Vol 2 | Issue 3 | July - September | 2022

ORIGINAL ARTICLE - PUBLIC HEALTH

IMPLEMENTATION OF EXTERNAL QUALITY ASSURANCE SCHEME (EQAS)-IMPACT ON RELIABILITY AND REPRODUCIBILITY IN PHC LABORATORY SERVICES

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Abstract

BACKGROUND: Assessment is a critical aspect of laboratory quality management, and it can be conducted in several ways. EQA is defined as a system for objectively checking the laboratory's performance using an external agency or facility. Directorate of Public Health and Preventive Medicine, Tamil Nadu has registered all its 2127 Primary Health Centre Laboratories to participate in the CMC-Biochemistry-External Quality Assurance Scheme (EQAS) from 2021 to ensure reliable and reproducible results.

AIM : To assess the impact of participation in Proficiency Testing (PT) to deliver quality laboratory services in a primary health care setting.

OBJECTIVES : To analyse the consistency in participation by PHC laboratories and the performance of laboratory investigations for Glucose Analyte from Jan – Sep 2022

METHODOLOGY : All the 2127 PHC laboratories in Tamil Nadu were registered under CMC-Biochemistry EQAS Program for the Year 2022 followed by adequate Quality Management Training to the Laboratory Technicians of PHCs by the State Public Health Laboratory and also through the District Public Health Laboratories. A Dashboard was created to analyse the participation and performance analytics of all the 2127 PHC labs individually and district wise.

RESULTS : In 2020, a total of 876 labs (41.2%) only were participated consistently. The participation has gradually increased to a total of 1398 labs (65.7%) in 2021 followed by1637 labs (77%) in 2022. Excellent score was obtained by 1655 labs (77.8%) in 2021 followed by 1640 labs (77.1%) in 2022.

CONCLUSION : Quality of laboratory investigations are paramount important to deliver reliable and reproducible test results in the primary health care centres to serve the rural community. Participation in EQAS will ensure and assure the

INTRODUCTION

Laboratory Quality Assurance encompasses a range of activities that enable laboratories to achieve and maintain high levels of accuracy and proficiency despite changes in test methods and the volume of specimens tested. Assessment is a critical aspect of laboratory quality management, and it can be conducted in several ways. One of the commonly employed assessment methods is that of External Quality Assessment.[1]

Assessment is a critical aspect of laboratory quality management, and it can be conducted in several ways. EQA is defined as a system for objectively checking the laboratory's performance using an external agency or facility. Several EQA methods or processes are commonly used. These include Proficiency Testing (PT), Rechecking or Retesting and On-site Evaluation.[1]

In Proficiency Testing, an external provider sends unknown samples for testing to a set of laboratories, and the results of all laboratories are analyzed, compared, and reported to the laboratories. The basic purpose of proficiency testing is to assess the performance of laboratories for their conduct of specific test.[2]

Participation in an EQAS programme provides valuable data and information, which allows comparison of performance and results among different test sites, provides early warning for systematic problems associated with kits or operations, provides objective evidence of testing quality, indicates areas that need improvement, Identifies training needs. EQAS helps to ensure Physicians, Patients and Health administration, that the laboratory can produce reliable results. Successful performance in an EQAS programme reflects the effectiveness of the laboratory's quality management, and allows for recognition of laboratory quality by external groups.

OBJECTIVE

To assess the impact of participation in Proficiency

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Testing (PT) to deliver quality laboratory services in a primary health care setting.

ABOUT CMC-CLINICAL BIOCHEMISTRY EQAS:

The Department of Clinical Biochemistry, Christian Medical College, Vellore under the banner of The Association of Clinical Biochemists of India (ACBI) is conducting an External Quality Assessment Scheme (EQAS) since 1978. The Participants represents all the states of India and also Andaman and Nepal. The participating laboratories include teaching and non-teaching hospital laboratories, government as well as private, small hospitals, private clinics and diagnostic centres.

It is a twelve-month program starting from January to December every year. Those labs who report results for at least six months alone are eligible for the participation certificates at the end of the cycle. Each laboratory is assigned a lab number and they are requested to secure the password.

There are two basic Biochemistry programs viz, Chemistry – I and Chemistry – II for the small and medium laboratories. Chemistry – II is ideal for small laboratories like PHCs labs catering to the need of rural community. This cover 9 analytes like Glucose, Urea, Creatinine, T. Bilirubin, T protein, Albumin, Uric acid, Cholesterol and Triglyceride.

MATERIALS AND METHODS

All the 2127 PHC laboratories under CMC-Clinical Biochemistry EQAS program from 2020 were included in this study, with necessary Hands-on-training to the PHC Laboratory Technicians, Provide Standard Operating Procedures (SOP) and uniformly implement the program across the state of Tamil Nadu and analyse the consistency in participation and the performance of laboratory investigations for Glucose Analyte from 2021 and 2022 (up to Sep 2022) through a Dash Board analytics.

The basic preparation of PT panel involves preparation of a master pool of human serum as per WHO recommended procedure, dispensing the correct volume into the vials and lyophilization. Homogeneity and stability checks are done as per the ISO 13528:2015 standards3. The lyophilysed vials are sealed, well packed in thick envelops and distributed through courier service or postal service to all the participating laboratories.

The laboratories are requested to reconstitute the correct sample, analyse and enter the results in the web site before the 20th of every month. Any amendments can be made only till the 25th of the month and it should be sent through an e-mail only clearly mentioning the lab number and reason for amendment. Once the report is published on the net, no amendment can be made. Evaluation of the report is based on WHO and ISO 13528:2015 recommended expressions such as Robust mean for the assigned value and SDI (Z score) for individual parameters. Details on monthly report and the statistical tools are available on the monthly summary page. Evaluated monthly report is uploaded into the net by 2nd working day of the succeeding month.

After the completion of the cycle, the yearly summary is updated into the web site for individual labs and certificates are sent to the eligible laboratories. The CMC-Biochemistry EQAS providers maintain confidentiality of the participants demographics, results, reports or any other information provided by them. A Dashboard analytics was created exclusively for the 2127 PHCs under the Directorate of Public Health and Preventive Medicine by CMC, Vellore through which the participation and performance analytes of the PHC labs can be assessed and ascertained by using the super admin username and password for the DPH&PM. DPH&PM Scientific Committee Permission was obtained.

RESULTS

A total of 2127 PHC laboratories were registered with CMC-Clinical Biochemistry EQAS Program for the year 2021,2021 and 2022. In 2020, a total of 876 labs (41.2%) only were participated consistently in all months. In 2021, the participation has gradually increased to a total of 1398 labs (65.7%) followed by1637 labs (77%) in 2022 indicating a 36% improvement in consistency in participation over a period of 3 years.

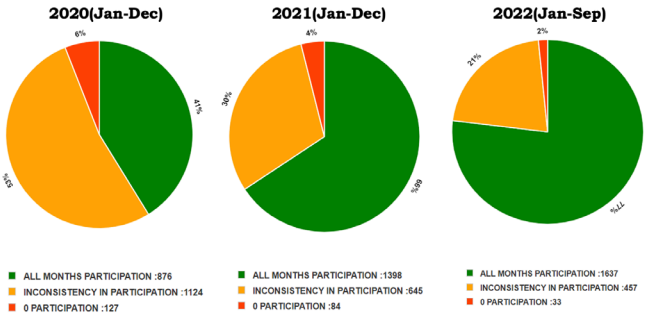

Figure 1 : Consistency in Participation from 2020-2022 (up to September)

Similarly, inconsistency in participation has also gradually reduced from 1124 labs (52.8%) in 2020 to 645 labs (30.3%) in 2021 followed by 457 labs (21.5%) in 2022 with a substantial reduction of 31.5%.

In the year 2020, a total of 127 labs (6%) did not participate in the EQAS Program followed by a total of 84 labs (3.94%)

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in 2021 and only 33 labs (1.55%) for the current year with a reduction in non-participation of 4.45%.

Further, district wise consistency status reveals that, in 2020, out of 37 districts excluding Chennai, 23 districts (62.1%) had representation of non-participated PHCs. In 2021, it has come down to 18 districts (48.6%) followed by in 2022, it has further reduced to 10 districts (25%).

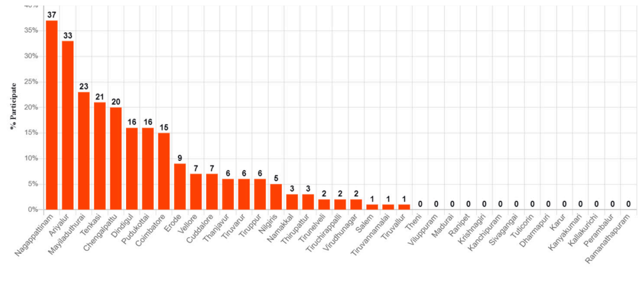

Figure 2 : District wise consistency in 2020

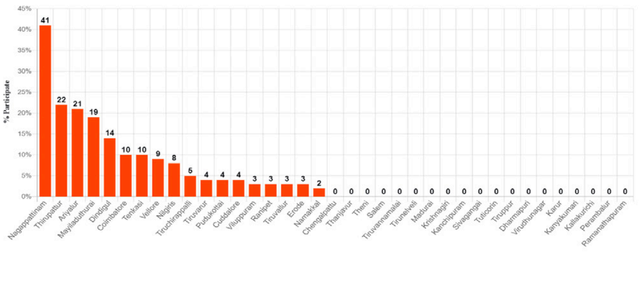

Figure 3 : District wise consistency in 2021

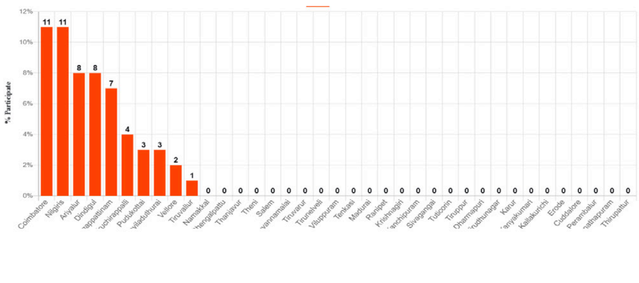

Figure 4 : District wise consistency in 2022

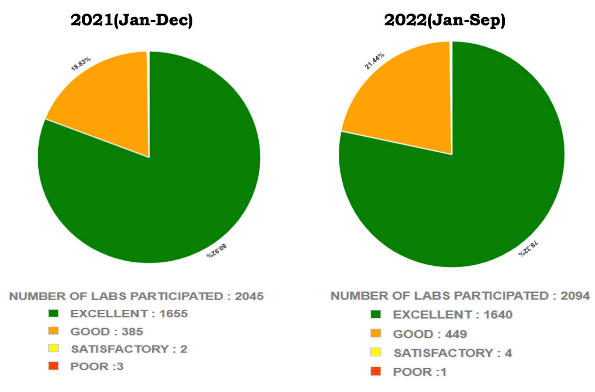

Figure 4 : Number of Labs participated

Out of the nine biochemistry analytes included under the Chemistry III program, Glucose, one of the basic investigations done in a PHC was taken for the performance assessment.

Excellent score was obtained by 1655 labs (77.8%) in 2021 followed by 1640 labs (77.1%) in 2022. Overall, only 0.14% of labs in 2021 and 0.04% of labs in 2022 have failed in the Glucose analyte.

DISCUSSION

EQAS is important for improvement of the laboratory quality management system, as it is a measure of laboratory performance. As it uses valuable resources, the laboratory should make the best use possible of its participation in EQAS. It should not be punitive. It should be viewed as educational and used as a tool to help direct improvement efforts in the laboratory. EQAS is one of the critical elements of a laboratory quality. [3]

There has been a substantial improvement in the participation of EQAS in 2127 PHC labs from 2020 onwards. Sensitizing the laboratory technicians on the importance of consistent participation in EQAS is very important. On the other hand, the laboratorian should always aim to achieve excellent score in each cycle thereby ensuring their skills, calibrated equipment, quality reagents and commitment to deliver reliable and reproducible results.

EQAS participation is usually required for accreditation. Out of the 2127 PHC labs, 5 PHCs have recently obtained Medical (Entry)Level Testing under NABL-M(EL)T Labs Program. EQAS participation creates a network for communication, and can be a good tool for enhancing a national laboratory network. Samples received for EQAS testing, as well as the information shared by the EQAS provider, are useful for conducting continuing education & Training activities.

CONCLUSION

The EQAS is providing the reliable information that allows laboratories to assess and monitor the quality status of internal procedures and processes, suitability of the diagnostic systems, accountability and competence of the staff.

ACKNOWLEDGEMET

Contribution made by the District Microbiologist under DPHL Network in Tamil Nadu for the implementation of EQAS is appreciated. Before the introduction of Dashboard, manual compilation of monthly performance report and analysis done by Mr.Velkumar, Health Inspector is acknowledged.

FINANCIAL SUPPORT

We thank the NHM-State Health Society to provide financial support for the implementation of EQAS in all the 2127 PHCs in Tamil Nadu.

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