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HOSPITAL MANAGEMENT OF DIABETES (A WALLIA AND JJ SELEY, SECTION EDITORS)

An Overview of Safety Issues on Use of Insulin Pumps and Continuous Glucose Monitoring Systems in the Hospital

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Abstract

Purpose of Review Summarize safety issues related to patients using insulin pump therapy and continuous glucose monitoring systems (CGMS) in the outpatient setting when they are hospitalized and to review steps that can be taken to mitigate risk associated with use or discontinuation of these devices.

Recent Findings Two recent consensus conferences were held on the topics of inpatient use of insulin pumps and CGMS devices. In addition to commonly known safety issues (e.g., device malfunction, infection), cybersecurity and the vulnerability of contemporary technology to hacking have emerged. CGMS capabilities offer the promise of advancing the goal for development of glucometry (centralized monitoring of real-time glucose data). Strategies to assuring safe use of insulin pumps and CGMS in the hospital include collaboration between the patient and staff, proper patient selection, and clear policies and procedures outlining safe use. Available data indicates few adverse events associated with these devices in the hospital.

Summary Current data suggests, with proper patient selection and a clear process in place for glycemic management, that adverse events are rare, and consensus favors allowing use of the technology in the hospital. The topic of insulin pump and CGMS in the hospital would greatly benefit from more institutions reporting on their experiences and prospective clinical trials.

Keywords Continuous subcutaneous insulin infusion · Continuous glucose monitoring systems · Insulin pump · Hospital · Inpatient · Diabetes mellitus

Abbreviations

CGMS	Continuous glucose monitoring systems
CSII	Continuous subcutaneous insulin infusion
DM	Diabetes mellitus

Introduction

Continuous subcutaneous insulin infusion (CSII) therapy, also known as insulin pump therapy, is currently approved by the FDA for use in the outpatient setting in patients with both type 1 and type 2 diabetes mellitus (DM). Recent market analysis indicates that in the USA, there are 5 million patients with DM who currently use CSII therapy [1]. Use of these technologies in patients with type 1 diabetes varies by age—as low as 4% in adolescents and up to 21% in selected subgroups (age ≥ 26 years) [2]. It is anticipated that the market for CSII therapy will approach $5 billion by the year 2022, and use of outpatient subcutaneous continuous glucose monitoring systems (CGMS) will reach $2 billion by 2022 [1, 3].

Insulin pumps currently approved for use and available in the USA are presented in Table 1. Older models have set basal rates programmed into the pump along with calculators or "wizards" to assist with insulin to carbohydrate ratios (amount of insulin to be given for a certain amount of carbohydrates consumed) and insulin sensitivity factors (amount of insulin to be given to correct a blood glucose that is above target). Newer models integrate with continuous glucose monitoring systems (CGMS) allowing the patient access to real-time blood glucose data. CGMS currently approved and available for outpatient use in the USA are presented in Table 2. CGMS provide information that can help patients adjust insulin therapy and reduce

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Table 1 Insulin pumps available in the USA

Brand	Models	Bolus Calculator	CGMS integration	Insulin suspend for hypoglycemia	Special Features
Medtronic	670G	Yes	Yes-Guardian	Yes	670G only hybrid closed-loop system on the market when operating in Auto mode
	630G		Yes-Enlite	Yes	
	530G		Yes-Enlite	Yes	
	Paradigm		No	No	
	Revel		No	No	
Tandem	T:slim	Yes	No	No	Touchscreen
	T:slim G4		Yes-Dexcom G4		T:flex allows for larger capacity insulin and bolus delivery
	T:slim X2		Yes-Dexcom G5		
	T:flex		No		
Insulet	Omnipod	Yes	No	No	Only detached "tubeless" pump on the market
Roche	Accu-Chek Spirit	No	No	No	Not applicable
Animas	OneTouchPing	Yes	No	No	No longer selling pumps in the US and Canada
	Animas Vibe		Yes		
Sooil	Dana Diabecare IIS	Yes	No	No	Menu uses icons instead of words
Valeritas	V-go	No	No	No	Applied once daily, administers continuous pre-set basal insulin plus on-demand bolus insulin in 2 unit increments

With permission from: Thompson B, et al. *J Diabetes Sci Technol*. 2018, 2018, Jul;12(4):880–889. doi: https://doi.org/10.1177/1932296818769933. Epub 2018 Apr 21) [4••]

glycemic excursions (hyper- and hypoglycemia). CGMS sample glucose subcutaneously through interstitial fluid every 1 min (Freestyle Libre) or every 5 min (Dexcom and Medtronic) for pattern identification including information on the trajectory of glucose change (increasing, decreasing, or stable), and the rate of glucose change (slow, fast, or steady). Both the Dexcom and Medtronic CGMS have real-time alarms to alert the wearer of hypo- and hyperglycemia, a feature that would be of great benefit in the hospital setting. CGM blood glucose levels must be confirmed by the hospital meter for any treatment or charting in the electronic health record.

The MiniMed 670G integrated insulin pump and CGMS is the only hybrid closed loop system currently available in the USA. This system relies on CGMS data to auto-adjust the basal insulin delivery rate although patients must still administer bolus doses for carbohydrates and correction of hyperglycemia and calibrate against a capillary glucose measurement obtained from a blood glucose meter [5]. How this closed loop technology, and others that may be under development, can best be safely integrated into an inpatient setting requires further discussion. A framework for their use in the hospital will become clearer as outpatient experience is gained and patients are admitted to the hospital wearing the device.

An emerging challenge to both patients and practitioners is how to approach and manage patients who use CSII in the outpatient setting alone or in combination with CGMS in the inpatient arena. The number of patients using either technology requiring hospitalization is unknown [2]. However, as the

Table 2 Subcutaneous continuous glucose monitors available in the USA

Brand	Models	Pump integration	Special features
Medtronic	Enlite	Yes-530G and 630G	
Medtronic	Guardian Connect	Yes-670G	670G AutoMode feature automatically adjusts basal insulin based on Guardian sensor readings
		No-can also be used as a stand-alone sensor	
Dexcom	G4 Platinum	No	-G5 and G6 glucose data available on a smart phone
	G5 Mobile	Yes-T:slim X2	
	G6 CGM		-No calibration required with G6
Abbott	Freestyle Libre	No	-No finger stick confirmation required
			- Does not communicate continuously with the reader, Requires swiping device with reader at least q8hrs to not lose data
			-Requires 12 h warm-up with no readings

number of outpatients utilizing these devices increases, it is reasonable to assume that practitioners will encounter more patients using CSII and CGMS in the inpatient setting.

Taken in the context of overall diabetes discharge data, encountering patients using any insulin pump technology will be infrequent. For instance in Mayo Clinic Arizona, encounters with inpatient insulin pumps are rising (Fig. 1), but still account for only a small percentage of more than 3000 annual discharges related to diabetes overall. Many patients may have a strong desire to self-manage their insulin pumps and CGMS while in the hospital and may be resistant to clinician input. Other patients may in fact be too ill or have an altered level of consciousness that interferes with their ability to self-manage these devices during all or part of their hospital stay. Non-endocrinology hospital staff cannot be expected to have a working knowledge of how to manage these technologies and support patients wearing them.

The European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) Diabetes Technology Working Group recommend evaluation of human performance within the outpatient setting as a way of identifying and avoiding potential adverse outcomes [6]. Some understanding of safety concerns of these devices in the context of the hospital stay is also recommended. The topic of operational recommendations (e.g., patient selection for use, need for a patient agreement, role of family members) for insulin pumps and CGMS use in the hospital has been extensively reviewed [4••, 7••, 8]. This manuscript expands information provided in previously published reviews by focusing on safety issues related to CSII/CGMS and steps that can be taken to mitigate risk. The following review focuses on the patient population who use CSII/CGMS technology as outpatients and who want to be considered for continuing therapy in the hospital.

Overview of Safety Considerations of CSII and CGMS

Patient safety with use of CSII and CGMS is a concern both in the outpatient and inpatient setting [6]. The Food and Drug Administration (FDA), in collaboration with the Diabetes Technology Society (DTS), assembled a panel of subject matter experts on two separate occasions to discuss issues related to pump operation, hardware, physical structure, electrical, chemical, and biological considerations [9, 10]. Tracking safety issues can be difficult with the current design of reporting databases [6]. The consensus reached from these initial safety conferences was that progress had been made with regard to insulin pump design and use. However, significant safety concerns remain. Panelists agreed on potential improvements which would increase the safety of inpatient use of these devices. Since this initial consensus panel, many of these improvements have been made. For instance, at the corresponding authors' institution, a process is now in place outlining how to transition therapy as the patient transitions into a procedural area. Despite this, concerns remain that are reviewed in the next sections. These concerns increase as the complexity of insulin pump and CGMS technology increases. Categories and examples of safety concerns are summarized below.

Software Problems

An error message is displayed in the absence of an identifiable problem, or there is a failure to indicate an error when one exists. Inpatient staff, and even patients, would not have knowledge of the meaning of these error messages or how to trouble shoot. The device toll free number can be helpful to clinicians for guidance on addressing these error messages.

Alarm Errors

The insulin pump fails to alarm for a critical problem, such as an occlusion (e.g., kinked tubing, presence of air in the infusion tubing, low battery alarm). In the case of CGMS, a failure to alarm for a pending hypoglycemic event would prevent timely intervention on the part of the patient. In addition, some patients report frequent false alarms from a CGMS that may prompt them to abandon the technology. Changes in skin perfusion, blood pressure, temperature, and some medications may affect accuracy of CGMS blood glucose systems. These possible interferences have not been well studied [11].

Human Factors

The design of the infusion pump screen has potential to confuse users. User manuals may also provide complex information to users unfamiliar with terminology [6]. A recent analysis documented increased insulin pump catheter-related events in users who prolonged the duration of wearing an insulin infusion set beyond the recommended time before changing (generally up to 72 h) [12]. Specialized patient education and re-enforcement of skills over time are needed to minimize confusion over operation of the device. Ideally, such skills and knowledge would be accomplished in the outpatient setting, but needs to be validated in the inpatient setting on an ongoing basis as a safety measure in allowing continued use by a patient. Not all patients are able to demonstrate safe use, and deficits in operational use of the pump may only become obvious in the controlled environment of the hospital [13].

Site Infection

Failure to change infusion sets or CGMS transmitters at the recommended intervals could place the user at risk of

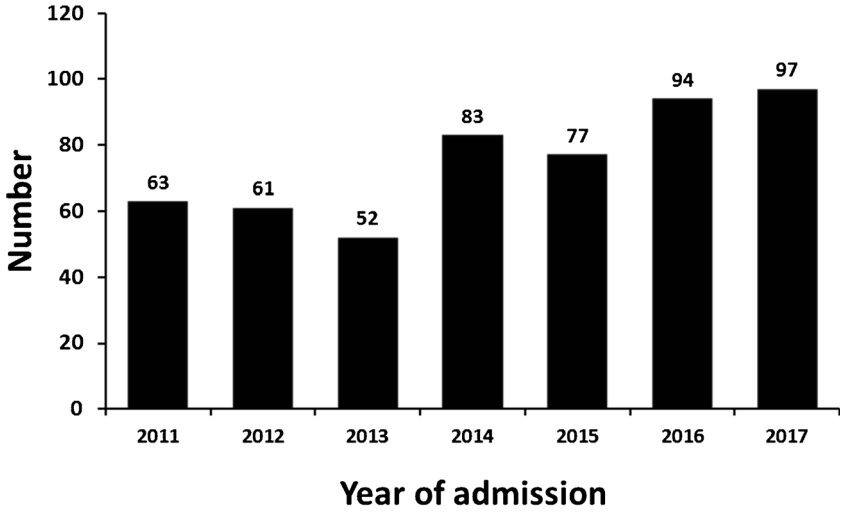

Fig. 1 Hospital discharges of patients with insulin pumps at Mayo Clinic in Arizona, 2011 to 2107

site infection. In the hospital, where methicillin-resistant staphylococcal aureus and other multidrug-resistant organisms are prevalent, a CSII/CGMS site infection could predispose to an abscess or necrotizing fasciitis. With this consideration, daily inspection of the sites and adherence to recommended site change intervals in the hospital (up to 72 h depending on type of cannula (48 h for metal, 72 h for plastic)) should occur if the patient is allowed to continue wearing their outpatient device in the hospital setting.

Broken Components

Pump labels or components have the potential to become damaged under routine use or with improper care. The plastic casing of an insulin pump can crack, or the pump damaged with exposure to water. Replacement of broken components would be difficult in the inpatient setting since they would not be stocked. In some circumstances, pump manufacturers may be contacted to request an express-mailed replacement or loaner.

Radiological Procedures

Exposure to ionizing radiation, which may be especially common in the hospital (e.g., computerized tomography), could be damaging to insulin pumps. Care must be taken to remove them or keep them out of the path of the procedure, or cover with a protective lead shield. In the case of MRIs, removal is necessary. After the pump is removed, it should be locked safely in the patient's room, radiology locker, or placed in the care of a family member to ensure it is not lost. Patients may require a temporary transition to subcutaneous insulin therapy or insulin infusion if the pump is expected to remain off for an extended period of time (e.g., 2 h).

Inpatient Transitions

Hospitalized patients often have to leave their hospital room and be transported for procedures that may last for varying lengths of time. These internal transitions of care represent potential points of failure for managing the patient with DM using CSII unless there is proper communication and a process in place that addresses the fact that a patient is using CSII in the procedural area. An effective "hand-off" with clear communication must occur between the patient's nurse and personnel in the procedure area, notifying them of the existence of the pump. The procedure area must have a process in place regarding continued use of the pump and monitoring of blood glucose levels. If the pump is disconnected, there should be instructions on whether to allow reconnection or transition to subcutaneous injections or an insulin infusion.

Cybersecurity: an Emerging Safety Issue

The newest safety concern for CSII and CGMS users is one of cybersecurity. Contemporary CSII and CGMS devices now rely on wireless technology. Consequently, these technologies are increasingly connected wirelessly to each other and to corresponding data-displaying reader devices. As with any other wireless technology, insulin pumps and CGMS are susceptible to hacking or medical hijacking (aka "medjacking"). The topic of medjacking has been extensively reviewed as it relates to diabetes technology and is now in the forefront of industry and government efforts to develop standardized countermeasures and protections [14–16]. For a user of CSII, this type of hack would allow, for example, an unauthorized command from the hacker to a nearby insulin pump to administer unsafe boluses of insulin, or perhaps undetected suspension of pump operations.

Potential cybersecurity threats have been described. A 2011 report described a potential hack within 300 ft of a pump

that instructed the CSII device to perform unauthorized commands [17]. Another report in 2016 raised concern over vulnerability with another branded device which could allow a hacker to deliver unauthorized insulin to a patient when in close proximity to the pump [18]. In addition, there remains the possibility that the privacy of this data could be compromised if "hacked" from the electronic medical record. Although cybersecurity of these devices in the inpatient setting is a potential threat, to the authors' knowledge, there are no reported occurrences in the literature. Nonetheless, the concern is real, and in the future, hospitals may not feel safe allowing continued inpatient use of a device that has not met a standard for cybersecurity.

Safety and Efficacy of CSII in the Hospital

A recent consensus conference on use of CSII in the inpatient setting was conducted in June 2017 [4••]. Although patients may be using this technology successfully in the outpatient setting, they are often unaware of potential problems with use in the hospital, especially in the setting of acute illness when blood glucose levels may be changing rapidly. Inpatient diabetes self-management using CSII refers to a process of collaboration between hospital staff and the patient where the patient is allowed to continue use of CSII in the hospital within a framework of policies and procedures. This hospital-based CSII self-management structure must exist within the broader context of processes that drive care for the general diabetes population, such as the prescribed frequency of blood glucose monitoring and the recognition and management of hypoglycemia.

The three essential building blocks for safe insulin pump use in the hospital are: (1) proper patient selection at time of admission, (2) establishment of a policy-driven process outlining initial and continuing care, and (3) effective patient-staff communication. The details of each of these components have been reviewed elsewhere [4••]. Briefly, patients who are critically ill or metabolically unstable, who have suicidal ideation, dexterity issues (e.g., following a stroke), impaired consciousness, who do not wish to comply with hospital policies, or who do not have their supplies (since the hospital is unlikely to stock them) would not be considered candidates for continued CSII use. A hospital policy and process that outlines roles of the patient, nurse, and prescriber staff should be in place [19, 20], Finally, patients need to be informed that while CSII in the hospital is a self-management paradigm, glycemic goals and management in the hospital may differ from those in the outpatient setting and that they should not make any changes in insulin pump settings without first notifying and discussing with staff.

Data regarding inpatient CSII use is currently limited, but a review of available literature indicated that outpatients on CSII therapy could be safely transitioned to allow continued use in the inpatient setting. Insulin pump malfunctions in the hospital while uncommon have been reported. In the largest published series to date, Cook and colleagues observed that there were no pump site infections, mechanical pump failures, or episodes of diabetic ketoacidosis. In their entire case series, there was only one adverse event of a kinked infusion catheter which resulted in hyperglycemia that was recognized early and corrected [19]. Noschese reported only 2 minor events (1 pump malfunction and 1 catheter infusion site problem) in 50 consecutive patients treated with CSII in the hospital [20]. Two cases of 'runaway pump" phenomenon have been reported in which patients received an unsolicited bolus of insulin. In both of these cases, the patients developed severe hypoglycemia [21].

Based on published experience, glucose control on CSII in the hospital is at least not inferior to subcutaneous insulin injections, although the frequency of hypoglycemia may be reduced with use of the insulin pump. Therefore, the goal of allowing a patient to transition their therapy from the outpatient setting into the hospital is not necessarily to achieve superior glycemic targets relative to other modes of insulin delivery that could control hyperglycemia. Rather, the purpose would be to allow patients to maintain a degree of independence in their diabetes self-management within parameters that optimize safety. Specific operational suggestions regarding inpatient management have been detailed elsewhere [4••, 7••, 8, 19, 20].

Safety and Efficacy of CGMS in the Hospital

As with insulin pumps, CGMS technology is approved for use in the outpatient setting as an adjunctive device to complement information obtained from standard home blood glucose monitoring devices and to aid in detecting hyper- and hypoglycemic episodes. Devices such as the G5 Mobile and G6 CGM (Dexcom, San Diego, CA) and the Freestyle Libre (Abbott Diabetes, Alameda, CA) are approved for making diabetes treatment decisions without confirmatory capillary blood glucose monitoring. The expected increased application of CGMS by outpatients with diabetes will likely lead to these being encountered in the inpatient setting as well. CGMS technology holds the promise of improving inpatient glycemic management through detection and early intervention of hyperglycemia and hypoglycemic events or trends that would otherwise be missed by sheduled point-of-care blood glucose monitoring [22]. Unlike insulin pumps, safety with CGMS mostly resides in the quality of the data produced, rather than electronic or mechanical characteristics. Additionally, ownership of sensor glucose data analysis, interpretation, and therapy decisions based on interpretation of this data would need to be determined, as would responsibility for device placement, care, and calibration (if required).

Outpatient use of a CGMS has been shown to improve glycemic control, and recent studies suggest that it is associated with higher patient satisfaction, less fear of hypoglycemia, and greater quality of life [23, 24]. Since those patients with diabetes who wear a CGMS as an outpatient find it helpful, it is reasonable to assume that many would prefer to continue use in the inpatient setting. However, therapeutic decisions based on CGMS data in the inpatient setting would be considered off-label use.

There is very little data available on transitioning outpatient CGMS devices to the inpatient setting. Use of CGMS in the hospital is potentially advantageous by providing information on the magnitude of glucose change as well as providing alerts for hypoglycemic and hyperglycemic episodes potentially earlier than they would be detected otherwise. However, futher evidence on the benefits of CGMS in the hospital is needed before it can be routinely recommended for use. Calibration with the patient's home glucose meter, which might be inaccurate, e.g., poorly handled or expired test strips, would compromise accuracy of the CGMS data [25]. Experts suggest that CGMS that require calibration should be calibrated against the hospital's glucose meter twice daily. CGMS data is not currently approved by FDA for inpatient insulin dosing, so point-of-care glucose measurements using the hospital's device must be obtained, and remain the cornerstone of therapeutic decision making with regard to insulin in the hospital.

Inpatient use of CGMS technology would be key to advancing the goal of developing inpatient glucometry systems [26]. Glucometry can be defined as the continuous measurement and transmission of glucose data to a centralized station that could be monitored by nurses or other trained personnel—analogous to cardiac telemetry. As suggested above, knowledge of glucose measurements in-between testing intervals could reveal new glycemic patterns that could positively influence management decisions. This methodology could allow early detection and intervention for hypoglycemic episodes that would otherwise be missed via standard point-of-care testing. A recent report, where the CGMS transmitter was connected to a smart phone, which in turn transmitted data to a tablet at the nurses station, demonstrated the feasibility of glucometry [26].

A 2015 consensus conference reviewed available published data on CGMS use in the hospital. Conferees agreed that, although data was limited, CGMS devices could be transitioned from the outpatient to inpatient setting and utilized safely. However, as with insulin pumps, there should be guidelines in place to determine how the devices are to be handled [7••]. In the future, if inpatient CGMS data are to be used to make therapeutic decisions for glucose management, methods are needed for uploading the CGMS data into the hospital electronic health record. This will mean that hospital patient care units will need to have software available for downloading these devices and storing data, preferably in real time. Devices may transfer data via bluetooth or infrared technology or a wired link to the pc, which imposes additional challenges to data-sharing in the hospital setting. Continuation of an outpatient CGMS in the hospital should be considered under specific circumstances if proper institutional procedures and guidelines are developed. At the very least, patients could continue to wear the outpatient CGMS device for their own comfort and safety and alert the nurse to perform a point-of-care blood glucose before taking action to prevent or treat hypo- or hyperglycemia.

Additional Considerations

Challenges of Integrated CSII/CGMS Technology

The above discussion considers insulin pumps and CGMS as separate entities. However, many patients may present wearing both devices that may or may not be integrated. Thus, while hospitals may have separate policies to guide CSII and CGMS use, one unified policy including both would be reasonable. Moreover, patients and pratitioners are witnessing increased integration of CGMS with insulin pumps, where the CGMS *talks to* the CSII and, for example, controls the basal insulin infusion rate to maintain glucose within a predetermined range. Thus, CGMS technology has advanced from simply taking measurements, to a state where the device can actually adjust insulin delivery rates being administered to the patient (i.e., determine amounts of insulin delivered). The best marketed example currently of such integration in the USA is the MiniMed 670G Hybrid Closed Loop System by Medtronic [5]. These integrated systems pose unique safety issues if transitioned into the hospital setting. As this technology allows for automated basal rate changes based on CGMS data and machine learning prior to the acute illness, accurate determinations and documentation of basal rates become more challenging. When operating in "Auto" mode, there is no set basal rate on these devices. Recording of auto basal rates in the electronic health record would be extremely difficult given the moment to moment variability in the infusion rates. To assure safe use of sensor integrated pumps, the automatic threshold suspend features may be turned off in the hospital, although doing so could remove the protection from hypoglycemic events. More experience is clearly needed with the use of these hybrid systems to provide evidence-based recommendations on how to proceed in the hospital setting.

Liability Risks

Insulin pumps and CGMS devices are complex devices that are infrequently encountered in the hospital depending on location of the institution. Hospital staff are likely to have little familiarity with their operation, or be able to trouble shoot if

something goes wrong. One agreed-upon component of an inpatient insulin pump or CGMS procedure is that these patients should be followed by an endocrinologist, or an advanced practitioner familiar with insulin pump and CGMS use [7••]. If there is no such provider available as may be the case in medically underserved areas (e.g., small rural hospitals), then consideration must be given regarding transfer of the patient to a facility familiar with use of these devices. Alternatively, videoconferencing, or a "virtual visit" with a site familiar with pump use, may be an option. If transferring the patient or videoconferencing is not an option and experienced hospital staff are not available, then strong consideration should be given to removing the devices and substituting with subcutaneous basal-bolus insulin therapy. Starting subcutaneous basal insulin doses can be based on basal insulin infusion rates from the CSII device. Bolus and correction insulin doses can be based on the patient's prior practices for carbohydrate counting, or the insulin/carbohydrate ratio and insulin sensitivity factor recorded in their pump as a place to start and then adjusted accordingly.

With use of CSII and CGMS devices, errors in management or unrecognized malfunction could result in metabolic decompensation or a severe hypoglycemic or hyperglycemic event, placing the hospital at legal risk. Each institution must weigh the risk and benefits of inpatient CGMS use based on their hospital infrastructure. Use of these devices in a hospital setting may not be feasible at institutions that do not have adequate ancillary support in the form of endocrinology/diabetes consult services, nursing expertise, or diabetes educators.

Conclusion

CSII and CGMS technologies are experiencing a rise in usage and are becoming more complex. Even with higher utilization, patients with diabetes employing these devices are still infrequently encountered in the hospital setting. There is no definitive data that shows that patients who transition their insulin pump and CGMS technologies into the hospital stay improves outcomes, and there are safety concerns. The decision whether to allow a patient to continue to use these methods of diabetes self-management impacts patient satisfaction. However, current data indicate with proper patient selection and a clear process in place for diabetes management, adverse events are rare. Thus, consensus favors allowing use of the technology in the hospital. The topic of CSII and CGMS in the hospital would greatly benefit from more institutions reporting on their experiences and prospective clinical trials.

Compliance with Ethical Standards

Conflict of Interest Bithika Thompson, Melinda Leighton, and Curtiss B. Cook declare that they have no conflict of interest.

Mary Korytkowski reports the following disclosures: other from Novo Nordisk, other from Department of Defense, other from Jaeb Center for Health Research and Leona Helmsley Foundation, other from American Diabetes Association and Vietnam Diabetes/Endocrine Association, other from American Board of Internal Medicine: Endocrinology and Metabolism Exam Committee.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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