

# A Novel Approach to Assess Patient Burden Using Data from a Digital Therapeutic for Type 2 Diabetes Predicts Glucose Outcomes

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## Background

- ❖ Maintaining glucose within specified targets is crucial to reducing risk of serious health complications of Type 2 diabetes and maintaining high quality of life<sup>1</sup>
- ❖ But many patients feel burdened by their illness and treatment and struggle to meet self-management demands
- ❖ Increasingly, clinicians and researchers recognize that patient burden and its impact on patient wellbeing are critical to measure and address<sup>2</sup>
- ❖ Digital therapeutics, which help patients manage chronic conditions with digital tools, present opportunities to assess patient burden and, possibly, alleviate certain treatment burdens

## Objectives

- ❖ In this study, we sought to answer the following research questions:
  - How can digital therapeutics be leveraged to assess patient burden?
  - What individual characteristics are associated with patient burden?
  - How is patient burden associated with diabetes outcomes?

## Methods

### Digital Therapeutic

- ❖ Retrospective data on users of BlueStar, an FDA-cleared digital therapeutic for Type 2 Diabetes
- ❖ BlueStar is a primarily mobile platform that facilitates self-monitoring of diabetes management and provides automated coaching<sup>3,4</sup>
- ❖ Users can contextualize self-management entries with structured (e.g., 'I feel sad') or patient-generated free-text (e.g., 'feeling bad, groggy, can't focus on work') annotations

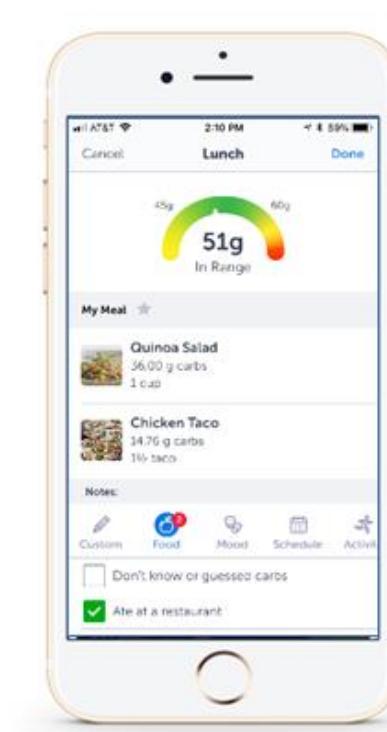


Figure 1. Screenshot of BlueStar app.

## Participants

- ❖ We focused analyses on a subset of users who:
  - 1) made at least one structured or free-text contextual annotation within 14 days of their first engagement with the app
  - 2) reported demographic information
- ❖ Yielded sample of 811 users (50.1% women, 64.3% aged 44-63, 54.5% A1c > 8.0%)

## Measurement of Patient Burden

- ❖ Computed a Patient Burden Annotation Index (PBAI) by summing structured and free-text annotations that reflected negative mood or health-related symptoms in a user's first 14 days of engagement
- ❖ Focused on the first 14 days of engagement to capture patient burden before major effects of the digital therapeutic

Table 1. Examples of burden-related annotations.

Theme	Example Annotations
Negative Mood	<i>Structured</i> : 'I feel stressed', 'I feel sad' <i>Free-Text</i> : 'stress levels on overload right now', 'I get very depressed when my BG is high because I want it to stay in the proper range'
Health-Related Symptoms	<i>Structured</i> : 'I feel sick', 'I am feeling light-headed' <i>Free-Text</i> : 'did not check b/s. still not feeling good', 'not sleeping well'

## Results

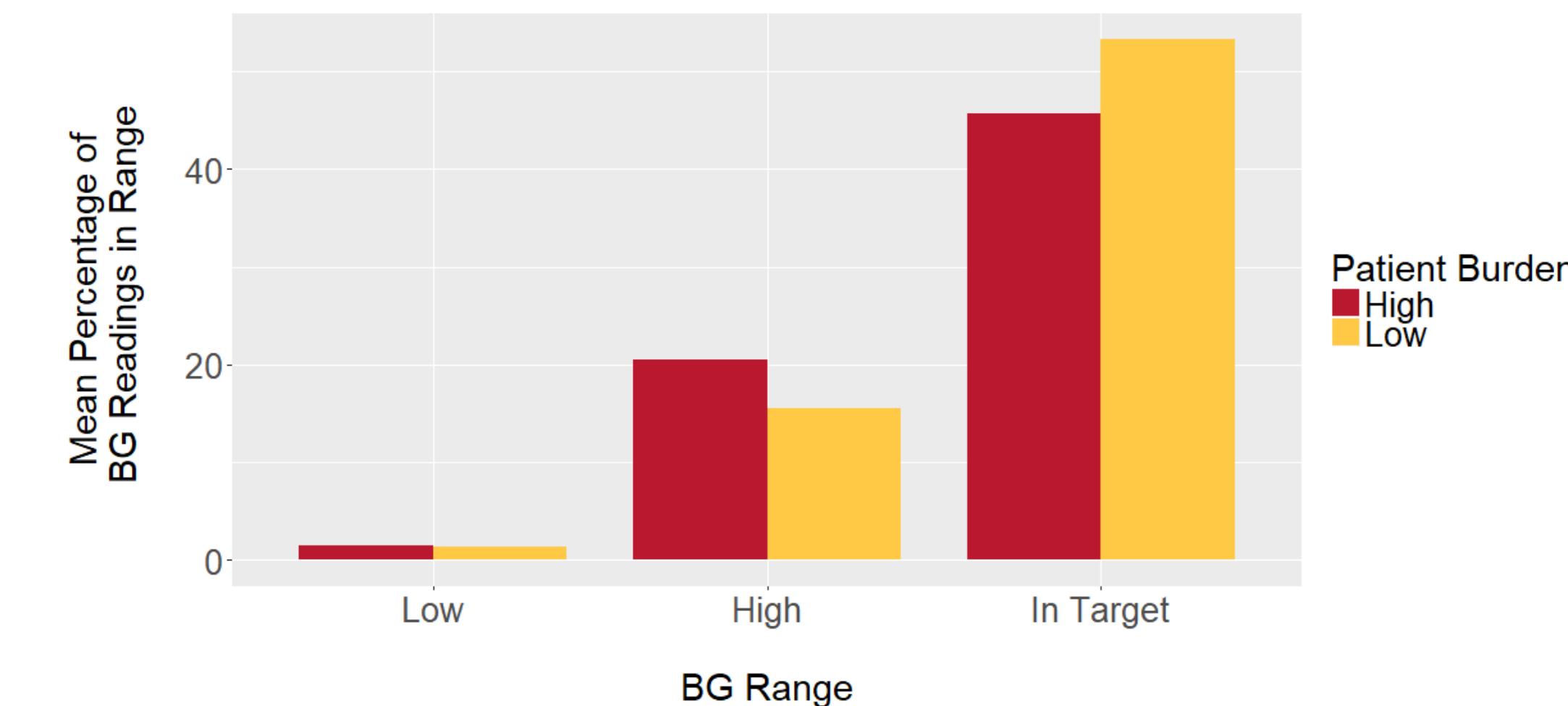
### Predictors of Burden

- ❖ A negative binomial regression analysis was conducted with patient characteristics modeled to predict the PBAI (offset by total annotation counts)
- ❖ Individuals with complex medication regimens (non-insulin and insulin injectables) had a greater PBAI than those with simple medication regimens (no meds and oral meds),  $\exp(b) = 1.31$   $p = .02$

## Burden and Glucose Control

- ❖ Patients tracked their blood glucose readings throughout their usage of BlueStar
- ❖ Blood glucose readings were categorized as in target, high, or low according to timing (e.g., fasting, post meal) and value
- ❖ We then estimated the relationship between patient burden and blood glucose control with negative binomial regression
- ❖ Patient burden was associated with lower proportion of 'in target',  $\exp(b) = .998$ ,  $p = .04$  blood glucose readings
- ❖ Also related to higher proportions of low ( $\exp(b) = 1.007$ ,  $p = .01$ ) and high ( $\exp(b) = 1.003$ ,  $p = .06$ ) blood glucose readings

Figure 2. Proportion of blood glucose readings in each range by burden.



## Conclusion

- ❖ Results suggest that data from digital therapeutics can be used to assess levels of patient burden among Type 2 diabetes patients
- ❖ Patient burden assessed during early engagement with a digital therapeutic is associated with worse blood glucose control
- ❖ Future research could explore using the PBAI to evaluate the impact of a digital therapeutic on patient burden over time and design interventions that precisely target individuals in need of additional support

## References



See our reference list by scanning this QR Code.