Analyzing real world ketone testing behaviors and glucose levels in FreeStyle Libre readers

Farhan Quadri[1], Samia Rahman[1], Naunihal Virdi[1]
[1]Abbott Diabetes Care, Alameda, California, United States

Presenter: Farhan Quadri *(farhan.quadri@abbott.com)* – Data Scientist

Disclosures

FQ and the coauthors are employees of Abbott Diabetes Care.

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Background and Aims

- Periodic ketone testing is important for people living with diabetes
- The FreeStyle Libre (FSL) Reader includes a port that can be used for blood ketone testing (OUS)
- This study investigated real world ketone testing patterns among users of FSL

Primary objectives:

- Distribution of ketone levels
- Ketone test frequency
- Relationship between glucose levels and ketone test timing

Methods

De-identified historical data was collected from FSL readers from **September 2014 – January 2025**.

Selection criteria below resulted in **165,108 readers** and **3,023,587 ketone tests** across **89 countries**

- Ketone data obtained from the FSL reader
- FSL readers in the US were not included as they do not have ketone testing ability

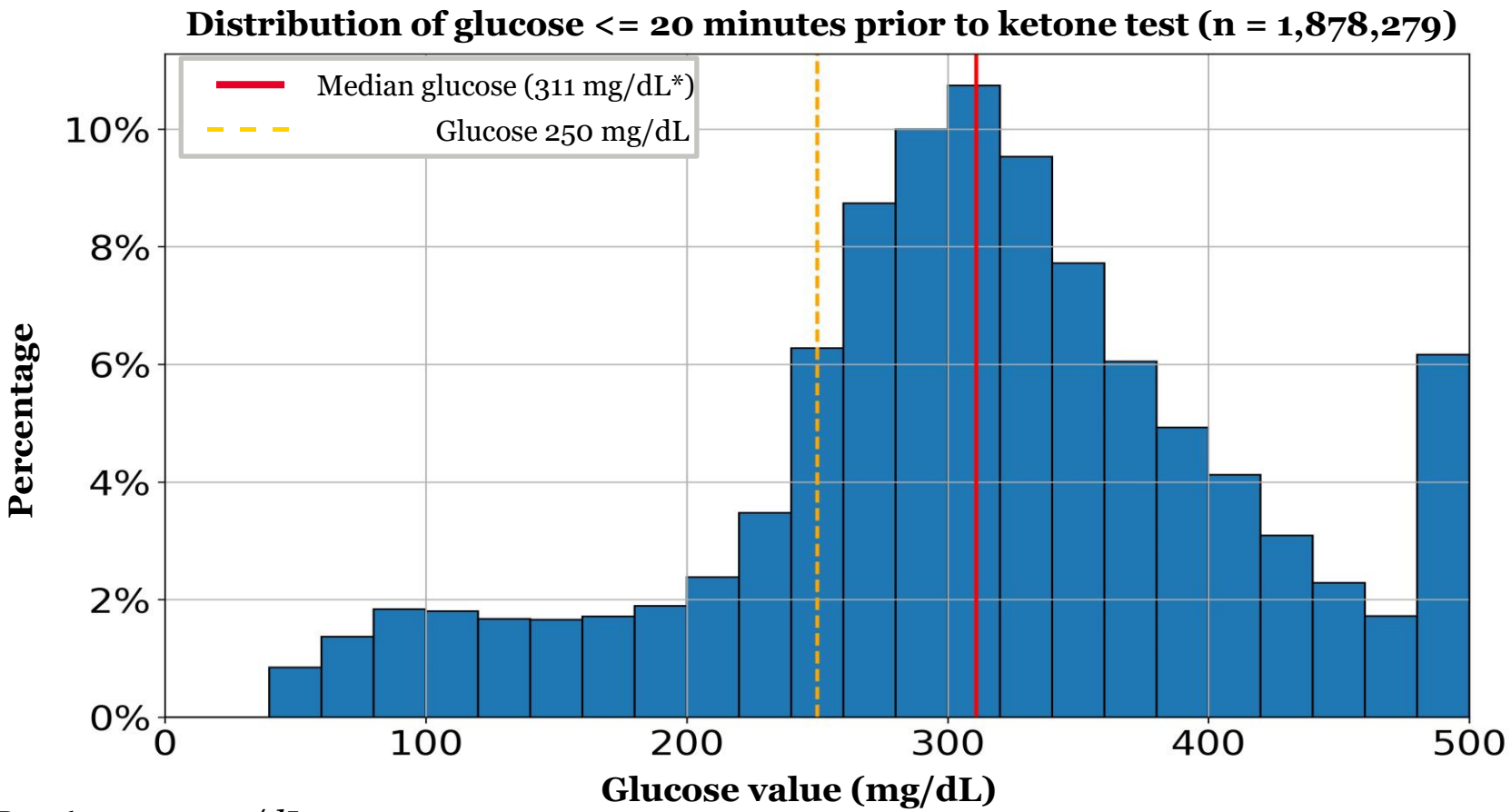
Metrics of interest

- Distribution of ketone tests and readers within ketone ranges
  - ≤0.5 mmol/L
  - >0.5 - <1.5 mmol/L
  - ≥1.5 - <3.0 mmol/L
  - ≥3.0 mmol/L
- Relationship between glucose values and ketone test timing
- The percentage of readers with glucose levels ≥250 mg/dL before ketone tests
- Frequency of ketone testing

7.9% (13,043) of readers had at least one ketone test with a level >= 3.0 mmol/L (DKA-risk)

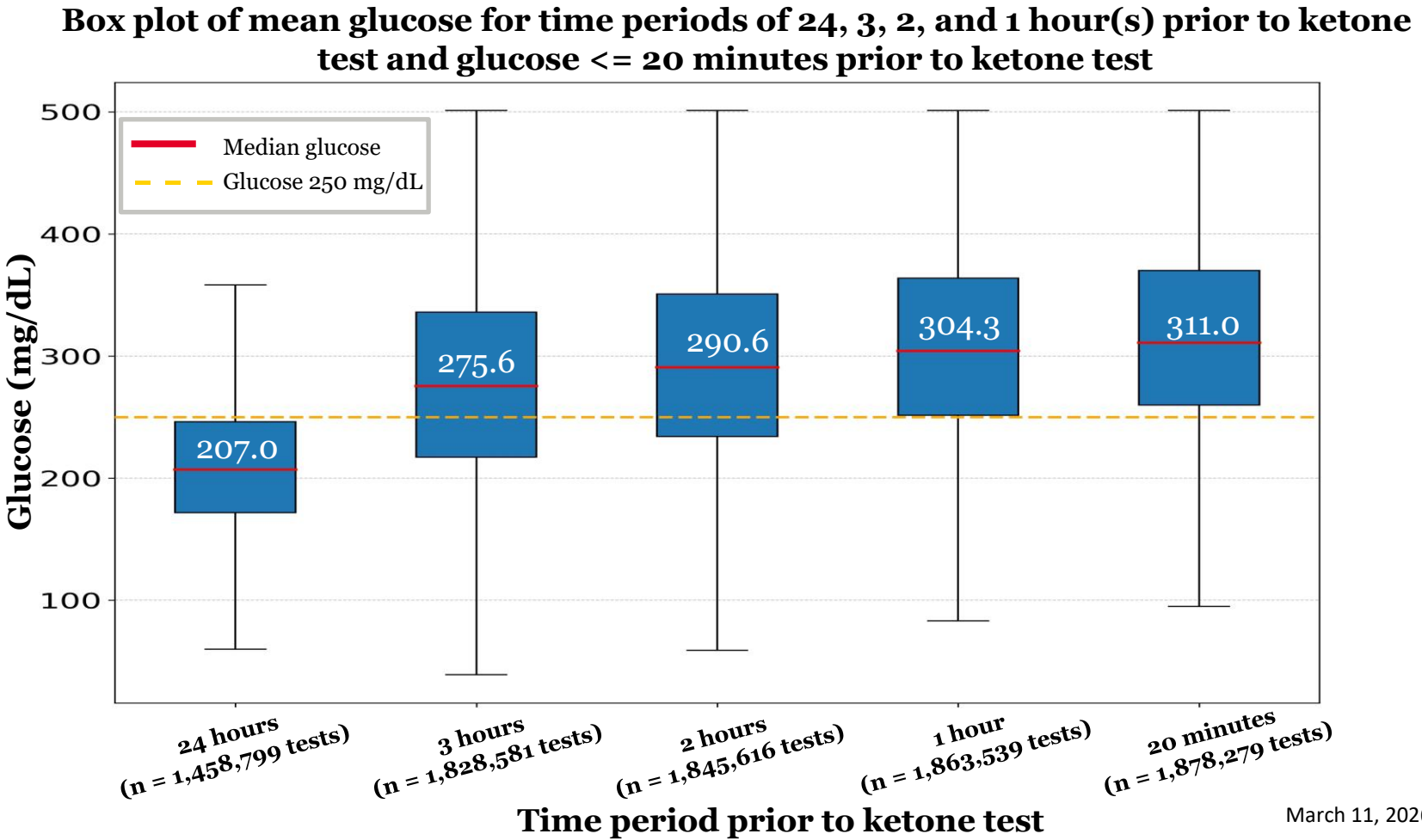
N = 3,023,587 ketone tests, N = 165,108 readers		
Ketone ranges	**% total ketone tests**	**% of readers with ketone test in range**
<=0.5 mmol/L	87.0%	98.3%
>0.5 - <1.5 mmol/L	8.4%	16.4%
>=1.5 - < 3.0 mmol/L	2.8%	14.2%
>= 3.0 mmol/L	1.8%	7.9%

Majority of testing performed when glucose was ≥ 250 mg/dL



IQR: 260 – 370 mg/dL

Glucose levels rose prior to ketone test



Higher ketone test frequency when ketone levels were elevated (>0.5 mmol/L)

Metric	Test frequency on days a reader tested for ketones	Test frequency on days a reader did a ketone test and had a ketone level of >0.5 mmol/L
Median	1.0 (IQR: 1.0 - 2.0)	2.0 (IQR: 1.0 - 3.0)

Conclusion

- Most ketone tests were performed after the glucose was ≥ 250 mg/dL, which aligns with clinical recommendations to perform a ketone test when glucose is elevated
- This may lead to missing euglycemic ketosis (e.g. during SGLT2i use or during pregnancy)
- When elevated ketone levels were detected, ketone testing frequency was higher, which is to be expected
- Adherence to ketone monitoring guidelines was poor in our data set (data not shown)
- Ketone monitoring adherence could improve if measurement was more convenient

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BACKGROUND AND AIMS

- Periodic ketone testing is important for people living with diabetes
- Users of FreeStyle Libre (FSL) can conduct a blood ketone test by utilizing the built-in test strip port on a physical reader
- This observational analysis investigated the patterns of blood ketone testing among users of FSL

Objectives:

- The primary objectives are to evaluate ketone test frequency, relation to glucose levels, and distribution of ketone levels

METHODS

- De-identified historical data was collected from FSL readers from September 2014 - January 2025
- Physical readers with at least one blood ketone test were included and users utilizing an app as their primary device were excluded, US readers were excluded (don't have ketone test strip port functionality)
- The frequency of ketone testing was determined for each reader
- The distribution of users within ketone ranges (normal [≤0.5 mmol/L], elevated [>0.5 - <1.5 mmol/L], high [≥1.5 - <3.0 mmol/L], DKA-risk [≥3.0 mmol/L]) was examined
- The relationship between glucose values and ketone test timing was explored by calculating mean glucose levels 24, 3, 2, and 1 hour(s) and last glucose level 20 minutes prior to a test
- The percentage of readers with glucose levels ≥250 mg/dL before ketone tests, and their corresponding glucose levels, was analyzed

RESULTS

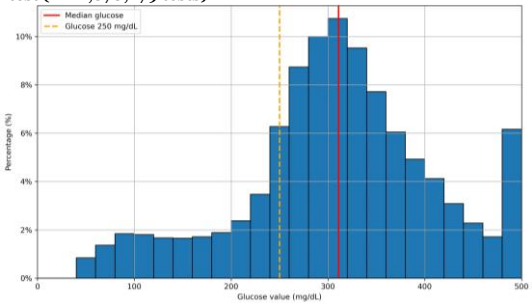
- A total of 3,023,587 ketone tests among 165,108 readers from 89 countries were analyzed

Table 1. Distribution of ketone levels

Ketone ranges	% ketone tests	% readers
<=0.5 mmol/L (normal)	87.0%	98.3%
>0.5 - <1.5 mmol/L (elevated)	8.4%	16.4%
>=1.5 - < 3.0 mmol/L (high)	2.8%	14.2%
>= 3.0 mmol/L (DKA-risk)	1.8%	7.9%

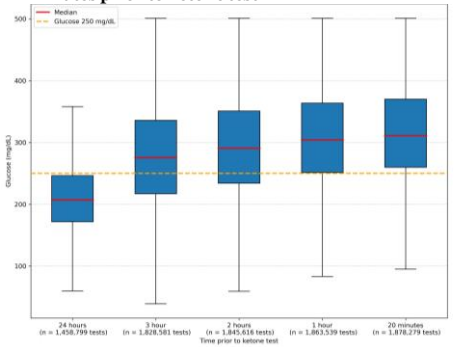
- The mean and median number of ketone tests per day on a day where ketones were tested was 1.4±1.0 and 1.0 (IQR: 1.0 - 2.0), and 2.4±2.0 and 2.0 (IQR: 1.0 - 3.0) on days with ketone levels > 0.5 mmol/L.

Figure 1. Distribution of glucose ≤ 20 minutes prior to ketone test (n = 1,878,279 tests)



- 78.7% of ketone tests were performed with glucose ≥250 mg/dL
- Median glucose within 20 minutes prior to ketone test was 311 mg/dL (IQR: 260 – 370 mg/dL)

Figure 2. Box plot of mean glucose for time periods of 24, 3, 2, and 1 hour(s) prior to ketone test and glucose ≤ 20 minutes prior to ketone test



***Note:** FSL can detect a minimum glucose threshold of 40 mg/dL and maximum glucose threshold of 500 mg/dL.*

CONCLUSIONS AND SUMMARY

- Most ketone tests were performed after the glucose was ≥ 250 mg/dL, which aligns with clinical recommendations to perform a ketone test when glucose is elevated
- This may lead to people with diabetes missing episodes of ketonemia that can occur at lower glucose levels
- When elevated ketone levels were detected, ketone testing frequency was higher, which is to be expected
- Adherence to ketone monitoring guidelines is known to be poor, which was observed in our data set
- Ketone monitoring adherence could improve if measurement was more convenient

DISCLOSURE: This study was funded by Abbott Diabetes Care, Alameda, CA, USA