**PROBAST**

Study:

Machine Learning Experiments with Noninvasive Sensors for Hypoglycemia Detection

Step 2: Type of prediction study

**Is the study a diagnostic or a prognostic study?**

**Prognostic**

**Is the study a development only, development and validation or validation only study?**

**Development only**

**What is the model of interest?**

Support vector machine

**What is the outcome of interest?**

Hypoglycemia

Step 3: Assess risk of bias

**Domain 1: Participants**

**Describe the sources of data and criteria for participant selection**

Data was contributed by a middle-aged male who has hadT1D since childhood.

**1.1 Were appropriate data sources used, e.g. cohort, RCT or nested case-control study data?**

N

**1.2 Were all inclusions and exclusions of participants appropriate?**

Y

**Risk of bias introduced by selection of participants:**

High

**Rationale of bias rating**

Only one patient. Very low generalizability.

**Domain 2: Predictors**

**List and describe predictors included in the final model, e.g. definition and timing of assessment**

The fitness band, a Basis Peak, provided data for heart rate (HR), galvanic skin response (GSR),and skin and air temperatures (ST and AT).

**2.1 Were predictors defined and assessed in a similar way for all participants?**

Y

**2.2 Were predictor assessments made without knowledge of outcome data?**

Y

**2.3 Are all predictors available at the time the model intended to be used?**

Y

**Risk of bias introduced by predictors or their assessment**

Low

**Rationale of bias rating**

Predictors can easily be applied, independent.

**Domain 3: Outcome**

**Describe the outcome, how it was defined and determined, and the time interval between predictor assessment and outcome determination:**

The medical devices, a Medtronic insulin pump and a Dexcom CGM system, provided insulin and blood glucose data.

**3.1 Was the outcome determined appropriately?**

Y

**3.2 Was a pre-specified or standard outcome definition used?**

Y

**3.3 Were predictors excluded from the outcome definition?**

Y

**3.4 Was the outcome defined and determined in a similar way for all participants?**

Y

**3.5 Was the outcome determined without knowledge of predictor information?**

Y

**3.6 Was the time interval between predictor assessment and outcome determination appropriate?**

Y

**Risk of bias introduced by the outcome or its determination**

Low

**Rationale of bias rating**

Hypoglycemia was based on CGM measurement and independent of predictors

**Domain 4: Analysis**

**Describe number of participants, number of candidate predictors, outcome events and events per candidate predictor**

Over the course of two months, there were 34 hypo-glycemic episodes lasting 10 minutes or more.

**Describe how the model was developed, predictor selection and risk group definition**

To use an SVM to detect hypoglycemia in practice, the threshold would be selected to achieve a desired trade-off be-tween sensitivity and specificity. For experimental purposes, the behavior of the SVM across the entire spectrum of possible thresholds is examined.

Initial results come from a linear SVM trained on all 36 feature

**Describe whether and how the model was validated, either internally (cross validation, random split sample) or externally (e.g. temporal validation, geographical validation, different setting, different type of participants)**

To train and evaluate the SVM models, the 1,292 examples were grouped by day and then partitioned into folds for25-fold cross-validation.

**Describe the performance measures of the model, e.g. calibration, discrimination, classification, net benefit, and whether they were adjusted for optimism**

Precision, Recall

**Describe any participants who were excluded from the analysis**

None

**Describe missing data on predictors and outcomes as well as methods used for missing data**

In selecting negative examples, points were excluded if hypoglycemia occurred within one hour or if there was more than one hour of missing data within the past day.

**4.1 Were there a reasonable number of participants with the outcome?**

N

**4.2 Were continuous and categorical predictors handled appropriately?**

Y

**4.3 Were all enrolled participants included in the analysis?**

Y

**4.4 Were participants with missing data handled appropriately?**

PN

**4.5 Was selection of predictors based on univariable analysis avoided?**

Y

**4.6 Were complexities in the data (e.g. censoring, competing risks, sampling of controls)**

**accounted for appropriately?**

Y

**4.7 Were relevant model performance measures evaluated appropriately?**

PN

**4.8 Were model overfitting and optimism in model performance accounted for?**

Y

**4.9 Do predictors and their assigned weights in the final model correspond to the results**

**from multivariable analysis?**

U

**Risk of bias introduced by the analysis**

High

**Rationale of bias rating**

Only one participant. Negative samples were selected based on where missing values were. Not enough metrics reported.

**Overall Risk of bias**

High