Investigating the quality control of laboratory information in university hospitals of Tehran in 2011

Hamid Moghaddasi[2,*] ,Hamid Reza Samzadeh[1]

[1]Health Information Management and Medical Informatics
[2]Health Information Management of Shahid Beheshti University of Medical Sciences.

* Corresponding Author: email address: moghaddasi@sbmu.ac.ir (H.Moghaddasi)

ABSTRACT

Clinical laboratory results play an important role in helping physicians in diagnosis and treatment. In view of the direct effect of the working methods on the quality of data in the laboratory, quality control of data and results in the Biochemistry Ward of Laboratory includes taking into account all the factors and variables relating to all the pre-analytical, analytical and post-analytical steps at this ward. The objective of this study was to examine the quality control of data and results in the biochemistry departments of hospital laboratories in universities of medical sciences in Tehran.

Current study was a descriptive research, and 40 biochemistry laboratories in universities of medical sciences in Tehran constituted the settings of the study. Data were collected by a checklist and a questionnaire using observation and interview. Using the checklist, 33 effective factors in the pre-analytical step; 18 effective factors in the analytical step and 8 effective factors in post-analytical step were examined. The questionnaire included questions relating to biochemical factors in the laboratories, while the factors affecting the quality of the results were examined by using checklist. Data from questions and observations were analyzed by using descriptive statistics and by determining the absolute and relative frequencies.

Results showed that in all settings of the study, 58%, 68% and 87% of the factors affecting the pre-analytical, analytical and post-analytical data and results were taken into consideration respectively. However, the biochemistry directors remarked that they considered 77% and 89% of the first two groups of factors respectively, and the third groups of factors were considered only by observation.

according to the findings by the checklists, sufficient attention was paid to 58% of the factors effective on pre-analytical data quality (Identifying the patient; Labeling the sample while collecting the sample; etc.), 68% of the factors effective on analytical data quality (Analyzing the samples during the 1 to 4 hours following the collection of the samples; Using control samples for evaluating the operation of instruments once in every 8 hours; etc.) and 87% of the factors effective on the post-analytical data quality (Legibility of the hand-written reports; Similarity of the hand-written reports to the typewritten report, in terms of patient ID data record; etc.) while there is no enough attention paid to other factors in pre-analytical step (Preparing the patient; Paying attention to the physiological changes of the patient's body; etc.), analytical step (availability of written guidelines for performing certain work where the samples are analyzed; Calibrating the instruments according to the standard program; etc.) and post-analytical step (precision in recording distinguishing features in real values). Also, by comparing the findings obtained using the two tools, it can be found out that the findings do not match each other in certain factors and that the amount of findings obtained from the questionnaire is more than the findings obtained from the checklists.

Keywords: Quality; Quality Control; Data; Results; Laboratory Biochemistry Department

INTRODUCTION

According to ISO, quality is described as all characteristics of an entity which can meet user's needs [1]. One of the most important issues regarding the quality is known as quality control (QC) which is used for measuring the amount of conformity of present situation with standards [2]. As part of the health care team, the clinical laboratory must have an ongoing quality assurance process for monitoring its analytic results [3]. Clinical laboratory is the health profession that provides laboratory information and services needed for the diagnosis and treatment of disease [4]. It is

estimated that 70% of all medical decisions made by physicians are based on laboratory findings [5]. Considering the role of data in diagnosis and treatment, responsibility for accurate and timely test reports generally lies with the laboratory [6]. The biochemistry ward is one of the major wards of any clinical laboratory where all biological samples such as blood, urine, feces, amniotic liquid, etc are examined and analyzed [7]. However, most tests are commonly carried out on blood samples in order to measure the types of materials and chemical compounds in the blood because certain patterns of abnormality in a group of blood materials and compounds make it possible to diagnose some diseases and disorders easily [8]. Laboratory error can be minimized if attention is paid to proper laboratory procedures and techniques. The quality control system for individual test methodologies can focus on controlling the test-specific variables [9, 10], quality control at the biochemistry ward should be in place in all steps of a test, and this can be achieved by taking into consideration in the quality control the entire effective factors in pre-analytical, analytical and post-analytical steps [7]. Considering the role of the results of the biochemistry ward, the present research was carried out in order to determine how to control the quality of data and results of the biochemistry wards of the laboratories of universities of medical sciences and health services in the city of Tehran.

MATERIALS AND METHODS

This research was a descriptive study, and the settings of the study included the biochemistry laboratories in the universities of medical sciences in Tehran. The sample size was in accordance with the population of the study. The method of collection of data included interview and observation, and the tools for collection of data were a questionnaire and a checklist, using which 33 factors effective on pre-analytical data quality, 18 factors effective on analytical data quality and 8 factors effective on post-analytical data quality were studied. The post-analytical step was evaluated only by checklist. Validity of tools for collection of data have been done according content validity method. Reliability of research tools (questionnaire) confirmed according to test-retest method (r =0.87). Data were analyzed by using descriptive statistics.

RESULTS

In general, findings achieved by using the checklist showed that, 42% (14 factor), 32% (6 factor), 13% (1 factor) affecting the pre-analytical, analytical and post-analytical data and results were not taken into consideration while, according to the findings from the questionnaires, biochemistry ward officials in all the studied hospital laboratories stated that only they don't consider 23% (8 factor), 11% (2 factor) of the factors respectively effective on data quality in pre-analytical and analytical steps. Findings were presented in tables 1-4.

Table 1. Factors influencing the pre-analytical step

Questioning	Observation	Effective factors
100	100	identifying the patient
100	100	controlling patients' personal characteristics
100	100	labeling the sample when sampling
97	97	fasting if necessary
100	100	remaining in a lying or sitting position
15	0	remaining in a lying or sitting position for 20 minutes
92	92	stretching out the patient's arm
95	95	not using the hand to which the serum is connected
97	97	not using the injured hand
25	0	patient's remaining for a long time in bed
40	40	daily body changes
17	0	the patient's traveling 5 days before sampling, flying on a plane on the test day
50	50	the patient's diet
82	47	drugs taken
22	0	lifestyle [16]

Table 2. Influential factors on sampling, transportation, storage and preparation of samples in pre-analytical step

Questioning	Observation	Effective factors
65	12	availability of a written guideline for sampling
87	87	sample volume
82	45	using disposal gloves
92	92	fastening the tourniquet
32	32	type of disinfectant used for anatomic area of sampling
87	0	waiting for the sampling area to dry completely after using the disinfectant
90	90	using of glassware
100	100	transferring the samples, including paying attention to the temperature
65	65	paying attention to leakage, hemolysis, contamination
55	55	transferring the samples, including paying attention to exposure to light, heat or wind
100	100	preparing samples of blood
70	0	preparing samples of serum
100	100	preparing samples of plasma
97	97	preparing samples of urine
100	100	centrifuging the samples in 2 hours after collection
82	17	using the recommended speed and time for centrifuging the samples
100	100	method of storage of samples (serum, plasma, urine) [16]

Table 3. Influential factors on Analytical step

Questioning	Observation	Effective factors
100	100	analyzing samples between 1 and 4 hours following sampling
70	45	availability of a guideline for sample analysis
85	85	considerations in the selection of analysis methods
100	100	paying attention to speed, simplicity and low costs of the method of analysis
95	95	participation in external quality control tests
92	82	evaluation of instruments using control samples, drawing statistical diagrams
97	97	using skilled personnel
47	37	comparing the result of the present test with those of the previous tests
80	80	using control samples for evaluating the operation of instruments every 8 hours
50	8	paying attention to changes of temperature
85	30	paying attention to the stability of electric power
100	100	considering the necessary points during sampling, which includes precision during pipetting
95	72	using appropriate, clean samplers
97	97	paying attention to the quality of water
65	3	accurate calibration of scales, glassware and volumeter
90	90	calibration of instrument according to the standard program
65	60	identifying normal range according physiological change of human
97	97	employing skilled personnel for carrying out the tests [16]

Table 4. Influential factors on post-analytical step

Observation	Effective factors
100	legibility of the hand-written reports (report-book)
100	similarity of the hand-written reports and the typewritten reports, in terms of patient id data record
100	similarity of the laboratory reports and the reports-envelope, in terms of patient id data record
100	similarity of the hand-written reports and the typewritten reports, in terms of test results record
57	attention in recording slashes (points) in real values(numbers)
100	recording the normal domain of quantities in laboratory reports
100	signature and date of laboratory reports
95	considering an appropriate interval (2 hours) in converting the hand-written reports to reports that can be presented to the patient [16]

DISCUSSION AND CONCLUSION

Clinical laboratories facilitate clinical activities of physicians and surgeons by providing reliable data rapidly [11]. The main reasons for controlling the quality of laboratory results are to provide results that can be depended on to aid the physician with the diagnosis, to follow the course of the disease closely, and to monitor the effects of therapy [12]. The analytic results of the test or tests done on a clinical specimen must be as accurate as possible so that the physician can rely on the data and use the information in the diagnostic and treatment plan for the patient [3].Quality control is a process that ensures us of the truth and precision of the laboratory results and provides a method for controlling the stability of the measurement system [7]. In fact, the laboratory quality control program consists of programmed and systematic activities for ensuring the test results [11]. Clinical laboratory quality control encompasses the entirely of the testing process beginning with a clinician ordering a test and ending with the clinician interpreting the test results [14, 17]. The correctness of the results and data prepared for medical care is directly related to the quality of laboratory services [13]. Clinical laboratories that do not follow proper procedures can cause incorrect data to be used in decision making [15]. Therefore, quality control of the data and results in the biochemistry ward includes paying attention to the working procedures and the effective factors in pre-analytical, analytical and post-analytical steps [7].

By comparing the findings obtained using the two tools, it can be found out that the findings do not match in certain effective factors and the amount of findings obtained from the questionnaire is more than the findings obtained from the checklists. In pre-analytical step in spite of the statements of head of biochemistry wards, lack of attention observed to some factors such as physiological changes of the patient's body,(which includes the patient's remaining for a long time in bed, daily bodily changes, the patient's traveling 5 days before sampling, flying on a plane on the test day, the patient's diet, drugs taken and lifestyle), remaining in a lying or sitting position for 20 minutes, Using disposal gloves, Type of disinfectant used for anatomic area of sampling, waiting for the sampling area to dry completely after using the disinfectant, Preparing samples of blood, serum, plasma, urine, and Transferring the samples, including paying attention to the temperature, leakage, hemolysis, contamination, and exposure to light, heat or wind.

In analytical step, in spite of the statements of head of biochemistry wards, lack of attention observed to some factors such as availability of a written guideline for analyzing the samples, Taking into account the necessary considerations in the selection of methods of analysis, which include paying attention to the ability to have an analysis method in providing an accurate and precise answer, having a high degree of sensitivity and specificity, using control samples for evaluating the operation of instruments every 8 hours, drawing statistical diagrams and comparing the result of the present test with those of the previous tests, paying attention to changes of temperature, paying attention to the stability of electric power, accurate calibration of the scales, glassware and volumeter. The post-analytical step was examined only by checklist.

REFERENCES

1.Moghaddasi, Hamid. Information Quality in Health Care Organization. Tehran: Vaajepardaaz, 1384.

2.Doris,L.Rross et al. Textbook of Urinalysis and body fluids.USA: Appleton-centry-Crofts;2000.

3.Linne, Jean Jorgenson et al. Clinical Laboratory Sciences,The basics. USA:Mosby; 2011.

4.University California, School of medicine; 2011. (www.med.unc.edu/ahs/clinical)

5. University of Wisconsin, Lacrosse Clinical laboratory; 2011. (www.uwlax.edu/clinicallabsci)

6.Henry, John Bernard. Clinical diagnosis and management by laboratory methods. USA: saunders;2001.

7.Saghgha, Hamid Reza et al. Comprehensive Book of laboratory sciences. Tehran: Mir; 1380.

8.Fishbach, frances. A manual of laboratory & diagnostic tests. USA: lippincott; 2010.

9.EL-Nageh, Mohammed M. quality systems for medical laboratories. Egypt: WHO; 1999.

10.Rakhshan, Mohammad. Clinical biochemistry. Tehran: andishe-e-no; 1380.
11.National Cancer Center, Japan; 2011.(www.ncc.go.jp/en/ncce)
12.Simmons, Arthur. Hematology. USA: Butter worth-heinemann; 2002.
13.Burtis, Carl A. et al. Tietz textbook of clinical chemistry. Third edition. USA: saunders; 2007.
14.Henry, John Bernard. Clinical diagnosis and management by laboratory methods. USA: saunders; 2010.
15. California, Environmental Protection Agency; 2011. (www.epa.gov/quality)
16.Bishop, Michael l. et al. clinical chemistry. USA: lippincott; 2010.
17. Lewandrowski, Kent. Clinical Chemistry. USA:lippincott; 2002.