Quality improvement measures as effective for prevention of laboratory diagnostic bias

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Abstract

Introduction: A state and local Public clinical diagnostic laboratory quality improvement usually monitored by laboratory improvement strategies. The Institute of Medicine (IOM) in 1999 delivered a report on medical errors, which later focus on patient safety.

Aim: The study was undertaken to find out the effect of quality improvement programme for the prevention of laboratory diagnostic errors.

Materials and Methods: Diagnostic bias is called as any error from placing order of tests to analysis of results. The diagnostic process in the laboratory mainly divided in to three stages such as, pre-analytical, analytical and post analytical phase.

Results: Out of 14,047 specimens, 14.01% requisition form found without any signature of clinicians and 6.88% with no brief clinical history and provisional diagnosis.

Conclusion: The concluded quality improvement implementation program for deficient of out of TAT in clinical chemistry laboratory is mandatory to achieve the patient safety goal. The last step of the PDCA cycle "ACT" to maintain constant continuous improvement as ever ending program is the responsibility of the unit team work.

Keywords: Laboratory diagnostic bias, Pre analytical phase, Analytical phase, Post analytical phase, Quality assurance and quality control.

Introduction

The main goal of laboratory system quality program is to provide continuous improvement of state and public clinical laboratories.[1] Institute of Medicine reported on medical errors in 1999 stated that in United States as many as 98,000 deaths per year were occurred due to medical bias. Medical errors can be divided in to 4 different types such as, diagnostic error, treatment error, disease control error, and miscellaneous. Approximately 60% to 70% of medical decisions depend on the laboratory diagnosis, therefore, quality control in clinical laboratory is necessary for the patient safety.[2] laboratory bias not only depend on the medical professionals, it also based on completeness and efficiency of the health care system. Quality management system involvement in clinical laboratory is necessary to improve the patient treatment outcomes.[3-5] Therefore, quality assurance and quality control is very important for increasing the patient safety. The quality-management systems maintain the quality of laboratories by comparing the performance of one laboratory to another. Various national and international bodies are involved in the quality management system such as, the National Accreditation Board for Testing and Calibration Laboratories (NABL) in India, the College of American Pathologists (CAP) and The Joint Commission International (JCI). The investigation of activities which develop laboratory bias are the important management stratagies.[6-10] The proper management of system and identify the critical areas are important for the patient safety. The proper error detecting system is necessary to manage the 3 phases of testing process.[11-15] The prevention of laboratory error can be managed by placing proper diagnostic by the physicians, appropriate sample collection and labeling, transport and processing of samples, analysis of test results and communication of results with the physicians.[16,17] Most of the physicians were complained about laboratory turn around time, also this problem raised in laboratory meeting. Therefore, the present study focused to reduce the turn around time for the laboratory report mainly for the Emergency department (ED) and outpatient department (OPD). The study was conducted to find out the efficacy of the quality improvement program for the prevention of laboratory diagnostic error.

Materials and Methods

Study Setting: The present study was carried out in King Fahad Hofuf Hospital, Clinical Chemistry Laboratory during year 2017, for one month period.

Study Population: Total number of requests received in a month -14,047. Average per day- 453 (ED, Wards, OPD and peripheral hospitals).The study focused on total laboratory testing cycle procedure such as, pre-analytical, analytical and post analytical phases. The study indicators were incomplete data on request (pre-analytical phase), frequency of request (pre-analytical phase.

Collection of Data: We documented the occurrence of pre-analytical, analytical, and post-analytical errors observed at the Fahad Hofuf Hospital, Clinical Biochemistry laboratory. All the specimens with requisition form were received from nurses, healthcare providers as well as from doctors. After receiving of specimens the biomedical scientists were verify the samples with labelling and corresponding requisition form. Any problem occurred on the requisite or in sample labelling was recorded in the complaint record book. The proper laboratory standard operating system was maintained during overall testing process and it was recorded on log book. The fully automated auto-analyzers were used to

analyze the test results. The calibrations, reagent lot number and troubleshooting was done as needed.

Ethical Consideration: The current study was approved by institutional ethical committee.

Statistical Analysis

After collection of data, it was entered in excel file**.** Data was analyzed by using SPSS 20.0 version software. P Value less than 0.05 was considered significant.

Results

Among 14047 samples, 14.01% requisite form found no signature with stamp of clinicians and 6.88% with no brief clinical history and diagnosis [Table 1]. Turnaround time increased in more number of samples and decreased in less number of specimens [Fig. 1]. In this study repeated requests in a month was 12.23% [Table 2].

Table 1: Number of incomplete requests

Total no. of samples performed & studied	No signature with stamp of clinicians		No brief clinical history / diagnosis	
14047	Total	%	Total	%
	1968	14.01	967	6.88

Table 2: Total number of repeated requests in percentage

Admitted patients (ward)		Total repeated Requests In a month ↓	No. of times repeated requests			
			2 Times	3 Times	4 Times	5 Times
Total Requests → received		704	537	139	22	6
Average Per Day →	192	24	18	4	<1 (0.7)	<1 (0.16)
Percentage (%) to Total Requests		12.23%	9.49%	2.41%	0.36%	0.08%

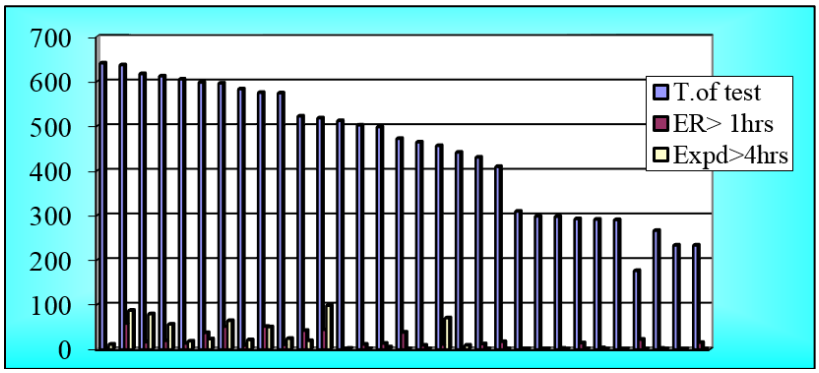

Fig. 1: Increased TAT is directly proportional to the increased total no. of samples

Discussion

The science of Quality Improvement (sometimes referred to as Continuous Quality Improvement or Total Quality Management) has been applied for decades in manufacturing and other industries to reduce defects and errors.[1] Its application to healthcare and to laboratory practice in particular, provides standard methods by which we can identify and remedy not only errors, but also inefficiencies and ineffectiveness in our practice. The ability to apply principles of Quality Improvement (QI) to evaluate systems performance is one of the five competencies defined by the Institute of Medicine as essential for all healthcare professionals. In this present study no probable diagnosis/brief clinical history of disorder was 6.88% and no signature with stamp was 14.01% [Table 1]. In the part of study oral enquiry with staff nurses, they are the one ticking mark of parameters on request form [LIS/SNI (Secure Network Interface) connectivity is not available] which may not be related to the disease. The reasons noticed that mainly because of the clinicians are in busy environment or some other professional reasons instructing the staff nurse as Bio-profile investigations get it done writing in the file, but unfortunately no panels of tests specific system disease involved ticking mark. These irrelevant tests ordered increasing the work load, increasing the TAT, utilizing the more reagents (abusing), early exhausting of reagents which increase demand and supply reflect on cost and effort. The incomplete data default is a chance of misusing the lab services by unqualified personnel's and ineligible patient. 12.23% frequency of request or repetition of sample for the same patient for same

parameters in the same day (very close frequency) is not ideal laboratory service utilization except close monitoring of patient prognosis in bad cases when necessary [Table 2]. Very close frequency/repetition of analysis without indications definitely increase the work load need more manpower, abusing of reagents and ultimately increase the TAT. Exceptional conditions depending on disease severity close monitoring of disease prognosis and also doubtful lab result can be acceptable. In our one month study found 12.28% repeated requests observed total 5753 cases most of them without specific condition. Technological facility of SNI (Secure Network Interface) connectivity which transfers the data of result from analyzer to interpretation and dispatching computers is not available. Manual writing of parameters result in computer after final result delaying the result dispatch –subsequently increases TAT.

Conclusion

In conclusion the method organized quality the out of TAT % reduction improvement after receiving the number of complaints from clinical departments & specially ER. All clinical departments and with the help of department of quality management clinical chemistry laboratory team work done and clarified current procedure. The source of the problem and the process variance identified as paramedical staff nurse ticking mark of tests on the investigation order form instead of clinicians. The close frequency (repeated) investigation requests should be reduced except life threatening cases for monitor.

Conflict of Interest: None.

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