

Commentary

External proficiency testing programme & quality of haematology tests in India

Routine haemogram is the most frequent test done in any person seeking medical help. Most of other (specialized and not-so-specialized) haematology tests are planned based upon the information obtained from haemogram. It cannot be overstated that all haematology laboratories must ensure to provide reliable test results with the requisite degree of accuracy and precision. Results are taken to be accurate when the estimated value is closest to the 'true' value. Reproducibility of estimated test results defines the term precision. A result may be precise without being accurate. Precision can be achieved by replicate tests and performing tests on previously measured test specimens. However, accuracy can only be achieved by use of reference materials which have been assayed by standard methods. Inaccurate and/or imprecise results can be produced by use of unreliable standards or reagents, incorrect instrument calibration or poor technique. Materials/reagents and methods, both are involved in the process of standardization. Reference preparations or material standard are utilized to calibrate analytic instruments and give quantitative values to calibrators. Working or recommended method is meant for routine use and takes account of cost-effectiveness of manpower and materials, and convenience of technique. Working or recommended method needs to be validated to be adequately reliable, when compared with a reference method¹.

Accurate and precise results can be achieved by a quality assurance programme which includes components like internal quality control, external quality assurance (EQA) and standardization. Pre- and post-analytic variables also need to be adequately controlled. External proficiency testing programme (EPTP) enlists the procedures adopted for functioning of an EQA scheme. Inter-laboratory and inter-method comparisons can only be made by EPTP¹.

The article by Saxena *et al*² in this issue could not have been more appropriately timed. This article

describes their experience of conducting an EPTP over a period of 14 years (1992-2006). Very basic and important parameters like haemoglobin (Hb), total leucocyte count (TLC), reticulocyte count and peripheral blood smear (PBS) were included in the analysis. The number of participating laboratories had gone up from 38 to 401, showing more than ten-fold increment. Region-wise distribution showed that the number of participants increased from south region; decreased from west and north east regions; and no significant difference was observed from central region. Automated methodology was used by 5 per cent participants in 1992; this rose to 90 per cent in 2006. Three types of automated counters have been listed, however the information regarding the type of models used is not available. Most of the participants (94.8%) were private laboratories whereas only 5.2 per cent participants were government institutes. A substantial improvement was observed in the reporting of Hb, TLC and reticulocyte count while PBS assessment showed only marginal improvement.

The improvement in the quality of results reported by laboratories participating in external haematology proficiency testing programme being run by the All India Institute of Medical Sciences (AIIMS), New Delhi is worth appreciating. This article highlights certain important issues concerning the basic diagnostic haematology tests²:

1. What is the reason for difference in region-wise distribution?
2. Multitude of factors like more frequent usage of automated counters, better training of the personnel, adherence to standard operating procedures, *etc.*, have all contributed to substantial improvement observed in the reporting of Hb and TLC. PBS assessment requires further improvement.
3. Overwhelmingly large proportion of participants is private laboratories. The results may be skewed

because of this uneven participation of private laboratories and government institutes.

4. Does it mean that government institutes are not willing / not able to participate in such programmes? Necessary action should be taken to make participation of government institutes' laboratories (in fact, all laboratories) in such proficiency testing programmes mandatory.

Different makes of blood cell analyzers vary in their response to EQA samples. Therefore it is recommended to analyze the results separately for different types / makes of blood cell analyzers, in all types of EQAs¹. These EQA surveys must be performed at definite intervals, based upon various factors (the diagnostic importance of the test, frequency of the request, and their technical reliability)¹. In addition the reliability of a test also depends upon competence of the technical staff; training in different aspects of quality assurance needs to be imparted to all the laboratory staff.

International and national EQA schemes make significant contributions for this purpose. United Kingdom National External Quality Assessment Scheme (UKNEQAS) is organized by WHO; haematology and immunochemistry, and immunology samples are received at two months intervals, coagulation samples are received at four months intervals. A fee is charged for immunochemistry and immunology survey

only, not for haematology and coagulation surveys (why do not more laboratories from India join this survey?).

On national level, Christian Medical College (CMC) Vellore, regularly conducts an 'ISHTM – CMC Vellore EQAS program - Hemostasis' (fee is charged).

Experience of Saxena *et al*² convincingly shows the utility of ETPT in improving the quality of participating laboratories, over a period of time. Ideally all practicing laboratories, whether government or private, should participate in a national or international EQAS. This exercise would entail generating wide scale awareness about the benefits of EPTP. Licensing and accreditation should be based upon the EPTP performance.

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