

# Threshold-based subgroup testing in logistic regression models

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**Abstract:** Associations between disease and predictors can differ across subgroups characterized by other covariates including treatment. In this paper, we consider a hypothesis testing problem for the existence of subgroups with heterogeneous disease risk models. Allowing multivariate predictors and/or covariates, we develop inferential procedures based on maximum of likelihood-ratio statistics in a threshold-based framework, where subgroups are characterized by unknown linear combinations of covariates. Numerical studies demonstrate the advantage of the proposed method compared to the alternative, existing two-step strategy that separates the estimation of the covariate combination.

From the testing of the threshold effect based on the estimated combination score. We further extend the method to two-phase sampling settings where the complete set of variables are only available from a subset of participants in the phase one cohort. We demonstrate the application of our method using a real example from a recent HIV vaccine trial, where we test for the existence of subgroups based on the Fc receptor genes that modified vaccine's effects on HIV acquisition risk.