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EXTERNAL QUALITY ASSURANCE – ROLE OF ACBI /CMC SCHEME

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The awareness of health care has been very rapid since the last ten years in India. It is no more a simple process and, laboratories play an important role in providing the data that are needed for the diagnosis of disease as well as monitoring of treatment. To achieve this, the tests requested must be appropriate to the medical problem, must be performed correctly, given to the clinician within the given time frame and the results interpreted correctly. Of all laboratory sectors, medical laboratories and especially clinical chemistry laboratories have a long tradition of internal and external quality control.

Correct analytical results are based on (i) quality management within the laboratory (ii) the quality of industrially prepared reagents (kits) and systems and (iii) on quality management of the pre-analytical phase outside the laboratory. A bad system, a wrong sampling or a kit with poor performance, will never produce a reliable result, even in a laboratory with the best quality management system.

According to ISO 8402 (1) quality is defined as the totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs. Medical laboratories must provide a high quality service by producing accurate, precise, relevant and comprehensive data that can be applied to the medical management of patients.

Quality assurance in the laboratory is intended to ensure the reliability of the laboratory tests. The objective is to achieve a precise and accurate result. Accuracy refers to the closeness of the estimated value, to that considered to be the true value. Precision refers to the reproducibility of a result, whether accurate or inaccurate.

1) Internal quality control

Internal quality control is based on monitoring the test procedures that are performed in the laboratory. It includes repeated measurements on routine specimens, as well as statistical analysis of data from tests that have been routinely carried out, day by day. Internal quality control is intended to ensure the reliability and the control over the test results that are released. However, it is primarily a check of precision (i.e. reproducibility) but not necessarily accuracy.

2) External quality assessment

External quality assessment is the objective evaluation, by an outside agency on the performance of a number of laboratories, on material that is supplied specially for the purpose. This is usually organized on a national or regional basis. Analysis of performance is retrospective. The objective is to achieve comparability, but again not necessarily accuracy, unless the specimens have been assayed by a reference laboratory, using methods of known precision, alongside a reference preparation of known value. External quality assessment (EQA) is an important supplement to the internal quality assessment that the same material is sent from a national or regional centre to a large number of laboratories. All the laboratories send the results back to the centre where, they are analyzed and interpreted by one of several procedures.

The main purposes of external quality assessment schemes include:

- assessment of the general standard of performance ('state of the art')
- assessment of the effects of analytical procedures (method principle, instruments, reagents, calibration)
- assessment of individual laboratory performance

The External Quality Assurance is for accuracy check and this is done monthly or once in two months. There are many companies that organize such schemes e.g., Bio-Rad, Randox The WHO operates one from Birmingham, UK.

External Quality Assurance Scheme in India

Quality concepts in analytical laboratories are changing very quickly.

According to the 1999 report on India at the Inter country Consultation, Yangon, Myanmar (2), the health set-up in the government sector consists of major hospitals at the centre and super specialty institutions

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at state level: 128 medical colleges, 440 district hospitals, 2289 upgraded PHCs, 21009 PHCs, 131 470 sub-centers and 27403 dispensaries. The laboratories are located up to PHC level. In metropolitan cities there are many private laboratories, and in many towns laboratories in the private sector have mushroomed. According to Jadhav, (3) 1997, there are more than 20,000 laboratories in India. Of these only 10% are participating in any EQA programme. The one with the largest number of participants is run by the department of Clinical biochemistry at CMC,Vellore in collaboration with the ACBI.

History

A pilot study was conducted by the CMC in 1977 to check the performance on commonly analyzed biochemical parameters in which 35 labs participated. It revealed alarming variations in the results reported by these laboratories and this led to the genesis of EQA in India. The first External Quality Assurance scheme in India was started under the banner of ACBI from CMC in the year 1978 with 50 laboratories participating in it (4). The number of participating laboratories increased steadily to 148 in 1980, 500 in 1990 and 1200 in 2000 and nearly to 1600 in 2005. Laboratories from all states of India and few labs from Nepal participate in this programme.

Present Scenario

This programme had two cycles of 6 month each, from January to June and July to December till 2000. But then onwards it is an annual programme starting from January to December every year. Every month a vial of ethanediol stabilized bovine serum is sent to each participating laboratory through either courier or post. The laboratory analyses the sample and sends the results through post. The results are evaluated statistically based on WHO recommendations and the report is sent along with the next month's sample. In the year 2004 a web site was launched for the CMC/ ACBI and it has tremendously decreased the turnaround time of receiving the results and sending the reports. Each participating laboratory can sign- in on the special page where they can enter or edit their address, method codes , send or amend results and view the report of any month. The results can be sent through this web site till the 20th of each month after which it is automatically locked to prevent late entries. The interpretation of the report is available for the better understanding of the same. There is also a facility to send e mails to the parent laboratory.

The salient features of the ACBI /CMC EQA are :

- Suitable for any type of laboratory- small, medium or large
- Continuous operation for the past 27 years
- Dispatch of fresh sample every month
- Internet facility to send and view results and reports
- For each parameter more than one method is available to suite the different kits used by the labs
- Statistical evaluation is done on WHO recommended methods
- Free consultancy to the participants
- Supply of standards on request
- Highly cost effective

Future plans

- to introduce lyophilisation of the QC material
- introduce lipid parameters and increase the enzyme spectrum
- to include hormones

CONCLUSION

The ACBI /CMC EQA programme gives confidence to the laboratories on their performance and reliability of reports. For laboratories seeking accreditation, this scheme is useful because participating in an EQA is mandatory for accreditation. The ACBI/ CMC EQA is priced low, enabling even the small laboratories to participate. We look forward to lyophilisation and thereby, to the introduction of more parameters, to meet the needs of many laboratories.

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