Congruity in Quality Indicators and Laboratory Performance

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Abstract Proficiency of laboratory services is the mainstay in clinical medicine in providing error free diagnostic results. The efficiency of the laboratory needs to be evaluated as per standard international criterion. The quality indicators of the different phases of total testing process are considered the fundamental measurable tool for evaluation of laboratory performance. In order to optimize the laboratory's proficiency and accreditate it as per international standard in our newly established lab, the study was conducted to evaluate the frequency of errors incurred by laboratory and nonlaboratory professionals during the whole testing process. Retrospective analysis was done for data received from April 2016 to Dec 2016 in our lab. Total number of samples received was 61,674, out of which 43200 samples could be analyzed for quality indicators. Total numbers of tests processed in these samples were 172,800. In the study samples, 26.5% errors were due to pre-analytical factors whereas 9.4% of errors were contributed by analytical phase and 18% by post-analytical phase. Inappropriateness of test requisition was observed to be the major attributing determinant for pre-analytical errors. Instrumentation efficiency in form of frequent breakdown (~7%), greatly affected the proficiency of analytical phase in our lab. 12% of post-analytical errors were ascribed by excessive turn-around-time. However, timeliness of critical value call out and reporting for STAT samples revealed high proficiency up to 97%. High error rates were observed in pre-pre- and pre-analytical phases that also accorded for high error frequency in post analytical phase. This emphasizes urgent need to formulate

guidelines for processing all steps of total testing process and initiate strategic measures for reducing risk of errors and increasing patient safety.

Keywords Quality indicators · Pre-pre-analytical errors · Pre-analytical phase · Analytical phase · Post-analytical phase

Introduction

Quality indicators (QIs) are considered as fundamental tool for quality laboratory services that can be measurable to assess each and every step of total testing process (TTP). Evaluation of these determinants would enable us to quantify laboratory's performance by comparing it to a standard criterion. Any potential QI need to fulfill primarily two inclusion criteria: (1) it must be an indicator of laboratory functions and (2) it must cater to at least one Institute of Medicine (IOM) health care domain [1]. The Technical Committee of International Organization for Standardization (ISO/TC 212) and International Federation of Clinical Chemistry and Laboratory medicine (IFCC), have achieved consensus in developing a model of QIs that encourages a patient-centered approach and emphasizes the need to follow standard protocol for laboratory testing and support clinicians in providing error free laboratory results for a conclusive clinical diagnosis and treatment monitoring [2].

The TTP embraces three phases: pre-analytical, analytical and post-analytical phases. Various studies according to the international standard for medical laboratories accreditation, the laboratories must periodically evaluate the critical aspects of all the three phases of TTP taking into consideration of the enlisted measurable determinants.

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This would help to identify the defects and initiate corrective measures to improve laboratory performance with respect to patient safety, effectiveness, equity, patient centeredness, timeliness and efficiency [3]. The current awareness in the knowledge of evidence based QI in laboratory testing has shifted the focus from old paradigm which was limited to laboratory itself, to the outer circle. Pre-pre-analytical phase consisted of the initial procedures performed outside clinical laboratory or at least in part, beyond the control of laboratory personnel. Hence, pre-pre-analytical phase is now considered as the initial phase of TTP and together pre- and pre-pre-analytical phases have been shown to be the most vulnerable phases for errors than those occurring in the laboratory during analytical phase [4].

With an aim to optimize the laboratory's proficiency and accreditate it as per international standard in our newly established lab, the study was conducted to evaluate the frequency of errors incurred by laboratory and non-laboratory professionals like the nursing staffs, ward attendants, staffs in billing section, during the whole testing process. This study would enable us in grading laboratory errors on the basis of their importance in patient safety and prioritize implementation of effective interventions to reduce testing related diagnostic errors in clinical medicine.

Materials and Methods

The clinical biochemistry section started in 2014 in the central laboratory of our institute is equipped with state-of-the-art instruments such as high throughput fully automated auto-analyzer with ISE (Beckman AU 480 from Beckman Coulter and Biosystems B400 from Biosystems), Electrolyte analyzer (Eschweiler and Ilyte), Direct Chemiluminescence for immunoassay (Cobas e411 from Roche and Advia Centaur XP from Siemens) and D-10 hemoglobin analyzer from Biorad. The lab deals samples from Out Patient Department (OPD), In-Patient Department (IPD) and Trauma and Emergency Unit, through-out the clock.

Though there are set Standard Operating Procedure (SOPs) in the laboratory and time to time monitoring of the laboratory activities are carried out, still unanticipated errors are made by laboratory and extra-laboratory staffs involved in the whole process. Relevant data were analyzed randomly for 09 months in our lab from April 2016 to Dec 2016 for the samples being received by our lab. Total number of samples received was 61674, out of which 43200 samples could be analyzed for quality indicators. Total numbers of tests processed in these samples were 172800. The various reasons ascribed to un-availability of data of the remaining samples are put down as below:

1. Un-availability of trained technical staff when samples were brought to lab as during lunch-time, or night emergency or during shift duty changeover, when samples were received by the non-technical staffs like lab attendants or cleaning persons.
2. During the rush hour or due to overcrowding of patient or due to reduced manpower, the technical staff either was unable follow SOP or might have missed to observe the requisite determinants.
3. Recruitment of new technical staff who was unaware of such process.

Results

Data for quality indicators collected for 172,800 tests performed on 43200 samples during the study period. Total number of errors identified was 23,281 (53.9% of all included samples). As illustrated in Table 1, 26.5% errors were accorded to pre-analytical factors whereas 9.4% of errors were contributed by analytical phase and 18% by post-analytical phase. Of total errors, the percentages of pre-analytical, analytical and post-analytical errors acknowledged were 49.2, 17.4 and 33.4% respectively. Incomplete information (71.3% of pre-analytical errors) concerned to patient identification, inappropriateness of test request, incomplete TRF and incomplete sample labeling were the major attributing determinant for pre-analytical errors (Table 2).

Inappropriateness of test request (~17%) was observed to be the major attributing determinant for pre-analytical errors (Table 2).

The ratio of unacceptable performances in external quality assessment programs and proficiency testing (EQUAS-PT) schemes in previously treated cause to the total number of unacceptable performances was quite high (14.3%) as shown in Table 3. Instrumentation efficiency in form of frequent breakdown (~7%), greatly affected the proficiency of analytical phase in our lab.

Table 4 depicts an excessive TAT (12%) which was ascribed to be a major source of error in post-analytical phase. However, timeliness of critical value call out and reporting for STAT samples revealed high proficiency (97%).

The performance level elaborated in table 5 revealed optimum efficiency in appropriateness of test request with respect to clinical question, physicians' identification, sufficient sample volume, samples lost or not received, sample hemolysis and number of critical call-outs. The unacceptable performance recorded in the TTP were that of patient identification, errors concerning test inputs and reporting within TAT period.

Table 1 Percentage of errors in the three phases of TTP

Phases of TTP	Percentage of errors		
	Total sample (N _S) = 43200	Total Tests performed (N _T) = 172800	Total no. of errors (N _E) = 22981
1 Pre-pre- and pre-analytical phase (n = 11447)	26.5	6.6	49.2
2 Analytical phase (n = 4052)	9.4	2.3	17.4
3 Post-analytical (n = 7482)	17.3	4.3	32.6

Discussion

The purpose of quality specific indicators is to assess and monitor the proficiency in the laboratory's TTP and accordingly strategies are formulated to implement a quality system. Quality performance is essential to gain confidence of clinicians and general public for our reports. In view of accreditation of our lab of international standard, it was highly required to gauge the efficiency of our laboratory and extra-laboratory operators to follow the set protocol. The QIs assessed in our study has been adopted from those 60 QIs related to key processes as enlisted by Plebani et al. [5] in their study. It consisted of 35 pre-, 7 intra-, 15 post-analytical and 3 support processes. In this study, as per our feasibility we chose 40 QIs from the list as enlisted by IFCC working group project "Laboratory errors and patient safety".

Error frequency observed was about 53.2% of all samples included in study (13% of all tests performed). Studies on laboratory testing errors had published that pre-pre- and pre-analytical steps accounted for an error frequency of 48–62% of total errors in laboratory medicine [4, 6–8]. The frequency of such errors in our study was found to be 49% (Table 1). Moreover, the most common error was observed in pre-pre-analytical phase. Nearly 17% errors were related to appropriateness of test in the clinical setting. Our study report emphasized on pre-pre-analytical errors pertaining to appropriateness of test request, test request order entry, patient preparation, sample collection, transportation and storage of samples in in-patient departments. Major studies do not consider these variables in their study [4]. Plebani et al. [9] had demonstrated pre-pre-analytical error frequency of 46–68.2%.

Requests with errors concerning patient identification (1.06%) were unacceptable as per proposed specification by IFCC (Table 2, Pt.3; Table 5, Pt.3). Missing patient details, incomplete name resulting in mix-up and exchange of results in case of patients having same name, misspelled or illegibly written names or wrongly mentioned gender or age group also led to misinterpretation of values either due to mix-up of reports or due to difference in reference values as per gender and age group.

We also found unacceptability for requests with errors concerning test inputs (2.13%). The relevant investigations were neither mentioned nor tick marked. Sometimes the test requests were not legibly written and raised confusion as in GCT/GTT (glucose challenge test or glucose tolerance test) or 24 h urine protein or creatinine. The consequence being delayed sample processing due to correction of confusion or repetition of the test after physicians comment. Such errors are of major safety concern for patients. Few studies conferred that 55–58% missed or delayed diagnosis were attributed to failure to order appropriate diagnostic tests in wards and emergency departments [10–12].

Sample anticoagulant volume ratio was again within unacceptable range (0.55) as depicted in Table 2, pt.22; Table 5, pt.15. Such errors were frequently seen in paediatric cases. Also seen in samples with TRF ticked with lot number of investigations and phlebotomists had to restrict the drawl in the 5 ml syringe. The samples, as in plasma sugar and Glycosylated hemoglobin (HbA1c) estimation, the samples found to be clotted and could not be processed.

Sample transport in inappropriate temperature, especially from in-patient departments, was the second most major concern in this phase. About 7% of samples those checked for temperature failed to meet the requisite condition.

In analytical phase, unacceptable performances in EQUAS-PT schemes in previously treated cause were highest (14% of all tests performed). This was particularly seen in three parameters, low density lipoproteins (LDL), triglyceride and urinary calcium estimation. These parameters were frequently found to have unacceptable 'z' score and required either frequent calibration/reagent change/change in reagent lot/frequent outsourcing. Such actions would result in delayed reporting and thus delayed TAT. Hawkins et al. reported an error frequency of 7–13% and Goswami et al. reported 7.9% in the analytical phase that included equipment malfunction, sample mix-ups, interference (endogenous or exogenous), undetected failure in quality control [8, 13]. The analytical errors estimated in our study was 9.4% of all samples which was similar to Hawkins et al. and Goswami et al. Instrumentation

Table 2 Detail description of errors in pre–pre- and pre-analytical phase

Pre–pre- and Pre-analytical indicators			No. of errors	Percentage
Appropriateness of test request	1	Number of test without clinical comments or diagnosis/total number of requests (43200)	7333	16.97
	2	Number of inappropriate requests with respect to clinical question/total number of requests reporting clinical question (35867)	663	1.85
Patient identification	3	Number of requests with errors concerning patient identification/total number of requests (43200)	459	1.06
	4	Number of requests with errors concerning patient identification, detected before release of results/total number of requests (43200)	263	0.61
	5	Number of requests with errors concerning patient identification, detected after release of results/total number of requests (43200)	67	0.16
	6	Number of misidentified patients/total number of requests (43200)	129	0.30
Request form order entry	7	Number of requests with errors in physician's identification/total number of requests (43200)	1005	2.33
	8	Number of requests with errors concerning test input (missing)/total number of requests (43200)	212	0.49
	9	Number of requests with errors concerning test input (misinterpreted/illegible handwriting)/total number of requests (43200)	921	2.13
	10	Number of missing TRF/total number of requests (43200)	66	0.15
Sample identification	11	Number of samples improperly labeled or sample mix-ups/total number of requests (43200)	69	0.16
Sample collection	12	Number of samples collected at inappropriate collection time/total number of samples to be collected in appropriate time (7549) [#]	42	0.56
	13	Number of samples collected with inappropriate sample type/total number of samples (976) [@]	4	0.4
	14	Number of samples collected in inappropriate container/total number of samples (43200)	60	0.14
	15	Number of samples with insufficient sample volume/total number of samples (43200)	42	0.10
Sample transportation	16	Number of empty tubes sent/total number of samples (43200)	6	0.01
	17	Number of samples damaged/total number of samples (43200)	15	0.03
	18	Number of samples transported in inappropriate time/total number of samples for which the transport time is checked (1956)*.	35	1.79
	19	Number of samples transported under inappropriate temperature conditions/total number of samples for which the transport temperature is checked (1956)*	135	6.90
	20	Number of samples improperly stored/total number of samples (43200)	111	0.26
Sample acceptance/rejection	21	Number of samples lost or not received/total number of samples (43200)	12	0.03
	22	Number of samples with inadequate sample-anticoagulant volume ratio/total number of samples with anticoagulant (13124) [^]	72	0.55
	23	Number of samples hemolyzed/total number of samples (43200)	78	0.18
	24	Number of samples clotted/total number of samples with anticoagulant (13124) [^]	54	0.05
	25	Number of lipaemic samples/total number of samples	36	0.08

[#] No. of samples for PPPG/GTT/GCT that needed to be collected at appropriate time

[@] No. of samples of urine/CSF/Other body fluids that were either not properly collected or got exchanged

* No. of samples for which transport time and temperature must be checked e.g. as per SOP samples for vitamin B12 estimation must reach within 30–45 min and at appropriate temperature

[^] No. of samples collected with anticoagulants as in plasma glucose and HbA1c estimation

breakdown attributed towards 7% of analytical errors in our study.

Highly unacceptable performance was ascribed to delayed TAT which consisted 12% of errors seen in post-analytical phase resulting in large number of reports being delivered outside the specified time (Table 4, pt.1; Table 5,

pt.18). Major cause for TAT delay was due to the errors in the previous phases. This reflects that reporting within specified time is highly dependent on the pre–pre- and pre-analytical factors which were the commonest errors seen in our laboratory. Equipment malfunction was also a common cause for delayed TAT as also depicted by Sakyi et al. [14].

Table 3 Detail description of errors in analytical phase

Analytical indicators			No. of errors	Percentage
Analytical performance	1	No. of tests not kept under control with EQUAS-PT per year/total no. of tests provided by service per year (172800)	21	0.01
	2	No. of unacceptable performances in EQUAS-PT schemes per year/total number of performances in EQA schemes (405)	21	5.2
	3	No. of unacceptable performances in EQUAS-PT schemes per year occurring in previously treated cause/total number of unacceptable performances (21)	3	14.3
	4	No. of IQC values that exceed the selected target, per year/Total no. of IQC values (30700)	294	1.0
Instrumentation efficiency	5	No. of reports delayed delivery for instrumentation failures, per year/total no. of reports (43200)	3077	7.1
	6	No. of repetition of sample analysis due alarms, per year/total no. of reports (43200)	192	0.4
	7	No. of reports delayed delivery due to reagent insufficient, per year/total no. of reports (43200)	108	0.25
Data entry	8	No. of incorrect results for erroneous transcription and/or manual entry data in computer system/total no. of results requiring transcription and/or manual entry in computer system (172800)	336	0.2

Table 4 Detail description of errors in post-analytical phase

Post-analytical indicators			No. of errors	Percentage
Timeliness of results reporting	1	No. of reports delivered outside the specified time/total no. of reports (43200)	5198	12.0
Accuracy of results reporting	2	No. of patients called back for a blood re-collection due to unsuitable samples or incorrect results/total no. of patients (43200)	1882	4.4
	3	No. of corrected reports/total no. of reports (43200)	336	0.8
Timeliness of results reporting	4	No. of critical values or STAT samples communicated within an hour (from result validation to result communication to clinician)/total no. of critical values to communicate (735)	715	97.3
	5	Time (from result validation to result communication to clinician) to communicate critical values (min)	25–90	–
<i>Indicators of support processes</i>				
Efficiency of LIS (interfaced between analyzers and computer for direct entry of results)	6	No. of LIS downtime episodes, per year	66	
Employee competence	7	No. of training events organized for all staff, per year	2	

The post-analytical errors were near about 18% in the received samples which corroborated with that of Goswami et al. (15%), Plebani et al. (12.5–20%) and Carraro and Plebani (23%) [6, 9, 13].

However, our laboratory professionals could very efficiently executed critical call out and communicated to respective departments (97.3%). Display of parameters along with the critical values might have conduced to carry out the action effectively in the laboratory. Optimum performance levels, as illustrated in table 5, were also observed for appropriate test requests with respect to clinical question, concern for physician's identification,

samples with insufficient volume, sample lost or not received and hemolyzed samples.

Current international initiatives recommended some priority areas of improvement in patient safety in laboratory medicine as given in Table 6 [9].

High error rates could be accorded to various reasons like lack of frequent training of laboratory and extra-laboratory staffs; complex steps of TTP and different professionals involved in carrying out the TTP; shortage of staffs; lack of automation in sample transport and lack of lab-to-clinics interfacing through LIS. The given facts emphasize the need for formulating strategic guidelines and intense

Table 5 Performance level in our laboratory compared to quality specifications proposed by IFCC Working Group Project

Pre-pre- and Pre-analytical indicators	Performance level					Our Report
	Optimum	Desirable	Minimum	Un-acceptable		
Number of test with clinical comments or diagnosis/total number of requests	>87	58–87	29–57	<29	83.03	Desirable
Number of appropriate requests with respect to clinical question/total number of requests reporting clinical question	>97	65–97	32–64	<32	98.15	Optimum
Number of requests with errors concerning patient identification/total number of requests	<0.4	0.4–0.5	0.51–0.6	>0.6	1.06	Unacceptable
Number of requests without/with errors in physician's identification/total number of requests	<5	5.0–6.0	6.1–8.0	>8.0	2.33	Optimum
Number of requests with errors concerning test input (missing)/total number of requests	<0.3	0.3–0.4	0.41–0.5	>0.5	0.49	Minimum
Number of requests with errors concerning test input (misinterpreted/illegible handwriting)/total number of requests	<0.2	0.2–0.25	0.26–0.3	>0.3	2.13	Unacceptable
Number of samples improperly labeled or sample mix-ups/total number of samples	<0.07	0.07–0.15	0.16–0.2	>0.2	0.16	Minimum
Number of samples collected in inappropriate container/total number of samples	<0.07	0.07–1.13	1.14–0.20	>0.2	0.14	Desirable
Number of samples with insufficient sample volume/total number of samples	<0.4	0.4–0.8	0.81–1.20	>1.2	0.10	Optimum
Number of samples damaged/total number of samples	–	<0.1	–	–	0.03	Desirable
Number of samples lost or not received/total number of samples	<0.2	0.2–0.4	0.41–0.6	>0.6	0.03	Optimum
Number of samples with inadequate sample-anticoagulant volume ratio/total number of samples with anticoagulant	<0.2	0.2–0.3	0.31–0.4	>0.4	0.55	Unacceptable
Number of samples hemolyzed/total number of samples	<1	1.0–1.5	1.6–2.0	>2.1	0.18	Optimum
Post-analytical indicators						
No. of reports delivered outside the specified time/total no. of reports	<0.4	0.4–0.5	0.6–0.7	>0.7	12.00	Unacceptable
No. of critical values or STAT samples communicated within an hour (from result validation to result communication to clinician)/total no. of critical values to communicate	>96	77–96	58–76	<58	97.30	Optimum
Time (from result validation to result communication to clinician) to communicate critical values (min)	<50	50–100	101–160	>160	25–90	Desirable

Table 6 Priority areas of improvement in patient safety in clinical laboratory

Priority areas	Frequency of error per 100 samples	Processes to reduce errors
1 Appropriateness of test request	17	Formulating guidelines for processing, in cooperation with clinicians
2 Accuracy of patient/specimen identification	1.1	Use of barcode for sample identification
3 Sample acceptability and rejection criteria	14.5	Frequent training of technical staffs handling samples in wards, OPD and in laboratory
4 Conformity of EQUAS-PT schemes	5.2	Use of stable reagents and proper maintenance of temperature of reagents and quality control materials
5 Communication of critical test results	2.7	Knowledge of critical values and availability of telephonic communication between lab and wards
6 Effectiveness of laboratory data communication	12	Interfacing Lab-to-clinics by LIS facility
7 Avoiding manual transcription of data	0.2	Establishing LIS communication between machine and computer for reporting

supervision of the extra-laboratory processing to reduce the risk of errors in TPP and improve patient safety.

Conclusion

Our study elaborates the performance of our lab as per the quality variables indicated by the IFCC working group project “Laboratory errors and patient safety”. High error rates were observed in pre-pre- and pre-analytical phases that emphasize strict intervention and supervision of the total testing process and inter-departmental cooperation to meet the target of providing quality laboratory services by early reporting, reducing risk of errors and increasing patient safety.

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Compliance with Ethical Standards

Conflict of interest No potential conflict of interest relevant to this article was reported.

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