

## LETTERS TO EDITOR

### RESPONSE TO REFERENCE RANGES FOR LYMPHOCYTE SUBSETS IN ADULTS FROM WESTERN INDIA: INFLUENCE OF SEX, AGE AND METHOD OF ENUMERATION

Sir,

I read the article by Das *et al.*<sup>[1]</sup> with great interest. I would like to point out certain missing points in the paper.

In what manner was the mandatory procedure of obtaining informed written consent from the subjects under the study carried out? Since the group also involved subjects below 18 years of age, was the parental/ guardian's consent sought? Were the subjects given the option to access their results? The ethics committee approval required for the study has also not been mentioned. These procedures are mandated by the STROBE guidelines on observational studies in epidemiology.<sup>[2]</sup> The study was conducted by SRL Ranbaxy Ltd., which is a major commercial laboratory with presence in almost all major cities of India. Therefore, a sample size of 252 subjects appears small. Was the sample size calculated by appropriate methods prior to this study?

The investigators have skipped a basic clinical examination prior to including subjects in their study. Findings such as lymphadenopathy, hepatomegaly, splenomegaly could easily have been ascertained clinically; these are markers of diseases like malignancy and tuberculosis. These diseases can be present asymptotically and can potentially alter the lymphocyte

subpopulations. Similarly the possibility of human immunodeficiency virus (HIV) infection in the subjects cannot be ruled out as they have neither been examined nor been tested for the same. Since absolute lymphocyte counts were also calculated, were patients with abnormally high or low counts excluded later?

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### REFERENCES

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2. Noah N. Editorial announcement: The STROBE initiative strengthening the reporting of observational studies in epidemiology (STROBE). *Epidemiol Infect* 2008;136:865.

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