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Interpretation of external quality assurance results on liver function test

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Abstracts

The quality of laboratory examination results must always be guaranteed in the sense that it can provide a level of accuracy and precision that can be accounted for. Therefore, a study of External Quality Consolidation (PME) was conducted. The purpose of this study was to describe the results of External Quality Monitoring in the field of clinical chemistry parameters of Serum Glutamic Oxalocetic Transaminase (SGOT) and Serum Glutamic Pyruvic Transaminase (SGPT) at the Public Health Center Laboratory in the Surabaya area. The population in this study was a health center in the area of the Surabaya City Health Office with a sample of 15 health centers that had examinations in the field of clinical chemistry. The sample used in this study was normal level control serum which was measured on the parameters of Serum Glutamic Oxalocetic Transaminase (SGOT) and Serum Glutamic Pyruvic Oxalocetic Transaminase (SGPT). The results of data analysis showed that the percentage of PME levels of SGOT with good VIS criteria was 73.33%, sufficient criteria was 0%, less criteria was 6.67%, poor criteria was 20%. While the SGPT parameters good criteria are 53.33%, sufficient criteria are 33.33%, less criteria are 13.33%, poor criteria are 0%.

Keywords: External Quality Consolidation, SGOT, SGPT, LFT

1. Introduction

Health Laboratory is a medical service that assists in making a diagnosis, monitoring treatment results, and determining disease prognosis. Health institutions in Indonesia include Community Health Centers, Public Health Institutions, Government and Private Hospital Institutions. Given the importance of the function of clinical trial results, the quality of clinical trial results must always be guaranteed.

In accordance with government regulations, clinical laboratories are required to carry out quality assurance, including internal quality assurance (PMI), abbreviated as PMI, and external quality assurance (PME) which is carried out by conducting serum control tests [1].

The Health Facility Research (Rifaskes) conducted by the Health Research and Development Agency (Badan Litbangkes) in 2011 also collected data on all government hospital laboratories, puskesmas laboratories and Independent Clinical Laboratories (LKM) throughout Indonesia. One of the first-level health services, namely Puskesmas, has an important role in the national health system, especially the health effort subsystem. A health service facility is a place used to provide health services, whether promotive, preventive, curative or rehabilitative carried out by the government, local government and/or the community [2].

External quality stabilization as regulated by the Ministry of Health in PERMENKES 364/Menkes/SK/III/2003 concerning Health Laboratories, the contents of which require health laboratories to participate in national and international accreditation. One of the requirements in the National Accreditation Guidelines regulated in PERMENKES Number 943/Menkes/SK/VIII/2002 is that laboratories must follow the External Quality Assurance Program (PME) to see the performance of the laboratory itself, but there are still many laboratories that have not implemented PME [3]. This is a concern in the quality of laboratory quality assurance at a certain time periodically, simultaneously, and continuously which is carried out by parties outside the laboratory by comparing the results of laboratory examinations of participants against the target value in terms of accuracy and precision of an examination result [4].

Participation in the clinical laboratory PME program is carried out in several parameters, one of which is the parameter of Serum Glutamic Pyruvic Transaminase (SGPT) and Serum Glutamic Oxaloacetic Transaminase (SGOT) where these two parameters are often used in routine monitoring in some communities because of the high incidence of Hepatitis B disease. , Hepatitis C. In participating in the PME program, an organizing institution provides control materials for examination in the laboratory, control materials usually use ready-made control materials [5].

Control materials were divided into 2, namely Assayed and Unasaayed. Unasaayed control material is a control material that does not have a reference value as a benchmark and has a cheaper price. While the assayed control material is a control material that already has a reference value and is more expensive. This control material is used to control accuracy and precision [6].

One of the obstacles in participating in PME implementation is the limited cost. Especially in laboratories that have a Primary level qualification. Based on this background, the researcher is interested in conducting research on the analysis of the results of External Quality Assurance on the SGPT and SGOT parameters in the Surabaya health center.

2. Experiments Procedure

Place and time of research

The research site was conducted in the Surabaya area health center as many as 15 locations that had implemented PME. The research time is from November to December 2019.

Data collection technique

This type of research is descriptive analytic. SGPT and SGOT levels in control serum (assayed) were collected by observation/observation through testing at the Surabaya Health Center laboratory which serves SGPT and SGOT examinations.

Tools and Materials

The tools used are tools in each health center. The materials used were SGPT and SGOT reagents at each Puskesmas.

Result Analysis

The data on the levels of SGPT and SGOT in the control serum that have been read are the results, then tabulated and then calculated the number and average and Standard Deviation (SD) of each laboratory. After obtaining SD, the VIS value of each laboratory can be calculated using the following formula:

$$V=\frac{X1-X2}{X2}\ X\ 100\ \% \rightarrow \quad VIS=\frac{V}{}\ X\ 100 \qquad (1)$$

Whre V is Percentage of Variation, X1 is Mean results of each laboratory examination, X2 is Precinorm Value 'U', VIS is Variance Index Score

3. Result and Discussion

Research result

Mean and SD . measurement results

The PME assessment has two ways, namely by analyzing the target value (reference) listed on the normal level control serum package insert and against the average value of all participants against the target value (reference). The following values for the normal control serum target (referene) level from the package insert are presented in Table 1.

Table 1. Value of Target (reference) Serum Normal level control from package insert

Information	SGOT	SGPT
Range	23,1-36,9	23,6-37,8
Target	30	30,7
SD	3,45	3,55
CV	11,5	11,56

Note: SD is Standard Deviation, and CV is Coevicien Variant.

Based on the data in Table 1, it can be seen that the control serum results for SGOT parameters have a range of 23.1-36.9 and for SGPT parameters have a range of 23.6-37.8.

The result of the target value of the average of all participants

After the results from each puskesmas are known, then analyze the target value of the average of all participants which is presented in Table 2

Table 2. Target Value of the average of all participants Control Serum Normal level

Information	SGOT	SGPT
Range	<37	<40
Target	32,067	33,2
SD	8,556	10,638
CV	26,682	32,042

Berdasarkan data pada tabel 2 dapat diketahui bahwa hasil serum control level Normal pada parameter SGOT memiliki rentang <37 U/L. Pada parameter SGPT hasil serum control level normal memiliki rentang <40 U/L.

Results Criteria VIS value of SGOT and SGPT parameters to the average value of target participants

The following is the data on the Percentage of Criteria Value for SGOT and SGPT VIS parameters to the average value of the target participants

Table 3. Percentage of VIS score criteria against the average value of target participants

Para-meter	Criteria			
	Good	Fair	Less	Poor
SGOT	53,33%	20%	6,67%	20%
SGPT	53,33%	20%	26,67%	0%

From the results, Table 3 shows the percentage of VIS score criteria on the average participants with examinations at 15 health centers. After finding the results of the percentage calculation, it can be seen: for the SGOT parameter, the percentage of the good category is 53.33%, the sufficient category is 20%, the less category is 6.67% and the bad category is 20%. For the SGPT parameter, the percentage of the good category is 53.33%, the sufficient category is 20%, the less category is 26.67% and the bad category is 0%.

Percentage of SGOT and SGPT parameter VIS scores against the average target value of participants (reference value).

The following is the data on the Percentage of Criteria Value for SGOT and SGPT VIS

parameters to the average target value of participants (reference value).

Table 4. Percentage of VIS score criteria against the average target value of participants (reference value)

Para-meter	Criteria			
	Good	**Fair**	**Less**	**Poor**
SGOT	73,33%	0%	6,67%	20%
SGPT	53,33%	33,33%	13,33%	0%

From the results of Table 4. shows the percentage of VIS value criteria against the average participant (reference value) with examinations at 15 health centers. After finding the results of the percentage calculation, it can be seen: for the SGPT parameter, the percentage of the good category is 53.33%, the sufficient category is 33.33%, the less category is 13.33% and the bad category is 0%. For the SGOT parameter, the percentage of the good category is 73.33%, the sufficient category is 0%, the less category is 6.67% and the poor category is 20%.

Discussion

This study used a normal level control serum sample. The reason the researcher chose the normal level is because the absolute level is a level that does not dominate high or low laboratory results. Where the sample has been tested. According to Permenkes [1] that the tested sample has a predetermined target value by the control company.

The pre-analytic stage in the control material transfer process must be considered, according to ISO 17025:2000 that the container is no more than to prevent sample leakage and has a temperature of 6oC can add ice packs and should not be shaken, because it will change the results. After that, do a homogeneous process so that the sample is evenly mixed and there is no clotting in the control serum. Then do the running process on the spectrophotometer. The research process that has the right to measure is the laboratory officer who has responsibility in the puskesmas laboratory [7].

PME results are influenced, among others, by analyte commutability, reagent quality, brand of reagents and calibrators, equipment used, operator competence and how to operate the equipment [8], [9] and the client's biological variation [10]. The effect of the client's biological variations in this case does not apply considering that the analytes come from the same administering institution. All these proximal and distal factors can lead to systematic errors and non-laboratory errors from pre to post analytic.

Based on the percentage of the parameters above to the target value (reference) and the average value of all participants, the values vary due to influencing factors. The first factor is the different tools with many different brands. Based on research on respondents consisting of 15 Puskesmas, the tools used are spectrophotometers of different brands and have different levels of sophistication. Of course, this can lead to mixed results. The second factor is because the control serum temperature fluctuates due to the delivery process at each Puskesmas so that it can affect the results. The third factor was the delay in the running process by the puskesmas, due to the large number of patient samples at the puskesmas. The fourth factor is the lack of calibration on the tool which makes the results less accurate. This study is in line with [11] that PMI evaluation and audit, PME experience and PME audit, temperature management and micropipette calibration are the main factors affecting measurement accuracy. Other factors such as MFI class, location area, person in charge and owner of

MFI, operator competence, quality of reagents, photometer or automatic have little effect on PME results.

The results that have been described above, this general picture found results that varied in each puskesmas. There are 2 measurements, namely the average value of all participants and the Target Value (reference), where both have a difference that is not much different. Judging from the histogram of the average value of all participants, none of the puskesmas had all of the good criteria, while the histogram of the target value (reference) also showed the same thing, namely that none of the puskesmas had good criteria at all [12].

Among the factors are the dissimilarity of the spectrophotometer used by each puskesmas and the lack of maintenance on equipment such as Quality Control. Quality assurance is very important in a laboratory because with good quality stabilization, the results that will come out will also be accurate and good, and with good quality stabilization will be able to increase customer confidence in the quality of a laboratory [13].

Not only an analyst who must know the importance of quality assurance, parties involved in the ranks of the laboratory must also understand the usefulness and function of quality assurance. If both parties understand the importance and usefulness of quality assurance, the quality of a laboratory will improve by itself.

4. Conclusion

Based on the results of the study, it can be concluded that the VIS and Criteria values for the Target Value (reference), are as follows: SGOT Parameter Good Criteria as much as 73.33%; Enough Criteria as much as 0%; Less Criteria 6.67%; Poor Criteria 20%. SGPT Parameter Good Criteria as much as 53.33%; Sufficient Criteria as much as 33.33%; Less Criteria 13.33%; Poor Criteria 0%. Suggestions, especially for laboratories, should follow PMI and PME so that accurate and thorough laboratory results are obtained.

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