

## Safe patient use of insulin pumps & CGM devices during hospitalization

### Issue:

Approximately 34.2 million, or just over one in 10, Americans have diabetes.<sup>1</sup> Many of these people rely on personal insulin pumps and continuous glucose monitoring (CGM) systems to improve their overall glycemic control and reduce the risk of experiencing hypoglycemic or hyperglycemic episodes. When hospitalized, the desire to continue using their personal pump or CGM system can present safety and quality risks for the organization. This issue of Quick Safety addresses how hospitals can safely implement patient use of these personal devices for their hospitalized diabetic patients.

The American Diabetes Association advocates allowing patients who are physically and mentally able to continue to use their personal insulin pumps when hospitalized.

### Safety actions to consider:

Hospitals that opt to allow patients to use their personal insulin pump or CGM system can use the following strategies/actions to help safely implement and support the use of these devices during a patient's hospital stay. These strategies/actions are categorized into seven areas and are based on Joint Commission requirements.

**Policies and procedures.** When developing policies, procedures, education, and training surrounding use of a personal device, organizations should have representation from multiple disciplines including nursing, pharmacy, risk management and physician leadership. Such policies and procedures should take into consideration contingency planning for the following:

- The patient's condition changes, and the patient can no longer safely manage the infusion.
- The availability of batteries if the patient does not have replacements
- The availability of replacement medication for the infusion device
- The infusion device fails or is damaged, rendering it unusable.

*Note: Per Environment of Care Standard EC.02.04.03, element of performance (EP) 1, The Joint Commission requires that all medical equipment must be inspected prior to being used. This inspection includes safety, operational, and functional checks. At a minimum, organizations should conduct a visual inspection of the device to determine that there are no obvious defects such as cracks, broken or missing dials or other components. Hospital staff can have patients demonstrate use of the device to both develop familiarity and gauge whether the device is operational.*

**Home medication usage.** Patients may also prefer to use their own insulin (i.e., insulin that is brought to the hospital from the patient's home). Organizations need to define under what circumstances medications brought in by the patient or family may be used and implement a process to identify and visually evaluate the medication's integrity. The process should be completed by an individual deemed qualified by the organization. Additionally, safe storage practices should be evaluated, including the following:

- Ensuring security to protect from theft, tampering and diversion.
- Complying with the product manufacturer's instructions for use, such as refrigeration and protection from light sources.
- Warning labels or alerts used to support safe use of the medication (i.e., high alert or look-alike/sound-alike).
- Any segregation of medications brought by the patient from those provided by the pharmacy for use on other patients.

**Medication self-administration.** When an organization permits a patient to self-manage their insulin administration via a personal infusion device, a written process is needed to guide safe and accurate self-administration of medication. While patients with diabetes are often well-versed on managing their insulin infusion and operation of their infusion and CGM devices, it's still important to educate the patient on your organization's policies and procedures regarding use and self-administration of medication brought from home. For example, communicating to staff:

- The results of glucose testing.
- Any changes to the rate of infusion, including basal and/or bolus rate adjustments.



Legal disclaimer: This material is meant as an information piece only; it is not a standard or a *Sentinel Event Alert*. The intent of *Quick Safety* is to raise awareness and to be helpful to Joint Commission-accredited organizations. The information in this publication is derived from actual events that occur in health care.

- Any event that may require an increase or decrease in the insulin infusion rate.
- Any signs or symptoms that suggest that glycemic control may be unstable.
- Any signs the device is malfunctioning and not delivering the insulin infusion.

**Orders: Insulin dosages and glucose monitoring frequency.** As with all medication, an insulin order from the licensed practitioner is required. Policies that address the type of medication orders permitted and the required elements of medication orders should address self-administered medication via an infusion device. When comparing medication information on home medications against the medication orders, practitioners need to be informed of the baseline basal rate and bolus settings in order to determine whether to continue the same treatment regimen or if any modifications are needed during the hospital encounter.

- Specific to glucose testing devices, there needs to be a process to verify the patient's personal glucose testing device is working appropriately. Organizations may consider verifying device functionality by performing a blood glucose with the approved multi-use hospital glucometer to ensure the results from both devices are within a range defined by the organization.
- If the organization allows a patient to use a CGM device, the process must comply with the manufacturer's instructions for use related to calibration of the device to ensure accurate results are provided.

**Medical record documentation.** While the organization determines where and how the use of a personal medical device is documented within the patient medical record, such documentation needs to be comprehensive to include:

- Medication dose, frequency, and route of administration.
- Orders from a licensed practitioner.
- Assessments and reassessments.
- Patient response to treatment.
- Any complications encountered during self-administration.

**Education of staff, patient and family.** Patients and families should receive education on applicable policies and procedures. This education should be based on the learning needs assessment, taking into consideration any treatment and/or environmental factors that may be a barrier to safe, self-administration (e.g., a patient receiving narcotic analgesics that may impair cognition).

Staff need to be educated on the organization's policies and procedures that apply to self-administration of medication via an infusion device. Such education may include requirements such as:

- Assessment and reassessment of the device.
- Assessment and reassessment of the insertion site.
- Documentation.
- Responding to critical test results.
- Provider notification of critical test results.
- Ongoing assessment of the patient's ability to safely self-manage their insulin administration and pump programing.
- Contingency plan if the device fails.

*Note: There is no requirement that staff be trained on the actual use of a personal infusion device as the intent is that the patient is responsible for managing the device. The organization determines any staff [training or competency](#) requirements.*

**Conducting a risk assessment.** When developing policies and procedures around self-administration of medications via an infusion device, organizations may find it helpful to conduct a risk assessment to identify risks associated with various options being considered.

A proactive risk assessment examines a process in detail including sequencing of events, actual and potential risks, and failure or points of vulnerability and that prioritizes, through a logical process, areas for improvement or mitigation based on the actual or potential impact (that is, criticality) of care, treatment, or services provided.

- An area of risk that organizations may consider when conducting a risk assessment should be whether use of these devices are permitted during high-risk or invasive procedures, such as surgical cases, interventional procedures, or imaging studies.



- Specific to surgical cases, the American Association of Nurse Anesthetists reports that continuation of the patients own personal insulin pump has been reported as a safe and more consistent method to maintain the blood glucose level over other means of insulin administration.<sup>2</sup>
- During an imaging study, organizations would be required to follow the manufacturer's instructions for use on how to manage personal devices when an MRI, CT or other imaging studies are performed. Therefore, evaluating these areas as part of a risk assessment can reduce the potential for adverse patient outcomes.

*Note: The introductory section of the Leadership (LD) chapter of The Joint Commission accreditation manuals provides an example of a proactive risk assessment model that an organization may use. However, this specific approach is not mandated as there are other risk assessment tools available that may better meet the needs of the organization. Other examples may include a root cause analysis, failure mode and effect analysis, plan/do/check/act process, or combinations and variations of these.*

#### **Resources:**

1. Centers for Disease Control and Prevention. Diabetes webpage. [CDC National Diabetes Statistic Report, 2020](#). Accessed April 9, 2021.
2. Rotruck S, Suszan L, Vigersky R, et al. [Should Continuous Subcutaneous Insulin Infusion \(CSII\) Pumps Be Used During the Perioperative Period?](#) Development of a Clinical Decision Algorithm. *AANA Journal*, 2018;86(3). Accessed April 14, 2021.

Other resources:

**American Diabetes Association:** Umpierrez GE and Klonoff DC. [Diabetes Technology Update: Use of Insulin Pumps and Continuous Glucose Monitoring in the Hospital](#). *Diabetes Care*, 2018;4(8):1579-1589. Accessed April 9, 2021.

**Association of Diabetes Care & Education Specialists:** [Continuous Subcutaneous Insulin Infusion \(CSII\) Without and With Sensor Integration](#), reviewed by the Professional Practice Committee, Updated March 2021. Includes recommendations for hospital insulin pump policy content.

**Centers for Disease Control & Prevention:** [National Diabetes Statistics Report, 2020](#)

#### **U.S. Food & Drug Administration**

- [Interference between CT and Electronic Medical Devices website](#). Feb. 26, 2018.
- [Safety Concerns with Implantable Infusion Pumps in the Magnetic Resonance \(MR\) Environment: FDA Safety Communication](#). Division of Industry and Consumer Education. Jan. 11, 2017.

*Note: This is not an all-inclusive list.*



Legal disclaimer: This material is meant as an information piece only; it is not a standard or a *Sentinel Event Alert*. The intent of *Quick Safety* is to raise awareness and to be helpful to Joint Commission-accredited organizations. The information in this publication is derived from actual events that occur in health care.