The Reference Guide to Integrate Smart Insulin Pens Into Data-Driven Diabetes Care and Education Services

Purpose

More than 7 million Americans who have diabetes use insulin therapy. The majority continue to use syringes and vials or traditional insulin pens to deliver their insulin doses. Using these tools to deliver insulin presents numerous challenges for both the person with diabetes and their clinicians. This article provides an in-depth introduction to a new category of insulin delivery devices and integrated management systems, referred to as smart insulin pens. The article includes information about how these integrated insulin delivery systems can reduce many of the challenges of rapid-acting insulin dosing via injection by enabling easier and more accurate dose recording, dose calculations, and sharing of diabetes management data with clinicians. This article also discusses new roles for diabetes care and education specialists in diabetes data-driven care and practice and addresses how smart insulin pens represent one of many newer digital diabetes management tools that can assist people with diabetes and their clinicians to optimally achieve and deliver quality, data-driven diabetes care.

Conclusions

Newer and simplified insulin delivery devices with their integrated management systems, such as smart insulin pens, have the potential to minimize the challenges and complexities associated with insulin injection therapy

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while also providing people with diabetes and their clinicians more complete and integrated data in easily transmitted reports that support more efficient data analysis.

The year 2021 will mark 100 years since the discovery of insulin. Until the early 1970s, when the first insulin pump became available, all people with diabetes who required insulin therapy used vials and syringes. The first insulin pen became available in 1985. Improvements have steadily been made to many of these delivery devices. Over the past several years, the US Food and Drug Administration (FDA) has approved several new insulin delivery devices. These devices all aim to reduce 1 or more of the daily challenges and complexities of taking insulin while also helping people with diabetes achieve several other goals, including improved glycemic management, ease of diabetes-related data analysis, and enhanced quality of life.

In 2019, the Association for Diabetes Care & Education Specialists (ADCES) launched Project Vision, a framework to promote expanded roles for diabetes care and education specialists as health care systems and the diabetes care ecosystem transform. Project Vision encourages diabetes care and education specialists to embrace changes occurring in health care delivery and gain new skills and competencies to practice at the highest level of their licenses and scopes of practice. This includes skills and competencies associated with myriad diabetes-care-related technologies, including insulin delivery devices, glucose monitoring equipment, and digital health tools. With these skills, diabetes care and education specialists can position themselves to be the experts, or technology champions, that build data-driven diabetes care and education services in practice settings. In this article, data-driven diabetes care and education services will be referred to as either data-driven care or data-driven practice. Three pillars of Project Vision reflect this intent: Leverage Technology, Drive Integration, and Promote Person-Centered Care. Over the next decade, diabetes care and education specialists will increasingly practice in digitally connected environments and utilize data-driven care to achieve optimal diabetes care outcomes within a cost-efficient framework.

The purpose of this article is to review the current challenges and unmet needs of people with diabetes who inject insulin as well as the clinicians who, in partnership with people with diabetes, strive to optimize their insulin therapy regimens and care. In particular, this article aims to:

- describe the evolution of insulin delivery devices, including the components needed to make the technology more useful to the person with diabetes (PWD) and their clinicians;
- introduce what makes an insulin pen a “smart” pen;
- discuss strengths, limitations, and challenges of currently available insulin delivery devices;
- introduce how to use data available through the smart insulin pen to improve diabetes care;
- describe how to build a data-driven diabetes care and education practice and services.

### Insulin Use and Delivery Methods in United States Today

Approximately 7.4 million Americans diagnosed with diabetes use insulin therapy. Approximately 1.6 million Americans, or 5% to 10%, of people with diabetes have type 1 diabetes (T1DM). Approximately 200 000 people with T1DM are younger than 20 years of age, and more than 1 million are older than 20 years. All people with T1DM require insulin therapy, and the majority use multiple daily injections of insulin known as MDI. Interpolating, it can be estimated that 5.8 million Americans with type 2 diabetes (T2DM) use insulin therapy.

Most people with diabetes treated with insulin therapy inject insulin via syringes filled from insulin vials or traditional insulin pens. Continuous subcutaneous insulin infusion (CSII) systems have been available for more than 40 years. Newer models integrate insulin dosing via insulin pump with data from continuous glucose monitors (CGM). CSII can enable the person who wears the system to overcome many of the challenges of implementing an insulin regimen with traditional insulin delivery devices as detailed in Table 1. Yet, only 30% of people with T1DM and less than 1% of people with T2DM use CSII. According to research from the T1D Exchange, CSII use is even lower in non-Hispanic whites with T1DM. Common reasons for not wanting to use CSII include lack of desire to continuously wear a device, need to master technology, maintaining an inventory of supplies, and potential cost burden.

In addition, research shows only modest advantages of CSII in glycemic management among varied populations. A 3-year, nonrandomized, prospective, real-world clinical trial (COMISAIR study) in adults with T1DM (N = 94) assessed 4 management plans: (1) real-time CGM with MDI, (2) real-time CGM with CSII,
(3) self-monitoring of blood glucose (SMBG) with MDI, and (4) SMBG with CSII. At 3 years, the people with diabetes who used real-time CGM with MDI or real-time CGM with CSII had significantly lower A1C and significant improvement of percentage of time spent in (glucose) range (TIR) than the 2 groups using SMBG, with no significant difference between the 2 groups using CGM. Researchers concluded that real-time CGM with MDI can be considered a clinically equivalent and lower cost alternative to management using real-time CGM with CSII.

**Challenges of Implementing an Insulin Regimen Using Traditional Dosing and Delivery Devices**

Implementing an insulin therapy regimen using traditional delivery devices, particularly MDI, is complex and challenging for both the PWD and their clinicians, as listed in Table 1. With traditional insulin delivery devices, people with diabetes must make important daily decisions to administer precise insulin doses without easy access to reliable information about the previous doses given and insulin-on-board (IOB). These devices are not linked with the ability to set reminders for insulin doses, nor do they record when the doses were taken. In turn, clinicians must assess the effectiveness of insulin therapy without sufficient or easily accessed clinical data. For example, clinicians must depend on self-reports, log books, and other recording tools that may or may not be maintained and/or shared by the PWD. For clinicians to extract, review, and synthesize these data and then use the data to counsel the PWD, make clinical decisions, and titrate insulin therapy is time-consuming and fraught with inaccuracies. These challenges collectively present significant barriers to optimizing glycemic management.

**Missed or delayed insulin doses**

In addition to intentionally skipped or delayed insulin doses based on sound judgment, sometimes people may intentionally omit insulin doses due to inconvenience or embarrassment associated with injecting in public. There are also times that people with diabetes accidentally forget or miss an injection or cannot remember if they took an insulin dose or not. With no way to verify if an injection was taken, people using a traditional insulin delivery device may choose to skip the dose or potentially administer a second dose (“double dose”).

Several studies reveal the impact of missed or delayed insulin doses on glycemic management. One study, presented as a poster at the 2018 American Diabetes Association Scientific Sessions, identified the rate of missed or late mealtime injections by evaluating...
326 days of CGM data from 24 subjects with diabetes (mean age = 33 years; range = 15-59). The subjects used the Type Zero InControl Phone connected to a Dexcom G5 sensor and Novo insulin pen with memory. Seven days of data were analyzed initially and 1 month later. More than one-quarter (27%; range = 8-55%) of subjects either took a late meal-time injection (13%, range = 2-30%) or missed a meal-time injection (14%, range = 2-38%). Missed meal-time injections correlated with higher A1C levels.

Another study using a Bluetooth-enabled insulin pen cap (Gocap) evaluated the timing and dosing accuracy of insulin in younger (18-35 years) and older (≥65 years) groups of 75 participants who injected both basal and meal time insulin 2 or more times per day. The Bluetooth-enabled pen cap registered the position of the pen plunger along with confirmation of dose and time. Twenty-four percent of meal-time and correction doses and 36% of basal doses were either not timed or dosed accurately. When dividing the study population into tertiles, those who timed or gave their doses correctly 85% of the time achieved better glycemic management defined by A1C (7.7 ± 1.1% vs 8.6 ± 1.5%, P < .03). Over the 1-month study period, 100% of participants omitted at least 1 insulin dose. The limitations of the study include the small sample size and lack of information regarding the reasons for missed doses.

A third simulation study used mathematical modeling to examine the impact on A1C of 5 sets of blood glucose profiles with and without forgotten injections in people with T1DM who use insulin therapy. The simulation determined that forgetting 2.1 meal-related injections per week would lead to a 0.3% to 0.4% increase in A1C and a 0.2% to 0.3% change related to forgotten basal injections per week. If 39% of all insulin injections were forgotten, the mathematical model demonstrated the potential for A1C to increase 1.8%.

**Numeracy skills for insulin dosing calculations**

Numeracy skills are basic math skills needed to understand and use numerical information in everyday life. Basic skills are needed to adjust insulin doses for changes in food intake and physical activity and to apply a correction scale. More advanced skills are necessary to calculate meal-time and correction insulin doses by applying insulin-to-carbohydrate ratios (ICR), IOB, and insulin sensitivity factors (ISF) plus carbohydrate counts. Several studies highlight the challenges that inadequate numeracy skills present.

In a study of 112 adults with a mean duration of 22 ± 13.2 years of T1DM from a randomly selected diabetes center population, researchers found literacy was not associated with A1C; however, numeracy skills were. Interestingly, numeracy skills were independent of socioeconomic status. Another study looking at numeracy skills in diabetes self-care found approximately 25% of people in the study population (N = 128) could not define target glucose values, 56% could not accurately assess the carbohydrate grams in a packaged snack food, and 59% could not accurately calculate an insulin dose with glucose and carbohydrate information.

A third study examined the association between diabetes-related numeracy skills, glycemic management, and other diabetes measures in a cross-sectional survey in 3 types of care settings using the Diabetes Numeracy Test (DNT) in adults with T1DM or T2DM (N = 398). The median DNT score was 65%. Common errors included misinterpreting glucose meter readings and miscalculating carbohydrate intake and medication dosages. A modest association between DNT score and A1C level was observed.

**Evidence of Improvement in Dose Calculations With Technology-Based Tools**

To date, several studies have demonstrated that the use of technology-based tools can improve dosing accuracy and timing, resulting in glycemic improved management. A 1-year open label randomized control trial in adults with T1DM (N = 123) compared use of insulin-dosing Accu-Chek Advisor software to usual care. Subjects in the experimental group showed A1C improvement at 3 and 12 months (P < .02). In this group, the A1C reduction of ≥0.6% was maintained at 12 months along with a 19% increase in TIR (70-150 mg/dL). A survey conducted among 1412 people with T1DM in the United Kingdom and Republic of Ireland using MDI with bolus doses calculated by the Accu-Chek Aviva Expert blood glucose meter and bolus advisor system assessed their attitudes and behaviors on the use of the device. Over three-quarters of respondents (n = 588) indicated that they used the bolus advisor often, that it reduced fear of hypoglycemia (39%), and that it made bolus calculations easier (78.8%). The BolusCal Study, conducted in Denmark, was a 16-week...
randomized controlled, open-label, 3-arm parallel design in adults with T1DM (N = 51) whose initial A1C results were between 8.0% and 10.5%. The aim was to investigate the impact of flexible intensive insulin therapy and an automated bolus calculator in people treated with MDI. Subjects in both the carbohydrate counting arm and the arm using carbohydrate counting plus the automated bolus calculator demonstrated similar A1C change (0.6%), but treatment satisfaction was significantly improved in the arm using the automated bolus calculator.36 A prospective randomized controlled, multinational trial studied 193 people with diabetes using MDI insulin therapy using the Accu-Chek Aviva Expert meter with an integrated bolus advisor to calculate doses in the experimental arm versus blood glucose meter with manual bolus calculation as the control. Subjects had mean baseline A1C of 8.9%. Significantly more subjects achieved an A1C reduction of >0.5% (56.0% experimental vs 34.4% control; P < .01) when using the Accu-Chek Aviva Expert meter with an integrated bolus advisor to calculate doses. In addition, treatment satisfaction was improved.37 In an effort to help both clinicians and people with diabetes understand the impact of timing of insulin doses on glycemia, a 2-week prospective observational study using a Bluetooth-enabled pen cap (Gocap) coupled with CGM data in adults with T1DM using MDI (n = 50) objectively assessed the relationship between the timing of insulin dosing and the impact on pre- and postprandial glucose levels.38 To date, no studies have been published to demonstrate clinical efficacy with the use of smart insulin pens. However, the 2020 ADA Standards of Medical Care in Diabetes for the first time recommends that people with diabetes who are interested in using an insulin dose calculator use those approved by the US FDA.20

**Evolution of Insulin Delivery Devices**

The literature review reveals that numerous challenges to people with diabetes and their clinicians with traditional insulin delivery devices exist, such as missed doses, trouble with insulin dose calculations, the inability to track IOB, the inability to sufficiently record dosing data, and the cumbersome transferal of diabetes data to the clinician. At least 3 factors have led to the development and FDA clearance or approval39 of a new cadre of delivery devices: (1) research demonstrating efficacy in assisting people with diabetes with insulin dose calculations, (2) understanding myriad challenges of taking insulin as detailed in Table 1, and (3) current technological capabilities that enable obtaining and utilizing integrated diabetes data.40 Figure 1 presents a conceptual roadmap for the categorization and evolution in sophistication of insulin dose delivery devices and integrated systems.19 More detailed descriptions of this roadmap follows.

- **Traditional insulin delivery devices (stage 0):** Traditional insulin pens are available for use with most of the commonly used insulins and insulin combinations. Insulin pens offer the ability to dose insulin more accurately, with less injection pain, more easily and conveniently, with greater user satisfaction than with vial and syringe.2,10,40 The FDA has, over the past decade, approved 2 simple insulin delivery patches3,5 and a device with cartridges to deliver inhaled ultra-rapid-acting insulin.4 Although all of these traditional insulin delivery devices aim to reduce the daily challenges of taking insulin, they do not have the capabilities to track doses, analyze insulin dosing data, or share integrated data with clinicians, as do smart insulin pens at stages 4-5.

- **Tracking insulin pens (stages 1-3):** Devices in these stages have increasingly sophisticated tracking capabilities that use built-in wireless communication and sensors to address some of the challenges detailed in Table 1. The Companion Medical InPen System shown in Figure 2, which became available to people with diabetes in 2017,45 represents an example of a stage 1 device that provides retrospective, accurate dose data.41 Several other insulin pens and related products, including caps or attachments for insulin pens, are in various stages of development and commercialization. One attachment is the Clipsulin from Diabnext,42 which interfaces with an app and appears to be available for use with various types of insulin pens. The second attachment is Common Sensing’s Gocap,43 which also interfaces with an app. While Gocap was used in research detailed earlier,29,38 it is not currently commercially available. Based on FDA regulations, insulin attachments and delivery devices go through 1 of several regulatory review pathways that include 510(k) exempt, clearance, or approval.39,44

- **Smart insulin pens (stage 4-5):** Smart insulin pens are represented in both stages 4 and 5. A significant benefit of smart insulin pens in stages 4 and 5 is that the intelligence and interface of the technology is located in the user’s smartphone. The first, and to date only, FDA-cleared smart insulin pen is the Companion Medical InPen System shown in Figure 2, which became available to people with diabetes in the United States in 2017.45 Smart insulin pens address many of the challenges and complexities of taking insulin listed in Table 1.19,20,26 At present, there are no smart insulin pens in stage 5. Stage 5 insulin pens offer the promise of advanced decision support, including weight-based insulin therapy settings, data-driven education, and dynamic dose titration. Global growth of smart insulin pens is expected.40
The InPen is a prescription item covered as a pharmacy benefit. It is a durable pen, with 1-year battery life, that is FDA-cleared for use by people with T1DM or T2DM of all ages for bolus dosing with Humalog, NovoLog, and Fiasp U-100 3 mL prefilled cartridges. To assist in achieving precise dosing, the InPen can dose in half-unit increments up to 30 units. It also automatically differentiates between priming and therapeutic doses, allowing for accurate tracking of active insulin-on-board. The InPen can determine insulin quality by monitoring the temperature and age of the insulin cartridge and remind the user about missed bolus doses and to take basal insulin doses. The InPen records the amount and timing of each insulin dose and wirelessly transmits the real-time data via Bluetooth connectivity to a proprietary mobile smartphone application (app) that can interface with continuous glucose monitors or Bluetooth-enabled blood glucose meters (BGM). The FDA-cleared app can be customized 3 ways when accounting for food and beverage estimates and consumption: (1) for use with carbohydrate counting, (2) adjustment of mealtime doses based on an individualized relative sizes of meals (usual size or smaller or larger than usual), or (3) taking a set or fixed insulin dose for each meal. Individualized settings can be entered for insulin-to-carbohydrate ratios, insulin sensitivity factors, target glucose levels, and duration of insulin action (DIA) that integrates with insulin-on-board. The app prepares and can send integrated data reports to the user’s diabetes team.

Using Data to Optimize the Insulin Regimen and Self-Management Plan Using Smart Insulin Pens

There are many sources of diabetes-related data from connected devices. Combining diabetes-related data from multiple devices (eg, glucose monitors, smart insulin pens, food databases, and activity trackers) into a single report enables ease for the PWD and their clinicians to analyze and use data. The Insights by InPen data management report integrates data from the Dexcom G5 and Dexcom G6 CGM. It also integrates data from
Bluetooth-enabled blood glucose meters and other health data through Apple Health. The insulin dose data tracked by the InPen can also be viewed in the Dexcom CLARITY report. Additionally, Tidepool and Glooko are data management platforms that assist in visualizing integrated diabetes-related data. Figure 3 provides a guide to using the Insights by InPen integrated data management report with details about key clinical considerations.

The presentation of data can be overwhelming for the PWD. It is important for clinicians to use a nonjudgmental approach as the PWD’s attitude toward technology is a major predictor of successful implementation. Data should be not be labeled as “good” or “bad” but as information to learn from in an effort to achieve personal goals. Having integrated data reports allows for less interrogative, more collaborative conversations. Working collaboratively fosters shared decision-making and a sense of partnership between people with diabetes and their clinicians.

**DATAA: A 5-Step Process for Reviewing Integrated Data**

A 5-step process for reviewing integrated diabetes-related data, given the acronym DATAA, has been developed by a group of experts who attended the 2019 ADCES diabetes technology summit. The DATAA process has been integrated into 1 of the two ADCES Perspectives in Practice publications focused on diabetes technology.

When interpreting integrated data reports with CGM data, it is optimal to have 14 days of data and at least 70% data sufficiency, meaning that 70% of data for that reporting period is available. If the PWD is using a Bluetooth-enabled blood glucose meter, a structured monitoring schedule that supports the individual’s insulin regimen is recommended.

The 5-step DATAA process involves:

- **D:** Data. Review relevant diabetes data. Verify that the PWD understands the various data measures, such as TIR, glycemic variability (GV), ratio of basal versus bolus insulin use, and so forth. During data review, it is important to engage the PWD in sharing observations. Identifying patterns of hypoglycemia, hyperglycemia, or GV can focus the data review.
- **A:** Assess Safety. Address hypoglycemia first. Discuss potential causes of hypoglycemia, such as skipped meals, stacking of bolus doses, and/or an unusually active day.
- **T:** Time in Range. Reviewing TIR provides an opportunity to focus on what aspects of self-management may have contributed to positive results. Identifying days when TIR is at the highest percentage allows for discussion of behaviors that supported in-range glucose levels such as fewer missed boluses, taking bolus insulin doses 15 minutes prior to eating, checking glucose levels prior to dosing, using the dose calculator to determine the dose, efforts toward more accurate carbohydrate counts, or activity.

**A:** Areas to Improve. The next step involves identifying times when glucose levels are above target or vary widely and discussing possible causes, such as overtreating hypoglycemia, taking less insulin than the dose calculator recommended due to fear of hypoglycemia, not trusting insulin therapy settings, stress, or illness. Common reasons for periods of wide GV include differences between weekday and weekend routines, vacation, high-stress events, or missed, late, or intentionally omitted doses. Explore reasons why the PWD is not dosing insulin as prescribed and, if necessary, discuss ways to resolve. Reviewing reasons for GV provides an opportunity to check the PWD’s injection technique, assess injection sites for lipohypertrophy, discuss injection site rotation, and review insulin storage practices.

**A:** Action Plan. An action plan serves as a tool to summarize the data review and can be shared with the data report. Developed collaboratively, examples of actionable steps include (1) track food/activity for at least 3 days prior to the next visit or virtual visit, (2) identify strategies to replicate the behaviors that supported increased TIR, (3) check glucose level before at least 70% of insulin doses and use the dose calculator to determine the amount of insulin to take at meals and correction doses, and (4) check glucose level 2 hours after a mealtime dose when unsure of carbohydrate intake to determine if a correction dose is needed.

Note that all 5 steps of the DATAA process do not need to be completed at every visit. If at any point the PWD seems uncomfortable about looking at the data further, the discussion can be discontinued until a future interaction. The case study in Table 2 demonstrates the use of the DATAA 5-step process to review integrated diabetes data.

**Building Data-Driven Diabetes Care and Education Services**

Diabetes care and education specialists have a significant opportunity to build and deliver data-driven services in varied practice settings. This opportunity is supported by a growing collection of connected diabetes devices, including blood glucose monitors, CGM, smart insulin pens, CSII, and others. In addition, many related connected devices, such as fitness trackers, blood pressure and heart rate monitors, and digital scales, can be
Figure 3. Guide to using the insights by InPen integrated data report.
Glucose Data
Observe average glucose, standard deviation; percent time in range, time below range, and time above range. The goal for most PWDs is >70% of time with readings within target range (70-180 mg/dL), <4% below 70 mg/dL, <1% below 54 mg/dL, <25% above 180 mg/dL, less than 5% above 250 mg/dL.

Modal Day Glucose Graph
Check to detect any patterns of hypo/hyperglycemia or variability at certain times of day. The first priority is to resolve any patterns of hypoglycemia.

Missed Doses
Detect if any particular meal time insulin dose or basal insulin dose is regularly missed. Ask the PWD if these doses are forgotten, intentionally omitted, or not taken because meals are skipped.
- As a first priority resolve any barriers the PWD has to taking insulin doses.
- Adjust meal time settings and reminders in the InPen app as needed.

Insulin Data
Observe Total Daily Dose (TDD) and distribution between basal and bolus doses. The optimal basal/bolus ratio is a 50/50 split though this may differ based on carbohydrate intake, other medications, fitness level, and degree of insulin resistance.
- Check to see that the PWD has their basal insulin reminder set in the InPen app and that they consistently record their basal doses.
- Observe average number of boluses per day. Consider how this corresponds with the PWD's reported usual routine.

Long-acting Assessment
Assess the need to optimize the basal insulin dose. The goal is to maintain glycemic stability in the fasting state with no more than 30 mg/dL change.

Dosing Behavior
Determine if PWD is using the dose calculator at meals and for corrections. If so, are they following the dosing recommendations? If not, explore the root cause(s) of why not e.g. lack of confidence in their therapy settings or fear of hypo/hyperglycemia.

Meal Assessment
Based on glycemic response to meal doses, assess adequacy of meal doses or insulin settings (Insulin to Carbohydrate Ratio [ICR] or meal-size doses recommended).

Daily Charts
Review the daily charts and consider the following:
- Is glucose checked before each dose?
- Is the meal size or grams of carbohydrate consumed recorded with meal doses? Does the PWD need more carbohydrate counting education? Would they benefit from access to a food database or help estimating meal sizes?
- How many meals does the PWD eat per day? Any missed meals? Explore why.
- Does timing of insulin dose relative to the meal need adjusting?
- Evaluate glycemic response when the dose calculator was used versus dosing more or less than recommended. If dosing recommendations are not followed explore why.
- How often are correction doses taken? Detect missed correction opportunities.
- Is the PWD stacking bolus doses?

Therapy Settings
Based on observations and discussions with the PWD, determine if therapy settings or meal times need adjusting for any time of day or particular meal.

On an ongoing basis, remember to consider the following basics of insulin therapy:
- If the PWD is missing doses, identify and address barriers to taking insulin first prior to making adjustments in the insulin regimen.
- Assess quality of insulin (storage, shipping), proper site rotation (examine for lipoatrophy), injection technique, timing of dose(s).
- Always address hypoglycemia first.
- Titrate (optimize) the basal dose first to create a strong foundation for fine-tuning other insulin therapy settings to optimize the meal time insulin regimen.
- Fine-tune the ICR. Having the ICR correct as well as accurate carbohydrate counting (or meal estimation) helps decrease the need for correction doses.
- Fine-tune the Insulin Sensitivity Factor (ISF) along with Duration of Insulin Action (DIA).

Figure 3. Guide to using the insights by InPen integrated data report.
integrated into diabetes care. The opportunity to deliver data-driven services has grown exponentially due to the ability to receive and analyze data remotely and deliver care virtually. The 3 hallmarks of data-driven care and practice are described next and are relevant to all diabetes-related technologies.

1. **Identify the right technology tools for each PWD as a standard of care.**\(^{20}\) A website, DiabetesWise,\(^{54}\) has been developed at Stanford University to help people with diabetes explore and identify the right technology tools for them based on several simple questions. Diabetes care and education specialists can use this resource for several purposes, including as a shared decision-making tool when assessing and/or selecting devices. This includes the use of a smart insulin pen when the PWD chooses insulin injections as the preferred mode of insulin delivery. Table 3 offers insights from a certified diabetes care and education specialist and nurse practitioner that focus on how to help people with diabetes become aware of the various devices and choices and to identify the right technology tools for them.

### Table 2

#### Case Using DAATA

**History:** Lisa is a 57-year-old female with T1DM for 29 years, treated with MDI therapy. She takes 2 to 6 units of insulin aspart at meals and snacks and 12 units insulin degludec in the morning. She is using a Dexcom G6 CGM device consistently. Her current weight is 143 pounds. Lisa tries to take a 1- to 2-mile walk most days but notes that recently she has not been walking. Her occupation is sedentary as a part-time medical receptionist. Lisa recently started using the smart insulin pen InPen. She has an appointment with a diabetes care and education specialist to optimize her insulin regimen and diabetes self-management plan. Her current A1C is 7.1%, but Lisa complains of symptoms of hypoglycemia, particularly in the early morning hours, that she verifies with blood glucose data from a meter if her CGM data do not match her symptoms.

#### Collaborative review of data using DATAA:

**D: Data:** Lisa has submitted her most recent 14-day InPen report (seen in Figure 3). Lisa’s TIR for this time period is 62%, close to the goal of 70%. Her average glucose of 171 mg/dL is consistent with her current A1C. The standard deviation\(^{a}\) (SD) of 53 indicates acceptable GV.

**A: Assess Safety:** Her blood glucose meter readings verify a tendency toward hypoglycemia in the early morning hours, which is also evident in the modal glucose graph and the daily reports (seen in Figure 3). Lisa has an even distribution between her basal and bolus insulin doses with a total daily dose of 23.5 units. She averages 3.3 bolus doses per day. Her long-acting insulin assessment shows a delta of –42 mg/dL, exceeding the recommended 30 mg/dL, indicating a possible need to decrease her basal dose.

**T: Time in Range:** Lisa consistently uses the dose calculator and follows the recommendations for bolus doses. She seldom misses bolus doses.

**A: Areas to Improve:** Lisa reports estimating versus actually calculating the grams of carbohydrate she consumes based on years of experience. Since Lisa is just getting started with InPen, the diabetes care and education specialist will explore Lisa’s understanding of basal versus bolus insulin, the concept of correction insulin doses, the need to avoid stacking insulin doses, as well as her understanding of the various insulin therapy settings. Note Lisa’s initial insulin Therapy Settings (9) and meal times in her report seen in Figure 3.

**A: Action Plan:** The diabetes care and education specialist works within her employer’s institution-approved protocol for insulin dose adjustment and recommends reducing the basal insulin dose by 1 unit to 10 units per day.\(^{53}\) Lisa is encouraged not to eat or bolus overnight unless her glucose is <80 mg/dL or >250 mg/dL so her basal dose can be tested for adequacy. The goal is to adjust the dose to maintain glucose stability (less than 30 mg/dL change) in fasting state (between meals and during sleep).\(^{52}\) Once Lisa’s basal dose is optimized, the next step will be to fine-tune her insulin therapy settings (ICR, ISF, and DIA.) (For guidelines on calculating and fine-tuning insulin therapy settings for smart insulin delivery refer to Table 4.) Lisa agrees to send an InPen report every 2 weeks to the diabetes care and education specialist. Lisa sets a goal to return to her daily walks. She also sets a goal to log her physical activity and will include this with her InPen report. She will also note any other influencing factors, such as stress, sickness, celebrations, etc, on her report.

**Follow-up:** At their next session, Lisa and her diabetes care and education specialist plan to work on improving her carbohydrate counting skills and developing a schedule for keeping food records so they can then refine the insulin therapy settings starting with the insulin to carbohydrate ratio. The diabetes care and education specialist communicates the assessment and action plan via the electronic health record to the referring provider.

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**Abbreviations:** CGM, continuous glucose monitoring; DIA, duration of insulin action; GV, glycemic variability; insulin to carbohydrate ratio; ISF, insulin sensitivity factor; MDI, multiple daily injections of insulin; T1DM, type 1 diabetes.

\(^{a}\)The coefficient of variation (CV) and standard deviation (SD) are both measures of glycemic variability. The goal is to have a CV <36% .\(^{50}\) To calculate CV: SD / mean glucose × 100.
2. **Configure the technology tool to match the routine, lifestyle, and therapy plan of the PWD.** As with any technology, it is important to anticipate a learning curve. The diabetes care and education specialist can provide assistance in configuring the diabetes device to match the PWD’s needs, including, in the case of smart insulin pens, providing individualized insulin therapy settings. Guidelines for calculating and refining insulin therapy settings for smart insulin pens are provided in Table 4. To avoid adding to the burden of self-management, setting clear expectations about how the new technology will support self-management is essential. ADCES’s DANATech web page (https://www.danatech.org) provides technology training resources, including how to prepare people with diabetes to be successful with technology. Table 5 offers insights from a certified diabetes care and education specialist and registered dietitian focused on how to help people with diabetes configure the right technology tools for them.

3. **Ongoing collaboration using the data to optimize care.** Using technology-enabled diabetes self-management education and support positively impacts health outcomes. The most effective technology-enabled diabetes self-management includes 4 key components: (1) 2-way communication with the health care team and the PWD, (2) patient-generated health care data (PGHD), (3) education, and (4) feedback. Smart insulin pens incorporate all 4 components of the technology-enabled diabetes self-management model and facilitate sharing PGHD. The detailed, structured reports with automatically recorded data allow the diabetes care and education specialist to provide individualized feedback and tailored self-management guidance. As experts in using data, diabetes care and education specialists can lead their care team in developing and integrating data-driven, continuous (virtual) care models. For technology devices such as smart insulin pens to be of value, it is imperative that the resulting PGHD be used on a timely basis in partnership with the PWD. Table 6 offers insights from a certified diabetes care and education specialist and pharmacist, who provides ongoing collaboration with people with diabetes to optimize therapy.

### Establishing Roles and Responsibilities in a Data-Driven Diabetes Practice

The diabetes care and education specialist can recommend evidence-based technology devices for people with diabetes and optimize their use. Serving as the expert, diabetes care and education specialists can guide other health care team members to utilize integrated diabetes-related data to optimize care and minimize therapeutic inertia. Table 7 describes the potential roles and responsibilities of various health care team members in a data-driven practice model, including the identification of a technology champion. Establishing a clinical workflow process for integrating evidence-based technology tools, such as smart insulin pens and resulting PGHD, into clinical practice is critical. This includes establishing protocols for both in-person and virtual care delivery. Table 8 details the steps required to build a data-driven practice model using smart insulin pens as an example, including determining roles and responsibilities for incorporating data into the care process as described in the Receive, Review, Respond model presented in the table.

### Building Virtual Care Models and Remote Patient Monitoring Capability

Diabetes self-management requires frequent and constant decision-making for the PWD or caregivers. Most people with diabetes do not receive sufficient support and guidance, particularly between visits with clinicians. Episodic (every 3-6 months) medical visits are insufficient for a majority of people with diabetes, particularly those who inject insulin. Connected devices offer the potential for clinicians to use Remote Patient Monitoring (RPM) and more frequent brief and timely touch points as needed. The ability to communicate regularly with people with diabetes, review their clinical and lifestyle data, and make adjustments and develop an action plan provides clinicians with unprecedented opportunities to improve clinical outcomes.

It is anticipated that virtually delivered diabetes care and self-management education and support services may be covered by private payers within fee-for-service or value-based models of payment. Medicare, through their Merit-based Incentive Payment System (MIPS), also incentivizes remote patient care in certain settings. For example, one of the MIPS Improvement Activities is the use of digital tools to monitor patient-generated health data with clinically validated tools that include an active feedback loop, as described in the technology-enabled diabetes self-management model discussed previously, that in turn provides actionable insights for the PWD.

In the final 2020 Physician Fee Schedule, the Centers for Medicare and Medicaid Services (CMS) state that RPM services involve “establishing, implementing, revising, and monitoring a specific treatment plan for a patient.” CMS
states that these services can be provided by clinical staff and billed “incident to” a billing practitioner’s services under “general supervision” of a practitioner. This means that the clinical staff, such as a diabetes care and education specialist, need not be present in the same physical location as the billing practitioner. A change from “direct” to “general” supervision allows clinical staff to render RPM services in a different location than the billing practitioner. With this change, staff members can perform these services outside of the physical location of the practice setting, allowing for scalability of services as costs (eg, office space, travel, and staffing) to be significantly reduced. A list of the specific CMS RPM codes are available. 

Table 3

CDCES Insights: Identification

<table>
<thead>
<tr>
<th>Interviewee: Colleen Miller-Owen, MSN, FNP-BC, APRN, CDCES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position: Nurse practitioner, Northwestern Medicine Regional Medical Group Endocrinology (an endocrinology practice within a large hospital system outpatient setting, Chicago, IL)</td>
</tr>
<tr>
<td>Q: How do you identify the PWD who may benefit from technology-based diabetes tools and assess their technology know-how, readiness to make shared decisions about the right diabetes technology for them?</td>
</tr>
<tr>
<td>A: It’s critical that everyone be made aware of the array of technology-based diabetes tools, including CGM and insulin delivery devices. I listen to each person’s concerns and frustrations about diabetes care. This allows me to highlight how various devices can ease their care burden, weigh the pros and cons, and come to a shared decision. I purposely don’t limit the devices I present or classify which people should use which devices. Interestingly, I’ve found that many older people really embrace technology and some younger, more tech-savvy people are resistant to it. As providers, we must respect peoples’ decisions; however, we need to regularly keep them abreast of their options.</td>
</tr>
<tr>
<td>Q: How do you work with PWD to configure technology tools/devices to meet their needs, including establishing the correct insulin therapy settings (insulin to carbohydrate ratio, insulin sensitivity factor, duration of insulin action, target blood glucose, meal times) and how and when to send reports?</td>
</tr>
<tr>
<td>A: I encourage people new to a device to send reports weekly or when making adjustments, including fine-tuning insulin therapy settings. I review reports in detail during office visits and via phone. I’ve found that my demonstrating the value of data to adjust and evolve treatment helps people with diabetes realize the value of their data.</td>
</tr>
<tr>
<td>Q: How have you expanded your practice or role to provide data-driven care services?</td>
</tr>
<tr>
<td>A: Our use of technologies and the related data has grown substantially. Use of both has allowed us to improve care and outcomes. Most of our patients who take insulin use some kind of device. To simplify and ease our workflow, we’ve developed standard systems for device onboarding, assisting with device approval, device training, and information about how and how often to send in reports.</td>
</tr>
<tr>
<td>Q: How has incorporating smart insulin pens into your practice helped improve your practice and your patients’ outcomes?</td>
</tr>
<tr>
<td>A: Use of smart insulin pens has improved patients’ outcomes. People experience reductions in A1C. People who use a CGM along with a smart insulin pen have downloads that reflect increased time in range and decreased episodes of hypoglycemia, particularly nocturnal hypoglycemia. We find use of the smart insulin pen improves patient safety because the person can now track insulin doses and insulin-on-board. As a clinician, having these data allows me to make more appropriate dosing changes. From a staff support standpoint, we find the paperwork for approval by insurance is minimal, as is the time needed for training. We have found it’s easy for patients to fax reports to us from their phone, requiring less staff time for downloading.</td>
</tr>
<tr>
<td>Q: What are your two recommendations to colleagues who want to build a data-driven practice?</td>
</tr>
<tr>
<td>A: First, be persistent and patient! Transitioning to data-driven care requires the PWD and providers to understand the value and recognize the benefits of this care. Second, keep learning about new technologies. Stay abreast of new developments. Stay open minded about people’s preferences, interests, and abilities.</td>
</tr>
</tbody>
</table>

Abbreviations: CGM, continuous glucose monitoring; PWD, person with diabetes.
Table 4
Calculations for Smart Insulin Pen Settings

<table>
<thead>
<tr>
<th>Method 1</th>
<th>Method 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Smart Insulin Pen TDD</td>
<td>Weight-based: kg × 0.5 or lb × 0.23</td>
</tr>
</tbody>
</table>

**Clinical considerations on smart insulin pen TDD**
- Average values from methods 1 and 2
- Hypoglycemic patients → Start at lower value
- Hyperglycemic patients, elevated A1C, or pregnant → start at higher value

**Smart Insulin Pen Dose Adjustment**

<table>
<thead>
<tr>
<th>Basal Dose</th>
<th>Insulin to Carbohydrate Ratio (ICR)</th>
<th>Insulin Sensitivity Factor (ISF) and Duration of Insulin Action (DIA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smart Insulin Pen TDD × 0.5</td>
<td>450/TDD</td>
<td>1700/Pump TDD</td>
</tr>
<tr>
<td><strong>Clinical Guidelines:</strong></td>
<td><strong>Clinical Guidelines:</strong></td>
<td><strong>Clinical Guidelines:</strong></td>
</tr>
<tr>
<td>• Review glucose trends over 2-3 days.</td>
<td>• Adjust based on moderate-fat meals with known carbohydrate content.</td>
<td>• To assess ISF, BG should be checked 2 h after correction; if BG is within 30 mg/dL of target range, ISF is correct.</td>
</tr>
<tr>
<td>• Adjust to maintain stability in fasting state (between meals and during sleep; &lt;30 mg/dL change in BG).</td>
<td>• Acceptable 2-h postprandial rise is ~50 mg/dL above preprandial BG.</td>
<td>• Make adjustments in 10-20% increments if 2-h postcorrection BGs are consistently above or below target.</td>
</tr>
<tr>
<td><strong>Alternate methods:</strong></td>
<td><strong>Additional considerations:</strong></td>
<td><strong>To check ISF</strong></td>
</tr>
<tr>
<td>• ICR (6 × weight in kg/TDD) or (2.8 × weight in lb/TDD)</td>
<td>• Check carbohydrate counting or meal size estimation skills. Assess glycemic index of carbohydrate choices and macronutrient distribution (meals with &gt;25 g protein and &gt;20 g fat can raise the glucose higher than carbohydrate count would indicate).</td>
<td>Check when glucose is &gt;250 mg/dL and PWD can wait to eat for another 5 h.</td>
</tr>
<tr>
<td>• Fixed meal bolus = (TDD × 0.5)/3 equal meals</td>
<td>• Optimal if glucose remains within 30 mg/dL above or below starting glucose 5 h after dosing (optimally check when there has been no bolus in the last 5 h and no food in the last 3 h); note unusual stress, schedule changes, sleep disruptions, sickness.</td>
<td>• Check BG every hour or use CGM.</td>
</tr>
<tr>
<td></td>
<td>• If glucose spikes after eating but returns to normal at 5 h, ICR likely correct. To avoid spike, bolus earlier relative to eating or choose lower GI, higher fiber, less processed carbohydrate choices, or lower carbohydrate meal.</td>
<td>• If BG &lt;70 mg/dL, stop checking and eat carbohydrates.</td>
</tr>
<tr>
<td></td>
<td>A different ratio may be needed for different meals.</td>
<td>• Adjust ISF if needed for hypoglycemia (increase 10%) or hyperglycemia (decrease 10%)—should consistently bring glucose to target within 4-5 h without hypoglycemia.</td>
</tr>
</tbody>
</table>

**Abbreviations:** BG, blood glucose; CGM, continuous glucose monitoring; DIA, duration of insulin action; GI, glycemic index; ICR, insulin to carbohydrate ratio; ISF, insulin sensitivity factor; PWD, person with diabetes; TDD, total daily dose.

*Factor can range from 1400 (A1C > 10.0%) to 2400 (A1C < 7.0%).*
Table 5

CDCES Insights: Configuration

<table>
<thead>
<tr>
<th>Interviewee: Jennifer Okemah, MS, RD, CDCES, CSSD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position: Owner/clinical director, Salute Nutrition, PLLC, Seattle, WA</td>
</tr>
<tr>
<td>Q: Describe your current practice setting.</td>
</tr>
<tr>
<td>A: I began working with a multispecialty physician group to create a diabetes self-management education and support service model that provided endocrinology and primary care offices with a dedicated certified diabetes care and education specialist, registered dietitian. I currently offer a similar model within my private practice. In addition, I have begun offering some services using telehealth.</td>
</tr>
<tr>
<td>Q: How do you and the clinicians you contract with configure technology tools to meet patients’ needs, including establishing accurate starting insulin therapy settings?</td>
</tr>
<tr>
<td>A: When we onboard people with diabetes to new technology, such as a smart insulin pen, we properly initiate and fine-tune their insulin therapy settings. We make sure the meal times match the person’s routine, help them set up missed dose reminders, and agree on a plan for sharing data reports. Diabetes care and education specialists must become THE key clinicians to properly and optimally configure technology tools to match the person’s unique care plan and lifestyle. They must become comfortable and confident in presenting their recommendations to providers. Over time, we will build trust and likely gain more respect and independence practicing in this manner.</td>
</tr>
<tr>
<td>Q: How have you expanded your practice or role to provide data-driven care services?</td>
</tr>
<tr>
<td>A: Data is CRUCIAL to gaining clinical insights and developing recommendations to optimize care. I train the clinicians who work in my practices to have a keen and critical eye to efficiently review data reports. Diabetes care and education specialists have the time and expertise to distinguish between the need for device-setting adjustments from behavioral aspects of care.</td>
</tr>
<tr>
<td>Q: How has incorporating the smart insulin pen into your practice helped improve your and your patients’ outcomes?</td>
</tr>
<tr>
<td>A: Incorporation of a smart insulin pen further removes the burdens of diabetes care on the PWD and decreases time spent by clinicians to assess all aspects of insulin therapy. Now instead of asking people a litany of questions, we have objective data with which to assess situations (“be the detective”) and recommend therapy changes. Access to these objective data also helps us offer visual “aha” moments and facilitates shared decision-making.</td>
</tr>
<tr>
<td>Q: What are your top 2 recommendations to colleagues who want to build a data-driven practice?</td>
</tr>
<tr>
<td>A: First, develop skills to efficiently review data reports to recommend care plan adjustments. Second, gain some competence with all devices. It’s better to know something about all devices than to limit your recommendations due to your lack of familiarity.</td>
</tr>
</tbody>
</table>

Abbreviation: PWD, person with diabetes.

Table 6

CDCES Insights: Ongoing Collaboration

<table>
<thead>
<tr>
<th>Interview with: Diana Isaacs, PharmD, BCPS, BCACP, CDCES, BC-ADM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position: Pharmacist, Cleveland Clinic Diabetes Center</td>
</tr>
<tr>
<td>Q: How have the integrated data reports for your patients treated with MDI of insulin who are using smart insulin pens helped you better partner to optimize their insulin regimen and improve outcomes?</td>
</tr>
<tr>
<td>A: The reports allow visualization of the insulin doses, including carbohydrate intake and correction doses. Similar to an insulin pump report, it helps the clinician easily determine where dosing adjustments can be made to optimize therapy.</td>
</tr>
<tr>
<td>Q: Describe how you are leveraging remote patient monitoring using the capabilities that smart insulin pens provide to easily deliver virtual care to a PWD.</td>
</tr>
<tr>
<td>A: I care for people with diabetes who live hours away from my clinic, so virtual visits offer a convenient opportunity to follow up on a timely basis. Since all of the data I need is automatically updated via Bluetooth, it is easy to review data together. Even for patients who live close to my clinic, they appreciate not having to drive and pay for parking since my clinic is located downtown.</td>
</tr>
</tbody>
</table>

(continued)
Table 7

Roles and Responsibilities of Members of the Data-Driven Care Team

<table>
<thead>
<tr>
<th>Data-Driven Care Team Member</th>
<th>Roles and Responsibilities to Receive, Review, and Respond to Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>PWD</td>
<td>• Share data with the care team on regular basis or as agreed on; be prepared to partner with the care team to proactively discuss potential changes to the overall care and self-management plan based on data insights</td>
</tr>
</tbody>
</table>
| Technology champion                         | • Serves as go-to resource for practice and the PWD on technology tools and implementation  
• Trains the PWD on use of technology and encourage ongoing engagement  
• Receives reports  
• Assures right care team member has access to reports to respond |
| Diabetes care and education specialist      | • Supports the PWD to achieve optimal use of technology tools in their self-management plan  
• Reviews data reports, recommends adjustments to the health care team  
• Discusses and obtains care plan and medication/insulin regimen changes  
• Leads care team in technology integration and data use       |
| Care coordinator                            | • Uses population-level data to identify patients who need intervention  
• Uses PGHD and reports to inform conversations with patient  
• Refers to appropriate team members to address particular patient needs |
| Check-in staff                              | • Identifies the PWD who uses technology tools  
• Assures data report sent  
• Determines that the PWD is signed up for electronic patient portal |
| Triage staff                                | • Assures the PWD has configured technology tool for current care plan                                                                                                                                                                                                    |
| Prescribing clinician                       | • Recommends technology tools to the PWD  
• Uses data during virtual and face-to-face touch points with the PWD to optimize the care plan                                                                                                                                                                    |
| Check-out staff                             | • Provides the PWD with updated treatment and self-care plan (After-Visit Summary)  
• Assures the PWD knows how and when to share data with care team for ongoing follow-up and collaboration                                                                                                                                   |
| Telephone/telehealth staff                  | • Requests the PWD to send data report via app if using technology tools                                                                                                                                                                                                   |

Abbreviations: PWD, person with diabetes; PGHD, patient-generated health data.
Table 8
Data-Driven Practice Model to Integrate Smart Insulin Pens Into Workflow

<table>
<thead>
<tr>
<th>Identify</th>
<th>Configure</th>
<th>Collaborate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Help the PWD identify the best route of insulin delivery for them. Smart insulin pens Indications for use:</td>
<td>Configure smart insulin pen to match the routine, lifestyle, and therapy plan of the individual.</td>
<td>Use the smart insulin pen data on an ongoing basis in collaboration with the PWD to optimize care.</td>
</tr>
<tr>
<td>- T1DM or T2DM all ages (younger than age 7 with supervision of an adult caregiver)</td>
<td>1. Provide personalized insulin therapy settings (see Table 4)</td>
<td>Determine data report workflow: Using receive, review, respond model</td>
</tr>
<tr>
<td>- Using mealtime insulin</td>
<td>2. Assure that the meal schedule in the app is adjusted to the PWD’s daily routine</td>
<td>Receive:</td>
</tr>
<tr>
<td>- Counting or estimating carbohydrates</td>
<td>3. Connect to available glucose monitoring devices</td>
<td>- Who receives the reports and assures the right team member reviews the report to take action?</td>
</tr>
<tr>
<td>Tech assessment:</td>
<td>4. Agree on a plan for sharing the data with the care team.</td>
<td>- When and how will reports be received and on what cadence?</td>
</tr>
<tr>
<td>- Has smartphone/uses apps</td>
<td>5. Be sure to check insulin injection technique, injection sites, understanding of priming, and proper insulin storage.</td>
<td>Review:</td>
</tr>
<tr>
<td>- Is monitoring blood glucose on regular basis</td>
<td>6. Set clear expectations regarding use of the smart insulin pen as part of daily self-management plan:</td>
<td>- Who will review and determine if care plan changes are warranted and if so, what member of the care team will be responsible to address (prescribing clinician, diabetes care and education specialist, care coordinator, or health coach)?</td>
</tr>
<tr>
<td>Prescription:</td>
<td>- Advise the PWD to check the app home screen for the last dose amount and time, last glucose, and any active insulin-on-board when unsure if they took a dose or not.</td>
<td>Respond:</td>
</tr>
<tr>
<td>- Smart insulin pen and prefilled insulin cartridges (Humalog, Novolog, or Fiasp)</td>
<td>- Encourage the PWD to check blood glucose and use the bolus calculator each time insulin is dosed.</td>
<td>- How does the designated care team member use the behavior-focused data to have a focused conversation with the PWD about the self-management plan?</td>
</tr>
<tr>
<td>- Insulin pen needles</td>
<td>- While fine-tuning settings and learning carbohydrate counting, ask the PWD to check blood glucose 2 hours after meal-time doses to determine if a correction dose is needed.</td>
<td>- How does the designated care team member use the clinical data to facilitate therapy changes? (See Figure 3.)</td>
</tr>
<tr>
<td>Note: Be sure the PWD has a current prescription for their basal insulin and any glucose monitoring supplies needed.</td>
<td>- Remind PWD to log additional insulin doses such as long-acting insulin and short-acting doses taken without the smart insulin pen in the Logbook.</td>
<td>- How are care plan changes communicated to the PWD and to the rest of the care team?</td>
</tr>
<tr>
<td></td>
<td>- Suggest the PWD review the Logbook as needed for daily history and adjust reminders for doses and glucose checks as needed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Ask the PWD to share data reports and engage with the care team between health care visits per plan.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Update Therapy Settings as care plan evolves.</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: PWD, person with diabetes; T1DM, type 1 diabetes; T2DM, type 2 diabetes.
Summary

Smart insulin pens offer a new tool to empower people with diabetes treated with insulin injection therapy to more accurately and precisely make daily dosing decisions and to partner with their diabetes care clinicians. Smart insulin pens are among the many connected devices available for people with diabetes that are enabling data-driven continuous care models. Enterprising diabetes care and education specialists who embrace these capabilities are well positioned to lead their care team in developing person-centric approaches to address the unmet needs of their diabetes population, including those treated with insulin injection therapy.

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**References**


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