

## TOTAL QUALITY MANAGEMENT, LABORATORY ACCREDITATION AND EXTERNAL QUALITY ASSESSMENT SCHEMES

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*Summary:* Two contradictory pressures, »high quality« and »cost reduction« require the clinical laboratories to adopt effective management techniques such as Total Quality Management (TQM). It is not merely a management process for quality improvement in all spheres of industrial functioning but also a management philosophy for overall organization development. TQM has been adopted by many health care organizations including clinical laboratories in the developed world. In the developing countries, however, majority are still using the traditional frame work of quality management. Through the concept of Quality Assurance (QA) and Quality Control (QC) in health care laboratories in India is more than two decades old, it developed in a highly unequal plane and still faces multi factorial problems. External QA/ Proficiency Testing (PT) is used to compare performance of laboratories. This is recently made mandatory for accreditation process in India. Unfortunately only <10% of laboratories participate in EQA programs possibly due to high cost. Professional bodies/Institutions (ACBI, IAPM, ISHTM-AIIMS EHPT) and Government of India are working hard to make EQA Programs available at reasonable cost. National Board of Testing and Calibration Laboratories (NABL) has been setup by Department of Science and Technology, Government of India which has started accreditation of clinical laboratories since 1999. So far 33 laboratories (0.17%) has been accredited and almost the same number of applications are in process. The program is voluntary at the beginning, may be made mandatory later. We see a Herculean task ahead for NABL but they are doing a good job at low cost similar to international organization like ACP. The formation of laboratory policy with quality control as its integral part is very imperative in achieving, total quality management of clinical laboratories in India.

*Key words:* total quality management, laboratory accreditation, external quality assessment scheme, Indian scenario

### Introduction

In today's competitive world, the pressures to curtail costs without compromising on quality, has become a common business reality. This is very much true for laboratory business of this service-oriented health care industry. Two paradoxical pressures, »high quality/cost reduction« require the laboratories to adopt effective management techniques. Lessons learned from manufacturing industry, teach the value of »Total quality management (TQM) process«. This is not merely a management process for quality improvement in all spheres of industrial functioning but also a management philosophy for overall organizational development.

The principles and concepts of TQM have been formalized into a quality management process. In doing so the traditional framework of quality management,

which emphasized the establishment of Quality laboratory processes (QLPs), Quality Control (QC) and Quality Assurance (QA), has been substituted with Quality Improvement (QI) and Quality Planning (QP) components. Quality improvement provides a structural process of problem solving which help identifying the root cause of a problem and a remedy for that. This remedy is than standardized, measures are established for monitoring the performance and it is ensured that the performance achieved satisfy quality requirements.

In the developed world many health care organizations including clinical laboratories have adopted TQM. However in the developing economies including India, are still using the traditional framework of quality management. This primarily involves identification and correction of the defects after they have occurred. However, few laboratory professionals have realized the effi-

cacy, economy and sustainability of quality with anticipated preventive checks on potential problems before they occur. Therefore, the concept of TQM is making its presence slowly in the clinical laboratories in India.

The objective of quality assurance/control is the right result from the right test at the right time on the right specimen from the right patient, interpreted by a right reference data. To accomplish this objective of everything right, all the five components of TQM work together in a feed back loop to achieve continuous improvement in quality, and quality assurance is build into laboratory processes.

The concept of Quality Assurance and Quality Control in health care laboratories in India is more than two decades old. However, it developed in a highly unequal plane and still face multifactorial problems.

There were more than 20,000 clinical laboratories in India in 1997 (1). This figure is even more today. Of the two major components of quality control i.e. Internal quality control (IQC) and External quality assessment (EQA), not many of these practice IQC and only less than 10% of them are participating in any External Quality Assessment (EQA) schemes. Also there are very few EQA schemes available. The one with largest number of laboratories participating (around 1200 laboratories) is run by the Association of Clinical Biochemists of India (ACBI) (2) from/by Christian Medical College (CMC), Vellore. The other one are EQA programs by Indian Association of Pathologists and Microbiologists (IAPM) (3) with 300 laboratories, Indian Society of Hematology and Transfusion Medicine – All India Institute of Medical Sciences External Haematology Proficiency Testing (ISHTM–AIIMS EHPT) (4) Scheme with 190 laboratories, and few commercial schemes run by commercial houses i.e. Biorad, Wellcome, Boehringer etc. with not more than 150 laboratories in total (Table 1). Most of these schemes are available for clinical chemistry only and that also for most routine analytes.

The analysis of the report on the largest EQA scheme run by ACBI in India reveals that 75% of these

participating laboratories exist in only 5 out of 28 (Maharashtra, Tamil Nadu, Kerala, Karnataka and Andhra Pradesh) states of India (making up to, only 30% of India's population). This infers that, a majority of the population has no access to these EQA program participating laboratories. Even today, the states that make more than 50% of this sub-continent's population (Bihar, UP, Madhya Pradesh, West Bengal and Rajasthan) represent only 12% of these laboratories (2) (Figure 1).

Looking at the sector of wise distribution of the laboratories participating in ACBI and IAPM EQA schemes, we find that only 14% of these laboratories belong to public sector. These are the laboratories which are catering to the poor population and operating with the public funds. Even ISHTM–AIIMS EHPT EQA scheme for haematology which was at the beginning offered to public laboratories only consists of 40% public and the rest to private laboratories (2–4) (Figure 2).

The results of the two major EQA schemes in clinical biochemistry (ACBI and IAPM) and two major EQA schemes in Haematology (IAPM and ISHTM–

Table I EQA programs in Laboratory Medicine

Program	Year of start/ Present status	Participating laboratories
WHO/Glasgow/DGHS	1976/Discontinued	App. 50 when discontinued
ACBI (2)	1977/Continued	50 in 1978 to >1200 in 2002
IAPM (3)	1991/Continued	29 in 1990 to >300 in 2002
ISHTM–AIIMS EHPT(4)	1982/Continued	39 in 1982 to 190 in 2003
Commercial EQA programs i.e. Biorad, Wellcome, Boehringer etc.	Continued	Some 100–150 in total

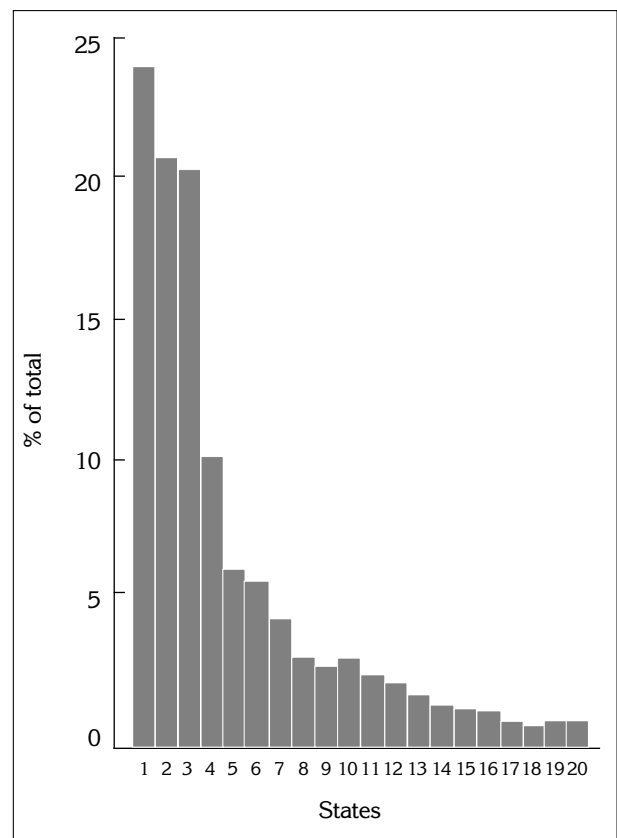


Figure 1. State wise Distribution of Laboratories in EQA (ACBI-QC data 2000):

1. Maharashtra, 2. Tamilnadu, 3. Kerala, 4. Karnataka,
5. AP, 6. Gujrat, 7. WB, 8. UP, 9. Rajasthan, 10. Delhi,
11. Bihar, 12. MP, 13. Punjab, 14. Orissa, 15. Assam,
16. Goa, 17. Haryana, 18. J&K, 19. Nepal, 20. Srilanka

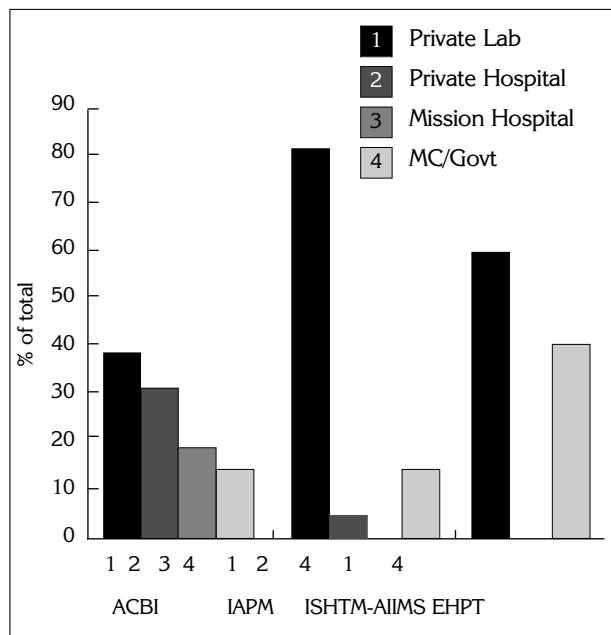


Figure 2. Sectorwise Distribution

AIIMS EHPT) clearly showed that participation in EQA program has significantly improved the quality performance of these laboratories, created awareness and improved the clinicians confidence in laboratory results. The program has also made realization of the importance of participating in EQA programs to the Hospitals and Laboratory administration. The need for in service training and introduction of new methodologies has been realized by participation in the Quality assessment programs (2–4).

Research on this unequal dispersion of the concept of quality within various clinical laboratories is necessary. A primary inquest finds, poor infrastructure, especially in the public sector as the principle cause. To understand the problem, let us look at the Union Government of India’s annual budget for the year 2001–2002. Expenditure on health is 5.2% of the GDP (20% public health spending) which amounts to app. \$3.3 per capital spending on health. A major part of this fund goes to the so called priority area of the government i.e. family planning, infectious diseases control, nutritional deficiencies control programs, etc. This priority area for the government has not changed since 57 years of our existence and has remained highly controversial. Of the funds allocated to public hospitals, a major part goes to clinical specialties. Of the small funding for non-clinical specialties, laboratories hardly get to share any funds let alone for quality control. The other major problem lies in the complete absence of training programs for laboratory personnel on the new concepts in the field of laboratory medicine or management.

An attempt was made in 1997 through a workshop on quality control by ACBI-AIIMS to understand the aptitude of laboratory managers towards in service training and their views on the importance and utility

Table II ACBI–AIIMS QC workshop study, 1997

Workshop structure was 50% theory & 50% practical	
Results:	
– Mean age of participants	40 ± 5.2 yrs,
– Prof experience of participants	10.2 ± 5.1 yrs
– 60% participants form large laboratory	
– 91% were familiar with the term QC but no professional training, 9% not familiar	
– 97% felt need for regular training program	
– Only 35 laboratory managers could be accommodated	
– Cost of the two days workshop	App US \$ 1000
– Projected figures for national QC	US \$ 2 million if at least one laboratory manager from one of the 20,000 laboratories to be trained once.

of such program. The result showed (Table II) that almost all the participants felt that there is a definite need for in-service training in various aspects of laboratory management and quality control on regular basis to make them more effective in delivering their best to the laboratory performance (5).

A major concern remains for the high cost of imported equipments and reagents. Apart from initial cost, almost 60–80% of equipments are under utilized or malfunction and await for technical support for long. However, importing technical knowledge and training with the import of equipment itself could improve the situation. Most of the laboratory imports are tainted with politics and lack technical scrutiny; they merely remain cosmetic and never render any solid foundation to the system. A better system could be possibly achieved, if all public funded imports be scrutinized by expert groups and made more accountable.

In house facilities to develop and manufacture laboratory equipments and reagents be developed in the country. Zafar et al, (6) 1992 have shown that the cost/test can be reduced by up to 500% if reagents are prepared from basic chemicals, substrates and enzymes imported from internationally reputed chemical company Sigma, UK, instead of using expensive imported clinical chemistry reagent kits without compromising the quality (6).

When comparing the international data on the performance of laboratories in EQA schemes in various countries (7) with the results of 1992 and 1998 of ACBI EQA program (2) (Figure 3), we found that there is a definite improvement in the performance of the laboratories participating in the EQA program between 1992 and 1998, however, there is a lot which needs to be done as we are still far behind the other countries including some developing economies (7).

As discussed earlier, the State has its own priorities, thus alternative sources of funding for quality control programs are needed. Industrial and other private funding can be moved in developing the infrastructure, for good quality, laboratory services in India.

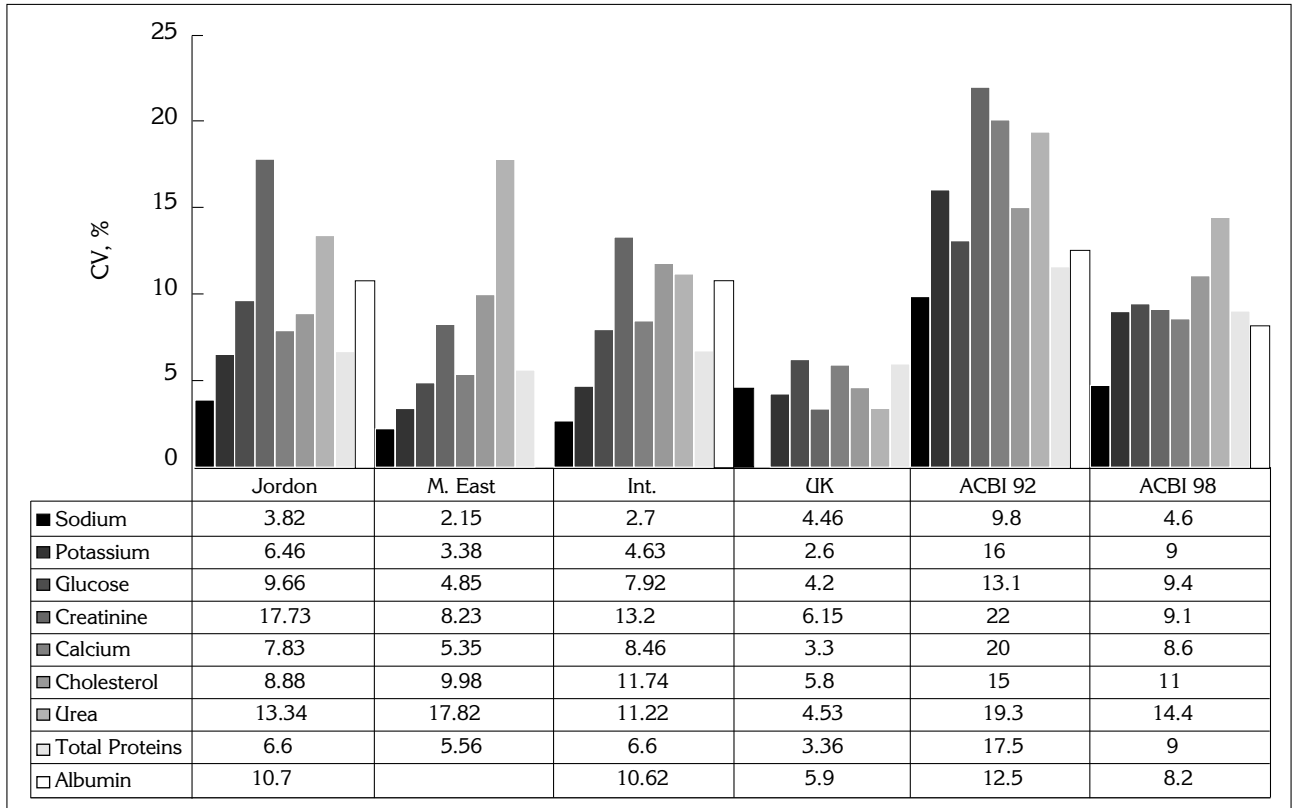


Figure 3. Effect of EQAS on CV (Global 1992 vs. India 92, 98)

Serious efforts are being made both by the government as well as the professional bodies in this direction. National Board of Testing and Calibration Laboratories (NABL) has been set up by the Department of Science and Technology, Government of India, which have started accreditation of the clinical laboratories since 1999 and till date about 33 laboratories have been accredited and another 30 are in the pipeline. NABL is also creating a group of trained laboratory assessors. It is a voluntary program at present. Unfortunately, here also most of the laboratories accredited or applied for accreditation till now belong to private sector. Accreditation of clinical laboratories is not yet made mandatory in India. Another establishment, the National Institute of Biologicals has been set up by the Government of India which is required to monitor the quality of the imported reagent kits apart from its other functions. However, it will take some time before the impact of these efforts by the government is felt.

Professional bodies like ACBI, IAPM and WHO/DGHS, National level Medical Institutions i.e. AIIMS, CMC Vellore etc. and some associations of practicing laboratory professionals i.e. The Association of Practising Pathologists (APP) (9) are putting up efforts in this direction by organizing EQA schemes and training to laboratory personnel and managers in various

aspects of laboratory quality and management. A number of commercial organizations such as Biorad, Wellcome, Boehringer etc. have also come up with their quality control products including EQA programs but they could not become popular with the public health laboratories due to high cost. A few international professional bodies such as CAP, ACP etc. have also started making their presence felt in the country by offering their EQA schemes and accreditation program.

Our experience with a multi centric study of Indian Council of Medical Research showed that sustained quality of laboratory results cannot be maintained without regular monitoring and even best performers loose quality timely and is non predictable, thus regular surveillance is required (7).

So many clinical laboratories in the country, and majority of being without quality control or quality assurance procedures, necessitate a National Clinical Laboratory Policy with quality control and quality assurance as an integral part. There is also an urgent need for a National Reference Laboratory, which would act as a nodal agency to provide quality and management solutions to various clinical laboratories in the country. Honest efforts are being made in this direction by the Ministry of Health & Family Welfare for the past few years, and soon we may have a national laboratory policy.

## TOTALNI MENADŽMENT KVALITETOM, LABORATORIJSKA AKREDITACIJA I SPROVOĐENJE SPOLJAŠNJE KONTROLE KVALITETA

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*Kratak sadržaj:* Dva kontradiktorna pristupa »visoki kvalitet« i »smanjenje troškova« postavljaju se pred kliničke laboratorije koje treba da sprovede principe upravljanja kao što je totalni kvalitet upravljanjem (TQM). Ovo nije samo proces upravljanja koji treba da poboljša kvalitet u svim oblastima funkcionisanja industrijskog razvoja već je filozofija koja doprinosi ukupnom razvoju organizacije. TQM su primenile brojne zdravstvene organizacije uključujući i kliničke laboratorije u razvijenom svetu. U zemljama u razvoju, međutim, većina laboratorija i dalje koristi tradicionalne principe upravljanja. Koncept sistema kvaliteta (QA) i kontrole kvaliteta (QC) u zdravstvenim laboratorijama primenjuje se u Indiji više od dve decenije, mada se suočava sa brojnim problemima. Spoljašnja QA/Iskustveno ispitivanje (PT) su iskorišćeni radi poređenja izvodljivosti rada u laboratorijama. Ovi principi su od nedavno postali obavezni u Indiji. Međutim, samo je manje od 10% laboratorija pristupilo programu EQA verovatno zbog previsoke cene koštanja. Profesionalne organizacije (ACBI, IAPM, ISTHM-AIIMS EHPT) i Vlada Indije rade na sprovođenju ovog programa i smanjivanju troškova. Nacionalni odbor za ispitivanje i kalibraciju u laboratorijama (NABL) uspostavio je Odeljenje za nauku i tehnologiju Vlade Indije koje je otpočelo sa procesom akreditacije u kliničkim laboratorijama počevši od 1999. godine. Do sada 33 laboratorije (0,17%) su akreditovane a takoreći isti broj je podneo zahtev za sprovođenje ovog procesa. U ovoj početnoj fazi program je dobrovoljan, da bi kasnije postao obavezan. Uspostavljanje laboratorijske politike o programu kontrole kvaliteta biće svakako integralni deo celokupnog popravljanja kvaliteta rada kliničkih laboratorija u Indiji.

*Ključne reči:* menadžment totalnim kvalitetom, akreditacija laboratorija, šema spoljašnje kontrole kvaliteta, indijski scenario

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