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Editorial

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Methods for Analyzing Immunodeficiency Data with a Lower Limit of Quantification

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Appropriate modeling of the limit of detection is critical in the sense that detecting small amount or concentration of agents can be extremely important to assess disease status, identify environmental exposure or quantify levels of viral load and vaccine antibody. In AIDS studies, for example, researchers have recently shown great interest in modeling viral load (plasma HIV-1 RNA copies) data after initiation of a potent antiretroviral (ARV) treatment. Viral load is a measure of the amount of actively replicating virus and is used as a marker of disease progression among HIV-infected patients. Viral load measurements are often subject to left censoring due to a lower limit of quantification. The below detection limit (BDL) depends upon the assay used, ranging from 500 copies/ml for the first assays available in the mid-nineties to 50 copies/ml for today's ultra sensitive assay. Despite the improvement in assay sensitivity recently, left censoring data still remains a critical issue, and the common methods in the literature for addressing this issue are: (1) substitution method [1] which uses either the observed BDL or some arbitrary value, such as half of BDL. Those approaches usually lead to biased predictions that are systematically higher than predictions based on the true unknown values of BDL. (2) Maximum likelihood estimation (MLE) method [2] which is usually considered as 'best' method. However, it does not perform well in the situations where the immunodeficiency data set is small, the percentage of censored values is high, and the outcome is skewed.

Recently developed methods such as skew-distribution mixture models [3] have ability to properly adjust for left-censoring due to detection limits and at the same time relax the stringent assumption of normality for taking into account the skewness of the response variable.

References

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