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Original Research Article

Accomplishments in external quality assurance scheme related to HIV testing of stand-alone state reference laboratory at a tertiary care institute of North India

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ABSTRACT

Background: Quality assurance (QA) implemented through quality management systems (QMS) is essential for HIV testing to ensure validity, reliability and accuracy of test results. The Department of Microbiology, PGIMS Rohtak, is working as stand-alone SRL for 117 underlying integrated counselling and testing centres (ICTCs) in whole Haryana state and regularly conducts external quality assurance scheme (EQAS) programs including retesting, proficiency panel testing (PT), etc. in collaboration with National AIDS Control Organization (NACO) and Haryana State AIDS Control Society (HSACS). Objective of study was to assess and analyse data related to EQAS activities viz. retesting and proficiency panel testing of all linked ICTCs in Haryana
Methods: Retrospective study was conducted over a period of six years (2017-2022). PT was conducted twice a year whereas rechecking of samples was done at quarterly intervals. Testing was done as per NACO guidelines.
Results: Total 19113 samples were received and tested at SRL from underlying ICTCs for EQAS retesting. Out of this, 998 samples were HIV positive with no indeterminate result. SRL also provided 4052 panel sera to ICTCs. All results were 100% concordant. Participation of ICTCs increased from 80% in 2017 to around 98% in 2022 with constant support, supervision and monitoring from SRL.
Conclusions: Important cornerstone for containing HIV remains timely and accurate diagnosis. It becomes ethical responsibility of everyone connected with laboratory framework to diligently follow QMS protocols. This ensures patients are accurately diagnosed and treatment initiated timely, thereby fulfilling ultimate goal of ending HIV epidemic as major public health threat by 2030.

Keywords: AIDS, External quality assurance, HIV, NACO, Proficiency testing, State reference laboratory

INTRODUCTION

Quality management system (QMS) can be described as a set of essential building blocks for a laboratory's work operation in order to fulfil defined quality objectives. Quality becomes an absolute requirement especially for HIV testing laboratory as generation of false positive and false negative reports will be accompanied with ethical, medical, social and legal implications.[1]

Quality assurance (QA) is a planned and systematic set of quality activities which focus on providing confidence that various quality requirements are fulfilled. It is a dynamic and ongoing process of monitoring a system for reliability and reproducibility of test results which provides an opportunity for appropriate corrective and

preventive action (CAPA) after going through the root cause analysis (RCA) in case there is discordance in results. It includes minimizing errors during pre-analytical, analytical and post-analytical phases of a laboratory's path of workflow for testing. So, quality assurance implemented through quality management systems (QMS) is essential for HIV testing to ensure validity, reliability and accuracy of test results.[1-3]

The Centre for Disease Control and Prevention (CDC) has developed guidelines for implementing and operating quality assurance programs and recommends various testing sites to participate in external quality assessments i.e., proficiency testing of panels, competency assessments and QA monitoring by an external organization.[4]

Proficiency panel testing (PT) is a periodic evaluation of a laboratory's performance by the organizing laboratory using proficiency panels which comprises a set of predefined validated specimen. The participating laboratory integrates the proficiency panel into the routine workflow in a manner that simulates handling of routine patients' samples. The proficiency testing samples are to be examined using the same procedures and kits as those used for client/patient samples and by the same designated personnel who routinely examine those samples and its results are than reported to the organizing laboratory within the defined stipulated time frame.[1-3]

Rechecking is a process by which a specified percentage of samples are collected systematically from the routine tested samples at the test site, during a pre- determined period of time and are sent to the SRL for verification.[1-3]

The Clinical Laboratory Standard Institute (CLSI) through a process of voluntary consensus has identified twelve quality system essentials (QSEs) as the fundamental building blocks that function effectively to support laboratory's path of work flow.[5]

National AIDS Control Organization (NACO) has established a three-tiered pyramidal HIV laboratory system in order to support quality management, mentoring and external quality assurance scheme (EQAS), with an apex laboratory and national reference laboratories (NRLs) situated at national level, through the state reference laboratories (SRLs) and then down to the point of testing sites at integrated counselling and testing centres (ICTCs).

The SRL, Department of Microbiology, Pandit BD Sharma PGIMS Rohtak, is working as standalone SRL for 117 underlying ICTCs situated in whole of Haryana State and regularly conducts its EQAS programs including retesting, proficiency panel testing, etc. in collaboration with Haryana State AIDS Control Society (HSACS).

Objective

To assess and analyse data related to EQAS activities viz. retesting and proficiency panel testing (PT) of all ICTCs in Haryana.

METHODS

Study type, place and period

A retrospective study was conducted in SRL, Department of Microbiology, Pandit BD Sharma PGIMS Rohtak over a period of six years (2017-2022) of EQAS proficiency panel testing and rechecking. Testing of samples was done as per latest NACO guidelines and instructions received from time to time.

Sample selection criteria

Samples which were not maintaining proper cold chain or were turbid as a result of contamination were outrightly rejected. Also hemolyzed, lipemic, wrongly labelled or those with mismatch in online entry, leaked/soiled or samples which were insufficient in quantity were not included.

Sampling technique

In case of rechecking, every 5th positive sample and every 20th negative sample which was routinely tested in first seven working days of the months of January, April, July and October in all underlying ICTCs were included as per NACO guidelines.

Total 19113 samples were received and tested.

Procedure of rechecking

It employed testing of at least 0.5 ml sample (20% positive samples and every 20th negative sample) by the 10th of respective month, after they were received in SRL by courier service/hand delivery maintaining proper cold chain. Testing was done as per NACO guidelines by using three different assays (A1, A2 and A3) based on different principles or different antigenic composition. Assay A1 was of high sensitivity whereas A2 and A3 had high specificity. A2 and A3 were able to differentiate between HIV 1 and 2 infection.[1-3]

An aliquot of samples sent for rechecking was kept back in the freezer compartment of the refrigerator till results were obtained. The results from rechecking were conveyed to the respective ICTC within seven days (turnaround time) from the receipt of samples.

Procedure of proficiency panel testing

It was carried out twice a year. SRL received eight-member blinded panel sera from NRL for itself. SRL tested the panel along with the routine test samples and

communicated the result in the prescribed format to NRL, National Centre for Disease Control (NCDC), New Delhi for analysis within the specified time of seven working days from the requisition of the panel sera.

SRL also received bulk four member non-blinded panel sera for testing, aliquoting and distributing to the underlying linked ICTCs from NRL.

About 300 µl of sample per ICTC was distributed. ICTCs were expected to receive the panel sera and report the results timely to SRL, otherwise the feedback report for non-compliance was sent to respective district nodal officers and HSACS. ICTC tested the panel along with their routine test samples and communicated the result in the prescribed format to SRL for analysis within the specified timeframe of seven working days of the requisition of panel sera.[1-3]

Statistical analysis

Entire data was collected and entered using Microsoft Office Excel worksheet. It was than exported to statistical package for social studies (SPSS software version 25) and subsequently analysed. Data was compiled in tabulated form and expressed as percentage.

RESULTS

EQAS retesting

A total of 19113 samples were received from underlying ICTCs for EQAS retesting in the past six years (2017-2022). Out of this, 998 samples were HIV positive and the rest were non- reactive for HIV. There was no indeterminate result (Tables 1 and 2).

Table 1: EQAS retesting results of ICTCs.

Years	Total samples sent to SRL for HIV retesting	Total HIV positive samples	Total HIV negative samples	Number of indeterminate samples
2017	2792	170	2622	0
2018	3119	195	2924	0
2019	3711	196	3515	0
2020	2175	86	2089	0
2021	3421	155	3266	0
2022	3895	196	3699	0
Total	19113	998	18115	0

Table 2: EQAS retesting results from ICTCs-SRL.

Period	Total no. of QC samples received at SRL	Total no. of QC samples retested at SRL	Number of samples discordant	% concordance
2017-2022	19113	19113	0	100%

Table 3: Participation of ICTC in EQAS retesting.

Year	Average yearly linked ICTCs	Average linked ICTC participated	Percentage participation
2017	99	86	86.9
2018	103	87	84.5
2019	107	92	85.9
2020	112	87	77.7
2021	113	102	90.3
2022	117	106	90.6

Table 4: Proficiency testing results from NRL-SRL.

Period	Number of proficiency samples (eight membered) received from NRL, NCDC, New Delhi	Number of proficiency samples (eight membered) tested at SRL	No. of samples discordant	% concordance
2017-2022	88	88	0	100

Table 5: Proficiency testing results from SRL-ICTC.

Period	Number of proficiency samples (four membered) sent to ICTCs	Number of proficiency samples (four membered) tested at ICTCs	Number of samples discordant	% concordance
2017-2022	4052	4052	0	100

Table 6: Participation of ICTCs in proficiency testing.

Year	Average yearly linked ICTCs	Average linked ICTC participated	Percentage participation
2017	99	79	79.8
2018	107	91	85
2019	112	81	72.3
2020	112	98	87.5
2021	117	98	83.8
2022	117	115	98.3

Participation of ICTCs increased from 86.9% in 2017 to 90.6% in 2022 with constant support, supervision and monitoring from SRL. There were around 99 ICTCs in 2017 and this number rose to 117 in 2022 as larger number of new ICTCs were developed and subsequently linked to SRL. Participation was less in year 2020 keeping in view of the ongoing COVID-19 pandemic and various lockdowns and other restrictions imposed by government (Table 3).

Proficiency panel testing

Total 88 proficiency panel sera tests were conducted from 2017-2022 at SRL of eight membered blinded panel sera which was received from NRL. There has been 100% concordance in results (Table 4). During same time period, 4052 panel sera tests were done in underlying ICTCs of four membered panel sera which were sent to them twice every year. Concordance has been 100% in results received from ICTCs too (Table 5). Participation of ICTCs in proficiency testing also increased from 79.8% in 2017 to 98.3 % in 2022 (Table 6).

DISCUSSION

An estimated seventy percent of medical decisions are said to be made solely on the basis of diagnostic laboratory test results. Laboratory is in fact a complex system, which involve many steps and many people are involved in it too. A laboratory quality system is only as good as staff that works with it. No matter how good a quality system is, if it is not carried out consistently in daily practise and routine workflow such that it becomes a habit, high standards of quality can never be guaranteed. So, the importance of trained laboratory personnel who can perform, supervise, interpret and validate laboratory analysis at all times cannot be underestimated. This is where role of continuous monitoring and supervision along with total coordination from higher authority comes in picture.

Our EQAS results were 100% concordant as these aspects were taken care of during routine training and monitoring of all underlying ICTCs. Pavani et al in their study reported 0.027% discordant results in retesting because of wrong labelling, transcriptional errors and incorrect testing technique.[6] Sushi et al in their study reported 0.50% discordance in retesting due to mislabelling, sample contamination, leakage in vials, transcriptional errors and wrong testing techniques.[7] They also reported 2.86% discordance in proficiency testing for which ultimately hands on training was provided after going through RCA, so that discordant centres report correct results on retesting. In another study by Sherwal et al, 0.44% discordance in EQAS retesting was reported which was attributed to the use of different test kits in blood banks (BBs) and at SRL.[8] So, the importance of uninterrupted supply of similar kits in BBs and SRL was emphasized for proper comparison and confirmation of EQAS retesting results.

Quality of the testing process can be compromised at any of the phases of the laboratory's path of workflow. Under pre-analytic stage, samples need to be collected in proper condition with correct technique in laboratory and transported at earliest maintaining proper cold chain and they should not be turbid due to contamination, hemolyzed, lipemic, wrongly labelled, leaked/soiled or insufficient in quantity. Analytic stage is where there can be possibility of dilution errors, not adhering to recommended temperatures at which test needs to be conducted, improper use of dropper or pipette tips, inconsistent technique, usage of non-calibrated or poorly maintained equipment (pipettes, centrifuge, digital thermometer, incubator, timer), using expired kits, mixing components/reagents from different kits/lots and not adhering to standard operating procedures (SOPs)/QC procedures. Post analytical phase also need to be taken seriously as it consists of delivering the accurate report to the right person accompanied by post-test counselling within the stipulated time frame.[1-5]

In addition to this, SRL at Microbiology Department, PGIMS Rohtak conducts regular training programmes and participates in regular onsite monitoring and mentoring of its linked ICTCs spread over whole of Haryana state. It also evaluates adherence of the testing sites to their QMS by using a standard checklist of laboratory indicators for systematic assessment of laboratory practices in all the three phases of testing. During these visits by technical officer (TO) posted at SRL, every aspect of HIV testing laboratory's QMS is assessed to identify gaps if any and to facilitate appropriate CAPAs after going through RCA wherever required.

In our study, participation of ICTCs increased from 80% in 2017 to around 98% in 2022 with constant support, supervision and monitoring from SRL. The reason for low participation earlier had been non-availability of designated and dedicated staff, shortage of testing kits or ICTCs remaining non-functional. Hence, efforts were made to constantly encourage and motivate ICTC incharges and district nodal officers of HIV/AIDS to participate in EQAS programmes with support and guidance from HSACS and NACO. Sherwal et al, in their study reported only 40% participation in proficiency testing during 1st round in 2011 due to non-availability of testing kits in those centres.[8] So, the importance of the concerned authority to provide them continuous supply of kits in adequate amount as well as the responsibility of the laboratory in charge of each linked centre to maintain a proper stock register so as to inform the higher authority well within time before they exhaust all the kits was emphasized upon.

Point of care tests have become increasingly popular in some places in Canada and USA over the past several years. These tests provide rapid, on-site HIV results in a format that is relatively easy for clinic staff to perform and for clinicians to interpret. However, the performance of these tests requires adherence to good laboratory quality control practices, QA, participation in HIV proficiency testing programs as well as the backup of some licensed diagnostic laboratory to provide confirmation and resolution in case of some positive or indeterminate result, so as to ensure that diagnostic laboratories provide accurate, timely and clinically relevant laboratory results.[9]

Various studies have been performed in different parts of the world which emphasize and analyse the importance of EQAS related to rechecking and proficiency testing in providing an indispensable opportunity to pick up erroneous test results which otherwise would have been left undetected. The recommendation from monitoring and evaluation in a QA program will play an important role in improving the standards of HIV testing centres and reliability of results among both patients and medical fraternity.[10-13]

German Medical Association has given immense stress in QA in their recent guidelines of diagnosis of infectious disease. These guidelines have been made mandatory for all the German laboratories. Sections B (B1-B5) specify the criteria for the quality of results and the evaluation of the individual test procedures for diagnosis of various diseases including HIV. The most conspicuous change compared to the already existing guidelines being that all quantitative medical laboratory tests performed by a medical laboratory are subject to internal quality control.[14]

Limitations

The present study was conducted among samples which were collected and received from ICTCs during a specific time period as per NACO guidelines for quality analysis from time to time. So, it shall be difficult to generalise our findings pertaining to daily quality implementation and other QC checks in all underlying laboratories on a real time basis.

CONCLUSION

An important cornerstone for containing HIV remains its timely and accurate diagnosis among various population groups. So, it becomes ethical and moral responsibility of all laboratory personnel connected with HIV testing network to diligently follow all QMS protocols at all levels.

This will in fact also ensure that clients/patients are accurately diagnosed and their treatment initiated timely, thereby fulfilling our ultimate goal of ending HIV epidemic as a major public health threat by 2030.

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