Pharmacist Role in Continuous Glucose Monitoring (CGM)

Gabriella Douglass, Pharm.D., BCACP, AAHIVP, BC-ADM
Assistant Professor, Harding University College of Pharmacy
Community Pharmacy Residency Program Director, ARcare
gdouglass@harding.edu

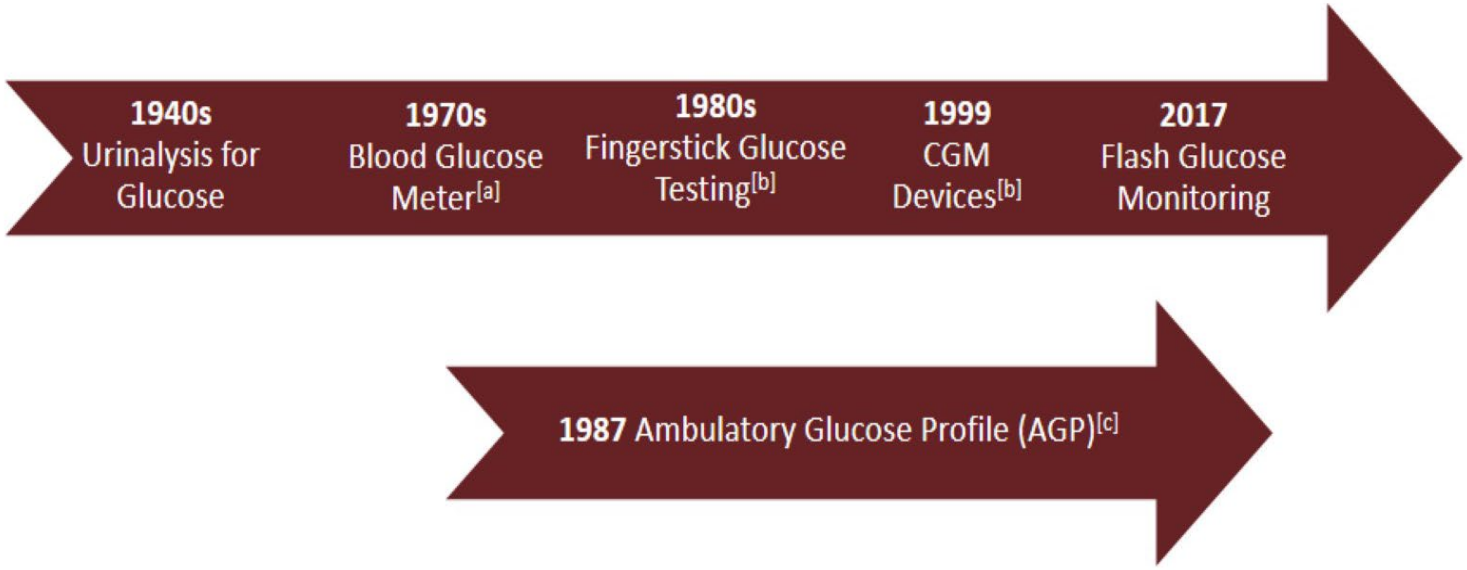
Disclosure to Participants

- I have no conflict of interests or financial relationships to disclose

Learning Objectives

1. Recognize the role of pharmacists in communicating about Continuous Glucose Monitoring (CGM) and providing patient education to improve CGM device selection and optimize adherence
2. Describe opportunities for pharmacists to perform diabetes management activities utilizing CGM.
3. Explain how pharmacists can collaborate with interdisciplinary health care teams to optimize the care of patients with diabetes.
4. Discuss potential outcomes of diabetes management activities provided by pharmacists

Brief History of Glucose Monitoring



a. Clarke SF, et al. *Br J Biomed Sci*. 2012;69:83-93.
b. Mazze RS. *Diabetes Technol Ther*. 2005;7:784-787.
c. Mazze RS, et al. *Diabetes Care*. 1987;10:111-117.

Problems with Current Strategies for Assessing Blood Glucose Control

HbA_{1c}

- Standard of Care, however
  - Impact of **hyperglycemia** and **hypoglycemia** not known
  - Unknown glucose variability

SMBG

- Provides glucose information for only points in time, however:
  - **Hypoglycemia** and **hyperglycemia** are often missed
  - Overnight data is impractical
  - Logbooks are difficult to interpret

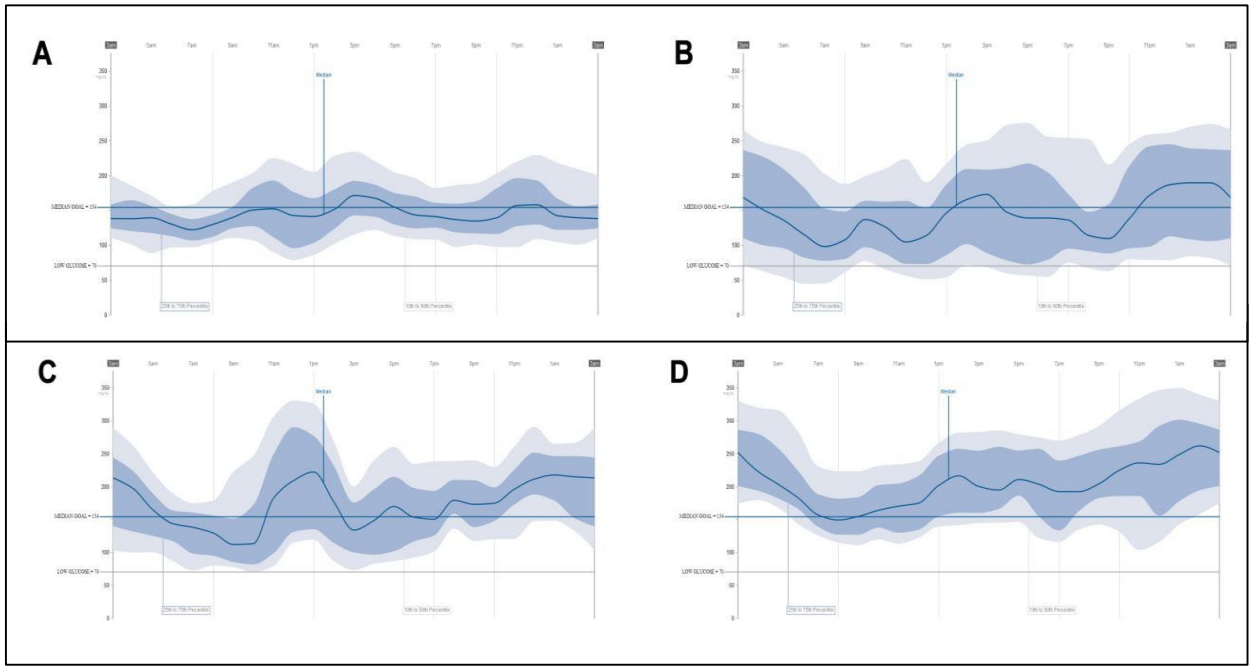
Evert, B. A. (August 4 – Monday, August 7, 2017). Making Sense of Glucose Data Meters and CGM [PowerPoint presentation]. American Association of Diabetes Educators (AADE) Annual Conference, Indianapolis, IN.

Current Strategy: HbA_{1c}

- 90 day average of glycemic control
- HbA1c can't show how glucose levels vary throughout the day.

Current Strategy: HbA_{1c}

Tale of Four Patients with HbA_{1c} between 7.6 to 7.7%



Source: Dunn TC, Hayter GA, Doniger KJ, Wolpert HA. Journal of Diabetes Science and Technology. Published online 17 Apr 2014.

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Did You Bring Your Meter/Log to Your Appointment Today?

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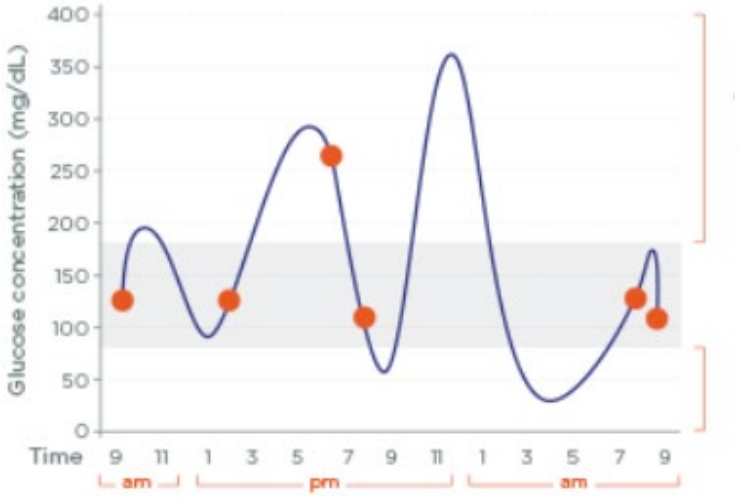
Current Strategy: SMBG

- **Challenges with self-monitored blood glucose (SMBG) handwritten logs:**
  - Organization of data
  - Uncertainty of times checked
  - Lack of individualized targets
  - Readings only provide points in time
  - Hyper- and **<u>hypoglycemia</u>** episodes can often be missed (even when testing blood glucose 6 times per day!!!)
- **Challenges for Pharmacists:**
  - Inadequate time to detect patterns in handwritten logbooks during MTM visits



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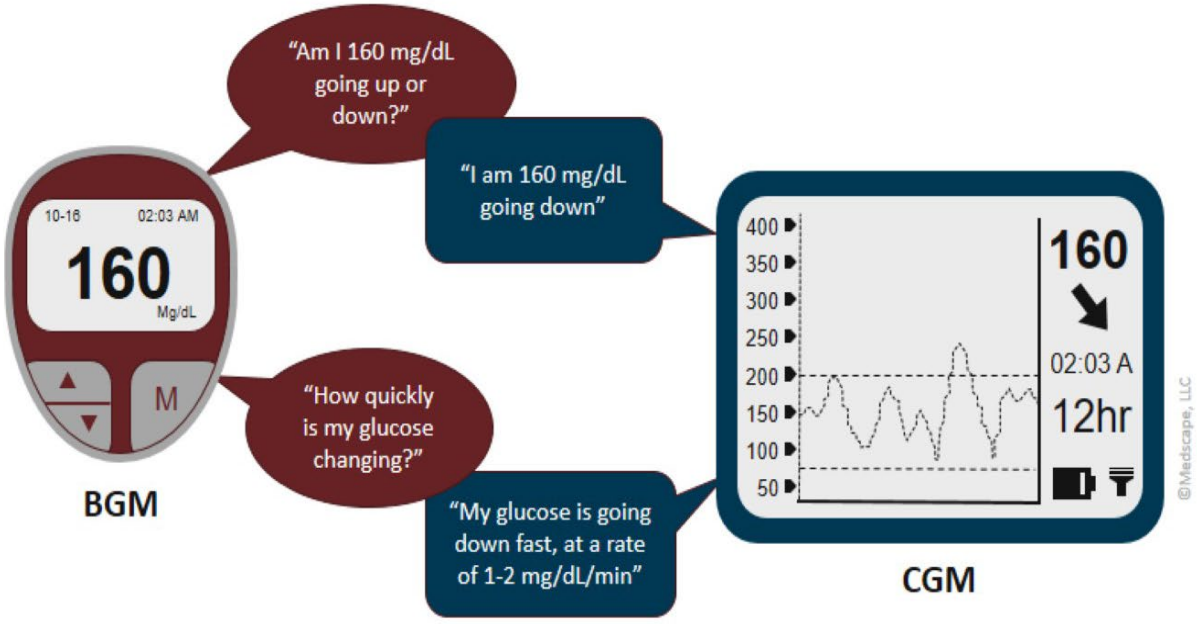
Harris MI. *Diabetes Care*. 24(6):979-982, 2001

Current Strategy: SMBG



CGM can provide the answers and a more complete picture to allow you to make the best decision about your diabetes management

De Block C, et al. *J Diabetes Sci Technol*. 2008;2:718-727.

Patient Case 1

- MJ is a 67-year-old man diagnosed with type 2 diabetes 14 years ago initially treated with lifestyle modification, metformin 500 mg BID, and glyburide 20 mg once daily
- 3 month Follow-up Visit: Worsening glucose control for several months, notes burning sensation in his feet; A1C: 9.4%, FBG 198 mg/dL and PPBG 255 mg/dL. Medications changed as a result to metformin 1000 mg BID, glimepiride 2 mg once daily, and basal insulin 20 units at HS
- After change in meds FBG 65 to 160 mg/dL and PPBG 100-245 mg/dl. Occasional symptoms of hypoglycemia between 9-10 am. Patient's wife told the doctor that last week her husband was "acting confused and irritable" and sweating profusely. The situation resolved after some apple juice. The patient doesn't remember the incident

Patient Case 1

What is your guidance for MJ?

A. Have him monitor his glucose fasting and 2 hours after one meal a day for the next week
B. Stop the glimepiride
C. Lower the basal insulin by 5 units
D. Schedule a diagnostic continuous glucose sensor
E. Increase his glucose targets to 100 mg/dl to 180 mg/dl
F. All of the above

New Strategy: The “Ideal” One

- Ideal monitoring tool for Assessing Blood Glucose Control
  - Actionable insights
  - Affordable
  - Easy to use

New Strategy: CGM

- Benefits of CGM therapy
- CGM provides **dynamic** glucose information
- CGM can help patient with T1D and T2D better manage blood glucose levels throughout the day and anticipate periods **of hypo- and hyperglycemia**

Pharmacist Involvement in CGM

- Assist patients with selection process
  - Select the system most appropriate to the individual needs of each patient
    - Professional
    - Personal
- Explain key differences between CGM and flash glucose monitoring
- Consider device features including accuracy alerts and alarms, data sharing, convenience, and cost

New Strategy: CGM

- Professional
  - Identification of glucose patterns hypo- or hyperglycemia
  - Adjustment of medication
  - New patient/client to your clinic to obtain baseline data
  - Have no idea what is going on
- Personal
  - Ability to see glucose trends
  - Prevention of severe hypoglycemia and reduction of prolonged hyperglycemia
  - Depending on the device can be used as an adjunctive device to complement, not replace, information obtained from SMBG

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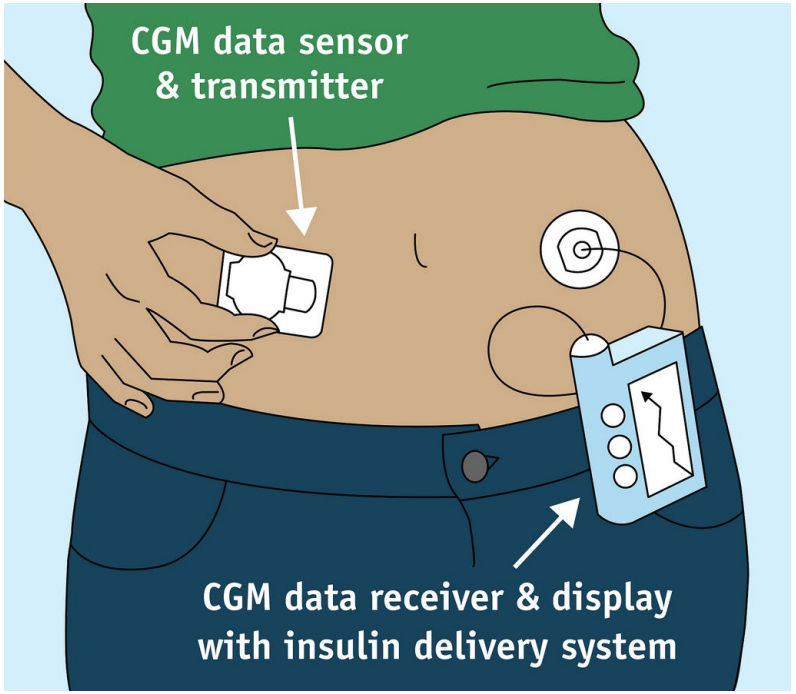
New Strategy: CGM

- Personal CGM in US
  - Hybrid closed loop pump:
    - Medtronic 670G
  - CGM enabled pump:
    - Medtronic 530G + Revel
    - Animas Vibe+G4
    - Tandem t:slim+G4
  - Stand Alone:
    - DexCom G5 + G4
  - Flash Glucose Monitoring
    - FreeStyle Libre



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New Strategy: CGM

- Professional CGM in US
  - Medtronic i-Pro2
  - Dexcom G4
  - Freestyle Libre Pro

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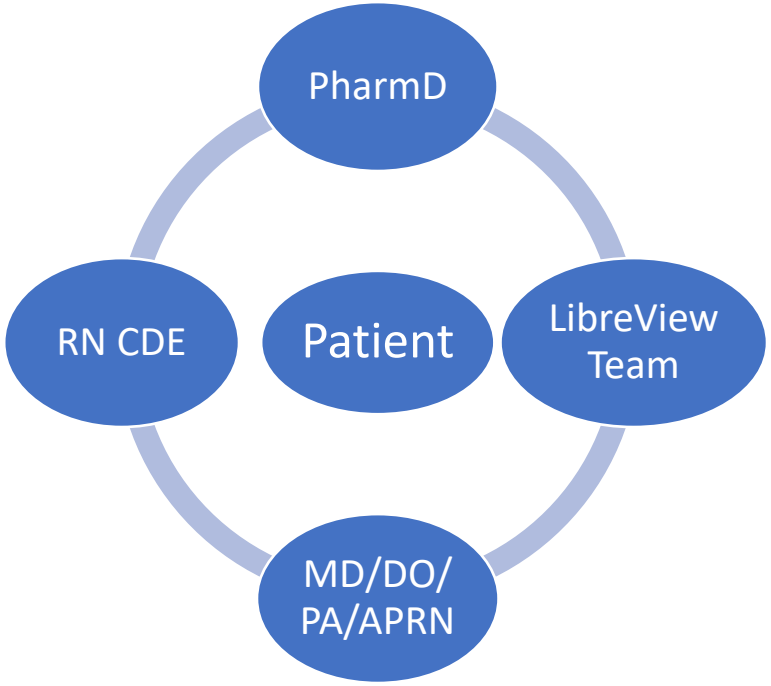
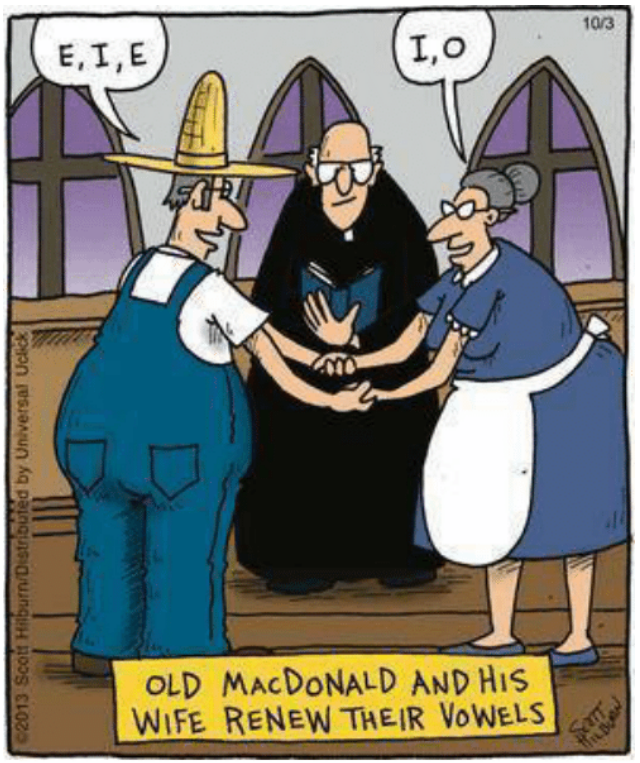
ARcare CGM Pilot Project The Dream Team

The Dream Team





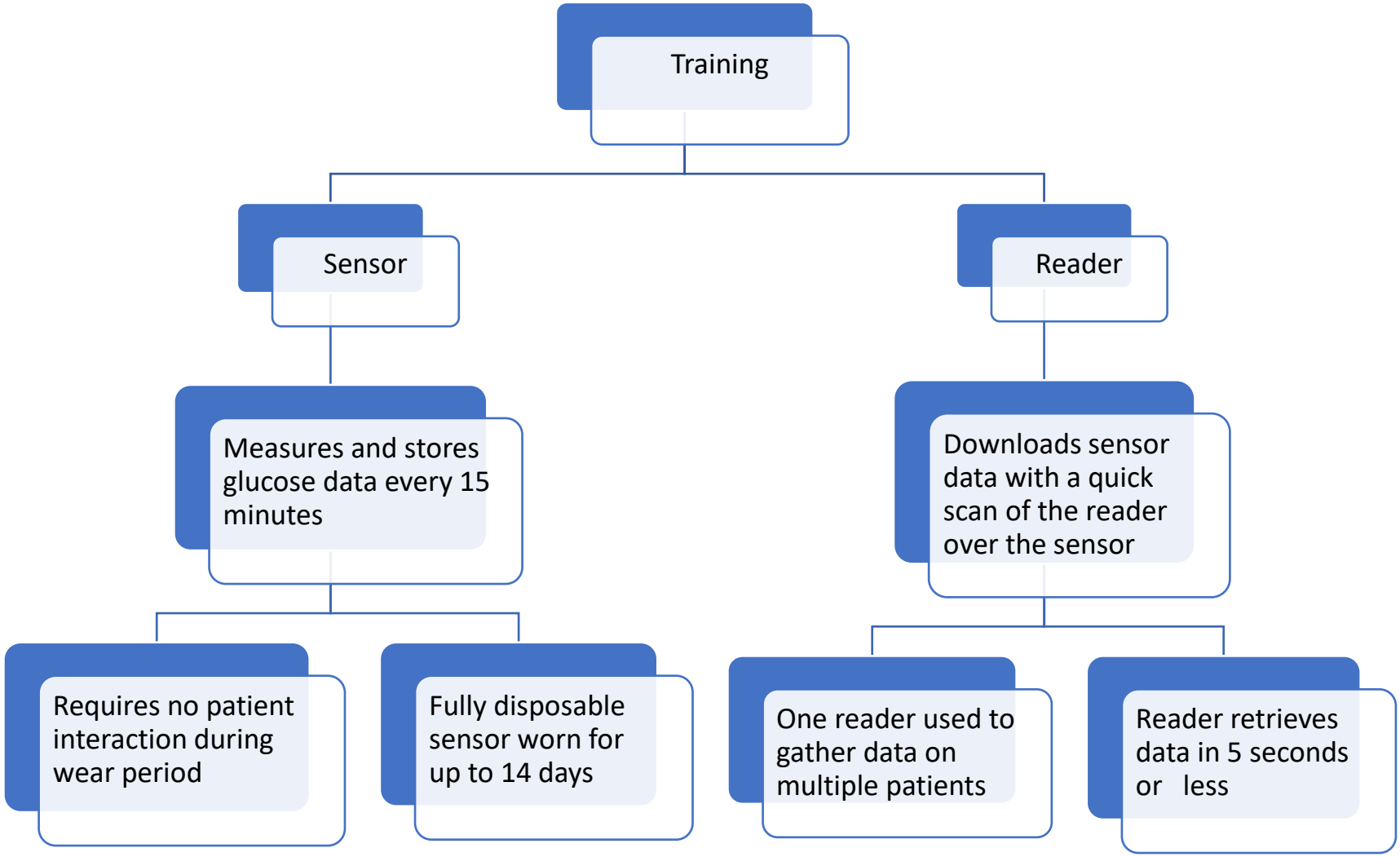
He fought a consonant battle to keep his wedding vowels.

ARcare CGM Pilot Project

The Team

Libre	RN CDE	PharmD	Provider	Patient
• Ask • Advise • Assess • Assist • Arrange	• Establish • Educate • Encourage • Empower • Engage	• Install • Interpret • Investigate • Inform • Improve	• Open-minded • Overseer • On the Ball • Okay • Order	• Use • Unearth • Understand • Under control • Uplifted

ARcare CGM Pilot Project



ARcare CGM Pilot Project

1 Application	2 Recording	3 Download	4 Interpretation
			
HCP applies a sensor onto patient at clinic.	Sensor is worn for up to 14 days and records glucose readings continuously.	Patient returns to the clinic. HCP scans the sensor to download the glucose data.	Reports generated from the data are interpreted by an HCP and used in patient consultation.
<5 min	Up to 14 days	<5 min	~10 min

ARcare CGM Pilot Project

- Therapeutic Insulin Dosing
  - CGM data used to initiate/adjust insulin regimen

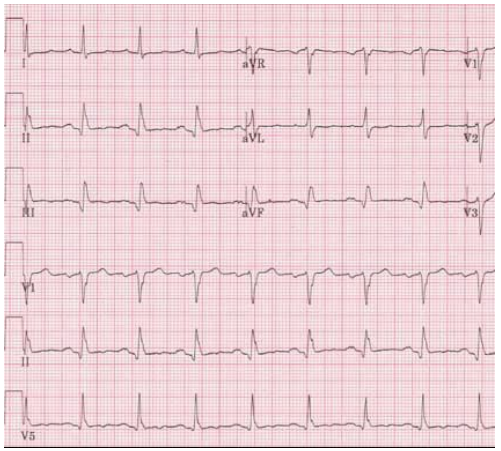
Pettus J, et al. Diabetes Technof Ther. 2016;18(Suppl 2):S234-S242.

Standard CGM Report

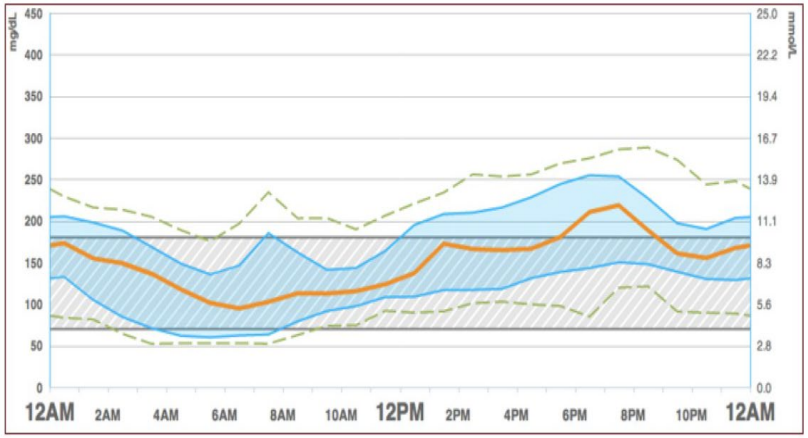
- Characteristics
  - Primary display should highlight actionable data, such as:
    - Current glucose level
    - Glucose trend arrows
    - Graphs showing glucose trends over past day
  - Trigger for hypoglycemia alerts
    - <70 mg/dL
  - Downloadable and customizable report
  - Produce a standardized report that includes such metrics as:
    - Time in range
    - Glycemic variability
    - Patterns of hypoglycemia and hyperglycemia

CONTINUOUS GLUCOSE MONITORING: A CONSENSUS CONFERENCE OF THE AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY. Endocrine Practice: August 2016, Vol. 22, No. 8, pp. 1008-1021.

Standard CGM Report



- Multiple devices:
  - Each device comes with proprietary software
  - Large amounts of data
- In 2012, the International Diabetes Center suggested using the Ambulatory Glucose Profile (AGP) as a standard glucose report
- The 24 hour AGP has the ability to standardize glucose reporting
- Similar to an EKG, the hope is that the AGP can be the standard glucose report to interpret



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Pharmacist Involvement: CGM

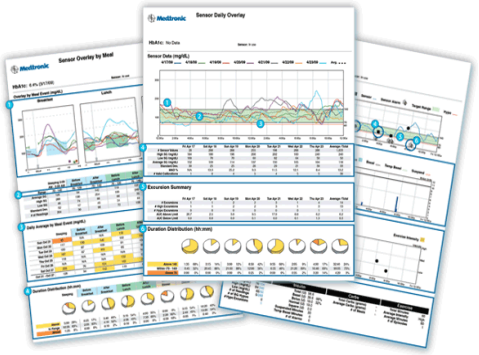
- Pharmacist can use the AGP to simplify the patient's life by:
  - Minimizing glucose variability
  - Identifying patterns
  - Determining Time in range
    - Determining time in low range
    - Determining time above range
  - Data can be used to promote change in treatment and/or patient lifestyle decisions
    - Better understanding of how diet, physical activity, and medications affect glucose levels

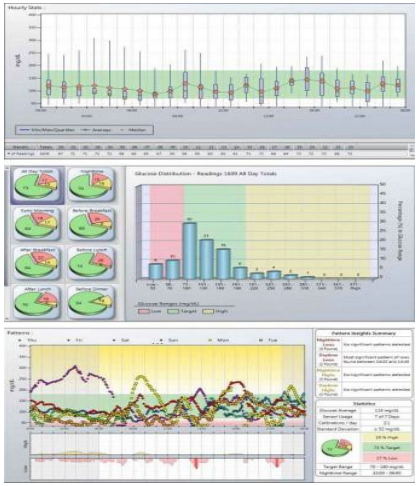
Pharmacist Involvement: CGM

- The pharmacist can optimize adherence and improve outcomes by:
  - Aid understanding and utilization of the CGM and the AGP report
  - Ensure patients are using CGM properly
  - Use CGM/ADP reports to help patient identify glycemic trouble spots
  - Look for patterns of hypo – and hyperglycemia
  - Review nutrition.
  - Assist in carbohydrate counting
  - Explain how and when to administer insulin and other medications.

CGM Reports

- Although each CGM company has different generated reports, the information is generally the same and includes:
  - Statistics/Summaries
  - Birds Eye View
  - Daily View





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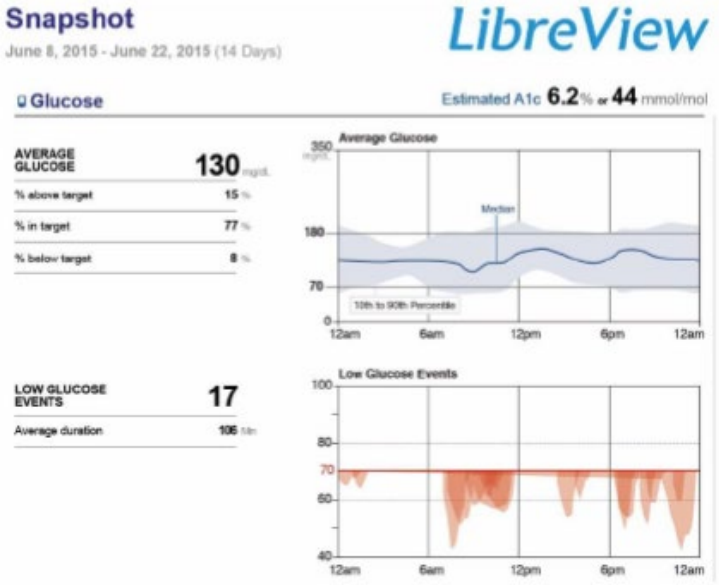
Statistics/Summary Reports

- Provide valuable information
  - Time in target range compared to time high or low
  - Accuracy of the sensor data
  - Quantitative analysis of glucose excursions



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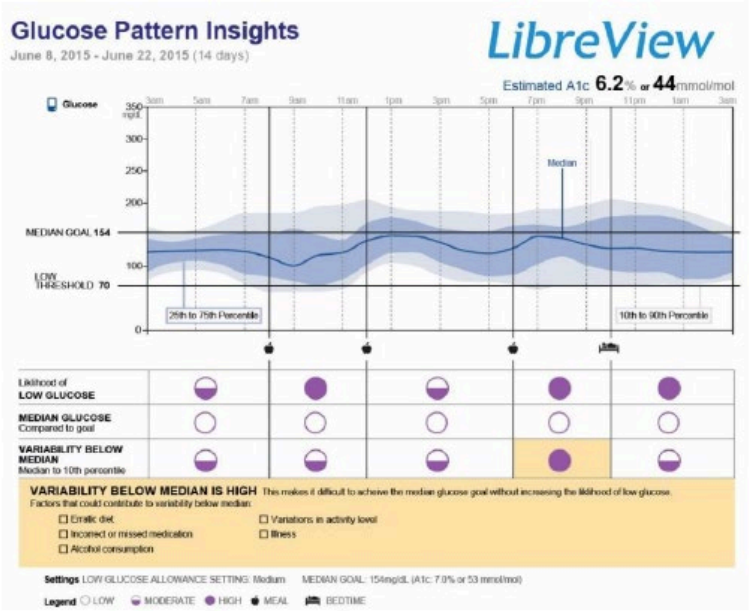
Birds Eye View

- Identify glycemic patterns (or lack of patterns)
  - Identifies glycemic patterns by overlaying the sensor readings of each day into one graph
  - Can assist in pattern and trend recognition.



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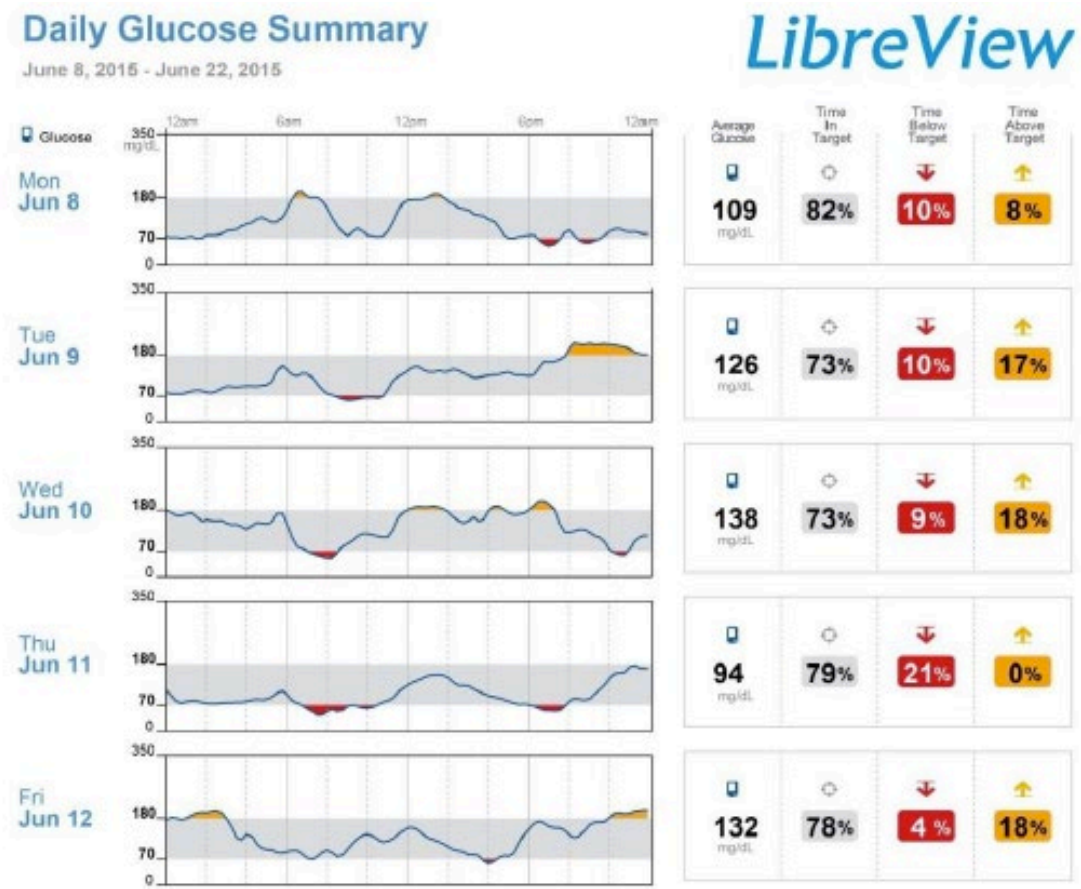
Daily View


Daily Glucose Summary
June 8, 2015 - June 22, 2015
LibreView
Glucose
12am
6am
12pm
6pm
12am
350
mg/dL
180
70
0
Mon Jun 8
Tue Jun 9
Wed Jun 10
Thu Jun 11
Fri Jun 12
Average Glucose
Time In Target
Time Below Target
Time Above Target
109 mg/dL
82%
10%
8%
126 mg/dL
73%
10%
17%
138 mg/dL
73%
9%
18%
94 mg/dL
79%
21%
0%
132 mg/dL
78%
4 %
18%

Patient Case 2

- JD – T1D, Asperger Syndrome, age 47, BMI: 28
  - 80+ year old parents
  - Lives at home alone
  - MDI: glargine 35 BID, lispro 20 units per meal
- A1c: 13%
- SMBG: Average - 183 mg/dL SD: 87
- Frequency SMBG: < 1 x/day

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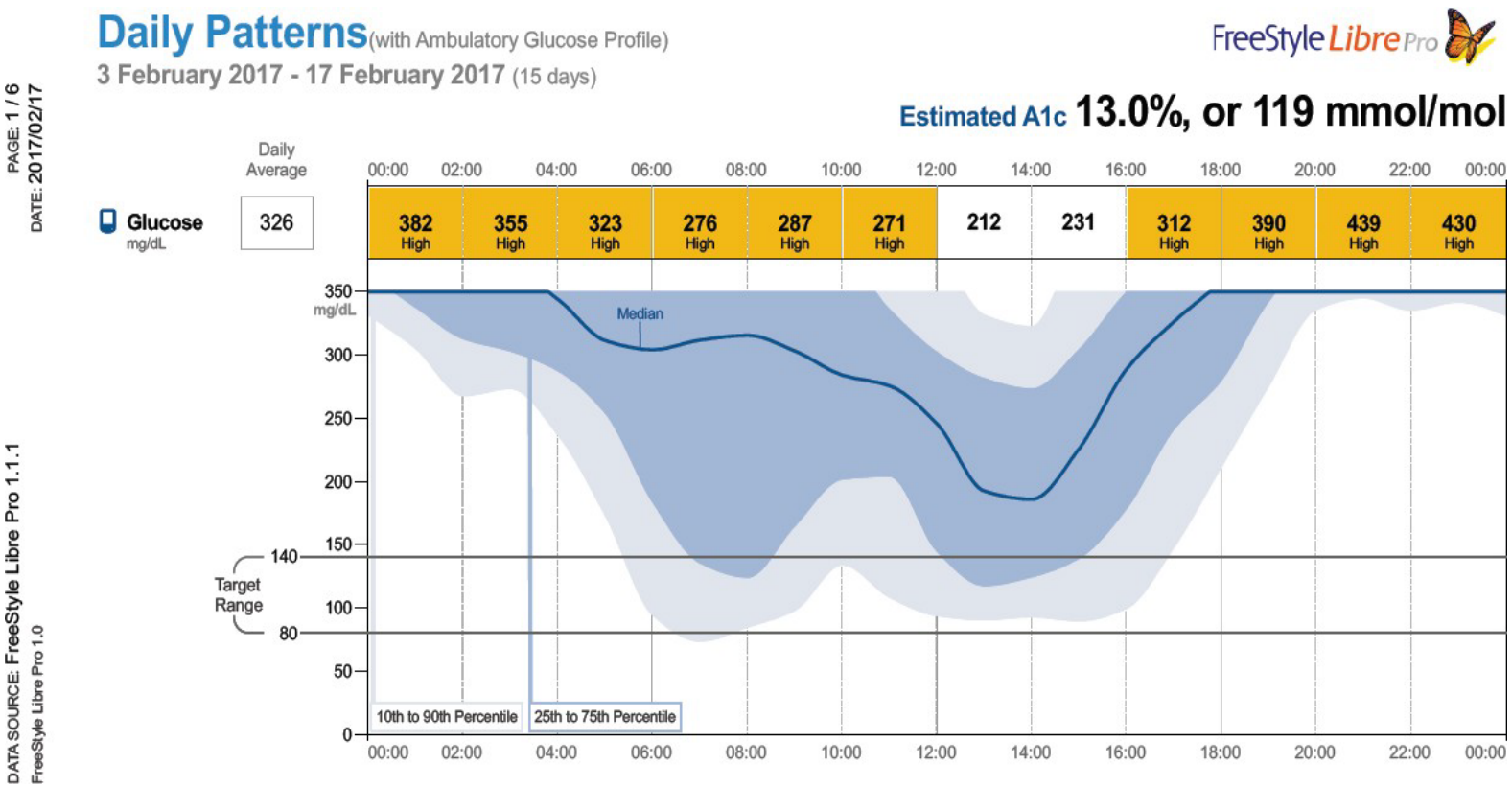
Patient Case 2



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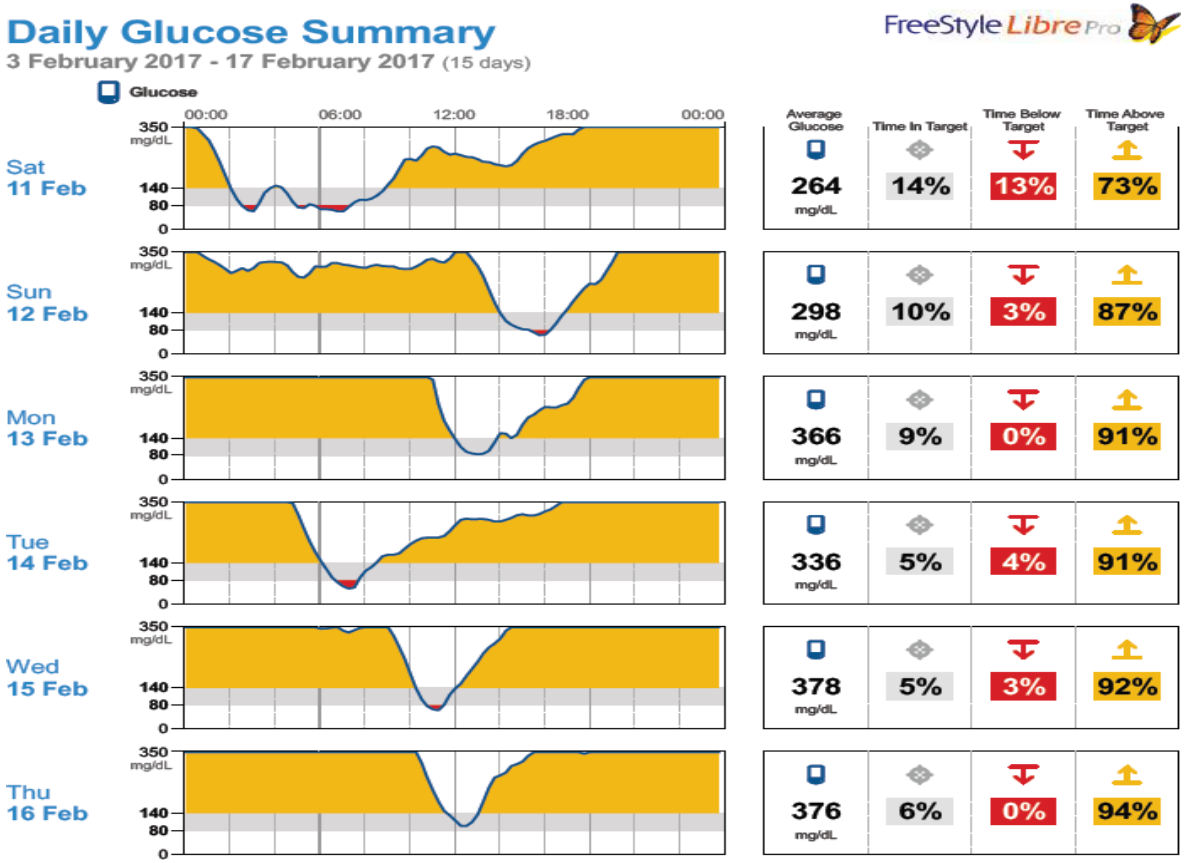

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Patient Case 2

- What do you believe is causing this patient's variations in blood glucose levels?
  A. Inconsistent medication use
  B. Inconsistent lifestyle (i.e. nutrition, physical activity)
  C. Insufficient insulin dose
  D. Inappropriate insulin regimen
  E. I have no idea, but I want to learn and help

Patient Case 3

- LJ - T2D x 28 yrs
  - Recently dx CKD stage 3, neuropathic pain in his feet and hands
  - BMI: 38
  - “Wake-up” call after learning of decline in renal function
  - First appointment ever with PharmD after CGM
- MDI:
  - Basaglar 25 units BID
  - Aspart – 10-20 units per meal based on “if he feels his sugar is high”

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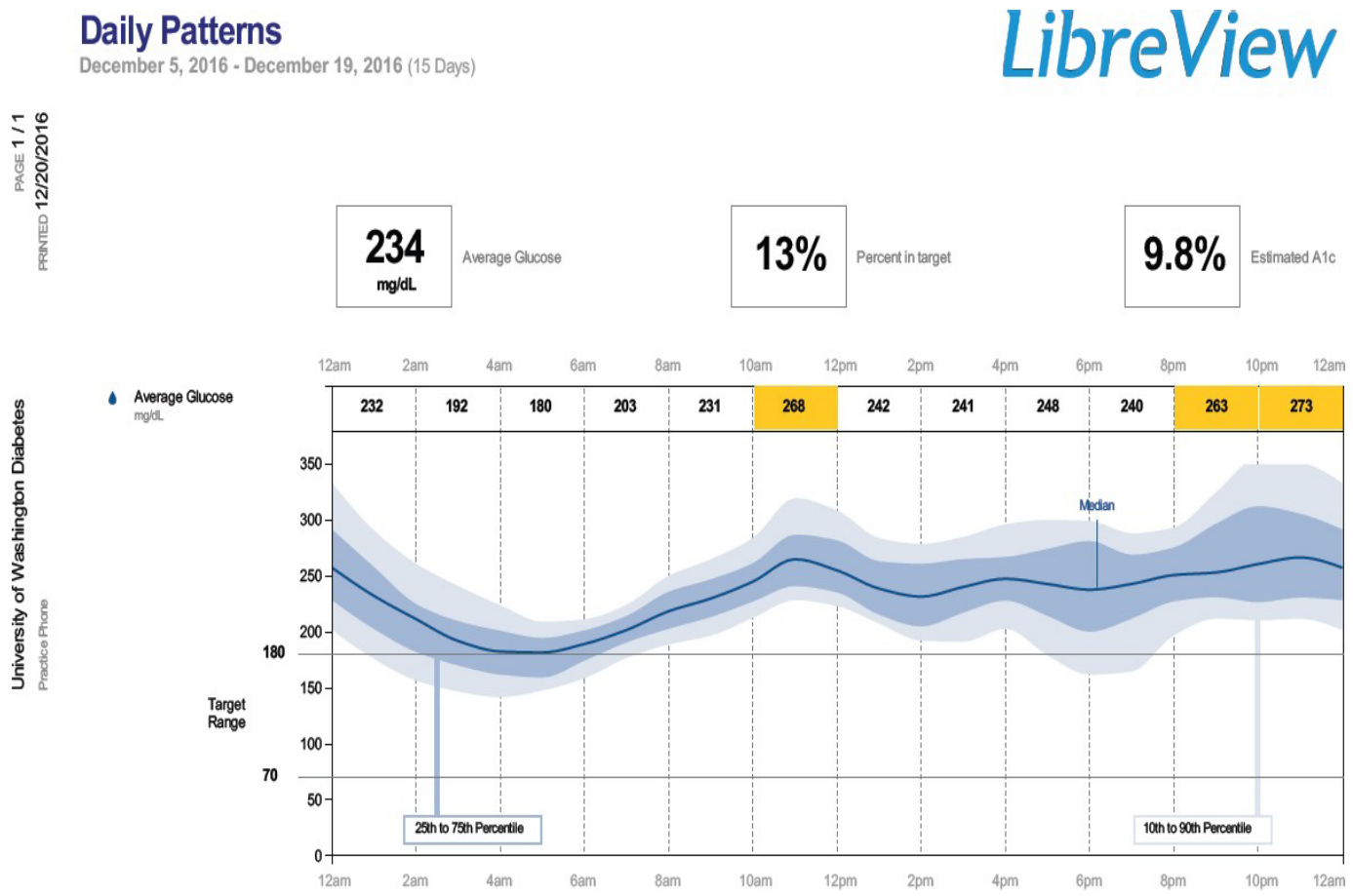
Patient Case 3



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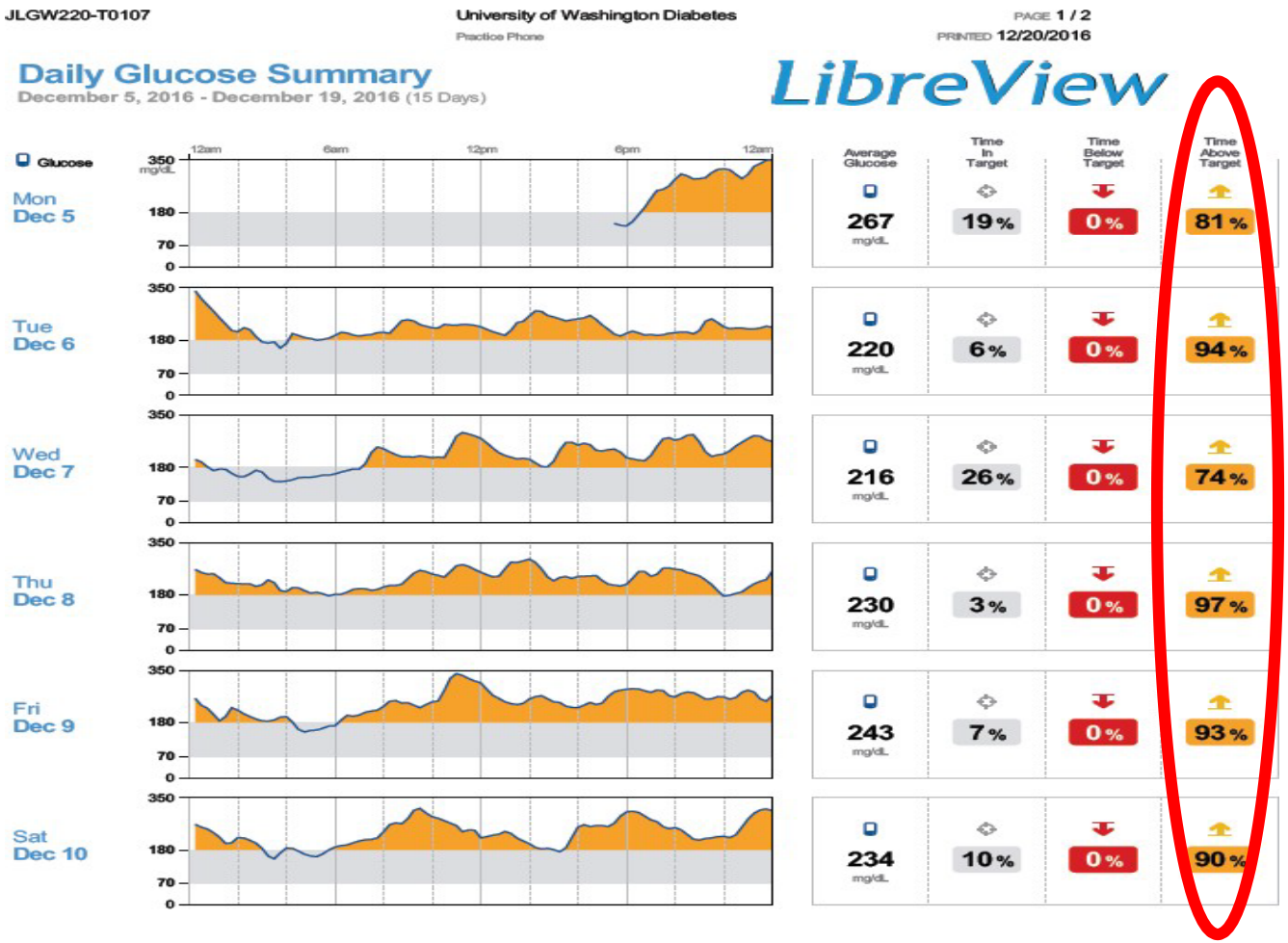

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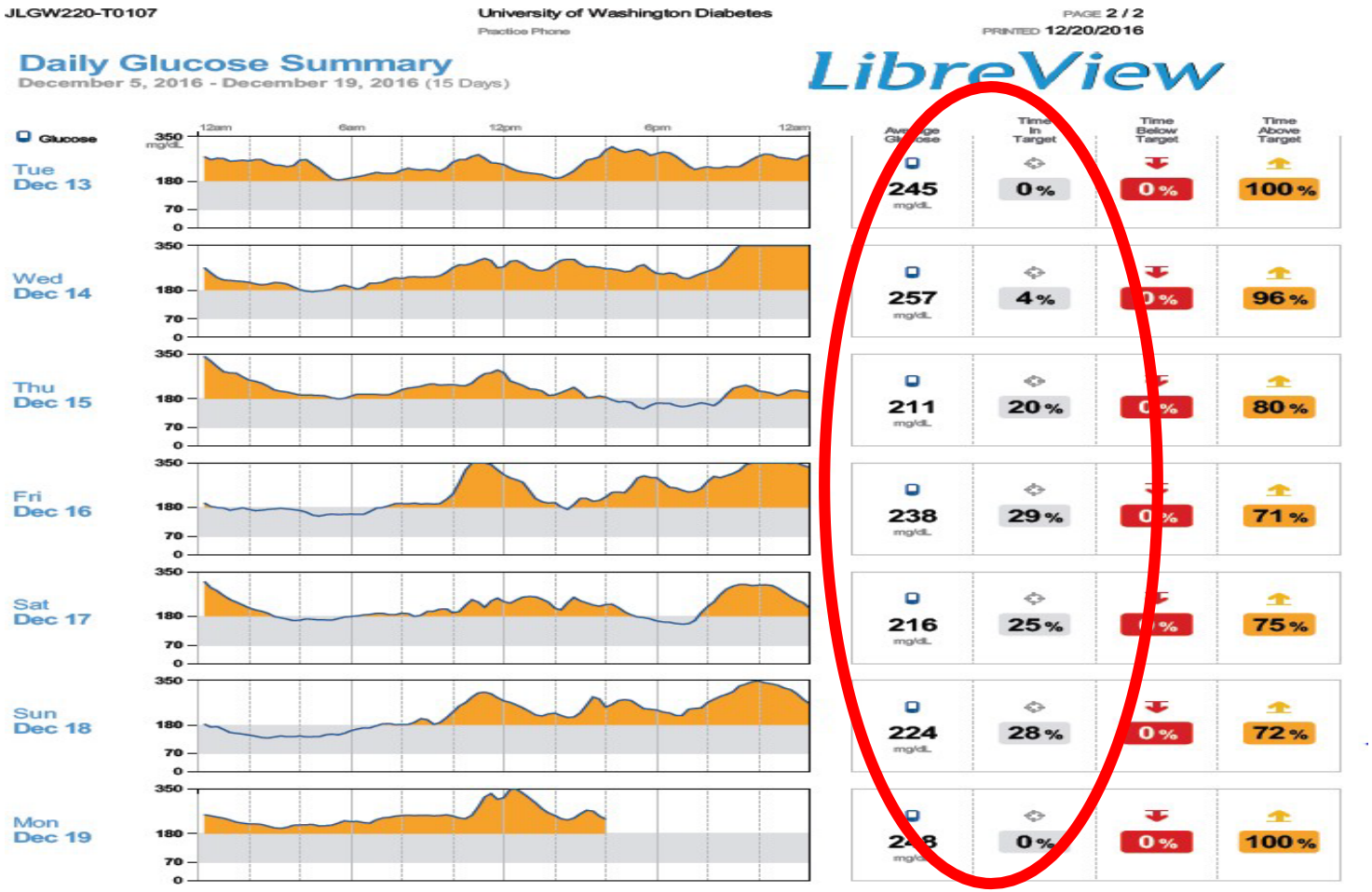

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  C. Insufficient insulin dose
  D. Inappropriate insulin regimen
  E. I have no idea, but I want to learn and help

Patient Education and Counseling

- **What the FreeStyle Libre Pro Sensor Does**
  - “The FreeStyle Libre Pro sensor continually measures and stores your sugar levels for up to 14 days.”
  - “After you’ve worn the sensor for up to 14 days, your doctor will download data from it that will give information about how your sugar levels are trending throughout the day and night. This will help your doctor personalize your treatment plan.”

Patient Education and Counseling

What the Patients Needs To Do*:

- Wear the sensor on the back of upper arm for up to 14 days
- **Continue regular blood glucose self-testing** per your doctor's recommendation
- Maintain a daily log of your blood glucose readings, diet, exercise, and insulin
- There's no need for you to interact with the sensor.
- Just go about your daily routine.
- Watch for medications that contain acetaminophen (can falsely raise BG readings)

Contact pharmacist or prescriber if:

- Sensor becomes loose or is removed
- Develop irritation or discomfort at the sensor site
- Have questions about sensor

*Note some devices may have different instructions

Patient Education and Counseling

- To avoid accidentally loosening or removing sensor counsel patients on these precautions:
  - Can be worn while bathing, showering, or swimming as long as it is not taken deeper than 3 feet or kept underwater for longer than 30 minutes at a time
  - Avoid catching the sensor on clothing while getting dressed
  - Intense exercise may cause the sensor to loosen due to sweat or movement of the sensor
  - If a patient has an MRI, a CT scan, or a diathermy treatment, he/she must remove sensor prior to the procedure.
  - Notify security of sensor at airport checkpoints

Patient Education and Counseling

- Removing the sensor:
  - Pull up the edge of the adhesive
  - Slowly peel away from skin in one motion
  - Note: Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.

Evidence in Favor of CGM

The Impact of Continuous Glucose Monitoring on Markers of Quality of Life in Adults With Type 1 Diabetes: Further Findings From the DIAMOND Randomized Clinical Trial

William H. Polonsky,[1,2] Danielle Hessler,[3] Katrina J. Ruedy,[4] and Roy W. Beck,[4] for the DIAMOND Study Group

Diabetes Care 2017;40:736–741 | https://doi.org/10.2337/dc17-0133

CONCLUSIONS

CGM contributes to significant improvement in diabetes-specific QOL (i.e., diabetes distress, hypoglycemic confidence) in adults with T1D, but not with QOL measures not specific to diabetes (i.e., well-being, health status). CGM satisfaction was associated with most of the QOL outcomes but not with glycemic outcomes.

Evidence in Favor of CGM

- DIaMonD Study: Multiple Daily Injections and Continuous Glucose Monitoring in Type 2 Diabetes

Ann Intern Med. 2017;167(6):365-374.

Indication for Use of CMG

- CGM may become more widely used following the Medicare approval of a new category called: “Therapeutic CMG” which applies if:
  - The beneficiary has diabetes mellitus; and,
  - The beneficiary has been using a home blood glucose monitor (BGM) and performing frequent (four or more times a day) BGM testing; and,
  - The beneficiary is insulin-treated with multiple daily injections (MDI) of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,
  - The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of therapeutic CGM testing results.

Who Benefits From CGM

Individuals with "undue" glucose variability

Individuals with T1D or T2D who have rapid increases and decreases in blood glucose

Individuals who have pronounced blood glucose reactions to stress

Individuals with T1D or T2D who have elevated HbA_{1c}

Individuals who perform multiple fingerstick tests/day

Individuals who regularly exercise

Patients taking rapid-acting insulin or MDI

Many people can benefit from CGM

Bailey TS, et al. *Endocr Pract*. 2016;22:231-261.

ADA Guidelines – Assessment of Glycemic Control

- SMBG and A1C have been available to health care providers and patients to assess the effectiveness and safety of a management plan on glycemic control
- CGM has gained an important role in assessing the effectiveness and safety of treatment in subgroups of patients with type 1 diabetes and in selected patients with type 2 diabetes
- Data indicate similar A1C and safety with the use of CGM compared with SMBG

American Diabetes Association; 6. Glycemic Targets: Standards of Medical Care in Diabetes—2018. Diabetes Care 1 January 2018; 41 (Supplement_1): S55–S64. https://doi.org/10.2337/dc18-S006

ADA Guidelines – Assessment of Glycemic Control

- **SMBG**
  - For patients using intensive insulin regimens (multiple-dose insulin or insulin pump therapy)
  - May help guide treatment decisions and/or self-management for patients taking less frequent insulin injections or noninsulin therapies
  - Key is to ensure that patients receive ongoing instruction and regular evaluation of SMBG technique, results, and their ability to use data to adjust therapy
- **CGM**
  - Used in conjunction with intensive insulin regimens to lower A1C in adults with type 1 diabetes who are not meeting glycemic targets
  - May be a useful tool in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes.
  - Key is to assess individual readiness for continuing CGM use prior to prescribing
  - Requires robust diabetes education, training, and support for optimal implementation and ongoing use
  - People who have been successfully using CGM should have continued access after they turn 65 years of age

American Diabetes Association; 6. Glycemic Targets: Standards of Medical Care in Diabetes—2018. Diabetes Care 1 January 2018; 41 (Supplement_1): S55–S64. https://doi.org/10.2337/dc18-S006

AACE/ACE Statement on CGM

CGM is likely to provide significant benefits to the following patient populations, although additional studies are needed:

- Patients older than 65 years with comorbidities and/or at risk for severe hypoglycemia
- Women with diabetes who are or are planning to become pregnant as well as women with gestational diabetes
- Patients with kidney disease
- Patients with diagnosed hypoglycemia unawareness
- Cost-effectiveness **studies are needed** to further document healthcare cost reductions associated with CGM.

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AACE/ACE Statement on CGM

- Extensive data from randomized controlled and other trials support the use of CGM in children and adults with **type 1 diabetes (T1D)**
- CGM may have similar benefits in insulin-using patients with type 2 diabetes (T2D) and pregnant women with diabetes
- Advances in CGM technology have improved the accuracy and reliability of these devices
- CGM is likely to reduce costs associated with hypoglycemia and severe hyperglycemia by alerting patients to impending or actual low or high glucose values and thereby facilitating prompt action and prevention of hospitalizations
- CGM use may also **reduce healthcare costs** due to chronic diabetes complications, although more studies of the economic impact of CGM are needed

CONTINUOUS GLUCOSE MONITORING: A CONSENSUS CONFERENCE OF THE AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY. Endocrine Practice: August 2016, Vol. 22, No. 8, pp. 1008-1021.

AACE/ACE Statement on CGM

- CGM data should be evaluated in context with other variables such as meals, treatments, exercise, illness, insulin boluses, and automated insulin delivery activity.
- Standardized metrics and reporting among available CGM devices would facilitate understanding by patients and clinicians and promote wider adoption of CGM technology.
- Automated, rapid access to CGM data is essential for utilization by clinicians and useful for patients.

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AACE/ACE Statement on CGM

- Whether CGM is used intermittently or continuously, patients should generally be able to see and react to glucose data.
- However, masked CGM may be beneficial when used intermittently with advice and supervision from clinicians
- CGM reports should be interpreted by trained clinicians but should include summary reports designed to be understood by patients
- CGM training for clinicians should be made widely available to all involved in diabetes management and should encompass the use and interpretation of CGM data as well as the delivery of CGM patient education
- CGM certification should not be required, as this would add another barrier and hinder wider adoption of CGM technology

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Call to Action

- Provide Patient education
  - **DON'T STOP TESTING! Unless you are told not to**
  - The FreeStyle Libre Pro sensor is not a replacement for SMBG
  - Continue your normal testing routine while wearing the sensor
- Health Care Providers education
  - HbA1c does not provide information on daily glucose patterns
  - Patients may experience periods of hyper- and hypoglycemia throughout the day, despite HbA1c levels measuring within the target range
  - Patients with similar HbA1c levels can have very different daily and nocturnal patterns of glucose excursions and rates of hypoglycemia

Call to Action

- Pharmacists are front-and-center
- Pharmacists can educate patients when they pick up test strips at the pharmacy
- Pharmacists can help transition patients to CGM and ensure they understand why CGM will be useful in their lives
- CGM can help improve diabetes management and be a valuable patient education tool
- Use CGM data in addition to HbA1cand SMBG to recommend medication changes
- Encourage patients to talk to their providers about CGM and flash glucose monitoring as appropriate

Pharmacist Role in Continuous Glucose Monitoring (CGM)

Gabriella Douglass, Pharm.D., BCACP, AAHIVP, BC-ADM
Assistant Professor, Harding University College of Pharmacy
Community Pharmacy Residency Program Director, ARcare
gdouglass@harding.edu