

# Department of pathology and laboratory medicine at Jigme Dorji Wangchuck National Referral Hospital striving for quality: external quality assessment scheme in hematology

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## ABSTRACT

**Introduction:** Quality Assurance comprising External Quality Assessment Scheme (EQAS) and Internal Quality Control (IQC) is an indispensable part of the laboratory analytical process to ensure reliable results from the laboratories. However, due to various challenges in many developing countries such as limitations in resources and manpower, EQAS samples are often given less importance at laboratories. The objective of this study is to assess performance on hematology EQAS samples received from Pacific Paramedical Training Center- External Quality Assessment Scheme (PPTC-EQAS) and International External Quality Assessment Scheme-United Kingdom (IEQAS-UK) since 2007 and 2008 respectively. The findings from this study will be helpful to establish an effective system to ensure timely follow up and corrective actions to improve the quality of laboratory services. **Methods:** The feedback of the EQAS results submitted thrice a year to the PPTC-EQAS and six times a year to the IEQAS-UK since 2007 and 2008 respectively were reviewed to assess the laboratory's performance and to determine the effectiveness of EQAS participation for improving the performance of laboratory hematology in Bhutan. **Results:** For PPTC-EQAS, the average yearly scores were 69.00%, 75.00%, 87.66%, 87.50%, 70.00%, 80.33%, 80.50%, 85.00% for the years 2007-2014. For IEQAS-UK, the average yearly scores were 76.66%, 75.95%, 77.91%, 85.83%, 92.50%, 63.88% and 98.14% for the years 2008-2014. Our results show inconsistent performances on both EQAS samples despite gradual improvement over the last seven years. **Conclusions:** We conclude that, strengthening the system for regular follow up and implementing corrective actions for the outlying results in addition to replacement of the equipment could improve the trend and ensure consistency of the performance.

**Keywords:** Corrective action; Quality assurance.

## INTRODUCTION

The importance of Quality Assurance (QA) in clinical laboratories has been overlooked in many developing countries. QA comprises Internal Quality Control (IQC), External Quality Assessment scheme (EQAS), proficiency surveillance and standardization<sup>1</sup>. IQC involves daily monitoring of the quality of the test results while EQAS involves the evaluation of the performance of participating laboratories by external agencies<sup>2</sup>. Limitations of resources and manpower, inadequate knowledge and training opportunities and the lack of management support are some of the major challenges faced in improving the quality of laboratory services. For the above reasons, laboratories in developing countries rarely participated in EQAS or do not use the EQAS reports for the correction of the laboratory errors. Although the Hematology Unit, Department of Pathology and Laboratory Medicine, Jigme Dorji Wangchuck National Referral Hospital (JDWNRH) has participated in the Pacific Paramedical Training Center- External Quality Assessment Scheme (PPTC- EQAS),

New Zealand and the International External Quality Assessment Scheme-United Kingdom (IEQAS-UK), since 2007 and 2008 respectively, it has not reviewed and used the information for the correction of the laboratory errors. We conducted a retrospective study regarding the performance of the hematology unit in EQAS conducted by PPTC- EQAS and IEQAS-UK since 2007 and 2008 to 2014 respectively.

## METHODS

EQAS samples were received three and six times a year from PPTC-EQAS and IEQAS-UK respectively. All the samples were analyzed at the Hematology Unit, Department of Pathology and Laboratory Medicine, JDWNRH, Thimphu, Bhutan. The samples were processed according to the instructions provided by the EQAS providers and analyzed according to the standard operating procedure of the department. The test results were mailed to the reference laboratory before the closing date and feedbacks was obtained within three weeks after the submission of the results.

In each cycle, PPTC-EQAS sent three stained blood smears for peripheral blood smear examination and interpretation, or photographs to examine with appropriate questions to be answered. The peripheral blood smears were accompanied by

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a brief clinical history and basic blood count parameters. The IEQAS-UK sample for each cycle consisted of fixed human platelets and pseudo white cells suspended in haemolysate for platelet, white blood cell and hemoglobin estimation respectively. The blood film examination included three slides: a May-Grünwald-Giemsa stain, methanol-fixed blood film for peripheral blood smear examination, a supravital stain (Brilliant Cresyl Blue) slide for reticulocyte count, and a methanol-fixed Giemsa stain slide for parasite identifications. However, in some cycles, lysate specimens or smears for reticulocyte or morphology or parasite identifications were not sent. The lysate specimen for platelet, white blood cell and hemoglobin estimations were run on a 5-part differential automated cell counter. The quality of the analyzer was checked and validated with use of three level (high, low and normal) commercial Quality Control (QC) materials prior to the analysis. The blood films for reticulocytes and parasites were examined by Medical Laboratory Technicians (MLT) whereas analysis of blood films for morphology and interpretation were performed by a Medical Technologist (MT) or Pathologist.

The overall scores provided by the PPTC- EQAS for each cycle are compared with the average peer scores. In IEQAS-UK, the performances in lysate specimen analysis and reticulocyte estimation were graded based on the standard deviation index (DI). The parameters with DI less than three were considered to be satisfactory while those above three were considered to be unsatisfactory. The numbers of acceptable results in each cycle

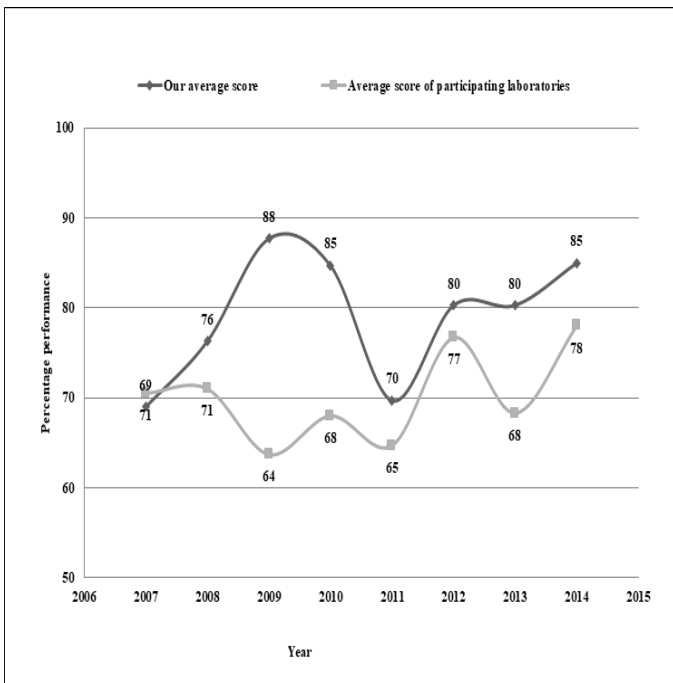
were counted and total acceptable results are presented.

The study protocol was approved by the Research Ethics Board of Health, Ministry of Health, Bhutan via letter no: REBH/ Approval/2015/040.

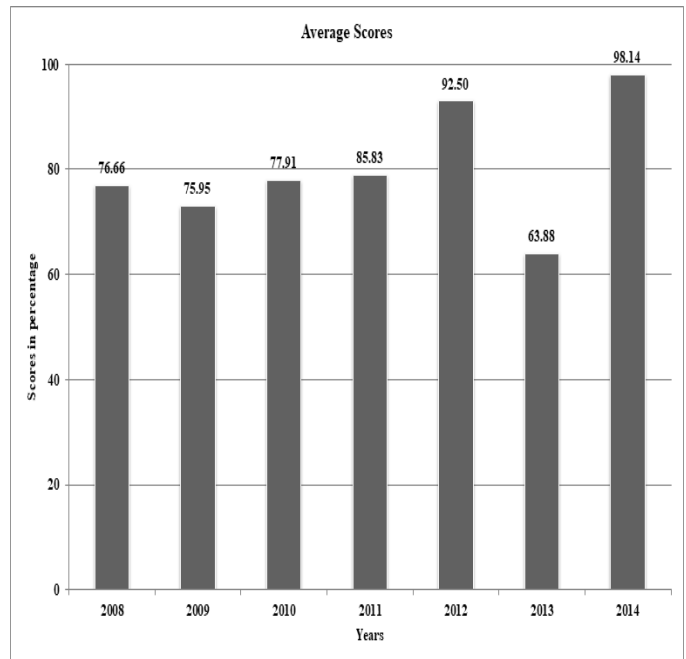
## RESULTS

For PPTC-EQAS, our average yearly scores were 69.00%, 75.00%, 87.66%, 87.50%, 70.00%, 80.33%, 80.50%, 85.00% for the years 2007 to 2014 respectively. The average peer performance score was 70.50%, 71.50%, 63.66%, 69.50%, 65.00%, 76.66%, 67.00% and 70.00% for the same respective years (Figure 1). The Figure 1 shows a gradual improvement through 2009, followed by a drop almost to the initial performance level in 2011; however, performance consistently improved since then. The graph shows better performances by our laboratory compared to average peer performance scores.

For IEQAS-UK, the average yearly score on all the 6 parameters were 76.66%, 75.95%, 77.91%, 85.83%, 92.50%, 63.88% and 98.14% for the years 2008-2014 respectively (Figure 2). The Figure 2 shows mild decline in performance in 2009 which gradually improved but dipped again in 2013 indicating inconsistency in performance over the last seven years. The performance on individual test parameters for seven consecutive years is summarized in Table 1 and Table 2.



**Figure 1.** The average yearly score in percentage of the hematology unit, Department of Pathology and Laboratory Medicine, JDWNRH compared to peer averages in PPTC-EQAS samples for eight consecutive years (2007 to 2014)



**Figure 2.** The average yearly scores in percentages of the hematology unit, Department of Pathology and Laboratory Medicine, JDWNRH in IEQAS-UK samples for seven consecutive years (2008-2014)

**Table 1. The number of acceptable performances from hematology unit, Department of Pathology and Laboratory Medicine, JDWNRH for seven consecutive years (2008-2014) in IEQAS-UK**

Year	WBC <sup>1</sup>	Hb <sup>2</sup>	Platelet	Reticulocyte count	Parasite identification	Blood film examination
2008	8	NR <sup>3</sup>	0	5	2	4
2009	7	NR <sup>3</sup>	2	7	6	6
2010	7	10	6	7	5	5
2011	5	8	8	NR <sup>3</sup>	2	4
2012	6	8	8	4	3	6
2013	7	10	3	4	7	4
2014	1	1	1	1	3	8

**Table 2. The percentages of acceptable performances from hematology unit, Department of Pathology and Laboratory Medicine, JDWNRH for seven consecutive years (2008-2014) in IEQAS-UK**

Year	WBC	Hb	Platelet	Reticulocyte count	Parasite identification	Blood film examination	Average Scores
2008	100.00	NR3	0.00	83.33	100.00	100.00	76.66
2009	87.50	NR3	33.33	87.50	85.71	85.71	75.95
2010	70.00	83.33	60.00	87.50	83.33	83.33	77.91
2011	62.50	100.00	100.00	NR3	66.66	100.00	85.83
2012	75.00	80.00	100.00	100.00	100.00	100.00	92.50
2013	58.33	83.33	25.00	50.00	100.00	66.66	63.88
2014	100.00	100.00	100.00	100.00	100.00	88.88	98.14

1. White blood cell
2. Haemoglobin
3. NR shows those results failed by the laboratory to report /samples not sent by EQAS provider/sample not satisfactory for analysis

## DISCUSSION

Our study showed that the performance of the Hematology Unit, Department of Pathology and Laboratory Medicine, JDWNRH in both EQAS was inconsistent over the years despite securing satisfactory performance in a majority of the cycles. We also found that, the overall performance in peripheral blood smear examination, development of correct morphological comments, identification of parasites and reticulocyte estimation was frequently excellent and acceptable in almost all cases. However, it was observed that there were difficulties in identifying *Plasmodium malariae* and *Plasmodium ovale* species. Since these species are rarely encountered in our routine practice, they are difficult to diagnose. The same pattern of difficulties in identification of *Plasmodium malariae* and *Plasmodium ovale* species were also faced by the National Institute of Health, Islamabad, Pakistan<sup>3</sup>.

The Figure 1 shows a gradual improvement in performance till 2009, followed by a drop almost to the initial

performance level in 2011. Performance improved gradually after this low level. This inconsistency in performance could be due to frequent changes in laboratory staff and inadequate exposure of the laboratory staff to the latest concepts and pattern of laboratory hematology practices. However, the graph shows that our laboratory performance is better than the peer group in terms of average peer performance scores. On IEQAS- UK samples, Figure 2 shows a slight decline in performance in 2009 which gradually improved, then dipped again in 2013. This shows inconsistency in performance over the last seven years because of the same logistic reasons stated above.

Table 1 and Table 2 shows poor performance in platelet estimation. However, similarly poor performances are also observed in many hematology laboratories in developing countries<sup>4</sup>. Higher rates of unsatisfactory results in platelet and white blood cell count estimations were seen for the entire period of the IEQAS-UK cycle for all the participating laboratories. One of the major reasons for our poor performance in platelet count estimation could be due to the unacceptable imprecision and bias

of the cell counter used in our laboratory. The principle of the current cell counter is based on electrical impedance and light scattering; thus, replacement of the cell counter with the latest and combined principle of analysis may give better precision and accuracy of blood count analysis. The incorrect reticulocyte estimation ( $n=7$ , 20.00%) from our laboratory was solely due to reporting of reticulocyte counts on unsatisfactory blood films.

Quality assurance is an essential procedure to ensure reliability of the laboratory investigations. The rapid replacement of manual laboratory test procedures with complex automation to meet the increasing demand for laboratory investigations has increased the need of constant quality monitoring<sup>5</sup>.

Although we have participated in EQAS programme since 2007, minimal corrective actions were taken and documented. This minimal usage of EQAS for benefit correlates with the unavailability of qualified supervisors for the period. Since most of the laboratories analyze the EQAS samples with additional care, any error observed should be considered the tip of the iceberg; thus even minor errors in EQAS should be seriously considered. In addition to the participation in EQAS; there should be a system to assure that corrective actions are taken adequately, promptly and appropriately so that participating laboratories benefit optimally.

Since this was a retrospective study, we could not trace few of the EQAS feedback from the initial cycles.

## CONCLUSIONS

Overall, our reports showed inconsistent performances over the last eight years. However, the performance has been found to be satisfactory and better than the peer average performance. We conclude that, the strengthening of the system for regular follow

up and corrective actions for the outlying results and replacement of the equipments could improve the trend and ensure the consistency of the performance.

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### AUTHORS CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under:

**KD:** Concept, design, literature search, data collection and analysis, manuscript writing and review.

**RJ:** Concept, design, data analysis, manuscript writing and review.

**PDS:** Concept, design, data analysis, manuscript writing and review.

**PR:** Concept, design, data analysis, manuscript writing and review.

**DW:** Concept, design, data analysis, manuscript writing and review.

Author agree to be accountable for all respects of the work in ensuring that questions related to the accuracy and integrity of any part of the work are appropriately investigated and resolved.

### CONFLICT OF INTEREST

None

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None