AN EXTERNAL QUALITY ASSESSMENT OF HAEMATOLOGY LABORATORIES - A GHANAIAN EXPERIENCE

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ABSTRACT
Developed countries have guaranteed the quality of clinical laboratories through quality assurance programmes. However, these programmes have not received the needed attention in Ghanaian haematology laboratories, as is the case in many developing countries where visual counting of blood cells are the usual procedures. To assess the level of analytical quality of haematology laboratories in the Ashanti region of Ghana, form of an external quality assessment scheme was undertaken. The survey covered twelve haematology laboratories in both the public and the private sectors. Control blood samples were sent to the laboratories to be analyzed. The study, which lasted for five months, covered such routine haematological parameters as Hb, PCV, Total WBC and platelets. The results from these laboratories were compared to that of an automated cell counter using the Cell-Dyn 3700 (Abbot Diagnostic Division, USA). About 80% of the laboratories studied which were using the manual counting, achieved the medically accepted analytical performance for all the parameters except platelets, where the percentage of the laboratories dropped to about 70%. The study has established the need for a continuous internal and external quality assessment in haematology. Such practice together with continuous education of laboratory personnel and the provision of automated instruments will help to achieve optimum laboratory quality needed for proper health care delivery in the country.

Keywords*:* External quality assessment, haematology laboratories, Ghana.

INTRODUCTION
In the clinical laboratory, both accuracy and precision are maintained by internal quality control (IQC) and complemented by external quality assessment scheme (EQAS) (England *et al*., 1998). External quality assessment is a system of retrospective and objective comparison of results from different laboratories by means of proficiency testing organized by an external agency (England *et al.,* 1998). IQC is a set of procedures undertaken by laboratory staff for the continuous monitoring of operation and the results of measure-

ments in order to decide whether results are reliable enough to be released (England *et al.*, 1998). The main purpose of EQAS is to establish between-laboratories and between-methods, including between instruments comparability and agreement with a reference standard as well as detecting systematic errors (bias) (Cheesbrough, 2000). Thus, an acceptable level of quality necessary for ensuring that clinical laboratory results are reliable would therefore require both IQC and EQAS (Cavill *et al.*, 1981; Gulati and Hyun, 1986; Whitehead and Woodford, 1981).

Full blood count (i.e. haemoglobin, packed cell volume, red blood cell count and indices, total white blood cell count, differential white blood cell count and platelet count) appears to be the greatest proportion of work in most haematology laboratories and a decline in analytical reliability is likely to have serious clinical effect (Lewis, 1995; 1998). It is therefore essential that countries with no national systems in place for EQAS as is the case in Ghana, could initiate an official EQAS starting with a few laboratories and solely dependent on commercially prepared controls, taking into account the different methods used; reagents or kits, instruments and equipment with regard to current practices.

Whilst IQC and EQAS programmes continue to play an integral part in clinical laboratories of developed countries, these programmes have not been accorded the same degree of importance in the laboratories of developing countries, including Ghana. This is because there is no national policy on the training and practice of Medical Laboratory Science in these countries as well as the existence of an independent body to assess the performance of clinical laboratories by EQAS. Even though, the Ministry of Health in January 2000, initiated a two-year programme to determine the feasibility of establishing a nation-wide quality assurance system for common tests performed at peripheral laboratories (Bates *et al.*, 2004), this programme is yet to be implemented.

Counting of blood cells is mostly visually performed in most haematology laboratories in Ghana. Manual methods used in haematology yield larger coefficient of variation (CV) than automated methods as a result of wide inherent and technical errors (Fink *et al*., 1997). This study which was conducted between February and June, 2006 with assistance from the Ghana Association of Biomedical Scientists, is aimed at assessing the performance of haematology laboratories in Kumasi, in the Ashanti region of Ghana, in the routine haematological parameters of Hb, PCV, WBC and Platelets. The study further sought to compare the results of manual and automated methods of estimation and to determine whether the level of precision currently achieved in the laboratories meet the medically useful criteria for the analytical performance.

MATERIALS AND METHODS

Samples preparation

The Inter-laboratory proficiency trials require volumes of preserved blood, which, are of constant composition and free from microbial contamination. Donor blood samples that were taken into blood bag containing anticoagulant Citrate Phosphate Dextrose Adenine solution, CPDA-1 (USP); non-reactive to HIV, HbsAg and HCV antibodies and had not been stored for more than 48 hours were used for the study. The blood was kept at 2-6ºC prior to its use.

A proportion of one part of fixative (40% Formaldehyde (6.7 ml), 50% Gluteraldehyde (0.75 ml), trisodium citrate (26.0 g), de-ionized (100 ml) water) to 50 parts of blood was made up freshly on each occasion to preserve the morphology of the blood cells for the analysis of all the parameters.

After the blood was fully re-suspended and evenly distributed by gently mixing, 200 ml of the blood was then transferred into a Winchester bottle to which 100 µg of penicillin and 250µg gentamicin were added in turns to serve as broad spectrum antibiotics to ensure sterility of the blood. This was then mixed well on a roller for about 60 minutes. An aliquot of (2.5 ml) of the prepared blood sample was then dispensed with the aid of a sy-

ringe into a glass vial and labeled with the distribution number, date and test to be performed.

Sample Distribution

A total of five control samples were distributed (i.e. one/month) to 12 laboratories in cold ice chest. The tests were performed on the day of distribution within 6 hours of collection and the results collected the following day. A sample from each batch was also run on the Cell-Dyn 3700 (Abbot Diagnostic Division, USA) which was quality-controlled using commercially prepared low, normal and high value samples. All the participants used the cyamethaemoglobin colorimetric method (Drabkin and Austin, 1932) for the estimation of Hb, the glacial acetic acid method (Turk's method) for WBC, the microhaematocrit method for PCV (International Committee for Standardization in Haematology, 1980) and the platelet count (Lewis *et al*., 1979).

Data Analysis

As recommended by the WHO quality assurance in haematology, WHO/LAB/98.4 (1998), the mean and coefficient of variation (CV) were calculated for each batch and then recalculated after exclusion of outliers by truncation at ±2SD from the untrimmed mean. The deviation index (DI) of individual results was calculated as the deviation of the individual result from the target value i.e. the difference between the individual laboratory's result and the median or mean (calculated from the results of all laboratories) and related to the SD. The deviation of the results of the participating laboratories from the target value (i.e. the recalculated mean) was divided by the recalculated mean, multiplied by 100 to give the percentage bias of the participant's results. The two-tailed *t*-test for paired data was used to determine the statistical significance of the difference between the recalculated means of the manual and automated methods. In all statistical tests, a value of $P<0.05$ was considered significant.

RESULTS

The manual method gave lower mean values for all the parameters except for Hb when the recalculated means of the measured parameters between the automated and the manual methods were compared. The difference was not however statistically significant for PCV and WBC (Table 1) but significant for Hb and platelet, even though this was still within the medically useful analytical performance level. Using the concept of deviation index (DI) for assessing analytical performance

Table 1: Statistical summary of the results for all specimens distributed

Parameter and Method	No. of samples distributed	Total no. of results	Recalculated mean	Recalculated CV (%)	Bias (%) mean (range)
PCV (%)					
Automated	5	13	35.4	4.8	4.0 (0.3-7.3)
Manual	5	38	34.7	13.3	7.8 (0.86-19.3)
Hb (g/dl)					
Automated	5	13	11.7	3.4	1.4 (0.0-6.0)
Manual	5	42	12.1*	7.6	3.8 (0.0-13.7)
WBC (x 10^9/l)					
Automated	5	13	4.4	0.9	6.2 (0.0-18.2)
Manual	5	42	4.2	0.2	15.3 (0.0-25.0)
PLT (x 10^9/l)					
Automated	5	12	228	14.3	10.4 (0.0-25.0)
Manual	5	23	204*	35	24.5 (0.5-75.9)

**P<0.05 shows statistical significant when the automated method was compared with the manual method*

(Lewis, 1998; UK NEQAS (H), 2000), the percentage of laboratories achieving the medically useful analytical performance were 84.3, 85.4, 81.8 and 71.4 for PCV, Hb, WBC and platelets, respectively (Table 2).

The performance for PCV and platelets dropped after the second sample distributions. There was a slight decline in the performances of Hb after the first distribution up to the third distribution after which there was a slight improvement in the fourth and a drop in the last distribution. The performance for WBC saw a significant drop from 100% to about 56% in the second distribution and then increased again to 90% in the third distribution (Figure 1).

DISCUSSION

The performance of the participating laboratories in the estimation of Hb appears to be consistent; from 90% to 80, 75, then 90, 90 for the 1st, 2nd, 3rd, 4th and 5th distributions respectively. Even though Hb did not attain 100% performance, there is not much fluctuation in the performance (Fig. 1) thus showing a better precision (Table 1). However, the counting of platelets appears to be the worst: from about 82% in the first distribution, to 95% in 2nd distribution; then to 50, 75 and 60, in the 3rd,

Table 2: Deviation index to evaluate the performance of Haematology laboratories in Kumasi according to their medically useful analytical performance

Parameter	No. (%) of results within indicated deviation index				No.(%) of results within the medically accepted limit of imprecision
	<1.0	1.0-2.0	2.0-3.0	>3.0	
PCV	33(64.7)	10(19.6)	3(5.9)	5(9.8)	43(84.3)
Hb	35(63.6)	12(21.8)	4(7.3)	4(7.3)	47(85.4)
WBC	30(54.4)	15(27.3)	4(7.3)	6(11.0)	45(81.8)
PLT	16(45.7)	9(25.7)	3(8.6)	7(20.0)	25(71.4)

Deviation index interpretation: *0.5 = excellent, 0.5 - 1.0 = satisfactory performance, 1.0-2.0 = acceptable but borderline, 2.0-3.0 = requires review of techniques and check on calibration, > 3.0 =defective, requiring urgent investigations.*

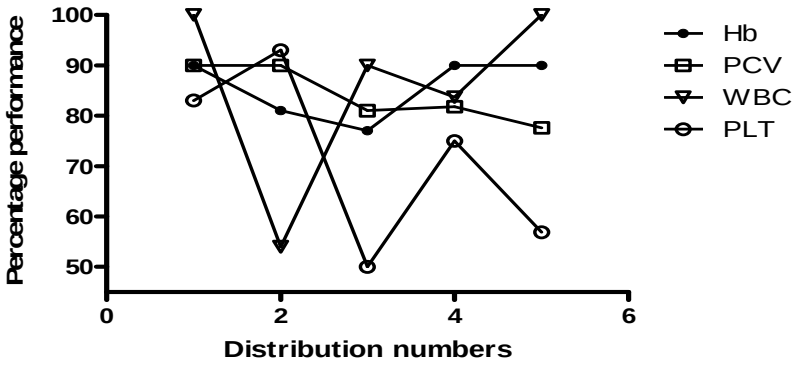

Fig. 1: Percentages of laboratories achieving medically accepted results for PCV, Hb, WBC, and Platelets by batch of specimen distributed

4th and 5th distributions, respectively. Apart from platelets, other parameters generally agree with previous work (Bilto, 1999), which showed an improvement along the various distributions. In his work, the results of the initial study were given to the participating laboratories who happily displayed their reports including histograms on the walls of their laboratories. This gave a high level of interest and competition among the participating laboratories and resulted in the improvement of overall performance. The deviation of platelets from this trend could be due to the tedious nature of manual platelets counting. Even though the purpose of the study was explained to the participating laboratory, for which they gave their consent, because there is no such scheme in the Ghana and that this was the first time they were participating in an EQAS, most of the laboratories at the beginning of the study thought the results may be used as a basis for licensing them and that might be the reason for giving their best during the start of the study.

The recalculated mean of the manual method obtained in the study was significantly lower than the automated method for platelets and higher for Hb ($P < 0.05$) but slightly lower for WBC (Table 1). An important observation made in this study is the good inter-laboratory precision in most of the parameters considered as indicated by the bias in Table 1. The number of results and percentage within indicated deviation index of <1.0, 1.0-2.0, 2.0-3.0 and >3.0 (Table 2) shows that 84.3% (PCV), 85.4% (Hb), 81.8% (WBC) of the laboratories which were using the manual counting, achieved the medically accepted analytical performance for all the parameters except platelets, where the percentage of the laboratories dropped to about 71.4% . This gives an indication that errors obtained were mainly errors of inaccuracy rather than imprecision.

The manual method yielded higher CVs for all the parameters except WBC when compared to the automated methods indicating higher precision using the automated method than the manual. This result is in conformity with the work of Fink *et al.* (1997) who observed that manual methods yielded higher CVs than automated counters for these parameters. Platelets showed the highest deviation and hence lowest performance in this study. This could be attributed to the problem associated with the manual count of platelets, such as platelets disintegrations (resulting in lower values) and platelets fragmentation (resulting in higher count) (Dacie and Lewis, 1996). The best performing parameters in this study were WBC and Hb. These two parameters gave lower CVs compared to the others (Table 1).

CONCLUSION

The overall performance of all the laboratories in the measurement of all the parameters studied was satisfactory in terms of the percentage achieving the medically useful analytical performance. The problem of imprecision associated with manual methods was still apparent in this study. There was however, good inter-laboratory precision giving the indication that haematology laboratories in Kumasi were performing well. However, the study has established the need for external quality assessment schemes to be introduced to evaluate the performance of these laboratories and thus improve the delivery of health care in the region and in the country as a whole.

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