A retrospective study of quality improvement in clinical biochemistry laboratory

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Abstract

Introduction: Laboratory bias can occur during the pre-examination, examination and post-examination stages. The appropriate laboratory practice has the great impact on health care system, more than 70% patient management mainly depend on laboratory test result. Current scenario shows huge importance of the laboratory errors and its negative impact on patient treatment outcomes. Quality improvement program main aim is to evaluate the total system performance and provide appropriate protocol to improve that performance. Therefore in this study we recorded the errors occurred in pre-examination.
Aim: The aim of this study was to access the importance of quality improvement program in clinical diagnostic laboratory to reduce or eliminate the diagnostic error.
Materials and Methods: The present study was conducted in King Fahad Hofuf Hospital Al-Assah (KSA) clinical biochemistry laboratory during a period of 2 years from March 2016 to June 2018. A total of 458,786 tests were performed on 147,746 outpatients and inpatients.
Results: A total of 4, 58,786 tests were performed in 1, 47,746 patients during the overall study period. The overall bias was recorded 4.35%. Out of total bias pre-examination bias was 3.15%, examination error was 0.2% and post-examination bias was 1% respectively. During 2 years study period no significant increase (P= 0.9) of total examination bias were found.
Conclusion: As laboratory scientist professionals, we need to acquire proper strategies to maintain the quality in diagnostic laboratory and concern with the physicians provide effective health care service to the patients. We recommend regular assessments in all the laboratories to assure the quality in the health sector.

Keywords: Pre-examination, Examination, Post-examination, Errors, Quality control.

Introduction

Improving the quality of health care is mandatory to keep up the standards of the laboratories. The accreditation bodies' assessment is very tough now a day. To get through that we need high quality labs and services should be standard. Hence, to assure the standards, regular auditing has to be conducted to the labs. Further the staff has to be trained regular basis on latest updated methods and techniques. The quality improvement program has been conducted since past to eliminate or decrease the bias in healthcare and other industries.[1] The quality management provides us standard techniques to rectify the errors as well as increase the quality in our practice. As per the Institute of Medicine, quality improvement programs are mandatory for health professionals to maintain the system performance.[2] The quality control and quality assurance are the different entity from the quality improvement. The quality control can be applicable for the detection of any bias occurred during testing process. The quality assurance means, a set of activities that helps laboratories to achieve and maintain high levels of accuracy and proficiency. The quality assurance can be performed by the development of standard operating procedures (SOPs) for the testing procedure and provide description regarding corrective measures when needed.[3] In contrast, Quality improvement program main aim is to evaluate the total system performance and provide appropriate protocol to improve that performance. Therefore in this study we recorded the errors occurred in pre-examination, examination and post-examination stages in our laboratory during the period of 2 years and discussed the standard protocol to reduce or eliminate these biases.

Materials and Methods

Study Design: Cross-sectional study
Study Setting: The present study was conducted at King Fahad Hofuf HospitaL-AL Assah (KSA).
Methods: Data was collected during the period from March 2016 to June 2018 from both inpatients and outpatients. We recorded the occurrence of pre-examination, examination, and post-examination bias found at the clinical biochemistry laboratory. The proper labeled specimens with patient information and requisition form were received from nurses and other healthcare professionals of various wards in the hospital. The biomedical scientists were responsible for collection and transport of outpatient department samples to the diagnostic laboratory. After receiving the specimens biomedical scientists in the laboratory were verify the specimens according to their requisite and any error observed were recorded in the log book. Standard laboratory practices were maintained during the overall testing process. The quality maintenance included such as calibrate the testing instrument before start the specimen testing, reagent lot number was checked and troubleshooting was done as needed.

Statistical Analysis

Data was analyzed by using SPSS20.0 version. After collection of data, it was entered in excel sheet and was analyzed. P value less than 0.05 was considered as significant.

Ethical Consideration: The study protocol was approved by Institutional Ethical Committee approved of King Fahad Hofuf HospitaL-AL Assah (KSA).

Result

A total of 4, 58,786 tests were performed in 1, 47,746 patients during the overall study period. The overall bias was recorded 4.35%. Out of total bias pre-examination bias was 3.15%, examination error was 0.2% and post-examination bias was 1% respectively. During 2 years study period no significant increase (P= 0.9) of total examination bias were found (Table 1).

rate of errors and increases the satisfaction of the customers. In this regard it is also important to consider the quality control system also. The quality control system has two major routes that are internal and external control systems. Internal system is mainly the staff of the lab that continuously observes, and assures the results are accurate. They may make use of standard control charts and rules available in the literature. The external system depends on the agency from which the lab is getting the components of lab which may be equipment's or the analysis kits. To attain the quality assurance it is responsibility of all the staff of the lab who should be dedicated to their job. Further clinical audit also should be considered on regular basis. It has to be performed by experienced staff. Otherwise it may be biased.[13]

The fully automated system in clinical diagnostic laboratories has great impact on total testing process with high sensitivity and specificity. Although there is highly

Table 1: Distribution of total analytical errors in percentage

Parameters	2016	2017	2018	Total
Pre-analytical	1.45% 3,134/2,15,674	1% 1,596/1,65,639	0.7% 529/77,473	3.15%
Analytical	0.064	0.068	0.06	0.2%
Post-analytical	0.4	0.3	0.4	1%
Number of tests	2,15,674	1,65,639	77,473	4,58,786
Number of patients	54,532	49,789	43,425	1,47,746

Discussion

As there is a drastic need for diagnosis of diseases in health sector, it is the need of time to increase the standards of the laboratory services. Laboratory testing plays a major role in most of the decision making of clinical cases. To achieve the standards, the labs has to work effectively in collaboration with other professionals of health care sector.[12] However, there are many obstacles in achieving the high standards. This makes it mandatory to assess the quality of services on regular basis which helps to identify the defects and barriers. Because once the barriers were identified, it will be easy to make an agenda to overcome those to reach the quality required and targeted. One of the major barriers is the acceptable error in testing. The second barrier is cost related issues. Hence, the agenda should be prepared in such a way that the cost of the services should be bearable for a common man at the same time the quality should be reliable. To achieve this goal there should be a perfect quality management system which should be actively functional. It should be independent to take decisions and implement the planning for the sake of improvement in the quality of the services. The laboratory should adopt the latest emerging technologies like computerization of all the processes and also automatize the assessment methods. This change is not a simple process, it needs a well quality management and assurance system and the opinions and ideas of the health care professionals should also be considered. Once, the quality management system is perfectly implemented, it not only increases the standard of services to labs but also decrease the

automated systems available for diagnostic purpose but this present study reported that laboratory errors occurred and it has negative impact on patient care. There were many research article regarding improvement of laboratory quality system, but still there are bias in clinical diagnostic laboratories.[4-6] In this study, we found out a total examination bias and discussed the standard protocol to reduce or eliminate its re-emergence. In this study we reported 4.35% was the rotal error with pre-examination, examination and post-examination contributing 3.15%, 0.2% and 1% respectively. Many other studies also recorded the error range in between 0.1% to 9.3%.[7-8] In our study the pre-analytical error rate was 3.15% which is mainly due to the wrong tubes for sample collection, hemolyzed blood and improper transportation of specimens to the laboratory. The similar findings were reported by other researcher.[3] There was problem occurred during sample collection and transport due to frequently changes of nurses, other healthcare workers and trainee students. We recorded examiantion error rate of 0.2% in this study. Another study showed 3.8% systemic analytical errors.[8] The highly automated system, proper laboratory technician training and participation in internal and external quality control program reduces the analytical errors in our laboratory. There was lot of studies done on reducing the analytical errors, which follows the similar approach.[9-11]To increase the quality system in our laboratory we participated on External Quality Assurance Programs. The total 1% error

was found in the post-analytical phase. 3.2% post-analytical error was reported by Goswani et al.[8] So according to our findings we can say that majority of errors can occur in pre-analytical and post-analytical phase. The incorrect phlebotomy practices may be due to lack of perfection or heavy work load. Therefore it is necessary to adopt proper phlebotomy practices. Hence, overall quality management system includes appropriate clinical diagnosis with ordering proper tests; perform standard testing procedures and proper interpretation of results. Therefore we recommend to adopt the habits of documentation of errors occur in every phases of examination and take necessary action to prevent or reduce these bias. In turn it will help us to protect the clinical diagnostic laboratory from such bias.

The improvement of the quality and standards of the lab is not an easy task which can't be achieved in a day. The quality management system should plan and implement the standards step wise to provide high standard diagnostic services up to the satisfaction of the customers.

Conclusion
As laboratory scientist professionals, we need to acquire proper strategies to maintain the quality in diagnostic laboratory and concern with the physicians provide effective health care service to the patients. We recommend regular assessments in all the laboratories to assure the quality in the health sector.

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