**Principles and Recommendations Related to the Collection and Use of
Patient Diabetes Management Data**

*A panel of diabetes care experts convened at the American Association of Diabetes Educators
headquarters in Chicago on Friday, October 17, 2014 to discuss current practices and make
recommendations related to the collection and use of patients' diabetes-related health data. The meeting
and subsequent reporting were supported by grants from Abbott Diabetes Care, Insulet, Novo Nordisk
and Sanofi. Panelists were Gary Scheiner, MS, CDE (Moderator), Deborah Greenwood, PhD, RN, CNS,
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Sarah Rosenbloom, RN, BSN, CDE, Jeanne Sheetz, RN, BSN, CDE, Roberta Stevens, RD, LDN, CDE,
and Mara Wilson, RN, MS, FNP-C, CDE. The major objectives of the panel discussion were to 1) enable
partner companies in the diabetes care industry to design better tools to manage patient data, 2) facilitate
effective interpretation and application of patient data by healthcare providers and patients, and 3)
enhance patient outcomes. A degree of standardization, while maintaining flexibility to meet individual
needs, was a key theme of the discussion. The following is a summary of the panel dialogue.*

How blood glucose data are collected

The panel discussed blood glucose monitoring by paper logs as well as by various monitoring devices,
including use of computer software and cloud-based solutions to manage data. The panel observed that
paper logs can capture more information than most blood glucose monitoring devices, specifically around
insulin dose adjustments, medication adherence, food intake and physical activity. A quick review of data
recorded in paper logs can reveal a great deal about the effectiveness of the care plan as well as the
patient's ability to implement their healthcare provider's recommendations. Caveats about use of paper
logs are listed under *Key Recommendations and Opinions*. Turning to monitoring devices, the panel
debated the positive and negative aspects of relying on patient data downloaded from blood glucose

meters and insulin pumps. In general, the panel observed that touch-screens rather than buttons may encourage patients to interact with their devices more consistently. For insulin pump users, automatic relay of glucose values from the meter to an insulin pump or dose calculator app can reduce the chance of human error in dosing calculations. Logging insulin doses within a blood glucose meter can aid healthcare providers in data interpretation, but may be cumbersome for patients.

The panel discussed general themes regarding the use of computer software and cloud-based solutions in the collection of blood glucose data, including information technology security and legal liability. While patients and healthcare providers can be empowered by greater access to personal health data, the United States Food and Drug Administration and individual healthcare institutions remain focused on compliance with data privacy and security standards. With the proliferation of software programs for specific devices, individual healthcare providers face pressure to stay up-to-date in terms of both technology and training.

Key Recommendations and Opinions

- Regarding use of paper logs, the panel offered a caveat that the only way to be certain a patient has performed self-monitoring of blood glucose (SMBG) at the times they have recorded is to download their glucose monitor as well, with the correct date and time having been set on the device.
- The panel observed that paper logs with all entries in the same ink, or on unwrinkled/unblemished pages, may indicate fabricated values.
- The panel noted that when patients use multiple blood glucose meters, merging the data stored across all the devices can be difficult because time/date settings may not be in sync, and all devices must be present for downloading.

- The panel observed that some blood glucose meters allow patients to 'tag' records to give context to the value (pre- or post-activity, illness, unusual food or drink, etc.) but this feature rarely captures sufficient details to make it useful. For example, different types of exercise affect glucose levels in different ways so a general 'post-exercise' tag may not provide enough information to identify patterns.

- The panel discussed the reliability of time-based intervals (assigning an event automatically based on the time of day, such as 6-9am = pre-breakfast) compared to using event tags. The panel agreed that time-based intervals are most appropriate for patients who adhere to a regular schedule that is consistent throughout the week. In the panel's experience, these patients tend to be under age 12 and cared for by parents, or older and retired.

- The panel agreed that time-based intervals could be made more useful by allowing healthcare providers and patients to set different profiles in blood glucose meters for "work/school days" versus "non-work/school days" (similar to basal rate profiles in insulin pumps). For most others, the panel found that event-tagging allows for more effective data analysis.

Data Presentation

Panelists commented that glucose summary analysis charts tend to be less useful for patients using SMBG alone than patients using continuous glucose monitoring (CGM). The panelists noted the value of CGM glucose summary reports that show the percentage of time above, below and within target glucose ranges by time of day and SMBG frequency over the period of a week, as well as reports that suggest key areas for review at the bottom of the page. Panelists commented that for CGM users, the modal day report is very important in assessing glycemic patterns. Turning to insulin delivery reports produced by pump software, the bolus override report generally reflects that patients are thinking critically about their doses. When boluses are reduced based on planned physical activity, the adjustment may be clinically appropriate; however, very frequent bolus overrides may reveal fear of hypoglycemia or a need to adjust doses because high or low glucose values tend to occur if the patient delivers the recommended dose.

Cross-platform compatibility is an important issue in data presentation and management. The panelists observed that device-specific software and cables increase the burden of training and create complexity for healthcare providers who may have to view several different types of reports throughout the day (and sometimes for the same patient). Sometimes diabetes educators are called on to spend clinic time downloading patients' devices because non-clinical administrative staff struggle with the procedures, which can have a direct impact on the quality of patient care.

Panelists observed that relying on the patient to bring their own downloaded data to appointments increases clinic efficiency and reduces the need for clinic or support staff to perform downloads. Yet panelists noted that patients can find home downloading software difficult to use, and downloading their diabetes devices on the day of their clinic visit can cut into the time for their appointment. As a result, some panelists ask patients to use paper logbooks despite expressing a preference for electronic downloading: during an appointment it can be quicker and easier to annotate glucose values in a logbook than to download the data from a device and highlight it within a printed report.

The panel also discussed standardized versus customized data presentation. The panel considered the ambulatory glucose profile (AGP) as an example of a standardized approach. Developed by the International Diabetes Center, AGP averages data by the minute and hour throughout the day and displays standard deviation from the mean to indicate glycemic variability according to time of day. In some instances, 25th/75th percentile and 90th/10th percentile values are displayed. Device and software manufacturers could use a similar report format, including color-coding, sharing and printing options, which would allow for consistency across clinical settings. The panelists emphasized that diabetes management software and action points highlighted within such software must be accessible to primary care providers and patients with basic literacy, and not only to healthcare providers with specific training in diabetes. The panel observed that data transmission and presentation preferences are likely to vary

based on clinic-specific workflow and priorities as well as individual patients' understanding and experience with diabetes self-management. Any method of data collection or sharing that engages an individual patient or caregiver in actively managing diabetes has value in clinical practice.

Key Recommendations and Opinions

- The panel found that use of different colors in a modal day report makes it easy to read on-screen, though less practical when printed in black-and-white. At the same time, they affirmed the ease of use of software that is easy to read on-screen and produces reports that can be printed in black-and-white to save on printing costs.

- The panel noted the usefulness of reports bringing together trend data and statistics on one page.

- The panel expressed enthusiasm for new search functionality tools that will allow patients or healthcare providers to set dynamic parameters to highlight trends within specific data sets – such as glucose values recorded within a specific time interval over a period of several days.

- The panel noted that highlighting work/schooldays versus off days in a report helps to distinguish patterns linked to daily schedules, and expressed a desire to sort data by day(s) of the week. For example, glucose patterns may be distinct on days in which a patient performs night shift work, exercises or has restaurant meals.

- Panelists pointed out that correct date and time settings on diabetes devices are essential for data interpretation. The panel proposed that a prompt should appear on the screen within a blood glucose meter downloading software program when a meter's time and date differs from the computer system, with a feature to allow the user to update the device settings with a single mouse click.

- Regarding pump software, panelists commented on the value of web-based programs that allow download and integration of a very wide variety of devices.

- The panel observed that glycemic variability could usefully be described in terms of an automatic calculation of the coefficient of variation, with the caveat that healthcare providers and patients may need support in understanding this metric.

- In terms of device or smartphone app feature accessibility, panelists called for more voice-activated data recording solutions for people with visual impairment, limited use of their hands, or time constraints. They also called for manufacturers of blood glucose monitoring systems to consider the ergonomics of the meter within the case, not only outside it, during the design process.

- The panel commented on the value of developing analysis software to show patients the cause-and-effect relationship of food and insulin on glucose levels.

- The panel observed that an at-a-glance indication of days on which few or no glucose values were entered into the pump is helpful for determining a patient's level of adherence to SMBG as well as insulin dosing behavior.

- With regard to insulin delivery reports, the panel proposed that healthcare providers should discuss with patients/caregivers the rationale for bolus adjustments shown in the bolus override report.

How blood glucose data are used

The panelists agreed that health outcomes are strongly linked to patients' self-monitoring of blood glucose (SMBG) according to healthcare provider recommendations. The panel also agreed that focusing on hemoglobin A1C (A1C) as a primary outcome measure can do patients and providers a disservice because A1C measurements, which reflect an overall glucose average, fail to address the *quality* of glucose control. The panel also noted that when hemoglobinopathies that may affect the accuracy of A1C results are present, periodic fructosamine tests are also recommended.

The panel considered which healthcare providers analyze patients' diabetes data, which providers *should* analyze patient data, and the extent to which patients should be encouraged to analyze their own data. The panel observed that diabetes educators, nurse practitioners, physicians and physicians' assistants may all play a role in analyzing patients' diabetes data. Diabetes educators generally have longer appointment time slots than physicians. When diabetes educators are on staff, physicians, nurse practitioners, physicians' assistants and patients tend to rely on them to provide support in interpreting data and making therapy recommendations. When a diabetes educator is not available, other healthcare providers tend to play a larger role in data analysis. In the panelists' experience, only a minority of patients with diabetes – perhaps as much 10% – analyze their own data. Non-clinical staff may download devices but they almost never interpret or analyze the data. Panelists agreed that diabetes educators and other healthcare providers with specific expertise in diabetes are best equipped to analyze patients' diabetes data using currently available tools. The panel commented on the potential of data management software and app tutorials to increase patients' skills in self-management. The panel also observed that the ability to compare current and historical data would be useful.

The panel considered the characteristics of the optimal diabetes data management program and noted advantages for these features:

- Day-by-day logbook
  - Easy to teach from, easy to use to detect patterns, easy to discuss with patients and their families, easy to see the number of data points
  - Indicates level of adherence with recommended SMBG frequency, which may be required by insurance companies or Medicare for coverage of DSM supplies.
- Ability to see event tags added by patients
  - Being able to link glucose values to pre- and post-prandial states, alcohol consumption, activity level, state of health, etc.
- Mean glucose, standard deviation, time or percentage of values within, below and above target range
  - Necessary to interpret the degree of glycemic variability
- Carbohydrate consumption, insulin doses, activity data
  - All provide context for glucose values
- Ability to overlay pump data, CGM data and SMBG data
  - Scrolling through different screens or different software reports to see all the data makes it more challenging to observe causes and effects of treatment decisions

- Ability to select and compare data across a range of several days
  - Provides insight into overall diabetes control and phenomena that may be linked to specific schedule/activity patterns
- For pump users: a snapshot record of changes to basal and bolus settings and pump refills/site changes
  - Offers the opportunity to check whether patient- or healthcare provider-initiated changes to settings have helped or hindered diabetes management
  - Indicates level of adherence with recommended self-management recommendations, information that may be required by insurance companies or Medicare for coverage of DSM supplies
- For CGM users: ability to compare one time interval to another time interval, records of rate of change and patterns of rates of change
  - To determine whether the timing of mealtime insulin doses is optimal compared to digestion and whether basal insulin adjustments are appropriate for managing glycemia during physical activity

The sharing/transmission of data between patient and healthcare provider is essential for collaboration and optimal decision-making. The panel identified a number of ways in which patients can share diabetes self-management data with healthcare providers, summarized in Table 1.

Table 1. Ways in which patients can share data with healthcare providers	
Phone	Written log sheets/logbook
Email	Photos shared at in-person appointment
In-office download from device	Photos shared via email
At-home download from device	Postal mail
Smartphone app	Direct upload to electronic medical record (EMR)
Patient's memory	

The panel discussed advantages and disadvantages of various methods of data sharing. Overall, members of the panel preferred obtaining data directly from patients' devices. Methods of obtaining patient data was ranked in order of preference:

1. In-office download

2. Remote download (patient
downloads data at home, makes it
accessible to the clinician)
3. Fax
4. Phone
5. E-mail
6. Postal mail

While postal mail was the least preferred method of data transmission among the panel, panelists

observed that populations with limited computer/internet access are likely to need to submit data in this

way.

Key Recommendations and Opinions

- The panel concurred that collection and analysis of glucose data can increase patients' knowledge
  of the impact of food choices, physical activity, stress or illness, and hormone fluctuations
  associated with puberty, menstruation, pregnancy and menopause, on their diabetes self-
  management.

- The panel agreed that because patterns of high/low readings and glucose variability are not
  detected when looking at the A1C alone, there is a need for evaluating fingerstick glucose values
  and continuous glucose monitor data in addition to A1C, as these allows for analysis of
  postprandial as well as preprandial glucose levels, glucose variability, patterns of hypoglycemia,
  and quantification of time (or values) above, below and within one's target glucose range.

- Panelists noted that SMBG is typically underutilized within a managed care environment, where a
  single-minded focus on A1C can permit issues with a patient's diabetes control to go undetected.

- The panel suggested that when CGM is not utilized, periodic glucose monitoring should take
  place 60-90 minutes after mealtime rapid-acting insulin administration.

- The panel noted that for those not taking mealtime insulin, occasional 1-2 hour postmeal
  monitoring can be useful for revealing the effects of different types of foods, and that postmeal
  data can indicate to healthcare providers the need for intensification of medical therapy.

- The panel agreed that in patients recently diagnosed with type-2 diabetes, persistent postprandial hyperglycemia may call for C-peptide and antibody tests to rule out misdiagnosed type-1 diabetes.

- The panelists expressed a desire to see patients more empowered to participate in data analysis and called on diabetes management software developers to focus on the needs of both healthcare providers and patients.

- The panelists expressed a desire for data management programs to function across multiple platforms, including Android phones and tablets, iPhones, iPads, and Apple and Windows personal computers.

- The panelists noted that because many younger patients with type 1 diabetes do not have the numeracy, literacy or maturity to understand and apply principles of diabetes data analysis, their parent or caregiver must be engaged in their care until they are ready for more active self-management.

- The panelists pointed out the potential value of remote access for parents to be able to check on data their child has entered into a smartphone app.

- The panel agreed that a one-page summary, while valuable, may need to be customized per patient based on their individual health needs, challenges and goals.

Invigorating use of diabetes data in clinical practice

The panel discussed approaches to invigorating the use of diabetes data by healthcare providers. The panel identified self-study, training by clinical managers and diabetes device company representatives, and Diabetes Technology Society certification as valid routes to increasing diabetes educators' knowledge of data analysis and interpretation. While calling for increased patient involvement in diabetes data analysis, the panelists recognized factors that prevent patients from taking a more active role as well as factors that may enable them to do so.

Interest and engagement in diabetes data management varies from person to person, and may fluctuate over time. Adults with type 1 diabetes tend to be highly engaged in using diabetes management smartphone apps or smart meters, not to mention insulin pumps. In contrast, patients with type 2 diabetes who are not using an intensive insulin approach tend to be less engaged in their self-care. Educating more primary care providers on how to analyze and interpret diabetes data could improve communication between providers and patients regarding the necessity of active self-management. Patients who are less engaged in their self-management tend to have higher rates of emergency room admission; active data management has the potential to reduce admission rates.

The panel discussed invigorating patient self-management through several popular smartphone apps designed for diabetes management and general well-being. "MySugr" was described as convenient, valuable for encouraging compliance through gamification, and useful because it automatically saves user-entered data to create reports that patients can email to healthcare providers. Other diabetes-specific apps mentioned by the panel included Glooko, Glucose Buddies and RapidCalc. Among apps with a broader emphasis on well-being, the panel appreciated the features of MyFitnessPal and GoMeals.

The panel discussed the potential use of rewards and positive peer pressure to increase patients' interaction with diabetes self-management data. For example, Fitness Tracker usage can be linked to real-world financial incentives like money-saving coupons for major retailers or charitable donations. Perhaps there is scope for developing similar programs for diabetes data management. At present, users of the mySugr diabetes management smartphone app can convert points they accumulate within the app into donations to certain diabetes-focused non-profit organizations. The panel also considered the role of a

virtual community, such as a peer group with the same diabetes type, in the same geographical area, with shared interests, in sustaining patient engagement with diabetes data management.

While the option of a reward or a community could be attractive to some patients, it could be equally unattractive to others. For this reason, the panel also discussed compelling visuals, games and the use of humor as possible drivers of engagement in diabetes data management. Taking advantage of patients' natural curiosity by searching for records according to given criteria may help improve self-management behavior. Introducing interactive features such as pop-up messages into data management software programs may also heighten engagement. Adding a feature to highlight gaps in monitoring, for example times of day when patients tend to not perform SMBG, can help point out the impact of sporadic glucose testing on diabetes control.

Key Recommendations and Opinions
- The panel noted that sometimes patients feel judged or guilty when interacting with healthcare providers and recommended that healthcare providers bear this in mind and attempt to show sensitivity and objectivity in reviewing reports with patients. Healthcare providers can use instances of glycemic excursions to educate patients about the actual and potential effects of various self-management decisions.
- The panel noted that healthcare providers need to see honest food diaries to understand patients' dietary choices, and that judging patients can discourage them from being candid about their behavior as well as their actual glucose data.
- Emphasizing that diabetes management data belongs to patients, not healthcare providers, the panel noted that encouraging patients to observe the effects of food, activity and other factors on their diabetes control can empower them to make educated choices and establish healthy habits.

- Because patients' level of literacy and ability to communicate in English can strongly influence their access to technical support from product manufacturers (most of whom tend to provide support in English), the panel suggested that instructional videos could be subtitled or voiced-over in multiple languages to supplement or replace English-only print resources.

Technology Considerations for inpatient vs outpatient settings

The panel discussed the challenges of outpatient electronic medical record (EMR) systems that do not integrate with diabetes data management software programs. Even the use of Diasend, which allows input from a range of diabetes devices, may be complicated by the need to print out and scan records into the EMR. Inpatient healthcare staff typically monitor patients' blood glucose levels and insulin doses and add the data to hospital medical records. In addition to healthcare institutions' policies on data-sharing that may prevent transmission to outpatient providers, hospitals often use dedicated institutional blood glucose monitors that cannot integrate with systems used by outpatient care providers. This can make it difficult for outpatient healthcare providers to access the information about their patients' diabetes control during a hospital stay.

Key Recommendations and Opinions

- The panel noted that cross-device and cross-system compatibility has the potential to enhance patient care in inpatient and outpatient settings.

Privacy/confidentiality matters

The panel discussed privacy and confidentiality issues around diabetes data management. Panelists highlighted that cloud-based solutions based outside of the United States, including Diasend, fall outside of US data security regulations. Additionally, patient data stored on servers owned by technology providers in the United States may become property of the technology provider. Furthermore, patients

may fear – rightly or wrongly – that sharing data from their diabetes devices with a healthcare provider will have an impact on their health insurance or employment status. Publicity regarding specific instances where diabetes devices have been "hacked" has increased some patients' anxiety over device safety. The panel discussed the potential use of an affidavit provided by the healthcare provider to clarify the security and privacy of data to the patient.

Key Recommendations and Opinions

- The panel agreed that people with diabetes need to be empowered to feel ownership of their data because reluctance to share data with healthcare providers may impede research activities as well as patient care processes.

Reimbursement issues

The panel discussed reimbursement for time spent downloading and interpreting data from patients' diabetes devices. The United States Centers for Medicare and Medicaid Services (CMS) have historically been reluctant to reimburse providers adequately for diabetes self-management education (DSME). Unless providers can use codes for SMBG meter data interpretation, behavior change, or telehealth provision, diabetes data interpretation is treated similarly to DSME overall. Panelists also noted that, despite some improvements in access to health insurance under the Affordable Care Act, many people with type 1 diabetes remain unable to afford insurance and depend on less sophisticated diabetes management tools. The panelists suggested that infrequent SMBG (using outdated or generic devices) and conventional insulin therapy with Regular and NPH human insulin may be the only options available to these patients.

Key Recommendations and Opinions

- Panelists all reported never having received reimbursement for diabetes data analysis as a broad category, though some providers have been reimbursed for CGM interpretation.

Health system use of data management applications

The panel discussed the challenges of providing equal care to patients with a variety of diabetes management tools and devices. When the majority of patients in a practice use the same diabetes management technologies, it can be easier for providers to ensure a consistent focus on data interpretation. However, patient choice remains important, so healthcare providers have a responsibility to be competent with and knowledgeable about a wide array of devices, and capable of downloading devices and interpreting reports using a variety of software programs. Panelists also discussed technologies that have proved inefficient or unworkable in practice, and the reasons why. For example, automatic text message reminders about self-care behaviors based on patient-reported blood glucose values did not reduce the amount of time that diabetes educators spent providing patient support by phone, although some patients' adherence to SMBG and insulin therapy improved during the period of use.

Key Recommendations and Opinions

- The panelists noted that while some healthcare institutions are proactive about cooperating with diabetes care companies to develop and validate new technologies, others are instituting policies against the use of branded products or visits from company representatives for instruction on the products. Considering that the diabetes care market is heavily branded, the panelists viewed these policies as usually counterproductive to providing adequate patient care.

The future of diabetes care and technology applications

In discussing the future of diabetes care provision and reimbursement, the panel considered the potential for diabetes care to be provided cost-effectively via remote consultations, and called for evidence to be gathered regarding both costs of care and outcomes related to telehealth in diabetes. The panel discussed the decline of endocrinology as a medical specialty. Primary care is increasingly taking responsibility for diabetes care because of both a shortage of endocrinologists and insurance co-pays that discourage patients from seeking the advice of a specialist. The panel expressed concern over the burgeoning privacy issues arising from managed care organizations' access to patient data. While it may help a patient to receive occasional contact from a health coach, tying support to real-time diabetes device data raises the possibility of insurance premiums being affected by glucose values.

The panel expressed enthusiasm for developments in artificial pancreas technology, particularly continuous glucose monitoring sensors. With improvements in manufacturing, the panel hopes to see sophisticated diabetes management tools in the hands of more patients and healthcare providers. The panel agreed that expanding access to diabetes technology has the potential to increase patients' engagement in self-care and improve outcomes. Furthermore, introducing a degree of automation and decision support into diabetes technology platforms could reduce self-treatment errors. Finally, the panel also noted that many diabetes technology products are sold only in English in the United States, and called for Spanish to be introduced as a language option to reflect demographic shifts over the past 30 years that are expected to continue.

Concluding Recommendations and Opinions

- The panelists agreed that it is necessary to evaluate fingerstick and/or CGM data in addition to A1C (or fructosamine) in order to assess qualitative aspects of glucose control, particularly in the postprandial timeframe.

- The panelists noted that glucose data alone are rarely sufficient for making appropriate clinical decisions. Diabetes data generally needs to include lifestyle and medical factors that influence glucose levels.

- The panel noted that written record keeping remains the preferred source of information for therapeutic decision-making due to its ability to capture multiple variables that influence glucose control. Electronic/download systems that allow greater flexibility and customization are highly desirable.

- While noting that record-keeping apps have the potential to improve patient outcomes, the panelists felt that patients' reluctance to use the apps and healthcare providers' dissatisfaction with app reports may limit their utility.

- The panelists agreed that standardization/unification of software, downloading processes, and reporting would improve the ability of patients and healthcare providers to benefit from diabetes data.

- The panel noted that diabetes educators are in an ideal position to collect and analyze patient data, and should be consulted in the development of diabetes devices and software.

- The panel advised that device and software designers must take the needs of low-literacy patients and the growing Spanish-speaking population into account when creating printed materials and phone & online support.

- The panel advised that diabetes device manufacturers need to take an active role in ensuring the security of patient data, establishing patient trust, and securing reimbursement for provider downloading/analysis of patient data.