

Phlebotomy is often addressed as a crucial process in the pre-analytical phase, in which a large part of laboratory errors take place, but to date there is not yet a consolidated methodological paradigm” Ialongo and Bernardini (2017).

Abstract:

Phlebotomy is often addressed as a crucial process in the pre-analytical phase, in which a large part of laboratory errors take place, but to date there is not yet a consolidated methodological paradigm. Seeking literature, we found 36 suitable investigations issued between 1996 and 2016 (April) dealing with the investigation of pre-analytical factors related to phlebotomy.

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We found that the largest part of studies had a cohort of healthy volunteers (22/36) or outpatients (11/36), with the former group showing a significantly smaller median sample size ($N = 20$, IQR: 17.5-30 and $N = 88$, IQR: 54.5-220.5 respectively, $P < 0.001$). Moreover, the largest part investigated one pre-analytical factor (26/36) and regarded more than one laboratory test (29/36), and authors preferably used paired Student's t-test (17/36) or Wilcoxon's test (11/36), but calibration (i.e. sample size calculation for a detectable effect) was addressed only in one manuscript. The Bland-Altman plot was often the preferred method used to estimate bias (12/36), as well as the Passing-Bablok regression for agreement (8/36). However, often papers did assess neither bias (12/36) nor agreement (24/36). Clinical significance of bias was preferably assessed comparing to a database value (16/36), and it resulted uncorrelated with the size of the effect produced by the factor ($P = 0.142$). However, the median effect size (ES) resulted significantly larger if the associated factor was clinically significant instead of non-significant ($ES = 1.140$, IQR: 0.815-1.700 and $ES = 0.349$, IQR: 0.228-0.531 respectively, $P < 0.001$). On these evidences, we discussed some recommendations for improving methodological consistency, delivering reliable results, as well as ensuring accessibility to practical evidences.

Reference:

Ialongo, C. and Bernardini, S. (2017) Preanalytical investigations of phlebotomy: methodological aspects, pitfalls and recommendations. *Biochimica Medica*. 27(1), p.177-191.

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