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Comparison of previous reports in indoor patients-a potential tool for internal quality assurance in clinical biochemistry

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Abstract: Laboratory testing is an important and integral part of the decision-making process and strongly influences medical diagnosis and therapies. Normally the extraneous results in a clinical report raise a doubt towards the quality assurance program of a laboratory. This communication is intended to highlight the potential use of previous reports of indoor patient in an indoor hospital laboratory as a tool for quality assurance. In this study approximately 10% of the doubtful reports were picked up randomly and the results were compared with the earlier reports of the patient retrieved from database. The study revealed that there was a significant reduction of more than 80% in the test repeats resulting in decrease in expenses on repeat tests (80%).There was a significant average reduction of time and human resource investment, decrease in the instrument working hours and increased workflow efficiency due to reduction in the test repeats. Moreover, there was an increase in the confidence level of consultant towards quality control program and authenticity of the reports.

Key words: Clinical Diagnosis; Therapies; Databases

Introduction

Quality laboratory services are the need of the hour in the field of health care. Laboratory testing is an integral part of the decision-making process, and results of laboratory testing often strongly influence medical diagnosis, case finding, diagnostic and therapeutic monitoring [1]. There is a long history of quality requirements in laboratory medicine, which have mainly concerned the analytic phase of this process. Owing to the substantial advances in technology, laboratory automation and analytical quality, there is increasing evidence that further quality improvements should be targeted to extra-analytic phases of laboratory testing. A number of approaches can be applied to improve the quality assurance program. Application of Sigma Metrics for the Assessment of Quality Assurance in Clinical Biochemistry Laboratory is also being tried in India [2]. Pre analytical variables have been shown to play a great role in quality of tests in laboratory medicine [3].

Laboratory testing is a highly complex process and, although laboratory services are relatively safe, they are not as safe as they could or should be. Quality and safety in diagnostic testing is, however, essential to furthering the goal of high-quality and safe healthcare [4]. Clinical laboratories have long focused their attention on quality control methods and quality assessment programs dealing with analytical aspects of testing. However, a growing body of evidence accumulated in recent decades demonstrates that quality in clinical laboratories cannot be assured by merely focusing on purely analytical aspects. The more recent surveys on errors in laboratory medicine conclude that in the delivery of laboratory testing, mistakes occur more frequently before (pre-analytical about 46-68.2% of total errors) and after (post-analytical about 18.5 -47.0% of total errors) the test has been performed [5]. Although the total testing process is classically divided into three separate but sequential areas (pre analytical, analytical and post analytical phases) yet a large body of evidence attests that most errors occur within the extra-analytical areas of testing, especially in the manually intensive pre analytical processes [6-10].

The last few decades have seen a significant decrease in the rates of analytical errors in clinical laboratories. Evidence demonstrates that pre- and post-analytical steps of the total testing process (TTP) are more error-prone than the analytical phase. Most errors are identified in pre-pre-analytic and post-post-analytic steps outside of the laboratory [11]. So pre and post-analytical processes are equally important for ensuring quality laboratory services. Process analysis has demonstrated that laboratory errors occur primarily in the pre-analytic phase, influencing patient outcomes and cost [12-15]. According to another study [16] patient preparation, patient identification, specimen acquisition, specimen handling, and documentary system (specimen recording and result reporting), turnaround time and verification of test results were important consideration factors and, one must design the strategies to detect and eliminate the non-analytical errors. If we achieve more reliable laboratory results by better control of influence factors and

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interference factors as well as by a more standardized pre-analytical process, we will produce more value at the same cost [17].

The internal QC involves the in-house procedures for continuous monitoring of operations and systematic day-to-day checking of the produced data to decide whether these are reliable enough to be released. The external QC involves reference help from other laboratories and participation in national and/or international inter-laboratory sample and data exchange programmes. Since inception of the laboratories, it has been endeavor of the scientists to improve work flow and to reduce the cost of running. Number of people has tried different methods to increase work flow and reduce the operational cost. Four stand-alone analyzers in a centralized laboratory were replaced by two modular analytical systems processing 45 methods of the general chemistry and specific protein segment [18]. This consolidation led to a reduction of the daily workflow and operational costs.

So there is a great need of some potential technique that could help in increased work flow, cost cutting, reduction in human investment and time investment and to authenticate the process of pre-analytical and post analytical phase. Keeping in view the above scenario, this study was designed to find out a quality assurance tool that works in multifarious way.

Material and Methods

The present study was conducted at central clinical laboratory at Post Graduate Institute of Medical Education and Research, Chandigarh. As a method of check 397 (about 10%) doubtful reports with extraneous values were selected randomly and the comparison was made with the data base of the laboratory for previous days. The reports of freshly enrolled patients were dropped out. The assessment parameters like reduction in test repeats, confidence level of consultant, expenses on the tests, instrument working hrs, instrument life, human resources investment, time investment and overall workflow were calculated and results were compiled.

Results

From the results (Table 1 and 2) it was observed that there was a significant decrease of 89% in the number of tests repeated in the doubtful reports. In a total of 3072 tests in 397 reports, 2742 tests were to be repeated under doubtful conditions but due to this technique laboratory saved repetition of 2742 tests and on an average daily 210 tests to be repeated were saved. The time investment was calculated as approximately one minute per test and on an average there was a reduction in the time investment of approximately 210minutes /day. If the minimum processing cost of one test is taken as Rs.10 approximately (which is generally Rs.25 if we include the cost of running machine and human resources investment) then there was an average saving of approximately Rs.7.56 lakh /year for repeated tests. On an average there was a reduction of 3.5 hours human resource investment per day.

Table 1:

Reduction in repeats	Expenses on tests saved per year (In lakh)	Time investment saved (minutes/day)	Number tests saved for repeats/day	Instrument working hours decreased	Instrument life increased
89%	7.56	210	210	3.5hr/day	53.22 days/year

Table 2:

Total Number Of Tests Screened	Number Of Tests Repeated	Number Of Tests Saved	Human Resources Investment Decrease	Human Error Detection
3072	330	2742	3.5hr/day	100%

The data shown is for the 10% randomly drawn reports

Conclusions

From the results it may be concluded that the comparison of previous reports in indoor patients can be used as a potential tool for internal quality assurance in clinical biochemistry. At the same time this tool can be used to reduce the number of repeats, significant reduction in expenses on repeat tests, reduction in human resource investment, reduction in instrument usage hrs hence increase in instrument life and increase in confidence level of the consultants in reporting. The significant reduction in repeats also increased the efficiency of the instrument.

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