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Original Article

Biochemistry Section

Quality Assurance Program in Clinical Biochemistry Laboratory at a Multispeciality Teaching Hospital, with Special Reference to Quality Indicators

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ABSTRACT

Introduction: Clinical laboratories have made considerable progress in addressing the needs of quality control, to make a difference in patient care by giving reliable results. With high degree of dependence on the laboratory results for the healthcare management, the quality of laboratory testing and reporting has become crucial for the better outcome of the healthcare delivery system, particularly in case of tertiary care hospitals. The goal of effective quality assurance program is to ensure execution of all required activities in a proper, professionally acceptable manner.

Aim: To evaluate the existing Quality Assurance Program (QAP) of the Clinical Biochemistry Laboratory and to assess the Quality Indicators (QI) in terms of pre-analytical, analytical and post-analytical phases.

Materials and Methods: The retrospective study was conducted in a Clinical Biochemistry Laboratory of a Multispecialty teaching hospital, Mysuru, Karnataka, India. The QAP available in the Department of Clinical Biochemistry and the QI data from January 2017-December 2017 was collected. The QI data was assessed under pre-analytical/analytical/post-analytical phases. The data collected was analysed using Microsoft Excel and Microsoft data analysis pack tool.

Results: A total of 29 parameters were evaluated to assess the execution of QAP being implemented in the clinical biochemistry laboratory. The existing QAP in the clinical biochemistry laboratory was assessed in terms of structure, process and outcome. We found that most of the processes were in place, as per the defined standards. The overall trend analysis of QI showed a consistent and good performance, though there were few areas where there was scope for improvement.

Conclusion: Assessing the performance of QI provides an insight into the efficacy of the QAP. Identifying the gaps in the QAP opens up new avenues for continuous quality improvement.

Keywords: Analytical errors, Clinical laboratory, Compliances, Total quality management

INTRODUCTION

The modern clinical laboratory has grown in stature gradually from a mere supportive role to be an active player in patient care. With the advent of evidence-based medicine, increased awareness among the general public and fear of legal hassles has increased the need for laboratories to adhere to strict quality assurance policy and generation of quality reports [1].

The results of investigations are crucial for screening, diagnosis, prognosis and the treatment of medical conditions. Laboratory test results influence approximately 60-70% of clinical decisions pertaining to assessment and management of patients [2].

The concept of Total Quality Management (TQM) in a clinical laboratory is generally managed in a cycle of 'five Qs' i.e., quality planning, quality laboratory procedure, quality control in laboratory, quality assessment and quality improvement. The Quality Management System (QMS) of any laboratory committed to Good Laboratory Practice (GLP), includes all the activities in the laboratory which aims at providing accurate and timely reports. These activities are generally categorized under structure, process and outcome [3].

Quality assurance means delivery of relevant and effective medical care in accordance with the standards. It is to ensure that the effective activities required are executed in a proper, professionally acceptable manner [4]. QAP is an ongoing process that is implemented to monitor and evaluate every step of the laboratory's testing operation, including pre-analytical, analytical and post-analytical processes. QAP is part of QMS designed to give maximum guarantee and ensure confidence that the service provided is up to the given accepted level of quality [1,5].

Pre-analytical Phase (Pre-examination processes): Process that starts in chronological order, from the clinician's request and includes examination request, preparation and identification of patient, collection of primary sample(s), and transportation to and within laboratory, and ends when the analytical examination begins.

Analytical Phase (Examination processes): Includes processing the quality control samples and also the patient samples.

Post-Analytical Phase (Post-examination processes): Processes following the examination including review of results, retention and storage of clinical material, sample (and waste) disposal, and formatting, releasing, reporting and retention of examination results [4,5].

Furthermore, quality assurance in clinical biochemistry laboratory also aims in identifying the errors and the procedures used to recognize and minimize them [6,7]. Many experts believe that 40% of errors in a laboratory are pre-analytical, 40% of errors are post-analytical and only 20% of errors are analytical [1]. Effective implementation of QAP is monitored by periodic capturing of QI. QI is defined as a quantitative tool that is used as a guide for monitoring, evaluating and improving the efficiency, effectiveness, reliability and completeness of management, clinical and support systems [8].

However, just introducing a QAP is not enough. Periodic assessment of the implementation of QAP is necessary to identify the deficiencies, so as to improvise upon the overall process. Hence, the present study was taken up to evaluate the existing QAP of the Clinical Biochemistry Laboratory in order to identify the gaps and avenues of improvement and assess the QI in terms of pre-examination, examination and post-examination phases.

MATERIALS AND METHODS

The present retrospective study was conducted at Clinical Biochemistry Laboratory of a Multispeciality Teaching Hospital, Mysuru, Karnataka, India.The study involved assessment of QAP and QI from January 2017-December 2017. Institutional ethical clearance was taken with approval letter No.JSSMC/IEC/07/01NCT/2018-19.

QAP implementation in the clinical biochemistry laboratory was evaluated under three main categories: structure, process and outcome. The categories and sub-categories were derived from literature and discussion with field experts and feedback from the peer group [9]. The adherence to the above program was evaluated as fully compliant (score 10), partial compliant (score 5) and/or non-compliant (score 0). The scoring pattern was adapted from National Accreditation Board for Hospital (NABH) and Health Care Providers scoring system [8].

The data was collected by utilizing Rejection log, Critical alert log, Monthly Re Do's and Amended report log, QI log (all the logs were maintained by the clinical biochemistry laboratory as a part of QAP) and Laboratory Information System (LIS). The data collected was analysed using Microsoft Excel and Microsoft data analysis pack tool.

RESULTS AND DISCUSSION

QAP in its various forms has become routine practice in fields of diagnostic branches, especially clinical biochemistry, where the results are in absolute quantitative figures. Over one third of all hospital laboratory examination is clinical biochemistry investigations [2]. With high degree of dependence on the laboratory results for the health care management, the quality of laboratory testing and reporting has become crucial for the better outcome of the health care delivery system. In the present study, the existing QAP in the clinical biochemistry was assessed with reference to structure (maximum score assigned-130), process (maximum score assigned-130) and outcome (maximum score assigned-30), thus adding up to a total score of 290.

Structure is defined in terms of availability of the basic resources infrastructure, and equipment/personnel. This category was assessed utilizing checklist for adequate infrastructure (availability of adequate work/personal space, ventilation, lighting and safety measures) adequate staff (qualification, training, HR policy, credentialed and privileged), equipment (process of equipment installation, preventive maintenance, regular quality control measures and breakdown services).

As a part of QAP, laboratory had a well-defined "Quality Policy" with respect to scope of services, laboratory personnel qualification, TAT, critical results, outsourcing, lab safety and reporting of results, which were documented and had a controlled accessibility to all the technicians. The study revealed that, all the Standard Operating Procedure (SOP) for primary sample collection, equipment and experimental procedures were available and the documentation part was adequate. The SOPs were clearly written and periodically reviewed and updated. Laboratory ensured display of quality policy, along with signboards and posters of the staff with contact details, scope of services, laboratory work flow, important communications, safety measures, emergency codes, BMW segregation, hand wash, needle prick management. In the present study, we observed that the laboratory was fully complaint under this category (score-10 for each criteria) and hence a maximum score of 130 was achieved in "Structure" category [Table/Fig-1].

Process: Comprises the procedures and practices followed in the laboratory to achieve the desired outcome [5]. The Clinical Biochemistry Laboratory has a robust and efficient Laboratory Information System (LIS) which is duly interfaced with Hospital Information System (HIS). Periodic maintenance and calibration of equipment is being carried out and updated continuously and related records maintained scrupulously. Daily IQC and monthly external QAP was performed and a careful maintenance and monitoring of these records were done. The procedures and practices with regards to primary sample collection, equipment and experimental procedures, lab safety precautions were followed as per the defined SOP's. Hence, all the above parameters were fully compliant (score of 10/10, respectively) [Table/Fig-1].

			Compliance (Score Achieved)		
			0	5	10
Category I = Structure					
i.	Infrastructure availability				√
ii.	Adequate manpower and staffing				√
iii.	Quality policy:-	Scope of services			√
		Laboratory personnel qualification			√
		Turn Around Time			√
		Critical Results			√
		Outsourcing			√
		Lab Safety			√
		Reporting of results			√
		Quality Assurance Programme			√
iv.	SOP for patient identification, preparation, collection, handling and disposal of samples				√
v.	SOP for equipment and experimental procedures				√
vi.	Signboards/Posters displaying the activities and services in the laboratory and the important contact numbers for communication at prominent areas				√
Score			130		
Category II = Process					
i.	Availability of HIS and LIS tools				√
ii.	Periodic calibration and maintenance of equipment's record				√
iii.	Equipment's Calibration and traceability certificates				√
iv.	Daily Internal Quality Control Records				√
v.	Monthly External Quality Assurance Records				√
vi.	Documentation of corrective and preventive actions			√	
vii.	Adherence to safety precautions checklist like infection control and laboratory waste management and periodic training for the same				√
viii.	Staff and Technician training records				√
ix.	Critical result alert log				√
x.	Rejection Log				√
xi.	Amended reports recall log				√
xii.	Adherence to Turn Around Time (TAT)				√
xiii.	Adherence to Standard reporting format				√
Score			125		
Category III = Outcome					
i.	Monthly assessment of Quality Indicators				√
ii.	Periodic Surveillance of test results				√
iii.	Feedback from stakeholders			√	
Score			25		
Overall Scores				10	270
Total Score			280/290		

[Table/Fig-1]: Compliance to structure, process and outcome parameters.

All the staff including technicians were qualified and trained in their respective areas including safety measures, handling emergencies (awareness about how to respond to hospital emergency codes) and Bio Medical waste management. Further, the adherence to these was monitored using a simple in-house check list. The respective training records were evident and hence fully compliant.

Critical results or findings requiring immediate attention of the treating doctor were defined in the policy in consensus with clinicians and well displayed in the lab. The critical alerts were communicated via

telephone and message as well as documented in the critical results alert log. The monthly statistics of critical results informed as well as the average time taken to inform these critical alerts is documented as shown in [Table/Fig-2]. All the reports were released under the standard reporting format as per the NABL ISO 15189 guidelines. In addition, policy for rejection of samples and amended reports recall was in place, and the details recorded in the respective registers. Hence, all these parameters were fully complaint (score of 10/10, respectively).

TAT is the time taken from sample collection to release of reports. TAT is usually defined by the individual laboratory, keeping in mind the need of stake holders. TAT of different investigations was defined in the policy and a monthly statistic of TAT was maintained, where in an average adherence to TAT per month was 93%.

Only one criterion under the "Process" category was partially complaint (5/10). Here, though a policy of Corrective And Preventive Actions (CAPA) was outlaid there was incomplete documentation with regards to preventive actions implemented.

Hence the total score under "Process" category was 125 out of maximum score of 130.

Outcome: It is the expected end-result as a consequence of adherence to the laid out "process" under the QMS [5].The outcome category was assessed under the following parameters; first, the assessment of QI captured month wise, the next was periodic surveillance of the results and finally, the feedback from stake holders (Doctors and Patients) [Table/Fig-2]. Periodic surveillance is a need-based approach, wherein structure and process are assessed to suit the requirement of the stake holders and ensure improvement in overall performance of the QMS; in order to attain expected result [Table/Fig-1]. This was carried out by Head of Clinical Biochemistry department on quarterly basis.

Sl No.	Phases	Subcategory	Parameters	Average/ month
I.	Pre-analytical	QI-1	No. of test orders with wrong request	10
		QI-2	No. of requests with incorrect patient demographics	30
		QI-3a	No. of unlabeled/ mislabeled samples	0.6
		QI-3b	No. of samples with Incorrect Vacutainer	1.4
		QI-3c	No. of venous samples for ABG	22
		QI-3d	No. of samples-Haemolysed	72
		QI-3e	No. of samples-Improper	17
		QI-3f	No. of samples-clotted	10
		QI-3g	No. of samples with insufficient volume	17
		QI-3h	No. of samples collected at inappropriate time	01
II.	Analytical	QI-4	No. of unacceptable performances in EQAS	4.8
		QI-5	No. of unacceptable performances in EQAS after correction with their previous samples	0
		QI-6	No. of parameters with CV >10%	4
		QI-7	Equipment related issues	6
III.	Post analytical	QI-8	% of reports delivered outside TAT	7.2
		QI-9	% of critical values reported	0.8
		QI-10	Average time taken to communicate critical values in minutes	5
		QI-11	No. of reports issued with comments	107
		QI-12	Total No. of amended reports issued	7.6
			No of Amended reports due to transcriptional errors	4

[Table/Fig-2]: Quality indicators in various laboratory functioning phases.

Out of the 3 parameters assessed in the outcome category, assessment of quality indicators and periodic surveillance were fully compliant, whereas feedback from the stakeholders (patients & doctors), was partially compliant (5/10) [Table/Fig-1]. The reason for this partial compliance was inadequate implementation of the feedback policy, wherein feedback from patients was collected, but there was failure in collecting the feedback from doctors.

Hence the total score under "outcome" category was 25 out of maximum score of 30.

Assessment of Quality Indicators: The QI are classified according to functional phases of laboratory [Table/Fig-2].The average total number of investigations/month for the year 2017; performed was 70,370; with the maximum number of investigations performed during the month of July (89,318) and minimum number in the month of February (59,214).

Quality indicators of Pre-analytical Phase: Pre-analytical phase basically involves collection, handling and transport of samples. Errors in this phase are considered as pre-analytical errors and are known to contribute to the delayed and suboptimal patient care.

In this study, Pre-analytical phase QI were sub-categorized from QI-1 to QI3 a-h [Table/Fig-2].

QI-1 quantified number of tests orders with wrong request. Wrong requests are the requests which are raised by mistake, confusion with the patient identification, wrong test raised, same test raised in duplicates and confusion with sound alike tests.The average number of wrong requests was 10/month. The highest number of wrong requests was reported in the month of July (total no.23). QI-2 quantified number of requests with incorrect patient demographics such as name, age, sex, addresses incorrect doctor/department details and inaccurate clinical history/diagnosis details. The average number of requests with incorrect patient demographics was 30/ month. The highest number of requests with incorrect patient demographics was reported in the month of July (total no.35). The probable reasons for this increase in wrong requests (QI – 1) and inappropriate test requests (QI-2) were due to the highest number of total investigations performed in the month of July and hence a proportionate increase was observed. QI-3 includes the parameters (3a-3h) as depicted in [Table/Fig-2], which basically includes sample collection, handling and transport. 3a-3h were also the indicators for sample rejection.

Preanalytical errors in laboratories vary from 46-68% [10]. Even in our study, pre-analytical errors constituted 51% of the total errors. As >50% errors occur in pre-analytical phase, it becomes pertinent to monitor this phase more meticulously, as it can be easily circumvented by providing adequate training to the phlebotomists, nursing staff and other personnel involved during sample collection and transport.

Quality Indicators of Analytical Phase: The most vital aspect of the analytical phase is ensuring the accuracy and precision of the reports, which is achieved by efficient and continual QAP (includes both internal and external QAP [11].

The performance of IQC and EQAS programs were captured by the estimation of Coefficient of Variation (CV) % and Number of unacceptable performances in EQAS respectively. Finally,equipment related issues were also captured under this functional phase [Table/ Fig-2].The parameters which were out of range in the IQC and EQAS were duly addressed after a thorough Root-Cause Analysis (RCA) using an in-house troubleshoot-checklist and corrective action taken was documented.

Equipment related issues in our study included minor issues (example: aspiration errors, tubing errors, water/cuvette quality issues, lamp failure) to major equipment breakdown. An equipment breakdown register was maintained, which highlighted the type of issue, downtime and measures taken to sort out the issue by the service engineers (in-house/company).

Quality indicators Post-analytical Phase (QI 8-12): Release of accurate, reliable and timely reports, constitute post-analytical phase. Our study observed that the lab had outlined the policies for TAT, amended report recall and critical result alert [Table/Fig-2].

The adherence to TAT observed was 93% (average) per month with a maximum of 94% in May and a minimum of 88.25% in October. A RCA was done which identified as repeated and prolonged equipment downtime as the reason for decreased TAT in October and necessary steps taken which resulted in an improvement of TAT from 88.25% observed in October to 90% in November.

Critical alert parameters identified were in agreement with stakeholder. This critical alert list was concurrent as shown in a meta-analysis study done by Wagar EA et al., across 163 clinical laboratories to compare the critical value alert system [12]. On an average the number of critical value alerts observed in our study was 539 per month (0.8%). The critical alert log was maintained meticulously and our study showed that the average time taken to communicate critical values to the care providers was approximately 5 minutes which was comparable to the studies which had a variable reporting time between 1.5 to 8 minutes [12,13].

Results of non-conforming examinations already released are recalled and the corrected reports are then released as "Amended Report". A test result that is corrected and updated when non conformities are detected due to any aspect of its examinations not conforming with its own procedures or the agreed upon requirements of its QMS or the requesting clinician [14]. On an average, the rate of amended reports in our study was 7.6 per month The number of amended reports observed in our study is comparable to the study by Valenstein PN et al, where the average rate of amended pathology reports was 1.5/1000 cases [15].

Transcriptional errors in our study constituted 53% of the total amended reports which was less when compared to other studies which constituted 60% [16].The transcriptional errors were usually seen in reporting of certain tests which were manually entered by technicians as the instruments running those tests were not interfaced with the existing laboratory information system.

LIMITATION

A more detailed comparative analysis of QI across successive years was not done and furthermore, cost benefit analysis was not performed depending upon the performance of QI.

CONCLUSION

Quality assurance means delivery of relevant and effective patient care in accordance with standards. Assessing the performance of QI provides an insight into the efficacy of the QAP. Establishing a standard protocol for capturing the QI might seem a daunting task but helps in strict assessment and monitoring of the quality assurance system and in turn insulates us from legal hassles. Identifying the gaps in the QAP opens new avenues for continuous quality improvement. This study helped in assessing and identifying the deficiencies in the total quality management system of the Clinical Biochemistry laboratory. Our study provides a basic check list which can be easily incorporated for the beginners in small size laboratories.

Further studies including a more exhaustive list for capturing different QI in the respective phases for a comprehensive assessment of QMS is needed. In addition, such studies carried out in large scale laboratories across different parts of the country are needed to produce a harmonized and standardized QMS program, which can be uniformly incorporated across all the clinical biochemistry laboratories in the country.

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