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# Some Statistical Considerations when Evaluating Heart Failure Biomarker Tests

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Biomarker tests related to heart failure are a diverse group. For such a diverse group, evaluating the performance presents challenges. Statistical considerations for evaluating heart failure biomarker tests, after finalization of these tests, are discussed in [1]. This editorial highlights some of the remarks and text that are in this reference.

There is a distinction between tests and biomarkers. A biomarker is a physiological, biochemical, or anatomical characteristic that is inherently present in an individual, while a test refers to the procedures, software and equipment employed for measuring a biomarker. This distinction is relevant when discussing performance of biomarkers because two different tests for the same biomarker may perform differently. Two facets of biomarker test performance discussed in this editorial are measurement validation and clinical evaluation.

Measurement validation refers to "characterization of various aspects associated with a test's ability to assess (e.g., detect or quantify) the biomarker". This aspect of performance evaluation is "often an underappreciated component of biomarker evaluation". A variety of analytical studies can be classified under measurement validation (e.g. measurement precision, measurement bias, limit of detection, limit of blank, limit of quantitation). Because "a biomarker is only as good as the procedure used to measure it," conducting measurement validation studies prior to clinical evaluation studies is important. Measurement validation commonly includes an assessment of bias and precision. Measurement bias is "the difference between the measured value of the biomarker and the true value," and measurement precision refers to "the closeness of agreement between replicate measurements on the same object (e.g., sample) under specified testing conditions". Additional details regarding measurement validation are in the cited reference.

Clinical evaluation is another aspect of evaluation for heart failure biomarker tests. The design of a clinical evaluation study is important because it impacts the statistical analyses and interpretation of results. But, the clinical study design depends upon multiple components, such as the clinical use of a test. In the cited reference, the dependency between clinical use of a test and clinical study design is emphasized by discussing clinical evaluation considerations separately for the following clinical uses: tests that measure the condition of interest at the time of testing (e.g. diagnosis, screening), tests that predict a future condition or event, tests that are used in combination with therapy, and tests that are used for monitoring. In addition to study design, some remarks about clinical study conduct and planning that influence the statistical analyses and interpretation of results are presented in the cited reference. Statistical analysis considerations for clinical evaluation studies also are presented in the cited reference.

The field of heart failure biomarker tests is changing, thanks to innovative and breakthrough findings about this disease. Reference [1] can serve as a resource for those seeking to evaluate the performance of any or all of these tests.

## Reference

1. De A, Meier K, Tang R, Li M, Gwise T, Gomatam S, et al. Evaluation of Heart Failure Biomarker Tests: A Survey of Statistical Considerations. J. Cardiovasc. Trans. Res. 2013; 6: 449–457.


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