols have been written and are in place, metrics have been established and a multidisciplinary Steering Committee has been formed, many institutions take it a step further by creating a frontline glycemic management team to accelerate and reinforce practice guidelines and improve the quality of patient care. These teams target individual patients or populations of patients, as well as providers, in the hospital in a more direct way, can be cost effective and are established strategies for top-performing hospitals[1-2].

However, in order for these teams to be successful, it is imperative they have the tools and infrastructure in place prior to implementation of the frontline team. Table 1 outlines the necessary support needed for success.[2-5]

Table 1. Core Components Recommended Prior to Establishing a Hospital Glycemic Management Team

Component	Details
Personnel	
Glycemic Control Steering Committee	Multidisciplinary committee composed of major stake holders. May include representatives from administration, hospital medicine, critical care, surgery, endocrinology, nursing (champions, educators, admin), glycemic management team, pharmacy, residency program, dietary, safety, care coordinators, IT, laboratory
Passionate Leader	Organize, lead, provide vision, participate in providing feedback, sell and represent the program to C-Suite and Hospital Patient Care/Safety Committees; track performance metrics and share with stakeholders
Glycemic Management Content Expert	Provide expertise and assist with protocol development and testing; can add credibility depending on the environment. This person can be an endocrinologist, hospitalist, mid-level provider, diabetes educator or anyone with advanced knowledge of diabetes in the inpatient setting.
Nursing Champions	Provide effective diabetes expertise and nursing leadership for individual units or services; can identify unit-specific barriers and assist in their resolution; act as a conduit of important information between the Steering Committee and their frontline care units
Pharmacy	Spectrum of help from providing daily lists of patients on insulin to managing or advising about ICU insulin drips and transitions
Support	
C-Suite	At a minimum provide commitment to a culture of safety related to inpatient glycemic control, but ideally also maintain glycemic control on administration dashboard and provide funding for CDE and diabetes NP, PA-C positions, FTE support for program leader(s), funding for participation in SHM mentor programs, QuesGen database and funding for national DM related education conferences
IT	Assist in designing protocols, order sets, alerts for EMR and adding them to the system in a timely fashion. Help in developing recurring reports of patient glycemic control data for uploading to QuesGen for benchmarking.
Tools	
Metrics	Rates of hypo- and hyperglycemia, HbA1c checks, appropriate use of insulins and protocols, insulin errors, use of oral hypoglycemic agents and documentation
Protocols and Order sets	For HbA1c checks, discontinuation of oral agents, timing of blood glucose checks, insulin dosing and meal delivery, management of hypo and hyperglycemia, DKA, insulin pumps, transition from intravenous to subcutaneous insulin, management algorithms for insulin drips and subcutaneous insulin; protocols for transitions out of the hospital

Without these core components in place, the team will almost certainly fail. They need the tools and support in place in order to succeed.

A. Team Design (Make-up)

Depending on the institution's resources and focus, these teams can be configured in a variety of ways. While most inpatient management teams provide direct medical management as well as education services, some utilize the same person for both medical management and education while others separate the two in a "divide and conquer" approach. This delineation is often driven by the billing abilities of the team members, trying to maximize the number of patients a billing provider can see. Teams also vary by their approach to delivery of these services with some designed as a consultation team providing recommendations only while others directly write orders. The approach chosen can directly impact the number of patients the team is capable of seeing each day with the consultation approach typically providing more time for more patients.

The onsite supervising clinician and active inpatient management team leadership roles are other variables that are influenced by the institution's environment, personnel and resources. The onsite supervising clinician is often an endocrinologist or hospitalist while the active inpatient management team leadership role usually varies between a physician (hospitalist or endocrinologist), a non-physician provider (NPP) with expertise in diabetes management (physician assistant [PA] or nurse practitioner [N]), a pharmacist or a registered nurse or registered dietitian who is usually also a certified diabetes educator.

The target population of the diabetes management team is also dependent on resources. While most serve non-critical care, medical critical care and surgical units, some focus on particular units, services or physical locations.

Examples of glucose management teams

- A few institutions with a very robust endocrinology presence get endocrinologists involved in the care of almost all hypoglycemic inpatients. Others use well-trained PAs, NPs or hospitalists to see these patients and either write orders or provide recommendations for both inpatient glucose management and transition to an appropriate outpatient regimen. The focus of this team might vary depending on available time and resources and might have a broader focus such as all surgery patients or more narrow focus such as ICU patients, CT surgery patients, perioperative patients or transplant patients.
- In other institutions, nurse case managers identify patients with hyperglycemia and target them for extra counseling and also target their doctors, urging them to be more aggressive with glycemic control and patient education. These professionals will often be enthusiastic and effective members of the medical center's inpatient Glycemic Control Steering Committee, and frequently play a role in data collection as well as being an education resource for other nurses, physicians and patients.

B. Five Important Characteristics for an Effective Inpatient Management Team

These traits include data-driven, proactive, passionate and motivated, skillful communicators and proficient educators.

Characteristic 1

Data-Driven. There is no substitute for good data.

Data is used to validate and guide improvement efforts. The primary data to begin with are the month-to-month metrics including hypo- and hyperglycemia rates, recurrent hypoglycemia, hypoglycemia management, etc. This group of data helps paint the overall road map as to where the team started, has been and where they should be focusing their efforts next. Being able to slice and dice the data by unit, service and even provider can be extremely beneficial, not only to identify outliers and guide efforts but also to use as support to facilitate change.

National benchmarking data helps put the outcomes of the institution's glycemic interventions into perspective by comparing your institution to other hospitals across the country.

Real-time data utilized by the glycemic management team to identify outliers on a day-to-day basis allows for "just in time" teaching and intervention to improve overall patient care.

Characteristic 2

Proactive. Actively seek out opportunities for improvement.

By identifying potential system failures, the team can take action, create interventions or modify current practices to improve work flow or quality of patient care. Active surveillance is one example of proactive management. Evaluating hyper- or hypoglycemia lists in real time to identify outliers, triage them and trigger interventions for care deficits can help improve glycemic control in the hospital today. "Just in time" education for both providers and nurses is another example, and taking advantage of these real-time situations for 1:1 education is a proactive way to facilitate quality improvement.

Characteristic 3

Passionate and Motivated. Quality improvement is not for the faint of heart.

There will be many bumps along the road and it takes passion and motivation to stay on course and not get beat down by the system and failures. Passion and motivation are also essential in overcoming provider inertia and facilitating policy acceptance and uptake by staff hospital-wide. There will be several resistant providers, nurses or patients and a passionate approach, in addition to education and convincing data, will help facilitate policy acceptance.

Characteristic 4

Skillful Communicators. Skillful communication is a crucial art.

The management team will be interacting directly with patients, patient families, nurses, physicians, residents, mid-level providers, other team members and multiple other people throughout the hospital on a daily basis, and effective communication will be crucial. Whether it be discussing the need for increased resources with the CEO, presenting data at a patient safety meeting or informing a patient why they will be on insulin during their inpatient stay rather than their usual outpatient orals, the tone, confidence and presentation of information can be as useful as the words spoken in achieving the intended results. The ability to read the audience and adjust the approach accordingly is also essential for skillful and successful communication.

Characteristic 5

Proficient Educators. Education establishes the foundation of success.

Effective education at all levels will be essential in establishing the baseline knowledge everyone from patients to providers will need to be successful. A proficient educator is competent, exudes a caring nature and has an understanding of and appreciation for diversity. Like communication, the approach taken for education will depend on the audience and will often need to be adjusted throughout the encounter to make sure the message is received as intended.

A proficient educator takes the whole patient into account and adjusts the focus and approach according to the individual. Realistic goals and achievable targets will be important to set the patient up for success. Focusing on survival skills and providing the patient with the tools, understanding and self-confidence necessary to make informed decisions regarding his/her own health will provide the most benefit in the long run.

Nurses are the only in-house caregivers in continual contact with the patients and as such, they provide a critically important bridge of care between the patients and their providers. Investing in their initial and continuing diabetes education will pay significant dividends. Given the large number of nurses at most institutions, a multifaceted approach using Web-based modules, 1:1 encounters, unit-based meetings and data review as well as the nursing champion system to disseminate information and education to each unit will be necessary.[2-5]

Provider education can be challenging and usually "less is more." Providers seem most open to 1:1 case-based feedback. Celebrating small wins and approaching providers in a non-confrontational way using real-time cases can be useful to obtain buy-in and long-term education for those who might have reservations or be resistant. Listen to their concerns and follow up the next day to be able to further adjust insulin and reinforce the education. Other useful approaches utilize CME programs and Grand Rounds as well as monthly didactics for residents.[2-5]

C. Team Extenders

No matter what the team design entails, the inpatient management team itself will be small in comparison to the number of patients, nurses and providers who will need intervention. Therefore, teams that exist with the support of "team extenders" are typically more successful than those who exist alone. These "team extenders" can include hospitalists, pharmacists, nursing champions or dietitians who have developed rapport with the team via 1:1 interaction, rounds or through educational efforts.

Table 2.

Examples of Team Extenders

Team Extender	Details
Patient Care/Education	
Unit-Based Nurses	Alert providers re: poor glycemic control during hospitalization or patient barriers to sustained outpatient glycemic control (physical, mental or financial) identified prior to day of discharge. Provide basic DM education including glucose meters and insulin injections.
Dietitians	Provide basic carbohydrate education and healthy eating habits for patients with diabetes.
Pharmacists	Assist with managing insulin drips in the ICU or medication reconciliation and insurance coverage upon discharge from the hospital.
Provider Care/Education	
Hospitalists	Implement and teach the basics of inpatient glycemic control on rounds to students, interns and residents. Hospitalist champions can also touch on glycemic control and/or present metrics at regular division meetings and serve as a resource for other colleagues.
Nursing Champions	Provide effective diabetes expertise and nursing leadership for individual units or services; can identify unit-specific barriers and assist in their resolution; act as a conduit of important information and education between the Steering Committee and their frontline care units.
Pharmacists	Provide medication recommendations during rounds, by request or as triggered by a non-standard order. Ensure orders meet requirements prior to verification.
Dietitians	Remind provider of changing insulin requirements when nutrition recommendations are changed.

It is important to understand that these groups are often working toward a common goal and that responsibilities will overlap and efforts should therefore be aligned. Rather than each group working in silos and trying to improve their small part alone, communication and coordination of efforts will help reduce redundancy and improve the effectiveness and efficiency of the inpatient management team so that their efforts can be spread more broadly to reach a greater number of patients and providers.

D. Day-to-Day Management

The inpatient diabetes management team will have a variety of responsibilities, but the extent and depth of these responsibilities will depend on the available resources as well as the focus and environment of the institution. Table 3 outlines several of the suggested responsibilities for Hospital Glycemic Management teams. [2-5]

Table 3.

Suggested Responsibilities for Hospital Glycemic Management Teams

Responsibility	Details
Systems Analysis	
Review glucometrics	Rates of hypo- and hyperglycemia, HbA1c checks; appropriate use of insulins and protocols; insulin errors, use of oral hypoglycemic agents, documentation
Identify process or protocol issues	Through frontline work, feedback from providers or review of incident reports
Identify outlier services/units	By slicing and dicing glucometric data
Education	
Provider education	1:1 case-based feedback, CME programs, Grand Rounds and monthly didactics for residents
Champion education	Nursing, pharmacy, dietary, etc.
Nursing education	In-services; Web-based; printed materials; nursing competency; knowledge assessment
Real-time care-specific 1:1 education	On the spot "just in time" education involving active cases
Serve as diabetes resource	For providers, pharmacists, champions and floor nurses
Direct Medical Management Services and Strategies	
Medical management	Consult request or pre-specified triggers for team to see patient; recommendations conveyed to primary team & nurse
Patient education	Individual DSME and printed education tools; team needs nursing, dietary and pharmacy partners for patient education tasks, allowing them more time for direct management and systems improvement
Round with high-risk services	To develop service-specific protocols and practices
Assist with DM transitions of care	Identify hyperglycemia prior to d/c; use HbA1c to guide post-d/c DM meds; refer to outpatient DSME and PCP follow-up; access to DM meds and supplies post-discharge. Integration into broader transitions of care efforts
Follow up with high-risk patients	To help adjust medications per blood sugars in outpatient environment, answer any questions and remind patient of follow-up appointment

In general, the fewer resources available the more broad the focus will need to be, but as the support increases or extenders are utilized, the team's responsibilities can expand. For example, if the management team is made up of only one person, then focus will need to be more broad, such as reviewing glucometrics and identifying process or protocol issues with the ability to intervene on only one or two high-risk services/units or groups of patients. This high-risk group of patients might be those with hypoglycemia, BG >299 mg/dL or HbA1c >12 percent. These cutoffs can be adjusted according to the resources available.

Also, the Glycemic Management Team design (consultation only versus "taking over" management and order writing) will influence the amount of provider education that is necessary. Generally, the more a team "takes over," the less education the providers will need. However, in the long run, this generally leads to a higher time requirement for the Glycemic Management Team, as providers are less and less capable of handling even simple cases on their own. To maximize the impact of the team, we suggest a combined approach where they "take over" select target populations (e.g., transplant, insulin pumps, etc.) and then use cases that they identify on a daily basis, where current management has deviated from the protocol, to serve as a prompt for one-on-one case-based education to the provider.

Technology and the EHR can also help a small team reach a larger number of patients by creating something like a virtual inpatient diabetes service that remotely identifies and monitors patients with poor diabetes control, and then remotely instructs the providers on patient-specific insulin dosing changes. With this approach, a single provider can reach a large number of patients in a relatively short amount of time and has proven to be effective.[6]

You can imagine various combinations of these models and decide if it is feasible to obtain support for them in your institution. One thing to emphasize is that glycemic management teams are an adjunct to, not a replacement for, the other interventions and performance improvement techniques outlined in this *Guide*. Depending on your institutional environment and baseline, they may be cost effective as well as adding extra power and reliability to sustain the other interventions outlined here in this *Guide*.

References

[1]Newton C, Young S. Financial implications of glycemic control: results of an inpatient diabetes management program. *Endocr Pract.* Jul-Aug;12 Suppl 3:43–8.

[2]O'Malley CW, Ramos P, MacIndoe J, Manjarrez E, Maynard G. "Characteristics Of Inpatient Glycemic Control Among Top Performing Hospitals." Oral presentation. *Society of Hospital Medicine National Meeting*, National Harbor, Maryland. April 2015.

[3]Munoz M, Pronovost P, Dintzis J, Kemmerer T, Wang N, Chang Y, Efird L, Berenholz SM, Golden SH. Implementing and Evaluating a Multicomponent Inpatient Diabetes Management Program: Putting Research into Practice. *Joint Commission J Qual and Patient Safety.* 2012; 38(5):195–206.

[4]Maynard G, Kulasa K, Ramos P, et al. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. *Endocr Pract.* published online Dec 22, 2014 ahead of print, 1–34. doi:10.4158/EP14367.OR.

[5]Rodriguez A, Magee M, Ramos P, Seley JJ, Nolan A, Kulasa K, Caudell KA, Lamb A, MacIndoe J, Maynard G. Best Practices for Interdisciplinary Care Management by Hospital Glycemic Teams: Results of a Society of Hospital Medicine Survey Among 19 U.S. Hospitals. *Diabetes Spectrum.* 2014:27(3):197–206.

[6]Rushakoff R, Sullivan M, MacMaster H. "The Virtual Inpatient Glucose Management Service: Improving Glucose Control and Decreasing Therapeutic Inertia". Poster Presentation. *The American Diabetes Association Scientific Sessions,* San Francisco, California. June 2014

Section V.3: Subcutaneous Insulin Order Sets and Protocols: Effective Design and Implementation Strategies

Uncontrolled hyperglycemia in inpatients with or without diabetes is associated with poor hospital outcomes, including infections, prolonged hospital stay, death and disability after the hospital stay.[1-3] Randomized trials in patients with type 2 diabetes admitted to general medicine and surgery services show improved glycemic control with basal bolus insulin regimens compared to sliding-scale regular insulin regimens, and a substantial proportion of the sliding-scale cohort required 'rescue' from hyperglycemia.[4-5] In the general surgery population with type 2 diabetes, the basal bolus approach resulted in a significant reduction in complications.[5] Clinical practice guidelines and major topic reviews recommend basal bolus insulin regimens as the preferred approach to glycemic control in the non-ICU setting.[6-10]

In spite of this evidence and consistent guidelines, adaption of basal bolus subcutaneous insulin regimens in the inpatient settings is often dramatically suboptimal, with clinical inertia to order appropriate insulin regimens even in the face of frank severe hyperglycemia.[11-12] Fear of hypoglycemia, the complexity of ordering insulin in the inpatient setting, competing priorities, inadequate provider skill set or knowledge base, and lack of measurement and infrastructure all contribute to this substandard performance.[10-12] Institutional protocols for subcutaneous insulin management and structured standardized order sets, supported by educational efforts, are key interventions to improve the care of hyperglycemic inpatients.[6-10]

Careful design and implementation of these tools can make the difference between success and acceptance by medical staff vs failure and mediocre results. In an earlier section in this *Guide*, we provided an overview of the principles for effective implementation and clinical decision support for interventions.[13] In this section, we illustrate those examples as applied to subcutaneous insulin management. This section will reflect many of the same enduring principles covered in past versions published on this topic by the Society of Hospital Medicine (SHM)[14,15] with updates and new insights gained from the SHM *Glycemic Control Mentored Implementation Program,* updates from the literature and new material reflecting the rapid expansion of the electronic healthcare record (EHR) and computerized physician order entry (CPOE).[6-10, 16-20]

The steps for developing and implementing successful protocols and order sets addressing the needs of the non-critical care inpatient with diabetes/hyperglycemia include:

- Form a Steering Committee for this work, assess the current processes of care and identify potential barriers.
- Identify best practices and preferred regimens to manage diabetes and hyperglycemia in the hospital.
- Integrate best practices and preferred institutional choices into an inpatient glycemic control protocol. Crystallize your protocol into a one-page summary.
- Place guidance from your protocol into the flow of work, by integrating it into standardized subcutaneous insulin order sets and other documentation and treatment tools. Use the principles for effective clinical decision support in designing the order sets.
- Monitor the use of your order sets and protocol.
- Intervene actively on non-adherents to your protocol and those with poor glycemic control, and revise your protocol/order sets as needed.

A. Identifying and Incorporating Key Concepts and Best Practices

A protocol is a document that endorses specific monitoring and treatment strategies in a given institution. This potentially extensive document should provide guidance for transitions, special situations (like steroids and total parenteral nutrition [TPN]) and should outline preferred insulin regimens for all of the most common nutritional situations. One of the most difficult parts of creating a protocol is the assimilation of all of the important information on which to base decisions. Your protocol and order set will be promoting a set of clinical practices. Fortunately, the current ''best practice'' for non-critical care hyperglycemic patients has been summarized by several authoritative sources including earlier sections of this *Guide*.[6-10,14,15,21]

Table 1 summarizes the key concepts that should be emphasized in a protocol for subcutaneous insulin management in the hospital. We recommend embedding guidance from your protocol into order sets, the medication administration record and educational materials. Although the details contained in a protocol and order set might vary from one institution to another, the key concepts should not. The remainder of this chapter provides practical information about how these concepts and guidance for preferred insulin regimens should be included in these tools.

Table 1.

Key concepts to emphasize in protocols and order sets for subcutaneous insulin use in non critically-ill inpatients.

1. Establish a target range for blood glucose levels
2. Standardize monitoring of glucose levels and assessment of long-term control (HbA1c)
3. Incorporate nutritional management
4. Prompt clinicians to consider discontinuing oral anti-hyperglycemic medications
5. Prescribe physiologic (basal-nutrition-correction) insulin regimens
   - **a.** Choose a total daily dose (TDD)
   - **b.** Divide the TDD into physiologic components of insulin therapy and provide basal and nutritional/correction separately
   - **c.** Choose and dose a basal insulin
   - **d.** Choose and dose a nutritional (prandial) insulin:
     - i. Match exactly to nutritional intake (see Table 2)
     - ii. Include standing orders to allow nurses to hold nutritional insulin for nutritional interruptions and to modify nutritional insulin depending on the actual nutritional intake
   - **e.** Add correction insulin
     - i. Match to an estimate of the patient's insulin sensitivity using pre-fabricated scales
     - ii. Use the same insulin as nutritional insulin
6. Miscellaneous
   - **a.** Manage hypoglycemia in a standardized fashion and adjust regimen to prevent recurrences
   - **b.** Provide diabetes education and appropriate consultation
   - **c.** Coordinate glucose testing, nutrition delivery and insulin administration
   - **d.** Tailor discharge treatment regimens to the patient's individual circumstances and arrange for proper follow-up

B. Standardize the Monitoring of Blood Glucose Values and Glycosylated Hemoglobin

Guidelines recommend that all patients have blood glucose (BG) testing on admission to hospital, and that those with BG values >140 mg/dL have ongoing testing for at least 24-48 hours to ensure uncontrolled hyperglycemia does not emerge without detection and appropriate treatment. The same approach should be taken in patients being initiated on therapies that commonly result in hyperglycemia, such as glucocorticoids and TPN.[7]

For inpatients with known diabetes/hyperglycemia, guidance for the coordination of glucose testing, nutrition delivery and insulin administration should be integrated into your protocols and order sets. For non-critical care areas, the minimal frequency for blood glucose monitoring for patients who are eating is before meals and at bedtime. For the patient designated ''nothing by mouth'' (NPO) or the patient on continuous tube feeding, the type of nutritional/correction insulin used should drive the minimum frequency (every four to six hours if rapid-acting analog insulins [RAA-I] are used, and every six hours if regular insulin is used). Directions for administering scheduled RAA-I immediately before or immediately after nutrition delivery should be incorporated into protocols, order sets and medication administration records. Unfortunately, having this guidance in the order sets and protocols does not automatically translate into its being carried out in the real world. Wide variability in the coordination of glucose monitoring, nutritional delivery and insulin administration is common, so monitoring the process to make sure the protocol is followed is important. More detail and tips to address this are provided later in this *Guide*.[22]

Obtaining a glycosylated hemoglobin (HbA1c) level is important in gauging how well the patient's outpatient regimen is maintaining glycemic control, distinguishing stress hyperglycemia from established diabetes and guiding the inpatient approach to glycemic control. HbA1c testing has become a default or "opt out" test in the subcutaneous insulin orders at many institutions. Guidelines and the Joint Commission Certification in Advanced Inpatient Diabetes Care endorse obtaining HbA1c levels of inpatients if these levels are not already available in the 60 days prior to admission.[7]

C. Establish a Target Range for Blood Glucose in Non–Critical Care Areas

It is important to adopt a glycemic target that is institution-wide, for critical care areas and non-critical care areas alike. There is a paucity of randomized control trial data to dictate any specific glycemic target with certainty, and guideline recommendations reflect extrapolation from other settings, consensus opinion, recognition of the association between hyperglycemia and adverse outcomes, and experience in several institutions that demonstrate these goals can generally be met without undue hypoglycemia.[6-8,16,19,23] For the majority of non-critically ill patients treated with insulin, a target BG range of 100-180 mg/dL is recommended.[6-8] Occasional clinically stable patients with a prior history of successful tight glycemic control in the outpatient setting may be maintained with a glucose range below the aforementioned cut points. In contrast, higher glucose ranges may be acceptable in terminally ill patients or in patients with severe comorbidities, as well as in those in patient-care settings where frequent glucose monitoring or close nursing supervision is not feasible.[6-7]

Your multidisciplinary Glycemic Control Steering Committee should pick the glycemic target it can most successfully implement and disseminate. It is fine to start with a conservative target and then ratchet down the goals as the environment becomes more accepting of the concept of tighter control of blood glucose in the hospital. Simplification of the message and slogans to reinforce glycemic targets, such as "Let's do a 180!" have been helpful in many institutions.[16]

Although the choice of glycemic target is somewhat arbitrary, establishing an institutional glycemic target is critical to motivate clinical action. Your committee should design interventions for instances when a patient's glycemic target is consistently not being met, including an assignment of responsibility.

D. Prompt Clinicians to Consider Discontinuing Oral Agents

Oral anti-hyperglycemic agents, in general, are difficult to quickly titrate to effect, and have side effects that limit their use in the hospital. In contrast, insulin acts rapidly and can be used in virtually all patients and clinical situations, making it the treatment of choice for treatment of hyperglycemia in the hospital.[6-8] In certain circumstances, it may be entirely appropriate to continue a well-controlled patient on his or her prior outpatient oral regimen. It is often also reasonable to resume oral agents in some patients when preparing for hospital discharge. In general though, the limitations of oral agents in the hospital relegate them to a minor role.

There are some early studies in the non-ICU setting using incretin-based therapy in the inpatient setting. A recent pilot open label randomized study used the oral dipeptidyl peptidase (DPP)-4 inhibitor sitagliptin for the inpatient management of patients with type 2 diabetes mellitus, either as a sole agent or in combination with low-dose insulin.[24] The results were promising with glycemic control similar to basal bolus regimen patients, lower insulin doses and low rates of hypoglycemia. Studies in the ICU setting with glucagon-like peptide (GLP)-1 receptor agonists also show promise.[25] However, limited inpatient experience, limited data on safety outcomes and gastrointestinal side effects for GLP-1 receptor agonists are all concerns, and guidelines do not currently incorporate these agents into their recommendations for inpatients.[26-27]

E. Incorporate Nutritional Management

Because diet is so integral to the management of diabetes and hyperglycemia, diet orders should be embedded in all diabetes or insulin-related order sets.[7] Diets with a consistent amount of carbohydrate with each meal should be the default rule for patients with diabetes, with carbohydrate counting or individualized plans available for select patients. Nutritionist consultation should be considered and easy to access for patients with malnutrition, obesity and other common conditions of the inpatient with diabetes.

F. Access Diabetes Education and Appropriate Consultation

Diabetes education should be offered to all hyperglycemic patients with normal mental status, complete with written materials, a listing of community resources and survival skills. Consultation with physicians in internal medicine or endocrinology for difficult-to-control cases, or for cases in which the primary physician of record is not familiar with (or not adherent to) principles of inpatient glycemic management, should be very easy to obtain, or perhaps mandated, depending on your institution-specific environment. Patients on subcutaneous insulin pumps mandate special attention, as outlined later in this *Guide.*

G. Prescribe Physiologic ("Basal-Nutritional-Correction Dose") Insulin Regimens

Physiologic insulin use is the backbone of the recommended best practice for diabetes and hyperglycemia management in the hospital. The principles of such regimens are summarized elsewhere in this *Guide* and in previous SHM publications.[14,21] These principles will not be reiterated in detail here, but the major concepts that should be integrated into the protocols and order sets will be highlighted.

Choose a Total Daily Dose

Clinicians need guidance on how much subcutaneous insulin they should give a patient. These doses are well known from clinical experience and the published literature. The fear of hypoglycemia usually results in substantial under-dosing of insulin, or total avoidance of scheduled insulin on admission. Your team should provide guidance for how much insulin to start a patient on when it is unclear from past experience how much insulin the patient needs. Waiting a few days to see how much insulin is required via sliding-scale-only regimens is a bad practice that should be discouraged for patients whose glucose values are substantially above the glycemic target. The total daily dose TDD can be estimated in several different ways as shown in the examples in this section, and protocols should make this step very clear for clinicians. Providing a specific location on the order set to declare the TDD may help ensure this step gets done more reliably. Some institutions with computer physician order entry (CPOE) provide assistance with calculating the TDD and the allocation of basal and nutritional components, based on data the ordering physician inputs into the system.

Choice of Insulin Preparations and Regimens

Table 2 summarizes insulin regimens SHM experts prefer for different modes of nutritional intake in the hospital. Even after limiting insulin regimens to those in Table 2, multidisciplinary glycemic control teams are still left with several options within these SHM-preferred regimens. We recommend that your team choose a single, institutionally preferred basal-nutritional-correction insulin combination for each situation.

Choosing one preferred option for these situations is advantageous because:

1. You can communicate preferred regimens more simply and succinctly to all staff.
2. You eliminate all inappropriate choices for insulin regimens for that situation, as well as some other less preferred, but acceptable choices.
3. You can encourage regimens that are most economical (by promoting the insulin regimens that reflect your hospital formulary choices).
4. Staff members can become very familiar with a few regimens, instead of being confused by a multitude of them. They can identify variations from your preferred choices and target these patients for extra scrutiny and actions should they fail to meet glycemic targets.

Although virtually every institution can provide specific guidance on insulin management in a protocol, there are trade-offs inherent in how restrictive you can be in pushing these preferred choices in your order sets. Should you eliminate alternate basal or nutritional insulin choices from your order sets? As you integrate more and more of your preferred algorithm and regimens into your order set, you will gain incremental improvement in the standardization of inpatient insulin management. However, you reduce not only variability in ordering, but also the choices available to your prescribers and patients, and in effect you are pushing the providers to use an insulin regimen that often differs from the patient's outpatient regimen. If your institution is not yet ready to go with a single preferred insulin, simply listing your preferred insulin first with the annotation "preferred" can be enough to increase the use of the preferred insulin.

We endorse building the most protocol-driven, proscriptive, insulin order set that the local Glycemic Control Steering Group believes their medical staff will accept. There are some caveats to this endorsement. First, there must be extra efforts on the ''back end'' of the admission, to ensure that the anti-hyperglycemic regimen is tailored to the unique needs of the patient (this is discussed further later in the *Guide*). Second, a protocol-driven approach is not a substitute for a good educational program for healthcare providers or well-informed clinical judgment. Education should reinforce

major concepts driving the protocol and should also highlight ''exceptions to the rule.'' Variance from the protocol-endorsed choices should be allowed (and even encouraged) when the variance is driven by patient factors (as opposed to provider whim). Learning from this variance is a key concept in refining protocols. Education ideally should not be limited to only protocol-endorsed choices, as staff should be familiar with the full range of anti-hyperglycemia regimens seen in inpatient and outpatient settings.

Select and Dose a Basal Insulin

Your protocol should describe how the TDD should be divided between basal and nutritional insulin. We generally recommend 50 percent of the TDD be given as basal insulin, with the other 50 percent administered on a scheduled basis to cover glycemic excursions from nutritional intake. The 50/50 rule is simple and generally works well, and should be widely promoted. However, there are exceptions to this rule that should be incorporated into your full protocol and educational programs. The order set should have separate steps for ordering basal insulin, nutritional insulin and correction insulin. The advantage to providing these insulin components separately is that it allows them to be independently manipulated (e.g., if a patient is unable to tolerate a meal, nutritional insulin is held, but basal insulin and correction insulin are continued).

SHM experts specifically endorse long-acting insulin (glargine and detemir) as the preferred basal insulin in the hospital setting, thus discouraging the use of neutral protamine Hagedorn (NPH) insulin and fixed combination insulin formulations (Table 2). In the absence of randomized controlled trials demonstrating superiority of the glargine or detemir to NPH insulin in the hospital, this endorsement deserves some further explanation. Although we believe that correctly dosed NPH containing insulin regimens can attain effective and safe glycemic control in the hospital setting, it is more difficult to standardize their use and adjust for fluctuations in nutritional intake. Glargine and detemir have much less pronounced spikes in their effect than NPH, rendering them relatively ''peakless'' in comparison. This pharmacokinetic profile allows for continued dosing with minimal or no correction when nutrition intake is variable, and allows for consistent reinforcement of the basal-nutritional-correction insulin concept.

There are some caveats to this general recommendation. First, patients who are well controlled on home regimens with NPH basal insulin can (and sometimes should) stay on the regimen that has worked well for them. However, extra vigilance in reducing the dose for reductions in nutrition is required, because NPH is generally used to cover both nutritional and basal requirements. Second, NPH has been considered the standard of care for diabetes in pregnancy and while there is increasing experience with detemir and it is now pregnancy category B, NPH has been used safely in obstetric populations for decades. Third, the insulin regimen used as an inpatient is not necessarily the preferred regimen to prescribe at discharge: cost, patient preferences, HbA1c level and other factors should be considered in making this choice.

Table 2.

A summary of recommendations for dividing the TDD into the appropriate components of insulin treatment (basal, nutritional and corrective), depending on the nutritional situation.

Nutritional situation	Necessary insulin components	Preferred regimen*
NPO (or clear liquids)	Basal insulin: 50% of TDD Nutritional insulin: None	Basal insulin: Glargine (or detemir) given once daily Nutritional insulin: None Provide dextrose infusion (e.g., D5 containing solution at 75-150 cc/hr) to prevent hypoglycemia in patients at high risk. Patients with type 1 diabetes undergoing a prolonged fast are better managed with an IV insulin infusion.
Eating meals	Basal insulin: 50% of TDD Nutritional insulin: 50% of TDD, divided between meals	Basal insulin: Glargine (or detemir) given once daily Nutritional insulin: Rapid-acting insulin preferred, given with the first bite of each meal. Nutritional insulin amount should match intake for each meal, and allow for customization around patient habits.
Getting bolus tube feeds	Basal insulin: 50% of TDD Nutritional insulin: 50% of the TDD, divided equally before each bolus feed	Basal insulin: Glargine (or detemir) given once daily Nutritional insulin: Rapid-acting insulin given at the initiation of each bolus
Continuous tube feeds	Basal insulin: 40%-50% of TDD Nutritional insulin: 50%-60% of the TDD, given continuously	No regimen clearly superior. Insulin should be given to continuously cover basal and nutritional needs.
Parenteral nutrition	Insulin is usually given parenterally, with the nutrition	Initially, a separate insulin drip allows for accurate dose finding. Then, regular insulin can be added to subsequent bags of nutrition.

**Note: The preferred regimens listed are examples. Preferred regimens may vary amongst different institutions. In addition, an appropriate dose of correctional insulin should be given with glucose checks as needed to correct hyperglycemia. NPO = "nothing by mouth," TDD = total daily dose*

Select and Dose a Nutritional (Prandial) Insulin

The step for ordering nutritional insulin should assist the clinician in matching the insulin to the type of nutrition that the patient is receiving. For example, rapid-acting insulin analogs are preferred over regular insulin in the eating patient, in view of their more physiologic profile, which averts the insulin stacking that can occur with regular insulin. If regular insulin is used as the preferred institutional choice for eating patients, the lunchtime dose should be reduced or eliminated altogether, to eliminate insulin stacking. Orders for nutritional insulin should allow for customization tailored to patient habits (e.g., the patient who skips or eats very little breakfast or has double portions for dinner).

There should be a standing order or embedded instructions to hold nutritional insulin when nutrition is interrupted, whether intentional or unintentional. Patients with interrupted tube feedings could have standing orders for a dextrose infusion to replace the tube feeding carbohydrate load and prevent hypoglycemia, or to hold nutritional insulin and monitor more closely. Ideally, there should also be a standing order allowing for real-time management of the patient with uncertain nutritional intake. For example, when a patient's pre-meal assessment reveals that she may not tolerate the meal, the patient should be allowed to attempt to eat, and then the nutritional insulin should be given after the meal, in proportion to the amount of food that was eaten. This type of order will require significant nursing education and process redesign in many hospitals, but is essential for matching nutritional insulin to actual intake.

Add Correction Insulin

There is no convincing evidence for the benefit of correction (sliding-scale) insulin in the inpatient setting, although a randomized trial demonstrating the superiority of basal/nutritional insulin regimens to ''sliding-scale only'' regimens did incorporate a correction insulin scale as an adjunct to the superior basal/nutritional regimen.[4] We again emphasize that control of hyperglycemia should be proactive and anticipatory of insulin needs, rather than reactive to hyperglycemia. Nonetheless, unexpected hyperglycemic excursions are common, and the use of correction insulin remains a pervasive and arguably logical practice. If correction insulin is used, it should be ordered as a separate step after considering basal and nutrition insulin needs. The doses of scheduled insulin should be adjusted regularly if correction insulin is consistently being required. Ideally, the prescriber should choose a preformatted corrective insulin scale, based on the patient's insulin sensitivity. Example order sets illustrate this technique. There should be a prompt to use the same type of insulin that is being used for nutritional insulin, and there should be instructions that this insulin is given in addition to the basal and nutritional insulin to correct for hyperglycemia. Nocturnal correction-dose scales should be reduced in the eating patient.

Adjust the Dose

Insulin requirements, nutritional intake, and medications are all in flux during hospitalization, and estimating insulin doses is an inexact science. Consequently, adjustments to insulin doses are frequently necessary. Guidance for these adjustments should be embedded in order sets and other tools whenever possible. The correction scale insulin used from the previous day can be added to the TDD, and thus adding to both the basal and nutritional doses. Alternately, the TDD can be adjusted upward by 20-30 percent with appropriate distribution between basal and nutritional insulins. Some EHR platforms and CPOE systems allow for one or two click adjustment of these doses and the related correction scale. In general, adjustment should maintain the "50:50" rule, rather than going up disproportionately on basal insulin alone. Glucose values <100 mg/dL should lead to consideration of decreases in insulin dosing.

"Basal Plus" Regimens in the Inpatient Setting

Many inpatients have reduced caloric intake as a result of their medical illness or surgery, which can make injudicious use of scheduled nutritional insulin problematic. The complexity of ordering and implementing basal bolus subcutaneous insulin regimens in this setting led to investigation of the efficacy and safety of a once daily basal glargine dose with supplemental RAA-I correctional insulin, without any scheduled nutritional insulin (aka basal plus regimen). The basal plus regimen was shown to be as effective as a basal bolus regimen in carefully selected type 2 DM inpatients.[28] Hypoglycemia was similar in the two regimens using basal insulin, and both were far more effective than correction scale alone. Some institutions may consider basal plus an attractive alternative to the use of basal bolus regimens.

There are several caveats and pitfalls to consider however. First, this was a very select group of Type 2 DM patients. Less than 20 percent were treated with any insulin as an outpatient, and it should only be used for patients who did not have exclusion criteria from the study: significant liver disease, renal disease, those without known diabetes, any glucose >400 mg/dL, cardiac surgery, steroid administration, expectation the patient may require ICU stay and basal requirement >20 units / day. It might be argued that this select population might do well on any regimen, but generalizing this strategy would be unlikely to be successful. Patients with type 1 DM and more pronounced hyperglycemia would still need basal bolus regimens. Attempts to standardize order sets might actually be paradoxically more complex, as both variants would need to be incorporated. Another potential danger is that increasing hyperglycemia would lead to inappropriate escalation of basal insulin to cover both basal and nutritional insulin requirements, which puts the patient at risk of hypoglycemia should nutrition be interrupted. Therefore, we urge caution and abundant education should this strategy be incorporated into institutional protocols, with vigilance to change to basal bolus regimens if insulin requirements are high (e.g., >20 units of basal insulin).

H. Special Situations

Most of the preferred regimens for different situations are outlined in Table 2 in a straightforward manner, and can be depicted in your protocols and order sets in the same way. Some conditions have enough complexity, however, that you will have difficulty placing all of the details into your one-page protocol and order set. Details should be placed on your more detailed protocol, and educational programs should include the topics outlined below. Although insulin infusion is often the option that would provide the most reliable and expedient control of hyperglycemia in these special situations, it is an option not available in many non-critical care settings. Therefore, the discussion is limited to subcutaneous insulin control regimens.

Patient on Continuous Tube Feeding

We endorse glargine or detemir as the basal insulin of choice for this setting. The nutritional and correction insulin of choice is either an RAA-I every four hours (q4h), or regular insulin every six hours (q6h). We endorse this choice because it retains the basal-nutritional-correction dose concept, generally allows for continued basal insulin use if the tube feedings become interrupted and is amenable to building a consistent institutional protocol.

There are some important caveats to this recommendation. First, realize that almost any regimen that provides a stable insulin supply would be acceptable, and many institutions will use glargine or detemir to cover both basal and nutritional needs. The downside to using large boluses of long-acting insulin in this clinical situation is that any unexpected interruption of the feedings will necessitate prolonged infusions of dextrose 10 percent solution (D10) to avoid hypoglycemia.

Second, because of the glycemic load inherent in tube feedings, maintenance of glycemic control in the setting of enteral feeding may be best managed by providing a higher percentage of the TDD as nutritional insulin. In these cases, ratios of basal to nutritional insulin of 40:60, or even less basal insulin, may be appropriate.

Glucocorticoid Therapy

High-dose glucocorticoids are strongly associated with increased insulin requirements. The degree of hyperglycemia induced by steroids varies significantly from patient to patient, and the pattern of hyperglycemia will vary depending on the pattern of steroid administration. The general principle to keep in mind is that the hyperglycemia induced by a steroid dose will peak 8-12 hours after it is given, so insulin regimens to address this should take this effect into account. For example, giving a long-acting basal insulin like glargine to accommodate the hyperglycemic effect of a steroid bolus given in the morning would be inappropriate because the steroid effect would wane and then disappear overnight, leading to insulin-induced hypoglycemia. NPH insulin can be ideal in this setting, either by itself, or by layering it on top of an existing regimen.

Another caveat: glucocorticoids exert their predominate effect on insulin sensitivity in muscle (as opposed to the liver), and as a result, have their most notable effect on postprandial glucose. For this reason, the best insulin regimens for this situation may use proportionally less basal insulin and more nutritional insulin. One common regimen calls for keeping the basal insulin dose the same as the pre-glucocorticoid dose, while escalating the RAA insulin dose at lunch and dinner.

Given the complexities of covering steroid-induced hyperglycemia and its high prevalence in certain populations (such as transplantation patients and patients undergoing chemotherapy), this would be an excellent area on which to focus expertise. Examples include routine endocrinology consultation, intervention by a special glycemic control team, or incorporating routine glucose monitoring and triggers for initiating insulin infusion into the protocols for chemotherapy and transplantation patients.

Regiment the Management of Hypoglycemia

Hypoglycemia is defined by the ADA as a blood glucose of 70 mg/dL or less, based on the physiologic changes that can occur at this glucose level, even in subjectively asymptomatic patients.[6,7, 29] Protocols for management of hypoglycemia should be linked to your diabetes/hyperglycemia protocols. Hypoglycemia management and prevention is discussed in great detail later in this *Guide*,[29] and only broad themes for effective implementation are presented here. First, the protocols need to walk the balance between simplicity of use, and the need to provide instructions that will provide guidance in a variety of patient situations. Second, the protocols need to be nurse-driven, so that nurses can initiate treatment without waiting for a physician order. Third, education and instruction regarding recognition of risk factors, and avoidance of hypoglycemia are needed to support a successful protocol. Importantly, any hypoglycemic event should lead to a reconsideration of the current anti-hyperglycemic regimen so that future events can be prevented.

I. Plan for Discharge and Provide Guidance for the Transition

Your institution should have policies and procedures outlining all the steps needed to complete the important transition out of the hospital. At a minimum, this planning should include adequate education (including a learner assessment), appropriate follow-up, referral to community resources and a discharge glycemic control regimen that is tailored to the educational, financial and motivational profile of a patient. The more your inpatient insulin management is driven by protocol, the more likely it is the patient will be on an inpatient treatment plan that differs from their outpatient regimen; therefore, it is even more important to plan this transition carefully and reliably.

Communicating the accurate hyperglycemia-related diagnosis and related problems to the primary care provider is important for good care, perhaps even more so for patients who had hyperglycemia while hospitalized without a prior diagnosis of diabetes. Some centers place a prompt for hyperglycemia-related diagnosis in the order set and/or discharge paperwork, to remind the clinician to convey the diagnosis to the primary provider, and to encourage more complete documentation.

Transitions in care are discussed in more detail elsewhere in this *Guide*. The principles outlined in these references should be incorporated into your institutional protocol. Briefly, not all patients require or are capable of intensive basal-bolus regimens upon discharge. The HbA1c can be very valuable in arriving at the optimal outpatient regimen.[7,30] The capacities and preferences of the patient and the context of his or her outpatient care environment (including the preferences of the primary care provider) must be taken into consideration as an outpatient management program is planned.

J. Pulling It All Together: Make Sure Your Protocol/Order Set is Easy to Use and Widely Utilized

When standardizing hospital management of diabetes and hyperglycemia, we recommend building the full protocol first, then crystallizing the protocol into a summary that can fit on the front and back of one page. An example of such an algorithmic protocol and supplementary text is shown in Figure 1A (front) and Figure 1B (reverse). This kind of summary protocol can serve as a reference and teaching tool, and also help guide design of the order set. This summary needs to focus on guidance that will suit 80-90 percent of patients, instead of being a resource that comprehensively covers all unique situations. By the same token, order set design should reflect the needs of most, rather than the outliers, that can be addressed via education and active monitoring techniques.

Figure 1A

INPATIENT HYPERGLYCEMIA MANAGEMENT OF THE NON-PREGNANT ADULT

Target inpatient blood glucose levels: 100-180 [1]

Consider a diabetes/ endocrine or medicine consult.

Step 1: **Discontinue non-insulin antihyperglycemic agents**[2]

Step 2: **Calculate the estimated total daily dose (TDD) of insulin** patient may require; consider adjusting this up or down based on pt's home regimen and their A1C:

- Standard (pt w/ normal body habitus): 0.4 units/kg/day
- If pt very lean, on hemodialysis or very sensitive to insulin (hypoglycemia risk factors): 0.3 units/kg/day
- If pt overweight: 0.5 units/kg/day
- If pt obese, on steroids, or known to be insulin-resistant: 0.6 units/kg/day (or more)
- If transitioning off of an iv insulin infusion, call pharmacy for assistance and take the average hourly rate over the last 6 hours and multiply by 20:
  - -if pt was receiving nutrition (tube feeds, TPN, D5 > 50 mL/hr or eating), this is the estimated TDD
  - -if insignificant nutrition during the last 6 hours, double the number to determine estimated TDD

Step 3: Determine the *distribution* of the TDD calculated above based on nutrition regimen.

If pt eating or receiving bolus tube feeds[3]:
Check blood glucose qac and qhs
Basal insulin: glargine (Lantus) -- 0.5 x TDD, Given once daily
Nutritional insulin: lispro (Humalog) -- 0.16 x TDD, Give with each meal
Correction insulin, in addition to nutritional insulin: use CPOE default values (adjust if necessary)

If pt receiving continuous infusions of tube feeds or parenteral nutrition[4]:
Check blood glucose q6h
Basal insulin: glargine (Lantus) -- 0.5 x TDD, dosed once a day
Nutritional insulin: regular insulin -- 0.125 x TDD, given q6h
Correction insulin, in addition to nutritional insulin: use CPOE default values (adjust if necessary)

If pt NPO (or nearly NPO, taking Zero Carb clear liquids only)[5]:
Check glucose qac/hs or q6h
Basal insulin: glargine (Lantus) -- 0.5 x TDD, dosed once a day
Nutritional insulin: none (discontinue previous)
Correction insulin: recommend regular insulin scale q 6 hours if pt NPO > 24hrs, otherwise lispro is OK
Consider starting low-dose dextrose infusion (D_5½NS at 75mL/hr)

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Step 4: Re-evaluate & adjust the TDD daily based on the glycemic control of the previous 24h:

- If any glucose > 180, and no threat of hypoglycemia, increase TDD by 10-20%
- If glucose consistently > 180-200, increase TDD by 30%
- If any episodes hypoglycemia (FS < 70), decrease TDD by 20% and consider starting D51/2NS at 75cc/hr

See reverse for special situations[6] *& more information about footnoted items*

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Figure 1B

Insulin Terminology:
Basal insulin: long-acting insulin required **at all times** in patients with Type 1 diabetes (and in most patients with Type 2 diabetes) to maintain euglycemia, ***even when NPO*** *(hepatic gluconeogenesis can serve as a continuous source of blood glucose).*

Nutritional insulin: scheduled short-acting insulin given with a meal, to prevent the glycemic spike that occurs due to carbohydrate ingestion (*given even when the pre-meal blood sugar is in the normal range*). Also refers to scheduled insulin given to cover the carbohydrate load from tube feeds or parenteral nutrition.

Correction insulin: short-acting insulin meant to lower high blood sugars given in addition to scheduled nutritional insulin, also given to treat hyperglycemia in NPO patients. If correction insulin dose is consistently required, consider increasing TDD insulin.

1- Target blood glucose range
For patients on insulin, pre-meal blood glucose target is 100-140 mg/dL with a random blood glucose target of less than 180 mg/dL. Less stringent targets may be appropriate in patients with severe comorbidities (i.e., end-stage disease or in whom hypoglycemia is a significant concern.)

2- Stopping oral medications
Oral anti-hyperglycemic agents and injectable non-insulin therapies are not indicated for the management of inpatient hyperglycemia.
Adjustments in these oral medications take too long to be effective in the hospital and most oral medications have significant side effects or contraindications in the hospital setting.

3- For patients eating meals or receiving bolus tube feeds
Glargine insulin is the most physiologic basal insulin and is recommended in these patients. Lispro insulin is more appropriate than regular insulin for nutritional doses due to its shorter, more predictable half-life and correspondence with meal times. Using the subcutaneous insulin orderset will allow for adjusted doses based on percent nutritional intake.

4- For patients receiving continuous enteral or parenteral nutrition
A. Consider using an insulin infusion for optimal control in this setting. Keep insulin separate from TPN until a stable dose is reached.
B. Glargine insulin is the most physiologic basal insulin and is recommended in these patients. Regular insulin is recommended as the nutritional insulin. Because of its longer half-life, it is better suited to continuous nutritional sources and can be dosed q6h I nstead of q4h.
C. If the tube feeds or parenteral nutrition are held or interrupted, the nutritional regular insulin doses should also be held. See: "Nutrition on Hold Unexpectedly Guideline."

5- For the NPO patient
Glargine insulin is the most physiologic basal insulin and is recommended in these patients. Nutritional or scheduled short-acting insulin should not be given to patients without a nutritional source. Correction insulin should be used to correct hyperglycemia when a patient is NPO. If NPO greater than 24 hours, regular insulin is recommended.

6- Special Situations
A. If patient is receiving nocturnal tube feeds, utilize the Nocturnal Tube Feeding orderset with scheduled regular insulin coverage.
B. If transitioning off of IV insulin infusion, see Step 2 of chart, call pharmacy for assistance, utilize the insulin drip calculator, and/or reference "Transition from IV to SQ Insulin Protocol."

7– Discharge Planning
A. Consider Endocrine/Diabetes consult for diabetes management and education.
B. Reference "Transition Guide: Inpatient to Outpatient Regimen" when determining discharge medications/home regimen.

The protocol guidance is then incorporated into the order set and nursing medical administration record (MAR). Again, we recommend the most proscriptive and protocol driven order set feasible within the constraints of medical staff support. The complexity and comprehensiveness of your order sets should reflect the sophistication of your current environment. For example, carbohydrate counting options and a unique option offered for nocturnal tube feedings can be added after staff become comfortable with more basic scenarios, like the eating patient, patient on around-the-clock enteral tube feedings and the routine NPO patient. Example annotated order sets illustrate this approach along with other desirable features:

1. Check-box simplicity on when to order appropriate glucose monitoring.
2. Prompt for the proper hyperglycemia-related diagnosis.
3. Prompts to document diagnosis and to order HbA1c level.
4. Use of encouraged insulin terminology: basal, prandial (or nutritional) and correction. Language is a powerful thing, and just getting staff to use these terms goes a long way toward the more physiologic prescribing of insulin.
5. Statement/reminder of a glycemic goal.
6. Prompts and contact information for appropriate consultation.
7. Elimination of unapproved abbreviations (such as U for units).
8. Stating both generic and brand names of insulin preparations.
9. Important timing cues for administration of insulin.
10. Several correction-dose scales suitable for different insulin sensitivities. One size does NOT fit all.
11. Incorporation of a simple hypoglycemia protocol into the order set.
12. Insulin dosing guidelines available at the point of care; once you have protocols and order sets to guide providers, you need to assure that they are used for the majority of hyperglycemic patients. Educational programs should introduce your interventions and the rationale for them. In order to make your method the default method of care, your team should survey all preprinted or CPOE insulin order sets of your institution. A review of postoperative, transfer and admission order sets that all services use may reveal a half-dozen or more embedded sliding-scale insulin order sets that should be removed, with prompts to use the standardized insulin order set being placed in their stead.

Computerized order sets present both challenges and opportunities. Wording limitations and the scrolling nature can make concepts less clear, yet there is a capability for incorporating a hierarchical structure that allows for guiding the user through a more algorithmic approach. In some CPOE environments, it is also a capacity to provide assistance with dosing calculations that do not exist in the paper world. Education remains of key importance for both methods.

The key principles for effective implementation and clinical decision support outlined earlier in this *Guide* are especially important when designing order sets with inherent complexity.

1. Keep it simple for the end user.
2. Do not interrupt the work flow.
3. Design reliability into the process (e.g., desired action is default, algorithms and reminders built in).
4. Pilot your protocol on small scale or with simulation before attempting wide implementation.
5. Monitor the use of your protocol and order set.

These principles are illustrated in the example order sets. This last key principle is discussed in more detail below.

K. Monitor the Use and Effectiveness of Your Protocols and Order Sets

Creating and implementing protocols, order sets and other tools is not the end of the journey to improve care. It is important to monitor order set utilization, insulin use patterns and parameters measuring glycemic control and hypoglycemia, as outlined in more detail in other sections in this *Guide*.[13,31] In addition to summary data every month or so, we recommend daily reports that spur action in near real-time. The hierarchy of reliability, first validated in VTE prevention efforts, has proven useful in glycemic control efforts as well.[19, 32-34] In this construct, the reliability of care is predicted by adding layers of infrastructure and process. Reliable delivery of best practices at Level 3 (approximately 65-75 percent reliability) is achieved when standard order sets are routinely delivering appropriate clinical decision support at the point of care. Level 4 (75-85 percent reliability) is achieved with regular audit and feedback, more comprehensive protocols, use of graphic flow sheets and the like. Finally, at Level 5, oversights are identified and mitigated in real time. This results in >90 percent reliability as you address lapses in care quickly and with added jjust-in-time education and interventions. This active surveillance technique is also known as measure-vention, as you measure potential non-adherents or lapses in care and intervene at the same time.

The active surveillance technique generally has three phases. First, there needs to be a trigger or alert mechanism for a potential lapse in optimal care. Examples of such triggers include a daily report showing all patients with uncontrolled hyperglycemia, hypoglycemia or nearing hypoglycemia, markedly elevated HbA1c levels, or non-physiologic insulin regimens. Next, there needs to be some further triage or further review to validate the trigger and to investigate whether appropriate action is already being taken or not. Ideally, the trigger and the investigation can take place efficiently within the EHR, without the need to switch back and forth between software programs and screens. Third, if the trigger is validated, there is an intervention that addresses any safety issues or deficiencies in care. This intervention may be a phone call to the ordering provider, a change in the orders via protocol authority, a pre-authorized consultation, extra diabetes education or other suitable intervention.

Qualitative feedback from the frontline caregivers, as well as this quantitative data, can assist the local glycemic control champions in designing even more effective protocols, order sets, focused educational efforts and concurrent mitigation of suboptimal care.

L. Conclusion

Diabetes, hyperglycemia and iatrogenic hypoglycemia are common and important conditions affecting the non-critically ill inpatient. Interventional trials to validate the recommended non-critical care unit glycemic targets are needed. Although there is a growing consensus on best practices to care for these patients, numerous barriers and the complexity of caring for inpatients hamper the reliability of best practice delivery. Institutional protocols and protocol-driven subcutaneous insulin orders, when implemented with the strategies outlined here, can be the key to delivering these best practices more reliably.

References

[1]Falciglia M, Freyberg RW, Almenoff PL, D'Alessio DA, Render ML. Hyperglycemia related mortality in critically ill patients varies with admission diagnosis. *Crit Care Med.* 2009;37:3001–3009.

[2]Umpierrez GE, Isaacs SD, Bazargan N, You X, Thaler LM, Kitabchi AE. Hyperglycemia: an independent marker of in-hospital mortality in patients with undiagnosed diabetes. *J Clin Endocrinol Metab.* 2002;87:978–982.

[3]Frisch A, Chandra P, Smiley D, et al. Prevalence and clinical outcome of hyperglycemia in the perioperative period in non-cardiac surgery. *Diabetes Care.* 2010;33:1783–1788.

[4]Umpierrez GE, Smiley D, Zisman A, et al. Randomized study of basal-bolus insulin therapy in the inpatient management of patients with type 2 diabetes (RABBIT 2 trial). *Diabetes Care.* 2007;30:2181–2186.

[5]Umpierrez GE, Smiley D, Jacobs S, et al. Randomized study of basal-bolus insulin therapy in the inpatient management of patients with type 2 diabetes undergoing general surgery (RABBIT 2 surgery). *Diabetes Care.* 2011;34:256–261.

[6]Moghissi ES, Korytkowski MT, DiNardoM, et al.; American Association of Clinical Endocrinologists; American Diabetes Association. American Association of Clinical Endocrinologists and American Diabetes Association consensus statement on inpatient glycemic control. *Diabetes Care.* 2009;32:1119–1131.

[7]Umpierrez GE, Hellman R, Korytkowski MT, et al.; Endocrine Society. Management of hyperglycemia in hospitalized patients in non-critical care setting: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab* 2012;97:16–38.

[8]American Diabetes Association. Standards of medical care in diabetes 2012. *Diabetes Care.* 2012;35(Suppl. 1):S11–S63.

[9]Inzucchi SE. Clinical practice. Management of hyperglycemia in the hospital setting. *N Engl J Med.* 2006;355:1903–1911.

[10]Cobaugh DJ, Maynard G, Cooper L, Kienle PC, Vigersky R, Childers D, Weber R, Carson SL, Mabrey ME, Roderman N, Blum F, Burkholder R, Dortch M, Grunberger G, Hays D, Henderson R, Ketz J, Lemke T, Varma SK, Cohen M. Enhancing insulin-use safety in hospitals: Practical recommendations from an ASHP Foundation expert consensus panel. *Am J Health Syst Pharm.* 2013 Aug 15;70(16):1404–1413.

[11]Umpierrez G, Maynard G. Glycemic chaos (not glycemic control) still the rule for inpatient care: how do we stop the insanity? *J Hosp Med.* 2006;1:141–144.

[12]Cook CB, Castro JC, Schmidt RE, et al. Diabetes care in hospitalized non-critically ill patients: More evidence for clinical inertia and negative therapeutic momentum. *J Hosp Med.* 2007;2:203–211.

[13]Maynard et al. Designing and Implementing Protocols for Optimal Inpatient Glycemic Control: An Overview. New citation from earlier in guide

[14]Wesorick D, O'Malley C, Rushakoff R, Larsen K, Magee M. Management of Diabetes and Hyperglycemia in the Hospital: A Practical Guide to Subcutaneous Insulin Use in the Non-Critically Ill Adult Patient. *J Hosp Med.* 2008 Sept/Oct Vol; 3 (S5)17–28.

[15]Maynard G, Wesorick D. O'Malley CW, Inzucchi S. Subcutaneous Insulin Order Sets and Protocols: Effective Design and Implementation Strategies. *J Hosp Med.* 2008 Sept/Oct Vol; 3 (S5) 29 - 41.

[16]Rogers K, Childers D, Messler J, Nolan A, Nickel WK, Maynard G. Glycemic Control Mentored Implementation: Creating a National Network of Shared Information. *Joint Commission J Qual and Patient Safety.* 2014,40(3):111–118.

[17]Maynard G, Lee J, Phillips GW, et al. Improved Inpatient Use of Basal Insulin, Reduced Hypoglycemia, and Improved Glycemic Control: Effect of Structured Subcutaneous Insulin Orders and an Insulin Management Algorithm. *J Hosp Med.* Jan 2009;4(1)3–15.

[18]Lee J, Clay B, Ziband Z, Clay B, Maynard G. Indication Based Ordering: A New Paradigm for Glycemic Control in Hospitalized Inpatients. *J Diabetes Science Tech. 2008;2(3):*349–356.

[19]Maynard G, Kulasa K, Ramos P, Childers D, Clay B, Sebasky M, Fink E, Field A, Renvall M, Juang PS, Choe C, Pearson D, Serences B, Lohnes S. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. *Endocr Pract.* 2014: published online Dec 22, 2014 ahead of print, 1–34. doi:10.4158/EP14367. OR.

[20]Umpierrez GE, Smiley D, Hermayer K, Khan A, Olson DE, Newton C, Jacobs S, Rizzo M, Peng L, Reyes D, Pinzon I, Fereira ME, Hunt V, Gore A, Toyoshima MT, Fonseca VA. Randomized study comparing a basal-bolus with a basal plus correction insulin regimen for the hospital management of medical and surgical patients with type 2 diabetes: Basal Plus trial. *Diabetes Care.* 2013;36:2169–2174.

[21]O'Malley CW and others Identify Best Practices for Management of the Hospitalized Patient with Diabetes / Hyperglycemia

[22]Reference for coordination of nutrition, testing, and insulin administration

[23]Maynard G, Ramos P, Kulasa K, Rogers KM, Messler J, Schnipper JL. How Sweet is It? The Use of Benchmarking to Optimize Inpatient Glycemic Control. *Diabetes Spectrum.* 2014:27(3):212–217.

[24]Umpierrez GE, Gianchandani R, Smiley D, et al. Safety and efficacy of sitagliptin therapy for the inpatient management of general medicine and surgery pateints with type 2 diabetes. *Diabetes Care.* 2013;36:3430–3435.

[25]Schwartz S, Defronzo RA. Is incretin-based therapy ready for the care of hospitalized patients with type 2 diabetes? The time has come for GLP-1 receptor agonists! *Diabetes Care.* 2013;36:2107–2111.

[26]Umpierrez GE, Korytkowski M. Is incretin-based therapy ready for the care of hospitalized patients with type 2 diabetes?: Insulin therapy has proven itself and is considered the mainstay of treatment. *Diabetes Care.* 2013; 36:2112–2117.

[27]Umpierrez GE, Schwartz S. Use of Incretin-based therapy in hospitalized patients with hyperglycemia. *Endocr Pract.* 2014;20:933–944.

[28]Umpierrez GE, Smiley D, Hermayer K, Khan A, Olson DE, Newton C, Jacobs S, Rizzo M, Peng L, Reyes D, Pinzon I, Fereira ME, Hunt V, Gore A, Toyoshima MT, Fonseca VA. Randomized study comparing a basal-bolus with a basal plus correction insulin regimen for the hospital management of medical and surgical patients with type 2 diabetes: Basal Plus trial. *Diabetes Care.* 2013;36:2169–2174.

[29]Maynard and others Hypoglycemia article reference later in this guide.

[30]Transitions home chapter later in this guide

[31]Maynard et al Choose Metrics and Develop a Data Collection Plan for your Glycemic Control Program

[32]Maynard G, Stein J. Preventing Hospital-Acquired Venous Thromboembolism: *A Guide for Effective Quality Improvement.* Prepared by the Society of Hospital Medicine. AHRQ Publication No. 08-0075. Rockville, MD: *Agency for Healthcare Research and Quality.* August 2008.

[33]Maynard G, Stein J. *Implementation Guide-* Optimize Prevention of Venous Thromboembolism at your Medical Center. Society of Hospital Medicine website, VTE Quality Improvement Resource Room. http://www.hospitalmedicine.org. last Accessed July 8, 2010.

[34]Maynard G, Stein J. Designing and Implementing Effective VTE Prevention Protocols: Lessons from Collaboratives. *J Thromb Thrombolysis.* 2010 Feb:29(2):159–166.

Section V.4: Designing and Implementing Insulin Infusion Protocols and Order Sets

Hyperglycemia has been associated with poor patient outcomes (including increased infection and mortality) in critically ill adult inpatients with a variety of conditions, consistent with a dose response relationship.[1-5] The beneficial effects of "very tight" glycemic control (80-110 mg/dL) in early trials involving intensive care unit (ICU) patients led to widespread interest in adopting insulin infusion protocols (IIPs).[6-9] The initial enthusiasm was tempered by failure to reproduce positive outcomes in large randomized trials of very tight glycemic control, hypoglycemia concerns and the resources needed to implement and monitor IIPs.[10-12]

Subsequent guidelines and major reviews now endorse more modest targets (discussed in more detail below).[12-14] The preponderance of evidence still supports insulin infusion and a standardized approach to uncontrolled hyperglycemia, but there is now a much greater emphasis on achieving glycemic targets safely.[12,13] Most medical centers are at least attempting to implement nurse-driven protocols that have demonstrated better performance than subcutaneous (SC) regimens[15] and physician-driven insulin infusions.[16,17] In this section, we outline several variables in IIP design and implementation and endorse several aspects of design and implementation that will likely result in improved staff acceptance and, ultimately, a more safe and effective IIP. This section will reiterate several enduring principles from a previous edition of this *Guide,*[18] but will offer updates on glycemic targets, benchmarking performance in the ICU setting, controversies on new Food and Drug Administration (FDA) regulations for point-of-care (POC) glucometer testing in the critically ill and other new insights. Diabetes keto-acidosis and the transition from insulin infusion to subcutaneous insulin are described in more detail elsewhere in the *Guide.*[19-20]

A. Preparing to Implement an IIP

Building the Team

Implementing a medical center-wide standardized insulin infusion order set with supporting policies, protocols, monitoring standards and the requisite educational programs is a major task for any hospital. This is not a simple maneuver involving only one or two interested individuals and requires much more than selecting a published protocol and disseminating it to various patient care units. Instead, to manage the full spectrum of diabetes programs and protocols, an institution must convene a multidisciplinary Steering Committee or Task Force. This should include representation from nursing, nursing administration, pharmacy, nutrition services and the quality improvement department. Physicians should include hospitalists, intensivists and endocrinologists but may also involve anesthesiologists and surgeons, as applicable. At times, additional members may need to be recruited according to project needs.

Identifying the Stakeholders, Current Practices and Baseline Performance

In developing or improving currently utilized IIPs, the multidisciplinary committee would benefit from careful background work before moving forward. First, administrative and institutional support must be secured to endorse uniform standards for insulin infusions, and to provide the important infrastructure needed to facilitate the work involved. Clinical and administrative stakeholders from the key departments then need to be identified.

All insulin infusion orders and policies/procedures presently used in the institution should be identified and examined. The developers and/or users of these order sets should be engaged in a dialogue and encouraged to share their experiences regarding their current practice and the attendant work flow, glucose monitoring and data collection and reporting. Immediate concerns should be clearly addressed. Measurement systems for glycemic control, hypoglycemia, and insulin use patterns should assess current practice and the impact of subsequent modifications of the protocol or initiation of new protocols. We recommend using ''glucometrics'' consistent with those endorsed by the Society of Hospital Medicine (SHM) elsewhere in this *Implementation Guide.*[21] Analysis of institutional performance to comparative

benchmarking with other medical centers is available for glycemic control, hypoglycemia and hypoglycemia management parameters via enrollment in the SHM Glucometric Data Reporting and Benchmarking Center.[22] Prioritization of efforts should be undertaken by reviewing glycemic control in the context of concurrent hypoglycemia rates, rather than in isolation.

Addressing the Burden of Change

Through this process, the Committee will uncover barriers, dysfunctional and inconsistent practices, and individuals who will pose challenges. Identifying these issues should not discourage the team, but rather it should guide the interventional strategies, and help build consensus that change may be required. There must be caution not to exclude significant individuals simply because they resist changes. Indeed, if they are included and have the opportunity to contribute to the process, success is much more likely.

It is important for process leaders to understand the implications of what is proposed, particularly for nursing services.[23] For example, it has been shown that IIPs require about five minutes per patient per hour for glucose monitoring and dose adjustments.[24] Acknowledging and attempting to address this burden proactively (often well over two hours per day) can gain staff acceptance more effectively than a laissez-faire approach. In this regard, some effort should be invested in nursing education of the benefits of tight glycemic management on critical care outcomes. The difficult-to-quantify work involved when patients' blood glucose is not well controlled (e.g., paging physicians for stat insulin orders) should also be part of this discussion.

Identifying and Addressing Barriers to IIP Implementation

There are numerous potential barriers to implementation of IIPs. Table 1 identifies some of the most frequent ones along with potential strategies or solutions. Very common barriers include skepticism surrounding the benefits of glycemic control, fear of hypoglycemia and difficulty obtaining good data and analysis on performance.

Fear of hypoglycemia is one of the most potent barriers to intensive insulin infusion implementation. Because hyperglycemia is such a common condition in critical care units, nursing and physician staff may have developed a skewed view of the definition of hypoglycemia, at times fearing for their patient when the glucose values reach a level of 100 mg/dL or so. Polling the nurses on what they think their own fasting glucose levels are, and then actually measuring them, can be an effective strategy (the nurses may be surprised that the patient's ''scary'' 90 mg/dL reading is higher than their own). It should also be emphasized that properly designed and implemented protocols may actually decrease the incidence of hypoglycemia when compared to ''standard care'' which may involve individually and sometimes improperly adjusted intravenous (IV) insulin (discussed further below).

Table 1.

Barriers to Effective Implementation and Utilization of Insulin Infusion Protocols, and Strategies to Address Them

Barrier	Strategy/Solution
Insufficient glucose meters to accommodate the increased testing needs	• Purchase additional glucose meters • Ask the vendor to provide extra on-site replacement meters at no charge until they are activated
Nursing time requirements involved in monitoring and adjustments	• Get ancillary help to check glucose values, e.g., nurse assistants • Make extra efforts to make protocols clear with few required calculations • Avoid duplicate recording • Consider meters requiring shorter time and a smaller sample (to avoid need for re-sampling)
Requirement for uncomfortable frequent sticks	• Utilize central lines or arterial lines - These tend to vary by <10% from POC readings - May not be available in non-critical care settings
Staff fear of hypoglycemia	• Educate on the benefit of glucose control and the true definition of hyperglycemia - Measure staff fasting glucose levels to demonstrate normal range • Establish metrics and publicly report hypoglycemia event rates • Pilot IIP on small scale • Protocol and education for prevention and hypoglycemia
Difficulty gaining consensus on glycemic target	• Compromise if needed on the glucose target - e.g., start with higher goal such as 90-140 mg/dL - Other will be willing to lower the goal when feasibility is seen • Allow for different targets in differ unit if indicated - maintain consistency in other respects
Focal points of resistance	• Identify a local nurse or physician champion within resistant site • Pilot the protocol in an area with least resistance - Will gain momentum with initial success and adjustments
Lack of integrated information and reporting systems	• Incorporate information systems personnel onto team • Advocate for improved reporting capability with administrative leaders • Use sampling methods to collect data until automated systems are available
Multiple providers, handoffs and opportunities for error and communication breakdown, diffusion of responsibility for glycemic control	• Involvement of varied frontline providers • Check lists for important items to communicate on transfer/transport • Common protocols/education for similar units

Ensuring a Safe Insulin Management Environment for the Protocol

No IIP can provide optimal results unless the safety environment is robust, with processes to minimize errors and inadvertent adverse drug events. Strategies to reduce errors include computerized physician order entry (CPOE), the use of smart pumps, minimizing available insulin concentrations, mandated independent double-checks of IV insulin dosing, prominent product labeling and detailed multi-professional investigations of errors and hypoglycemic events.[12] These should be in place when implementing or redesigning an IIP.

B. Elements of an Optimal Insulin Infusion Protocol

Several components (summarized in Table 2) should be integrated into the institutional IIP.

Glycemic Target

Protocols should integrate the desired glycemic range, and ideally should also include a trigger for initiating insulin infusion. Van den Berghe, et al demonstrated benefits of intensive glycemic control (80-110 mg/dL) in a single center prospective randomized trial among surgical ICU patients.[25] Others found the results difficult to replicate and often reported unacceptably high hypoglycemia rates. A recent large randomized trial (NICE SUGAR) found slightly higher mortality and more hypoglycemia with strict euglycemic targets compared to a comparison group with insulin infusion initiation for blood glucose (BG) >180 mg/dL.[26]

Revised guidelines now reflect higher desired glycemic ranges and targets, while still striving to prevent uncontrolled hyperglycemia. The AACE – ADA guidelines recommend insulin therapy be initiated if BG is ≥180 mg/dL and maintained between 140 and 180 mg/dL in critically ill patients. Lower glucose targets (110–140 mg/dL) might be appropriate in selected patients based on limited evidence.[13,27] American College of Physicians (ACP) Clinical Practice Guidelines recommend against using intensive insulin therapy to reach euglycemia, and recommend a BG level target range of 140-200 mg/dL. The Society of Critical Care Medicine (SCCM) suggests that a BG ≥150 mg/dL in critically ill patients should trigger interventions (usually insulin infusion) to maintain BG below that level, and absolutely below 180 mg/dL.[14] SCCM and other guidelines emphasize the need to monitor hypoglycemia and avoid BG levels <100 mg/dL, and to use protocols that achieve a low rate of hypoglycemia.[12,27] The orders should require a single physician signature and limited physician choices as the vehicle initiating the nurse-driven protocol. The glycemic target range for your institution will depend in large part on the efficacy and safety of your insulin infusion protocol as well as the patient population you are treating. The more effective and safe the protocol is, the lower the achievable target can be while still avoiding hypoglycemia. The glycemic target range should be explicitly identified, and guidance for calling the physician and how to handle interruptions in nutrition should be embedded in the order set.

Frequent Monitoring

Frequent monitoring of glucose levels is necessary for the safe infusion of insulin. Guidance for how often the monitoring is required must be explicit and included in the infusion order set. Monitoring every one to two hours is generally required to ensure safety and timely adjustment. Standardization of documentation of the infusion rates and glucose values is highly desirable.

Providing Dosing Guidance – Choosing the Insulin Infusion Protocol

IIPs should provide clear and timely guidance for insulin infusion dosing adjustment to reach and maintain glycemic goals in a timely and safe manner. Head-to-head trials of different algorithms have not been tested in clinical trials.

There had been few published insulin protocols aimed at reaching specific glucose goals when the Leuven surgical ICU experience[25] was published in 2001. These early publications featured algorithms that adjusted insulin infusions solely on the basis of glucose level, and did not take the velocity of change, direction of change, proximity to glycemic target or different insulin sensitivities into account. These early protocols targeted glucose goals inconsistent with current standards, were relatively unstructured and their use led to high hypoglycemia rates in clinical settings.

The Yale protocol and Portland protocol are prominent examples of structured methods that use the present glucose and change from last glucose to constantly adjust to any situation.[28-32] These methods are purported to be relatively agile and flexible. However, they usually involve several calculation steps by the nurse, and paper versions tend to be complex. In spite of the relative complexity, they have been used safely and effectively in published reports. Adjustments are defined as units, percent change, or a combination of both.

Most recently, the Yale protocol was modified to reflect updated consensus guidelines,[27] and demonstrated excellent results in the single parent institution.[31] This protocol is available at

http://inpatient.aace.com/sites/all/files/Yale_IIP_MICU120-160_2011.pdf.

TABLE 2

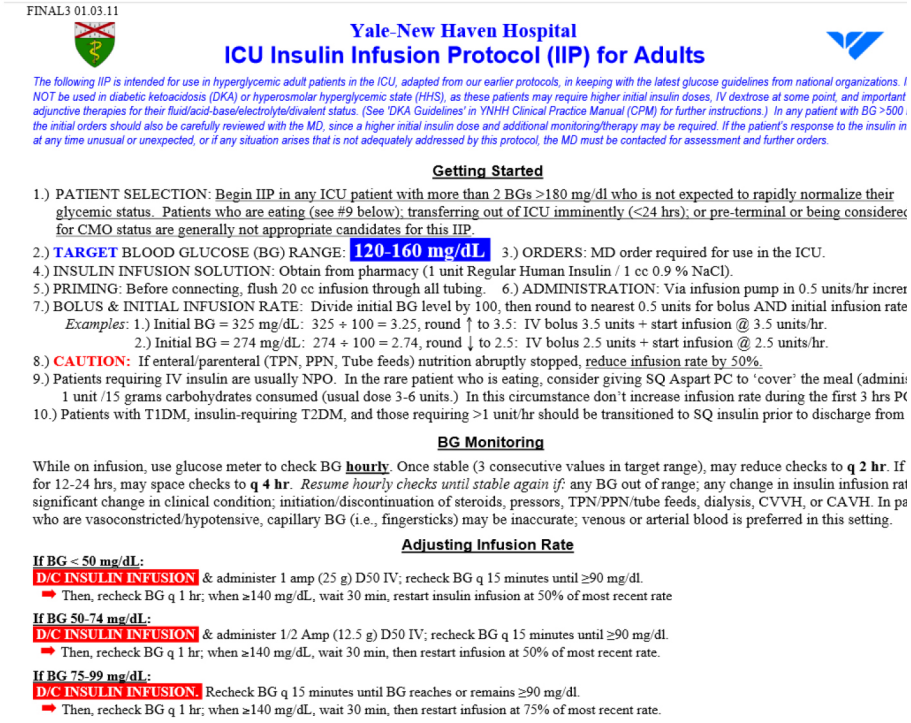
Ingredients for Insulin Infusion Protocol Orders

- ☐ Identifies the glycemic target range
- ☐ Includes clear dosing instructions with acceptable calculation requirements for nurses
- ☐ Incorporates glucose monitoring expectations
- ☐ Easy physician ordering, check box simplicity
- ☐ Criteria for calling the physician
- ☐ Includes guidance on steps to follow for interruption of nutrition
- ☐ States guidelines on when to initiate the infusion and when to stop
- ☐ Defines the insulin concentration clearly and consistently
- ☐ Considers changing insulin sensitivity as well as the current glucose value and rate of change in attempting to reach goal and avoid hypoglycemia
- ☐ Includes or refers to a standardized hypoglycemia treatment protocol and prevention protocol.
- ☐ Incorporates guidelines and cautions for transition to subcutaneous insulin
- ☐ Ideally adaptable outside of critical care unit—clear definition of locations where order set is to be used.

Note that the Yale IIP has several steps:

1. Identifying the ICU patient with 2 BG values >180 mg/dL, and verifying patient is a candidate for the IIP.
2. After initial BG determined, calculations for initial bolus and infusion rate are offered in the "Getting Started" section.
3. Regular BG monitoring begins, with instructions to adjust the dose based on current BG value and the change/direction from prior BG value.

Guidance for several other aspects of the IIP are incorporated, consistent with our recommendations in this chapter.



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ICU Insulin Infusion Protocol (IIP) for Adults

The following IIP is intended for use in hyperglycemic adult patients in the ICU, adapted from our earlier protocols, in keeping with the latest glucose guidelines from national organizations. I NOT be used in diabetic ketoacidosis (DKA) or hyperosmolar hyperglycemic state (HHS), as these patients may require higher initial insulin doses, IV dextrose at some point, and important adjunctive therapies for their fluid/acid-base/electrolyte/divalent status. (See 'DKA Guidelines' in YNHH Clinical Practice Manual (CPM) for further instructions.) In any patient with BG >500 the initial orders should also be carefully reviewed with the MD, since a higher initial insulin dose and additional monitoring/therapy may be required. If the patient's response to the insulin in at any time unusual or unexpected, or if any situation arises that is not adequately addressed by this protocol, the MD must be contacted for assessment and further orders.

Getting Started

1.) PATIENT SELECTION: Begin IIP in any ICU patient with more than 2 BGs >180 mg/dl who is not expected to rapidly normalize their glycemic status. Patients who are eating (see #9 below); transferring out of ICU imminently (<24 hrs); or pre-terminal or being considered for CMO status are generally not appropriate candidates for this IIP.

2.) **TARGET** BLOOD GLUCOSE (BG) RANGE: **120-160 mg/dL** 3.) ORDERS: MD order required for use in the ICU.

4.) INSULIN INFUSION SOLUTION: Obtain from pharmacy (1 unit Regular Human Insulin / 1 cc 0.9 % NaCl).

5.) PRIMING: Before connecting, flush 20 cc infusion through all tubing. 6.) ADMINISTRATION: Via infusion pump in 0.5 units/hr increr

7.) BOLUS & INITIAL INFUSION RATE: Divide initial BG level by 100, then round to nearest 0.5 units for bolus AND initial infusion rate

Examples: 1.) Initial BG = 325 mg/dL: 325 ÷ 100 = 3.25, round ↑ to 3.5: IV bolus 3.5 units + start infusion @ 3.5 units/hr.

2.) Initial BG = 274 mg/dL: 274 ÷ 100 = 2.74, round ↓ to 2.5: IV bolus 2.5 units + start infusion @ 2.5 units/hr.

8.) **CAUTION:** If enteral/parenteral (TPN, PPN, Tube feeds) nutrition abruptly stopped, reduce infusion rate by 50%.

9.) Patients requiring IV insulin are usually NPO. In the rare patient who is eating, consider giving SQ Aspart PC to 'cover' the meal (admini 1 unit /15 grams carbohydrates consumed (usual dose 3-6 units.) In this circumstance don't increase infusion rate during the first 3 hrs P

10.) Patients with T1DM, insulin-requiring T2DM, and those requiring >1 unit/hr should be transitioned to SQ insulin prior to discharge from

BG Monitoring

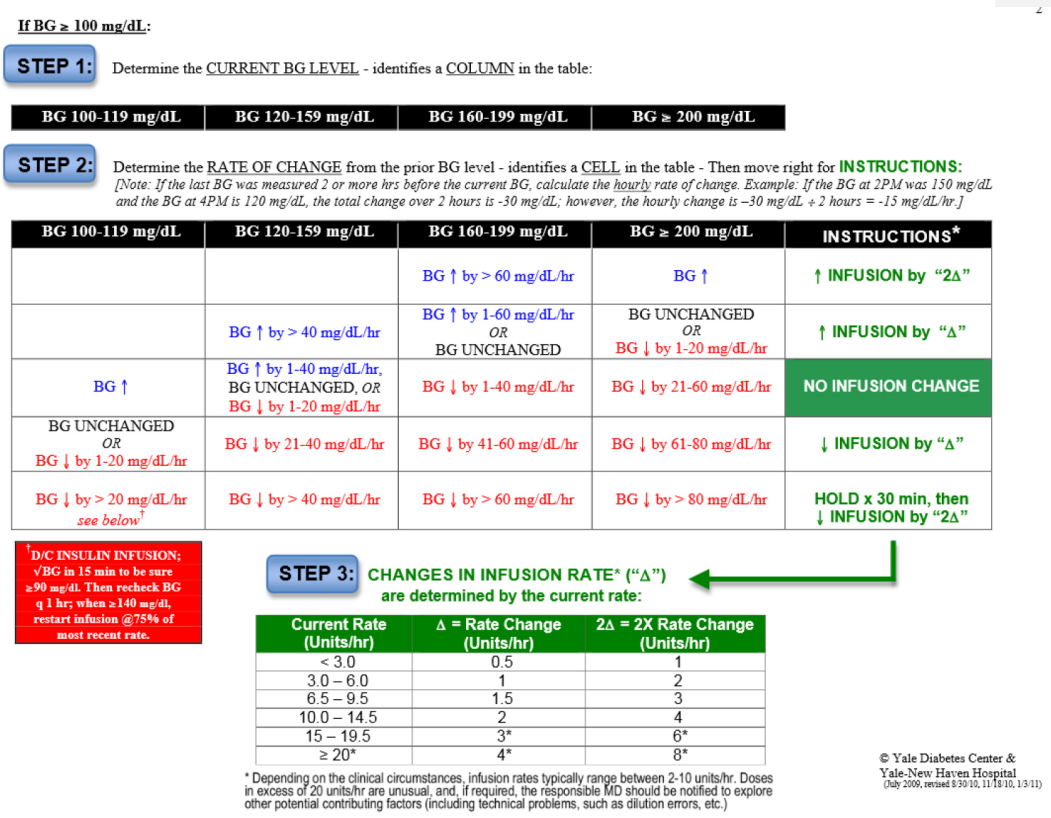
While on infusion, use glucose meter to check BG **hourly**. Once stable (3 consecutive values in target range), may reduce checks to **q 2 hr**. If for 12-24 hrs, may space checks to **q 4 hr**. *Resume hourly checks until stable again if:* any BG out of range; any change in insulin infusion rat significant change in clinical condition; initiation/discontinuation of steroids, pressors, TPN/PPN/tube feeds, dialysis, CVVH, or CAVH. In pa who are vasoconstricted/hypotensive, capillary BG (i.e., fingersticks) may be inaccurate; venous or arterial blood is preferred in this setting.

Adjusting Infusion Rate

If BG < 50 mg/dL:
D/C INSULIN INFUSION & administer 1 amp (25 g) D50 IV; recheck BG q 15 minutes until ≥90 mg/dl.
➡ Then, recheck BG q 1 hr; when ≥140 mg/dL, wait 30 min, restart insulin infusion at 50% of most recent rate

If BG 50-74 mg/dL:
D/C INSULIN INFUSION & administer 1/2 Amp (12.5 g) D50 IV; recheck BG q 15 minutes until ≥90 mg/dl.
➡ Then, recheck BG q 1 hr; when ≥140 mg/dL, wait 30 min, then restart infusion at 50% of most recent rate.

If BG 75-99 mg/dL:
D/C INSULIN INFUSION. Recheck BG q 15 minutes until BG reaches or remains ≥90 mg/dl.
➡ Then, recheck BG q 1 hr; when ≥140 mg/dL, wait 30 min, then restart infusion at 75% of most recent rate.



If BG ≥ 100 mg/dL:

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

BG 100-119 mg/dL	BG 120-159 mg/dL	BG 160-199 mg/dL	BG ≥ 200 mg/dL

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 or more hrs 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 120 mg/dL, the total change over 2 hours is -30 mg/dL; however, the hourly change is –30 mg/dL ÷ 2 hours = -15 mg/dL/hr.]

BG 100-119 mg/dL	BG 120-159 mg/dL	BG 160-199 mg/dL	BG ≥ 200 mg/dL	INSTRUCTIONS*
		BG ↑ by > 60 mg/dL/hr	BG ↑	↑ INFUSION by "2Δ"
	BG ↑ by > 40 mg/dL/hr	BG ↑ by 1-60 mg/dL/hr *OR* BG UNCHANGED	BG UNCHANGED *OR* BG ↓ by 1-20 mg/dL/hr	↑ INFUSION by "Δ"
BG ↑	BG ↑ by 1-40 mg/dL/hr, BG UNCHANGED, *OR* BG ↓ by 1-20 mg/dL/hr	BG ↓ by 1-40 mg/dL/hr	BG ↓ by 21-60 mg/dL/hr	NO INFUSION CHANGE
BG UNCHANGED *OR* BG ↓ by 1-20 mg/dL/hr	BG ↓ by 21-40 mg/dL/hr	BG ↓ by 41-60 mg/dL/hr	BG ↓ by 61-80 mg/dL/hr	↓ INFUSION by "Δ"
BG ↓ by > 20 mg/dL/hr *see below*†	BG ↓ by > 40 mg/dL/hr	BG ↓ by > 60 mg/dL/hr	BG ↓ by > 80 mg/dL/hr	HOLD x 30 min, then ↓ INFUSION by "2Δ"

† D/C INSULIN INFUSION; √BG in 15 min to be sure ≥90 mg/dl. Then recheck BG q 1 hr; when ≥140 mg/dl, restart infusion @75% of most recent rate.

STEP 3: CHANGES IN INFUSION RATE* ("Δ") are determined by the current rate:

Current Rate (Units/hr)	Δ = Rate Change (Units/hr)	2Δ = 2X Rate Change (Units/hr)
< 3.0	0.5	1
3.0 – 6.0	1	2
6.5 – 9.5	1.5	3
10.0 – 14.5	2	4
15 – 19.5	3*	6*
≥ 20*	4*	8*

* Depending on the clinical circumstances, infusion rates typically range between 2-10 units/hr. Doses in excess of 20 units/hr are unusual, and, if required, the responsible MD should be notified to explore other potential contributing factors (including technical problems, such as dilution errors, etc.)

Another major category of protocol guides dosing through calculation of insulin sensitivity. Paper versions generally use column methods with the individual columns representing different categories of insulin sensitivity, placing the most sensitive category on the left with the highest level of insulin resistance on the far right, as first published by Markowitz.[33] These methods use a multiplier to adjust for sensitivity, aka insulin sensitivity factor. They are constructed according to the ''rule of 1500, 1700, or 1800,'' thereby adjusting for changes in insulin sensitivity that follow surgery or other changes in physiologic stress in the acute setting. ''Rate of change'' is addressed by shifting to the right if correction of hyperglycemia is too slow and to the left if the glucose is dropping too rapidly. Like the Yale protocol, complexity and several calculations or steps are required by nursing staff to adhere to the protocol.

Other protocols can be viewed on the AACE website:

http://inpatient.aace.com/protocols-and-order-sets

Practical factors such as the complexity of the protocol, the required process steps or calculations, the evidence for staff acceptance and the level of resources required to support the protocol often play at least as prominent of a role in IIP selection as literature reports of efficacy and safety.

Computerized vs Paper Protocols

As noted above, modern IIPs use bolus insulin to expedite control and adjust the infusion rate based on the velocity and direction of glucose change, not just the most recent glucose value. Insulin resistance adjustments and multiple calculation steps are required in several reported protocols. The improved dosing guidance and control refinements come at a cost of increased complexity.[34,35] Computerization and automation of the calculation steps of the Yale protocol, the column insulin multiplier method and other methods has been undertaken in an attempt to simplify the clinical

decision support for insulin adjustment.[35-38] Multiple comparative studies demonstrate superiority of the computerized protocols in reaching and maintaining glycemic targets with low rates of hypoglycemia, with the added advantage of automated reminders for repeat BG testing.[38-43] While many of these studies were before/after cohort studies, several randomized control studies have confirmed these findings.[35,44-46] Computerized methods also facilitate data collection for analytical purposes.

In summary, computerized systems (both commercial and home-grown versions) are becoming more common and appear to hold significant benefits as long as they are backed by a validated algorithm. There are some barriers, including the need for FDA approval for some devices, the need for bedside computers, the need to recognize situations that might "trick" the computerized protocol and expense.[35] Whereas many institutions are not yet in a position to integrate such protocols into their standard or electronic record systems, we expect the trend for increased implementation to continue.

Special Teams

Another method of simplification is having a special team or limited set of providers run the IIP and transitions to subcutaneous insulin. This specialized team is most often pharmacy, but can include specialized mid-levels, hospitalists/intensivists or diabetes educators. The protocol will still be run by nursing, but this specialized team will serve as the main resource for monitoring, questions and troubleshooting the IIP and providing dosing recommendations for transition to subcutaneous insulin.

C. Implementation: Addressing Safety Issues

The use of insulin infusions comes with several potential hazards. Many of these potential complications can be proactively addressed, thereby minimizing accidental injuries to the patient on an insulin infusion.

Standardizing Insulin Infusion Preparations and Priming New Tubing

Varied concentrations or types of insulin for insulin infusions can lead to serious errors. Insulin infusions should generally be centrally prepared with a standard concentration of regular insulin in the pharmacy (usually 1 unit/cc), and the infusion concentration should be included in your infusion order set. Insulin binding to IV tubing can lead to false elevation of insulin requirements, potentially followed by serious hypoglycemia. When nurses change IV tubing or initially set up an insulin drip, education/instructions on priming new tubing with a small amount of insulin infusion to saturate the binding to the polyvinyl chloride tubing should be incorporated into their routine. Although 50 mL has often been recommended for priming, a recent study[47] found that 20 mL of insulin infusion is enough to reach the saturation point.

Avoiding Over-Reliance on the Insulin Protocol

Nurse-driven insulin infusion protocols automate frequent insulin adjustment and reduce unnecessary calls to the physician. Although this is generally a decided advantage, the care team can be lulled into a sense of false security by the presence of orders that allow for such adjustment. Increasing the rate of an insulin infusion without thoughtful attention to factors that may be playing a role in this increased requirement (such as developing sepsis, other medical decompensation, steroid boluses or an increase in carbohydrate intake) can have serious consequences. By the same token, an unanticipated rapid decrease in insulin requirement should lead to a reassessment of the infusion, and an inquiry about cessation of glucocorticoid therapy or nutrition. Rarely, a pharmacy or nursing error may induce a pseudo-change in insulin requirements. The protocol should lead the nurse to seek advice and alert the physician to review potential causes of dramatic changes in insulin requirements, rather than simply adjusting insulin or nutrition to correct the present abnormal value.

Interruption of the Insulin Infusion

Interruption of insulin infusions may occur for many reasons, either intended or unintended. At times, the doctors or nurses may temporarily stop the protocol to allow for delivery of blood products or medications when IV access is limited. Infusions may mistakenly not be restarted, or deliberate discontinuation may not be adequately communicated, potentially leading to worsening hyperglycemia or even the development of ketoacidosis, and other adverse clinical outcomes. Therefore, the algorithm should have clear orders for the nurses to contact the ordering physician if the infusion is stopped for any reason, other than protocol-driven cessation due to falling blood glucose concentrations.

Interruption of Nutrition, Field Trips and Communication

Insulin infusion commonly provides both basal and nutritional insulin requirements. Interruptions in nutritional intake are extremely common in the inpatient setting, with a potential to cause serious hypoglycemia.[48-50] Feeding tubes are often pulled out without warning; enteral nutrition may also need to be halted if high gastric residuals are noted or during certain diagnostic tests. At times, IV carbohydrate sources (dextrose, partial parenteral nutrition, total parenteral nutrition) may be interrupted as well. In some cases, ''field trips'' out of the critical care units to the operating room, imaging studies or other hospital locations add another layer of challenges to managing the IIP.

Staff in these various areas may not be familiar with the IIP or monitoring standards and techniques, and potentially may not even be aware that the patient is on an insulin infusion. It is therefore crucial to anticipate these pitfalls and develop effective institutional procedures for addressing them. For example, many institutions use D10 solution to replace the carbohydrate calories that are lost when tube feedings have to be interrupted in a gram-per-gram fashion. Patients should be clearly identified as being on an insulin infusion. The requirement for consistent glucose monitoring, hypoglycemia recognition and treatment and insulin infusion adjustment requires either critical care nurse care of the patient on the field trip, or training in the same skills in areas such as endoscopy, interventional radiology and operating rooms including the preoperative and postoperative care units. In any case, all services should be involved in crafting solutions that will ensure a consistent approach to glycemic control as the patient travels off-unit. Monitoring and treatment equipment needs to be readily available in all sites, and hypoglycemia protocols need to be distributed and supported in all areas.

Preventing and Treating Hypoglycemia

Some hypoglycemia will occur with infusion protocols, no matter how carefully a protocol is crafted and how well it is administered. Hypoglycemia protocols should therefore be incorporated directly into an infusion order set. Treatment of hypoglycemic events with a full 50 mL of D50 solution is equivalent to 25 g of carbohydrate, which will raise glucose levels in the average patient by 125 mg/dL. Many institutions discourage the overcorrection of hypoglycemic events by encouraging giving lesser aliquots of D50 based on the degree of hypoglycemia. Preventing hypoglycemia by recognizing hypoglycemia risk factors, proper monitoring and anticipating reductions in insulin requirements from decreasing severity of illness, nutritional intake or steroid dosing can also reduce the frequency of hypoglycemic events. Additional information on hypoglycemia management and prevention is available elsewhere in this *Guide*.[49]

Medical and Surgical Patients Are Different

The most convincing evidence for stringent glycemic control evolved from studies of surgical patients.[4,5,7] Acknowledging this fact, along with the greater degree of difficulty in achieving glycemic targets safely in critically ill medical patients, have led many to endorse higher glycemic targets for certain populations than others.[5,7] Although we generally favor a uniform glycemic target for a unit serving a particular patient population, adopting a less stringent glycemic target in medical ICU settings compared to the surgical ICU setting is reasonable and prudent in many institutional settings. However, the accompanying challenges regarding ''boarding'' patients and ''floating'' nurses between units would also need to be considered.

Glucose Meters in the Critical Care Setting

While point-of-care glucose meters are the mainstay for inpatient glucose testing, there are some important limitations, especially in the critical care setting. Your team should provide guidance about the potential problems of using point-of-care glucose testing in settings with hypotension, sepsis, pressor use, peripheral edema and other conditions that may impair the accuracy of capillary glucose readings.[51] Central venous samples can also lead to erroneous high or low values if the proper steps to obtain an undiluted sample are not taken, and education and guidance should be provided to avoid this situation. In addition, point-of-care glucose meters for hospitalized critically ill patients are now at risk because of new enforcement policies proposed by the Centers for Medicare & Medicaid Services prohibiting the off-label use of these devices.[52] Given the expense, poorly studied accuracy and long analysis time of the alternatives, the consequences of such enforcement could be disastrous.[53] At the time of this publication, extensive lobbying and discussion with regulatory agencies as well as plans for validation studies by the meter companies to provide supportive data for the use of glucose meters in the ICU are underway.

Local Factors and Implementation Methods Matter

The success or failure of a protocol depends on local factors and implementation methods as much as it does on the structure of the protocol itself. IIP development and implementation is a process that must be approached systematically and with attention to detail.[19] Errors in approach can delay or abort the implementation, or potentially lead to an ineffective or unsafe protocol for the institution.

The Yale experience again provides us with a salient example.[54] Initial efforts to implement an IIP failed due to a number of factors: a complicated protocol, insufficient nursing involvement and inadequate training and education led to incomplete buy-in, and nursing concerns over ''hypoglycemia'' that actually was within the goal range of the protocol. Successful implementation was not achieved until the leaders learned from their mistakes. Nurses and other clinical allies were involved and educated. Important stakeholders, who were not included earlier, were now involved, and frontline nursing staff were engaged in proactive troubleshooting.

D. Implementation: Educating and Engaging Nursing and Physician Staff

Nursing staff generally bear the brunt of the burden on the front line of implementing intensive IIPs. Educational efforts for nurses should include the rationale for intensive insulin therapy and use of an IIP. Additionally, detailed, case-based instruction on utilization of the IIP is required. Properly educated, nursing staff often become the strongest advocates of the IIP. In addition, they can frequently provide important input when situations arise that require troubleshooting. Regular feedback sessions early in implementation that address ease of use, clarity of orders and difficulties encountered by nurses can be invaluable. Improvement teams need to provide frequent in service training and updates

on the IIP selected after implementation. This is imperative to promote nursing acceptance and adherence to the chosen IIP, particularly with consideration for traveling nurses. The importance of nursing champions to design and carry out this work cannot be overstated. Educational programs focusing on the physician staff can also be very useful, particularly when focused on high-volume physicians and influential thought leaders.

E. Implementation: Addressing Common Clinical Situations

Steroids

Steroid boluses are commonly an integral part of regimens targeting a variety of conditions, such as critical illness, transplant rejection, reactive airways disease, certain infections, cancer and a variety of autoimmune disorders. This can lead to glycemic excursions and rapidly varying insulin requirements. Educational efforts and treatment regimens should address the disproportionate impact that steroids have on postprandial glycemic excursions. To minimize the glycemic impact of glucocorticoid therapy, a team should investigate promoting the use of steroid infusions in situations when a bolus is not absolutely necessary.

Dealing with the Eating Patient and Other Sources of Carbohydrate-Induced Glycemic Excursions

Glucose levels can be difficult to control in patients who are eating while on insulin infusion, because the infusion ''chases'' the glycemic excursions through frequent adjustments, often with a late overshoot and inappropriate reduction in dose. We instead recommend providing bolus nutritional insulin to cover the expected glycemic excursion caused by carbohydrate ingestion. Carbohydrate counting and using a unit of insulin for each 10-15 g of carbohydrate consumed can smooth out the rapid fluctuations in glucose. Guidance for this should be incorporated into the order set.

Transition Off of Insulin Infusion

Rational strategies for dealing with this transition are covered in detail elsewhere in this *Guide*. Guidance for managing this transition should be integrated into your insulin infusion and subcutaneous order sets. The transition to subcutaneous insulin may represent a separate order set but is sometimes best integrated into the IV insulin infusion order set itself.

IIPs Outside of the Critical Care Setting

IIPs are most commonly used in the critical care setting. In some institutions, IV insulin protocols are safely and effectively employed outside the ICU. Obviously, the number of nurses and other personnel who must be familiar with such protocols is much higher outside the ICU, and protocol errors are therefore likely to be somewhat higher. In addition the nurse-per-patient ratio is usually lower outside of the critical care setting. As a result, suggestions for safe implementation of insulin infusion regimens outside of the critical care setting include:

- Choose an infusion protocol with a higher glycemic target.
- Limit the medical and surgical units where this expertise will be developed.
- Consider simplified infusion protocols but stay consistent with format.
- Automated or computerized assistance of calculations may reduce human error and nursing burden.

F. Assessing the Impact of Your Efforts: Follow-Up and Follow-Through

Monitoring, Recording and Analyzing Glycemic Control Data

Once the IIP is implemented, it is critical that the impact on glycemic control, hypoglycemia, insulin use and other factors be analyzed and used for improving the IIP and care delivery. Frequent monitoring of glucose levels is necessary for the safe infusion of insulin. Guidance for how often the monitoring is required must be explicit and included in the infusion order set. Intermittent auditing for compliance with the frequency of glucose testing and appropriate dose selection is good practice. Attention should be paid to how the glucose level is obtained, recorded and made available to the healthcare team in your institution.

All glucose readings should be recorded electronically for ongoing analyses and retrieval, and ideally, this could be done in an automated or single-step method. Try to eliminate duplication of effort, such as asking the nurse to record the glucose level and his or her reaction to it on paper and again in an electronic format.

Reports on the time to reach the glycemic target, glycemic control while on infusion and the incidence of hypoglycemia should be reviewed by the multidisciplinary Steering Committee. The Society of Hospital Medicine Glycemic Control Task Force recommends analysis by patient-day and by patient-stay (or insulin infusion run) as preferred methodologies for analysis of glycemic control and hypoglycemia rates over the method of using each individual glucose reading as the unit of analysis. (The latter tends to under-value the frequency of hypoglycemia.) Detailed practical recommendations for analyzing and summarizing glycemic control data are available elsewhere in this *Guide*.[18] These data should drive decisions on modification of glycemic targets and the protocol structure. Patients meeting pre-specified criteria should be referred to the Improvement Team for review. For example, patients who experience any glucose readings of <40 mg/dL, or who take more than 12 hours to reach the upper limit glycemic target, should be referred to the team for a case review.

Assessing Adherence to the Protocol and Ease-of-Use Issues

Focused audits in the pilot and early implementation phases should look for non-adherence to the protocol. Deviations should be evaluated according to the patterns identified. For example, variation in application in some cases is specific for an individual and in others is characteristic of a specific group or the whole. Accordingly, this may point to gaps in education or attitudes about the importance of this endeavor. Frontline staff may deviate from the protocol because they find it ineffective, unsafe or impractical for certain situations or specific patients. Many IIPs are the subject of nursing errors related not only to the knowledge and acceptance of the nurse but also the complexity of the protocol. Appropriate modifications to the protocol based on these cases can frequently improve the ease of use and effectiveness of the protocol. The ongoing review process should identify issues that must be addressed with permanent solutions rather than accepting frequent individual alterations to meet goals. Revisions require supplementary education and rapid and wide dissemination. Although educational efforts and monitoring are often most intense in the early implementation phase, periodic retraining should continue to achieve optimal results and safety. Educational tools must consider nursing time commitments and will often include an interactive Web-based module that gives more flexibility for trainers and clinical nurses alike.

G. Conclusion

Insulin infusions are a powerful clinical tool in the inpatient setting to maintain glycemic control. Many IIPs have been developed and used successfully. The institutional challenge is to select, modify and implement the IIP to reduce hyperglycemia and improve outcomes without excess hypoglycemia. In order to accomplish this goal safely and efficiently standardized processes and collaboration between physicians, nurses and pharmacists are needed. The keys to minimizing errors include developing a culture of safety and cooperation, back-up checks, standardization, automation and robust training for all those who are involved in the care of a patient on an insulin infusion. Although we encourage standardization and the use of protocols, providers always need to consider the unique clinical circumstances and potential problems presented by each individual patient. It is important to recognize the many barriers to successful implementation of an IIP, but strategies exist to overcome these. Finally, remember that the process does not end with the development phase. Continued review is paramount to success. Note variations in use, analyze them and learn from them, in order to continually improve the process of care.

References

[1]Bagshaw SM, Egi M, George C, et al. Australia and New Zealand Intensive Care Society Database Management Committee: Early blood glucose control and mortality in critically ill patients in Australia. *Crit Care Med.* 2009;37:463–470.

[2]Falciglia M, Freyberg RW, Almenoff PL, et al. Hyperglycemia-related mortality in critically ill patients varies with admission diagnosis. *Crit Care Med.* 2009;37:3001–3009.

[3]Finney SJ, Zekveld C, Elia A, et al. Glucose control and mortality in critically ill patients. *JAMA.* 2003;290:2041–2047.

[4]Freire AX, Bridges L, Umpierrez GE, et al. Admission hyperglycemia and other risk factors as predictors of hospital mortality in a medical ICU population. *Chest.* 2005;128:3109–3116.

[5]Krinsley JS. Association between hyper-glycemia and increased hospital mortality in a heterogeneous population of critically ill patients. *Mayo Clin Proc.* 2003;78:1471–1478.

[6]Furnary AP, Zerr KJ, Grunkemeier GL, Starr A. Continuous intravenous insulin infusion reduces the incidence of deep sternal wound infection in diabetic patients after cardiac surgical procedures. *Ann Thorac Surg.* 1999;67(2):352–360.

[7]Furnary AP, Gao G, Grunkemeier GL, et al. Continuous insulin infusion reduces mortality in patients with diabetes undergoing coronary artery bypass grafting. *J Thorac Cardiovasc Surg.* 2003;125(5):1007–1021.

[8]Krinsley JS. Effect of an intensive glucose management protocol on the mortality of critically ill adult patients. *Mayo Clin Proc.* 2004;79(8):992–1000.

[9]Van den Berghe GP, Weekers F, Verwaest C, et al. Intensive insulin therapy in the critically ill patients. *N Engl J Med.* 2001;345(19):1359–1367.

[10]Griesdale DE, de Souza RJ, van Dam RM, Heyland DK, Cook DJ, Malhotra A, Dhaliwal R, Henderson WR, Chittock DR, Finfer S, Talmor D. Intensive insulin therapy and mortality among critically ill patients: a meta-analysis including NICE-SUGAR study data. *CMAJ. 2009;* 180:821–827.

[11]Devos P, Preiser JC. Current controversies around tight glucose control in critically ill patients. *Curr Opin Clin Nutr Metab Care.* 2007;10(2):206–209.

[12]Jacobi J, Bircher N, Krinsley J, Angus M, Braithwaite SS et al. Guidelines for the use of an insulin infusion for the management of hyperglycemia in critically ill patients. *Crit Care Med.* 2012:40:3252-3276.

[13]American Diabetes Association. Standards of medical care in diabetes 2012. *Diabetes Care.* 2012;35(Suppl. 1):S11–S63.

[14]Qaseem A, Humphrey LL, Chou R, Snow V, Shekelle P. Use of Intensive Insulin Therapy for the Management of Glycemic Control in Hospitalized Patients: A Clinical Practice Guideline from the American College of Physicians. *Ann Intern Med.* 2011;154(4):260-267.

[15]Li JY, Sun S, Wu SJ. Continuous insulin infusion improves postoperative glucose control in patients with diabetes mellitus undergoing coronary artery bypass surgery. *Tex Heart Inst J.* 2006;33(4):445–451.

[16]Quinn JA, Snyder SL, Berghoff JL, Colombo CS, Jacobi J. A practical approach to hyperglycemia management in the intensive care unit: evaluation of an intensive insulin infusion protocol. *Pharmacotherapy.* 2006;26(10):1410–1420.

[17]Kanji S, Singh A, Tierney M, Meggison H, McIntyre L, Hebert PC. Standardization of intravenous insulin therapy improves the efficiency and safety of blood glucose control in critically ill adults. *Intensive Care Med.* 2004;30(5):804–810.

[18]Ahmann A, Maynard G. Designing and Implementing Insulin Infusion Protocols and Order Sets. *J Hosp Med.* 2008;(5 Suppl):42-54.

[19]DKA article in this Guide

[20]Maynard et al Section V.5 Section G. Transition from IV to Subcutaneous Insulin

[21]Maynard et al Section IV Choose Metrics and Develop a Data Collection Plan for your Glycemic Control Program

[22]Maynard G, Schnipper JL, Messler J, Ramos P, Kulasa K, Nolan A, Rogers K. Design and Implementation of a Web-Based Reporting and Benchmarking Center for Inpatient Glucometrics. *J Diabetes Science Tech.* 2014:published online May 12, 2014. DOI: 10.1177/1932296814532237.

[23]Preston S, Laver SR, Lloyd W, Padkin A. Introducing intensive insulin therapy: the nursing perspective. *Nurs Crit Care.* 2006;11(2):75–79.

[24]Aragon D. Evaluation of nursing work effort and perceptions about blood glucose testing in tight glycemic control. *Am J Crit Care.* Jul 2006;15(4):370377.

[25]Van den Berghe G, Wouters P, Weekers F, et al. Intensive insulin therapy in critically ill patients. *N Engl J Med.* 2001;345:1359–1367.

[26]NICE-SUGAR Study Investigators, Finfer S, Chittock DR, et al. Intensive versus conventional glucose control in critically ill patients. *N Engl J Med.* 2009;360:1283-1297.

[27]Rodbard HW, Jellinger PS, Davidson JA, et al. Statement by an American Association of Clinical Endocrinologists/American College of Endocrinology consensus panel on type 2 diabetes mellitus: an algorithm for glycemic control (Erratum in: *Endocr Pract.* 2009;15:768-770). *Endocr Pract.* 2009;15:540–559.

[28]Goldberg PA, Siegel MD, Sherwin RS, et al. Implementation of a safe and effective insulin infusion protocol in a medical intensive care unit. *Diabetes Care.* 2004;27(2):461–467.

[29]Goldberg PA, Sakharova OV, Barrett PW, et al. Improving glycemic control in the cardiothoracic intensive care unit: clinical experience in two hospital settings. *J Cardiothorac Vasc Anesth.* 2004;18(6):690–697.

[30]Goldberg PA, Roussel MG, Inzucchi SE. Clinical results of an updated insulin infusion protocol in critically ill patients. *Diabetes Spectr.* 2005;18:188–191.

[31]Shetty S, Inzucchi S, Goldberg PA, Cooper D, Siegel MD, Honiden S. Adapting to the New Consensus Guidelines for Managing Hyperglycemia During Critical Illness: The Updated Yale Infusion Protocol. *Endcr Practice.* 2012;18:363–370.

[32]Furnary AP, Wu Y, Bookin SO. Effect of hyperglycemia and continuous intravenous insulin infusions on outcomes of cardiac surgical procedures: the Portland Diabetic Project. *Endocr Pract.* 2004;10(Suppl 2):21–33.

[33]Markovitz LJ, Wiechmann RJ, Harris N, et al. Description and evaluation of a glycemic management protocol for patients with diabetes undergoing heart surgery. *Endocr Pract.* 2002;8(1):10–18.

[34]Wilson M, Weinreb J, Hoo GW. Intensive insulin therapy in critical care: a review of 12 protocols. *Diabetes Care.* 2007;30(4):1005–1011.

[35]Eslami S, Abu-Hanna A, de Jonge E, de Keizer NF. Tight glycemic control and computerized decision-support systems: A systematic review. *Intensive Care Med.* 2009;35:1505–1517.

[36]Marvin MR, Inzucchi SE, Besterman BJ. Computerization of the Yale Insulin Infusion Protocol and Potential Insights into the Causes of Hypoglycemia with Intravenous Insulin. *Diabetes Technol Ther.* 2013;15(3):246–252.

[37]Davidson PC, Steed RD, Bode BW. Glucommander: a computer-directed intravenous insulin system shown to be safe, simple, and effective in 120,618 h of operation. *Diabetes Care.* 2005;28(10):2418–2423.

[38]Newton CA, Smiley D, Bode BW, Kitabchi AE, Davidson PC, Jacobs S, Steed RD Stentz F, Peng L, Mulligan P Freire AX, Temponi A, Umpierrez GE. A comparison study of continuous insulin infusion protocols in the medical intensive care unit: computer-guided vs. standard column-based algorithms. *J Hosp Med.* 2010;5:432–437.

[39]Dortch MJ, Mowery NT, Ozdas A, Dossett L, Cao H, Collier B, Holder G, Miller RA, May AK, A computerized insulin infusion titration protocol improves glucose control with less hypoglycemia compared to a manual titration protocol in a trauma intensive care unit. *J Parenter Enteral Nutr.* 2008;32:18–27.

[40]Cordingley JJ, Vlasselaers D, Dormand NC. Wouters PJ. Squire SD, Chassin LJ, Wilinska ME, Morgan CJ, Hovorka R, van den Berghe G, Intensive insulin therapy: enhanced model predictive control algorithm versus standard care. *Intensive Care Med.* 2009;35:123–128.

[41]Shulman R, Finney SJ, O'Sullivan C, Glynne PA, Greene R, Tight glycaemic control: a prospective observational study of a computerised decision-supported intensive insulin therapy protocol. *Crit Care.* 2007;11:R75.

[42]Vogelzang M, Loef BG, Regtien JG, van der Horst IC, van Assen H, Zijlstra F, Nijsten MW. Computer-assisted glucose control in critically ill patients. *Intensive Care Med.* 2008;34:1421–1427.

[43]Davidson PC, Steed RD, Bode BW, Hebblewhite HR, Prevosti L. Cheekati V. Use of a computerized intravenous insulin algorithm within a nurse-directed protocol for patients undergoing cardiovascular surgery. *J Diabetes Sci Technol.* 2008;2:369–375.

[44]Blaha J, Kopecky P, Matias M, Hovorka A, Kunstyr J, Kotulak T, Lips M, Rubes D, Stritesky M, Lindner J, Semrad M, Haluzik M. Comparison of three protocols for tight glycemic control in cardiac surgery patients. *Diabetes Care.* 2009;32:757–761.

[45]Cavalcanti AB, Silva E, Pereira AJ, et al. A randomized controlled trial comparing a computer-assisted insulin infusion protocol with a strict and a conventional protocol for glucose control in critically ill patients. *J Crit Care.* 2009; 24:371–378.

[46]Plank J, Blaha J, Cordingley J, et al. Multi-centric, randomized, controlled trial to evaluate blood glucose control by the model predictive control algorithm versus routine glucose management protocols in intensive care unit patients. *Diabetes Care.* 2006;29:271–276.

[47]Goldberg PA, Kedves A, Walter K, et al. ''Waste not, want not'': determining the optimal priming volume for intravenous infusions. *Diabetes Technol Ther.* 2006;8(5):598–601.

[48]Reference for coordination of nutrition, testing, and insulin administration

[49]Maynard and others Hypoglycemia article reference later in this Guide.

[50]Cobaugh DJ, Maynard G, Cooper L, Kienle PC, Vigersky R, Childers D, Weber R, Carson SL, Mabrey ME, Roderman N, Blum F, Burkholder R, Dortch M, Grunberger G, Hays D, Henderson R, Ketz J, Lemke T, Varma SK, Cohen M. Enhancing insulin-use safety in hospitals: Practical recommendations from an ASHP Foundation expert consensus panel. *Am J Health Syst Pharm.* 2013 Aug 15;70(16):1404–1413.

[51]Jacobi J, Bircher N, Krinsley J, Agus M, Braithwaite SS, Deutschman C, Freire AX, Geehan D, Kohl B, Nasraway SA, Rigby M, Sands K, Schallom L, Taylor B, Umpierrez G, Mazuski J, Schunemann H. Guidelines for the use of an insulin infusion for the management of hyperglycemia in critically ill patients. *Crit Care Med.* 2012 Dec;40(12):3251–3276.

[52]FDA letter

[53]Klonoff DC, Vigersky RA, Nichols JH, Rice MJ. Timely hospital glucose measurement: here today, gone tomorrow? *Mayo Clin Proc.* 2014 Oct;89(10):1331–1335,. doi: 10.1016/j.mayocp.2014.08.005. Epub 2014 Sep 6.

[54]Goldberg PA. Memoirs of a root canal salesman: the successful implementation of a hospital-wide intravenous insulin infusion protocol. *Endocr Pract.* 2006 Jul-Aug;12 Suppl 3:79–85.

Diabetic ketoacidosis (DKA) is a serious and life-threatening condition often resulting in coma, altered mental status and end organ damage. It is characterized by a serum glucose level greater than 250 mg/dL, pH less than 7.3, serum bicarbonate level less than 18 mEq/L with elevated serum ketone level and dehydration. Protocols and order sets can help standardize the recommended treatment and decrease the time to resolve DKA.[1] Treatment should start immediately upon recognition in the Emergency Department (ED) and not wait until transfer to the ICU. Care should follow guidelines below that are documented from evidence-based medicine, the American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE). The goal of therapy is to correct the acidosis. Treatment should include: 1) aggressive IV fluids, 2) continuous insulin infusion with boluses as needed, 3) frequent monitoring of labs including glucose, potassium and anion gap. Intravenous fluids and insulin should be constantly adjusted based on the changing labs. Completion of treatment occurs when the anion gap is closed, acidosis is resolved and the patient is ready to transition to subcutaneous insulin.

A. Diagnosis

Patients will have an elevated serum glucose level (usually greater than 250 mg/dL). They also present with an elevated serum ketone level, anion gap metabolic acidosis, serum bicarbonate level less than 18 mEq/L and generally have pH<7.3 unless they have a mixed disorder. Symptoms include polyuria, polydipsia, polyphagia, weight loss, vomiting and abdominal pain. Signs include dehydration, weakness, Kussmaul respirations, tachycardia, hypotension, alteration in mental status, shock and coma. Occasionally hematemesis or guaiac positive stools are noted due to hemorrhagic gastritis.

B. Monitoring

These patients should be monitored very closely. Recommendations include checking the serum glucose hourly, and basic electrolytes, serum osmolality and venous/arterial pH every two to four hours.[16] If potassium replacement is required (see below) then electrolytes should be checked every two hours. Although DKA can be the result of noncompliance of diabetic medications, other underlying causes should be determined and treated.

C. Fluid Replacement

Many DKA patients are depleted by 6-8 L of fluid. This fluid should be replaced over a 24-hour period. Aggressive fluid resuscitation has been shown to give a better response to low-dose insulin therapy. Typically three types of fluids are utilized and are based on the patient's clinical condition and electrolyte status.

The first step is to give isotonic saline to expand extracellular volume and stabilize cardiovascular status. Optimal fluid rate is patient dependent but is recommended to start at 15 to 20 mL/kg lean body weight per hour. This calculates to approximately 1,000 mL/hr and should be continued for one to three hours.

Next, fluids should then be changed based on the serum electrolyte level and clinical hydration. The corrected sodium (see equations) can be a helpful guide to determine normal saline or half normal saline for the next set of fluid. The corrected sodium accounts for the hyponatremia caused by the shift of water from intracellular fluid (ICF) to extracellular fluid (ECF) in hyperglycemia. If the corrected sodium is less than 135 mEq/L, then isotonic saline should be continued at 250-500 mL/hr. If the corrected sodium is normal or elevated then half-isotonic saline should be continued at 250-500 mL/hr.

Finally, once the plasma glucose reaches approximately 200 mg/dL, IV fluids should be changed to half normal saline with 5-10 percent dextrose at 150-250 mL/hr. Insulin will be adjusted at this point as well (see Insulin section).[4-8, 10-15]

D. Potassium Replacement

Insulin therapy, correction of acidosis and volume expansion decrease serum potassium concentration. Patients also lose potassium through osmotic dieresis. Because of the cellular shift of potassium in the acidic state, regular hospital potassium replacement protocols should NOT be used. Replacement usually starts when serum potassium is in the upper limits of normal, approximately 5.0-5.2 mEq/L. Once serum potassium drops below this level, the replacement should be started at 20-30 mEq potassium in each liter of IV fluid. Occasionally DKA patients present with hypokalemia. Patients with hypokalemia should start with IV fluids, and insulin should be held until the serum potassium is greater than 3.3 mEq/L.[17]

One specific protocol recommends:

If K <3.3 mEq, then give 20-40 mEq/hr. Do not give insulin until potassium reaches 3.3 mEq.
If K is 3.3-5.3 mEq, give 20-30 mEq per liter IV fluid to keep potassium between 4 to 5 mEq/L.
If serum K is above 5.3 mEq/L, check potassium every 2 hours.

E. Insulin

Once fluid resuscitation has occurred, only low doses of insulin are usually required. Be sure not to start insulin until the serum K is greater than 3.3 mg/dL because insulin will drop the potassium even further. Start with an initial insulin bolus of 0.1 unit/kg using Regular. Next, the infusion should start at 0.1 unit/kg/hour. (If you prefer, research shows that you can skip the bolus, but run the insulin infusion at 0.14 unit/kg/hour.[9]) If blood glucose decreases by 50-100 mg/dL/hour, then continue current insulin infusion. However, if blood glucose does not decrease by at least 50 mg/dL in one hour, bolus 0.1 unit/kg IV every hour until BG decreases by at least 50 mg/dL in one hour. If BG decreases by greater than 100 mg/dL/hour, then reduce insulin infusion rate by 50 percent. When BG reaches less than or equal to 200 mg/dL, reduce insulin infusion rate by 50 percent and add dextrose to IV fluids (see fluid recommendations).

Consider stopping the insulin infusion when the BG is <200 mg/dL, the serum bicarbonate level is ≥15 mEq/L and the calculated anion gap is ≤12 mEql/L. Subcutaneous insulin should be started two hours prior to stopping the insulin drip (see Transition from IV to Subcutaneous Insulin). If this is not done, there is a risk of severe hyperglycemia or even return to acidosis.

Some common mistakes with the insulin infusion include: 1) starting the insulin when the potassium is less than 3.3 mg/dL. 2) Stopping the IV insulin when the blood glucose is normalized but before the anion gap has resolved. 3) Stopping IV insulin prior to giving subcutaneous insulin.[2, 4-8]

Some research and new practices believe that an initial insulin bolus “priming” is not necessary. If this practice is preferred, then the insulin infusion should be started at 0.14 units/kg/hour.[9]

F. Bicarbonate

Studies of patients with a pH level of 6.9 or higher have found no evidence that bicarbonate is beneficial, and some studies have suggested bicarbonate therapy may be harmful for these patients. Because there are no studies on patients with a pH level below 6.9, giving bicarbonate as an isotonic solution still is recommended. Bicarbonate therapy lowers potassium levels; therefore, potassium needs to be monitored carefully.[18-20]

If included on an order set, the use of bicarbonate should be carefully worded. For example, *"Bicarbonate (HCO3) is usually not indicated but may be considered for the following situations: 1) Severe acidosis with pH less than 7, 2) Serum HCO3 less than 10 mEq/L or 3) Severe hyperkalemia with K greater than 6.5 with EKG changes or K greater than 7.0."*

G. Transition from IV to Subcutaneous Insulin

Transitioning from IV to subcutaneous insulin instructions should be included in your DKA order set or at least referral to another order set. There are multiple ways to transition, but this should be decided by your facility. See section on Transitions to see which protocol would work best for your facility.

H. Key Concepts and Best Practices

The treatment of DKA can be very complicated and includes frequent checking and changing of treatment throughout the process. Order sets can help standardize treatment to follow best practices. Table 1 outlines the recommended treatment of DKA. These steps should be included in any order sets that are created to treat DKA. In addition, a protocol or order set that aids in the continuation of treatment without frequent checking with the physician and nurse prevents interruption in the treatment of DKA. See attached order set examples that allow treatment to occur by nursing without frequent request for orders. Finally, treatment should begin in the ED upon recognition of DKA. This prevents worsening of the acidosis prior to getting to the ICU.

When creating order sets or protocols, it is best to include a multidisciplinary team. This assures that best practices are followed, and that it is usable by the end-user. The multidisciplinary team should include at least: physician, pharmacist, diabetes educator, ICU and ED nurses, and an administrator.

Table 1.

SUMMARY OF TREATMENT

Fluid Therapy

1. Initial Fluid Therapy: Normal Saline at 1 L/hr
2. Switch to Normal Saline or ½ Normal Saline at 250-500 mL/hr (based on corrected Na)
3. Switch to D5 ½ Normal Saline at 150-250 mL/hr when blood glucose reaches 200 mg/dL

Potassium Replacement

1. After initial fluid resuscitation, start 20-30 mEq/L until potassium is 5-5.2

Insulin

1. Bolus 0.1 mg/kg
2. Insulin infusion at 0.1 mg/kg/hr
   - If blood glucose does not decrease by at least 50 mg/dL in one hour, bolus 0/1 unit/kg IV every hour until BG decreases by at least 50 mg/dL in one hour
   - If BG decreases by greater than 100 mg/dL/hour, then reduce insulin infusion rate by 50%

Bicarbonate

1. Usually not recommended
2. But can consider for pH <7, HCO3 <10 or K >6.5 with EKG changes or K>7

EQUATIONS

Corrected Sodium

Measured Sodium + (Glucose mg/dL – 100) X 1.6 / 100

Or Estimated Corrected Sodium = add 2 mEq/L to the plasma sodium concentration for each 100mg increase of glucose above normal glucose concentration.

Anion Gap

Calculation without Potassium	Na – (HCO3 + Cl) =	Normal < 12
Calculation with Potassium	(Na + K) – (HCO3 + Cl) =	Normal < 16

Example of DKA Order Set

Adult DKA Order Set

References

[1]Freudenthal R, Tufton N, Podesta C, Mulholland R, Rossi M. Fluid Management in Diabetic Ketoacidosis. Are We Adhering to Recommended Guidelines? *British Journal of Diabetes & Vascular Disease.* 2013;13(3):138–142.

[2]Luzi L, Barrett EJ, Groop LC, Ferrannini E, DeFronzo RA. Metabolic effects of low-dose insulin therapy on glucose metabolism in diabetic ketoacidosis. *Diabetes.* 1988;37:1470–1477.

[3]DeFronzo RA, Matzuda M, Barret E. Diabetic ketoacidosis: a combined metabolic-nephrologic approach to therapy. *Diabetes Rev.* 1994;2:209–238.

[4]Kitabchi AE, Umpierrez GE, Murphy MB, Barrett EJ, Kreisberg RA, Malone JI, Wall BM. Management of hyperglycemic crises in patients with diabetes. *Diabetes Care.* 2001;24: 131–153.

[5]Kitabchi AE, Umpierrez GE, Murphy MB. Diabetic ketoacidosis and hyperglycemic hypersmolar state. In: *International Textbook of Diabetes Mellitus*, 3rd, DeFronzo RA, Ferrannini E, Keen H, Zimmet P (Eds), John Wiley & Sons, Chichester, UK 2004. p.1101.

[6]Kitabchi AE, Umpierrez GE, Murphy MB, Kreisberg RA. Hyperglycemic crises in adult patients with diabetes. *Diabetes Care.* 2006;29:2739–2748.

[7]Kitabchi AE, Umpierrez GE, Miles JM, Fisher JN. Hyperglycemic crises in adult patients with diabetes. *Diabetes Care.* 2009;32:1335–1343.

[8]Kitabchi AE, Umpierrez GE, Fisher JN, Murphy MB, Stentz FB. Thirty years of personal experience in hyperglycemic crises: diabetic ketoacidosis and hyperglycemic hyperosmolar state. *J Clin Endocrinol Metab.* 2008;93:1541–1552.

[9]Kitabchi AE, Murphy MB, Spencer J, Matteri R, Karas J. Is a priming dose of insulin necessary in a low-dose insulin protocol for the treatment of diabetic ketoacidosis? *Diabetes Care.* 2008;31:2081–2085.

[10]Kitabchi AE, Umpierrez EG, Miles JM, Fisher JN. Hyperglycemic crises in adult patients with diabetes. *Diabetes Care.* 2009;32:1335-1343.

[11]Umpierrez GE, Jones S, Smiley D, Mulligan P, Keyler T, Temponi A, Semakula C, Umpierrez D, Peng L, Ceron M, Robalino G. Insulin analogs versus human insulin in the treatment of patients with diabetic ketoacidosis: a randomized controlled trial. *Diabetes Care.* 2009:32;1164–1169.

[12]Nyenwe EA, Kitabchi AE. Evidence-based management of hyperglycemic emergencies in diabetes mellitus. *Diabetes Res Clin Pract. 2011;94:340-351.*

[13]Savage MW, Dhatariya KK, Kilvert A, et al. Joint British Diabetes Societies guideline for the management of diabetic ketoacidosis. *Diabet Med. 2011;28:508-515.*

[14]Hamdy O, Khardori, R. Diabetic Ketoacidosis Treatment & Management. *Medscape* .Oct 29, 2014.

[15]Bratusch-Marrain PR, Komajati M, Waldhausal W. The effect of hyperosmolarity on glucose metabolism. *Pract Cardiol.* 1985; 11:153–163.

[16]Middleton P, Kelly AM, Brown J, Robertson M. Agreement between arterial and central venous values for pH, bicarbonate, base excess, and lactate. *Emerg Med J* 2006;23:622.

[17]Murthy K, Harrington JT, Siegel RD. Profound hypokalemia in diabetic ketoacidosis; a therapeutic challenge. *Endocr Pract.* 2005;11:331–334.

[18]Viallon A, Zeni F, Lafond P, Venet C, Tardy B, Page Y, Bertrand JC. Does bicarbonate therapy improve the management of severe diabetic ketoacidosis? *Critical Care Med.* 1999; 27:2690–2693.

[19]Morris LR, Murphy MB, Kitabchi AE. Bicarbonate therapy in severe diabetic ketoacidosis. *Ann Intern Med.* 1986; 105:836–840.

[20]Latif KA, Freire AX, Kitabchi AE, et al. The use of alkali therapy in severe diabetic ketoacidosis. *Diabetes Care.* 2002; 25: 2113.

Patients undergoing surgery present a special challenge. They are faced with not only the physiologic and mental stress of surgery, but also the hazards of multiple handoffs across several care teams, all with different priorities and cultures. The importance of following principles of performance improvement and effective implementation cannot be overstated. We will echo some points made elsewhere in the *Guide* as we lay out the steps of effective implementation of perioperative glycemic control protocols.

A. Identify Key Players and Engage Them in the Process

Surgeons, anesthesiologists, hospitalists, intensivists, cardiologists, endocrinologists and primary care physicians may all be involved in the care of the perioperative patient. Engaging these physicians is of vital importance, whether they are part of your core glycemic control steering committee or not. Nursing, pharmacy and non-physician providers must also be a part of the process. It is particularly important to get the assistance of the nursing staffs from the multiple clinical settings the typical patient will see during the perioperative period. Make sure these individuals have an interest in your goal and are not unwillingly assigned. This will help improve your team success.

B. Understand the Process: How Do Patients Get From Home to the OR and Back Again?

There is marked variability across institutions (and often within institutions) in how a patient moves between surgical, anesthesiology and medical providers and between inpatient and outpatient settings. Your team needs to understand your own perioperative flow and procedures and to improve it when possible by answering several questions:

- Who does most of the preoperative medical evaluations?
- Do you have an integrated, single-site clinic that the great majority of patients go through (e.g., Cleveland Clinic model)? Or do you have multiple clinics? Or are the preoperative evaluations done in a variety of private offices?
- Is there a standardized process for triaging surgical patients who need more thorough preoperative anesthesiology, cardiology or medical evaluations? Or is it left to individual judgment?
- Are all the surgeries done at one site?
- How many and what types of surgeries are performed at your institution per month?
- Is there a perioperative/OR committee in place? How has it addressed patient flow, safety and standardization? Are protocols in place for perioperative antibiotics, beta-blockers, VTE prophylaxis and the like? If so, you can leverage the committee's efforts and integrate your glycemic control protocol with the broader perioperative protocol.
- Does anesthesia administer and monitor insulin infusions in the OR?
- What is the routine for monitoring glucose values in different care settings?

Focus on leverage: Do most patients have to travel a common pathway to the OR

Drawing a process flow map can be very helpful and may suggest areas where you can most efficiently focus your efforts. For example, you may find that 80% of patients going to the OR go through a pre-op anesthesiology clinic, whereas only half undergo a pre-op "clearance" evaluation in a variety of offices. The obvious implication would be to focus your efforts on early identification and mitigation of pre-op hyperglycemia in the common pathway areas, where you can initiate a standardized protocol more easily. The preanesthesia area and operative check-in areas are the last line of defense and a safety net for any patient who may have gotten through earlier evaluations without a glycemic control assessment.

If possible, identify and adjust therapy of patients with diabetes and hyperglycemia early

Patients with a history of diabetes or hyperglycemia on screening should have an HbA1c drawn or available and a history taken to assess their long-term glycemic control. Virtually all patients should be screened for hyperglycemia before they go to the OR, even if they are asymptomatic and have no history.

Ideally, patients would be diagnosed and treated for hyperglycemia for weeks to months before elective surgery, but obviously this is not always possible. Although no randomized controlled trials of this practice have occurred, many centers defer elective surgery of hyperglycemic patients with HbA1c elevated above a given level and even perform point-of-care HbA1c tests on hyperglycemic patients in pre-op clinic or on the day of surgery (if not previously obtained). Under this construct, a patient observed to have a reasonable HbA1c but have hyperglycemia on the day of surgery would be considered to have stress hyperglycemia and could still go to the OR after acute hyperglycemia was controlled with insulin, whereas a patient with a markedly elevated HbA1c and hyperglycemia would be considered at risk for oxidative stress and impaired wound healing and may have surgery deferred. At this point, communication with the patient's primary caregiver is important to help modify their diabetes treatment plan.

The process of screening patient populations does not end when patients enter the system, as the stress of surgery, medications, TPN and other factors can initiate hyperglycemia even after admission. Your team needs to make sure it is part of the routine procedure to check glucose levels at transitions of care or when factors that can change insulin requirements are introduced.

Introduce and implement perioperative glycemic management protocol

The bare bones of a perioperative glycemic control protocol are not unduly complicated, as you can see by the sample protocols that follow. The difficult part of the protocol is not writing it, but trying to make sure the steps occur with a high degree of reliability. In the end, protocols will make the task easier with more consistency of care. Also, your team needs to work on linking this protocol to all of the other related protocols in your institution, such as the insulin infusion and subcutaneous insulin protocols. Achieving glycemic control in the OR is of less value when rampant hyperglycemia occurs when the patient goes to the PACU, ICU or non-critical ward or leaves the hospital. So paying attention to all these areas and the transitions between them is critical. Integrate the guidance from your protocol into order sets, check sheets and the fabric of frontline care (see samples of perioperative guidelines below).

C. Pre-Operative Management

Pre-Operative Screening: HbA1c should be checked in all patients with diabetes instead of diabetic patients. Also consider checking an HbA1c in patients with a BMI over 30 or age over 40 years. An elevated HbA1c represents uncontrolled diabetes which can cause oxidative stress and poor wound healing.[1-7] Patients who are being considered for elective surgery and have an elevated HbA1c may benefit from improved glucose control by working with their primary care physician or endocrinologist. An HbA1c goal should be set for elective surgeries. Some facilities set a goal of 8.5 percent, but there is no published research to support this number.

Educate Patients: Patients who are coming from the outpatient setting need to be educated about their diabetic medications and nutrition prior to surgery. Creating a handout may be helpful to confirm a good understanding of what medications should be taken the night before and morning of surgery. It should also address food intake and treatment of hypoglycemia. This can be given to the patient on a pre-op visit. Although research is not strong, current guidelines recommend that oral antidiabetics and noninsulin injectables should not be taken on the day of surgery. Also, consider changing insulin dosing.[11-13]

Insulin	*Day before Surgery*	*Day of Surgery*
Long-acting, peakless	No Change	75-100% of morning dose
Intermediate-acting	75% of evening dose	50-75% of morning dose
Fixed-combination	No Change	50-75% of morning dose
Short- or rapid-acting	No Change	Hold the dose

Upon Arrival: A pre-op management order set helps the nurses and physicians manage the diabetic patient just prior to surgery. It is not uncommon for the patient to experience malglycemia prior to surgery since they are not taking their usual diabetic medications and not on their usual diet. The patient may also experience stress hyperglycemia. The order set should be tailored to your facility. It should include the desirable blood glucose target range. It should also give directions on when and how to correct hyper- and hypoglycemia. Correction scales should be given as well as a protocol for rechecking blood glucose until it is normalized.[13-17]

D. Intra-Operative Management

Prior to the surgery or procedure, a plan should be made regarding where blood sugars will be checked and how blood glucose will be controlled. For short procedures, subcutaneous insulin can be used. For longer procedures or type 1 diabetics an IV insulin drip should be considered. An intra-operative management order set helps the anesthesiologist with glycemic control during the surgery or procedure. The order set should include blood glucose goals and directions for a continuous insulin infusion. It should also include treatment for hypoglycemia and transitioning from IV to subcutaneous insulin if an insulin infusion is used. Many published order sets use a goal of 100-180 mg/dL, with 100-150 mg/dL for special populations such as cardiac surgery.[12-15]

E. Post-Operative Management

A good history of blood glucose results and insulin treatment should be given to the post-operative staff. There should also be a continuation plan for future treatment, such as transition to oral medications, treatment with subcutaneous insulin or continue the IV insulin infusion. This plan should be communicated to the staff and the patient. Post-operative nausea and vomiting should be controlled to promote oral intake when appropriate.

Focus on handoffs and communication issues at all transitions

Most errors occur during transitions in care. The team should really focus on all areas where information is exchanged and the patient changes hands from one care team to the next. Put a lot of thought into the processes around these handoffs, looking for methods to make the communication as standardized and reliable as possible. Creation of a standardized handoff report may be beneficial.

Patient monitoring

It is recommended to create a system to record blood glucose results, treatment and time. This will differ by facility, especially depending upon the use of electronic versus paper charting. Some recommended times to check blood glucose include upon arrival to the pre-op area, prior to the induction of anesthesia or prior to incision, upon awaking

from anesthesia and on transfer to post-op. For longer surgeries, check blood glucose every hour, especially if on insulin infusion. Check more frequently if hyper- or hypo treatment was required, i.e., every 15 minutes.[14]

Work at making everybody's job easier, as you ask them to do more

Perioperative glycemic monitoring and ensuring the protocol is followed can be labor intensive. Your team should spend at least as much time on making this work simpler to do, understand and document as you do in creating the protocol in the first place. Ask your frontline workers for feedback and suggestions on how to make this happen. Pilot various parts of your protocol before rolling it out on a wide scale.

Triggers for involvement of a glucose management team or for automatic consultation with endocrinology or internal medicine may be appropriate, especially for high-risk patients such as transplant patients or CABG patients.

Monitor reliability of your protocol and the glycemic control obtained with it; identify and mitigate oversights

As we've stressed throughout the *Guide*, implementing your protocols is really just a starting point. If you wish to achieve excellent perioperative glycemic control, you will need to monitor your results for glycemic control, safety and compliance with recommended protocol strategies. When variation or poor results occur, the team should scrutinize the incident and look for the root systemic causes of the problems. Does there need to be focused education, a change in process or the addition of a redundant double-check to make sure a key step occurs? Or is the variation from your protocol happening because some aspect of it is not user friendly or because the needs of a particular patient were not met?

Best Practices

PERI OP AND PERI-PROCEDURE ORDERS

General rules

- Procedures should preferably be scheduled for the early morning to have the least impact on insulin dosing. (If not practical, bring patient to hospital/procedure suite in the early AM for glucose monitoring, etc., until procedure.)
- BGs should be checked every 1-2 hours before, during, and after procedure.
- Use of insulin sliding scale as the only insulin is discouraged because of greater likelihood of wide BG fluctuations.
- Favor subcutaneous administration of insulin to achieve and maintain target glucose levels rather than IV insulin in the ambulatory patients undergoing short procedures. IV insulin should be used for patients undergoing long procedures.
- Infusion insulin preferred for patients with major surgery requiring prolonged NPO status.
- Provide clear and consistent instructions regarding plans to return to preoperative antidiabetic regimen and management of potential hypoglycemia.
- Order sets should include instructions to transition from IV to subcutaneous insulin.
- Order sets should include instructions to treat hyperglycemia and hypoglycemia.
- Triggers should be set for involvement of a glucose management team or for consultation with endocrinology or internal medicine, especially for high-risk patients such as transplant patients or CABG patients.
- Preoperative Screening
  - Check HbA1c in all patients with diabetes within 90 days of surgery.

- Preoperative Management
  - Glucose target 100-180 mg/dL
  - Treat with IV or subcutaneous insulin for BG >180 mg/dL
- Intraoperative Management
  - Make plans to use subcutaneous or IV insulin infusion to correct hyperglycemia
  - Keep blood glucose between 100-180 mg/dL or 100-150 mg/dL for cardiac surgery
- Postoperative Management
  - Check BG upon arrival to post-op
  - Give clear history of blood glucose results, treatment and response
  - Create a plan for discharge home versus hospital room

Type 1 diabetes

- Need insulin at all times, even if NPO. Can become ketotic within 12-24 hours if basal insulin is held (even if BG <250 mg/dL).
- Recommend starting insulin drip (maintenance rate of 1-2 units/hour) with D5W at 75-100 cc/hour, adjusted to maintain BG 100-180 mg/dL.
- If patient is on glargine or detemir, give usual dose of basel insulin the day before and day of surgery, although to provide a safety margin, especially for those under tight control, a reduction in dose of about 20% is reasonable on day of surgery.
- For patients on NPH, give between half and two-thirds on the morning of procedure.
- Do not give short-acting insulin (e.g., lispro, aspart, glulisine) unless BG >200 mg/dL and then in small doses (1-4 units to achieve BG 100-180 mg/dL).

Type 2 diabetes

When patient is NPO, BGs tend to improve. Should not become ketotic if insulin held, although hyperglycemia may result.

- If on an oral agent that can result in hypoglycemia (sulfonylurea, DPP4 inhibitors or other insulin secretagogues), hold medication on day of procedure and resume when tolerating normal diet.
- For other oral agents that do not result in hypoglycemia:
  - Metformin must be held for safety concerns (i.e., possible decrease in renal function peri-op). Regular metformin (Glucophage®) can be held beginning on day of procedure; the sustained-release formulation (Glucophage® XR) should be held beginning evening before procedure. Metformin can be resumed 48 hours post-op after normal renal function is secured.
  - α-Glucosidase inhibitors should be held (only work when taken with meals).
  - If pills allowed, thiazolidinediones (TZDs) can be continued (although missing a dose or two should not affect glycemic control, because of the long duration of action of TZDs).
  - If on a GLP-1 agonist (exenatide), hold until patient is eating normally.

- If on insulin:
  - If patient on glargine or detemir, give usual dose day before and day of surgery, although to provide a safety margin, especially for those under tight control, a reduction in dose of about 20% is reasonable on day of surgery.
  - Give half of NPH on the morning of procedure
  - Place on insulin drip (maintenance rate of 1-2 units/hour; those taking large insulin doses at home may require more) with D5W at 50-75 cc/hour, adjusted to maintain BG 100-150 mg/dL.
  - Do not give short-acting insulin (e.g., lispro, aspart, glulisine) unless BG >200 mg/dL and then in small doses (1-4 units to achieve BG 100-150 mg/dL).

References

[1]Drange AS, Perkal MF, Kancir S, Concato J, Aslan M, Rosentahl RA. Long-term glycemic control and postoperative infectious complications. *Arch Surg.* 2006;141:375–80.

[2]Kao LS, Meeks D, Moyer VA, Lally KP. Peri-operative glycemic control regimens for preventing surgical site infections in adults. *Cochrane Database of Systematic Reviews.* 2009;3: CD006806.

[3]Wiener RS, Wiener DC, Larson RJ. Benefits and risks of tight glucose control in critically ill adults: a meta-analysis. *JAMA.* 2008;300:933–44.

[4]Latham R, Lancaster A, Covington J et al. (2001). The association of diabetes and glucose control with surgical-site infections among cardiothoracic surgery patients. *Infect Control Hosp Epidemiol.* 2001;22(10):607–612.

[5]Swenne CL, Lindholm C, Borowiec J et al. (2005). Peri-operative glucose control and development of surgical wound infections in patients undergoing coronary artery bypass graft. *J Josp Infect.* 61:201–212.

[6]American Diabetes Association. Standards of medical care in diabetes—2009. *Diabetes Care.* 2009;32:S13–61.

[7]Nathan DM, Buse JB, Davidson MB, Ferrannini E, Holman RR, Sherwin R, Zinman B (2009) American Diabetes Association, European Association for Study of Diabetes Consensus Committee. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care.* 32:193–203.

[8](1998). Standards of medical care for patients with diabetes mellitus. *Diabetes Care.* 21 (Suppl 1):23S–31S.

[9]Cohen O, Dankner R, Chetrit A. et al (2003). Multidisciplinary intervention for control of diabetes in patients undergoing coronary artery bypass graft (CABG). *Cardiovasc Surg.* 11(3):195–200.

[10]Lauruchskat A. (2005). Prevalence and risks of undiagnosed diabetes mellitus in patients undergoing CABG. *Circulation.* 112(16):2397–2402.

[11]Meneghini, LF, (2009). Perioperative management of diabetes: translating evidence into practice. *Cleveland Clinic Journal of Medicine.* 76:S53–S59.

[12]Griesdale DEG, de Souza RJ, van Dam RM, Heyland DK, Cook DJ, Malhotra A, Dhaliwal R, Henderson WR, Chittock DR, Finfer S, Talmor D. (2009). Intensive insulin therapy and mortality among critically ill patients: a meta-analysis including NICE SUGAR study data. *CMAJ.* 180:821–7.

[13]Joshi G, Chung F, Vann M, Ahmad S et al. (2010). Society for ambulatory anesthesia consensus statement on perioperative blood glucose management in diabetic patients undergoing ambulatory surgery. *Anesthesia & Analgesia.* 111:1378–1387.

[14]Wong J, Zoungas S, Wright C, Teede H (2010). Evidenc-based guidelines for perioperative management of diabetes in cardiac and vascular surgery. *World J Surg.* 34:500–513.

[15]Pichardo-Lowden A, Gabbay, RA (2012). Management of hyperglycemia during the perioperative period. *Curr Diab Rep.* 12:108–118.

[16]Vann MA. Perioperative management of ambulatory surgical patients with diabetes mellitus. *Curr Opin Anesthesiol.* 2009;22:718–24.

[17]Sato H. Carvalho G. Sato T. (2010). The association of preoperative glycemic control, intraoperative insulin sensitivity, and outcomes after cardiac surgery. *J Clin Endocrinol Metab.* 95(9):4338–4344.

[18]Polk HC Jr. Renewal of surgical quality and safety initiatives: a multispecialty challenge. Mayo Clin Proc 2006;81:345–52 5. Moghissi ES, Korytkowski MT, Dinardo M, Einhorn D, Hellman R, Hirsch IB, Inzucchi SE, Ismail-Beigi F, Kirkman MS, Umpierrez GE. Am Association of Clinical Endocrinologists and Am Diabetes Association consensus statement on inpatient glycemic control. *Diabetes Care.* 2009;32:1119–31.

Section V.7: Improving Reliability of Care across Transitions: Into, Within and From the Hospital

A. Introduction

The position statement of the Inpatient Diabetes and Glycemic Control: A Call to Action Consensus Conference identified one of the barriers to inpatient glycemic control as "Patients frequently move across a spectrum of care providers and geographic locations during a single inpatient stay, entailing multiple handoffs, communication challenges, and opportunities for error. The complexity of the task of achieving safe handoffs and consistency in the approach across this spectrum of care is a significant challenge."[1]

This section will discuss several components of the complex topic of transitions. Part A discusses the specific details of transitions that lead to changes in therapy for inpatients with hyperglycemia including:

- Emergency department (ED) to inpatient ward
- Home to hospital
- Transitioning off of insulin infusion: timing, selecting insulin types and doses, daily adjustments and strategies
- Transitions around tube feedings
- Transitioning to home: re-starting home oral agents, adjusting home therapy and adding insulin

**Note: Transitions around perioperative care are covered in Section V.6.*

Part B addresses some of the tools and tips for provider to provider handoffs.

B. Specific Patient Transitions in Hyperglycemic Therapy

Evidence-based protocols for high-risk transitions including conversion from insulin infusion to intermittent subcutaneous insulin, perioperative care and post-discharge conversion should be created, used and monitored.[2,3] This section will discuss these and other specific transitions in detail.

Emergency Department to Inpatient Ward

Care in the Emergency Department (ED) is often focused on urgent issues that detract attention from managing hyperglycemia. However, hyperglycemia is common and inpatients often have their hospital stay begin with initial treatment in the ED. Initiation of protocols for management of hyperglycemia have been successful in reducing mean blood glucose in the ED without increasing hypoglycemia or length of stay. For those admitted, they also reduced mean blood glucose during the inpatient stay by linking the ED treatment and inpatient protocols.[4,5] This can be best accomplished by initiating the inpatient protocols and following them accurately as soon as the decision has been made to admit. ED stays can be long while patients wait for beds but all inpatients should have the same targets and protocols regardless of their physical location.

Home to Hospital

As discussed in the subcutaneous insulin section, The Endocrine Society Clinical Practice Guidelines published in 2012 recommend that when patients are admitted to the hospital, their outpatient hyperglycemic therapy be transitioned to insulin therapy for the majority of patients.[6] While this leads to a transition in therapy, it is necessary to provide the flexibility with variable oral intake, changing daily requirements and new or temporary contraindications to prior therapy.

While this is a "one size fits all" for the type of therapy, the initial doses should use the information gained from review of the prescribed home medications, medication adherence and outpatient control as measured by the HbA1c and frequency of hypoglycemia. The Guidelines recommend that patients treated with insulin prior to admission have their regimen temporarily modified as a way to reduce the risk of hypoglycemia. This modification can take a variety of forms and includes changing from fixed split or basal only to basal/bolus, adjustments to the total daily dose, and adjustments in the basal insulin to more closely mimic physiologic insulin with approximately 50 percent basal and 50 percent nutritional to maximize flexibility. The following are several examples of appropriate modifications:

- **Example 1:** A patient with a HbA1c of 14 percent has been having their insulin doses escalated by their PCP for the last six months and are now on >100 units of basel insulin. Based on this and the interview, you suspect non-adherence. Weight-based estimates or half of their home dose would be an appropriate start.
- **Example 2:** A patient with a HbA1c of 8percent on a daily dose of 80 units of basal insulin a day who seem adherent. and well controlled at home in that they describe in detail their home regimen and diet and have very rare hypoglycemia. A total daily dose of 80 units will be used but the type of insulin changed to be 50 percent basal and 50 percent bolus at meals to allow flexibility for variable nutritional and changing needs in the hospital.
- **Example 3:** A patient with an HbA1c of 10 percent recently started on basal insulin in addition to his oral agents. He is still on 10 units of long-acting insulin daily and has had no titration. Home blood glucose values have been above goal. His TDD insulin is 10 units but his needs are greater and the home dose just hasn't been titrated up properly yet. In this case, using weight-based dosing is more appropriate than using his home TDD that is still so low because it has just been initiated.[7] This patient is also on several oral agents which will be held upon admission to the hospital, so this is another reason why his insulin requirements in house will be higher than his home 10 units.

Most importantly, although the home regimen will be changed to fit into the institutional order sets and maximize flexibility, the plan at discharge has to be actively reviewed and is a very separate decision from what therapy to select on admission.

Transitioning Off Insulin Infusion:

After a period of moderate glycemic control for patients on insulin infusions, the transition to subcutaneous insulin is a time of high risk of loss of glucose control and deserves special mention. Guidance for managing this transition may be integrated into your insulin infusion and subcutaneous order sets or managed by a specific team/interdisciplinary member (e.g., pharmacist) who develops comfort and expertise in making the conversion. Regardless of who will be specifically responsible for the transition, the timing, selection of insulin types and doses, and daily adjustments will need to be considered.

Timing: Providers and patients might be anxious to discontinue insulin infusions due to the associated workload. However, patients who are intubated and sedated are unable to display signs of hypoglycemia, subcutaneous insulin absorption is unpredictable in patients in shock and their insulin requirements change quickly while critically ill.

Therefore, critically ill patients should be assessed for transition from IV to subcutaneous insulin when they meet the following criteria:

- no IV vasoconstricting medication infusing
- stable blood glucose values within the desired target
- no longer intubated
- able to tolerate a meal or other nutritional intake

Consideration may be made to avoid transition during the night because of the absence of a meal, and/or reduced staff availability to address questions, and it may result in additional testing and injections during the hours of sleep.

To prevent recurrence of hyperglycemia during the transition period to subcutaneous insulin, it is important to allow an overlap between discontinuation of IV insulin and the administration of subcutaneous insulin. The first dose of basal insulin should be given two to three hours before the insulin infusion is discontinued.[8] However, because Lepore et al. found that the full effect on glycemic control is not seen for four hours and this overlap has been an area of non-adherence in several studies, some institutions have begun to turn off the drip and give 10 percent of the basal dose as rapid-acting insulin along with the dose of basal.[9] Other guidelines recommend giving a dose of short or rapid-acting insulin one to two hours prior to discontinuing the insulin infusion.[8,10,11] This is often well timed by transitioning around a meal. Long-acting insulins without a peak can be given every 24 hours and have been demonstrated in ambulatory studies to not need to be given at the standard HS time.

Selecting insulin types and doses: Just as infusion protocols do not differ for those with diabetes and those without, transition protocols also safely estimate initial insulin needs for both populations.[12,13,14,15] All patients with type 1 diabetes and most patients with type 2 diabetes treated with oral antidiabetic agents or insulin therapy before admission require transition to subcutaneous long- and short-acting insulin. However, as a measure of safety, guidelines suggest that patients without a history of diabetes on infusions at an average rate of 1-2 unit/h or less at the time of transition be transitioned to correction insulin only initially and then adjusted thereafter.[6,16] In summary, patients with known diabetes and those with new hyperglycemia on higher infusion rates (>1-2 units/hr) should be transitioned to scheduled subcutaneous insulin.

Most transition protocols use the average infusion rate in the last six to eight hours to estimate a 24-hour requirement or total daily dose (TDD). This dose is reduced by 20 percent to account for the expected decrease in requirements given improvement in their clinical condition. In patients who are eating, receiving tube feeds or TPN at the time of transition, the TDD should be divided into 50 percent basal and 50 percent nutritional. The division of the TDD into nutritional and basal components helps to prevent hypoglycemia in the case of the sudden resolution of insulin resistance and also allows flexibility for variable nutritional intake. One final component that many protocols include is a maximum TDD or basal insulin dose. This provides a measure of safety when the insulin infusion may have overestimated actual needs (i.e., infusion delivery problems, increased insulin sensitivity because of improving illness and decreasing dextrose-containing IV fluids). Another strategy for dealing with this is to have all doses over a certain amount be reviewed by a local expert (pharmacist, nursing champion or physician) to assure that they are correct. Many commercially available insulin infusion protocols also include transition dosing components but they are also largely based on the same principles.

Daily adjustments: One of the significant concerns about the use of scheduled insulin is the perceived risk for hypoglycemia. Each of the transition studies demonstrated low rates (1-12 percent depending on definition) and no increase compared with standard practice. However, most of the studies only evaluated the first 48 hours of transition.[17] Nonetheless, given that the patient's clinical status will continue to improve, diligent attention to their daily glucose values is essential to prevent hypoglycemia. Guidelines recommend decreasing the TDD by 20-30 percent if any values are <10mg/dL and about 50 percent if < 70mg/dL.[18] If patients are hyperglycemic, the TDD should be increased by 10 percent. The distribution of insulin should be reapportioned each day to approach a distribution of 50 percent basal and 50 percent nutritional. See the section on hypoglycemia prevention and management for additional details.

Specific strategies for implementation from IV to subcutaneous:

Critical to realizing the benefits of adequate doses and timing during the transition from IV to subcutaneous insulin is an effective strategy for implementation. The best strategy for your institution will depend on the resources and acceptable option for your providers but some options include:

1. Have a separate order set for the IV to subcutaneous transition that includes both medication dosing and the nursing orders. This is preferred and most reliable.
2. Have an order in the infusion protocol that triggers a phone call to a pharmacist or the diabetes management team when the transition criteria are met and they will then handle conversion.
3. Include conversion orders on the original IV insulin infusion order.
4. Include the conversion orders and/or dosing guidelines as part of the standard subcutaneous protocol your team develops for general medical ward patients.

Options 1, 3 and 4 above could all include an EMR-based calculator to determine insulin types and doses based on insulin gtt rates. Additionally, adding nurse-driven checklists with the criteria for transitioning to the orders is a strategy to add reliability into the timing and dosing. Whichever option you choose, be sure to review the specific policies, guidelines and algorithms to ensure that all areas are given uniform instructions.

Transitions around Tube Feedings

Several effective options to standardize the transitions during tube feeding are:

1. Include tube feeding instructions on the same insulin protocol form as that used for patients who are eating, with additional instructions for tube feedings.
2. Have a separate order set for continuous tube feeds. Some hospitals then transition them to a protocol for various other scenarios (i.e., insulin protocols for planned stop of tube feeding, for adult receiving continuous tube feed plus liquid diet, and for adult receiving continuous tube feed plus solid oral diet).

Adding additional orders (either in one large order set or as part of separate order sets) provides specific instructions for unique situations but also adds complexity that will require additional planning and education. Important components of orders for patients on tube feeds include:

- Instructions that basal insulin should not exceed 50 percent of the total daily dose of insulin. This provides a measure of safety if tube feedings are stopped.
- Instructions for if tube feeds are stopped: Orders that rely on nursing to notify a physician of tube feeding being stopped are generally not proscriptive enough because the physician may also be distracted by other changes or forget that the patient is on long-acting insulin. One way to possibly build in more safety is to include automatic substitution of IV dextrose in place of enteral feedings. Some methods for doing this are:
  - *Begin D10 intravenous fluids at the same rate as tube feedings if the latter are interrupted and glargine has been given within the last 24 hours and then discontinue IV dextrose-containing fluids 24 hours after last dose of glargine and 12 hours after last dose of NPH or when enteral nutrition is restarted.*
  - *Notify primary service of this plan so patient's fluid status and prior glucose control may be considered.*
  - *Check blood glucose two hours after tube feeds are discontinued, do not cover with supplemental insulin and call physician to adjust rate or concentration of dextrose drip.*
  - *More frequent blood glucose monitoring during the transition to identify trends early.*

Transitioning to Home

The large majority of times, the inpatient regimen will not be continued at discharge. The recommendations for inpatient therapy favor flexibility and reliability so that staff and systems can become standardized. However, at the time of discharge, the anti-hyperglycemic therapy must be patient-centered.[19,20] Key factors among patients to consider in determining the discharge therapy include:

- Patient goals
- Life expectancy
- Prior outpatient regimen and control
- Current inpatient therapy and control
- Risk factors or contraindications to specific types of therapy
- Patient education and understanding
- Physical factors like vision, amputation
- Closeness of follow-up and blood glucose testing/monitoring
- Cost of all components (medications, testing supplies, follow-up, etc.)

Beginning on hospital day one, information including the HbA1c should be included with patient factors to determine the optimal home regimen. The HbA1c can be used to define the patient's diagnosis (i.e., stress-induced hyperglycemia vs new diagnosis of diabetes in a patient with new hospital hyperglycemia) and assess their control prior to admission.[21,22] **For patients with known diabetes and acceptable preadmission glycemic control without new contraindication, the preadmission anti-hyperglycemic regimen should be resumed.** This will be something that needs to be emphasized during education of providers as there is often inertia to continue the inpatient regimen when unnecessary. For those not at goal, there are several algorithms to guide adjustments in therapy for patients with DM across the course of their chronic disease.[18,23] They all include a foundation of recommending intensive lifestyle modification and metformin for all patients who can tolerate it. Many of the other details of the recommendations favor different aspects—safety, volume of evidence supporting, impact of therapy on patient weight, general acceptability for patients or cost. Overall, each additional therapy improves the HbA1c by 0.9-1.1 percent so when HbA1c is far from goal, dual or triple therapy may be necessary. Together these guidelines can be considered in the context of the patient-specific factors to determine the discharge plan:

HbA1c	New hyperglycemia	Known DM prior to admit
<5.7 percent	Stress-induced Hyperglycemia: follow as an outpatient with a GTT and fasting blood glucose	Assess pre-admit hypoglycemia and de-escalate home regimen if present
5.7-6.4 percent	Pre-Diabetes: AACE algorithm recommends the addition of metformin or acarbose vs. TZDs or GLP1-RA for those with multiple risk factors	Controlled DM
6.5-7.4 percent	Newly-diagnosed Diabetes: lifestyle + metformin	Controlled DM
7.5-9.0 percent	Newly-diagnosed Diabetes, uncontrolled Mono or Dual therapy	Uncontrolled DM: Dual therapy
>9 percent	Newly-diagnosed Diabetes, uncontrolled Double or Triple therapy	Uncontrolled DM: Triple therapy
>10 percent	Newly-diagnosed Diabetes, uncontrolled *metformin + basal/nutritional insulin preferred especially if symptoms. After glucose toxicity resolved, may be able to transition to po.	Uncontrolled DM: *metformin + basal/nutritional insulin preferred until glucose toxicity resolved

Diabetes is a chronic and progressive disease requiring continuous adjustments in therapy over time with many patients eventually requiring insulin therapy to achieve goals. Therefore, small steps toward improvement in control achieved around the time of discharge (e.g., education, use of insulin, addition of monitoring or added steps to therapy) may be the first or next step toward goals.[24,25,26] Given the high risks around this transition, safety should take priority and the step-up of therapy match with patient characteristics. "Less is more" when considering how much to escalate therapy and the multidisciplinary team planning education must consider that the same clinical inertia that is a known barrier to escalating therapy in outpatients with DM can lead to inappropriate continuation of basal + nutritional + correction therapy at discharge. This should be monitored and actively prevented given the risk to patients.

Starting oral anti-diabetes drugs: Oral anti-diabetes drugs are usually held while a patient is admitted to the hospital because of the transient occurrence of contraindications and the inability to rapidly titrate to achieve glycemic goals. Once medical conditions are improved, oral intake is established and renal function stabilized, oral agents can be restarted. This is generally done on the day of discharge or the first day home.

Transitioning to insulin +/- other

For patients who will have insulin as part of their outpatient therapy, guidelines suggest that the new insulin regimen be instituted at least one day prior to discharge to allow assessment of the efficacy of the transition.[1] If this is not feasible, options include accepting less stringent glycemic control during the initial period of transition, using a lower initial dose of basal insulin, using rapid-acting insulin for correction doses, increased monitoring by the patient and close outpatient follow-up.

If patients are going to be discharged on basal insulin in addition to other agents, there are several options to determine the dose:

1. Discontinue mealtime bolus insulin but continue the same dose of basal insulin.
2. Start 10 units qhs.[27]
3. Start 0.1-0.3 units/kg qhs of basal.

Once discharged, the long-acting insulin dose can be safely increased in patients with creatinine <2 mg/dL every three days by two units if the a.m. fasting blood glucose is still >100 mg/dL.[27, 28]

If patients are going to be discharged on basal + nutritional

1. Continue QID hospital basal + nutritional doses. (Note: if the specific type of basal or nutritional insulin switches to another analog at discharge, that should be able to be 1:1 conversion. If switching to intermediate and short-acting insulins, dose adjustments will be necessary to consider the peak.)
2. Continue hospital basal + one nutritional dose per day with the largest meal of the day.
3. BID Split mixed insulin such as 70/30 or 75/25.

If the patient is being discharged on nutritional insulin coverage, insulin secretagogues should be discontinued.

Physicians will also need to assure that patients have all of the necessary supplies to administer insulin. This is served well by having a "discharge insulin order set" to group common diabetic supplies and needs at discharge. Supplies that must be included are:

- Insulin (vials or pens)
- Syringes or pen needles, if needed
- Blood glucose meter and strips
- Lancets and lancing devices
- Urine ketone strips (type 1 diabetes)
- Glucagon emergency kit (insulin treated patients)
- Medical alert application/charms

Follow-up and Discharge Documentation

Regardless of the discharge medical regimen, plans should include call parameters that would intercept a downward or upward trend of blood glucose (see the Education Section, V.8) and clear discharge follow-up recommendations. Any patient started on insulin at the time of discharge should be followed up at least by phone call within one week and others within one month.

At the time of discharge, complete written documentation to safely and effectively facilitate change in care environments and communicate with care providers is essential. Medication lists with changes introduced during hospitalization, reference to the patient's glycemic control and suggestions for outpatient treatment and follow-up should all be part of the discharge information. The patient's readiness and capability to assume an active role in his or her care should be evaluated and shared with the outpatient provider (see the Education Section, V.8).

Close follow-up is imperative when any changes in medication are made. Blood glucose initially should be measured at least twice a day to help minimize the risks.

Summary

Because discharge is a high-risk transition even with lower risk medications and conditions, the vulnerability around this time is even more significant when considering anti-diabetic medications.

- When patients are admitted to the hospital, their outpatient hyperglycemic therapy should be transitioned to basal/nutritional/correction insulin therapy.
- Patients with known diabetes and those with new hyperglycemia on higher infusion rates (>1-2 units/hr) should be transitioned to scheduled insulin using the infusion rate to estimate the TDD.
- Daily adjustments are essential following transition from IV to subcutaneous insulin given that dose requirements change rapidly with the improvement in critical illness.
- For patients with known diabetes and acceptable preadmission glycemic control without new contraindication, the preadmission anti-hyperglycemic regimen should be resumed at discharge.
- Given the high risks around this transition, safety should take priority and the step-up of therapy should match with patient characteristics. "Less is more" when considering how much to escalate therapy.
- Medication lists with changes introduced during hospitalization, reference to the patient's glycemic control and suggestions for outpatient treatment and follow-up should all be part of the discharge information.
- Close follow-up is imperative when any changes in medication are made. Blood glucose initially should be measured at least twice a day to help minimize the risks. Patients discharged on insulin should have follow-up within the first week.

C. Provider to Provider Handoffs

The Joint Commission and many specialty societies have identified transitions of care as an important area to develop tools and resources (http://www.jointcommission.org/toc_resources_and_tools.aspx) and your organization likely adopted a standardized approach to handoff communication, such as "SBAR."[29]

Issues for your team to consider:

What kind of standardized approach for handoffs is used in your institution?

- *Does it include standard prompts specific for patients with hyperglycemia. This should include recent doses of insulin, recent blood glucose values, prior hypoglycemia and predisposing factors for hypoglycemia (specifically, recent change in caloric intake or oral hypoglycemic medications or new renal failure; see previous sections of the Guide for a full description).*

How is report given? Consider all areas of transition. Some important ones are:

1. Emergency department to inpatient unit.
2. From emergency department or ward to procedures (e.g., cardiac catheterization, radiology services, endoscopy).
3. Perioperative transitions (the pre-op holding area, then to the operating room, to the postanesthesia care unit and finally to the surgical/medical ward or intensive care unit).
4. During nursing shift change.
5. From physician to physician (at change of shift, at change of a rotation, before vacation).
6. Discharge to outpatient primary care follow-up, skilled nursing facility, rehabilitation facility or transfer to another hospital.

Medication Reconciliation: You cannot talk transitions without closely linking to the process of medication reconciliation. Spend time understanding the workflow for medication reconciliation for inpatients at your facility. This is essential in the care of hyperglycemic patients because the total daily dose of insulin in a day is used to determine the following day's dose. Caregivers should be aware of recent medication changes as a patient transfers from one care setting to another so they can anticipate new hypo- or hyperglycemia. In addition, physicians consider the home regimen and prior glycemic control to determine if changes in medications are necessary at discharge.

Issues for your team to consider:

- *How are medications reconciled throughout a hospitalization?*
- *Who does it?*
- *Are there organization-wide documents that govern consistent practice and articulate the hospital's expectation that staff will cooperate with that practice?*
- *Do such documents specifically prompt caregivers to report recent insulin doses (or other diabetic medications), recent blood glucose values, history of hypoglycemia and risk factors for hypoglycemia?*

D. Conclusion

Transitions of care are a high-risk aspect of patient care and deliberate, well-planned approaches to each of the key areas is necessary to maintain safe glycemic control.[30] Attention needs to be paid to specific components of the transition and to fit those procedures into the current workflow and practices of your institution.

References

[1]Garber AJ, Moghissi ES, Bransome ED Jr, et al., American College of Endocrinology Task Force on Inpatient Diabetes Metabolic Control. American College of Endocrinology position statement on inpatient diabetes and metabolic control. *Endocr Pract.* 2004;10:77–82.

[2]Cobaugh DJ, Maynard G, Cooper L, et al., Enhancing insulin-use safety in hospitals. Practical recommendations from an ASHP Foundation expert consensus panel. *Am J Health-Syst Pharm.* 2013:Vol 70.

[3]American Society of Health System Pharmacists and the Hospital and Health System Association of Pennsylvania. Recommendations for safe use of insulin in hospitals. 2005. Available at: http://www.ashp.org/s_ashp/docs/files/Safe_Use_of_Insulin.pdf. Accessed March 28, 2015.

[4]Jennifer B, Bernard JB, Munoz C, Harper J, Muriello M, Rico E, Baldwin D. Impact of a subcutaneous insulin protocol in the emergency department: Rush Emergency Department Hyperglycemia Intervention (REDHI) ED to inpatient. *J Emer Med.* 2011;40(5):403–408.

[5]Bernard JB, Munoz C, Harper J, Muriello M, Rico E, Baldwin D. Treatment of Inpatient hyperglycemia beginning in the emergency department: A Randomized Trial Using Insulins Aspart and Detemir Compared With Usual Care. *J Hosp Med.* 2011 May/June;6(5):279–284.

[6]Umpierrez GE, Hellman R, Korytkowski, MT, Kosiborod M, Maynard GM, Montori VM, Seley J, Van den Berghe G. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2012: 97(1):16–38.

[7]Umpierrez GE, Smiley D, Zisman A, Prieto LM, Palacio A, Ceron, M, Puig A, Mejia R. Randomized study of basal-bolus insulin therapy in the inpatient management of patients with type 2 diabetes (Rabbit 2 Trial). *Diabetes Care. 2007;* 30:2181–2186.

[8]Lepore M, Pampanelli S, Fanelli C, et al. Pharmacokinetics and pharmacodynamics of subcutaneous infection of long-acting human insulin analog glargine, NPH insulin, and Ultralente human insulin and continuous subcutaneous infusion of insulin lispro. *Diabetes.* 2000;49:2142–2148.

[9]DeSantis AJ, et al. Inpatient Management of Hyperglycemia: The Northwestern Experience. *Endocr Pract.* 2006 Sep–Oct;12(5):491–505.

[10]Olansky L, et al. Cleveland Clinic Cardiovascular Intensive Care Unit Insulin Conversion Protocol. *J Diabetes Sci Technol.* 2009; 3(3): 478–486.

[11]Schmeltz LR, et al. Conversion of intravenous insulin infusions to subcutaneously administered insulin glargine in patients with hyperglycemia. *Endocr Pract* 2006;12:641–650.

[12]O'Malley CW, Keuth J, Schiller K, Gerkin R, Bikin D. "Improving Glycemic Control with the Use of a Nurse Driven Protocol For the transition from Intravenous to Subcutaneous Insulin Therapy." SHM Annual Meeting 2011.

[13]Weant KA, Ladha A. Conversion from continuous insulin infusion to subcutaneous insulin in critically ill patients. *Ann of Pharm.* 2009 April; (43) 629–634.

[14]Bode BW, et al. Intravenous Insulin infusion therapy: indications, methods, and transition to subcutaneous insulin therapy. *Endocr Pract.* 2004;10 Suppl 2:71–80.

[15]Ramos P, Childers D, Maynard G, Box K, Namba J, Stadalman K, Renvall M. Maintaining glycemic control when transitioning from infusion insulin: a protocol-driven, multidisciplinary approach. *J Hosp Med.* 2010:8:446–451.

[16]Houlden R, Capes S, Clement M, Miller D. Clinical Practice Guidelines In-hospital Management of Diabetes Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. *Can J Diabetes.* 2013;37:S77eS81.

[17]Czosnowski Q, et al. Evaluation of glycemic control following discontinuation of an intensive insulin protocol. *J Hosp Med.* 2009;4:28–34.

[18]Moghissi ES, Korytkowski MT, DiNardo M, Einhorn D, Hellman R, Hirsch IB, Inzucchi SE, Ismail-Beigi F, Kirkman MS, Umpierrez GE; American Association of Clinical Endocrinologists, American Diabetes Association: American Association of Clinical Endocrinologists and American Diabetes Association consensus statement on inpatient glycemic control. *Diabetes Care. 2009;* 32:1119–1131.

[19]Inzucchi SE, Bergenstal RM, Buse JB, et al. Management of hyperglycemia in type 2 diabetes, 2015: a patient-centered approach. Update to a position statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care.* 2015;38:140–149.

[20]Garber AJ, et al. American Association of Clinical Endocrinologists' Comprehensive Diabetes Management Algorithm 2013 Consensus Statement. *Endocr Pract.* 2013;19 (Suppl 1):1–48.

[21]Robbins JM, Webb DA. Diagnosing diabetes and preventing rehospitalizations: the urban diabetes study. *Med Care.* 2006; 44:292–296.

[22]Standards of Medical Care in Diabetes—2015. *Diabetes Care.* Volume 38, Supplement 1, January 2015.

[23]American Association of Clinical Endocrinologists: AACE Inpatient Diabetes Resource Center. http://inpatient.aace.com/transitioning-to-outpatient-care. Accessed March 29, 2015.

[24]Hirschman KB, Bixby MB. Transitions in care from the hospital to home for patients with diabetes, *Diabetes Spectrum.* 2014; Vol. 27, No. 3.

[25]Lavernia F, Treating hyperglycemia and diabetes with insulin therapy: transition from inpatient to outpatient care. *Medscape J Med.* 2008;10(9):216; quiz 216. Epub 2008 Sep 17.

[26]Dombrowski NC, Karounos DG. Pathophysiology and management strategies for hyperglycemia for patients with acute illness during and following a hospital stay. *Metabolism.* 2013 Mar;62(3):326-336.

[27]Riddle M, Rosenstock J, Gerich J, Investigators IGS. The treat-to-target trial: randomized addition of glargine or human NPH insulin to oral therapy of type 2 diabetes patients. *Diabetes Care.* 2003;26:3080–3086.

[28]Davies M, Storms F, Shutler S, Bianchi-Biscay M, Gomis R. Improvement of glycemic control in subjects with poorly controlled type 2 diabetes. *Diabetes Care.* 2005;28:1282–1288.

[29]SBAR technique for communication: a situational briefing model. Available at http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/SBARTechniqueforCommunicationASituationalBriefingModel.htm. Accessed March 28, 2015.

[30]O'Malley CW, Emanuele MA, Halasyamani L, Amin A. Bridge over troubled waters: safe and effective transitions of the inpatient with hyperglycemia. *J Hosp Med.* 2008 Sep;3(5 Suppl):55–65.

Summary comparing outcomes and the protocols for transition from IV to subcutaneous insulin

Study	Patients (N)	Dosing strategy for basal	Nutritional	Duration	% in range (range)	Hypoglycemia % (definition)
Schmeltz[11]	All CV surgery patients on insulin GTT	(Last 6 hour avg X 4) X 40%, 60% or 80% (RCT comparing the 3)	At providers discretion, not controlled	24 hours	40%-58.7% (80-150mg/dL)	40% = 1 patient (<50 mg/dL)
					60%=44.4%	60%=0
					80%=67.6%	80%=0
Olansky[10]	All CV surgery patients on insulin GTT	(last 8 hours X 3) X 50% =glargine dose. Soft max of 30 units	None, but later added 10% of glargine dose	Not specified	80-150 mg/dL	1% (41-80 mg/dL)
Bode[14]	Surgical ICU, type 1 DM and all patients with avg of >0.5 units/hr	(Last 6 hour avg X 4) X 80%	Added when taking full po	Not studied, only recommendation in consensus		
Ramos[15]	Mixed, basal if 1. Meds for DM 2 2. HbA1c ≥6 OR >60 mg/day prednisone AND infusion of > 1 unit/hr	TDD calculation=6 hour avg X 20 if was on full nutrition or 40 if minimal nutrition 50% of TDD given as glargine (max 100 units)	50% of TDD divided into 3 meals	48 hours after transition	Diabetics 60.2% (80-180 mg) Without DM 80.1%	9% (41-70 mg/dL) 3% (<40 mg/dL)
Weant[13]	Neurosurg ICU	60-70% of TDD as basal NPH divided bid	none	48 hours after transition	78% (80-150 mg/dL)	4.2% in diabetics, 2.2% in non-diabetics (<80 mg/dL)
O'Malley[12]	CV surgery HbA1c≥6.5, known DM, or insulin infusion >1.5 units/hr avg Tolerating more than clear liquids	Review last 7 hour infusion rates Eliminate the 2 highest 5 hour total units X 4=TDD 50% TDD	50% TDD hold if full liquid or <50% of meal	Until discharge	81.7% (70-180 mg/dL)	29.6% (40-69 mg/dL) 1.9% <40 mg/dL

Transition_ UCSD Transition IV to SQ insulin

A comprehensive educational program should involve educating the staff as well as the patients.

A. Staff Education

The role of education in quality improvement is complex. Educational efforts alone do not usually result in major changes in practice, as the other sections of this *Guide* have made very clear. However, it would be ridiculous to believe that an institution could enact major changes in the attitudes, knowledge and practices of its staff without some kind of information transfer. How much the success of a quality improvement effort depends on education is contingent on the complexity of the intervention. For example, if the goal of a quality improvement effort were simply to increase the number of patients with heart failure taking an ACE inhibitor, a simple electronic reminder system might be effective, which might not require any education beyond what is stated in the reminder. However, if the goal is to change practice in more substantial ways, particularly if the desired change depends on the acquisition of new knowledge, education takes on a more important role.

Developing Educational Materials

When developing educational materials for use in a quality improvement project, a few rules should be kept in mind:

1. **Define the target audience** (and the objectives for them). Educating people about what they do not need to know is wasteful, but failing to educate even a few of those who do need to know can undermine the success of the project. Recognize that educational efforts often need to be directed toward people from many professions and with different levels of training. Identify educational objectives that are both general and institution-specific for each component of the audience. The former helps support the initiative and the latter helps with the practical applications of the interventions (such as familiarity with an order set or institutional policy).

2. **Do not reinvent the wheel.** In many cases, at least some of the necessary educational materials (especially the general knowledge part) may already exist.

3. **Plan the delivery.** Creating the educational materials is the easy part. The hard part is ensuring that the content finds its way into the knowledge base of all the right people. If the project is small (e.g., focused on only a single unit or service), this is less of an issue. However, for bigger projects (e.g., spanning an entire institution), getting the message to everyone can be difficult. Easy access to training is a key factor. Usually, the most cost-effective way to accomplish broad-based training is Internet- or Intranet-based learning modules, often augmented with hands-on or lecture materials. However, even if the educational materials are widely accessible, it might still be difficult to make sure all key personnel participate. Some methods to optimize participation include:

   a. Make participation mandatory for important topics. Mandatory participation is fairly common among nursing, pharmacy and ancillary staff and is usually well accepted. It is more difficult to mandate physician staff to participate in educational programs, particularly at institutions that use the open medical staff model, but it may be possible if the education is directed toward a discrete group whose leadership is committed to the project (e.g., a residency program).

   b. Make the educational program as enjoyable as possible. Regardless of whether the training is mandatory, educational programs are more effective if they are concise, clear, case-based and interactive. Use local cases to illustrate the principles and to help the learners walk through making decisions and learning the predictable outcomes if the recommended steps are not followed (e.g., hyperglycemia if sliding scale only used, post-prandial hyperglycemia if only low dose basal used, hypoglycemia if patient's entire TDD is prescribed as basal insulin).

c. Create other incentives for participating, if the education cannot be made mandatory. The incentives offered usually depend on the resources available. An example of a common incentive is offering an educational presentation as part of a program that includes a nice dinner. Hospitalist groups or other providers may get recognition or a competitive advantage for certification or full participation in training. CME, CEU and Pharmacy educational credits may be valuable for many learners as well.

4. **Evaluate and track** the participation and performance of staff in the educational program and the impact of the educational program as a whole. Revise and update based on your experience with delivering it to the first group. Just like you will be piloting your order sets and other interventions, "pilot" your educational session with a smaller group and plan to revise. An important tip is to allow time for questions or to prompt individuals to write on a 3x5 card what is still unclear. That way you can be sure to get to the bottom of their concerns and questions and improve on the program in the future. Even the best educational module will have no effect on those not exposed to it. Keeping track of who has, and has not, been educated will allow the latter to be identified for special intervention. If the process is mandatory, the intervention might be disciplinary, but even for non-mandatory programs, the QI team might be able to come up with innovative ways of making sure that everyone is educated. For example, members of the QI team could provide abbreviated, one-on-one education for noncompliant members of the target group (academic detailing). The worst-case scenario would be to post an educational module on the Internet and just assume that everyone has completed it. Modern Web-based learning modules allow evaluation of performance on questions as well as tracking participation.

Identify the Target Audience and the Learning Objectives

Inpatient glycemic control and prevention of hypoglycemia require a broad educational effort for nearly all nurses, pharmacists and physicians. All hospital providers who are part of the process of delivering care to this population of patients need to be aware of the issues of how their part may impact the overall care a patient with diabetes receives while in the hospital. This obviously includes the nurses and physicians, but may also include the patient care technicians who are checking the sugars, or team members who are providing or delivering diabetic trays. The degree of education should be targeted to the audience instead of a 'one-size-fits-all' approach such as developing one online slide lecture and expecting all staff involved to review it. It might also be helpful to prioritize the education objectives and choose three to four top principles to focus on very well in multiple ways, rather than try to educate on all objectives at once.

Core knowledge for physicians, advance practice providers and pharmacist

GENERAL

- ❒ Impact of blood glucose on hospital outcomes, evidence for inpatient glycemic control
- ❒ AACE/ADA targets for blood glucose
- ❒ Concepts for estimating insulin dose (TDD)
- ❒ Terminology — basal/nutritional/correction
- ❒ Insulin product knowledge
- ❒ Hypoglycemia prevention and treatment
- ❒ Changes in regimens at transitions in care

INSTITUTION SPECIFIC

- ❒ Effective response to colleagues
- ❒ Insulin order set/protocol features
  - ◆ Glycemic targets
  - ◆ Hypoglycemia protocol
  - ◆ Preferred regimens for different situations

Core knowledge/competencies for nurses

GENERAL

- ❒ Impact of blood glucose on hospital outcomes, evidence for inpatient glycemic control (This aspect less intensive for nursing)
- ❒ AACE/ADA targets for blood glucose
- ❒ Bedside glucose-monitoring technique
- ❒ Terminology: basal/nutritional/correction
- ❒ Insulin administration technique and storage
- ❒ Optimum timing of subcutaneous insulin shots
- ❒ Hypoglycemia prevention and treatment
- ❒ Patient need for nutrition information
- ❒ Skills for teaching patients — generic
- ❒ Plans for teaching patients with diabetes
- ❒ Nurse mentoring in the care of patients with diabetes
- ❒ Transitions to outpatient regimens
- ❒ Culture of safety issues

INSTITUTION SPECIFIC

- ❒ Blood glucose and insulin dose documentation, medication administration record (MAR) features
- ❒ Insulin order set, and protocol features
  - ◆ Glycemic targets
  - ◆ Hypoglycemia protocol
  - ◆ Preferred regimens for different situations
- ❒ Patient education materials, resources and documentation
- ❒ Effective response with colleagues (chain of command)

It may also appropriate to create similar lists for clerks/patient care technicians or others who may be part of the project. As you review the objectives and desired core knowledge/skill sets, define again who among your staff needs this training.

Don't Reinvent the Wheel: What Resources Are Available?

The Society of Hospital Medicine (SHM) *Glycemic Control Toolkit* features a PowerPoint-based educational module for physicians/pharmacists outlining the best practice for the management of diabetes and hyperglycemia in the hospital patient. Soon, we hope to have these available in a more interactive learner-based format, where participation and performance on questions can be tracked. For now, they can be reviewed for self-education or downloaded and/or modified to educate others. Similarly, a host of resources are available that provide information about the use of insulin and the management of diabetes and hyperglycemia in the hospital (see the Educate section of the SHM *Glycemic Control Online Toolkit*).

A project whose goal is standardization of the use of subcutaneous insulin in an entire institution would need to provide education for every physician who cares for hospital patients, including house staff, virtually all the nursing staff, many midlevel practitioners, pharmacists, clerks and others.

Planning the Delivery

We advocate mandatory education for most of those on the inpatient nursing and pharmacy staff who will be relevant to the project. Scheduling and logistics of the educational program can be challenging, but Web-based learning modules can make them easier. Mandatory training of all pertinent inpatient staff may not be feasible, but targeting pulmonary critical care physicians, hospitalists and cardiologists/CT surgeons can go a long way toward having a more standardized and rational mode of hyperglycemia care. Also, plan for ongoing education when new staff join your organization. Think of how a new hire who missed your initial wave of education will learn. Provider education can be challenging and usually "less is more" and 'just in time' is more effective. Providers seem most open to one-on-one case-based feedback; this can be accomplished by a glycemic control team member who provides feedback to teams with patients who have glucoses outside of the target range in the hospital on a real-time basis. Other useful approaches utilize CME programs and Grand Rounds, as well as monthly didactics for residents. [1-4]

Evaluating and Tracking Performance of Staff

Create a roster of all those on staff who need the training, stratified by type of care provider and whether each person's participation is mandatory or optional. To try to evaluate not only participation but also actual performance and comprehension, use questions in your educational program that address core knowledge areas. Map out the time lines for delivery, and plan incentives/strategies for reaching voluntary participants. The overall impact of your program can be assessed in part by the progress you make toward better glycemic control and reduction of hypoglycemia in your institution. After the initial education effort, plan how often abbreviated or ongoing training sessions or competencies should be repeated; the most common approach is yearly.

Having a defined mechanism and process for the delivery of education to frontline providers becomes imperative during your project when you identify lapses of knowledge or uncover 'myths' that exist within the hospital pertaining to glycemic control—for instance, when it is noted that nursing is not following insulin orders correctly due to an inappropriate fear of hypoglycemia, or when physician staff are reverting to sliding-scale regimens due to lack of knowledge. You can incorporate these educational topics into your educational program on an ongoing basis.

B. Patient Education

Patient education is especially important in the management of diseases like diabetes, for which self-management is the rule. Creating a comprehensive inpatient educational program about diabetes and hyperglycemia is a complex task that must include the following steps:

1. *Assess the patient.*
2. *Define which knowledge is essential for the patient.*
3. *Decide who will teach the patient.*
4. *Teach the teachers.*
5. *Decide what will trigger the educational effort.*
6. *Make sure the educational program has been successful.*

1. ***Assess the patient.*** To be successful, an educator must assess the learner's current knowledge, cognitive abilities and motivation to learn. A healthcare professional cannot simply walk into a patient's room and begin lecturing on diabetes (or any topic). Rather, first assess what the patient already knows and is able (and willing) to learn. Non-adherence to medication and treatment regimens is often related to a patient's health literacy, knowledge level, motivation and willingness to change, which need to be assessed as part of a comprehensive educational program. With changes in a patient's disease status, living circumstances, therapies and other adherence-related factors come expected changes in both knowledge and motivation. Family members should be included whenever possible as well to support and reinforce the education. Hospitals wishing to achieve excellence in patient education will need to incorporate patient assessment into their educational initiatives. More information and tools pertaining to patient assessment can be found in the Case Management Society of America's Case Management Adherence Guidelines and at the CMAG website.

2. ***Define which knowledge is essential for the patient.*** Diabetes education cannot take place solely in the hospital. Trying to teach everything about diabetes can easily overwhelm inpatients, especially if diabetes is not the primary reason for the hospitalization. However, some skills and knowledge are considered essential for patients or their caregivers to understand to be able to appropriately manage their diabetes/hyperglycemia at home. These essential skills/knowledge are to[5]:

- Understand the basic definition of diabetes
- Understand basic meal planning
- Understand how to manage diabetes medications, including injecting insulin, with special emphasis on any changes made to a prior regimen
- Understand how to monitor blood glucose
- Understand how to recognize and respond to low and high blood glucose measurements
- Understand when to call the managing physician or go to the emergency room

Ideally, each hospital would identify the essential diabetes information that all patients must know and use this foundation of knowledge to build a patient education tool that allows both an educational assessment of the patient and documentation of the education. One such educational tool is the diabetes patient education record. Many online resources provide high-quality information for patient education. Some of these can be found at the *Glycemic Control Online Toolkit.* Written discharge instructions on diabetes self-care, offered in the patient's primary language whenever possible, should be reviewed and provided at the time of discharge.

3. ***Decide who will teach the patient.*** Although it would be ideal for the patient's nurse to do all the teaching, many nurses lack the expertise to do this well. Some hospitals try to get around this problem by hiring trained diabetes educators to teach patients. However, there are often so many patients with diabetes/hyperglycemia that it overwhelms the few educators available. Therefore, it is likely that hospitals will need to develop programs to ensure that nurses can educate patients, not about every aspect of diabetes, but about the essentials. More complicated cases can be referred to an inpatient diabetic educator if staffing allows. Define criteria for which education should take place by which staff members. For instance, if you would prefer a diabetic educator for multiple admissions, HbA1c >10 percent , newly diagnosed being discharged with insulin, for example. Hospital patients should also have access to trained diabetes educators for situations that require more sophisticated teaching (e.g., a new diagnosis). Diabetes education provided by staff nurses, diabetes educators and diabetes nurse champions have all shown to be effective, so the design of the program will depend on the environment of the institution and available resources.[1,6-10]

4. ***Teach the teachers.*** The best way to ensure that hospitalized patients will learn what they need to know is to standardize the educational process. As noted above, the first step is to identify who will be the patient's educator. These educators (usually nurses) must then be given the knowledge and tools they need to educate patients in a standardized way. Therefore, providing excellent education to patients in most hospitals depends on providing excellent education to nurses. Nursing education in this area will be enhanced by tools to standardize the educational approach (such as the diabetes patient education record, on the following page). Given the large number of nurses at most institutions, a multifaceted approach using Web-based modules, one-on-one encounters, unit-based meetings and data review as well as the nursing champion system to disseminate information and education to each unit will be necessary.[1-4]

5. ***Decide what will trigger the educational effort.*** Will it be done for all patients with diabetes? Will it be reserved only for those with new diagnoses or "special needs"? What mechanism will be used to ensure every patient gets the education he or she needs? Early intervention is also important so the patient will have more opportunity to practice and master survival skills, so this trigger should occur as early on in the hospitalization as possible.

6. ***Make sure the educational program has been successful.*** Just as patients must be assessed before an educational effort, they must also be assessed afterward to make sure they can demonstrate mastery of the new knowledge or skills. This can be done as part of the education utilizing 'Teach Back.' You can also conduct surveys to patients and staff about the success of the current resources and processes for this patient population. If this is delegated to bedside nurses, then a recurring survey to assess their perception of success and personal competence in this area would be an important factor to track over time.

C. Conclusion

While never a solution in isolation, education must be a mainstay of any successful glycemic control program. Programs must be developed to address education of all hospital staff involved in the process of glycemic control in addition to the patients themselves. Often these programs are developed and monitored by the same oversight team. Regardless, the Glycemic Control Team involved in the quality project must integrate with these other efforts to address deficiencies noted that may be preventing a hospital from attaining its goals around glycemic control care. It is important for your team to review, and potentially modify, the material and processes/policies in place to train staff and patients. Once you are familiar with the material being presented and the mechanisms of delivery, you can utilize this program to address deficiencies in knowledge that are uncovered during the project.

References

[1]Top performers abstract

[2]Munoz M, Pronovost P, Dintzis J, Kemmerer T, Wang N, Chang Y, Efird L, Berenholz SM, Golden SH. Implementing and evaluating a multicomponent inpatient diabetes management program: putting research into practice. *Joint Commission J Qual and Patient Safety.* 2012. 38(5):195–206.

[3]Maynard G, Kulasa K, Ramos P et al. Impact of a hypoglycemia reduction bundle and a systems approach to inpatient glycemic management. *Endocr Pract.* 2015 April 15th pub pend.

[4]Rodriguez A, Magee M, Ramos P, Seley JJ, Nolan A, Kulasa K, Caudell KA, Lamb A, MacIndoe J, Maynard G. Best Practices for Interdisciplinary Care Management by Hospital Glycemic Teams: Results of a Society of Hospital Medicine Survey Among 19 U.S. Hospitals. *Diabetes Spectrum.* 2014:27(3):197–206.

[5]Endo Society guidelines

[6]Corl D, Guntrum P, Graf L, Suhr L, Thompson R, Wisse B. Inpatient diabetes education performed by staff nurses decreases readmission rates. *AADE In Practice.* March 2015.

[7]Healy SJ, Black D, Harris C, Lorenz A, Dungan KM. Inpatient diabetes education is associated with less frequent hospital readmission among patients with poor glycemic control. *Diabetes Care.* 2013 Oct;36(10):2960–7. doi: 10.2337/dc13-0108. Epub 2013 Jul 8.

[8]Corl DE, McCliment S, Thompson RE, Suhr LD, Wisse BE. Efficacy of diabetes nurse expert team program to improve nursing confidence and expertise in caring for hospitalized patients with diabetes mellitus. *J Nurses Prof Dev.* 2014 May-Jun;30(3):134–42. doi: 10.1097/NND.0000000000000068.

[9]Dungan K, Lyons S, Manu K, Kulkarni M, Ebrahim K, Grantier C, Harris C, Black D, Schuster D. An individualized inpatient diabetes education and hospital transition program for poorly controlled hospitalized patients with diabetes. *Endocr Pract.* 2014 Dec;20(12):1265–73. doi: 10.4158/EP14061.OR.

[10]Rodriguez A, Magee M, Ramos P, Seley JJ, Nolan A, Kulasa K, Caudell KA, Lamb A, MacIndoe J, Maynard G. Best Practices for Interdisciplinary Care Management by Hospital Glycemic Teams: Results of a Society of Hospital Medicine Survey Among 19 U.S. Hospitals. *Diabetes Spectrum.* 2014:27(3):197–206.

Section VI:

1. Implement Safe Insulin Management Practices and a Hypoglycemia Reduction Bundle

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2. Inpatient Diabetic Diets and Coordination of Nutritional Delivery, Glucose Monitoring and Insulin Administration

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3. Safe Use of Insulin Pens in the Hospital and Transition to Home Use

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Section VI.1: Implement Safe Insulin Management Practices and a Hypoglycemia Reduction Bundle

A. Introduction

Hypoglycemic adverse drug events (ADEs) are a prominent limiting factor for inpatient glycemic control efforts.[1,2] Fear of hypoglycemia often leads to clinical inertia, with attendant non-treatment of potentially harmful hyperglycemia and overutilization of sliding-scale insulin regimens.[3-5] Every medical center needs to address hypoglycemia prevention and management as part of a comprehensive glycemic control effort. This section is designed to assist improvement teams by walking through the quality improvement steps introduced earlier in this *Guide*, as applied to hypoglycemia. These steps include reviewing the evidence and epidemiology, evaluating local hypoglycemia patterns and etiologies, distilling the most important best practices down to the most impactful ones and integrating guidance and education on these best practices into protocols, order sets and documentation. Other important steps, such as good measurement and monitoring systems, and multiple interventions designed to reinforce the protocols, will also be covered in this section.

B. Hypoglycemia in the Inpatient Setting

Definition

The modern definition of hypoglycemia is a blood glucose (BG) <70 mg/dL. In the 60-69 mg/dL range, the brain becomes neuroglycopenic and counter-regulatory hormones are released, while warning symptoms often do not appear until BG <60 mg/dL. Severe hypoglycemia has been defined as a hypoglycemic event requiring third-party assistance, or BG <40 mg/dL.

Consequences of Hypoglycemia and Prevalence

While many hypoglycemic events resolve quickly without sequelae, unpleasant symptoms, transfer to higher levels of care, seizures, stroke and death can occur. Patients with diabetes who develop hypoglycemia during hospitalization have longer lengths of stay, higher costs and greater odds of being discharged to a skilled nursing facility than their counterparts without hypoglycemia.[6-8] Patients with impaired cognition or communication skills, which are common conditions in the elderly, are at highest risk for unrecognized hypoglycemia or slow responses from the healthcare team.[9-12] The Institute for Safe Medication Practices (ISMP) identifies insulin as an inpatient high-alert medication.[13] Approximately one-quarter of all patient safety incidents involving insulin result in patient harm, and insulin has been implicated in one-third of all medication-related deaths.[8,13-16]

Iatrogenic hypoglycemia is common, but incidence estimates vary widely in different reports, depending on definitions, units of analysis (patient-day vs patient-stay vs glucose value) and the population described. The Office of the Inspector General (OIG) recently released a study of ADEs in hospitals.[17] ADEs represented one-third of all hospital-acquired conditions in the hospital, and hypoglycemic ADEs were among the top three sources of ADEs (along with anticoagulants and opioids). To qualify as an ADE, a hypoglycemic event had to be induced by an anti-hyperglycemic agent and have documented signs or symptoms of hypoglycemia, or require therapy. On the basis of 25,145 hospital visits in the Medicare Patient Safety Monitoring System sample, an estimated 10.2 percent of inpatients exposed to insulin/hypoglycemic agents experienced an ADE, representing 930,000 ADEs per year nationally.[12]

In Society of Hospital Medicine (SHM)-published benchmarking data, 94 hospitals reported a very wide range of hypoglycemia and severe hypoglycemia in non-ICU wards (Table 1).[18] For example, a mean of 13.4 percent of patient-stays suffered hypoglycemia (BG <70 mg/dL), but the range was 2.8 percent at the highest performing hospital, and more than ten times higher (33.5 percent) at the hospital with the worse performance. Findings from 84 hospitals reporting ICU data showed slightly more hypoglycemia overall with a similarly wide range of performance.[19]

Table 1.

Hypoglycemia and severe hypoglycemia rates in non-ICU wards, from 94 reporting hospitals.

		Patient-Stay	Patient-Day
Percent of stays or days with hypoglycemia (BG <70 mg/dL)	Top Quartile	≤10.5%	≤3.9%
	Mean	13.4%	5.1%
	Median	12.5%	4.7%
	Range	2.8% - 33.5%	1.8% - 14.8%
Percent of stays or days with severe hypoglycemia (BG <40 mg/dL)	Top Quartile	≤1.0%	≤0.3%
	Mean	1.9%	0.5%
	Median	1.7%	0.4%
	Range	0% - 7.3%	0% - 2.4%

Data extracted from the RALS-PLUS™ system from 575 hospitals showed results similar to SHM data.[20] On non-ICU wards, they found a mean of 5.7 percent patient-days with a BG <70 mg/dL and 0.8 percent of patient-days <40 mg/dL (compared to 5.1 percent and 0.5 percent, respectively, in SHM data). In the ICU, 6.3 percent of patient-days had a BG <70 mg/dL, and 1.1 percent of patient-days had severe hypoglycemia (compared to 5.2 percent and 0.7 percent in SHM benchmarking).

Hypoglycemia Risk Factors

The risk for hypoglycemic events can be increased by multiple factors inherent to the patient, and by a large number of iatrogenic factors, which are essentially failure modes in providing care.[8,22]

Risk factors inherent to the patient include:

- Advanced age
- Malnutrition/cachexia/low body mass index
- End stage liver disease
- End stage renal disease
- Sepsis
- Congestive heart failure
- Multi-organ failure
- Advanced malignancy

Presence of one or more of these risk factors should lead to consideration of less stringent glycemic targets and reduced doses of anti-hyperglycemic agents, reinforced by education and clinical decision support in order sets.

There are dozens of iatrogenic risk factors for hypoglycemia. Insulin-related medication errors have been reported at multiple points across each step (prescribing, transcribing, storage and dispensing, administering and monitoring) of the medication-use process.[8,21] Table 2 shows examples of insulin errors at each phase of the process outlined by a recent expert consensus panel, convened by the *American Society of Health-System Pharmacists* (ASHP) *Research and Education Foundation*.[8]

Table 2.

High-Priority Insulin Errors, by Phase of Medication Use Process

Phase	Error or Failure Mode
Prescribing	Incorrect dosage / irrational insulin orders
Transcribing	Incorrect transcription of verbal or telephone orders Transcription of an incorrect dose
Dispensing and Storage	Failure to double check insulin infusion pre-administration Look-alike containers Unsecure and/or non-segregated storage in patient care areas and/or pharmacy areas
Administering	Administration of incorrect doses Incorrect use of insulin pens Name confusion Relationship of insulin administration to nutrition
Monitoring	Failure to appropriately monitor for insulin effects and adjust accordingly Delays in obtaining glucose values during insulin infusion.

Modified from Am J Health-Syst Pharm – Vol 70. Reference 8.

The three most common sources of iatrogenic hypoglycemia in many studies are prescribing errors, failure to respond to unexpected nutritional interruption and failure to appropriately manage a prior hypoglycemic event. Studies indicate high proportions (more than half in many studies) of hypoglycemic ADEs are preventable.[22-27]

Common prescribing errors include over-reliance on sliding-scale insulin as a sole means of attaining glycemic control, inappropriate use of basal insulin to control both basal and nutritional needs, having a glycemic target too low for a patient with hypoglycemia risk factors, inappropriate use of oral hypoglycemic agents in the inpatient setting and failure to adjust insulin doses appropriately as glucose levels decline.[28]

Unexpected interruption of nutritional intake (discontinuation of enteral or parenteral feedings, taking in less than expected nutrition after nutritional insulin has been delivered, unexpected transport from the unit, for example) is a very common and potentially preventable source of iatrogenic hypoglycemia in a number of studies, because it leads to nutritional insulin mismatch.[22,25-27] Even routine NPO orders can lead to hypoglycemia if education and appropriate clinical decision support are not in place. Poor coordination of nutrition delivery, glucose testing and insulin delivery is a common condition in many hospitals that can lead to glycemic excursions (either high or low).[22,28] More on the coordination issue is available later in this *Guide.*

One of the strongest predictors of an inpatient hypoglycemic event is a prior hypoglycemic ADE in the same hospital stay. More than 40 percent of patients who experience one iatrogenic hypoglycemic ADE go on to suffer at least one additional distinct hypoglycemic event.[22,25,26] About half of the recurrences could have been prevented by altering caloric intake or changing the diabetes regimen.[22,26] Documentation of any assessment for the root cause of the hypoglycemic event, and management of the event, are often meager or missing altogether, and the timeliness of documented re-testing and resolution is very poor[22,25-27] (several hours in some studies, borne out also by SHM benchmarking studies[18,19]).

C. Assessing the Contributing Factors, Incidence and Etiologies of Hypoglycemia in Your Hospital

Reviewing the epidemiology and risk factors for hypoglycemia from the literature presented above is only the beginning point for understanding your local environment. Improvement teams should review their infrastructure supporting safe insulin management, access or create measures to gauge the frequency and patterns of hypoglycemia and perform local case review to ascertain the most common contributors to hypoglycemic ADEs in their own hospital.

Assessing Your Environment and Infrastructure

High rates of iatrogenic hypoglycemia are often a reflection of the environment and infrastructure of the hospital. An institutional self-assessment can be very helpful in identifying areas for improvement. Some guidance for performing such an assessment are presented elsewhere in this *Guide*.[29]

The Safe Use of Insulin Interdisciplinary Panel convened by the ASHP reviewed all the literature on safe insulin management and through a structured process in three stages. They developed ten best practices thought to have the highest impact to further enhance safe use of insulin in the inpatient setting.[8] These recommendations were addressed to improvement teams in medical centers, rather than to the individual provider, and therefore captured important elements like protocol-driven evidence-based insulin order sets, standardizing insulin concentrations, protocols to manage insulin pens, coordinating meal delivery, BG testing, insulin delivery and implementing good measurement and educational programs (Box 1). An institutional self-assessment focused on these high-impact practices is recommended as an efficient way to prioritize your improvement efforts in hypoglycemia prevention.

Box 1. Expert Panel Consensus High-Impact Recommendations for Safe Management of Insulin.

Prescribing

1. Develop protocol-driven and evidence-based order sets for specific uses of insulin such as transition of administration route from intravenous to subcutaneous, administration via subcutaneous insulin pumps, post-discharge dosing, diabetic ketoacidosis, hyperosmolar states, hyperkalemia, postcardiac surgery care. These order sets should include orders for glucose monitoring and decision support capabilities that guide insulin use based on the patients' nutrition status. In addition, protocol-driven and evidence-based order sets for the management of hypoglycemia should be developed and integrated into the care of all hospitalized patients who receive insulin.
2. Eliminate the routine administration of correction/sliding scale insulin doses as a primary strategy to treat hyperglycemia.
3. Eliminate the use of "free text" insulin orders in electronic and paper medical records and replace with protocol-driven and evidence-based order sets that allow for the prescribing of complex insulin regimens.

Storing and dispensing

4. Store only U-100 concentration insulin and U-100 administration devices (e.g., syringes, pens) in patient care areas and ensure that they are stored in a secure fashion and segregated from other medications.
5. Develop hospital-wide standard concentrations for insulin infusions to be adopted and used in all patient care areas.

Administering

6. Limit preparation, including for procedural areas, of all intravenous bolus insulin doses and intravenous insulin infusions to the pharmacy department.
7. Hospitals must develop policies and procedures to ensure that insulin pens are used for individual patients only. In addition, hospitals must establish policies and educational programs to ensure the safe use of insulin pens and disposable needle tips.

Monitoring

8. Ensure that insulin-use is linked directly to patients' nutrition status. Meal delivery, point-of-care glucose testing and insulin administration should be well coordinated and standardized. Patients and their family caregivers should be educated to request administration of rapid-acting insulin when the patient begins her/his meal. In patients with variable nutritional intake, prandial insulin administration should be delayed until completion of the meal. Protocol-driven and evidence-based order sets should be developed for insulin-use and blood glucose monitoring upon planned and unplanned interruption of enteral nutrition or total parenteral nutrition.

Evaluating

9. Every hospital should prospectively monitor/measure rates of hypoglycemia and hyperglycemia; insulin use; and coordination of insulin administration, glucose testing and nutrition delivery. Real-time, institution-wide glucose reports should be provided to healthcare team members to ensure appropriate surveillance and management of patients with unexpected hypoglycemia and hyperglycemia.

Planning

10. Provide standardized education, including competency assessment, to all hospital-based health professionals who are responsible for the use (e.g. prescribing, compounding, dispensing, administering, monitoring) of insulin.

D. Assessing Your Hypoglycemia Rates and Comparing Your Performance to Others

Trying to improve rates of hypoglycemia without objective measures to assess baseline and track progress is like driving in the dark on a rain-slicked highway without lights, a speedometer, road signs or directions. You might move somewhere, but you might not like where you end up. Major guidelines and professional societies all strongly recommend a uniform method of collecting and evaluating BG data in a systemic way (aka glucometrics) to inform improvement efforts.[2,8,18,19,28,30]

A fairly detailed review with recommendations for practical metrics for hypoglycemia rates, hypoglycemia management and other parameters is available elsewhere in this *Guide*.[30] Here we summarize some of the more salient points with regards to metrics to assess rates of hypoglycemia:

- Objective measures that capture all pertinent hypoglycemic events (rather than reliance on voluntary reporting systems) are necessary to accurately track and trend hypoglycemia rates.
- In non-ICU settings, using point-of-care (POC) BG readings is sufficient and recommended, while in critical care units, other sources of glucose value testing that drive care can be included. Critical care and non-ICU rates should be tracked separately.
- Metrics should include patient-day and patient-stay as the unit of analysis, whereas using the glucose value as the unit of analysis is not recommended. This approach results in metrics more meaningful to the providers, and reduces bias from variance in testing frequency.
- Exclusion of reflex testing values (repeat values obtained within 5-10 minutes of a prior low value) is recommended.
- We recommend defining hypoglycemia as BG <70 mg/dL and severe hypoglycemia as BG <40 mg/dL, but other cut-offs can also be used, and clinical criteria (e.g., clinical symptoms, need for treatment, etc.) can also inform the analysis.
- Not all hypoglycemic events in the hospital are iatrogenic adverse drug events. Case review of hypoglycemic cases, or exclusion of hypoglycemic events without prior exposure to a hypoglycemic agent in the attribution time window is desirable.
- Metrics that capture recurrent hypoglycemic events are recommended as a marker of the efficacy of management of the index hypoglycemic event. By the same token, metrics quantifying the timeliness of hypoglycemic episode treatment and resolution can be valuable to assess adherence to hypoglycemia management protocols.
- We recommend that hospitals should seek comparison / benchmarking data, either from within their system or via external benchmarking glycemic monitoring systems.
- Uni-dimensional benchmarking, focusing solely on hypoglycemia rates in isolation, or glycemic control in isolation, can be misleading. We recommend reviewing performance on glycemic control within the context of concurrent performance on hypoglycemia rates.
- External sources should not be the sole source of information of glycemic control teams. Active surveillance, insulin use patterns and a host of other measures are needed to complement the glucometrics described above.
- Run-charts and other graphic depictions of data are more intuitive and easier to digest than tabular data.

Hypoglycemia rates can be tracked across time, and can be used to identify services or units to prioritize improvement efforts. Figure 1 is a hypoglycemia report by service that also depicts quarter to quarter progress over time. In this particular example, very high rates of hypoglycemia on the Burn Surgery service led to changes in how tube feedings were handled during burn dressing changes, resulting in improvement over time.

Figure 1. Hypoglycemia rates by service, quarter by quarter (example courtesy of University of California, San Diego, Drs. Kulasa and Maynard)

Patient-Days with at least one glucose < 70 mg/dL							
DischargeService	Q3 2011	Q4 2011	Q1 2012	Q2 2012	Total	TotalCount	< 70 Count
Medicine Hillcrest	7.1%	8.1%	8.2%	7.5%	7.8%	5636	437
Medicine Thornton	8.6%	8.4%	9.5%	5.8%	8.2%	2228	182
Cardiology	7.5%	5.0%	7.2%	4.4%	5.9%	2034	119
Cardiothoracic Surgery	4.6%	8.9%	10.8%	6.6%	7.8%	790	62
Bone Marrow Transplant	0.7%	6.5%	1.0%	3.4%	3.0%	737	22
Family Medicine	5.3%	2.8%	5.6%	5.9%	4.8%	712	34
Surgery, Green - TH Onc Surg	10.8%	2.7%	3.0%	3.5%	4.3%	702	30
Neurosurgery	3.1%	0.9%	2.4%	4.3%	2.9%	691	20
Trauma Surgery	7.2%	9.9%	8.1%	6.8%	7.9%	618	49
Neurology	4.6%	6.3%	7.1%	3.9%	5.5%	567	31
Orthopaedic Surgery	0.0%	2.0%	1.2%	4.8%	1.6%	501	8
Transplant Surgery, Liver	7.3%	8.0%	8.0%	0.0%	6.2%	484	30
Transplant Surgery, Kidney	3.7%	1.9%	7.5%	0.0%	3.6%	473	17
Surgery, Blue - TH General Surg/Colorectal	0.0%	3.6%	3.2%	9.0%	3.6%	386	14
Pulmonary Vascular Medicine	11.1%	12.9%	10.8%	11.2%	11.7%	368	43
Surgery, White - HC Acute General Surg	6.8%	6.4%	0.0%	8.1%	5.9%	356	21
Urology	4.7%	5.7%	2.0%	1.6%	3.6%	335	12
Owen Hillcrest	5.3%	8.8%	7.5%	5.6%	6.6%	316	21
Surgery, Red - HC Vascular	4.2%	18.2%	2.0%	3.6%	7.3%	247	18
Burn Surgery	30.0%	10.7%	15.0%	7.5%	12.5%	232	29

Many medical centers and systems are unable to produce both internal metrics and comparison benchmarking, thus external sources for glucometrics can be very helpful. The most prominent external sources capable of providing glucometric reports are the Remote Automated Laboratory Systems (RALS® Medical Automation Systems, Charlottesville, Virginia) application[31], the Yale Web-based system,[32-34] and the SHM Glucometrics Web-based system.[18,19] These systems are compared and contrasted elsewhere in the *Guide*.[30] To date, only the SHM service offers on-demand reports, benchmarking and metrics for hypoglycemia management.

E. Diving Deeper – Hypoglycemia Case Review

Automated reports on hypoglycemia and the overview of hypoglycemia epidemiology from the literature are very helpful, but in the end, some careful manual chart review is often beneficial. A review of a hypoglycemia case series is perhaps the best way to answer questions like:

- Was this a true case of hypoglycemia, or a false positive test or error in documentation?
- Was the hypoglycemia episode attributable to a hypoglycemia-inducing medication (an adverse drug event)? If so, was the medication administered as an inpatient? Which medications contributed to the ADE?
- If this was an ADE, was there any perceptible error or failure mode, or was this an unpredictable episode that occurred in spite of following best practices and local protocols?

- Was the management of hypoglycemia appropriate and consistent with local protocols (timeliness, documentation, treatment dose of glucose agent, steps to prevent recurrent hypoglycemia)?
- Are there high-priority system issues or educational opportunities about hypoglycemia?

Some careful forethought and practical tips from experienced sites can make the case review process more productive and efficient. Some of these principles are also available in webinar form on the SHM website.[35]

Define the population of interest, with explicit inclusion and exclusion criteria, and sampling strategy.

ICU and non-ICU review should probably be performed separately. Decide in advance if you will be reviewing only adult vs pediatric cases, the cut-off for evaluation (e.g., <70 mg/dL vs <50 mg/dL), whether or not to exclude certain populations (like pregnant patients) or time periods (events in first 24 hours), etc. Exclude redundant glucose checks after an event (consider reviewing only the first hypoglycemic value on any given patient-day). Consecutive cases of hypoglycemia or random sampling is less prone to bias than convenience sampling.

Collect what you need (and nothing else).

Envision the summary of hypoglycemia in your hospital before you begin to collect data, make sure you collect the data you need to fill out that description and avoid collecting extra information that is less important.

Include early stopping rules for data collection if hypoglycemia does not represent an inpatient ADE.

After recording basic demographics (patient identifiers, unit, service, hospital day, low glucose value, date, time, presence/type of diabetes, etc.) ascertain early if the hypoglycemia value that triggered the event was real. Falsely low recordings can be quite common, especially in the ICU setting. An immediately repeated test or series of tests with normal values in an asymptomatic patient, without intervening treatment, should be recorded as a false positive value and further review for etiology can stop. Next, ascertain if the hypoglycemic event represents an adverse drug event. For example, a hypoglycemic event could be implicated if there was exposure to a long-acting basal insulin within 24 hours prior to an event, eight hours prior to regular or NPH insulin, or up to six hours after exposure to a rapid-acting analog insulin, but hypoglycemia without prior exposure is not unusual, especially in critically ill/terminally ill populations. If the hypoglycemic event does not represent an ADE, the review for further root causes can stop.

Describe consequences of the hypoglycemic ADE.

Consider a pull-down menu or checkboxes that would allow for easy documentation. Consider capturing both symptoms and consequences of the hypoglycemic event.

- **Symptoms:** Documentation not available, documented asymptomatic, hunger, headache, irritability, shaky or tremulous, confusion, diaphoresis, nausea, seizure, slurred speech, agitation, drowsiness, stroke, death, other
- **Consequences:** Treatment or extra monitoring required, Rapid Response Team deployed, code called, prolonged stay, transfer to higher level of care or monitored bed, temporary or permanent harm

Investigate etiology of hypoglycemic ADE, looking for most common failure modes.

As noted previously, there are literally dozens of potential contributing factors to hypoglycemic ADEs. Focusing on the most common etiologies from the literature[22-27] and the National Action Plan for Adverse Drug Event Prevention[36] makes case review more productive.

- Nutritional interruption without reducing insulin or adding carbohydrate (most often unscheduled interruption, but can also occur with mismanaged routine NPO status)
- Prior hypoglycemia without medication or carbohydrate adjustment
- Prescribing errors (especially excessive basal insulin dosing that inappropriately covered nutritional, as well as basal needs, failure to discontinue oral agents and failure to adjust insulin dose when insulin requirements diminish and glucose values decrease quickly or drop under 100 mg/dL)

Having a glycemic target that is too stringent for the individual patient, delays in glucose monitoring during insulin infusion, failure to adjust insulin after rapid decrease in steroid dosing, insulin therapy for hyperkalemia without covering for potential hypoglycemia, non-standard concentrations of insulin, and dispensing, transcription or administration all can (and do) occur, albeit less frequently than the first three sources.

Tailor data collection and interpretation to the sophistication of the data collectors.

Classifying the contributing sources of a hypoglycemic event can become quite complex, with prescribing errors representing the most difficult and complex to sort out, especially for a less sophisticated reviewer (e.g., a student or resident). Adjudication of any complex case by a more expert reviewer is advisable, as is tailoring the data collection tool to the sophistication of the primary reviewers.

Evaluate management of the hypoglycemic event as well as the etiology.

A hypoglycemia management protocol should set standards for dose and route of treatment, acceptable time interval for rechecking the BG, assessment and mitigation of the underlying cause of the hypoglycemic event and finally for documentation standards to record related symptoms, treatment and notification to ordering providers. While automated reports from SHM can capture the timeliness of a hypoglycemic event management and resolution, manual review is the only way to fully assess some of these other aspects of hypoglycemia management.

Pilot the data collection tool before finalizing it, and check inter-observer issues early.

We suggest having two to three observers collect data on four to five cases early on, to eliminate ambiguity from the data collection tool, gain agreement on definitions and to make sure all data collectors are collecting data in a consistent manner.

Regularly revisit trends and systems issues.

Ultimately, hypoglycemia case review should inform the improvement teams about the most important failures in preventing and managing hypoglycemic events, and focus improvement efforts accordingly. A comment section at the end of the survey can be used to explicitly call out systems issues or areas in need of improvement that were illustrated by the case review.

An example hypoglycemia case review form is on the next page.

Glycemic Control Data Collection Sheet - revised 11/17/14

Patient Name (Last, First)		Service	
MRN		Service Other	
Pt/Encounter ID		Facility	
		Unit	
Date/Time		Blood Glucose	
Reviewer		Patient Weight (kgs)	

1. Real BG Value

Yes
No (If no you do not have to continue past this point)
Unclear, referred to Dr. Kulasa to evaluate

Erroneous BG Value

BG < 70 mg/dL, with the repeat value of ≥ 70 within 5 minutes and no treatment

2. On a glycemic regimen?

Yes
No (If no you do not have to continue past this point)
Unclear, referred to Dr. Kulasa to evaluate

Reason for Referal:

Glycemic Regimen

Insulin glargine SQ 48 hrs prior to hypoglycemic event
Insulin NPH SQ 24 hrs hrs prior to hypoglycemic event
Insulin regular SQ 12 hrs prior to hypoglycemic event
Insulin lispro SQ 12 hrs prior to hypoglycemic event
Insulin regular IV 4hrs hrs prior to hypoglycemic event
Oral anti-diabetic medications 48 hrs prior to hypoglycemic event

3. Type of regimen? *(check all that apply)*

Basal/Nutrition/Scale
Basal/Scale
Scale only
Nutritional/Scale
Oral/Insulin
Infusion
Oral meds
Other (describe below)

4. Etiology (check all that apply)

Nutrition discordance (N/V, appetite)
NPO routine
Failure to adjust after hypoglycemic event

Prior hypoglycemia (BG < 70 mg/dL on this admission)		
BG value		
Date		
Time		
Comment		

Other (describe below)

TF/TPN held

Nutrition on Hold Protocol followed?
Yes
No (please add comment)
Comment

Renal function (GFR < 50 mL/min)

GFR

Prescribing - Incorrect Dose

Comment

5. Hypoglycemia protocol followed? (check all that apply)

Yes
No

1st recheck not within 30 min
2nd recheck not done within 30 min
No documentation regarding recheck
Other (describe below)

No documentation to possible cause
MD/Pharmacy not notified
Dextrose not given
Insulin not adjusted

6. Computer protocol followed in previous 3 blood glucose checks?

Yes
No
Not Real BG Value
Comments

1 hr check **2 hrs check**

Computer Protocol Not Followed

Inappropriate frequency of BG checks
Inappropriate insulin dose adjustment
Lack of communication w/ M.D. & Pharm.D. when recommended insulin infusion rate does not fit clinical picture of the patient.

7. Other Comments

F. A Hypoglycemia Reduction Bundle of Interventions and Best Practices

Multiple interventions are needed to minimize hypoglycemia, as there are multiple root causes and contributing factors. In fact, there are so many causes that hypoglycemia prevention efforts can be stymied by lack of direction and focus, as well as "analysis paralysis." Local metrics and case review should help prioritize efforts, but prioritization of interventions is also informed by an understanding of the most common failure modes from the literature, and from interventional bundles with demonstrated success.

The National Action Plan for ADE Prevention[36] places their strategies for reduction of inpatient hypoglycemic ADEs into four categories:

1. **Patient and Family Engagement:** Individualized target setting, use of Teach Back methods and self-management education, understanding patient adherence to medication and diet, etc.
2. **Effective Communication and Coordination of Care:** Multidisciplinary coordination and collaborative healthcare professional partnerships, education on importance of communication and coordination, engagement at the time of discharge, minimizing fragmentation of care and support for the development of tools for prescribing, identifying root causes of hypoglycemic events and improving patient adherence.
3. **Science Driven Prevention and Treatment:** Protocols and order sets, assessing causes of hypoglycemic event as routine part of hypoglycemia management, capturing critical information associated with hypoglycemic events at transitions, etc.
4. **Promotion of Best Practices within Communities:** Encouraging multidisciplinary care coordination, considering individual patient circumstances and ensuring professional supervision during medication changes.

These are all consistent with the ASHP Foundation expert consensus panel and the high impact interventions, as summarized in Box 1 earlier in this section.[8]

A recently reported AHRQ funded effort at the University of California, San Diego modeled the successful implementation of a Hypoglycemia Reduction Bundle, as summarized in Table 3.[37]

Table 3.

Hypoglycemia Reduction Bundle

Failure Mode	Hypoglycemia Reduction Bundle Strategies and Solutions
Inappropriate prescribing	Standardized order sets for subcutaneous insulin, IV insulin, transitions, and monitoring. Pre-formatted insulin regimens to match nutritional intake patterns. Forcing functions (mandating use of protocol-driven orders) Intelligent clinical decision support (CDS) in order sets. Elimination of free text insulin orders CDS discouraging correction / sliding scale insulin as primary strategy to control hyperglycemia, and discouraging oral agent use. Educational tools for physicians, nursing, pharmacists, and patients.
Glycemic target too low	CDS to tailor glycemic targets for those at risk of hypoglycemia.
Matching nutritional intake to insulin dosing	Policies, protocols, and order set CDS for managing unexpected interruption of nutrition. Coordination of nutrition delivery, glucose testing, and insulin administration Patient and family educational tools.
Failure to manage hypoglycemia and adjust appropriately	Hypoglycemia management protocol that features a structured assessment of the etiology, and suggests mitigation strategies. Regular feedback on glucometrics, tracking timeliness of hypoglycemia management, and the percentage of patients with one hypoglycemic event that suffer another hypoglycemic day
Monitoring deficiencies and failure to proactively recognize and manage glycemic excursions	Tracking, trending, and feedback of glycemic control, hypoglycemia, and hypoglycemia management parameters on a monthly basis. EHR daily reports of glycemic outliers serve as a stimulus for concurrent intervention, aka measure-vention. Glycemic control flow sheets that graphically display glycemic trends and insulin dosing, and pull together other pertinent parameters to assist with management (e.g., serum creatinine, HbA1c) assist in measure-vention and also raise awareness of glycemic control issues for the primary inpatient team. Standards for timely monitoring of glucose, assure adherence
Storing and dispensing	Insulin concentrations limited to U-100. Insulin and syringes are clearly labeled and segregated from other medications.
Administering	IV bolus and infusion insulin prepared only in pharmacy.

IV = intravenous; CDS = Clinical Decision Support; EHR = Electronic Health Record

The interventions were designed to address the most common sources of remediable failure modes contributing to iatrogenic hypoglycemic ADEs. In this large study of almost 23,000 monitored non-ICU patients, glycemic control, hypoglycemia and hypoglycemia management parameters were compared over the course of implementation efforts. Hypoglycemia was defined as BG <70 mg/dL, severe hypoglycemia <40 mg/dL and severe hyperglycemic days defined as a hospital day with any BG >299 mg/dL. The relative risk for suffering from a hypoglycemic event or severe hypoglycemic event during the stay was reduced by 29 percent and 56 percent, respectively, while glycemic control was improved, and the risk of a severely hyperglycemic day was reduced by 24 percent. Overall the medical center achieved top-quartile performance in both hypoglycemia and glycemic control, an achievement reached by fewer than 10 percent of participating hospitals. These top-performing hospitals illustrate that it is feasible to achieve glycemic control and hypoglycemia goals simultaneously, and that these goals are not necessarily mutually exclusive.[18,19] In fact, many of the monitoring, standardization and education tools necessary to achieve good glycemic control are also necessary to achieve low hypoglycemia rates.

Some of the interventions in the bundle are self-explanatory and can be achieved by pharmacy/nursing policy, such as the storing and dispensing, and administration aspects of the bundle. Some additional detail and practical tips are provided for the remaining portions of the bundle.

Improving Prescribing Practices

Standardized order sets should be designed to guide providers in ordering insulin in a safe, standardized manner while retaining ease of use, and flexibility to adjust for individual patient circumstances. A full discussion of design and implementation issues is beyond the scope of this section, and more detailed guidance is available elsewhere in this *Guide* (ref subcut orders, infusion orders, transitions, periop)[38-41] and here we only highlight major points pertinent to hypoglycemia prevention and selected practical strategies.

The ASHP expert panel outlined a large number of prescribing areas to be addressed (See Table 1),[8] and most improvement teams will be unable address all areas at once. Reviewing hypoglycemia rates (ICU vs non-ICU vs OR-related, etc.) and case reviews of hypoglycemic ADEs should help your team prioritize the most important areas. Review where standardization of prescribing is already in place, and focus on the area most in need. Be sure to build in clinical decision support for glycemic targets, and to provide guidance about when a more liberal glycemic target is indicated. Bringing pertinent information on HbA1c and hypoglycemic risk factors to the ordering provider during the ordering process in EHRs can raise awareness and avert overly aggressive protocols. Discouraging free text orders, oral hypoglycemic agents and sliding scale insulin orders as a sole method of glycemic control are often priorities.

Education is always a necessary element to improve prescribing practices. Case-based, simulation and "just in time" education are often more effective than traditional methods of education. Unfortunately, while nursing and pharmacy staff may frequently have competency-based mandatory training for insulin, physician training and understanding of appropriate prescribing are often lacking.[42]

Matching Nutritional Intake to Insulin Dosing

Unexpected interruption of carbohydrate intake is a top source of hypoglycemia worthy of educational efforts, and integration in protocols and order set clinical decision support. Patients and families can be educated and trained on the concepts and become important advocates for their own safety. An algorithmic guideline for unexpected interruptions was very helpful to guide teaching efforts and practice (see Figure 2). The guideline was reinforced by ongoing educational and competency training and language embedded in order sets and the Medication Administration Record (MAR). An electronic best practice alert can be triggered if tube feedings or TPN rates are reduced downward and the patient in on insulin infusion. Color-coded coordinated labeling on insulin infusion pumps and tube feedings (as shown in Figure 3) can help raise awareness about hypoglycemia risk if feedings are interrupted.

Poor coordination of insulin delivery, meal delivery and BG testing can also contribute to glycemic excursions. This topic is covered more completely later in this section. Routine "NPO after Midnight" status, with an expected nutritional interruption, generally should only rarely lead to hypoglycemia if insulin is dosed appropriately (watching out especially for overuse of basal insulin to cover nutritional needs), but this is a common source of confusion and variable practice. Providing clinical decision support in the order set and MAR to allow routine withholding or adjustment of nutritional insulin based on nutritional intake can reduce unwanted variability from care. For example, at UCSD Medical Center, comments allowing nurses to hold the nutritional insulin dose until after the meal in the setting of nausea or poor appetite, and guidance to adjust the dose of nutritional insulin based on the percent of tray consumed were added to nutritional insulin orders and the medication administration record.

"Give with first bite of food (or up to 30 minutes after first bite of food if patient is nauseated or has poor appetite). Give 0 units if patient ate less than 50% of the meal, give half of the scheduled dose if patient ate 50% of the meal, and give the full dose if patient ate more than 50% of the meal."

This guidance provided nurses with the flexibility to match the dose of nutritional insulin to the amount of food consumed and reduced calls to the ordering providers.[37]

Figure 2. Algorithm Guiding Care for Inpatients on Insulin with a Sudden, Unexpected Interruption of Nutrition (Provided by K. Kulasa and G. Maynard, UCSD Medical Center)

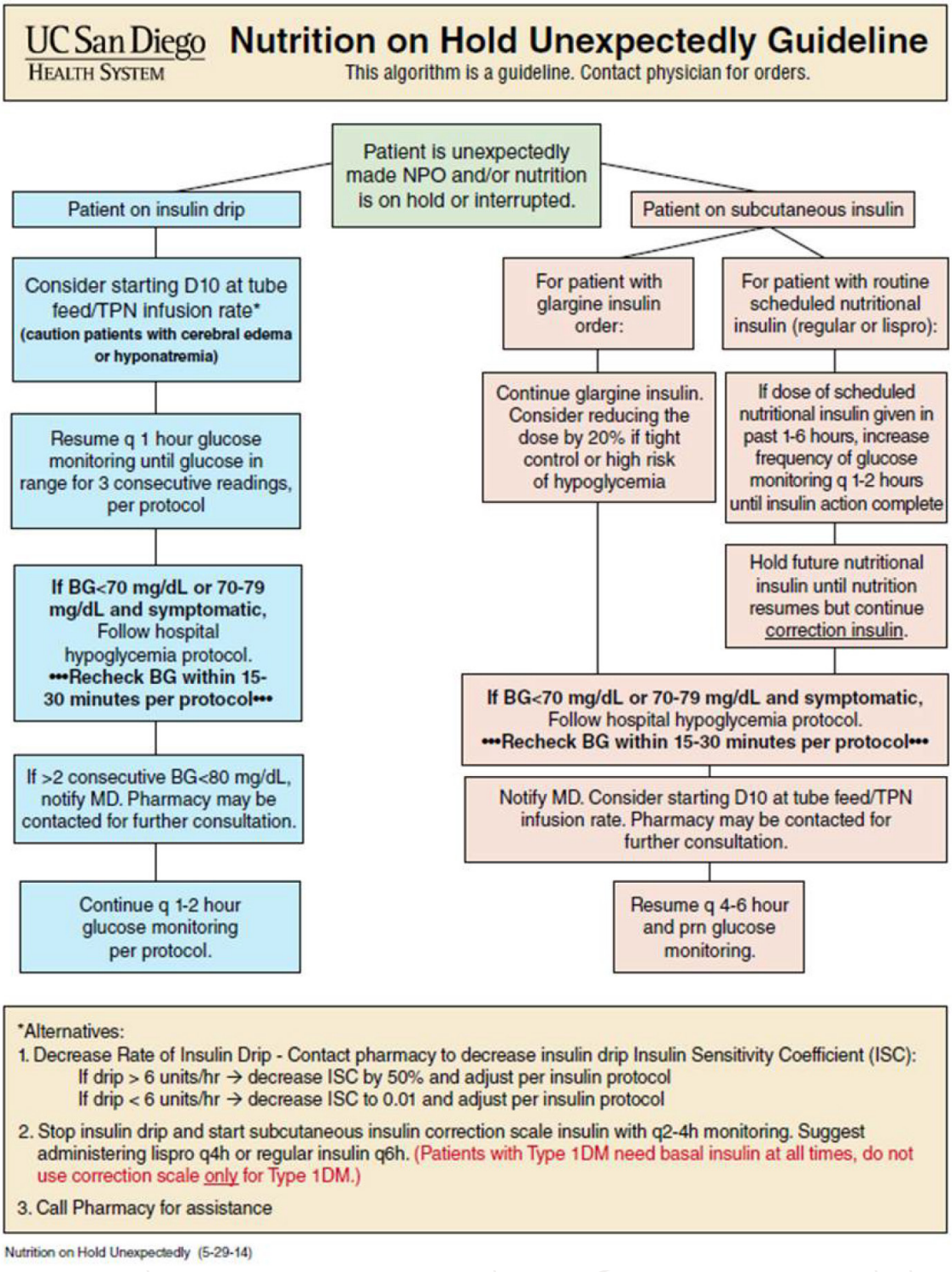
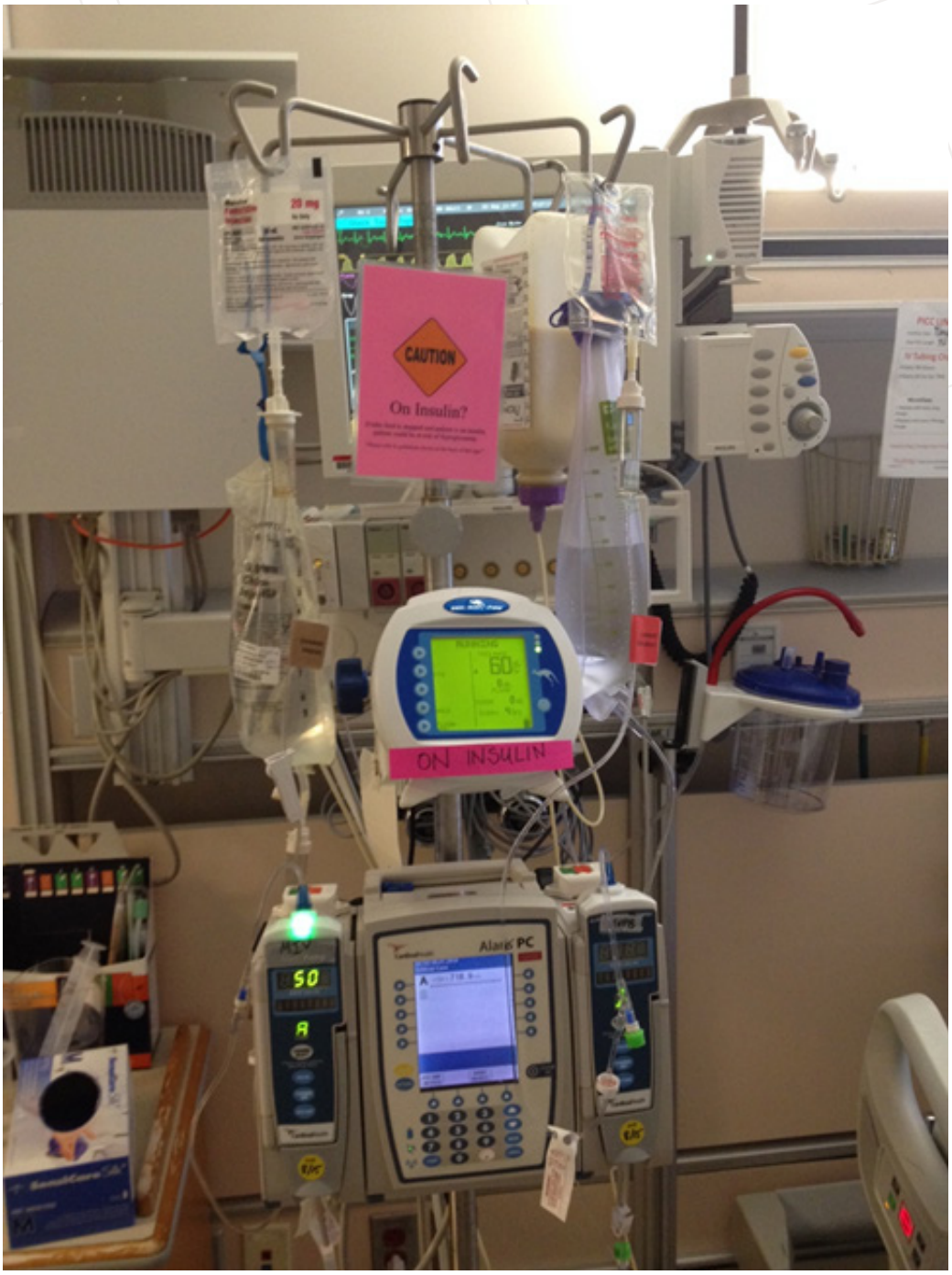


Figure 3. **Color-coded Matching Reminders Raise Awareness About Hypoglycemia Risk for Patients on Insulin Infusion and Enteral Tube Feedings (Provided by K. Kulasa and G. Maynard, UCSD Medical Center)**



Managing Hypoglycemia and Adjusting Appropriately After a Hypoglycemic Event

As already noted, hypoglycemia management is often delayed, poorly documented and fails to prevent recurrent hypoglycemic events.[22,25-27] Nursing-directed hypoglycemia management protocols must therefore address and monitor timeliness, the quality of documentation and effectiveness in assessing and mitigating the factors leading to the index hypoglycemic event.

Automated reports (like those offered by SHM) can track time intervals between the hypoglycemic event, repeat testing and hypoglycemia resolution, with further resolution being available with manual chart review. Audit and feedback to individual units can be very effective in this regard. Improved timeliness of hypoglycemia management has often correlated with reductions in hypoglycemia and recurrent hypoglycemia rates.

Hypoglycemia management protocols and documentation tools should have a prominent section for assessing the etiology of the hypoglycemic event and the steps taken to address the contributing factors. The Federal Interagency Workgroup to prevent ADE provided an example of components to be included in clinical decision support for the evaluation of hypoglycemia (Figure 4).[36]

Figure 4. Proposed Clinical Decision Support Display for Hypoglycemia Evaluation Suggested by the Federal Interagency Workgroup to Prevent Adverse Drug Events.

Report etiology of hypoglycemic event after event resolution

	Etiology of hypoglycemic event
	Nutritional interruption without reducing insulin or adding carbohydrate
	Prior hypoglycemic event without medication or carbohydrate adjustment
	Excessive basal insulin dosing that inappropriately covered nutritional needs, as well as basal needs
	Glycemic target that is too stringent for patient condition/co-morbidities
	Failure to discontinue oral hypoglycemic agents in the inpatient setting
	Time interval between testing was too long
	Other failure mode: _____
	No preventable factors detected.

Report ACTION taken to MITIGATE hypoglycemia

	ACTION
	Call to reduce hypoglycemic agent
	Call to increase CHO
	Education/reinforcement of policy/protocols
	Other

Other examples illustrating effective hypoglycemia management protocols and related documentation and intervention issues are available in the Glycemic Control Online Toolkit.

Addressing Monitoring Deficiencies and Using Active Surveillance

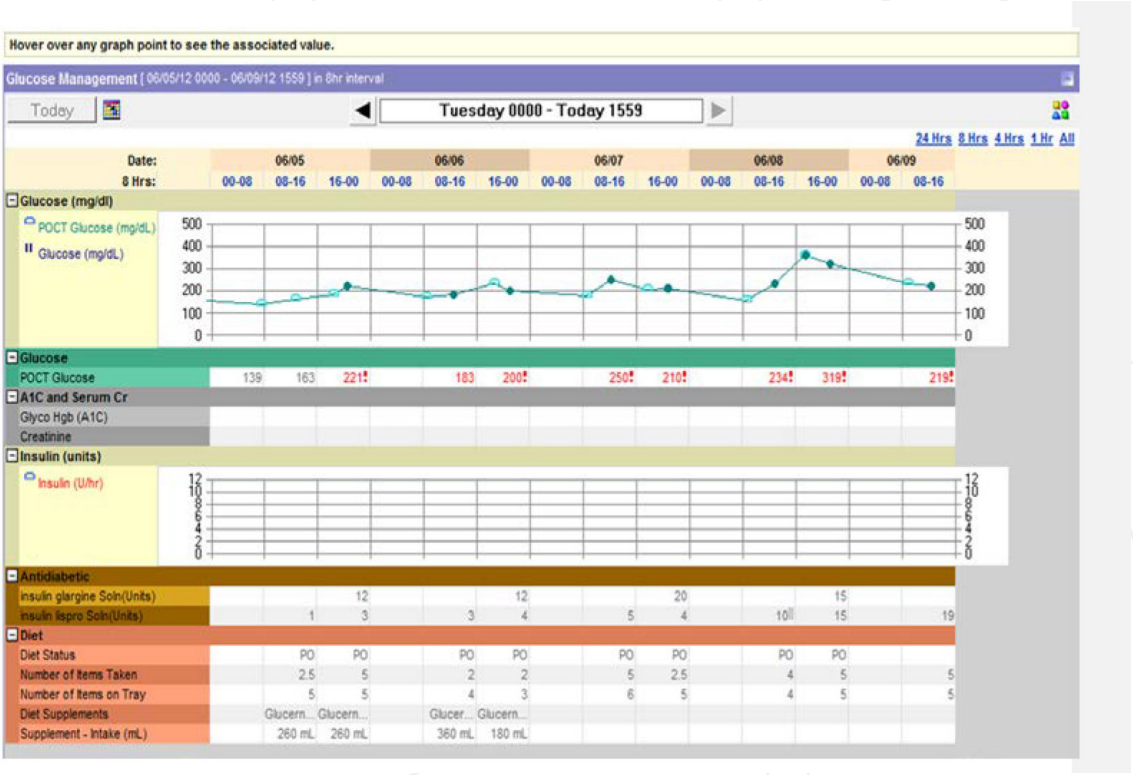
Monitoring deficiencies can occur at several layers. Lack of measurement around glycemic efforts, without month-to-month or quarter-by-quarter assessment of glucometrics and other measures, and lack of comparison benchmarking, can be viewed as failure in monitoring efforts in the broadest sense.[2,8,28,30,36] This essential component of improvement is described in detail elsewhere in the *Guide*.[30] Free or low-cost external glucometrics are available from the Yale Glucometrics site and the Society of Hospital Medicine, and the combination of internal and external measurement tools may work best for many centers.[18,19,30,32-35]

Adherence with monitoring standards on infusion insulin can be problematic, with delays occasionally leading to dangerous glycemic excursions (both low and high). Automated measures or audit and feedback can result in improved performance on the timeliness of monitoring. Streamlining the steps in obtaining the glucose value, documenting the BG and administering the correct insulin dose (e.g., wireless monitors that upload the BG data without extra nursing effort) can improve timeliness of monitoring as well.

Individual ordering providers do not always prioritize BG monitoring, and every effort should be made to bring all the pertinent information together that is needed to manage hyperglycemia. A glucose management page that displays several variables together in an organized manner (such as HbA1c, glucose values, renal function, nutrition intake, insulin dosing, etc.) enables providers to quickly assess the patient's glycemic trend, and plan on revisions in the regimen. Color coding and the use of graphic displays with Run Charts can further raise awareness and spur appropriate action on declining glucose values.[8,28,37] Figure 5 and Figure 6 are examples of glucose management pages with some of these properties.

Figure 5. Glucose management sheet from Cerner EHR at Virginia Mason Medical Center, courtesy of Dr. Thérèse Franco. Note that insulin orders, dosing, diet, glucose values and insulin administered are all available on the glycemic management page, and just a few clicks gets into revision of orders. Glycemic zones are color coded.

Figure 6. Glucose management page in Epic, provided by K. Kulasa and G. Maynard and UC San Diego Medical Center. Note HbA1c, creatinine, insulin dosing, portions of meal and supplement taken, and other factors are available at a glance. Glucose management sheets make review more convenient and raise awareness regarding a trend toward lower glucose values preceding hypoglycemia.



A third layer of monitoring goes beyond month-to-month metrics and glucose management pages to address one of the recommendations from the ASHP Expert Consensus panel:

"Real-time, institution-wide glucose reports should be provided to health care team members to ensure appropriate surveillance and management of patients with unexpected hypoglycemia and hyperglycemia."[8]

Identifying and addressing quality outliers in real time (as opposed to relying solely on month-to-month metrics) is a form of active surveillance we have termed measure-vention, coupling real-time measurement with concurrent intervention. The measure-vention technique was first demonstrated to be effective in optimizing thromboprophylaxis, and has since been utilized in a number of improvement efforts in our institution and others.[43-45] Most recently, measure-vention was used successfully as part of the hypoglycemia reduction bundle at UC San Diego.[37]

This active surveillance or measure-vention consists of three steps. In the first step, a patient in the hospital with a potential deficit in care (for example, a patient with a BG value of 75 mg/dL) is identified. In the second step (ideally all within the medical record) the case is triaged efficiently, often using tools like the glucose management pages depicted above. In some cases, a BG of 75 mg/dL, might be perfectly appropriate and the ordering provider may have already made changes to ensure the BG value will not cross into hypoglycemic territory, in which case no action is taken by the reviewer. On the other hand, if no change in nutrition or insulin dosing is ordered with a BG of 75 mg/dL, and the glycemic trend is steeply declining, the third step (a proactive intervention, such as a call to the ordering provider) could prevent the patient from have a hypoglycemic ADE. Automated reports and glucose management pages can make this a fairly efficient process, and the threshold for screening can be modified to fit local resources.

G. Transitioning Out of the Hospital

Hypoglycemic ADEs are a frequent source of acute hospitalizations, Emergency Department visits and readmissions.[36,47] Medication errors and ADEs are frequently linked to poor communication of instructions at the point of discharge.[36,48-50] Standardized instructions specifically for insulin and supplies at hospital discharge can reduce adverse events.[51]

Many factors must be taken into account to craft the optimal glycemic control regimen for the patient on transition out of hospital. The outpatient regimen and control the patient had with it (HbA1c), major changes from recent illness and hospitalization and the inpatient regimen and control all need to be considered. Patient preferences, engagement in their own care, fiscal/psychosocial issues and access to follow up and monitoring supplies all play a valid role.[28,36,51]

For a more robust discussion, please refer to the Transitions section elsewhere in this *Guide*.[46]

H. Conclusion

Hypoglycemic adverse drug events are a common, but frequently preventable source of morbidity and cost. Prioritizing interventions on the most common sources of inpatient hypoglycemic ADEs (prescribing errors, failure to respond to unexpected nutritional interruption and failure to appropriately manage a prior hypoglycemic event), along with ongoing measurement and monitoring, provide a solid foundation for improvement.

References

[1]Cryer PE. Hypoglycaemia: the limiting factor in the glycaemic management of type I and type II diabetes. *Diabetologia . 2002;*45:937–948.

[2]American College of Endocrinology and American Diabetes Association Consensus Statement on Inpatient Diabetes and Glycemic Control: A call to action. *Diabetes Care.* 2006;29(8):1955-1962.

[3]Phillips LS, Branch WT, Cook CB, et al. Clinical inertia. *Ann Intern Med.* 2001;135(9):825-34.

[4]Cook CB, Castro JC, Schmidt RE, et al. Diabetes care in hospitalized noncritically ill patients: More evidence for clinical inertia and negative therapeutic momentum. *J Hosp Med.* 2007;2(4):203–211.

[5]Umpierrez G, Maynard G. Glycemic chaos (not glycemic control) still the rule for inpatient care: how do we stop the insanity? *J Hosp Med.* 2006;1(3):141-144.

[6]Curkendall SM, Natoli JL, Alexander CM, Nathanson BH, Haidar T, Dubois RW. Economic and clinical impact of inpatient diabetic hypoglycemia. *Endocr Pract.* 2009;15(4):302-312.

[7]Farrokhi F, Smiley D, Umpierrez GE. Glycemic control in non-diabetic critically ill patients. *Best Pract Res Clin Endocrinol Metab.* 2011 Oct;25(5):813–824.

[8]Cobaugh DJ, Maynard G, Cooper L, et al. Enhancing insulin-use safety in hospitals: Practical recommendations from an ASHP Foundation expert consensus panel. *Am J Health Syst Pharm.* 2013;70(16):1404-13.

[9]Boucai L, Southern WN, Zonszein J. Hypoglycemia-associated mortality is not drug-associated but linked to comorbidities. *Am J Med.* 2011;124:1028-1035.

[10]Kagansky N, Levy S, Rimon E, et al. Hypoglycemia as a predictor of mortality in hospitalized elderly patients. *Arch Int Med.* 2003;163(15):1825-1829.

[11]Amori RE, Pittas AG, Siegel RD, et al. Inpatient medical errors involving glucose-lowering medications and their impact on patients: review of 2,598 incidents from a voluntary electronic error-reporting database. *Endocr Pract.* 2008;14(5):535-542.

[12]Classen DC, Jaser L, Budnitz DS. Adverse drug events among hospitalized Medicare patients: epidemiology and national estimates from a new approach to surveillance. *Joint Commission Journal on Quality and Patient Safety/Joint Commission Resources.* 2010; 36(1):12-821.

[13]Institute for Safe Medication Practices. ISMP's list of high-alert medications available at: http:// www.ismp.org/tools/highalertmedicationLists.asp. Accessed December 5, 2014.

[14]Cousins D, Rosario C, Scarpello J. Insulin, hospitals and harm: a review of patient safety incidents reported to the National Patient Safety Agency. *Clin Med.* 2011;11:28-30.

References (continued)

[15]Deal EN, Liu A, Wise LL et al. Inpatient insulin orders: are patients getting what is prescribed? *J Hosp Med.* 2011;6:526–529.

[16]Hellman R. A systems approach to reducing errors in insulin therapy in the inpatient setting. *Endocr Pract.* 2004;10 Suppl 2:100–108.

[17]Office of the Inspector General. Adverse events in hospitals: National Incidence among Medicare beneficiaries. 2010.

[18]Maynard G, Ramos P, Kulasa K, Rogers KM, Messler J, Schnipper JL. How Sweet is It? The Use of Benchmarking to Optimize Inpatient Glycemic Control. *Diabetes Spectrum.* 2014:27(3):212–217.

[19]Maynard G, Schnipper JL, Messler J, Ramos P, Kulasa K, Nolan A, Rogers K. Design and Implementation of a Web-Based Reporting and Benchmarking Center for Inpatient Glucometrics. *J Diabetes Science Tech.* 2014; published online May 12, 2014. doi: 10.1177/1932296814532237.

[20]Swanson CM, Potter DJ, Kongable GL, Cook CB. Update on inpatient glycemic control in Hospitals in the United States. *Endocr Pract.* 2011;17(6):853–861.

[21]Pennsylvania Patient Safety Authority. Medication errors with the dosing of insulin: problems across the continuum. *Pa Patient Saf Advis.* 2010;7:9–17.

[22]Maynard GA, Huynh MP, Renvall M. Iatrogenic Inpatient hypoglycemia: risk factors, treatment, and prevention: analysis of current practice at an academic medical center with implications for improvement efforts. *Diabetes Spectr.* 2008; 21(4): 241–247.

[23]Anthony M. Treatment of hypoglycemia in hospitalized adults: a descriptive study. *The Diabetes Educator.* 2007;33(4):709–715.

[24]Braithwaite SS, Buie MM, Thompson CL, et al. Hospital hypoglycemia: not only treatment but also prevention. *Endocr Pract* 2004.10 Suppl 2:89–99.

[25]Varghese P, Gleason V, Sorokin R, et al. Hypoglycemia in hospitalized patients treated with antihyperglycemic agents. *J Hosp Med.* 2007;2(4): 234–240.

[26]Garg R, Bhutani H, Jarry A, et al. Provider response to insulin-induced hypoglycemic in hospitalized patient. *J Hosp Med.* 2007;2(4): 258–260.

[27]Rajkanna J, Martin D, Whittle L, Oyibo SO. Hypoglycaemia in hospital: a re-audit and root cause analysis using a hypoglycaemic events reporting system. *Practical Diabetes.* 2013:30(8): 336–339.

[28]Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of hyperglycemia in hospitalized patients in the non-critical care setting: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metabol.* 97(1):16–38.

[29]Rogers et al. Assess the current state of glycemic management in your facility complete ref when published or posted

[30]Maynard et al. Choose Metrics and Develop a Data Collection Plan for your Glycemic Control Program complete ref when published or posted.

[31]Alere™ Informatics Website for Remote Automated Laboratory Systems (RALS®). http://www.rals.com/index.html. Accessed February 14, 2014.

[32]Goldberg PA, Bozzo JE, Thomas PG, et al. ''Glucometrics''— assessing the quality of inpatient glucose management. *Diabetes Technol Ther.* 2006;8:560–569.

[33]Thomas P, Inzucchi SE. An internet service supporting quality assessment of inpatient glycemic control. *J Diabetes Sci Technol. 2008;*2(3):402–408.

[34]Yale Glucometrics Website: http://metrics.med.yale.edu. Accessed January 2, 2014.

[35]Maynard G. Evaluation of hypoglycemia - a practical approach for QI. Society of Hospital Medicine Webinar presented January 15, 2014. Accessed December 15, 2014.

[36]U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion.(2014). National Action Plan for Adverse Drug Event Prevention. Washington DC. Available at www.health.gov/hai/pdfs/ADE-Action-Plan-508c.pdf. Accessed December 10, 2014.

[37]Maynard G, Kulasa K, Ramos P et al. Impact of a hypoglycemia reduction bundle and a systems approach to inpatient glycemic management. *Endocr Pract.* 2015 April 15th pub pend.

[38]Maynard et al Section II Section D.1: Subcutaneous Insulin

[39]Maynard et al Section II Section D.2: Insulin Infusion and transition to Subcutaneous

[40]New chapter on transitions

[41]Maynard et al Section II Section E: Transition to the Outpatient Setting

[42]Rodriguez A, Magee M, Ramos P, Seley JJ, Nolan A, Kulasa K, Caudell KA, Lamb A, MacIndoe J, Maynard G. Best Practices for Interdisciplinary Care Management by Hospital Glycemic Teams: Results of a Society of Hospital Medicine Survey Among 19 U.S. Hospitals. *Diabetes Spectrum.* 2014:27(3):197–206.

[43]Maynard G, Stein J. Designing and implementing effective VTE prevention protocols: lessons from collaboratives. *J Thromb Thrombolysis. 2*010; Feb:29:159-166.

[44]Maynard G, Morris T, Jenkins I, et al. Optimizing prevention of hospital acquired venous thromboembolism: prospective validation of a VTE risk assessment model. *J Hosp Med.* 2010 Jan;5:10–18.

[45]Maynard G, Stein J. Preventing Hospital-Acquired Venous Thromboembolism: A Guide for Effective Quality Improvement. Prepared by the Society of Hospital Medicine. AHRQ Publication No. 08-0075. Rockville, MD: Agency for Healthcare Research and Quality. September 2008, last accessed September 15, 2008 at http://www.ahrg.gov/qual/veguide/.

[46]Transitions chapter from this guide

[47]Budnitz DS, Lovegrove MC, Shehab N, Richards CL. Emergency hospitalization for adverse drug events in older americans. *N Engl J Med.* 2011;365(21):2002–2012.

[48]Kripalani S, Roumie CL, Dalal AK, Cawthon C, Businger A, Eden SK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: a randomized trial. *Ann Intern Med.* 2012;157(1):1–10.

[49]Kripalani S, Jackson AT, Schnipper JL, Coleman EA. Promoting effective transitions of care at hospital discharge: a review of key issues for hospitalists. *J Hosp Med.* 2007; 2:314–323.

[50]Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. The incidence and severity of adverse events affecting patients after discharge from the hospital. *Ann Intern Med.* 2003;138:161–167.

[51]Lauster CD, Gibson JM, Dinella JV, Dinardo M, Korytkowski MT, Donihi AC. Implementation of standardized instructions for insulin at hospital discharge. *J Hosp Med.* 2009;4(8):E41–2.

Section VI.2: Inpatient Diabetic Diets and Coordination of Nutritional Delivery, Glucose Monitoring and Insulin Administration

Achieving good glucose control is not only dependent on knowing and having the right insulin orders, but also on the important nursing and food service processes that are necessary to avoid hypo- and hyperglycemia. It is an obvious statement that the food consumed by patients and how they receive their insulin while inpatients will impact their glucose control. However, many glycemic control projects only focus on the physician ordering of insulin. This section will guide you through important aspects of nutrition and coordination of meal delivery and insulin administration.

A . Consistent Carbohydrates

A consistent carbohydrate diet is the standard for hospitalized patients with diabetes and helps to improve the matching of carbohydrates and mealtime insulin administration.[1-2] The "ADA" diet is no longer current practice as it may unnecessarily restrict calories and evidence does not support the use of "no concentrated sweets," "no sugar" diet or the avoidance of sucrose-containing foods.[3-4] A consistent carbohydrate meal plan provides flexibility in calorie content and food choices to better meet patients' needs and preferences. With appropriate insulin dosing and administration, snacks do not have to be automatically included in the nutrition plan for patients on basal bolus insulin therapy and can be included based on patients' preferences and nutrition goals.[4-5]

Menus labeled with the carbohydrate content of food can help patients select appropriate foods and can be used as a teaching tool.[4] Once patients gain a better understanding of carbohydrate-rich foods, appropriate substitutions to meet individual preferences can be made. The achievement of glycemic goals is more likely when patients, nurses and meal service staff understand carbohydrates and the rationale behind the meal plan.[4]

B. Snacks and Supplements

Snacks and supplements may be needed to provide adequate calorie and protein intake, but do not need to be automatically included in the nutrition plan as snacks are not absolutely required.[4-5] Snacks and supplements should be provided based on a patient's preferences and nutritional needs.

A variety of snack options should also be present. Many hospitals have developed a list of low or no carbohydrate snack options for patients who are hungry between meals or at night to help improve patient satisfaction and nutritional needs without jeopardizing glycemic control.

Depending on the patient and carbohydrate content of the snack or supplement, additional insulin coverage may be required. Additional insulin orders should have appropriate administration instructions with indication and holding parameters to help the RN match the insulin with the corresponding snack or supplement.

C. Food Service Challenges

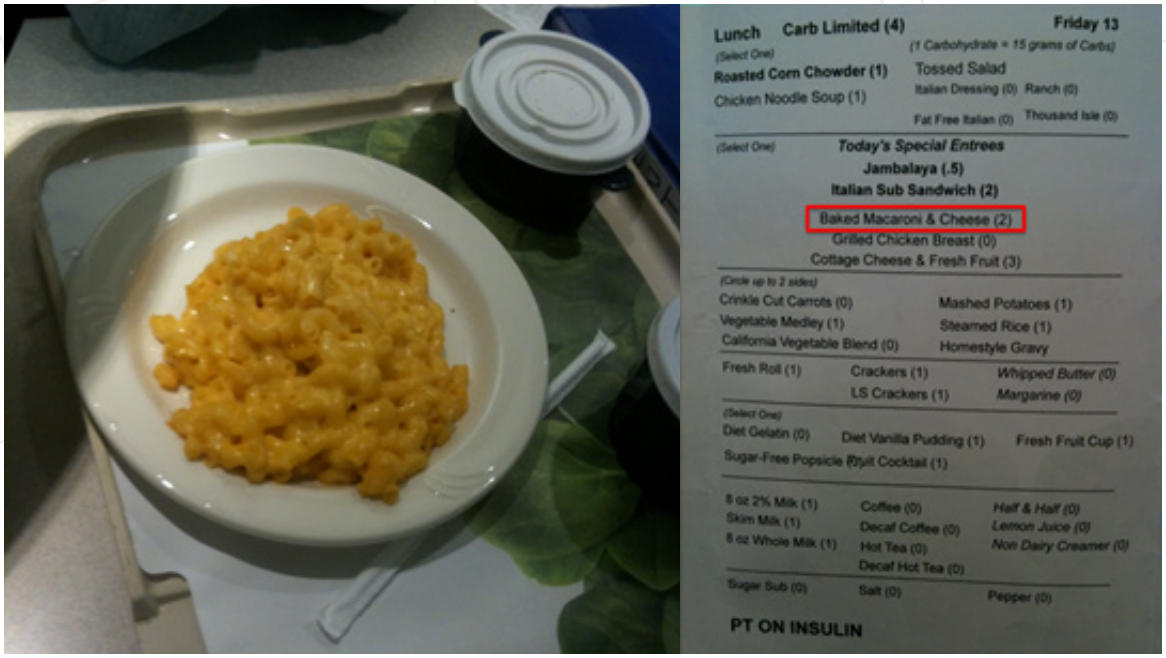
The challenges of providing consistent carbohydrate meals starts down in the kitchen. It is important to map the process from the very beginning in order to capture and resolve many of the problems.

Starting with the menus, the carbohydrate content of food needs to be labelled clearly and the corresponding portions on each tray need to match. For example, Figure 1 shows a picture of macaroni and cheese labeled as two carbohydrate servings (which would be a 2/3-cup portion); however, the portion on the plate was more like two to three cups (which would be 6-9 carbohydrate servings). A discrepancy like this could obviously lead to problems with glycemic control, but also introduces confusion for patients when they are using the menus as tools to help learn the carbohydrate content

of foods and appropriate portion sizes. In order to remedy this problem, more 1/3-cup scoops needed to be ordered for the kitchen so that the food service workers didn't have to use other scoop sizes when the appropriate scoop was not available, or could not be found in a timely manner. Also, education for the food service workers was implemented to teach them about diabetes, the impact of carbohydrates on blood sugars and the impact the scoop size has on the patient's overall inpatient glycemic control and healing process.[6]

Once the trays are accurate in regards to patient choice and appropriate portion sizes, data then needs to be collected to assess timing of tray delivery. Gathering data on timing of tray delivery (both to the floor and to the patient) will be important to assess tray temperatures and quality of food upon arrival to the patient as well as coordination with BG check and insulin as above. The different steps involved in each of these processes will vary by institution and cooking/delivery method, but each hospital should try to standardize these steps as much as possible.

Figure 1



D. NPO

During periods when patients are not receiving nutrition, nutritional insulin should be held. When appropriate indication and holding parameters are built into the insulin order sets, the insulin orders do not even need to be changed, especially during brief periods of NPO for a procedure or study. This helps minimize errors related to timing and writing of insulin orders. For periods of prolonged NPO or for patients at high risk of hypoglycemia, low-dose dextrose IVFs can be added to reduce the risk of hypoglycemia, but this is not required in the majority of hospitalized patients with diabetes.[7]

E. Mealtime Insulin Dosing

Mealtime insulin should be dosed to match the pattern in which nutrition is being delivered. For example, if a patient is receiving meals or bolus tube feeds, rapid-acting insulin can be given along with each meal or bolus tube feed to cover the glycemic peak that is caused by the meal. The rapid-acting analog insulin can also be given up to 30 minutes after the meal or bolus tube feed for cases in which it is not clear if the patient will actually eat or tolerate the nutrition. A reduction in the insulin dose proportionate to the amount of nutrition actually taken can then be made to decrease the risk of subsequent hypoglycemia. Indications, holding and adjustment parameters should be built into the insulin order sets to improve standardization and the chances of the orders being administered appropriately.[7]

One of the most challenging issues is the timing of insulin administration with glucose monitoring and meal delivery. While it is easy to state the goals of having these three distinct processes done in a coordinated and timely manner, achieving this in the complex inpatient environment is challenging. In the outpatient environment, this entire process is controlled by one individual (the patient); however in the hospital, as many as four to five different people may have roles to play, and some of these participants may not realize the impact of the role they are playing in achieving this goal. Thus education, communication and coordination of each of the roles as well as administrative backing and appropriate supporting policies are needed to meet this challenge.

The goal should be for glucose monitoring, meal delivery and insulin administration to occur within a 30-minute time frame with the insulin being given within 15 minutes of the first bite of the meal, or up to 30 minutes after the first bite of the meal in certain clinical situations. Ideally the patient would have their glucose checked, insulin dose calculated, meal delivered and insulin administered in a timely succession. However, the ways in which this is accomplished varies widely between hospitals and even among floors of the same hospital. Multiple staff members and departments have responsibilities for various aspects of this process — and without communication and coordination, the results can be disastrous. In the worst case, a tech is responsible for drawing the CBG, someone from the kitchen delivers all meal trays to the floor without identification of diabetic trays, someone else delivers the tray to the patient's room, the patient plays a role by deciding whether they are eating the food and keeping with predictable eating patterns, and a nurse is responsible for giving the insulin. In the most simplified version, a designated diabetic cart is delivered to the floor, each nurse who is assigned a patient with diabetes takes the tray to the room, checks the CBG before the patient starts eating, leaves the room to calculate and draw up the insulin and returns to give the insulin as the patient is beginning their meal.

F. Assessing Baseline

Most hospitals are very surprised when they observe this process as it is not often noted as a problem until it is properly investigated. Many issues may be uncovered including glucose monitoring that may occur hours before meal delivery (most common in early morning where night shift techs measure CBGs at 05:00 or even 04:00), insulin always being given after the completion of a meal (which can be over an hour after commencement of the meal), CBGs not being checked until after the meal in some circumstances, or nurses frequently holding doses on insulin for non-evidence based reasons. Often floors are not aware of the number of individuals involved and the lack of clear responsibilities that exist between them.

In many hospitals these three events must be observed to measure the current state accurately. Two of the data points should exist within the EMR, the first being the timestamp of the CBG and the second the timing of the insulin administration. Of course both of these may be altered, and commonly we can see the insulin timing being left as the time it was scheduled and not being accurately recorded as the time it was actually administered. The time of meal

delivery to the patient is often a difficult measure to find and can be laborious to assess, as it usually requires personal observation. In addition to this baseline data, a process-mapping session utilizing frontline workers is also recommended in order to investigate current practices and to plan interventions to improve them.

We recommend doing an observation and tracking these times. You can also try to involve reliable patients by giving them a monitoring sheet and asking them to write down when these times occur. Of course all of these methods have flaws, but again your goal is to get an idea of current practices so you can motivate change, and even small data samples can do this.

G. Common Issues Encountered

- Meal tray delivery times are inconsistent from the kitchen
- CBG monitoring done far before mealtime without realizing impact
- Poor communication between person drawing CBG and nurse administering insulin
- Trays delivered to rooms without coordination of either CBG or insulin
- CBGs being checked after patient has started meal
- Nurse concerned about hypoglycemia and unwilling to give insulin until completion of meal which is often delayed >one hour after meal completion
- Room service delivering meals directly to patients without notification or coordination with nursing or techs

H. Necessary Steps

The process established to coordinate the nutritional delivery, glucose monitoring and insulin administration will depend on the institution and available resources, but the necessary steps typically include:

1. Make a hospital policy to define acceptable timeframes for glucose monitoring, meal tray delivery and insulin administration
2. Monitor floors and provide baseline data
3. Allow floors to play active role in designing the processes needed to achieve this goal
4. Use floors that have achieved the goal as ‘best practice’ for other floors who are unable to meet the goal
5. Standardize as much as possible to help improve reproducibility and auditing
6. Continue to monitor long term as performance will often drift back to previous state without feedback

Ongoing collaboration between hospital nutritional services, nursing leadership, pharmacists, laboratory personnel and physician champions is vital to developing sustainable and reproducible processes. Ideally each facility should choose a preferred standardized approach based on its unique needs.

I. Recommended Quality Improvement Interventions

Several organizations and authors have recommended quality improvement interventions to address mealtime processes which include:[5,8-9]

- Minimize the time between blood glucose monitoring, insulin administration and meals; consider a goal of <30 minutes.
- Adapt practice to recheck blood glucose if a meal is not delivered within 30 minutes of the first glucose check.
- Implement practice of Nutrition Services calling up to announce tray delivery to serve as a sign that CBG checks should begin (to ensure completion before meals, but not >30 minutes before the meal).
- Alert nurses to tray arrival so cascade of events can occur in a timely manner.
- Reduce the number of staff involved in POC glucose monitoring, insulin administration and meal tray delivery (e.g., have nurses responsible for all three steps).
- Educate nurses to give insulin with tray delivery as default except in select patients who have unpredictable meal intake.
- Stock appropriate snacks on the unit for patients who are hungry between meals or at night.
- Incorporate prandial carbohydrate intake into the patients' insulin regimen.

References

[1]American Diabetes Association: Standards of medical care in diabetes 2014. *Diabetes Care. 2014;17(Suppl. 1):S14-S80.*

[2]Boucher J, Swift C, Franz M, Kulkarni K, Schafer R, Pritchett E, Clarg N. Inpatient management of diabetes and hyperglycemia: implications for nutrition practice and food and nutrition professionals. *J Am Diet Assoc. 2007;* 107:105–111.

[3]American Diabetes Association: Nutrition therapy recommendations for the management of adults with diabetes. *Diabetes Care. 2014;37(Suppl. 1):S120-S143.*

[4]Swift C. Nutrition therapy for the hospitalized and long-term care patient with diabetes. *American Diabetes Association Guide to Nutrition Therapy for Diabetes.* 2nd ed. Franz M, Evert A, Eds. Alexandria, VA, American Diabetes Association, 2012, p 229-245.

[5]Ryan D, Swift C. The mealtime challenge: nutrition and glycemic control in the hospital. *Diabetes Spectrum.* 2014:27(3):163–-168.

[6]Maynard G, Kulasa K, Ramos P et al. Impact of a hypoglycemia reduction bundle and a systems approach to inpatient glycemic management. *Endocr Pract.* 2015 April 15th pub pend.

[7]Maynard et al Section VI.2 Section E: Mealtime Insulin Dosing

[8]Umpierrez G, Hellman R, Korytkowski M, Kosiblorod M, Maynard G, Montori V, Seley J, van den Berge G. Management of hyperglycemia in hospitalized patients in noncritical care setting: an Endocrine Society clinic practice guideline? *J Clin Endocrinol Metabol.*. 2012;97:16-38.

[9]Institute of Safe Medication Practice: Acute care guidelines for timely administration of scheduled medication, 2011. Available from http://www.ismp.org/tools/guidelines/actuecare/tasm.pdf. Accessed March 2, 2015.

Section VI.3: Safe Use of Insulin Pens in the Hospital and Transition to Home Use

Diabetes and stress hyperglycemia are common conditions in the inpatient setting.[1,2] Insulin is the recommended agent to achieve glycemic control for the majority of hospitalized hyperglycemic patients.[3-5] There are multiple modes of giving insulin including the subcutaneous and intravenous routes. For subcutaneous administration, either the syringe and vial or insulin pens are available. Ease of treatment, safety, cost, patient acceptance and continued adherence to insulin regimens after release from hospital are all things to consider when deciding whether to use the vial and syringe vs. the insulin pen for subcutaneous insulin dosing in the inpatient setting. We are not proposing that one specific way is better than the other. We are pointing out risks and benefits to the newer form of injecting insulin, the insulin pen. Although we point out many benefits to the insulin pen, many hospitals have elected to stay with the vial and syringe method because of errors and risks that have occurred with the pen even when regulations were in place.

A. Insulin Pen Basics

All insulin pens are designed for single-patient use. Once a needle is attached to the pen, the pen should be primed by dialing in a 2-unit dose and expelling the insulin into the air, insuring that insulin will flow through the pen properly and making sure there is no air in the cartridge or needle.[6] A dial or dosing knob is used to set the dose of insulin to be administered. The needle should be inserted at a 90-degree angle into the area of skin, and left in place long enough (6 to 10 seconds is recommended) to ensure the insulin has been injected through the relatively short needle.[6]

There are two types of insulin pens: disposable pens with pre-filled insulin cartridges, and reusable pens that can be loaded with cartridges of insulin that are sold separately.[6] Reusable pens are less expensive but less convenient than disposable pens, and are not suitable for the inpatient setting. Disposable insulin pens generally contain 3 mL of insulin (300 units of 100 unit/mL concentration), as compared to a standard 10 mL vial of insulin. Insulin pens for the inpatient setting have an integrated safety needle that uses a passive automatic safety cover or shield to prevent the risk of needle stick injury to the user.[6,7] Pens that are used at home do not have this protection.

B. Patient Preference, Ease of Use and Adherence to Insulin Post-Hospitalization

Insulin pens are often favored by outpatients as a convenient and discrete way to carry insulin, especially for patients requiring multiple injections a day. A recent systematic review showed that two-thirds of outpatients across 28 trials either preferred insulin pen devices or chose to continue treatment with insulin pens instead of vials and syringes.[8] Some insulin pens come with visual and audible cues to support dosing accuracy and simplify the self-administration of insulin.[9] Compared to patients treated with conventional insulin vials and syringes during hospitalization, increased patient satisfaction and adherence to continued insulin administration has been demonstrated by patients treated with insulin pens.[10] Even hospitals that do not use insulin pens for inpatients should therefore have a process to offer insulin pens to suitable patients who prefer them, along with educational programs to insure they can use them safely and effectively. The Teach Back Method is a good method of education, as it reinforces the education and also assures the caretaker that the patient is able to manipulate the equipment appropriately. Documentation of the patient's proficiency with demonstrating both methods prior to discharge is recommended, as insurance coverage of insulin pens varies and may not be known at the time of discharge. Patients should be instructed in the type of insulin pen they will use at home, as the pen and pen needle may be different than what is used in the hospital setting.

C. Provider Satisfaction

In a survey of nurses, insulin pens were preferred when compared to vial and syringe. They felt that the pen was more convenient, required less time to prepare and administer insulin and did not increase nursing time to teach patients self-injection.[10] While this inpatient study was small and quasi-experimental, it is consistent with the findings across a variety of clinical settings and healthcare providers, demonstrating improved provider confidence in accurate dosing and patient adherence to insulin regimens, and less time required to teach patients.[11-15]

D. Cost

Hospital Cost: Use of insulin pens can reduce costs compared to vial and syringe administration. Hospital-wide implementation of insulin pens involving more than 4,000 patients resulted in more than a 50% reduction in insulin costs.[16] Davis et al. previously also showed a lower average direct cost per patient with insulin pens compared to the vial and syringe group.[10] Some of the savings come from avoiding waste when using an individually labeled 10 ml insulin vial. New 3 mL vials are now being offered which may reduce this advantage.

A retrospective study of a Medicaid database revealed that the annual healthcare costs were significantly lower for patients on pen therapy over a matched cohort using syringe and vial insulin.[17] Medicaid patients who were initiated on insulin pen therapy had fewer outpatient visits and hospitalizations. Other studies of outpatients also reveal lower insulin treatment cost, diabetes attributable cost, improved insulin adherence and less hypoglycemia in the outpatient setting.[18-19]

Patient Cost: The patient and physician may prefer to have the pen prescribed for home use upon discharge, however it may be unattainable if the patient does not have medical insurance or it is not covered by insurance. To determine this it would be helpful to call the prescription to the pharmacy at least a day prior to discharge. The pharmacy can run the prescription through the insurance and determine the cost to the patient. Sometimes it may be an issue of pre-authorization which can be resolved in a few hours. Whatever the situation, you do not want the patient to learn there are issues when they are standing at the pharmacy counter. Also, do not forget to prescribe the pen needles.

E. Needlestick Injury

Needlestick injuries are a major concern for healthcare workers. Up to a quarter of needle stick injuries occur during recapping a used needle. As described above, insulin pens used in the inpatient setting have an integrated safety needle that uses a passive automatic safety cover or shield.[9] Traditional subcutaneous insulin syringes typically also have safety needles, but most require activation by the nurse to engage or slide the safety sheath into position to cover the exposed needle, as opposed to the passive automatic mechanism on insulin pens.[9] The introduction of automatic safety pen needles on insulin pens was associated with an 80 percent decrease in needlesticks.[20]

F. Infection Risks with Insulin Pens

Insulin pens are designed for use by a single patient. Patient's blood or epithelial cellular material can backflow in the pen cartridge after an injection, leaving potential exposure to blood-borne pathogens even if a new needle is used between patients.[21,22,23] Since 2008, thousands of patients have possibly been exposed to blood-borne pathogens through the sharing of multi-dose insulin pens intended for use by single patients in a variety of VA and non-VA healthcare settings.[6, 23-25] In one case, it was discovered that a diabetes nurse educator was inappropriately using lancets and insulin pens intended for teaching purposes on multiple patients over a period of five years.[6] Exposure episodes have continued to occur in spite of repeated warnings and publications from government and safety organizations.[6,26-30] Concerns about costly and serious contamination episodes have led many hospitals to avoid using insulin pens altogether, in spite of several potential advantages they offer. The FDA now requires that pens and packaging containing multiple doses of insulin and other injectable diabetes medicines display a warning label stating "For single patient use only."

G. Other Safety Issues with Insulin Pens

Multiple reports of using insulin pens like vials (by aspirating contents out of the pen cartridge with a needle) raise concerns about introducing air into the delivery system and dosing errors as well as concerns regarding cross contamination.[7] Finally, flawed insertion and too rapid withdrawal from the subcutaneous needle can lead to leakage from the injection site with subsequent under-dosing of insulin.[7] There are multiple insulin pen manufacturers with different designs, leading to difficulty in educating nursing staff. Therefore, it is recommended that ongoing staff education and proficiency documentation of proper use of insulin pens by nurses is conducted.[31]

H. Other Safety Issues with the Vial and Syringe

Unlabeled syringes have led to dosing errors. Insulin can be drawn into a syringe and unintentionally left in a patient care area to be given to another patient. Also, the U-100 designation on the insulin vial has been misunderstood to represent 100 units per vial, causing severe overdose. Another error with the syringe and vial has been using the wrong syringe. The patient is overdosed with insulin by giving mls of insulin rather than units of insulin.

I. Education

Many of these safety issues could be avoided with proper education. There should be standardized education for the use of insulin in your facility. This can be in the form of a PowerPoint, eLearning, video, etc. Standardization can help avoid variety in teaching content and can also be helpful as new hires occur. Standardized teaching for patients can also help prevent missing important content. Your diabetes team, as well as manufacturer representatives, can help provide written and audio material.

J. Conclusion

Whether the hospital decides to use insulin pens or vial and syringe, specific safety measures which have been developed by The Joint Commission and the American Society of Health-System Pharmacists (ASHP) should be followed.

1. Each patient should receive their own insulin pen or insulin vial.
2. Patient identifiers should be placed on each pen or vial.
3. There should be a process for storing insulin safely and noting dates of expiration.
4. Staff should be educated on the safe and appropriate use of insulin pens and syringes.

   Education of all newly hired staff is especially important, as nurses may not have experience in using insulin pens at another facility. A competency checklist, requiring step-by-step demonstration by the nurse, should be utilized. In addition, emphasis should be placed on the "one pen per one patient" motto to ensure safe use of insulin pens. Posting this reminder in every medication room provides a constant reminder of safe use of insulin pens.
5. Safety devices should be on insulin pen needles and syringe needles.

While there are potential issues with safe use of insulin pens in the hospital setting, with appropriate staff education and safety administration practices in place, the advantages of insulin pen use as outlined above may outweigh the risks.

Pens have many advantages, and if used safely could potentially be superior to vials. Overall, data shows that patients prefer the pens so they would be more likely to be compliant with their use. However, multiple barriers must be overcome to see these advantages safely. Nurses must be properly trained in the use, labeling, storage and disposal. Patients must be trained in the use and storage. Finally, the patient must be able to afford the supplies.

References

[1]Umpierrez GE, Isaacs SD, Bazargan N,You X, Thaler LM, Kitabchi AE. Hyperglycemia: an independent marker of in-hospital mortality in patients with undiagnosed diabetes. *J Clin Endocrinol Metab.* 2002;87:978–982.

[2]Frisch A, Chandra P, Smiley D, et al. Prevalence and clinical outcome of hyperglycemia in the perioperative period in non-cardiac surgery. *Diabetes Care.* 2010;33:1783–1788.

[3]Moghissi ES, Korytkowski MT, DiNardo M, et al.; American Association of Clinical Endocrinologists; American Diabetes Association. American Association of Clinical Endocrinologists and American Diabetes Association consensus statement on inpatient glycemic control. *Diabetes Care.* 2009;32:1119–1131.

[4]Umpierrez GE, Hellman R, Korytkowski MT, et al.; Endocrine Society. Management of hyperglycemia in hospitalized patients in non-critical care setting: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab* .2012;97:16–38.

[5]American Diabetes Association. Standards of medical care in diabetes 2012. *Diabetes Care.* 2012;35(Suppl. 1):S11–S63.

[6]Department of Veterans Affairs, Office of Inspector General, Office of Healthcare Inspections. Healthcare Inspection: Inappropriate Use of Insulin Pens at the VA Western New York Healthcare System in Buffalo, New York. http://www.va.gov/oig/pubs/VAOIG-13-01320-200.pdf. Published May 9, 2013. Accessed April 10, 2015.

7Cohen MR. Pharmacists' role in ensuring safe and effective hospital use of insulin. *Am J Health-Syst Pharm.* 2010;67 (Suppl 8);S17–S21.

[8]Molife C, Lee LJ, Shi L, Sawhney M, Lenox SM. Assessment of patient-reported outcomes of insulin pen devices versus conventional vial and syringe. *Diabetes Technol Ther.* 2009;11(8):529–538.

[9]Davis EM, Foral PA, Dull RB, Smith AN. Review of insulin therapy and pen use in hospitalized patients. *Hosp Pharm.* 2013;48(5):396–405.

[10]Davis EM, Christensen CM, Nystrom KK, Foral PA, Destache C. Patient satisfaction and costs associated with insulin administered by pen device or syringe during hospitalization. *Am J Health Syst Pharm.* 2008;65(14):1347–1357.

[11]Goldstein HH. Pen devices to improve patient adherence with insulin therapy in type 2 diabetes. *Postgrad Med.* 2008; 120(3):172–179.

[12]Davis EM, Bebee A, Crawford L, Destache C. Nurse satisfaction using insulin pens in hospitalized patients. *Diabetes Educ.* 2009;35(5):799–809.

[13]Peyrot M, Rubin RR. Physician perception and recommendation of insulin pens for patients with type 2 diabetes mellitus. *Curr Med Res Opin.* 2008;24(8):2413–2422.

[14]Shaghouli AA, Shah BR. The prescription of insulin pen devices versus syringes for older people with diabetes. *Diabetes Technol Ther.* 2009;11(7)439–442.

[15]McDowell JR, Coates V, Davis R, et al. Decision-making: initiating insulin therapy for adults with diabetes. *J Adv Nurs.* 2009;65(1):35–44.

[16]Ward LG, Aton SS. Impact of an interchange program to support use of insulin pens. *Am J Health-Syst Pharm.* 2011;68(14)1349–1352.

[17]Pawaskar MD, Camacho FT, Anderson RT, Cobden D, Joshi AV, Balkrishnan R. Health care costs and medication adherence associated with initiation of insulin pen therapy in Medicaid-enrolled patients with Type 2 diabetes: a retrospective database analysis. *Clin Ther.* 2007:29(spec no):1294–1305.

[18]Lee WC, Balu S, Cobden D, Joshi AV, Pashos CL. Medication adherence and the associated health-economic impact among patients with type 2 diabetes mellitus converting to insulin pen therapy: an analysis of third-party managed care claims data. *Clin Ther.* 2006;28(10):1712–1725.

References (continued)

[19]Cobden D, Lee WC, Balu S, Joshi AV, Pashos CL. Health outcomes and economic impact of therapy conversion to a biphasic insulin analog pen among privately insured patients with type 2 diabetes mellitus. *Pharmacotherapy.* 2007;27(7):948–962.

[20]U.S. Department of Health and Human Services. National Institute for Occupational Safety and Health Alert: preventing needlestick injuries in healthcare settings. http://www.cdc.gov/niosh/docs/2000-108/. Accessed April 11, 2015.

[21]Le Floch JP, Herbreteau C, Lange F, Perlemuter L. Biological material in needles and cartridges after insulin injection with a pen in diabetic patients. *Diabetes Care. 1998;*21(9):1502–1504.

[22]Sonoki K, Yoshinari M, Iwase M, Tashiro K, et al. Regurgitation of blood into insulin cartridges in the pen-like injectors. *Diabetes Care.* 2001;24(3):603–604.

[23]ISMP Medication Safety Alert! Acute Care. Cross contamination with insulin pens. *Institute for Safe Medication Practices* (ISMP). February 12, 2009, Vol.14(3).

[24]Hakre S, Upshaw-Combs DR, Sanders-Buell EE, Scoville SL, Kuper JD, Jagodzinski LL, et al. An investigation of bloodborne pathogen transmission due to multipatient sharing of insulin pens. *Mil Med* 2012;177:930–938.

[25]Wisconsin Office of Rural Health. Important Patient Safety Notification. http://worh.dreamhosters.com/state-news/important-patient-safety-notificationdisclaimer. Published August 29, 2011. Accessed April 10, 2015.

[26]American Society of Health-System Pharmacists, Health-System Association of Pennsylvania. Recommendations for safe use of insulin in hospitals. http://www.ashp.org/s_ashp/docs/files/Safe_Use_of_Insulin.pdf. Accessed April 10, 2015.

[27]Food and Drug Administration. Information for Healthcare Professionals: Risk of Transmission of Blood-borne Pathogens from Shared Use of Insulin Pens. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm133352.htm. Published March 19, 2009. Accessed April 10, 2015.

[28]FDA Drug Safety Communication: FDA requires label warnings to prohibit sharing of multi-dose diabetes pen devices among patients. (2-25-2015). http://www.fda.gov/Drugs/DrugSafety/ucm435271.htm. Published February 2, 2015. Accessed April 10, 2015.

[29]Centers for Disease Control and Prevention. Insulin Pen Safety – One Insulin Pen, One Person. http://www.oneandonlycampaign.org/content/insulin-pen-safety. Published 2012. Accessed April 10, 2015.

[30]Cobaugh DJ, Maynard G, Cooper L, Kienle PC, Vigersky R, Childers D, Weber R, Carson SL, Mabrey ME, Roderman N, Blum F, Burkholder R, Dortch M, Grunberger G, Hays D, Henderson R, Ketz J, Lemke T, Varma SK, Cohen M. Enhancing insulin-use safety in hospitals: Practical recommendations from an ASHP Foundation expert consensus panel. *Am J Health Syst Pharm.* 2013 Aug 15;70(16):1404–1413.

[31]Centers for Disease Control and Prevention. CDC Clinical reminder: Insulin Pens must never be used for more than one person. http://www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html. Published January 5, 2015. Accessed April 22, 2015.

Section VI.4: Patients with Insulin Pumps

Most providers and facilities wish to support diabetes self-management for hospitalized patients who have been receiving Subcutaneous Insulin Pump Therapy or Continuous Subcutaneous Insulin Infusion (CSII) in the ambulatory care setting. However, in order to safely proceed with this, teams will need to have either an internal insulin pump specialist or consult the patient's outpatient prescriber, define circumstances when pump therapy will be interrupted/discontinued temporarily, methods to ensure competence of the patient/caregiver in performing self-management and a process to ensure safe and accurate administration of insulin via the pump.

Any time that insulin pump therapy will be interrupted for more than one hour, alternative insulin via infusion or basal/bolus must be implemented.

Physicians or the designated diabetes care team will need to assess the appropriateness of continuing the pump therapy in the hospital. It is generally considered appropriate if the patient is cognitively intact, has a functioning pump with adequate supplies and is knowledgeable of all pump program functions. Based on those requirements, the following are generally considered to be contraindications for patient self-management of their insulin pump:

1. Altered level of consciousness or other impairment in cognition.
2. Patient receiving medications that alter his or her state of consciousness. (Note: some anesthesiologists will accept keeping the insulin pump running for surgeries where the anesthesia time is <1 hour.)
3. Patient with impaired judgment or at risk of suicide.
4. Uncontrolled blood glucose trends or acute situations for which patient or caregiver cannot make appropriate self-adjustments to basal rate or bolus dose such as DKA.
5. Patient whose insulin pump is not working properly.
6. Patient does not have the appropriate supplies for the insulin pump.
7. Patient/Caregiver refusal or inability to participate in the Subcutaneous Insulin Pump Therapy.
8. Patient/Caregiver refusal to comply with the necessary requirements laid out in the institution's pump policy.

Because of the unique features of each insulin pump, patients need to provide all required pump supplies and insulin during the hospitalization. Methods of assessing patient/caregiver knowledge of the pump and documenting the therapy include records of the basal rates throughout the day, insulin-to-carbohydrate ratio, sensitivity factor and correction dosing plan. These are generally paper forms completed by the patient, nursing verification of the settings on the insulin pump as the patient goes through the screens on their pump and then the information is entered in the electronic medical record (EMR) by nursing. Patients should then be responsible for completing a daily blood glucose and insulin log sheet that includes the time and result of blood glucose values, basal rate changes, timing and doses of bolus insulin and the carbohydrate content of meals and snacks.

Most hospitals have policies regarding patient self-management, patient home medications and insulin pumps specifically. As other parts of this *Guide* have suggested, you will want to review the current policies and might identify areas that would benefit from revisions or policy creation. Policies should address specific populations and circumstances based on your hospital and setting.

Special Circumstances:

- Patients who meet criteria for continuation may still need temporary interruptions during CT or MRI to avoid damage to the insulin pump. The time for interruption should be limited by removing and replacing the pump immediately before and after the test, respectively.
- For pediatric patients, the caregiver is often managing the pump therapy as an outpatient and may assume responsibility when the child is an inpatient.
- Obstetric patients with diabetes are frequently managed with insulin pumps and specific policies around labor and delivery will be needed.

References

Grunberger G, Abelseth JM, Bailey TS, et al. Consensus Statement by the American Association of Clinical Endocrinologists/American College of Endocrinology Insulin Pump Taskforce, *Endocrine Practice. 2014 May;Vol. 20 No. 5.*

American Diabetes Association. Standards of Medical Care in Diabetes - 2014. *Diabetes Care.* 2014;37 Suppl 1:S14–S80.

Lansang MC, Modic MB, Sauvey R, et al. Approach to the adult hospitalized patient on an insulin pump, *J Hosp Med.* 2013;8:721–727.

Section VII: Continuing to Improve, Holding the Gains and Spreading Your Improvement

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A. Introduction

Changing the culture of glycemic control in the entire facility can be a daunting task. It may be a better idea to start with small steps and focus on individual nursing units or smaller areas of the hospital. After determining the basic deficiencies, goals can be set. For example, is hyperglycemia of hospitalized patients being addressed daily? Are changes being made to the insulin regimen? This can take place in the form of a PDSA cycle (Plan, Do, Study, Act). With each cycle, new problems are identified and new plans can be made.

Measuring outcomes through data collection and analysis is very helpful when determining if the goals are being met. For example, what is the frequency an order set is being used, both before and after education? When the goals are met and the team is happy with the process and results, it is important to maintain the gains. If you don't hold the gains, it is always easier to take the easy route and you will find that processes will fall apart and people will go back to their old ways. You can decrease the monitoring that took place during the process changes, but make plans to reassess your data on a regular but less frequent basis. Give reminders if you start to see old habits occur. Confirm that protocols/order sets are still being used. Post your data so that employees know you are still monitoring, and they can see their results. Encourage them to measure their own success. Create training days to reemphasize the procedures and goals. Make sure that new hires are trained appropriately to follow protocols. Allow the newly trained to train others once you are comfortable with their competency. Written training programs or PowerPoint presentations help to confirm that training is consistent and all points are addressed.

B. Deviation

When you are monitoring, watch for deviation from the protocols. This can provide you with excellent information as to why your goals are not being met.

1. *Does this deviation occur because of lack of understanding?* If this is the case, it may need to be taught in a different way. Or you may find that the protocol is too difficult to follow. You may need to go directly to the end user to find this information. Question them directly about why they did not follow the protocol.
2. *Does the deviation occur because of lack of caring or unwillingness to change?* Again you may need to go to the end user to find this out. If this is the case, show data to support the protocols. Show good and bad outcomes. This will help show that you have not proposed a bunch of new random rules, and that your proposed process has evidence to do what is best for the patient.
3. *Does deviation occur because the new protocol conflicts with other hospital protocols?* If this is the case, one or the other will need to budge. Look up evidence-based research to determine the best protocol for all. Work with hospital administration, pharmacy, physicians, nurses and educators to determine the best protocol for patient care. Devise a method to measure deviation from the protocol. Record suggestions from others. Revise protocols and order sets based on user and patient needs or as new evidence-based research is found.

C. Spread

Once you are happy with your goals, it is time to spread the improvement. This may be to other nursing units, other specialty areas of the facility or other facilities in your region. This process should be much smoother since you have learned from your errors during the first round. This is why it is important to document plans, gains and failures. It is just as important to document failures as well as successes so that they are not repeated. Document your PDSA cycles. Also, you will have data to show that the given protocols, changes and improvements are beneficial for the patient for those people who have a difficult time with change. It is important when making change to listen to the end user. Their input may explain why a certain protocol may or may not work in their area.

D. Continue to Improve

Knowledge is changing daily. Be responsible for staying updated on new recommendations and evidence-based research. Read about new literature and network with others in your field. Keep your team involved by asking them to read an article or attend a conference and report back to the team. Always encourage new thoughts and ideas from team members.

E. Conclusion

- Schedule regular assessments to trend your metrics
- Always monitor for maintaining gains
- Schedule interval reviews of the literature
- Schedule sessions to update the protocol/order set
- Identify the priority areas to “spread” the improvements you have achieved

Congratulations

This is a hard process, and change can take many years. You have made a good start by reading these guidelines. There is a lot of dense information presented here. As you start your process, re-familiarize yourself with the corresponding sections of this *Implementation Guide*. Start with small steps and drive forward.

Appendices:

A. UCSD Insulin Pump Order Set Example
B. First Edition Acknowledgments

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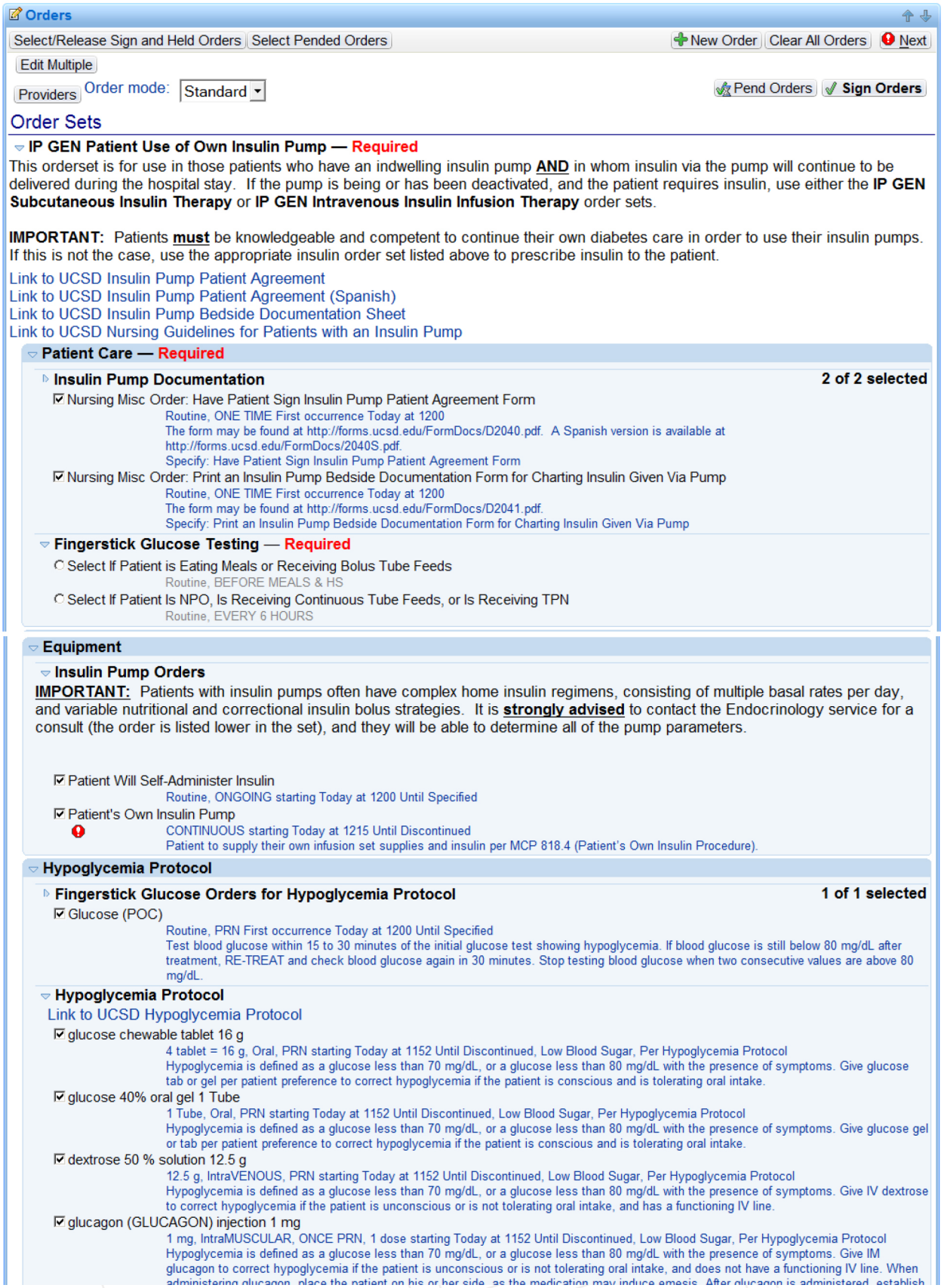
Appendix A: UCSD Insulin Pump Order Set Example

To view this full order set and others Click Here



Orders

Select/Release Sign and Held Orders | Select Pended Orders | New Order | Clear All Orders | Next

Edit Multiple

Providers | Order mode: Standard | Pend Orders | Sign Orders

Order Sets

IP GEN Patient Use of Own Insulin Pump — Required

This orderset is for use in those patients who have an indwelling insulin pump **AND** in whom insulin via the pump will continue to be delivered during the hospital stay. If the pump is being or has been deactivated, and the patient requires insulin, use either the **IP GEN Subcutaneous Insulin Therapy** or **IP GEN Intravenous Insulin Infusion Therapy** order sets.

IMPORTANT: Patients **must** be knowledgeable and competent to continue their own diabetes care in order to use their insulin pumps. If this is not the case, use the appropriate insulin order set listed above to prescribe insulin to the patient.

Link to UCSD Insulin Pump Patient Agreement
Link to UCSD Insulin Pump Patient Agreement (Spanish)
Link to UCSD Insulin Pump Bedside Documentation Sheet
Link to UCSD Nursing Guidelines for Patients with an Insulin Pump

Patient Care — Required

Insulin Pump Documentation — 2 of 2 selected

- ☑ Nursing Misc Order: Have Patient Sign Insulin Pump Patient Agreement Form
  Routine, ONE TIME First occurrence Today at 1200
  The form may be found at http://forms.ucsd.edu/FormDocs/D2040.pdf. A Spanish version is available at http://forms.ucsd.edu/FormDocs/2040S.pdf.
  Specify: Have Patient Sign Insulin Pump Patient Agreement Form
- ☑ Nursing Misc Order: Print an Insulin Pump Bedside Documentation Form for Charting Insulin Given Via Pump
  Routine, ONE TIME First occurrence Today at 1200
  The form may be found at http://forms.ucsd.edu/FormDocs/D2041.pdf.
  Specify: Print an Insulin Pump Bedside Documentation Form for Charting Insulin Given Via Pump

Fingerstick Glucose Testing — Required

- ○ Select If Patient is Eating Meals or Receiving Bolus Tube Feeds
  Routine, BEFORE MEALS & HS
- ○ Select If Patient Is NPO, Is Receiving Continuous Tube Feeds, or Is Receiving TPN
  Routine, EVERY 6 HOURS

Equipment

Insulin Pump Orders

IMPORTANT: Patients with insulin pumps often have complex home insulin regimens, consisting of multiple basal rates per day, and variable nutritional and correctional insulin bolus strategies. It is **strongly advised** to contact the Endocrinology service for a consult (the order is listed lower in the set), and they will be able to determine all of the pump parameters.

- ☑ Patient Will Self-Administer Insulin
  Routine, ONGOING starting Today at 1200 Until Specified
- ☑ Patient's Own Insulin Pump
  CONTINUOUS starting Today at 1215 Until Discontinued
  Patient to supply their own infusion set supplies and insulin per MCP 818.4 (Patient's Own Insulin Procedure).

Hypoglycemia Protocol

Fingerstick Glucose Orders for Hypoglycemia Protocol — 1 of 1 selected

- ☑ Glucose (POC)
  Routine, PRN First occurrence Today at 1200 Until Specified
  Test blood glucose within 15 to 30 minutes of the initial glucose test showing hypoglycemia. If blood glucose is still below 80 mg/dL after treatment, RE-TREAT and check blood glucose again in 30 minutes. Stop testing blood glucose when two consecutive values are above 80 mg/dL.

Hypoglycemia Protocol

Link to UCSD Hypoglycemia Protocol

- ☑ glucose chewable tablet 16 g
  4 tablet = 16 g, Oral, PRN starting Today at 1152 Until Discontinued, Low Blood Sugar, Per Hypoglycemia Protocol
  Hypoglycemia is defined as a glucose less than 70 mg/dL, or a glucose less than 80 mg/dL with the presence of symptoms. Give glucose tab or gel per patient preference to correct hypoglycemia if the patient is conscious and is tolerating oral intake.
- ☑ glucose 40% oral gel 1 Tube
  1 Tube, Oral, PRN starting Today at 1152 Until Discontinued, Low Blood Sugar, Per Hypoglycemia Protocol
  Hypoglycemia is defined as a glucose less than 70 mg/dL, or a glucose less than 80 mg/dL with the presence of symptoms. Give glucose gel or tab per patient preference to correct hypoglycemia if the patient is conscious and is tolerating oral intake.
- ☑ dextrose 50 % solution 12.5 g
  12.5 g, IntraVENOUS, PRN starting Today at 1152 Until Discontinued, Low Blood Sugar, Per Hypoglycemia Protocol
  Hypoglycemia is defined as a glucose less than 70 mg/dL, or a glucose less than 80 mg/dL with the presence of symptoms. Give IV dextrose to correct hypoglycemia if the patient is unconscious or is not tolerating oral intake, and has a functioning IV line.
- ☑ glucagon (GLUCAGON) injection 1 mg
  1 mg, IntraMUSCULAR, ONCE PRN, 1 dose starting Today at 1152 Until Discontinued, Low Blood Sugar, Per Hypoglycemia Protocol
  Hypoglycemia is defined as a glucose less than 70 mg/dL, or a glucose less than 80 mg/dL with the presence of symptoms. Give IM glucagon to correct hypoglycemia if the patient is unconscious or is not tolerating oral intake, and does not have a functioning IV line. When administering glucagon, place the patient on his or her side, as the medication may induce emesis. After glucagon is administered, establish

Appendix A: UCSD Insulin Pump Order Set Example (continued)

Consults

Consults - Physician — **1 of 1 selected**

☑ IP Consult to Endocrinology

P Reason for consult: Patient has indwelling insulin pump
Did you call the consulting service? No

Additional Orders

Remote Viewer — ? Close

UC San Diego HEALTH SYSTEM

PATIENT AGREEMENT TO USE OF OWN INSULIN PUMP

Patient Identification

You may be able to use your own insulin pump during your hospital stay at UC San Diego Health System. In order to assure your safety and assist your health care team in coordinating your care, it is important that you understand your responsibilities before you sign this agreement. If you have any questions, please ask your doctor or nurse.

During my hospital stay, I agree to:

1. Update the nurse regarding any bolus doses given by writing down bolus doses I give myself on the paper called "Patient's Own Insulin Pump – Bedside Documentation Sheet."
2. Only make changes to the basal rate when asked to by my doctor.
3. Change the infusion set every 48-72 hours (2-3 days) or as needed.
4. Provide my own medical supplies and insulin that I need for my pump. My nurse will check my blood glucose using UC San Diego Health System equipment.
5. Report any signs of low blood sugar, such as feeling dizzy, shaky, or sweaty, to the nurse as soon as possible.
6. Report any pump malfunctioning or other problems to the nurse or doctor as soon as possible.
7. Tell the nurse or doctor if I am no longer able to operate my pump for any reason.

During my hospital stay, I understand the pump may be stopped or removed if:

Remote Viewer — ? Close

Patient Summ...
Chart Review
Synopsis
Results Review
Allergies
History
Problem List
mmunizations
Medications
Doc Flowsheets
ntake/Output
MAR
Notes
Order Review
Order Entry
Orders (Inf Ctr)
Admit-Txfr-Dis...
Rounding + C...
Order Set
Remote View...

UC San Diego HEALTH SYSTEM

PATIENT'S OWN INSULIN PUMP-BEDSIDE DOCUMENTATION SHEET
(To be completed by patient)

Patient Identification

Date: ____/____/____

Pump model and manufacturer: _____
Type of Insulin (check one): ❒ aspart (Novolog®) ❒ lispro (Humalog®) ❒ glulisine (Apidra®)

Time	1a	2a	3a	4a	5a	6a	7a	8a	9a	10a	11a	Noon	1p	2p	3p	4p	5p	6p	7p	8p	9p	10p	11p	MN
Glucose																								
Nutritional bolus																								
Correctional bolus																								
Basal Rate (units/hr)																								

Carbohydrate Ratio
_____ units per _____ grams of carbohydrate (Breakfast)
_____ units per _____ grams of carbohydrate (Lunch)
_____ units per _____ grams of carbohydrate (Dinner)

OR **Fixed Doses**
_____ units at breakfast
_____ units at lunch
_____ units at dinner
_____ units with snacks

High Glucose Correction
_____ unit for every _____ mg/dL over _____ mg/dL (target glucose) OR *provide copy of written scale*

Completed by: _____ **Reviewed by:** _____ / _____
(Patient Name) *PM Nurse(s)* *AM Nurse(s)*

D2041 (12-10) ref: MCP 818.4

SHM 2008 Glycemic Control Task Force

SHM thanks all the members of the Glycemic Control Task Force, who encompass a distinguished panel of experts with representation from the AACE, ADA, ACP and other organizations whose expertise was essential to the construction of this field guide for improving inpatient glycemic control.

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SHM is dedicated to the continuous improvement of the products and services that we offer. This *Guide* continues to be a work in progress; we highly encourage and welcome constructive criticism and feedback via email to glycemiccontrol@hospitalmedicine.org