Indirect estimation of reference intervals for complete blood count: Applicability of *refineR* to a base hospital laboratory in Sri Lanka

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Interpreting laboratory test results requires comparison to reference intervals (RIs) which can be established by direct or indirect methods. The application of direct methods is limited due to resource requirements, sample definition, and ethical issues, leading to the development of alternative algorithms. RefineR, an inverse-modeling algorithm, offers a free alternative to direct RI estimation methods, but its effectiveness and applicability for routine hematological tests in diverse ethnic populations remain unknown. Therefore, the present study aimed to investigate the applicability of the refineR in determining RIs of complete blood count (CBC) in a base hospital laboratory in Sri Lanka. A retrospective, cross-sectional study was conducted from June 2023 to May 2024. Routine CBC test reports stored at Base Hospital, Chavakachcheri, Jaffna, were extracted and subjected to data cleaning by removing pathological fractions and invalid data. The cleaned data were portioned by sex and subjected to RI calculation by refineR. The obtained RIs were compared with the RIs used by the hospital by calculating the bias ratio (BR). The BR of more than ±0.375 was considered a significant difference according to the conventional specification of allowable bias at the minimum level. Statistical analysis was performed using SPSS version 18. During the study period, 19,145 CBC data were recorded, among which 6,542 male and 8,456 female data were qualified for RIs calculation. Out of 13 CBC parameters analyzed, 8 RIs for males and 7 RIs for females were similar to existing RIs (BR < 0.375). Furthermore, 6 RIs for females and 1 RI for males showed > 0.375 BR either in the upper limit or lower limit ranges albeit 2 RIs for males were slightly different (BR > 0.375) from currently used RIs in the hospital. RefineR can be used as a cost-effective alternative method for calculatingRIs of CBC for resource-limited base hospitals in Sri Lanka using appropriate data cleaning methods.

Keywords: Complete blood count, Reference intervals, RefineR, Base hospital, Sri Lanka