ORIGINAL RESEARCH PAPER
Volume - 13 | Issue - 07 | July - 2024 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

EVALUATING ROLE OF EQAS IN ASSESSING AND IMPROVING QUALITY IN REMOTE PHC MEDICAL LABORATORIES

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ABSTRACT

Introduction: The External Quality Assessment Scheme (EQAS), where an outside agency evaluates the analytical performance of several laboratories on test samples it provides, has been demonstrated to be indicative of the quality of patient specimen testing in a clinical laboratory. The laboratory's performance in the EQAS clinical chemistry monthly program conducted by CMC Vellore was evaluated for the period from January 2023 to December 2023. The analysis of the mean OMZ scores for the 9 parameters evaluated during the EQAS cycles from January 2023 to December 2023 revealed the following performance: 77.78% of the parameters achieved an "Excellent" grade, with OMZ scores ranging from 0.00 to 1.00; and the 2.01 to 2.99 range; 0% of the parameters were classified as "Unacceptable", with OMZ scores beyond the ±3.00 threshold. The evaluation of the remote laboratory's performance in the EQAS program has revealed both consistent "Excellent" and "Good" ratings, which instilled confidence in the remote laboratory's ability to provide accurate and reliable test reports to patients. The few instances of "Satisfactory" performance have also highlighted areas for improvement, motivating the Apollo Telehealth (ATH) remote laboratory to enhance its quality management practices and drive continuous quality improvement.

KEYWORDS

External Quality Assessment Scheme (EQAS), SDI/OMZ-Score, clinical chemistry, Remote Public Center Labs

INTRODUCTION

India with being one of the largest democratic republics in world shows in its recent data that only 20% of all the illnesses were treated in public healthcare facilities and 80% in private sector facilities which is alarming. Primary health centers (PHCs) and community health centers (CHCs) are providing only preventive healthcare services.[1] In Healthcare offering pathology services with high-quality, low-cost diagnostic services accessible to rural India, numerous health-care hurdles make it challenging for individuals to access the care they need. The challenges are Limited Resources Remote or Remote PHC Labs often face constraints in terms of budget, infrastructure, and access to advanced technology. This affects the ability to acquire high-quality equipment and employ skilled personnel also supply Chain Challenges Rural regions encounter difficulties in procuring and maintaining a consistent supply of reagents, consumables, and other essential laboratory materials. Limited transportation options and logistical challenges can exacerbate these issues. Remote PHC labs struggle to meet these standards due to a lack of awareness, resources, or expertise in navigating regulatory frameworks. Rural populations have unique healthcare needs and a higher prevalence of certain diseases compared to urban areas which is a challenge itself for Remote PHC Labs.[2] Apollo TeleHealth specialises in integrated healthcare delivery to provide services such as Tele Consultations, Tele Radiology, Tele Cardiology, Tele Condition Management, and Tele Emergency, Tele Laboratory services among others. Apollo Telehealth laboratory aims to fulfil one of the healthcare needs is to report accurate, reliable, and timely laboratory test results. It is crucial for effective disease screening, diagnosis, and patient monitoring.[3] In the process to achieve the quality of laboratory performance, External Quality Assessment Schemes (EQAS) or Proficiency Testing (PT) programs play a vital role. Through these programs laboratory analytical performance is evaluated by analyzing samples provided by an external agency which allows for inter-laboratory comparison and potential error identification.

The role of EQAS-PT schemes has been of prime importance for analytical quality, method standardization, and harmonization of laboratory results. These schemes have been an essential part of the modern Total Quality Management (TQM) concept in the public health system. They have been conducted to assess user performance (participant assessment) and to evaluate different methods and instruments (method assessment). The quality of control materials has been crucial to achieving these goals.

This study was undertaken to evaluate the performance of an ATH laboratory for biochemical parameters by analyzing the Standard Deviation Index (SDI) derived from the Proficiency Testing (PT) or EQAS results. With Clinical laboratories Tele laboratory also have been mandated to deliver accurate, reliable, and timely test results, which are used in decision-making for disease screening, diagnosis, and monitoring. The constant endeavor to improve the quality of results and maintain them at those levels has constituted the quality improvement process through such scheme. Internal quality control programs in tele laboratories only evaluates the performance of the laboratory, including the operator, reagents, analytical procedure, measurement equipment, and analytical result. And In telehealth laboratories, the use of external quality programs (EQAS) has been essential to evaluate the overall performance, it has provided confidence in the reliability of patient test results and enabled the assessment of result accuracy, performance over time, and comparisons with instruments, methods, and peers.

External quality assessment (EQA) or proficiency testing (PT) use blinded samples of patients and retrospectively monitor reporting accuracy by comparing results with those of colleagues. EQA samples must be treated like patient samples and should be examined by the person who normally uses the device. This increases the reliability of patient test results.

A good EQA scheme allows comparison of performance between laboratories, frequent and fast reporting processing time to minimize the amount of time errors are missed. High-quality materials in a format that suits participating lab. It also provides well-designed report that allows quick, easy, and immediate troubleshooting of erroneous

results. Sample matrix like real patient samples, the large number of participants provides a large peer group to compare results, realistic range of analyte concentrations and with integrated program for running all tests proves to be an economical solution also help with training.[4-5]

METHOD

Apollo Telehealth (ATH) has network of remote Primary Health Center (PHC) laboratories across various states in India, including Meghalaya, Assam, Indore, Karnataka, Andhra Pradesh, Odisha, West Bengal, and Rajasthan. The Apollo Telehealth (ATH) remote laboratory participated in the EQAs clinical chemistry II monthly program conducted by Christian Medical College (CMC), Vellore from January to December 2023. The program included the evaluation of 9 parameters: blood glucose, urea, creatinine, total protein, albumin, total bilirubin, total cholesterol, triglycerides, and uric acid. The EQAS samples were received quarterly as lyophilized powders.

Before analysis, the lyophilized samples were reconstituted with 2 ml of distilled water. The tests were performed on a semi-automated clinical chemistry analyzer, Agape Mispa, at the participating remote laboratories. The analyzed test results were uploaded to the CMC Vellore website on the scheduled dates, and the performance reports were downloaded the following month.

The statistical tool used by the EQAS provider was the Standard Deviation Index (SDI), which is a measure of bias. The SDI was calculated using the formula: SDI = (Difference between lab value and target value) / (Standard Deviation of the mean for the comparison group). The SDI is interpreted if the target SDI is 0, which indicates there is no difference between the laboratory mean and the designated value (DV) an SDI of -1.8 indicates a negative bias of 1.8 standard deviations from the method mean (DV)

RESULTS

On analyzing the mean OMZ- Score of each parameter in the clinical chemistry monthly program for the program period of January 2023 to December 2023, of the 9 parameters from the EQAS Cycle-1 overall 77.8% with excellent score, 21.6 % Good and 0.6 % satisfactory. the total results falling in the category respectively in terms of 0MZ- score. The interpretation of the SDI is presented in Table 1

Table-1 Test results falling in different score categories of OMZ - Score %

OMSDI Range	Grade	Remarks	Cyde 1 from January 23 to December 23
0.00 to 1.00	A	Excellent	77.8%
1.01 to 2.00	B	Good	21.6%
2.01 to 2.99	C	Satisfactory	0.6%
Beyond ±3.00	D	Unacceptable	0.0%

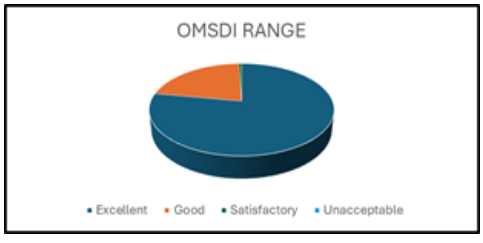

Table 2 Test results falling in different score categories of Mean SDI.

Analyte	OMSDI Range	Mean SDI
GLUCOSE II	0.45 to 1.1	0.7
UREA II	0.47 to 1.21	0.7
CREATININE II	0.49 to1.39	0.8
T. BILIRUBIN II	0.57 to 2.07	1.5
T-PROTEIN II	0.42 to 1.28	0.9
ALBUMIN II	0.34 to 1.1	0.7
URIC ACID II	0.39 to 1.11	0.8
CHOLESTROL II	0.55 to 1.27	0.8
TRIGLYCERIDE II	0.49 to 1.14	0.7

On analyzing the monthly Mean SDI of 9 parameters 8 parameters mean SDI between (0.7 to 0.9) one parameter T. Bilirubin value Mean SDI is 1.5.

Table -3 Test results falling in different categories.

Analyte	A %	B %	C %	D %
ALBUMIN II	89.5%	10.5%	0.0%	0.0%
CHOLESTROL II	89.5%	10.5%	0.0%	0.0%
CREATININE II	79.0%	21.1%	0.0%	0.0%
GLUCOSE II	89.5%	10.5%	0.0%	0.0%
T-PROTEIN II	63.2%	36.8%	0.0%	0.0%
T. BILIRUBIN II	15.8%	79.0%	5.3%	0.0%
TRIGLYCERIDE II	94.7%	5.3%	0.0%	0.0%
UREA II	89.5%	10.5%	0.0%	0.0%
URIC ACID II	89.5%	10.5%	0.0%	0.0%

On analyzing parameters albumin, cholesterol, glucose, Urea, and uric acid fall in the 89.5 % excellent, 10.5 % good category. Creatinine 79.0%, T. protein 15.8%, T. BILIRUBIN 15.8%, and Triglyceride 94.7% fall in excellent category. Creatinine 21.1%, T. protein 36.8%, T. BILIRUBIN 79.0%, and Triglyceride 5.3% fall in the good category. T. BILIRUBIN 5.3% falls in the satisfactory category.

DISCUSSION

PHCs are the second level of the rural health care structure, designed to provide medical and preventive care to the rural population, focusing on preventive and promotional aspects, to run such service quality of lab services are vital. Apollo Telehealth (ATH) has 278 labs all over India which conduct 95 types of tests other than routine biochemical tests cardiac biomarkers tests like natriuretic peptides (NPs), CK-MB fraction, myoglobin, and cardiac troponins are also conducted. In Apollo Telehealth laboratories other than conventional lab setup and has PCoT devices for screening tests of Tuberculosis, anemia and other. As a participant in the proficiency testing program, the laboratory strictly followed the departmental standard operating procedures (SOPs) and manufacturers' instructions for performing the prescribed tests. The impact of EQAS extends beyond the standardization process, as it also influences the post-analytical phase by ensuring the proper use of units of measurement, rounding off, and decimal point reporting of results [6]. EQAS programs were introduced to address the observed variations in results when aliquots of the same sample were analyzed in different laboratories. This was primarily due to the use of different measurement methods and calibration procedures across centers. The commutability of the EQAS samples with clinical patient samples is a critical concept in the design of these programs [7-8]. In the EQAS, participating laboratories receive aliquots of pooled serum samples and perform the nominated parameters, submitting the results for statistical analysis by the coordinating agency.

A Target SDI of 0.0 indicates no difference between the laboratory and the target means The OMSDI values for the various biochemical parameters reflect the deviations from the target or expected results. Significant deviations require the laboratory to implement corrective measures, ranging from kit changes to instrument maintenance, and the deployment of trained personnel. The overall performance of the laboratory for the study period, based on the OMSDI scores of the test results for the 9 parameters in Cycle 1, was acceptable, with no parameter falling in the unacceptable range.

Test results may be in an unacceptable range due to inaccuracies in the sample, storage conditions, reagents, test methodology and others. The instability of biological compounds in lyophilized and liquid serum samples stored at different temperatures has been described in the literature. The maintenance of temperature during the shipping of EQAS samples to the participating laboratories is an area of concern. Additionally, some inconsistencies were observed in the test results for analytes like Creatine kinase and HDL cholesterol, which could be attributed to temperature-related influences and the potential impact on assay reproducibility. The poor performance for Direct Bilirubin could be due to photolysis during storage and reconstitution. The inconsistent performance in some analytes may also be attributed to random errors, such as volume errors in reconstitution, reagent, and sample pipetting, as well as time and temperature-dependent changes in analyte activities and improper storage of samples.[9]

CONCLUSION

The challenges in maintaining quality in remote PHC medical labs of

ATH are arduous compared to any other medical labs but participating in the External Quality Assessment Scheme (EQAS) program plays a pivotal role in improving the efficiency and quality of laboratory services, which is crucial for optimizing the overall healthcare system. Participation in EQAS also enables performance evaluation, addresses patient care and safety concerns, and enhances the quality of remote laboratory practices. To obtain reliable and quality test results, Apollo telehealth laboratories ensure the optimal performance of instruments, use of good quality kits, maintain appropriate sample storage, and have qualified well-trained staff. Widespread global participation in EQAS programs can significantly improve the quality of hospital and PHC services, as no healthcare facility can be entirely self-sufficient, and there is a constant need for continuous improvement and development within the system. The EQAS program provided valuable insights and opportunities for remote laboratories to continuously enhance their capabilities, ultimately contributing to the overall quality of remote patient care.

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