

Assessment of National External Quality Assurance Programme of Pakistan as a tool for improving quality of lab results among participating laboratories

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Abstract

Objective: To assess the impact of the National External Quality Assessment Programme of Pakistan NEQAPP in improving the quality of laboratory results among the participating laboratories.

Method: The cross-sectional observational study was conducted from July to December 2020 at the Department of Chemical Pathology and Endocrinology, Armed Forces Institute of Pathology, Rawalpindi, Pakistan, in association with the National Quality Assurance Programme of Pakistan. A survey questionnaire was developed and sent to the participating laboratories via email. Frequencies of their responses were calculated and data was analysed using SPSS 21.

Results: Of the 150 laboratories approached, 145(96.6%) responded. Among them, 140 (96.6%) laboratories were satisfied by the information provided on the programme's portal, 123(84.8%) were pleased with the responsiveness of the programme manager, 140(96.6%) reported quality of services had improved after participation in the programme, 129(89%) indicated that the clinician's confidence had enhanced, and 122(84%) said the participation in the programme had improved the credibility of their respective of laboratories.

Conclusion: The National External Quality Assessment Programme of Pakistan was found to have significantly contributed in improving the quality of laboratory results among the participating laboratories.

Keywords: Quality control, External quality assurance, NEQAPP. (JPMA 72: 882; 2022)

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Introduction

Globally, medical laboratories (lab) play an important role in clinical practice by providing timely and accurate results which help the clinicians to reach diagnosis, and their importance is growing day by day. It is estimated that 60-70% of medical decisions are lab-dependent.¹ As erroneous results may delay the diagnosis and treatment and may further lead to complications and deterioration of patients, it is essential to maintain and improve the quality of lab results.² In low socioeconomic countries, like Pakistan, where the cost of tests and treatment is a much higher factor for the general population, the right diagnosis in a minimal time may play a role in cutting the cost and lessen the burden of disease on an already compromised health system. Therefore, the quality of lab results is critical for clinician's confidence as well as early and right diagnosis and subsequent treatment of the patient to meet the analytical goal of avoiding errors in analyses.³

Quality control (QC) in the labs ensures that all processes and operations are functioning efficiently, and guarantees the production of accurate and reproducible results.⁴ Internal quality control (IQC) in the lab is

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performed using control materials to ensure the reliability of test results and to evaluate the testing system.⁵ External quality assessment (EQA), also referred to as proficiency testing (PT), intends to bring harmonisation and standardisation of processes by ensuring the evaluation and monitoring of test results through inter-lab comparison across different laboratories over time.⁶

The National External Quality Assurance Programme of Pakistan (NEQAPP) is a standardised platform that systematically determines the quality of the results of the participating laboratories.⁷

It was started in 1996 by the Armed Forces Institute of Pathology (AFIP) in collaboration with the National Institute of Health (NIH) with the aim of minimising the risk of errors in lab results and to incorporate and promote the standardisation of clinical laboratory practices in Pakistan by providing cost-effective external quality assurance services. Initially, it was started in Chemical Pathology labs, but later it was extended to the specialties of Haematology, Microbiology, Endocrinology, and Histopathology. It is also aimed at providing better patient care and quality results of clinical labs in Pakistan along with fulfilling regulatory and accreditation requirements, and at present has 181 labs in its fold.⁷ The NEQAPP programme is run in quarterly rounds every year. Lyophilised control materials are provided to the labs all

at once on a yearly basis, while liquid-based control materials are provided on a quarterly basis. Samples are tested quarterly and results are submitted online on the NEQAPP portal. The current study was planned to assess the quality of NEQAPP as perceived by the participating laboratories in terms of improvement in quality services.

Materials and Methods

The cross-sectional observational study was conducted from July to December 2020 at the Department of Chemical Pathology and Endocrinology, AFIP, Rawalpindi, Pakistan, in association with NEQAPP.

After approval from the institutional ethics review committee, a questionnaire was designed on the basis of literature review.^{8,9} The semi-structured questionnaire, which was scored on a Likert scale, had 12 closed questions. The questionnaire was validated through evaluation by the quality manager of the institution. The questionnaire had 3 sections. Section A related to NEQAPP online portal information and friendliness, response of the programme manager and the cost of participation. Section B related to sample shipment, packaging, integrity and quantity. Section C assessed NEQAPP criteria and the impact of NEQAPP participation in improving the quality of lab results. A pilot study was conducted by sending the questionnaire to 10 qualified lab managers who were not part of the survey. The reliability of internal consistency using Cronbach alpha demonstrated strong reliability (>0.8).

All public and private laboratories registered with NEQAPP and actively participating for >2 years were included, while laboratories participating for <2 years were excluded. The questionnaire was sent without any demographic distribution via email to the selected laboratories, and the responses were received via email as well.

Data in the form of the responses was analysed using SPSS 21.

Results

Of the 181 laboratories registered with NEQAPP, 150(82.9%) were included, and the questionnaire was emailed to them. Of them, 145(96.66%) labs responded. Among them, 5(3.44%) labs were enrolled in 5 specialties, 16(11.3%) in 4 specialties,

21(14.4%) in 3 specialties, 49(33.7%) in 2 specialties, and 54(37.1%) in 1 specialty.

Responses showed that 138(95.2%) labs concurred with the content provided on the NEQAPP portal, 123(84.8%) were satisfied with the responsiveness of the programme manager, and 130(89.6%) reported that the cost of NEQAPP was reasonable (Figure-1).

Further, 136(93.8%) labs agreed they got timely, adequate and intact PT samples, and 131(90%) said they received samples in appropriate packing (Figure-2).

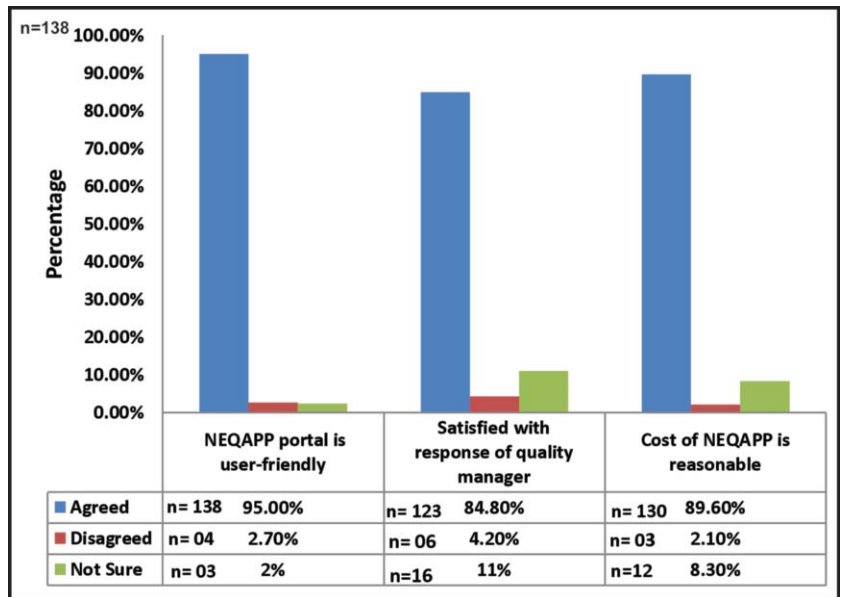
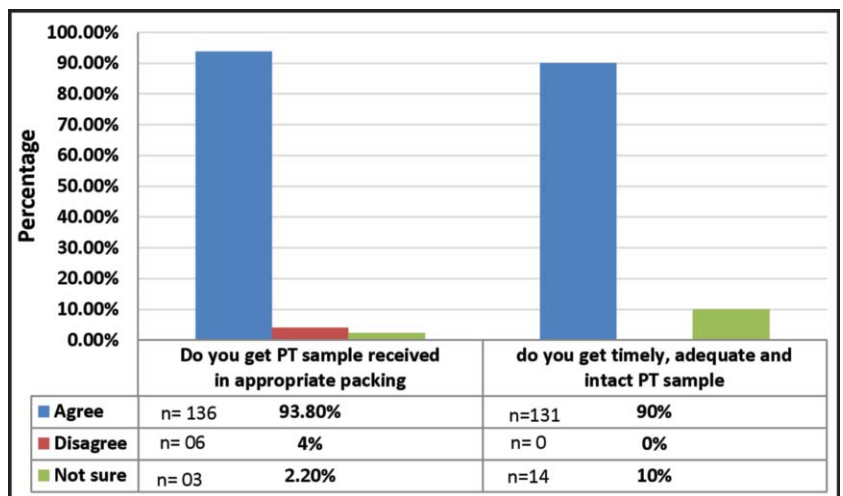


Figure-1: Results of Section A of the questionnaire regarding the National External Quality Assessment Programme of Pakistan (NEQAPP) portal, response of quality manager, and the cost of NEQAPP.



PT: Proficiency testing.

Figure-2: Result of Section B of the questionnaire related to proficiency sample packing.

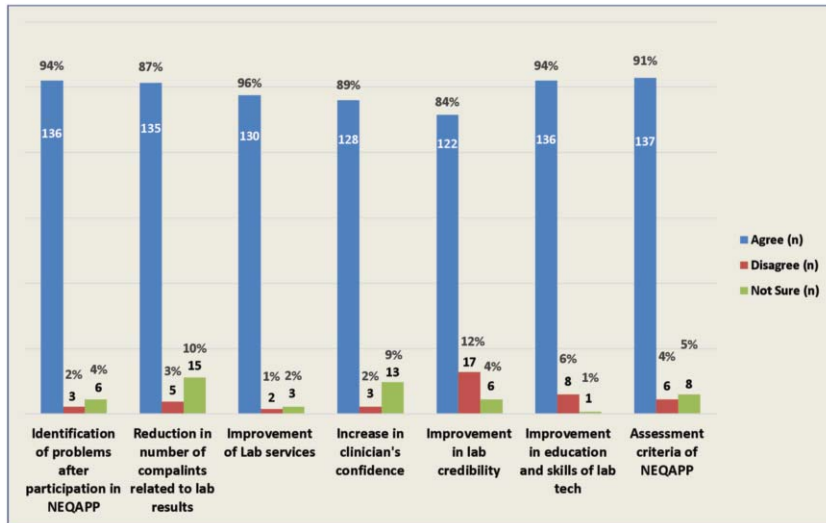


Figure-3: Impact and assessment criteria of the National External Quality Assessment Programme of Pakistan (NEQAPP) (Section C).

Finally, 138(94.5%) labs agreed with the assessment criteria of NEQAPP, 136(93.8%) said NEQAAPP helped in improving technician's education and skills, 136(93.7%) acknowledged that the participation had helped them in identifying problems, 125(86.2%) reported a reduction in the number of complaints related to lab results, 140(96.6%) said the quality of their lab services had improved after participation in NEQAPP, 129(89%) indicated that the clinician's confidence had enhanced, and 122(84%) labs said participation in NEQAPP had improved their credibility (Figure-3).

Discussion

The idea of EQA was introduced in laboratory medicine more than seven decades ago.¹⁰ EQA aims at ensuring that the labs can produce reliable results for clients, such as clinicians, patients and health professionals.¹¹

User-friendliness is a key factor in any website's success and should never be overlooked. The survey responses showed that majority of the responding labs agreed that the NEQAPP portal was user-friendly and had sufficient information. These findings are consistent with guidelines mentioned in literature.¹²

In recent years, various attempts have been made to make EQA schemes web-friendly. In several schemes, both data processing and outcome evaluation are accessible through the internet, which dramatically reduces the time needed to send and receive EQA/PT reports.¹³

An effective EQA requires efficient communication between the participating laboratories and EQA management. Participation in EQA builds a network which can be a great

platform to develop a national laboratory network.¹⁴

The results revealed that 84.8% of lab managers were satisfied with the feedback of the programme manager, while 4.2% reported to have communication gap, which may be attributable to lack of staff dedicated for communication and this gap needs to be resolved in order to enhance quality of communication in the future.

Laboratories in the underdeveloped world are unable to participate in EQA as the standard cost of participation is high. Worldwide, quality assurance programmes are costly, like the clinical chemistry External Quality Assurance Services (EQAS) programme costs about \$700 per annum, and the cost of Randox International Quality Assessment Scheme (RIQAS) ranges from

\$800 to \$1,000 per year. The cost of NEQAPP is quite low compared to these programmes at only \$80 per year. As Pakistan is a developing country, the cost of PT has a significant impact on participation, especially for the smaller laboratories.

PT products should be identified to select the most suitable form of sample packaging and transport. The current study found that 90% participants were of the opinion that they received the PT sample in appropriate packing. This is consistent with World Health Organisation (WHO) guidelines.¹⁵

To accomplish the objective of EQA, the analysis of the EQA samples must demonstrate the consistency of the testing system in the lab, and this target cannot be achieved if a compromised PT sample is used. The current study identified that the majority of participants of the study reported that they received shipment timely having an intact sample. These findings are consistent with the recommendations of a review of PT services for clinical laboratories in the United States.¹⁶

The EQA sample should hold an adequate volume for analysis, potential use by the lab in trainings and process assessment. The current survey revealed that the majority of the labs got an adequate sample volume. The finding is consistent with a study in which only 2.7% labs were not satisfied with the quantity of the PT.¹⁷

According to the current survey, majority of participating labs were satisfied with the evaluation criteria of NEQAPP. Initially, the assessment criteria of NEQAPP were based on standard deviation index (SDI) and error percentage. In 2019,

z-score was included in the assessment criteria to standardise NEQAPP with international EQA programmes. A z-score is a measure of the deviation of the result (X_i) from the assigned value (X) for that determinant, and is calculated as $z = (X_i - X)/\sigma$, where σ is the standard deviation.¹⁸

EQA schemes are used in labs to detect inappropriate practices, allowing for appropriate corrective action. According to the current survey, majority of the laboratories acknowledged the role of NEQAPP in identifying problems in their respective labs and providing appropriate action. These results are consistent with the WHO recommendations for the detection of unsafe activities in laboratories.¹⁵

EQA programmes are critical for labs to constantly enhance and regulate IQC of their results. According to the current study, majority of the labs agreed that participation in NEQAPP had improved the quality of their lab services. The finding is consistent with literature.¹⁹

EQA systems are aimed at improving labour efficiency, expertise and qualifications through education, metrological recommendations and standardisation. According to the current survey, majority of the participants said NEQAPP participation had resulted in significant improvement in technical skills of their staff. This finding is in line with that of an earlier study.²⁰

The current study revealed that majority of the labs were of the opinion that NEQAPP participation had improved the quality of lab services in terms of accuracy, and had decreased result-related complaints, thereby improving lab reputation and physician's confidence. These results are consistent with earlier findings.²¹

Conclusion

NEQAPP was found to have significantly contributed towards improving the quality of results among the participating laboratories in terms of problem identification, timely corrective action, improving lab quality services, and standardising lab processes.

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Conflict of Interest: None.

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