DIABETES TECHNOLOGY & THERAPEUTICS
Volume 21, Number 8, 2019

DOI: 10.1089/dia.2019.0105

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COMMENTARY

A Clinical Guide to Advanced Diabetes Devices and Closed-Loop Systems Using the CARES Paradigm

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Keywords: Type 1 diabetes, CSII pump, CGM, Artificial pancreas, Hybrid closed-loop, PLGS.

Introduction

Advanced diabetes devices are the most sophisticated technologies available for self-management of insulin-requiring diabetes.[1,2] Advanced diabetes devices are insulin pumps that integrate with continuous glucose monitors (CGM) and contain algorithms that change insulin delivery in response to CGM glucose levels. These devices include low glucose suspend and predictive low glucose suspend (PLGS) insulin pumps, as well as automated insulin delivery systems, such as hybrid closed-loop (HCL) systems. While many diabetes providers and diabetes educators are confident with traditional insulin pump therapy and glucose sensors, advanced diabetes devices represent a new class of insulin pump therapy and additional training may be needed.[3]

The purpose of this article is to highlight some of the clinically relevant aspects of advanced diabetes devices, using the updated CARES paradigm: How each system *calculates* insulin delivery, which parameters can be *adjusted*, when users should *revert* to traditional insulin pump settings, critical *education* points, and key aspects of the *sensor and sharing* capabilities of the system. This tool is intended to be used by diabetes clinicians and diabetes educators who have general familiarity with insulin pumps and CGM to support their ability to provide comprehensive care to individuals with insulin-requiring diabetes.

Advanced Diabetes Devices

Advanced diabetes devices are defined here as systems that combine insulin pump and CGM technology with an algorithm to adjust insulin delivery in response to sensor glucose values in real-time.[4] Examples of advanced diabetes devices include low glucose suspend systems, PLGS systems, and HCL systems. Currently, all advanced diabetes devices can be used not only with advanced features enabled but also as traditional insulin pumps (with or without CGM). Several advanced diabetes devices are currently available for individuals with diabetes, and five systems are highlighted here.[5] Other systems may be available in different regions worldwide, with more likely to become available in the upcoming decade.

Low glucose suspend

The most simple advanced diabetes devices, low glucose suspend systems, suspend insulin infusion when CGM glucose levels fall below a hypoglycemia threshold (e.g., 70 mg/dL). Insulin remains suspended for a period of time and may resume after a fixed time interval, after the system determines that CGM glucose levels are rising or are back into a target range (e.g., >70 mg/dL), or after user override of the suspension. The MiniMed 630G (MiniMed, Northridge, CA) is an example of a low glucose suspend system that suspends insulin delivery when sensor glucose levels are in the hypoglycemic range.[6,7]

Predictive low glucose suspend

Advancing beyond low glucose suspend technology, PLGS systems contain prediction algorithms that forecast future hypoglycemia (e.g., within the next 20 min) and preemptively suspend insulin delivery before the occurrence of hypoglycemia. Similar to low glucose suspend systems, PLGS systems will resume insulin under conditions such as rise in glucose levels, glucose levels above a certain threshold, or user override of the suspension. Low glucose suspend systems and PLGS systems have been proved effective for reducing duration and frequency of hypoglycemia events without increased risk for ketosis.[6,8,9] Three commercially available systems with PLGS functionality include the t:slim X2™ with Basal-IQ™ (Tandem, San Diego, CA), the MiniMed® 640G (available in Europe), and the MiniMed® 670G (MiniMed, Northridge, CA).[6,8,9] The 670G system is also an

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The topic of this manuscript has been presented, in part, at the Advanced Technologies and Treatments for Diabetes conference in Berlin, Germany, February 20–23, 2019.

HCL system (described below), but offers PLGS functionality when it is not in HCL mode but has an active CGM.[10]

Hybrid closed-loop

To date, the most sophisticated advanced diabetes devices are HCL systems. HCL systems are broadly considered ''automated insulin delivery'' systems, because they actively calculate and modify insulin doses in response to CGM glucose levels and trends. HCL systems attempt to bring glucose values into a target range and minimize hypoglycemia and hyperglycemia.[11,12] This is done by automating basal insulin doses either independently of preprogrammed pump settings or by modifying preprogrammed pump settings. The user is still required to program insulin boluses for meals or hyperglycemia.[13–15] This is why the system is considered a ''hybrid closed-loop,'' as the user must still participate in programming and delivering insulin doses. Early evidence indicates that HCL may improve time-in-range when the systems are used in HCL mode consistently.[12,14–16]

To note, the term ''open-loop'' is often used as a contrast to HCL and fully closed-loop system. This term refers to the automated insulin delivery systems working as traditional insulin pumps, where preprogrammed insulin settings are used and automation is turned off. The term open-loop is less clear in the context of low glucose suspend and PLGS systems, as these systems use traditional insulin pump settings, however, use algorithms to suspend insulin delivery.

The first commercially available HCL system, the MiniMed 670G, received regulatory approval in the United States in 2016 and received CE mark in Europe in 2018. The 670G, like all HCL systems, can operate as a HCL system (called ''Auto Mode™'') or as a traditional insulin pump (called ''Manual Mode''), where the basal insulin delivery is not calculated by the system, but instead is delivered per the preprogrammed basal rates. The Diabeloop DBLG1 is another HCL system that was recently approved in Europe, and may soon be commercially available.[17] Additional HCL systems are also in development,[16,18–20] with the t:slim X2™ with Control-IQ™ HCL (Tandem) currently undergoing phase 3 clinical trials,[21] and the Omnipod Horizon™ HCL (Insulet, Acton, MA) undergoing prepivotal trials.[18,22] In addition, the Do-It-Yourself (DIY) community has partnered with Tidepool to explore bringing the Loop DIY device to commercialization.[23]

Future devices

New devices are in development that do not require user-input to bolus for meals. These systems are called ''fully closed-loop'' systems, which are designed to automate all insulin delivery, including basal insulin delivery and bolus doses for meals or hyperglycemia. Other systems are being developed that automatically deliver both insulin and glucagon and are referred to as ''bihormonal'' systems. Extensive engineering work has been published for both fully closed-loop[24–29] and bihormonal systems,[19,30–32] detailing algorithms and hardware components.

Overall, advanced diabetes devices offer greater ability to improve glycemic control compared to traditional insulin pumps because they are able to respond to CGM glucose levels to various degrees and change insulin delivery automatically.

The Need for a Clinical Framework for Advanced Diabetes Devices

What do these technologies practically mean for diabetes clinicians and educators? This complex and rapidly shifting technological landscape may lead to confusion, misunderstanding, and inappropriate clinical decisions, even for clinicians who are experienced with traditional insulin pump therapy and CGM. Advanced diabetes devices are fundamentally different from traditional insulin pumps and each advanced device has important differences from other advanced devices. Clinicians require practical knowledge of each device to provide quality care to their patients with diabetes.

To complicate matters further, commercial systems often use brand specific terminology to describe their device features, making it difficult to decipher what the devices do and even more difficult to distinguish the differences and similarities between devices. For example, how should the clinician distinguish between ''Basal-IQ,'' ''Control IQ,'' and ''Auto Mode''? ''Basal IQ'' is a predictive low glucose system and ''Auto Mode'' and ''Control IQ'' are both HCL system functions, but the commercial names do not provide any insight into what they do or how they should be classified.

Another challenge is how clinicians must comprehend the different ''clinical rules'' that apply to different systems, such as the 670G HCL system compared with Control-IQ HCL: When using a 670G, a user can adjust insulin action time to influence high glucose correction boluses in HCL. However, this parameter cannot be adjusted for the Control-IQ HCL. As another example, Control-IQ HCL offers a ''sleep mode,'' which changes the glucose target used to calculate insulin doses in HCL overnight, but this setting is not available in 670G HCL mode. These details have significant implications for optimizing device settings, delivering competent education, troubleshooting the system, and setting expectations.[33]

To provide clinician guidance and highlight practical concepts for advanced diabetes technology, we previously published with a multicenter diabetes group the CARE framework (*Calculate*, *Adjust*, *Revert*, and *Educate*): understanding how a system *Calculates* insulin delivery, how the user can *Adjust* insulin dosing parameters to optimize system performance, when to *Revert* to traditional pump mode (from advanced features), and important *Education* tips for system use.[34] This acronym has been used to guide educational efforts at our large academic clinical center for pediatric type 1 diabetes care.[35] Through ongoing experience and development work with advanced diabetes devices at our Center, in addition to feedback from the academic diabetes community, we have updated the framework to include information specific to CGM sensors and remote monitoring capabilities, thus expanding the acronym to CARES (S for *Sensor/Share*). There are currently large differences in CGM platforms, making this additional category essential to the full clinical picture of advanced diabetes devices. With the addition of *Sensor/Share* capabilities, the improved CARES paradigm provides a practical, clinically focused framework to help clinicians identify concepts important for using advanced diabetes devices.

The purpose of this article is to compare aspects of new and emerging advanced diabetes devices using the updated CARES paradigm (Table 1). This information will highlight

Table 1. Updated CARES Paradigm for Advanced Diabetes Devices

C: Calculate	• How does the algorithm calculate insulin delivery? • Which components of insulin delivery are automated (e.g., basal suspensions, basal modulation, high glucose corrections, food boluses, etc.)?
A: Adjust	• How can the user adjust insulin delivery? • Which parameters can be adjusted to influence insulin delivery during automation (e.g., carbohydrate ratios, insulin action time, basal rates, sensitivity factors)? • Which parameters are fixed?
R: Revert	• When should the user choose to revert to open-loop/no automation? • When will the system default to open-loop/no automation?
E: Educate	• What are the key education points for the advanced diabetes device (e.g., essential training, tips and tricks, best practices, etc.)? • How does the user optimize time using the automated features? • Where can users and clinicians find additional education?
S: Sensor/Share	• What are relevant sensor characteristics for each device (e.g., calibration and therapeutic blood glucose requirements, duration of sensor wear, etc.)? • What are the system capabilities for remote monitoring and cloud-based data sharing?

the fundamental similarities and differences in current low glucose suspend, PLGS, and HCL systems and provide a foundation for understanding future systems as well. The goal of this tool is to aid diabetes clinicians in distinguishing between different advanced diabetes devices, thus supporting quality care for individuals with insulin-requiring diabetes.

Updated CARES Paradigm

While clinicians do not need proficiency in the algorithmic nuances of advanced diabetes devices, they do need to understand key device characteristics to provide clinical support and guidance for individuals with diabetes. The CARES paradigm aims to provide this clinical insight by highlighting fundamental components of advanced diabetes devices that may be clinically relevant. Table 1 summarizes the fundamental components of the CARES paradigm, while Tables 2 and 3 provide specific details for current advanced diabetes devices.

Calculate

Clinicians must understand how advanced diabetes devices compute or alter insulin delivery compared to a traditional insulin pump. There are substantial differences in the parameters used in each system's algorithm that have implications for behavior and optimizing insulin dose settings.[11,36] Some important terms for clinicians to know related to advanced diabetes devices include the following:

- Low suspend threshold: This is the glucose level at which a low glucose suspend system will suspend basal insulin delivery. For PLGS devices, the suspend threshold is the *predicted* glucose level a PLGS system is aiming to avoid when suspending basal insulin. Some PLGS systems allow the user to change the suspend threshold, whereas others do not. Table 2 delineates these parameters for selected commercially available systems.
- Target range or set-point: These terms are used specifically for HCL systems/future fully closed-loop systems, and they describe the parameters for which the system automates insulin delivery. Some algorithms for HCL systems aim to keep glucose levels within a target range (e.g., 110–150 mg/dL), whereas other algorithms use a singular point as the algorithm target, called the set-point (e.g., 120 mg/dL). The set-point or range are not necessarily identical to clinical glucose guidelines, rather are intended to provide parameters for the algorithm to use when calculating insulin doses.
- HCL: As indicated above, HCL systems automate basal insulin delivery in response to CGM glucose levels. These systems are considered HCL, because they still require the user to program bolus doses of insulin for carbohydrate consumption, and some for high glucose corrections as well.
- Open-loop: This refers to traditional pump therapy (e.g., preprogrammed basal delivery) and indicates that the ''closed-loop'' features of the system are not active. This term is only used in discussion of HCL and automated insulin delivery systems, as the term is less clearly understood in the context of low glucose suspend and PLGS.

Overall, the algorithms used to calculate insulin delivery in advanced diabetes are proprietary and differ from each other in meaningful ways.

Adjust

Based on the foundational information of how systems *Calculate* automated insulin, clinicians must know what settings the device users can manipulate to optimize system performance. *Adjust* refers to which settings can be modified by the user and which are fixed in the system. For low glucose suspend and PLGS systems, hypoglycemia prevention may be individualized if low suspension thresholds are modifiable, as is the case for some devices (Table 2). Likewise, for HCL systems, only specific insulin pump settings may be adjusted in HCL mode and are entirely device-dependent (Table 3). For example, users can adjust active insulin time in the 670G HCL, however, not in the Control-IQ HCL. Alternatively, adjusting preprogrammed basal rates will influence how much insulin is delivered in the Control-IQ HCL, but will not influence insulin delivery in the 670G HCL. Additional device-specific details related to adjusting insulin settings are described in Table 3. While advanced diabetes devices are currently approved

Table 2. Comparison of Low Glucose Suspend and Predictive Low Glucose Suspend Systems Using the CARES Paradigm

	MiniMed® 630G	*MiniMed® 640G/670G (in open-loop)*	*t:slim X2™ with Basal-IQ™*
Calcule	Low glucose suspend system (referred to as "Suspend on Low") • Suspends insulin at *modifiable threshold* of 60–90 mg/dL • Resumes insulin delivery after 2 h or when user manually resumes insulin delivery	PLGS system (referred to as "Suspend Before Low") • 640G: Suspends insulin when glucose predicted to be 20 mg/dL above modifiable threshold of 60–90 mg/dL Resumes after 2 h or when user manually resumes delivery • 670G: Suspends insulin delivery when glucose predicted to be 20 mg/dL above modifiable threshold of 50–90 mg/dL Resumes after 30–120 min depending on predicted rise in glucose	PLGS system (referred to as "Basal-IQ") • Suspends insulin when glucose predicted to be <80 mg/dL in 30 min or if glucose value reaches 70 mg/dL • Resumes with first glucose value rising • Max suspend is 2 h out of every 2.5 h
Adjust	User can modify: • All pump settings • Suspend threshold 60–90 mg/dL (to determine when insulin will suspend) User cannot modify: • N/A	User can modify: • All pump settings • Suspend threshold (to determine when insulin will predictively suspend) User cannot modify: • N/A	Can modify: • All insulin pump settings Cannot modify: • Suspend threshold
Revert	• System will automatically revert to traditional pump therapy (e.g., no automatic insulin suspension) if loss of CGM data • Users can turn off feature at any time	• System will automatically revert to traditional pump therapy (e.g., no automatic insulin suspension) if loss of CGM data • Users can turn off feature at any time	• System will automatically revert to traditional pump therapy (e.g., no automatic insulin suspension) if loss of CGM data • Users can turn off feature at any time
Educate	• Consider treating hypoglycemia with less CHO (e.g., 5–10) if system has not delivered insulin (been suspended) for period of time before low glucose	• Consider treating hypoglycemia with less CHO (e.g., 5–10) if system has not delivered insulin (been suspended) for period of time before low glucose	• Consider treating hypoglycemia with less CHO (e.g., 5–10) if system has not delivered insulin (been suspended) for period of time before low glucose • System may suspend/resume insulin frequently, leave suspend alerts off for less interruptions
Sensor/Share	MiniMed Guardian® 3 • Requires 2–4 calibrations for optimal use • 6–7 day sensor life • Blood glucose checks needed for diabetes management decisions • Important to calibrate when glucose is stable (i.e., before meals, bedtime, or when no sensor trend arrows) to prevent calibration errors	MiniMed Guardian® 3 • Requires 2–4 calibrations for optimal use • 6–7 day sensor life • Blood glucose checks needed for diabetes management decisions • Important to calibrate when glucose is stable (i.e., before meals, bedtime, or when no sensor trend arrows) to prevent calibration errors	Dexcom G6® sensor • Factory calibrated sensor (manual calibrations optional, not required) • 10 day sensor life • Can use sensor value for diabetes management if sensor value and arrow are present • Can remotely follow glucose levels with Follow app

CGM, continuous glucose monitors; CHO, carbohydrates; PLGS, predictive low glucose suspend.

Table 3. Comparison of Two Hybrid Closed-Loop Systems Using the CARES Paradigm

	MiniMed® 670G	*t:slim X2™ with Control-IQ™*
Calculate	• HCL system (referred to as "Auto Mode™") • Uses total daily insulin *calculated* from last 2 to 6 days to determine algorithm parameters • Automated basal *calculated by system* every 5 min • HCL set point = 120 mg/dL • No automated correction doses. Manual correction doses based on HCL algorithm and not on programmed sensitivity factors	• HCL system (referred to as "Control-IQ") • Uses weight and total daily insulin *input by user to determine algorithm parameters* Automates basal by *modulating programmed basal rates* • Automated correction dose (max 1/h)-delivers 60% of calculated dose, user can also give manual correction doses • HCL target range = 112.5–160 mg/dL
Adjust (for HCL mode)	User can modify in HCL: • I:C ratios (for meal boluses), Active insulin time (for subsequent correction doses), Temp target of 150 mg/dL (to change HCL set point) User cannot modify in HCL: • Basal rates, insulin sensitivity factor, HCL set point of 120 mg/dL (except when using temp target)	User can modify in HCL: I:C ratios (for meal boluses), basal rates, insulin sensitivity factor (for correction doses) • HCL target range for Exercise mode (target range 140–160 mg/dL) and Sleep mode (target range 112.5–120 mg/dL) User cannot modify in HCL: • Active insulin time (5 h), Correction target of 110 mg/dL (for correction doses of insulin)
Revert	• Will automatically revert to open-loop (referred to as "Manual Mode") if persistent hyperglycemia, maximum or minimum delivery thresholds, loss of CGM data, sensor integrity concerns • User must manually turn off HCL to use temporary basal rates and/or combo boluses • Consider turning off for illness/ketones as system may suspend insulin. If insulin needs temporarily increase during illness, HCL may not be able to respond quickly enough. Use temp basals in open-loop during illness if persistent hyperglycemia. • Consider turning off HCL for dramatic change in insulin sensitivity (e.g., steroid use) due to system taking days to readjust	• Will automatically revert to open loop if loss of CGM data for prolonged periods • User must turn off HCL to use temporary basal rates • Consider turning off for illness, ketones as system may suspend insulin.
Educate	• Consider treating hypoglycemia with less CHO (e.g., 5–10) if system has not delivered insulin (been suspended) for period of time before low glucose • Important to prebolus for optimal mealtime management (similar to traditional insulin pump) • System may display "BG required" for HCL functioning: when user is required to enter a fingerstick BG value into the pump. This is different from a sensor calibration • Follow system prompts for "BG required" • For insulin dosing adjustments, change I:C ratios (10%–25%) and active insulin time • Cannot use temp basals and/or combo boluses in HCL mode ("temp target" feature will allow for temporary reduction in basal insulin delivery in HCL mode)	• Consider treating hypoglycemia with less CHO (e.g., 5–10) if system has not delivered insulin (been suspended) for period of time before low glucose • Important to prebolus for optimal mealtime management (similar to traditional insulin pump) • Can adjust insulin doses with many insulin pump parameters to improve system performance • Do not override boluses: extra insulin already on board from autocorrections and increased basal rates. Overriding may cause hypoglycemia • Individuals with short active insulin times may need to adjust doses to accommodate for 5 h active insulin time in HCL • Cannot use temp basals in HCL mode ("exercise mode" will allow for temporary reduction in basal insulin delivery in HCL mode) • Can program an extended bolus in HCL mode, but only for a maximum of 2 h
Sensor/ Share	MiniMed Guardian® 3 • Requires 2–4 calibrations for optimal use • 6–7 day sensor life • Perform blood glucose check for diabetes management decisions • Important to calibrate when glucose is stable (i.e., before meals, bedtime, or when no sensor trend arrows) to prevent calibration errors	Dexcom G6® sensor • Factory calibrated sensor (manual calibrations optional, not required) • 10 day sensor life • Can use sensor value for diabetes management if sensor value and arrow are present • Can remotely follow glucose levels with Follow app

HCL, hybrid closed-loop.

to be used with rapid acting insulin analogs, future devices may allow for ultrarapid acting formulations, providing a new dimension to consider when adjusting insulin settings. Overall, knowing how to adjust insulin settings is perhaps the most important tool for clinicians to use with individuals using advanced diabetes devices. Competent insulin adjustments can optimize system performance, potentially improving the user experience with advanced diabetes devices.

Revert

To date, all advanced diabetes devices allow the advanced features to be turned off, and the systems can operate as traditional insulin pumps. The systems require a functioning CGM to use the advanced features, so when CGM is not active, the systems default to traditional insulin pump settings. Low glucose suspend and PLGS systems can be manually turned on and off by the user. For current HCL systems, there are additional considerations where the system may automatically remove the individual from HCL (getting ''kicked out'' of HCL). In the case of the 670G, these include prolonged hyperglycemia or maximum/minimum insulin delivery thresholds. Alternatively, users may elect to exit HCL and use the device as a traditional pump for various reasons, such as using features such as temporary basal rates (which are not available in HCL). These system-constrained and user-initiated exits to open-loop differ by device (Table 3).

Educate

As with any technology, education is a key factor in success. Each advanced diabetes device comes with its own ''clinical pearls'' or educational tips that can dramatically change the user experience and confidence in the device. These are often derived from clinical trial experiences and expert recommendations. Clinicians can empower their patients with system-specific education tips, focusing on device use and diabetes self-care behaviors. Another important aspect of education is awareness of where to find additional support and resources. Finally, an awareness of strengths and weakness of different devices can help clinicians advice their patients on which devices may suit their lifestyles and behavior patterns.

Sensor/Share

Continuous glucose monitoring technology is currently transitioning to longer duration sensor wear, factory calibration, or minimal daily calibration requirements, and replacement of blood glucose checking for insulin dose decisions.[37–40] Low glucose suspend, PLGS, and HCL systems are all subject to the constraints of the CGM, and thus sensor attributes remain an important part of advanced diabetes device experience and education.[41,42] These sensor specific attributes are important for understating the user experience with an advanced diabetes device.

Furthermore, many systems now offer the ability to share data remotely with cloud connectivity and smartphone-based apps to monitor CGM glucose levels. These advanced capabilities will allow remote monitoring for some systems, when the CGM user can invite parents, spouses, or caregivers to monitor glucose levels or receive alerts from a cell phone or computer. This can enhance the safety of an advanced diabetes device by providing a second layer of supervision.

Additionally, devices that perpetually upload data to a secure cloud-based server have unique advantages. This continual connectivity can allow for real-time assessment of retrospective glucose patterns. Devices that have continuous connectivity do not need to be manually uploaded by a user or clinic, minimizing the burden associated with sharing device data between the user and the clinician. It is likely that future devices will all offer the features of perpetual connectivity.

The CARES Paradigm for Current Low Glucose Suspend, PLGS, and HCL Devices

We have selected a handful of advanced diabetes devices to highlight the clinically important aspects of each device using the CARES paradigm. Table 2 highlights three systems that aim to mitigate hypoglycemia: the 630G device (low glucose suspend), the 640G device (PLGS), and Basal-IQ device (PLGS). Table 3 highlights two HCL systems: the 670G and Control-IQ HCL devices. With the exception of Control-IQ, all of these devices are commercially available. The authors have extensive experience with these devices from both clinical care and clinical research. Control IQ is currently undergoing pivotal clinical research trials at our Center and others.[21]

The language used in the tables is intended to standardize terminology for advanced diabetes device features: low glucose suspend, PLGS, HCL, and traditional insulin pump. Even while standardizing the language of advanced automation, it becomes clear that each system is akin to a new species of insulin delivery, different from past devices and different from each other. The ''Calculate'' component of the CARES framework highlights the wide variability in functionality, customization, and programmability of advanced diabetes devices. From this starting point, the differences in ''Adjust,'' ''Revert,'' and ''Educate'' become apparent. Using the CARES paradigm and standardized language for advanced features, a diabetes provider can more readily engage in meaningful care of individuals using devices, such as understanding that the 670G users may need to increase their insulin to carbohydrate ratio to optimize settings,[14,15,35] and that the Control-IQ users can adjust basal rates during HCL use.

The comprehensive utility of the CARES paradigm is only as useful as the information contained within. Tables 2 and 3 are current as of summer 2019 but will quickly need updating as new devices and data accumulate. It will further take on new dimensions if fully closed-loop systems and bihormonal systems are commercialized. This content is therefore available on our diabetes technology website, http://BDCPantherDiabetes.org, and will be updated on a continuing basis by the authors and diabetes technology specialists at the Barbara Davis Center. This website is available to freely access and share with all diabetes technology stakeholders.

Conclusion

A practical working knowledge of advanced diabetes devices is now necessary for clinicians who work with insulin-requiring individuals with diabetes. Advanced systems and automated insulin delivery are in their infancy, and the technological landscape will continue to evolve with more robust systems and increased ease of use. The CARES paradigm must be continually updated and expanded to include new devices and concepts. Having it freely available

at http://BDCPantherDiabetes.org will aid in this effort to provide standardization and current information.

Where do we go from here? It would be helpful for the CARES model to be adopted by industry partners as a standard paradigm with which to contextualize advanced diabetes devices for clinician training. Industry often works in a vacuum, unaware of how to best equip clinicians who must possess working knowledge across a broad landscape of diabetes devices. Furthermore, brand-specific nomenclature obscures direct comparison and understanding of technological features within commercial context, and use should be minimized by all parties. If industry partners were to adopt a standardized clinical paradigm with which to present their devices, clinicians could make more informed decisions about how to work with and recommend advanced diabetes devices. Generic terms such as ''hybrid closed-loop, ''open-loop,'' and ''predictive low glucose suspend'' should be widely used, with paradigms such as the CARES model used to elucidate how proprietary systems differ.

The CARES paradigm is only the first step in fostering mutually beneficial discussions between clinicians and individuals with diabetes. Although designed as a clinician tool, similar paradigms may benefit patients and families when choosing a diabetes technology. This will likely require a more expansive approach to advance diabetes devices, with focus on user experience, workload, goals, and expectations.[33] The CARES paradigm does not provide comprehensive comparison of device strengths and weaknesses from a user-perspective. Predictors of diabetes technology uptake and sustainment are currently being studied to determine best practices for recommending devices for a variety of users. An expanded CARES paradigm with additional user-centric elements would be beneficial in this quest, and usher in a data-driven approach to device selection and expectations.

Finally, the CARES paradigm highlights a discipline-wide need to provide comprehensive education to health care providers and diabetes educators on advanced diabetes devices. To do this, industry partners and philanthropic foundations should sponsor international education courses or certifications in advanced diabetes technology. The CARES paradigm and other resources should be systematically studied to determine best practices in implementation, be it an exclusively online resource, part of formal device education, or part of a certification process. It is not possible for diabetes clinicians to be experts in every device on the market, however, a universal understating of advanced diabetes technology basics should be required.

In summary, the CARES paradigm promotes standardization and clarity to the confusing landscape of advanced diabetes devices. While primarily a tool is designed for clinicians, this paradigm should be expanded to meet the needs of individuals with diabetes, industry partners, and diabetes technology stakeholders.

Acknowledgments

The authors most importantly thank the Barbara Davis Center pediatric faculty and staff who help contribute to diabetes technology resources (PANTHER group: Practical AdvaNced THERapies in Diabetes): Robert Slover, MD, R. Paul Wadwa, MD, Brigitte Frohnert, MD, PhD, G. Todd Alonso, MD, Samantha Lange, RN, CDE, Emily Jost, RD, CDE, Lindsey Towers, BS, and the pediatric clinical research team. We also thank David Maahs, MD, PhD, Bruce Buckingham, MD, and Korey Hood, PhD at Stanford University, as well as Stuart Weinzimer, MD and Jennifer Sherr, MD, PhD at Yale University, who all contributed to the original CARE framework. We also thank the international diabetes community for providing feedback on important diabetes device characteristics. Finally, thanks to all the patients and families at the Barbara Davis Center, who ask tough questions and provide ongoing insight into diabetes technology. Part of this work was funded by time from an NIH K12 award (NIDDK 2K12DK094712-06).

Author Disclosure Statement

L.H.M. has served as a consultant for Tandem Diabetes Care, Clinical Sensors, and Capillary Biomedical, and is a contracted trainer for Medtronic. C.B. is a contracted trainer for Medtronic and has received speaking honoraria from Insulet. G.P.F. has received research funding from Medtronic, Dexcom, Abbott, Tandem, Insulet, Bigfoot, Beta Bionics, and TypeZero; he has served as a consultant/speaker for Medtronic, Dexcom, Abbott, and Tandem.

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