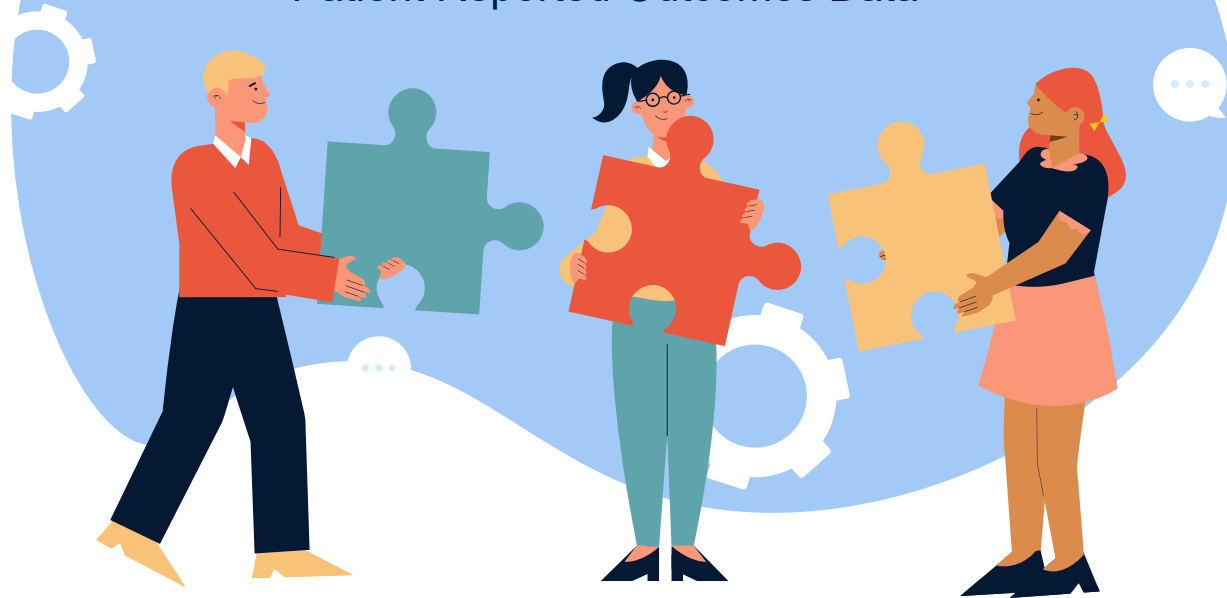


Keeping Blood Glucose Sweet NLow

Optimizing Continuous Blood Glucose Monitoring with
Patient Reported Outcomes Data



OUR TEAM



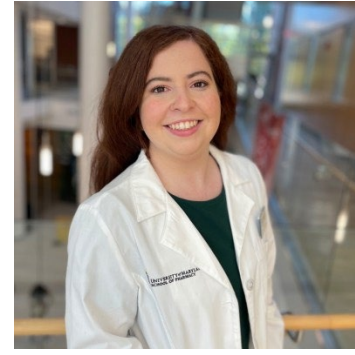
Sabrina
Wang



Joanna
Shaju



Sumbel
Malik



Rebecca
Faulkner



Ivan
Baizon

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OUR MAIN OBJECTIVE



**Optimize use of current CGM technology
to implement more subjective data and
improve interface experience of diabetic
patients**

01 BACKGROUND

Continuous Glucose Monitoring



- What?
 - A non-invasive method of consistently checking a patient's blood glucose
- When?
 - Before CGM: finger prick testing
 - 1999: First FDA approved continuous glucose monitoring system
 - 2016: First long term wear CGM technology with direct patient use
- Who?
 - Approximately 2 million Diabetics utilize a CGM device

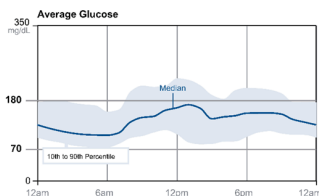
Freestyle Libre

Snapshot

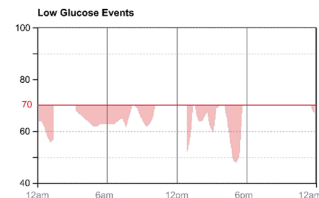
February 27, 2020 - March 11, 2020 (14 Days)

Glucose

AVERAGE GLUCOSE	141 mg/dL
% above target	19 %
% in target	77 %
% below target	4 %

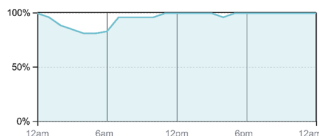


LOW GLUCOSE EVENTS	4
Average duration	202 Min



Sensor Usage

SENSOR DATA CAPTURED	97 %
Daily scans	4



LibreView

DAILY CARBS **351** gram/day

INSULIN

RAPID-ACTING INSULIN unit/day

Meal

Correction

User Change

Manual

LONG-ACTING INSULIN unit/day

Total Daily Insulin unit/day

Comments

• There was a ketone test. The result was 0.6 mmol/L.

• Gaps found in the insulin data. 14 days

in this reporting period have no recorded insulin events.

• Gaps found in food data. 1 day in this reporting period has no recorded food events.

Jack Smith
DOB: 03/10/1980
MRN: _____
DEVICE: FreeStyle Libre

PreProd
PHONE: 7607101920

PAGE: 1 / 1
GENERATED: 12/20/2019

AGP Report

December 7, 2019 - December 20, 2019 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

December 7, 2019 - December 20, 2019 **14 Days**
% Time CGM is Active **97%**

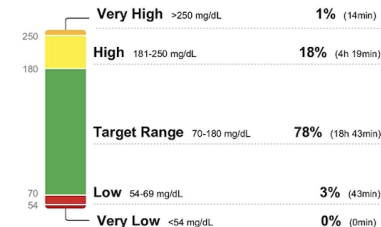
Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	Targets % of Readings (Time/Day)
Target Range 70-180mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (57min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h 0min)
Above 250 mg/dL	Less than 5% (1h 12min)

Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.

Average Glucose **141** mg/dL
Glucose Management Indicator (GMI) **6.7** %
Glucose Variability **31.6** %

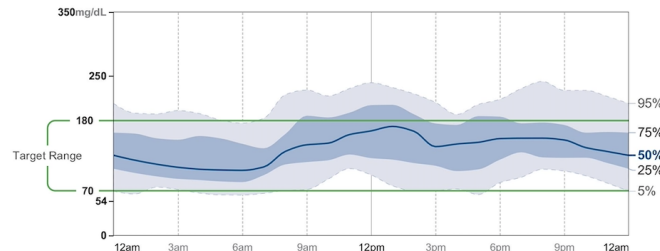
Defined as percent coefficient of variation (%CV); target ≤36%.

TIME IN RANGES



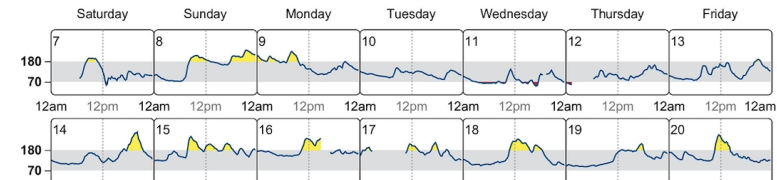
AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.

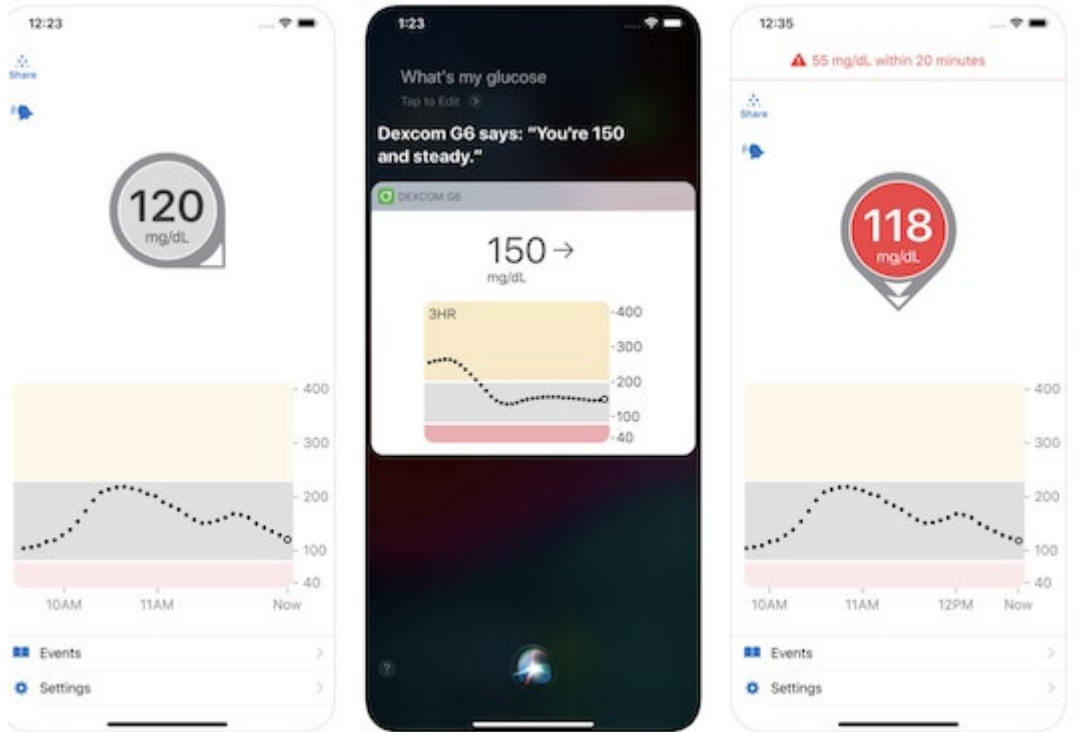


DAILY GLUCOSE PROFILES

Each daily profile represents a midnight to midnight period with the date displayed in the upper left corner.

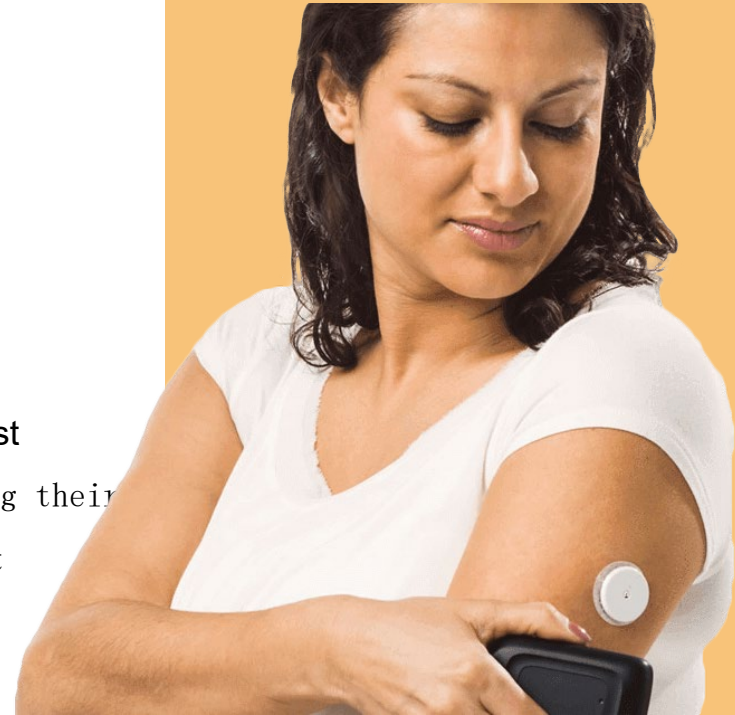


Patient Interface



PROBLEM 02

- **Diabetes control is personal**
 - Needs patient's subjective input
- **More involvement and actionable items**
- **Should be instantly implementable**
 - No need to wait for a healthcare professional
- **CGM Adherence levels**
 - “Only 27% of users downloaded data from their device at least once per month, and $\leq 15\%$ of users reported downloading their device at least weekly. Among participants who used CGM at baseline, 41% had discontinued within 1 year,” (Wong et al, 2014).



FDA Center/Office Regulatory Science Research Priority Areas for CERSI Program

Implement patient
input into
regulatory- decision
making

Patient reported
outcomes offer
personalized
feedback

Analysis of
effectiveness,
safety, and patient
experience

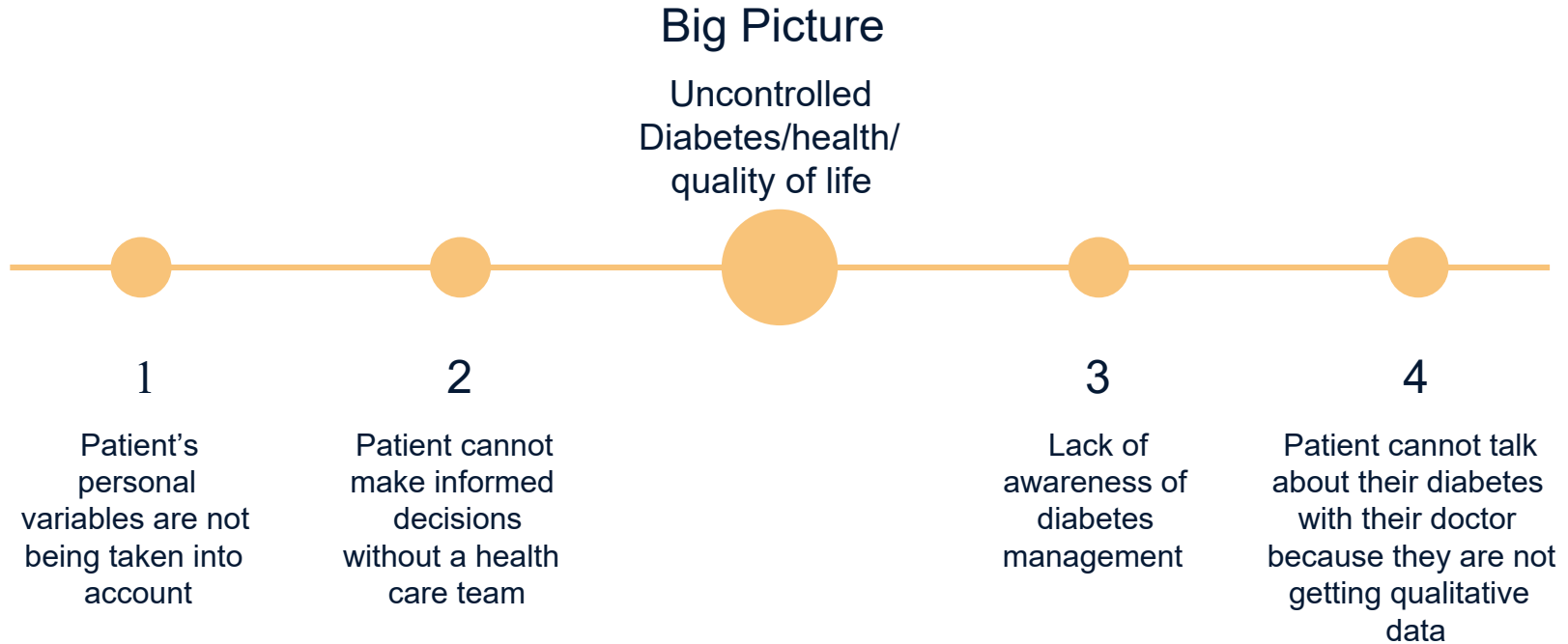
03



CONSEQUENCES



HOW IS THIS AFFECTING PATIENTS?



04

SOLUTION

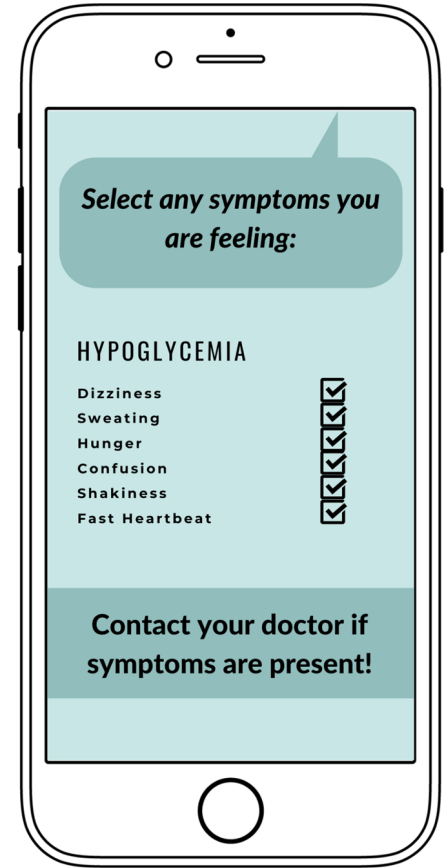
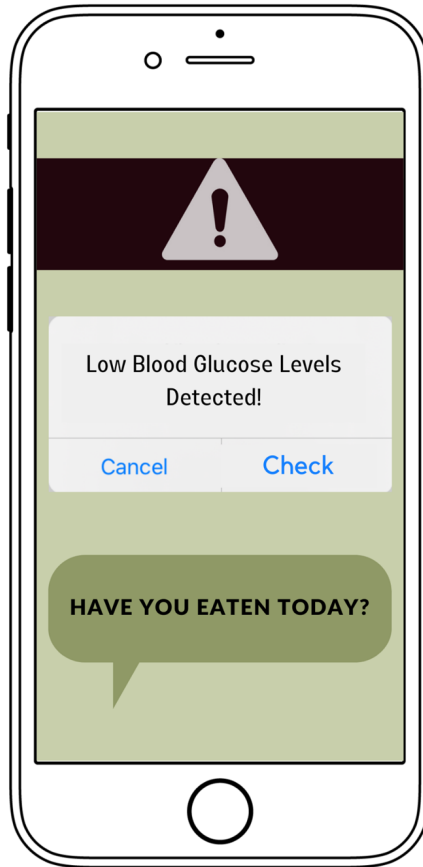
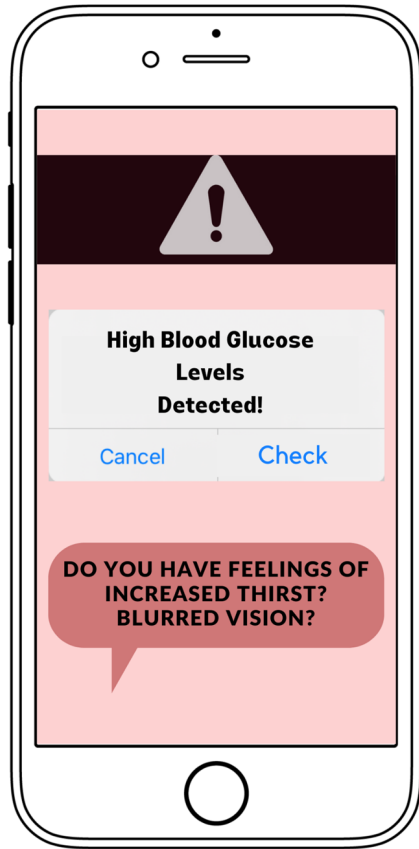
Enter... Patient Reported Outcomes (PROs)!



Proposal

Design a standardized interface that:

- Allows input of patient's subjective data
 - Symptoms
 - Daily Activity
 - Health Complications
- Logs food and calorie intake
- Simplifies and extracts data that is collected from the CGM
- Displays a series of prompts that appear when a patient's glucose levels are out of range.
 - Have you eaten recently?
 - Are you thirsty?
 - Do you have blurry vision?
- Can be incorporated with existing CGM programs



RELEVANCE

05

“

Most [diabetic patients] described needing and expecting health professionals to interpret historical CGM data and determine changes to background insulin doses and mealtime ratios...

”

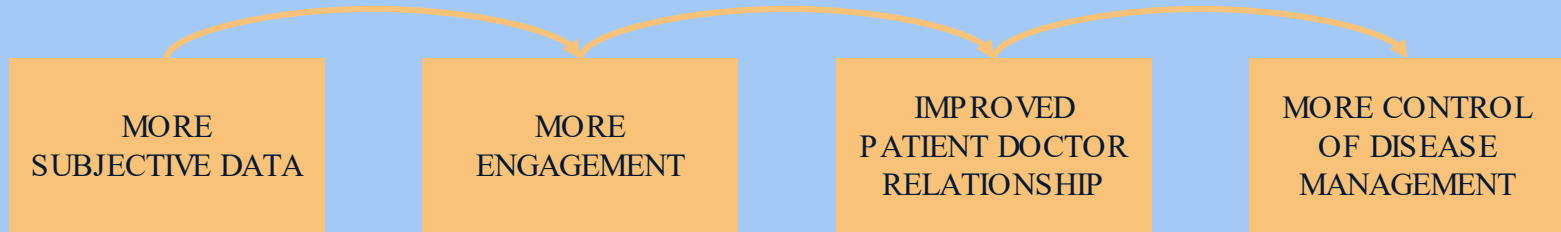
Results of PROs in Diabetes Management

- Incorporating PROs into diabetes interventions has been shown to improve HbA1c levels.
- PROs can also provide supplemental information regarding diabetes complications



06

IMPACT



THANKS!

Do you have any questions?

We would like to thank our advisors Dr. James Polli and Dr. Sandy Weinger for their help!

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