**PROBAST**

Study:

Changes in telemonitored physiological variables and symptoms prior to exacerbations of chronic obstructive pulmonary disease

Step 2: Type of prediction study

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

Diagnostic

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

Development only

**What is the model of interest?**

Linear regression

**What is the outcome of interest?**

COPD symptom score,

Step 3: Assess risk of bias

**Domain 1: Participants**

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

The patients were selected by their general practitioners as having moderate/severe COPD and being at risk of a hospital admission. There were four participating practices situated in relatively deprived areas of Lothian. The only exclusion criterion was moderate/severe dementia.

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

**Y**

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

Y

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

Low

**Rationale of bias rating**

Proper eligibility criteria for COPD

**Domain 2: Predictors**

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

Physiological measurements were oxygen saturation (SpO2), pulse rate and forced expiratory volume in onesecond (FEV1)

**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 applicable and independent of outcome

**Domain 3: Outcome**

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

Patients used a touch screen computer (IntelCorporation, Santa Clara, California) to record a vali-dated symptom score,2 comprising three questions asking about the cardinal symptoms of an exacerbation,12and five which aimed to detect possible infective triggers.

From the symptom data we generated a total symptom score (one point for each item present, range 0-8).2 In line with global guidelines,8 we used two indicators of exacerbations: the first was whether the patient met Anthonisen’s et al. criteria (three or more symptoms including at least one of increased breathlessness, sputum amount or sputum colour for at least twodays12), which has been widely applied in studies using the validated symptom score2,3,10 and the second was whether the patient was taking an antibiotic on that day.

**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**

Outcome is appropriate for AECOPD, independent of predictors and assessed in a similar way.

**Domain 4: Analysis**

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

19 patients included in analysis. There were 172 treated exacerbation episodes suitable for analysis. The median number of exacerbations was 7 per patient

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

We then tested the association of FEV1, pulse and SpO2 with total symptom score using multilevel regression, nested by individual and adjusted for the autocorrelation present in the data by specifying an AR(1) correlation structure to the models.

**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)**

No validation. Model to assess goodness of fit between predictors and symptom score

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

Standard error, correlation coefficient, p-value

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

Of the 33 patients recruited to the telemonitoring service,19 participants (mean age 67 years, 3 female) collected. Of the 33 patients recruited to the telemonitoring service,19 participants (mean age 67 years, 3 female) collected

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

No imputation of missing data.

**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?**

N

**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?**

Y

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

N

**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**

Small amount of patients. Many patients excluded due to incomplete data. Missing data were left blank. No external validation / test set for predictions.

**Overall Risk of bias**

High