

UNIVERSITY OF THE YEAR MANARDS LE 2020

Assessment of the Risk of Bias in

EHR

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Prediction in clinical applications

- Diagnostic Models
- Probability of a certain condition being present
- Cross-sectional studies
- **Prognostic Models**
- Probability of an outcome/condition developing in the future
- Longitudinal studies



Risk of Bias

Bias is defined as the presence of systematic error in a study

Shortcomings in the study design

Shortcomings in the study conduct

Shortcomings in the analysis

Assessing Bias in Clinical Predictive Models

- What is the research question?
- What is the type of prediction model evaluation?
- Development only, development and validation
- Assess Risk of Bias
- **Participants**
- **Predictors**
- Outcome
- Analysis
- Overall Score of Bias





reported multivariable analysis?†

Prediction Model Studies, Annals of Internal Medicine, 2019.

Assessing Bias in Clinical Predictive Models

1. Participants	2. Predictors	3. Outcome	4. Analysis
Signaling questions			
1.1. Were appropriate data sources used, e.g., cohort, RCT, or nested case-control study data?	2.1. Were predictors defined and assessed in a similar way for all participants?	3.1. Was the outcome determined appropriately?	4.1. Were there a reasonable number of participants with the outcome?
1.2. Were all inclusions and exclusions of participants appropriate?	2.2. Were predictor assessments made without knowledge of outcome data?	3.2. Was a prespecified or standard outcome definition used?	4.2. Were continuous and categorical predictors handled appropriately?
	2.3. Are all predictors available at the time the model is intended to be used?	3.3. Were predictors excluded from the outcome definition?	4.3. Were all enrolled participants included in the analysis?
,		3.4. Was the outcome defined and determined in a similar way for all participants?	4.4. Were participants with missing data handled appropriately?
1	1	3.5. Was the outcome determined without knowledge of predictor information?	4.5. Was selection of predictors based on univariable analysis avoided?†
1	1	3.6. Was the time interval between predictor assessment and outcome determination appropriate?	4.6. Were complexities in the data (e.g., censoring, competing risks, sampling of control participants) accounted for appropriately?
1	r	1	4.7. Were relevant model performance measures evaluated appropriately?
J.	P	ì	4.8. Were model overfitting, underfitting, and optimism in model performance accounted for?†
+	###	í.	4.9. Do predictors and their assigned weights in the final model
Wolf et al. PROBASI: A Lool to Assess the Risk of Bias and Applicability of	Risk of Blas and Applicability	/ of	correspond to the results from the reported multivariable analysis?+

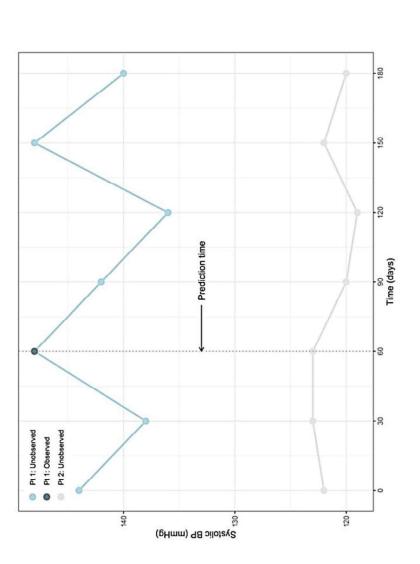


Bias in Electronic Health Records

- Informative Presence in Electronic Health Records
- Implies missing not at random process
- Fundamentally different than missing data since there were no intention of collecting the data
- Informative Observation in Electronic Health Records
- Timing, frequency and rate of a patient's longitudinal data



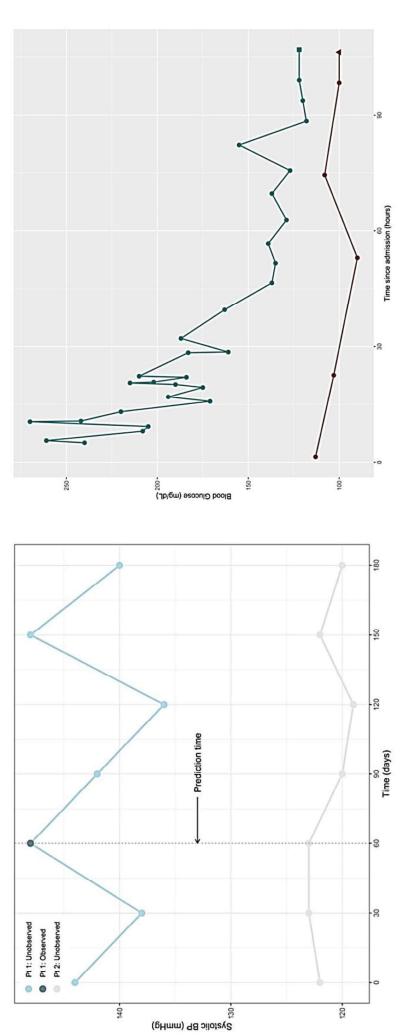
Bias in Electronic Health Records



Sick et al. 'Informative presence and observation in routine health data: A review of methodology for clinical risk prediction', Journal of American Medical Informatics Association, 2020.



Bias in Electronic Health Records



Sick et al. 'Informative presence and observation in routine health data: A review of methodology for clinical risk prediction', Journal of American Medical Informatics Association, 2020.



Summary

- Risk of Bias should be assessed and identified
- Electronic health records include inherently biases:
- Informative Presence
- Informative Observation

References

- Wolff et al. 'PROBAST: A Tool to Assess the Risk of Bias and Applicability of Prediction Model Studies', Ann Intern Med., 2019.
- review of methodology for clinical risk prediction', Journal of the American Sick et al. 'Informative presence and observation in routine health data: A Medical Informatics Association, 2020.