Tecnologia nel paziente ricoverato

Enrico Gabellieri
SC Endocrinologia e Malattie del Metabolismo
AO SS Antonio e Biagio Alessandria

Riccardo Fornengo
S.S.D. di Diabetologia
ASLTO4

- Il dr. Gabellieri Enrico dichiara di aver ricevuto negli ultimi due anni compensi o finanziamenti dalle seguenti Aziende Farmaceutiche e/o Diagnostiche:
    - Boehringer
    - Astrazeneca
    - Merck
    - Lilly
    - Novo Nordisk
    - Sanofi
    - Guidotti
    - Neopharmed Gentili

- *Dichiara altresì il proprio impegno ad astenersi, nell'ambito dell'evento, dal nominare, in qualsivoglia modo o forma, aziende farmaceutiche e/o denominazione commerciale e di non fare pubblicità di qualsiasi tipo relativamente a specifici prodotti di interesse sanitario (farmaci, strumenti, dispositivi medico-chirurgici, ecc.).*

- Il Dott. Riccardo Fornengo dichiara di aver ricevuto negli ultimi due anni compensi o finanziamenti dalle seguenti Aziende Farmaceutiche e/o Diagnostiche:
    - nessuno

- *Dichiara altresì il proprio impegno ad astenersi, nell'ambito dell'evento, dal nominare, in qualsivoglia modo o forma, aziende farmaceutiche e/o denominazione commerciale e di non fare pubblicità di qualsiasi tipo relativamente a specifici prodotti di interesse sanitario (farmaci, strumenti, dispositivi medico-chirurgici, ecc.).*

7. Diabetes Technology: *Standards of Care in Diabetes—2023*

Diabetes Care 2023;46(Suppl. 1):S111–S127 | https://doi.org/10.2337/dc23-S007

Nuha A. ElSayed, Grazia Aleppo, Vanita R. Aroda, Raveendhara R. Bannuru, Florence M. Brown, Dennis Bruemmer, Billy S. Collins, Marisa E. Hilliard, Diana Isaacs, Eric L. Johnson, Scott Kahan, Kamlesh Khunti, Jose Leon, Sarah K. Lyons, Mary Lou Perry, Priya Prahalad, Richard E. Pratley, Jane Jeffrie Seley, Robert C. Stanton, and Robert A. Gabbay, on behalf of the American Diabetes Association

Inpatient Care

Recommendation

7.30 People with diabetes who are competent to safely use diabetes devices such as insulin pumps and continuous glucose monitoring systems should be supported to continue using them in an inpatient setting or during outpatient procedures, once competency is established and proper supervision is available. E

This should occur based on the **hospital's policies for diabetes management and use of diabetes technology**, and there should be supervision to ensure that the individual is achieving and maintaining glycemic targets during acute illness in a hospitalized setting where factors such as infection, certain medications, immobility, changes in nutrition, and other factors can impact insulin sensitivity and the insulin response

16. Diabetes Care in the Hospital: *Standards of Care in Diabetes—2023*

Diabetes Care 2023;46(Suppl. 1):S267–S278 | https://doi.org/10.2337/dc23-S016

Nuha A. ElSayed, Grazia Aleppo, Vanita R. Aroda, Raveendhara R. Bannuru, Florence M. Brown, Dennis Bruemmer, Billy S. Collins, Marisa E. Hilliard, Diana Isaacs, Eric L. Johnson, Scott Kahan, Kamlesh Khunti, Jose Leon, Sarah K. Lyons, Mary Lou Perry, Priya Prahalad, Richard E. Pratley, Jane Jeffrie Seley, Robert C. Stanton, and Robert A. Gabbay, on behalf of the American Diabetes Association

Point-of-care BGM remains the approved method for glucose monitoring in hospitals, especially for dosing insulin and treating hypoglycemia

Diabetes Care Specialists in the Hospital

Recommendation

16.3 When caring for hospitalized people with diabetes, consult with a specialized diabetes or glucose management team when possible. **C**

A target glucose range of 140–180 mg/dL (7.8–10.0 mmol/L) is recommended for most critically ill and noncritically ill patients. More stringent goals, such as 110–140 mg/dL (6.1–7.8 mmol/L) or 100–180 mg/dL (5.6–10.0 mmol/L), may be appropriate for selected patients and are acceptable if they can be achieved without significant hypoglycemia

Inpatient care: diabetes technology

Diabetes devices: FGM/CGM - CSII/AID

Inpatient care

Health care professionals (diabetologist) should be knowledgeable of CGM/CSII/AID systems and nuances of different systems, including their distinguishing features as well as strengths and weaknesses

People with diabetes who are familiar with treating their own glucose levels can often adjust insulin doses more knowledgeably than inpatient staff who do not personally know the individual or their management style

AID systems terminology	
Sensor-augmented pump (SAP)	Insulin pump with use of a CGM either on a separate device or displayed directly on the pump. These systems allow for viewing of the sensor data, but insulin delivery is not altered on the basis of sensor glucose values.
Low glucose suspend (LGS) or predictive low glucose suspend (PLGS)	Insulin pump system that suspends insulin delivery for actual hypoglycemia due to sensor glucose value (LGS) or for predicted hypoglycemia (PLGS).
Hybrid AID (also known as hybrid closed loop)	Insulin pump system that automatically increases or decreases basal insulin delivery in response to sensor glucose values; user still needs to dose prandial insulin manually. Advanced hybrid AID systems are also available now. These next-generation systems not only adjust basal insulin delivery but also have the capacity to deliver automatic correction boluses. However, they still require the person with diabetes to dose prandial insulin.
Full AID	AID system that automatically adjusts all insulin delivery, including prandial insulin.
DIY AID (also known as Loop, OPEN APS, Android APS)	"Do-it-yourself" AID system using a commercially available CGM system and insulin pump, plus an open-source algorithm; currently not approved by regulatory agencies.
Artificial pancreas (AP)	This term was used often in the past as a synonym for AID, but the AP does not take into account the exocrine functions of the pancreas.
Bihormonal (bionic pancreas)	AID systems that incorporate two hormones (insulin and glucagon); insulin and pramlintide are also being studied.

Actors

CRITICAL POINT:
Often, there are no healthcare policies in place that can safeguard the use of CGM or AID systems in the inpatient setting and delineate the roles of the patients, nurses, and HCPs

Hospital policy
Hospitals **need** to develop plans, including process maps, protocols, staff educational resources

Hospital
Healthcare policies

Patient
Self-management

- cognitive, emotional, physical ability and competences to

Patients who wish to continue use of CGMs or AID systems in the acute care setting should read a detailed set of information and should review and **sign a patient agreement about hospital policy**

- back-up supply (CGM or CSII)

When using CGMs or AID systems in the acute care setting, specialty consultation, if available, is required and the request for consultation should be documented

Consensus Guideline

Continuous Glucose Monitors and Automated Insulin Dosing Systems in the Hospital Consensus Guideline

Journal of Diabetes Science and Technology
2020, Vol. 14(6) 1035–1064

DOI: 10.1177/1932296820954163
journals.sagepub.com/home/dst
SAGE

- April 2020
- International expert panel: 77 recommendations were classified as either strong or mild, 1 failed to reach consensus
- The panel's recommendations are intended to support clinical practice, future research, and improved hospital policies, to facilitate the use of these tools
- Five topics

Potential opportunities
Potential barriers
Recommendations

The Five Topics Discussed at the Continuous Glucose Monitors and Automated Insulin Dosing Systems in the Hospital Panel.

Topic 1: Continuation of home continuous glucose monitors after hospitalization
Topic 2: Initiation of continuous glucose monitors in the hospital
Topic 3: Continuation of automated insulin dosing systems in the hospital
Topic 4: Logistics and hands-on care of hospitalized patients using continuous glucose monitors and automated insulin dosing systems
Topic 5: Data management of continuous glucose monitors and automated insulin dosing systems in the hospital

Recommendations

- Current recommendations advocate the establishment of clear policies and procedures to guide patients and hospital staff in the management of diabetes with the use of CGM/insulin pumps
- The patient's cognitive, emotional, physical ability and competence to manage his/her CGM/insulin pump during the hospitalization should be considered when deciding whether to continue use of devices while the patient is hospitalized
- The hospital provider should obtain a detailed record of the type of insulin formulation and the CGM/pump settings on admission, including basal rate/rates, the carbohydrate ratio (grams of carbohydrate for 1 unit of insulin), and the correction or sensitivity factor
- A signed patient agreement that specifies all the necessary tasks to be performed by the patient, consent to share information regarding pump settings with the health care staff, and the need to report any issues is also recommended
- Clear physician's orders with specifics on the type of diet, frequency of point-of-care glucose testing, basal rate, bolus, and correction-dose insulin settings should also be in place
- The pump settings also include a target glucose level (140-180?) CGM TIR ? (tight glucose control may be too low for the hospital setting)

Hospital Policies

- Hospitals **need** to develop institution-specific plans, including process, maps, protocols, staff educational resources, and order sets for the proper use of CGM/CSII or AID systems during a hospitalization (and also for prescribing CGM use during hospitalizations)

- Hospitals **need** to develop protocols for using CGM/AID systems during elective procedures and surgeries

- Hospitals **need** to develop policies for when to discontinue or temporarily suspend the use of CGM/AID systems

- Hospitals **need** to require that patients using CGM/AID systems bring with them sufficient supplies for these devices during a hospitalization

Patient agreement

Patients who wish to continue use of CGMs or AID systems in the acute care setting should read a detailed set of information and should **review and sign a patient agreement about hospital policy**

I_____currently have a continuous glucose monitor and/or insulin pump in place and wish to maintain this therapy during my admission to the Hospital. I understand and agree as follows:

Patient's Continuous Glucose Monitor

1. I may continue to wear my continuous glucose monitor (CGM) during my hospital stay but my blood glucose will also be monitored using a hospital-approved blood glucose meter and treatment decisions will be based on these results.
2. I will keep a back-up supply of all CGM supplies including, without limitation, sensors and dressings.
3. I will change the CGM sensor every 7-14 days depending on the device instructions.
4. I will notify my nurse immediately if my CGM indicates my glucose reading is trending out of target (i.e., trending low or high) so that my blood glucose can be tested to confirm the trending and appropriate treatment initiated according to the prescriber's order.
5. I will allow my nurse to assess the sensor site every shift.
6. If I need any surgery or procedure, then the hospital might need to remove my sensor. If I elect to leave my CGM sensor on during any surgery or procedure it may present a risk of damage to my CGM sensor during the surgery or procedure.
7. If I need an MRI scan, then I will remove the sensor prior to the procedure so that the transmitter and receiver can be either secured by staff or sent home with a designated family member/significant other.
8. If I need an X-ray or CT scan, then my CGM will be covered by a lead apron.
9. Any of my CGM supplies stored by hospital staff will be returned to me prior to my discharge.

By signing below, I acknowledge that I have read, understood, and agreed to the above and that all of my questions have been answered.

Patient Signature: _____

Nurse/Provider Signature: _____

Nurse/Provider Print Name: _____

Unit/Service: _____

Date & Time: _____

CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (INSULIN PUMP)
ASSESSMENT DOCCUMENT

The following doccument must be completed before you are allowed to use your pump in the hospital.

Please complete the document and return it to your nurse for your hospital chart.

Pump Information	
Manufacturer	
Model	
Customer support number	
Insulin type	
Infusion set type Do you use an inserter?	☐ Yes ☐ No

You must provide your own insulin pump, insulin supplies and insulin while in the hospital

Do you have your insulin pump supplies with you? ☐Yes ☐ No

How many days supplies do you have?_____

Pump Settings

Basal Rates:

Start Time (hhmm)	End Time (hhmm)	Basal Rates (units/hour)

Insulin/Carbohydrate Ratios

	Fixed Dose (u)		Start Time	End Time	Units insulin per grams carbohydrate
Breakfast		**OR**			
Lunch					
Dinner					
Other					

Correction Bolus

- _____ unit(s) for every _____ mmol/L over blood glucose target of _____ mmol/L

OR

- One unit of insulin decreases glucose by _____ mmol/L

OR

- Provide copy of written scale

Patient/ guardian's name	Signature	Date (yyyy/mm/dd)

Patient Self-Management of Insulin Pump Consent Form

For your safety and optimal care if you would like to use your insulin pump while you are in the hospital, we request that you agree to the following terms. If at any time you are not able to follow these terms we will discontinue your insulin pump and treat your diabetes with insulin injections and/or intravenous infusion until you are able to follow these terms and resume management.

I or my designated caregiver/parent will manage my insulin pump during this hospital stay. I understand that hospital stays and the stress of illness may cause unexpected changes in my blood glucose and that I may not be used to managing such changes in my blood sugar with my pump.

During my hospital stay, I agree to:

1. Take full care of my insulin pump, including starting and stopping the insulin and making any changes needed to keep it working correctly.
2. Use my insulin pump in the hospital knowing the potential risk of:
   - High/low blood glucose
   - Diabetic ketoacidosis
   - Infection
3. Change the infusion set every 48-72 hours or as needed for:
   - Skin problems
   - Two blood glucose readings greater than 14 mmol/L in 4 hours
4. Provide my own insulin supplies (including my brand of insulin if not available through the KGH Pharmacy Formulary)
5. Record all of my insulin infusion rates and bolus doses on the flow sheet provided
6. Have my blood glucose checked regularly using hospital glucose meters and lancets, according to hospital policy. I may use my own blood glucose meter for any additional tests if a physician order has been written and the accuracy of the glucose meter has been verified using a split sample according to G4735 Nursing Policy: Glucose monitoring split sample analysis.
7. Let the nurse and/or physician know immediately if:
   - I feel like I have low blood glucose
   - I have a problem with my pump
   - I have two blood glucose readings greater than 14 mmol/L in 4 hours
   - I feel like I can no longer take care of my pump

I understand that my pump may need to be stopped and insulin may be given to me in a different way for any of the following:

- Radiology procedures
- Changes in my mental state
- Any other reason stated by my doctor/nurse practitioner

The use of my insulin pump during my hospital stay has been explained to me and I have had an opportunity to fully inquire about the above terms. I understand the terms and at this time, I feel that I am able to care for my insulin pump while in the hospital.

_____ _____

Date(yyyy/mm/dd) / Time(hhmm) Patient Signature

_____ _____

Date(yyyy/mm/dd) / Time(hhmm) MD/NP Signature & Designation

Inpatient flow sheet

Practical Diabetes

In-Hospital Management of Adults Using Insulin Pump Therapy

Robyn L. Houlden MD[a,*], Sarah Moore RN(EC), BScN, MN[b]

[a] Division of Endocrinology, Queen's University, Kingston, Ontario, Canada
[b] Diabetes Consult Service, Kingston General Hospital, Kingston, Ontario, Canada

CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (INSULIN PUMP)
INPATIENT FLOW SHEET

Date_____ to _____
(yyyy/mm/dd) (yyyy/mm/dd)

Nurse initials required BID/ prn to confirm patient has completed the flowsheet

	0800 h	0900 h	1000 h	1100 h	1200 h	1300 h	1400 h	1500 h
Blood Glucose (mmol/L)								
Basal Rate (units/h)								
Meal Bolus (units)								
Correction Bolus (units)								
Carbohydrate (g)								
Site change/Other								
Nurse Initials								

	1600 h	1700 h	1800 h	1900 h	2000 h	2100 h	2200 h	2300 h
Blood Glucose (mmol/L)								
Basal Rate (units/h)								
Meal Bolus (units)								
Correction Bolus (units)								
Carbohydrate (g)								
Site change/ Other								
Nurse Initials								

	2400 h	0100 h	0200 h	0300 h	0400 h	0500 h	0600 h	0700 h
Blood Glucose (mmol/L)								
Basal Rate (units/h)								
Meal Bolus (units)								
Correction Bolus (units)								
Carbohydrate (g)								
Site change/ Other								
Nurse Initials								

Patient Name: _____ Patient Signature: _____

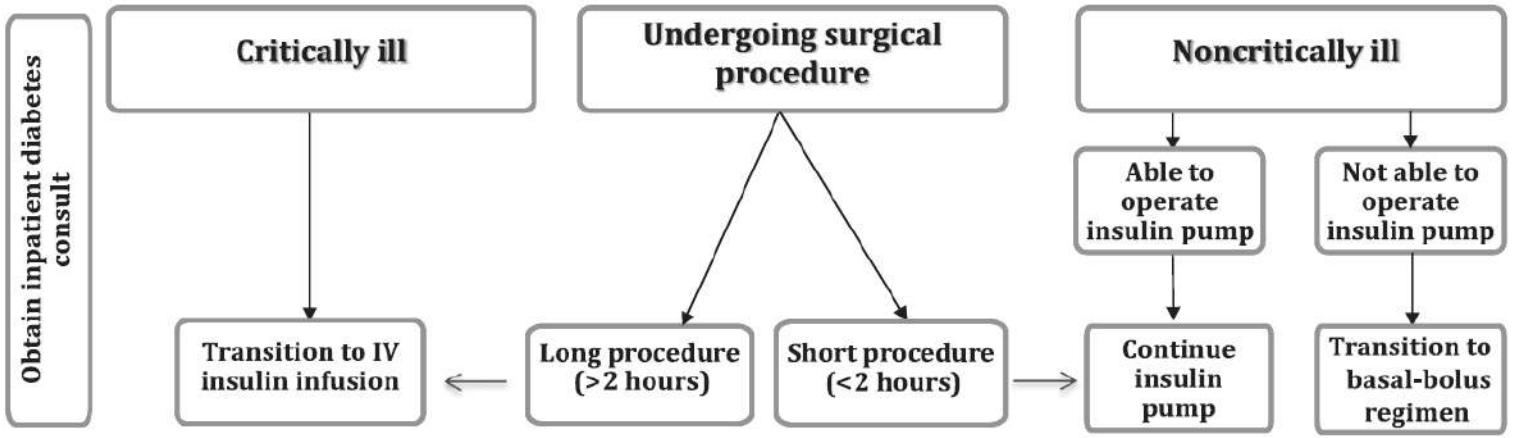
Date (yyyy/mm/dd) _____ Time (hhmm): _____

Diabetes Technology Update: Use of Insulin Pumps and Continuous Glucose Monitoring in the Hospital

Guillermo E. Umpierrez[1] and David C. Klonoff[2]

Diabetes Care 2018;41:1579–1589 | https://doi.org/10.2337/dci18-0002

Patient With Insulin Pump Admitted to Hospital



Changes to Pump Therapy With Imaging Studies	
X-ray/CT	Pump should be covered by lead apron
MRI	Pump and metal infusion set should be removed
Ultrasound	No need to remove pump but transducer should not be pointed directly at the pump
Cardiac catheterization	Pump should be covered by lead apron
Pacemaker/automatic implantable cardioverter defibrillator (AICD)	Pump should be covered by lead apron
Colonoscopy/EGD	Pump can remain in place
Laser surgery	Pump can remain in place

Potential Barriers

- Patient-related (critically ill hospitalized patient-hypovolemia or sepsis)
- Hospital-related (no policies in place)
- Device-related (insufficient supplies, malfunction, CGM compression, potential interactions of certain medications with CGMs)
- Medication-related (such as glucocorticoids, nutritional interruptions)
- Surgical procedure-related (insert the sensor and the insulin cannula away from the operative field and change the sites one day prior to the surgery, insulin requirements are expected to fluctuate significantly intraoperatively)

Contraindications to CSII and AID System in Hospital

Contraindications to CSII System and AID System Therapy in the Hospital.

Impaired level of consciousness (except during short-term anesthesia)
Patient's inability to correctly demonstrate appropriate CSII system settings
Critical illness requiring intensive care
Psychiatric illness that interferes with a patient's ability to self-manage diabetes
Diabetic ketoacidosis and hyperosmolar hyperglycemic state
Refusal or unwillingness to participate in self-care
Lack of CSII system supplies
Lack of trained health care providers, diabetes educators, or diabetes specialists
Patient at risk for suicide
Health care decision

AID, automated insulin dosing; CSII, continuous subcutaneous insulin infusion.

Transition from CSII to MDI

Diabetes Technology Update: Use of Insulin Pumps and Continuous Glucose Monitoring in the Hospital

Guillermo E. Umpierrez[1] and David C. Klonoff[2]

Diabetes Care 2018;41:1579–1589 | https://doi.org/10.2337/dci18-0002

—Transition from CSII to subcutaneous (SC) insulin regimen "pump holiday protocol"

Stop CSII ~2 h after SC basal insulin is given.

Calculate 24-h basal dose of insulin delivered from pump setting. Total basal daily insulin can be given as once-daily or twice-daily injections.

Prandial insulin can be calculated as half of a patient's usual total daily dose of insulin divided by 3. Alternatively select the dose using I:C ratio

Capillary BG should be measured before meals and bedtime.

A correction-dose algorithm of rapid-acting insulin to be added to the prandial dose should be ordered for high BG levels based on the patient's usual insulin sensitivity factor or by a sliding-scale protocol:

BG before meals	Dose
<180 mg/dL (<10 mmol/L)	No correction
181–220 mg/dL (10.1–12 mmol/L)	1 unit
221–260 mg/dL (12.1–14 mmol/L)	2 units
261–300 mg/dL (14.1–16 mmol/L)	3 units
301–340 mg/dL (16.1–18 mmol/L)	4 units
341–380 mg/dL (18.1–20 mmol/L)	5 units
>380 mg/dL (>20.1 mmol/L)	6 units, notify physician

Adjust basal and prandial insulin dose daily based on glucose values and nutritional intake.

The pump can be restarted when the patient is able to resume responsibility or at hospital discharge.

Questions still remain regarding:

- The acquisition, storage, display and use of data
- The Information Technology departement is needed to assist with licenses to download the data, and install the software into each Hospital system. In particular how to source data: 1- obtaining the data directly on a platform provided by the manufacturer or 2- obtaining the data from a third –party aggregator

- Standardized, clear, and interpretable summery metrics be established in order to facilitate the clinical use of CGM data in the hospital setting

Hospital policies

- Hospitals **need** to develop appropriate security protocols, dedicated data storage, visualization tools, and adequate cyber insurance coverage (also known as "data at rest")
- Hospitals **need** to integrate AID system data into the EHR system for nursing and HCPs to have easy access to this information
- Hospitals **need** to determine the number of laboratory or POC BG tests that must be performed while patients are using CGMs or AID systems in the hospital
- Hospitals **need** to adopt the Unique Device Identifier system for healthcare facilities to track devices in the EHR
- Hospitals **need** to identify CGM data reports in the patient's EHR to distinguish them from laboratory glucose results
- Hospitals **need** to present clear criteria to clinicians to identify data that will require intervention
- Hospitals **need** to implement CGM- and AID system-specific PROs to improve patient care
- Hospitals **need** to develop a universal platform for their EHRs that can be used by all CGMs to present core data elements, summary glucometrics, consistent formats, and uniform interfaces across all CGM products
- Hospitals **need** to arrange for CGM results to be automatically uploaded into the EHR
- Hospitals **need** to manage CGM data with the same safety and security measures as all other PHI

CGM Data Integration Complexity Across Three Key Domains.

Data extraction (from least to most complex)	Data storage (from least to most complex)	Data display (from least to most complex)
1. Static, standard reports	1. Web storage, linked to EHR	1. Text and graphic reports
2. Custom reports	2. Native EHR data tables	2. Structured data fields with native analytics
3. Structured summary data	3. External storage and computing environment	3. Embedded analytics displayed from a web service
4. Structured continuous data		4. Native integration of manufacturer analytics platform
5. Device metadata		

EHR, electronic health record.

Take Home Messages

- Support continuation of outpatient CGM/AID systems in the hospital under specific circumstances if proper institutional procedures and guidelines are developed
- Develop healthcare policies that can safeguard the use of CGM or AID systems in the inpatient setting and delineate the roles of the patients, nurses, and HCPs
- A signed patient agreement is recommended
- Take into account potential barriers and contraindications to the use of CGM/AID systems in the inpatient setting and issues related to the acquisition, storage, display and use of data