

DOI: <http://dx.doi.org/10.33846/hn50302>
<http://heanoti.com/index.php/hn>



RESEARCH ARTICLE

URL of this article: <http://heanoti.com/index.php/hn/article/view/hn50302>

Correlation Between Implementation Intensity of Internal Quality Control and the Outcome of External Quality Control at Public Health Center Laboratories

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ABSTRACT

Quality control is a process in a procedure conducted to evaluate testing process, with the purpose of ensuring the outcome of laboratory examinations, minimizing, as well as identifying the source of deviations. It consists of two, the internal and external quality control. This study aims to determine correlation between implementation intensity of internal quality control and the outcome of external quality control in the parameter of complete blood count in Public Health Centers Laboratories in Gianyar Bali. This study was a correlational observational study with cross-sectional approach. Total samples of 13 laboratories were taken from total population. As many as 15.38% of Public Health Center carried out internal quality control every day, 53.85% once a week, 7.7% biweekly, and 23.07% carried it out once a month. As for external quality control with parameter of complete blood count, 61.54% of the centers were good, 23.07% were average, and 15.38% were poor in handling abnormally low level of complete blood count. At normal level, 76.92% were good, 15.38% in average, and 7.7% were below average. At abnormally high level, 53.85% were good and 46.15% were in average. Statistical test results showed p-value >0.05. It can be concluded that there is no correlation between implementation intensity of internal quality control and the outcome of external quality control with parameter of complete blood count in Public Health Center laboratories in Gianyar Bali.

Keywords: internal quality control; external quality control; complete blood count

INTRODUCTION

Background

Public Health Centers is a First Level Health Facility as the technical implementation unit of the district/city health office that organizes public health efforts and is responsible for its working area, a whole area or part of the area of a sub-district⁽¹⁾. The implementation of health care efforts at the Public Health Centers is supported by supporting examination facilities, the laboratories. Laboratory services at the Public Health Centers consist of various types of examinations. One of these services is the examination of Complete Blood Count (CBC)⁽²⁾. Complete Blood Count examination plays a role in defining normality, abnormality, and the nature of abnormalities of blood cells or blood pigments. Complete Blood Count examination is very important to determine overall health conditions, and is often used in health screening and is included in medical checkup⁽³⁾.

With the development of health technology and the increasing demands of the community for fast and qualified health services as well as high quality examination results, Public Health Centers develop and improve service processes, especially in laboratories by using Automatic Hematology Analyzer for a Complete Blood Count examination. The use of this equipment makes it easier for health analysts in the laboratory to examine many blood samples so that the examination time is faster and the accuracy of the examination results is higher than manual Complete Blood Count examination. To optimize the quality of services by providing precise and accurate laboratory examination results, Public Health Centers are required to follow laboratory quality assurance that is recognized by the government⁽⁴⁾.

There are two laboratory quality control, the internal quality control and external quality control. Public Health Centers laboratories are obliged to follow regular and periodic external quality control as regulated in Article 6 of the Minister of Health Regulation number 411 of 2010, and Regulation of the Minister of Health of

the Republic of Indonesia number 37 of 2012, and is one of the requirements for accreditation by the National Accreditation Committee. According to BBLK Surabaya (2018) external quality control of Complete Blood Count was carried out in 2 cycles with parameters including hemoglobin, leucocytes, erythrocytes, hematocrit and hemoglobin using whole blood control ⁽⁵⁾.

Observations conducted by the authors in Gianyar Bali area showed that all Public Health Centers laboratories had used Automatic Hematology Analyzer for Complete Blood Count examination. The current problem was the irregularity of the laboratories in carrying out activities for internal quality control, calibration, and less intensive equipment maintenance as well as the lack of laboratory participation in external quality control activities, even though these activities can affect the quality of laboratory examination results. Given the importance of Complete Blood Count examination, we examined correlation between the implementation intensity of internal quality control and the outcome of external quality control with parameter of Complete Blood Count in Public Health Centers laboratories in Gianyar Bali.

This study aims to determine correlation between implementation intensity of internal quality control with the outcome of external quality control with parameter of Complete Blood Count in Public Health Centers laboratories in Gianyar Bali.

METHODS

This research was a correlational observational study with a cross-sectional approach. Population in this study were 13 Public Health Centers laboratories in Gianyar Bali in 2019. Sampling used in this study was total sampling, involving whole population of the study, comprising 13 Public Health Centers laboratories in Gianyar Bali. This study was conducted between December 2019 and June 2020. The variables in this study were the intensity of internal quality control and the assessment criteria based on the deviation index value.

In this study the data were collected from primary data in the form of a questionnaire and the results of a whole blood control examination with the parameter Complete Blood Count which was distributed to 13 Public Health Centers laboratories.

Whole blood control was prepared in three levels: abnormally low, normal, and abnormally high. Each level was coded: L for low abnormal level, N for normal level, and H for high abnormal level. Whole blood control was put into a cool box where the temperature was kept in accordance with the refrigerator temperature (4-8°C) and then sent to participant laboratories. Then, the whole blood control was adjusted to room temperature. The whole blood control was examined by participant laboratories with the same procedure and method according to ordinary treatment to patients' blood sample. The results of the Complete Blood Count examination from each participant were analyzed by determining mean, standard deviation, and deviation index of each participant.

Data analysis in this study used the Chi-square statistical test to determine correlation between implementation intensity of internal quality control and the outcome of external quality control with the parameters of Complete Blood Count at Public Health Centers laboratories in Gianyar Bali.

RESULTS

Table 1. Percentage of external quality control based on average scores of the participants

Examinations	Levels	Based on participants' average scores			
		Good	Average	Less	Poor
Leukocytes	Abnormally low	69.23%	23.07%	0%	7.7%
	Normal	76.92%	15.38%	0%	7.7%
	Abnormally high	15.38%	46.15%	23.07%	15.38%
Eythrocytes	Abnormally low	53.85%	23.07%	15.38%	7.7%
	Normal	53.85%	30.77%	15.38%	0%
	Abnormally high	61.54%	30.77%	7.7%	0%
Hemoglobin	Abnormally low	69.23%	7.7%	23.07%	0%
	Normal	38.46%	46.15%	15.38%	0%
	Abnormally high	61.54%	38.46%	0%	0%
Hematocit	Abnormally low	69.23%	7.7%	15.38%	7.7%
	Normal	76.92%	15.38%	0%	7.7%
	Abnormally high	69.23%	15.38%	7.7%	7.7%
Thrombocytes	Abnormally low	38.46%	53.85%	0%	7.7%
	Normal	92.30%	0%	0%	7.7%
	Abnormally high	84.60%	7.7%	7.7%	0%

Table 1 showed that the results of the normal level of platelet examination have good criteria of 92.30%, the results of the examination of abnormal low platelets have sufficient criteria of 53.85%, while the results of the examination of abnormally high leukocytes have bad criteria of 15.38%.

Table 2. Percentage of external quality control outcome based on true value

Examinations	Levels	Based on true value			
		Good	Average	Less	Poor
Leukocytes	Abnormally low	61.54%	23.07%	7.7%	7.7%
	Normal	76.92%	15.38%	0%	7.7%
	Abnormally high	61.54%	7.7%	0%	30.77%
Eythrocytes	Abnormally low	38.46%	46.15%	7.7%	7.7%
	Normal	46.15%	46.15%	7.7%	0%
	Abnormally high	69.23%	15.38%	15.38%	0%
Hemoglobin	Abnormally low	53.85%	30.77%	15.38%	0%
	Normal	38.46%	46.15%	15.38%	0%
	Abnormally high	61.54%	38.46%	0%	0%
Hematocit	Abnormally low	38.46%	30.77%	7.7%	23.07%
	Normal	69.23%	23.07%	0%	7.7%
	Abnormally high	53.85%	38.46%	0%	7.7%
Thrombocytes	Abnormally low	61.54%	23.07%	0%	15.38%
	Normal	76.92%	15.38%	0%	7.7%
	Abnormally high	92.30%	0%	0%	7.7%

Table 2 showed that the results of abnormally high platelets have good criteria of 92.30%, while the results of abnormally low erythrocytes show the criteria of 46.15%, in addition, the results of abnormally high leukocytes show bad criteria of 30.77%.

Table 3. Chi-Square statistical test

Variables	Levels	Asymp Sig.	Notes
Implementation of internal quality control and external quality control assessment criteria	Abnormally low	0.168	No correlation
	Normal	0.488	
	Abnormally high	0.057	

Table 3 shows the results of the test of implementation intensity of internal quality control as compared to the results of external quality control. Data analysis showed no correlation between the implementation of internal quality control and external quality control assessment criteria.

DISCUSSION

An activity required to obtain qualified laboratory examination results is the implementation of laboratory quality control which aims to ensure the accuracy of laboratory examination results. Quality control in laboratory consists of internal quality control and external quality control. Internal quality control is carried out to control the outcome of laboratory examinations every day and to detect irregularities in laboratory outcomes so that they can be corrected immediately. External quality control is an activity that is carried out periodically by other parties outside the laboratory to monitor and assess the performance of a laboratory in certain areas of examination. Quality control in the laboratory aims to ensure the reliability of laboratory examination results. The reliability of an examination method is a measure how far a test can be applied for clinical use, both as a screening test and as a diagnostic test. The reliability of a laboratory test includes: precision, accuracy, sensitivity and analytical specificity⁽⁶⁾.

The percentage of external quality control with complete blood count parameter in 13 Public Health Centers laboratories in Gianyar Bali indicated that several Public Health Centers had quality control outcomes in accordance with Ministry of Health standards.

Based on the mean value of the participants, external quality control with parameter of leukocyte at abnormally low level showed 69% had good outcome, 23.07% had average outcome, and 7.7% had poor

outcome. At normal level, 76.92% showed good outcome, 15.38% average outcome, and 7.7% poor outcome. At abnormally high level, 15.38% showed good outcome, 46.15% average outcome, 23.07% less outcome and 15.38% poor outcome.

External quality control with parameter of erythrocyte at abnormally low level showed that 53.85% had good outcome, 23.07% had average outcome, 15.38% had less outcome, and 7.7% had poor outcome. At normal level, it showed that 53.85% had good outcome, 30.77% had average outcome, and 15.38% had poor outcome. At abnormally high level 61.54% had good outcome, 30.77% had average outcome, and 7.7% had poor outcome.

External quality control with parameter of hemoglobin at abnormally low level showed 69.23% had good outcome, 7.7% had average outcome, and 23.07% had poor outcome. At normal level, 38.46% had good outcome, 46.15% had average outcome, and 15.38% had poor outcome. At abnormally high level, 61.54% had good outcome, and 38.46% had average outcome.

External quality control with parameter of hematocrit at abnormally low levels showed 69.23% had good outcome, 7.7% average outcome, 15.38% less outcome, and 7.7% poor outcome. At normal level 76.92% had good outcome, 15.38% had average outcome, and 7.7% had poor outcome. At abnormally high level 69.23% had a good outcome, 15.38% had a average outcome, 7.7% had a poor outcome, and 7.7% had a bad outcome.

External quality control with parameter of hemoglobin at abnormally low level showed that 38.46% had good outcome, 53.85% average outcome, and 7.7% poor outcome. At normal level 92.30% had good outcome, and 7.7% had poor outcome. At abnormally high level 84.60% had good outcome, 7.7% average outcome, and 7.7% less outcome.

External quality control with true value for parameter of leukocyte at abnormally low level showed 61.54% had good outcome, 23.07% average outcome, 7.7% less outcome and 7.7% poor outcome. At normal level, 76.92% had good outcome, 15.38% average outcome, and 7.7% poor outcome. At abnormally high level 61.54% had good outcome, 7.7% average outcome, and 30.77% had poor outcome.

External quality control with parameter of erythrocyte at abnormally low level showed 38.46% had good outcome, 46.15% average outcome, 7.7% less outcome, and 7.7% poor outcome. At normal level 46.15% had good outcome, 46.15% average outcome, and 7.7% less outcome. At abnormally high level 69.23% had good outcome, 15.38% had average outcome, and 15.38% had less outcome.

External quality control with true value for parameter of hemoglobin at abnormally low level showed 53.85% had good outcome, 30.77% had average outcome, and 15.38% had less outcome. At normal level 38.46% had good outcome, 46.15% average outcome, and 15.38% less outcome. At abnormally high level 61.54% had a good outcome, and 38.46% had average outcome.

External quality control with true value in parameter of hematocrit at an abnormally low level showed 38.46% had good outcome, 30.77% average outcome, 7.7% less outcome, and 23.07% poor outcome. At normal level 69.23% had good outcome, 23.07% average outcome, and 7.7% poor outcome. At abnormally high level 53.85% had good outcome, 38.46% average outcome, and 7.7% poor outcome.

External quality control with true value on the parameter of hemoglobin at abnormally low level showed 61.54% had good outcome, 23.07% average outcome, and 15.38% poor outcome. At normal level 76.92% had good outcome, 15.38% average outcome and 7.7% had poor outcome. At abnormally high level 92.30% had good outcome and 7.7% had poor outcome.

Of the five parameters, leucocytes, erythrocytes, hemoglobin, hematocrit and hemoglobin, hemoglobin showed the highest good outcome because hemoglobin have higher coefficient of variation (CV) of 20% than other parameters so that the variation of the outcomes did not give high results on the deviation index. The Ministry of Health (2013) states that the greater the coefficient of variation, the more accurate the results or method are. Pamungkas' study (2019) on laboratory external quality control with parameters of erythrocyte and hemoglobin at Public Health Centers in Mojokerto showed that the highest good outcome was in the hemoglobin parameter⁽⁷⁾. This finding was similar to the results from our study.

Implementation intensity of internal quality control related to the outcome of external quality control in Public Health Centers laboratories in Gianyar Bali area showed that 15.38% of the Public Health Centers were in good category with the implementation of internal quality control every day, 53.85% in average category with the implementation of internal quality control for once a week, 7.7% in less category with implementation of internal quality control every two weeks, and 23.07% in poor category with implementation of internal quality control once a month. External quality control with parameter of complete blood count at abnormally low levels showed that 61.54% of the Public Health Centers were in a good category, 23.07% in average category, and 15.38% in poor category. At normal level, 76.92% of the Public Health Centers were in a good category, 15.38% were in average category, and 7.7% were in poor category. At high abnormal level 53.85% had good category and 46.15% had average category.

Poor results at each Public Health Centers can be influenced by several factors, including the lack of or not performing periodic calibrations of the instruments, lack of maintenance activities on the instruments so that they are not accurate and the results obtained are also less accurate. Apart from that, different brands of

instruments also have an effect. If the instruments in one Public Health Centers are different from other Public Health Centers, the methods and principles are also different.

The results were analyzed using chi-square statistical test so that the significance value of the three levels of whole blood count was found not significant (no correlation). The significance value of the parameter of complete blood count at abnormally low level was 0.168, normal level was 0.488, and abnormally high level was 0.057. Data analysis showed $p > 0.05$, so it was concluded that there was no correlation between implementation intensity of internal quality control and the results of external quality control with parameter of complete blood count in Public Health Centers laboratories in Gianyar Bali.

According to Herawati et al (2011) the results of quality control are influenced by several other factors, i.e. pre-analytic factors, analytic factors and post-analytic factors. The pre-analytic factors are storage, delivery, homogeneity and specimen processing. Poor sample homogeneity, inappropriate delivery temperature in the coolbox, and decreased sample stability due to repeated use will result in incorrect results. Analytical factors are instrument calibration, instrument maintenance, and reagent quality testing. Calibration and maintenance of the instruments that are not carried out regularly can cause the instruments to work inaccurately and the results obtained are less accurate, thus affecting the results of quality control. Post-analytic factors include results writing, interpreting and reporting. Although the laboratory carries out internal quality control activities on a regular basis, but the results obtained are still "out of control", it will affect the results of external quality control, so that the results of the assessment are weak or bad. Conversely, if the laboratory carries out internal quality control activities irregularly, but the results obtained are appropriate, this will affect the external quality control results so that good or sufficient results are obtained. For example, in a Public Health Centers with code M, the implementation of internal quality control is carried out only once a month, while the results of quality control are good. This is probably because calibration and maintenance of the instruments are carried out regularly and the results of the quality control are "in control"⁽⁸⁾. In addition, properly performed standard operating procedures (SOPs) will also affect quality control results⁽⁹⁾.

Hartina (2019), who compared EDTA blood homogenization technique with the inversion technique and the number eight technique on the hemoglobin count, explained that each sample homogenization technique produced different hemoglobin results. This shows that pre-analytic stage of homogenization process affects the results of examination⁽⁹⁾.

CONCLUSION

There is no correlation between the intensity of the implementation of internal quality control and the results of external quality control with the parameter of complete blood count in Public Health Centers laboratories in Gianyar Bali.

Suggestions

For the Laboratory: To obtain good external quality control results, a laboratory must follow pre-analytic, analytic and post-analytic standard operating procedures properly and correctly. Internal quality control activities should be carried out regularly and calibration and maintenance of hematology analyzer must be carried out so that the laboratory examination results are more accurate.

For future researchers: It is necessary to study other factors that relate to quality control, such as the correlation between the implementation of calibration and the results of quality control.

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