

Reporting guidelines for diagnostic accuracy studies that use Bayesian latent class models (STARD-BLCM) - DTU Orbit (09/11/2017)

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Evaluation of medical tests is usually based on comparing their results to those from a perfect reference (gold standard) procedure. The Standards for Reporting of Diagnostic Accuracy (STARD) initiative (<http://www.equator-network.org/reporting-guidelines/stard/>) developed reporting guidelines for studies designed to estimate the accuracy of tests when disease status is known. The original STARD statement was initially published in seven journals, while an updated version — STARD2015 — has been recently released. More than 200 biomedical journals encourage its use in their instructions to authors. An affordable, reliable, and noninvasive reference standard does not always exist as is the case for infectious diseases with a long latent period (e.g., in chronic infections such as tuberculosis). In such situations test accuracy can be estimated using latent class models that do not require knowledge of disease status (i.e., disease status is a latent variable). Statistical methods were introduced in this context by Hui and Walter and have been successfully applied since then, with the majority of the work being carried out in a Bayesian framework. While STARD provides useful reporting guidelines for diagnostic accuracy studies when a reference standard is available, it required modification and extension to address crucial aspects that are unique to latent class analysis: In the absence of a perfect reference test, the target condition must be explicitly described when performing a latent class analysis to estimate test accuracy. Latent class models, in conjunction with what the tests under evaluation actually detect (e.g., organisms or immune responses to organisms), define the latent status. Thus, a definition/interpretation of the latent disease or infection under consideration from a biological perspective is critical to communicate effectively the contextual meaning of the sensitivity and specificity estimates. A detailed description of the latent class model and its assumptions is required. A meta-analysis found that 28% of the studies that used latent class models to estimate diagnostic test accuracy failed to report any evidence that assumptions were verified or that the underlying models were of adequate fit to the data at hand. Bayesian latent class analysis requires reporting the details and justification of the prior distributions used in the primary and sensitivity analysis. This task takes on increased importance when using non-identifiable latent class models. We adapted the STARD checklist in order to fulfill the reporting requirements for diagnostic test accuracy studies that use Bayesian latent class models. The new guidelines, termed Standards for the Reporting of Diagnostic accuracy studies that use Bayesian Latent Class Models, have been recently published and are available online (<https://www.equator-network.org/reporting-guidelines/stard-bldcm/>). Further, a mailing list has been created and those interested can freely subscribe (<http://lists.uth.gr/mailman/listinfo/lcmate>). Standards for the Reporting of Diagnostic accuracy studies that use Bayesian Latent Class Models is relevant to both Bayesian and frequentist estimation methods but the focus is on the former. It should prove to be a useful tool for the sound application of latent class models in the evaluation of diagnostic tests and promote optimal reporting practices for studies that use such models.

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