

Saint James School of Medicine, Hugues Medical Center, and Aegle Monitoring Technologies

# Assessing Clinical Outcomes and Monitoring A1C Levels in patients living with diabetes in Anguilla in Reference to the Aegle Glucose Monitoring Technology

A longitudinal cohort study in Anguilla

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# Background and Significance

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## Current Landscape in treating T2DM?

Continuous Glucose-Monitoring Devices are widely used in Europe and the United States.

Their availability is lacking in the Caribbean region and patients are using the classic Finger Sticks to measure blood sugars at home. This potentially decreases compliance of treatment, and the lack of feedback on a daily basis limits patients and physicians in the optimization of personalized treatment.

## What Makes This Research important?

The app leverages disruptive technology such as artificial intelligence and machine learning to pave the way toward precision care and an advanced approach to personalized preventative medicine.

Therefore, obtaining more data and results from Type II Diabetes Mellitus studies will allow us to revise and better Aegle's algorithm, which in turn will create more personalized and precise measurements/ranges for the patients.

## Future Considerations

The Aegle monitoring device is the first of its kind to be made available for patients with T2DM in Anguilla, British West Indies.

The results could potentially be changing the way doctors and healthcare professionals monitor and treat the disease and improve disease outcomes, as well as reducing the burden of T2DM country-wide (primary prevention, improved compliance, long-term socioeconomic benefit)



# Research Question

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## Objective

This primary research aims to assess Diabetes patients' hemoglobin A1C levels with the usage and monitoring of the Aegle Glucose Monitor Technology and to determine whether there has been an improvement in average glycemic control in the selected patient population.

## Research Question

Do Anguillans with Type II Diabetes experience improved glycemic control over a 3-month period when guiding and continuously monitoring their glucose levels using the Aegle application?

## PICOT

P: Anguillans with Type II Diabetes

I: Patients while using the Aegle app and glucose sensors to monitor their blood glucose

C: Patients while not using the Aegle app to monitor their blood glucose levels

O: Improved blood glucose levels

T: 3 month interval (entrance and exit)

# Literature Review

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- 37.3 million Americans— about 1 in 10—have diabetes, and about 1 in 5 people with diabetes don't know they have it (CDC, 2023)
- Diabetes and diabetes-related health complications can be serious and costly. The seventh leading cause of death in the United States, diabetes costs a total estimated \$327 billion in medical costs and lost work and wages. Diabetes is, still today, a major cause of blindness, kidney failure, heart attacks, stroke, and lower limb amputation (CDC, 2023)
- Continuous Glucose Monitoring Devices (CGMD) improve the gap in personal collaboration between healthcare professionals and patients by allowing 24-hour glucose monitoring, leading to a better understanding of the "big picture" for each patient. Online and instant data tracking and improved information also allow for less routine visits and finger pricks. Effective use of this technology has the potential to provide precision medicine (Cleveland Clinic, 2023)



# Hypothesis



# Potential Confounders/Bias

## Null Hypotesis

Subjects using the Aegle app will have no improvement in glycemic control levels as compared to not using it over the 3-month trial.

## Alternative Hypothesis

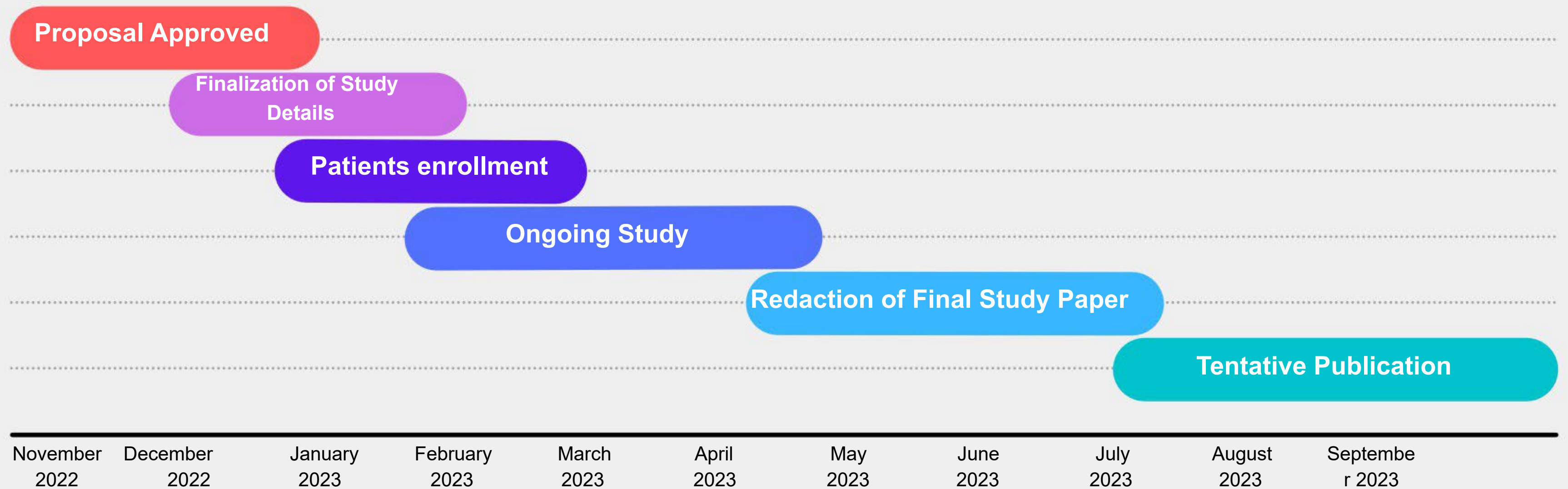
Subjects using the Aegle app will have improvement in glycemic control levels as compared to not using it over the 3-month trial.

- Demographics: Age, Gender, Other Medical Conditions
- Sociological: Available Phone Technology, Island-wide Internet/Power Outages
- Other: Activity levels, Dietary Changes, Hawthorne Effect
- Sample: Island/time limitations affecting sample size



# Roadmap to Publication

Expected delivery of each component



Note: These tentative dates are subject to revision

# Methods and Data Collection

18 subjects with Type II Diabetes Mellitus have been enrolled and will be monitored for 3 months, under the supervision of their physician at Hugues Medical Clinic.

These 18 participants will use the Aegle app software as the tested intervention over a period of 3 months. The data will be recorded daily, for 2 weeks per sensor. After this, there will be another 2-week period without a sensor. This will be repeated three times. Their HbA1C will be monitored before and after the study to assess changes and trends over time.

## Equipment:

- Sensor FreeStyle Libre 2 by Abbott Laboratories
- Aegle Application on a Smartphone
- Hemoglobin HbA1C (before and after study)



# Study Design (Observational)

- Hemoglobin A1C will be collected by all subjects at the beginning and end of the trial (quantitative).
- Using a subjective qualitative questionnaire, an entrance and exit interview will be conducted by the research team with all subjects (qualitative).
- Throughout the trial, subjects in the intervention group will need to scan their phone to their sensor every 8 hours to upload the data to the application.
- Patients will use sensors on a 2 weeks on, 2 weeks off basis during the entirety of the trial (for a total of 6 weeks with sensor and 6 weeks without sensor)
- Data will be collected directly from the software company and provided to the researchers.
- Patient names and identifiers will be excluded from the data to preserve the blind analysis.



# Methods and Data Collection

## Analyzing Results

The data will be used to measure the effectiveness of the app in improving blood glucose levels. The effect at the 2-week check-in as well as the final results after 3 months will be measured and analyzed for any statistically significant evidence of improved blood glucose levels.

A p-value under 0.05 will indicate statistically significant results rejecting the null hypothesis, and a p-value indicating statistically insignificant results will fail to reject (therefore accept) the null hypothesis.

**Analysis of results will be conducted using the following categories:**

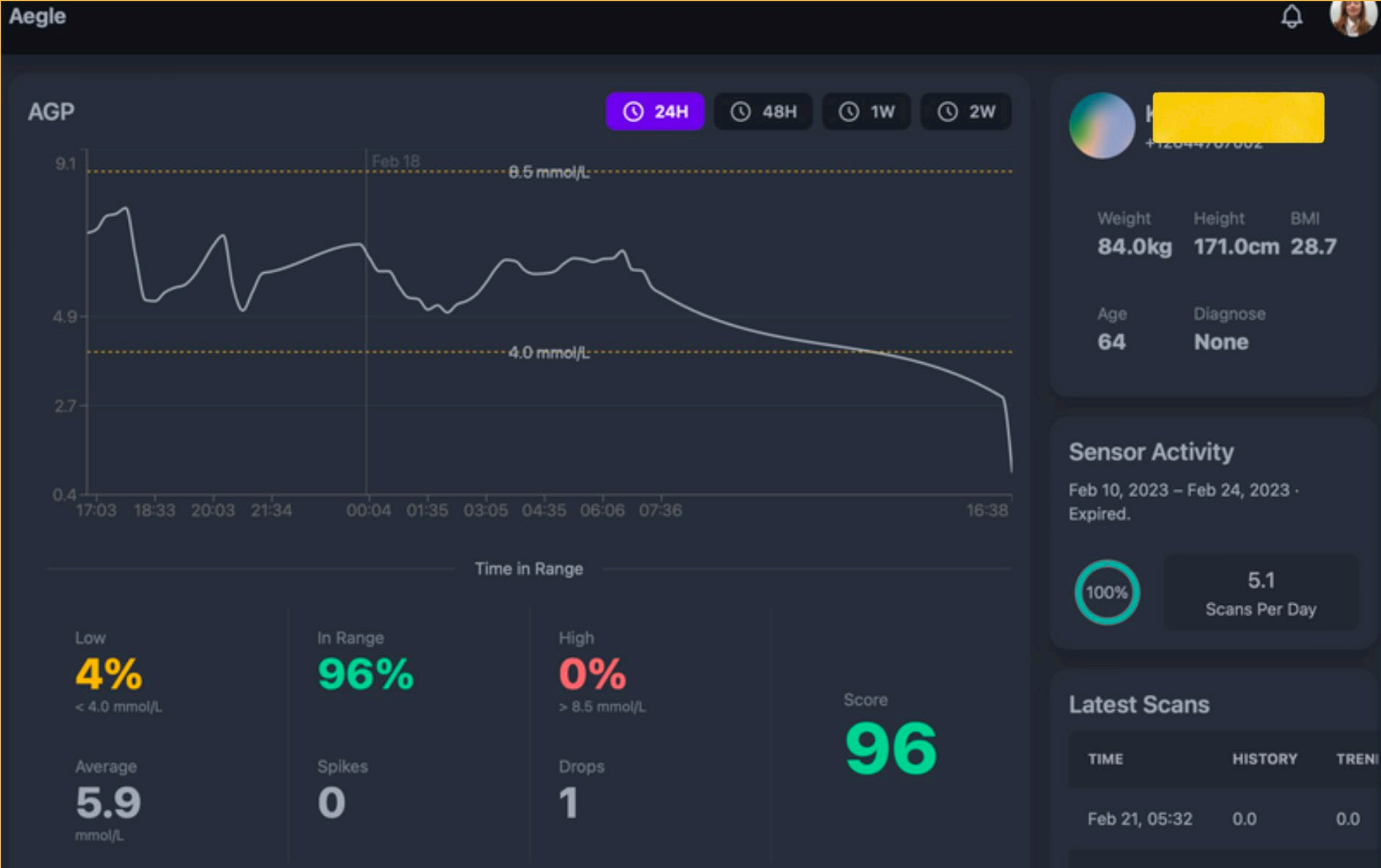
1. Potential sources of error
2. Significance of identified confounding variables
3. Potential conclusions of trends over time
4. Subject feedback from entrance and exit interviews
5. Potential impact subject feedback has on the results of the trial
6. Subject compliance with the intervention
7. Modifications/implications of future follow-up research



# Results (first 2-week trial)

- The study is still ongoing, so the results presented only affect the patients having the sensor activated on February 9-10, 2023.
- After attrition and Sensor Defects/ Data Outage, 11 patients used the sensor for the first 2 weeks (February 9-23, 2023)
- The average HbA1C (converted in mmol/L) of the participants (13 total, 2 had no compatible device) before the trial was **8.94 mmol/L**
- Of all 11 patients that completed the first 2-week trial, the average of "In Range Average" was **72.1%**
- This means that 72.1% of patients were in a healthy range average for the period of 2 weeks overall. The healthy average range was determined by the application, factoring in personal data (age, weight, BMI, A1C results as per ADA 2023)
- The average glucose levels over a period of 2 weeks for all 11 patients was **6.20 mmol/L**
- On average, participants had **7 spikes** (high sugar levels surpassing their "In Range Average") over the 2-week period.

# Results Dashboard Example (24 hours)



Weight

84.0kg

Height

171.0cm

BMI

28.7

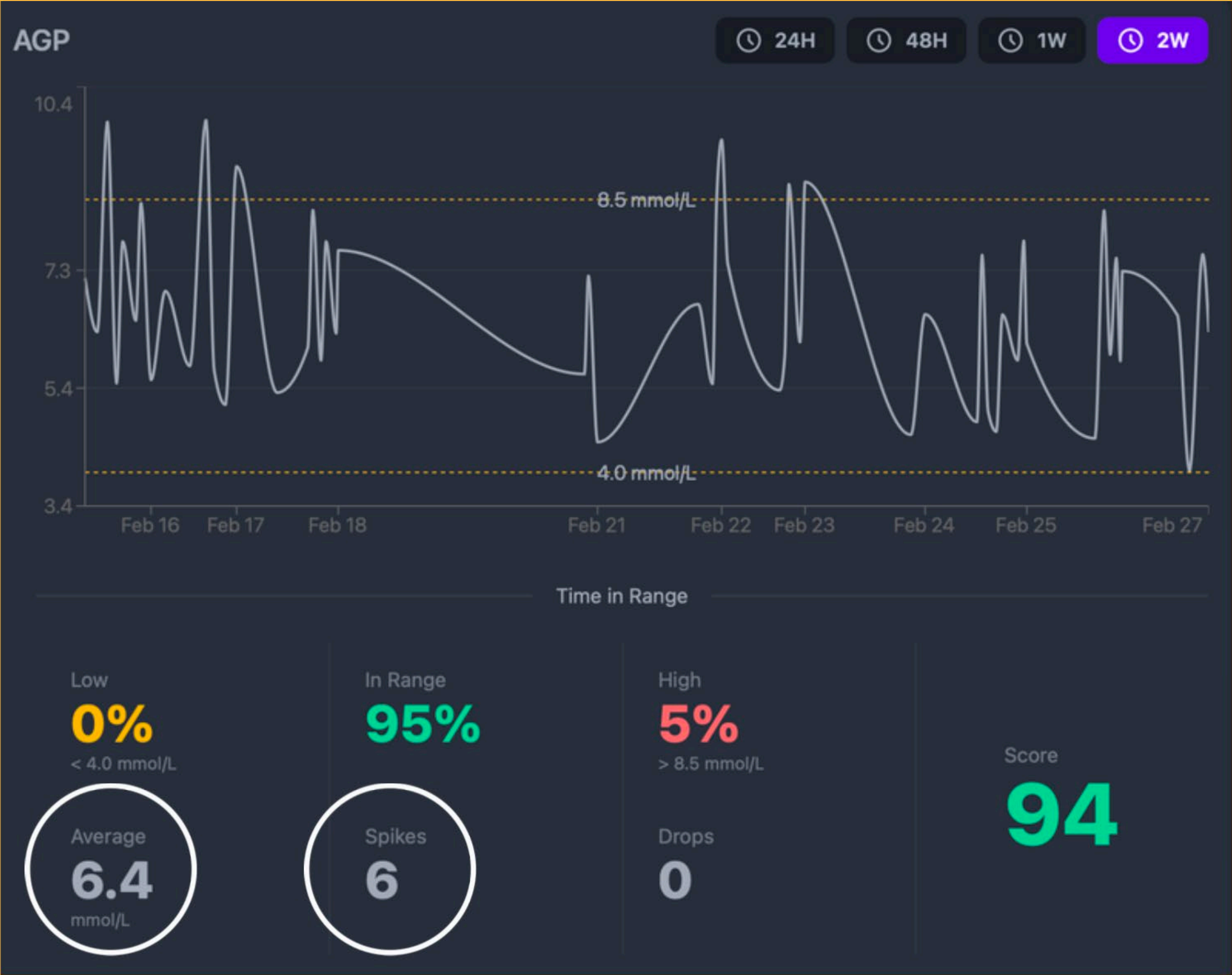
Age

64

Diagnose

None

# Results Dashboard Example (2 weeks)



# Study Advantages

Why does glucose-continuous monitoring devices can be a great tool in communities and population health?

**1** Ease of Use = Improved Compliance

**2** Sensor captures data at different times of the day (no need for the finger pricks)

**3** Helps the patients feel in control of the disease (seeing change impacting data)



**4** Reinforces the importance of diabetes conversation with HCPs and Patients and gives clarity to physicians at regular intervals

**5** Provides a cost-effective option for uncontrolled populations and primary health providers

## Study Limitations



- 1 The first set of sensors was not compatible with most phone models in Anguilla (older Androids) that do not have NFC.
- 2 Attrition rate of participants due to constant monitoring, appointments, and sensor application/removal.
- 3 Study population is relatively small due to real-life factors, possibly not representative of the whole population of Anguilla
- 4 Time and budget constraints to keep the study ongoing and evaluate deeper the insights over long-term use of sensors.

# Conclusion & Discussion

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## To Conclude

The utilization of Continuous Glucose-Monitoring Devices (CGMD) has been showing global improvements in disease management and control for patients with Type 2 Diabetes.

Their price and availability are the main challenges to implementing them as a primary care tool.

A first 2-week trial of the Aegle CGMD has shown an average reduction in glucose levels of 2.74 mmol/L compared to baseline.

In an area where primary care is essential to population health, this tool could reduce the burden on healthcare practitioners and on society as a whole.

## Future Considerations

More studies are needed to evaluate the benefits in Anguilla, and potentially in the Caribbean as a whole. A broader study sample reflecting the real-life diverse patient population would help in the decision to consider the wide use of CGMD in the country.

A cost-benefit analysis would be an interesting next step to consider since the importation of sensors to Anguilla can bear a high cost, at the risk of the payers and patients.



## Special Mention

To everyone who helped us achieve the first in-person study in Anguilla since the COVID-19 pandemic at SJSM!

**“the combination of science and the art of helping others.”**

- 01 Our mentor, Dr. Claude-Bernard Iliou, who helped us plan, write, shared his contacts, and helped organize the study with Hugues Medical Center.
- 02 Dr. Alona, Dr. Hughes, and Dr. Hodge at the Hugues Medical Center, and all their staff for facilitating our research experience, allowing us to use their laboratory for HbA1C assessment of all patients.
- 03 Mr. Antti Pasila, from Aegle Inc. who gave us direction, helped us day and night with the recruitment of patients, sensor challenges, data optimization, and random questions!

# Thank You



Questions?

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## ASSESSING CLINICAL OUTCOMES AND MONITORING A1C LEVELS IN PATIENTS LIVING WITH DIABETES IN ANGUILLA IN REFERENCE TO THE AEGLE GLUCOSE MONITORING TECHNOLOGY

Taha Al Youssif, Aseel Alhiri, Rachel Beaulieu, Amanda Lepkyj, Corvonn Peebles, Atemkeng Tazi

Mentor: Dr. Claude-Bernard Iliou

### INTRODUCTION

Continuous Glucose-Monitoring Devices are widely used in Europe and the United States.

Their availability is lacking in the Caribbean region and patients are using the classic Finger Sticks to measure blood sugars at home. This potentially decreases compliance of treatment, and the lack of feedback on a daily basis limits patients and physicians in the optimization of personalized treatment.

The app leverages disruptive technology such as artificial intelligence and machine learning to pave the way toward precision care and an advanced approach to personalized preventative medicine.

Therefore, obtaining more data and results from Type II Diabetes Mellitus studies will allow us to revise and better Aegle's algorithm, which in turn will create more personalized and precise measurements/ranges for the patients.

### RESULTS/FINDINGS

- The study is still ongoing, so the results presented only affect the patients having the sensor activated on February 9-10, 2023.
- After attrition and Sensor Defects/ Data Outage, 11 patients used the sensor for the first 2 weeks (February 9-23, 2023)
- The average HbA1C (converted in mmol/L) of the participants (13 total, 2 had no compatible device) before the trial was 8.81 mmol/L.
- Of all 11 patients that completed the first 2-week trial, the average of "In Range Average" was 73.90 %.
- This means that 73.90 % of patients were in a healthy range average for the period of 2 weeks overall. The healthy average range was determined by the application, factoring in personal data (age, weight, BMI, A1C results as per ADA 2023)
- The average glucose levels over a period of 2 weeks for all 11 patients was 6.20 mmol/L.
- On average, participants had 6 spikes (high sugar levels surpassing their "In Range Average") over the 2-week period.

### OBJECTIVE

This primary research aims to assess Diabetes patients' hemoglobin A1C levels with the usage and monitoring of the Aegle Glucose Monitor Technology and to determine whether there has been an improvement in average glycemic control in the selected patient population.

### RESEARCH QUESTION

Do Anguillians with Type II Diabetes experience improved glycemic control over a 3-month period when guiding and continuously monitoring their glucose levels using the Aegle application?

### METHODOLOGY

18 subjects with Type II Diabetes Mellitus have been enrolled and will be monitored for 3 months, under the supervision of their physician at Hugues Medical Clinic.

These 18 participants will use the Aegle app software as the tested intervention over a period of 3 months. The data will be recorded daily, for 2 weeks per sensor. After this, there will be another 2-week period without a sensor. This will be repeated three times. Their HbA1C will be monitored before and after the study to assess changes and trends over time.

Equipment:

- Sensor FreeStyle Libre 2 by Abbott Laboratories Aegle
- Application on a Smartphone
- Hemoglobin HbA1C (before and after study)

Hemoglobin A1C will be collected by all subjects at the beginning and end of the trial (quantitative).

Using a subjective qualitative questionnaire, an entrance and exit interview will be conducted by the research team with all subjects (qualitative).

Throughout the trial, subjects in the intervention group will need to scan their phone to their sensor every 6 hours to upload the data to the application. Patients will use sensors on a 2 weeks on, 2 weeks off basis during the entirety of the trial (for a total of 6 weeks with sensor and 6 weeks without sensor)

Data will be collected directly from the software company and provided to the researchers.

Patient names and identifiers will be excluded from the data to preserve the blind analysis.

### CONCLUSION & DISCUSSION

The utilization of Continuous Glucose-Monitoring Devices (CGMD) has been showing global improvements in disease management and control for patients with Type 2 Diabetes.

Their price and availability are the main challenges to implementing them as a primary care tool.

A first 2-week trial of the Aegle CGMD has shown an average reduction in glucose levels of 2.61 mmol/L compared to baseline.

In an area where primary care is essential to population health, this tool could reduce the burden on healthcare practitioners and on society as a whole.



RESULTS DASHBOARD EXAMPLE (2 WEEKS)

### AFFILIATIONS & ACKNOWLEDGEMENTS

- Our mentor, Dr. Claude-Bernard Iliou, who helped us plan, write, shared his contacts, and helped organize the study with Hugues Medical Center.
- Dr. Alonsa, Dr. Hughes, and Dr. Hodge at the Hugues Medical Center, and all their staff for facilitating our research experience, allowing us to use their laboratory for HbA1C assessment of all patients.
- Mr. Antti Pasila, from Aegle Inc, who gave us direction, helped us day and night with the recruitment of patients, sensor challenges, data optimization, and random questions!

### FUTURE CONSIDERATION

The Aegle monitoring device is the first of its kind to be made available for patients with T2DM in Anguilla, British West Indies. The results could potentially be changing the way doctors and healthcare professionals monitor and treat the disease and improve disease outcomes, as well as reducing the burden of T2DM country-wide (primary prevention, improved compliance, long-term socioeconomic benefit)

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