External Quality Assessment Scheme for Transfusion Transmissible Infections among Blood Service Facilities in the Philippines, 2018

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ABSTRACT

External Quality Assessment Scheme (EQAS) is an important and vital component of a quality system to which a retrospective and periodic assessment of quality can be undertaken by an independent external agency.

The Transfusion Transmissible Infections–National Reference Laboratory (TTI-NRL) annually provides an EQAS program for transfusion transmissible infections to all blood service facilities in the Philippines as a requirement for the renewal of their license to operate and raise the quality standards of testing for infectious diseases.

A total of 188 participants registered in the 2018 test event and were given an EQAS panel comprised of a serology program (HVHT4120) and malaria program (MLRA415). Results from the participants were submitted through an online informatics system managed by OneWorld Accuracy Canada using the ISO 13528:2008 Robust Statistics method (Huber's Method). Results were analyzed and evaluated with the reference result from the TTI-NRL.

The HVHT4120 program generated 15,330 results and the MLRA415 generated 940 results. 97 results (0.63%) and 80 results (8.51%) were reported as aberrant from each program respectively and were either due to random or systematic errors.

The data generated from this test event are used for the improvement of the quality processes of each participant and the subsequent renewal of their license to operate as required by local health regulations.

Key words: EQAS, transfusion transmissible infections, blood safety, quality improvement

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INTRODUCTION

Quality assurance comprises all activities and programs that are planned, developed and practiced to establish the confidence that products or services meet customer expectations. An important and vital component of a quality system is assessment to which a retrospective and periodic assessment of quality can be undertaken by an independent external agency.[1]

Participation in an external quality assessment scheme is an annual requirement for the licensure of blood service facilities in the Philippines as regulation is one of the objectives of the Department of Health to ensure access to quality services.[2] This also aims to stimulate performance improvements and raise the standards of testing.

Transfusion of safe blood involves a number of processes from donor selection until the administration to the recipient. The blood service facilities play a major role in the provision in the transfusion process and errors in screening donated blood can have serious implications for the recipients of these blood products.

This report evaluates the results of the participants of the external quality assessment scheme provided by the Transfusion Transmissible Infections – National Reference Laboratory in 2018.

METHODOLOGY

Panel Composition

The 2018 transfusion transmissible infections test event consists of two programs, (a) HVHT4120 for blood donor serology and (b) MLRA415 for malaria microscopy.

The HVHT4120 program consists of twenty (20) pooled plasma samples obtained from blood donors from different regions in the country. Each pooled sample was prepared by mixing similar volumes of at least two samples that had similar antibody and antigen profiles. All samples were subjected to filtration prior to aliquoting. The samples were aliquoted, and their homogeneity confirmed. The serology profile for HIV, Hepatitis B and C, Syphilis of each sample were identified using serological assays: chemiluminescence assay (ChLIA), enzyme immunoassay (EIA), Rapid Plasma Reagin (RPR), Particle Agglutination (PA) and a Differentiation/Supplemental Assay (SA).

The MLRA415 program consists of five (5) blood smears and the samples were obtained from malaria patients in Palawan. These were prepared by the National Reference Laboratory for Malaria and other Parasites of the Research Institute for Tropical Medicine.

Participants

The 2018 transfusion transmissible infections panel were distributed to 188 participants nationwide (Figure 1) and were charged a registration fee to cover expenses for the test event. 46% (n=87) of the participants are from private institutions, 40% (n=75) from government institutions and 14% (n=26) from the Philippine Red Cross (Figure 2).

Data Analysis

Participants were asked to enter assay results through the online informatics system developed and operated by Oneworld Accuracy Systems (OASYS™). Results reported by the participants for assay interpretations and final status were compared with the relevant reference results for qualitative evaluation. An assay interpretation that is different from the reference result is marked as aberrant.

ISO 13528:2005 Robust Statistics method (Huber's Method) was used to identify outlying results (numerical test results found to be statistically different from other test results reported by participants that tested the same sample in the same assay) for the created peer groups. A peer group is defined as a set of laboratories that utilize the same test format and assay test kit for screening TTI. The said method uses the mean as an estimator and outlying test results were removed from statistical calculation.

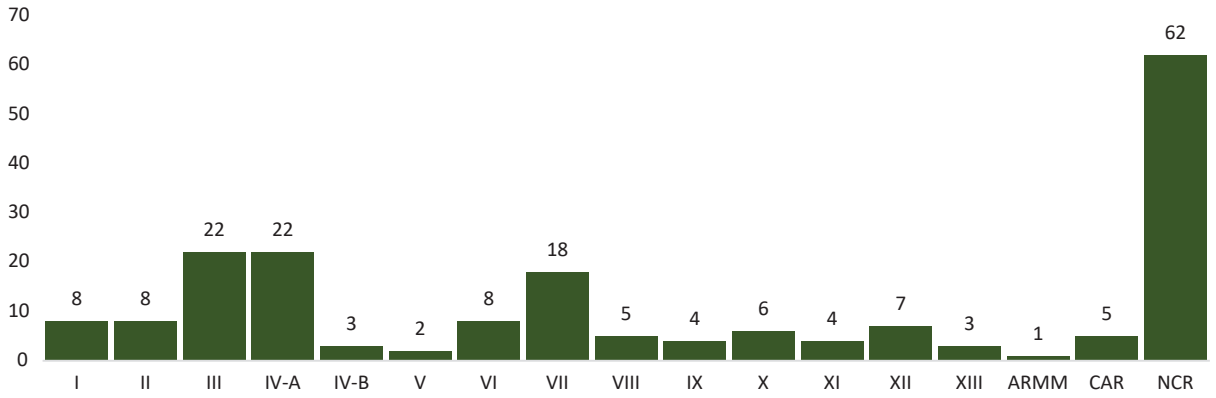

Figure 1. Regional distribution of participants, 2018 TTI-NRL EQAS.

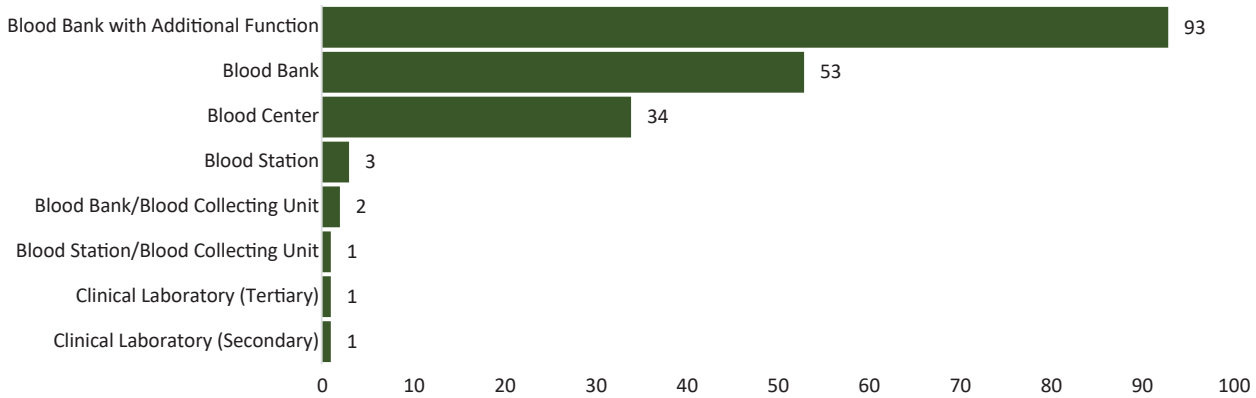

Figure 2. Distribution of participants according to License to Operate issued by the DOH-Health Facilities Services and Regulatory Bureau.

RESULTS AND DISCUSSIONS

A total of 15,330 results were generated from 75 assays for the HVHT4120 program and 940 results were generated through malaria microscopy for the MLRA415 program.

Data entry errors

One (1) participant reported a "reactive" test results but submitted a "negative" assay interpretation. Two participants reported a "negative" test result but submitted a "reactive" assay interpretation.

False positive results

Seven (7) participants reported false reactive results on known negative samples. Twenty-five participants reported false reactive results on samples with a different analyte present.

False negative results

Nine (9) participants reported false negative results on initial testing.

Educational sample (HBsAg and Anti-TP reactivity)

One (1) participant reported a "negative" result for Anti-TP on the HBsAg and Anti-TP reactive sample. One (1) participant reported a "reactive" test result for HIV Ag/Ab.

Educational sample (HIV p24 Antigen)

Four (4) participants reported a "reactive" result using a 3rd generation HIV assay. Seven (7) participants reported a "negative" result using a 4th generation HIV. Two (2) participants reported a different analyte present on the sample.

From the total number of results generated in the HVHT4120 program, 97 results (0.63%) were reported as aberrant.

Scoring Criteria

A participant shall be rated as an unsatisfactory performer in the HVHT4120 program if one of the following criteria are met:

a. at least one false negative result
b. at least twenty percent (20%) false positive results

Participants with aberrant results are given an investigation checklist to aid them in identifying errors and perform the corrective action needed. A 2nd set of the HVHT4120 program are given to participants if the unsatisfactory performance was due to a testing error. Eleven (11) participants were given a second set of samples wherein three (3) participants reported aberrant results (2 false reactive results and 1 inconclusive result).

From the total number of results generated in the MLRA415 program, 80 results (8.51%) were reported as aberrant.

Figure 3 shows the participants' rating according to the following grading scheme:

1. EXCELLENT – 100% acceptable results on the initial panel (all final results were correctly identified in comparison with the reference results);
2. VERY SATISFACTORY – Less than 100% acceptable results on the initial panel without being given a second panel for retesting;
3. SATISFACTORY – 100% acceptable results on retesting of the second panel; or had an aberrant result in the initial panel due to a clerical error, given that the participant was able to identify this error through the EQAS investigation checklist;
4. POOR – Participant did not follow minimum requirements as per Department of Health issuance (Department Circular No. 2013-0132) or less than 100% acceptable results on retesting of the second panel; or had an aberrant result in the initial panel due to a clerical error which the participant had failed to identify in the EQAS investigation checklist.

CONCLUSION

Majority of blood service facilities use serological assays to screen for malaria, the malaria EQAS program is limited to blood smears as majority of these assays require freshly collected samples. Participants are recommended to be equipped with the gold standard of malaria diagnosis which is microscopy.

Participation in the external quality assessment scheme for transfusion transmissible infections by all screening blood service facilities in the Philippines is critical and necessary to ensure the accuracy of results generated from serological tests.[3] This shall enable the EQAS provider to assess and monitor the quality of laboratory results generated by the participants. The performance report given at the end of the cycle to the participants shall aid them in analyzing the essential corrective and preventive action for outliers and/or aberrant results and shall also compare their performance with other laboratories which shall improve their quality processes.

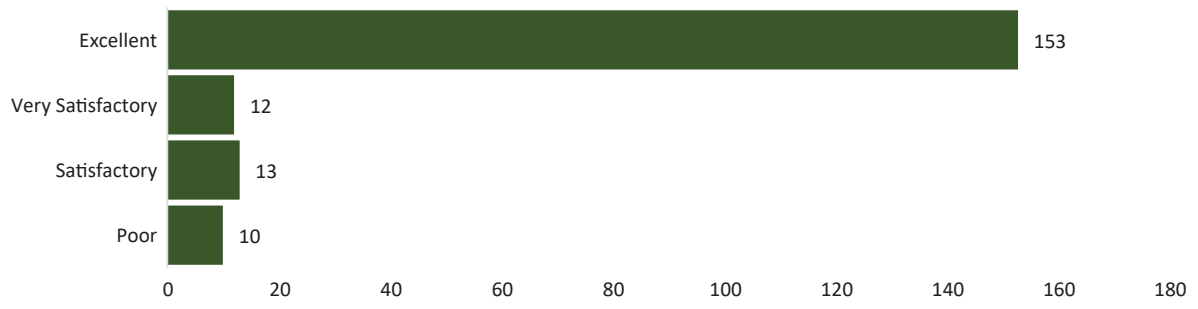

Figure 3. Participant rating distribution, 2018 TTI-NRL EQAS.

RECOMMENDATION

Participation in the external quality assessment scheme in the Philippines is a mandatory requirement for the renewal of the license to operate of all laboratories. The participants should take this as an opportunity to challenge their current quality management system as they should be adhering to the standards set by the Department of Health.

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STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

AUTHOR DISCLOSURE

The authors declared no conflict of interest.

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