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An Interventional Study on Total Testing Process of Clinical Chemistry Laboratory of a Tertiary Care Teaching Hospital

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ABSTRACT

Background: *In the 21st century, laboratory service has become the pioneer of patient's healthcare. Although improvement in technology and innovations has reduced human work with computerized machines, then also errors occurs at various phases of total testing process. In this study, we tried to observe and evaluate the errors taking place in total testing process and how such errors could be minimized, results into decreased turnaround time and thus improve the quality of total testing process.* ***Aims:*** *To observe, analyze and evaluate the errors taking place in total testing process of biochemistry section of clinical chemistry laboratory before and after intervention.* ***Method:*** *The study has been conducted in a tertiary care super specialty teaching hospital. An observational and interventional study was carried out on the samples collected in OPD collection centre and from different IPD wards received in particularly biochemistry section of clinical chemistry laboratory for a period of one year in different phases.* ***Result:*** *The study data shows that after intervention the pre-analytical, analytical and post-analytical errors got reduced to almost 1/3rd in case of OPD samples and ½ in case of IPD samples in comparison with before intervention.* ***Conclusion:*** *From the study we also conclude that the single intervention in terms of training might not produce sustainable reductions in error as per the requirement. So, to have best results from training, there should be periodic sessions and training using different methods to focus on the problems.*

Keywords: Analytical, Laboratory errors, Pre-analytical, Post-analytical, Total testing process, Turnaround time

INTRODUCTION

In the modern world of technology and innovations, the laboratory diagnosis is largely dependent upon the integrity of laboratory test results [1,2]. Laboratory diagnostics (i.e., the total testing process) is a virtual loop, originally referred to as ''the brain to brain cycle'' by George Lundberg. The generation of any laboratory test result involves nine steps: ordering, collection, identification, transportation, separation or preparation, analysis, reporting and action [3].

Laboratory test performed within clinical laboratory is the main source of medical error that affects patient's safety [4-6]. Therefore, it is a necessity that laboratory testing process must be monitored at periodic interval of time and evaluated to ensure reliable test results for well-organized patient's supervision. Total testing process (TPP) is a simplified and cyclic framework having three-phases in its process - a pre-analytical phase, an analytical phase and a post-analytical phase. Thus, TTP is a multi-step process that begins and ends with the needs of patients [7].

The laboratory has various standard protocols to be followed within the laboratory to ensure good quality and integrity of the samples and to verify and interpretate that results produced are accurate. At certain phases of TTP if the sample

collection or analysis of sample or its reporting has not properly performed, it results in wrong diagnosis or treatment of the patient. These errors result in poor quality of management, wrong interpretation, lack of training, extra cost burden, poor patients' impression and bad reputation of laboratory or hospital. A laboratory error is defined as "any defect that occurs during the entire testing process, from ordering tests to reporting results", that in any way influences the quality of laboratory services [8].

The healthcare system and patient safety both are dependent on reliable laboratory diagnostics and its services. From past few years there has been an increase concern seen towards quality improvement in laboratory testing and patient safety in healthcare [9,10].

Various articles related to quality of healthcare revealed that many patients, doctors, nurses and healthcare organizers are concerned about the fact that the patient care delivered is not necessarily the care they should receive [11,12]. Nowadays laboratory error and patient safety concern has become an important theme in medical conferences, professional society meetings and activities of academic medical centres, healthcare organizations and professional organizations.

Laboratory errors can take place in anyone phase or all the phases of the total testing process (pre-analytical, analytical and post-analytical phase). Laboratory errors whenever occurs or detected, it results into sample rejection and repeat collection and delay in reporting results with economic burden and extra service of the staff towards the laboratory work. These results to impact laboratory's poor service quality, customer dissatisfaction and decreases patient health safety too by delaying the diagnosis, prognosis or treatment required to overcome certain diseases. After M. Plebani's article on medicine error in 1997, the laboratory errors became a lime light picture for doing research and majority of scientific articles were published on TTP.

Intervention, one of the term defined to interfere with the intent of modifying the outcome. The intervention in term of training, regarding laboratory errors is done as an evidence to minimize the errors occurring in the clinical laboratory. It shows how variations are observed in TTP errors before and after intervention that helps to evaluate the significance of training at periodic interval time. Certain interventions may require time to be adjusted to achieve desired outcome while others might not work at all in various conditions. So, it becomes important to record the effectiveness of all interventions. Those interventions which significantly reduce error shall be applied to particular areas while that which doesn't work could be recorded so that they are not repeated in future.

METHODOLOGY

Study design

It is hospital based prospective observational and interventional study.

Ethics approval

The study is carried out after getting approval from Sumandeep Vidyapeeth Institutional Ethical Committee (SVIEC).

Sample size and groups

The blood samples collected for the laboratory investigation particularly in biochemistry section is taken from OPD and IPD patients coming to Dhiraj Hospital. The study is divided into four phases; each phase consists of three months and same sample size (10211) in each phase. The detailed study was planned as tabulated below (Table 1).

Inclusion criteria

- All the blood specimens received for routine clinical biochemistry and immunoassays were accepted.
- Only venous blood samples shall be taken in account except in neonates.
- Repeat sample of same patient coming for same or different investigation in a single day or during follow up of treatment for any particular diseases after few days or months.

Exclusion criteria

- Samples other than biochemistry like pathology, histopathology, cytology, microbiology (serology) and others were excluded.

- Fluid samples like CSF, pleural, peritoneal, etc. and urine samples were not included.
- Samples which are to be sent outside for certain investigations.
- Hemolysed and lipaemic samples (except in dialysis patients, paediatric patients and others).

Table 1 Study design for all the phases, place and duration of study

Phase	Duration	OPD	IPD
Before training and intervention			
1	1st May, 2014 to 31st July, 2014	Observed Pre-analytical, Analytical and Post-analytical errors for samples of OPD collection centre of CCL	NA
3	1st March 2015 to 31st May, 2015	NA	Observed Pre-analytical, Analytical and Post-analytical errors for IPD samples coming to CCL of Dhiraj Hospital
After charts, training and intervention			
2	1st August 2014 to 31st October, 2014	Observed Pre-analytical, Analytical and Post-analytical errors for samples of OPD collection centre of CCL	NA
4	1st June 2015 to 31st August, 2015	NA	Observed Pre-analytical, Analytical and Post-analytical errors for IPD samples coming to CCL of Dhiraj Hospital

RESULTS

In this study errors (pre-analytical errors, analytical errors and post-analytical errors) took place were recorded in the error recording log book and data collected were noticed by visiting OPD sample collection centre and sample receiving area of CCL. All the errors observed were compared and evaluated in a tabulated form as shown in Table 2, before and after intervention.

Table 2 Frequency (%) comparison of all the errors taking place during total testing process

Pre-analytical Errors Observed	Phase-1 (OPD)		Phase-2 (OPD)		Phase-3 (IPD)		Phase-4 (IPD)	
	No.	Frequency (%)	No.	Frequency (%)	No.	Frequency (%)	No.	Frequency (%)
Misidentification of patient	10	0.10	04	0.04	6	0.06	2	0.02
Order of sample collection	69	0.68	33	0.32	-	-	-	-
Incomplete test requisition form (TRF)	-	-	-	-	1397	13.7	586	5.74
Container inappropriate	10	0.10	3	0.03	6	0.06	3	0.03
Sample quantity not sufficient	2468	24.17	882	8.64	1261	12.3	432	4.23
Labeling error	112	1.10	48	0.47	53	0.52	24	0.24
Illegible handwriting	1222	11.97	391	3.83	724	7.1	340	3.33
Prolonged tourniquet time	11	0.11	5	0.05	-	-	-	-
Blood collected without using of tourniquet	18	0.18	9	0.09	-	-	-	-
Improper mixing of sample	96	0.94	6	0.06	82	0.8	38	0.37
Antiseptic used before collection of blood	24	0.24	8	0.08	-	-	-	-
Fast pooling of blood sample	38	0.37	12	0.12	-	-	-	-
Wrong capping of samples	12	0.12	2	0.02	6	0.06	2	0.02
Sample collected rapidly without relaxation	80	0.78	26	0.25	-	-	-	-
Sample collected from another vein	7	0.07	4	0.04	-	-	-	-
Samples not collected	3	0.03	2	0.02	4	0.04	2	0.02
Sample lost	4	0.04	3	0.03	6	0.06	2	0.02
Loose capping of samples	-	-	-	-	12	0.12	7	0.07
Repetition of sample	38	0.37	10	0.10	114	1.12	66	0.65
Interface problems	34	0.33	12	0.12	58	0.57	32	0.31
Proper discard of biomedical waste	48	0.47	21	0.21	-	-	-	-
Sample collected without proper safety	18	0.18	5	0.05	44	0.43	28	0.27
Transportation error	70	0.69	11	0.11	102	1.0	56	0.55

Total errors	**4392**	**43.01**	**1497**	**14.66**	**3875**	**37.9**	**1620**	**15.87**
Analytical errors observed								
Wrong entry	28	0.27	12	0.12	22	0.22	11	0.11
Delay in centrifugation	306	3.0	61	0.6	186	1.82	51	0.50
Random error	133	1.3	51	0.5	91	0.89	48	0.47
Systemic error	5	0.05	3	0.03	7	0.07	4	0.04
Calibration drift	32	0.36	19	0.21	23	0.23	20	0.20
Non-conformity with quality control	22	0.24	17	0.19	27	0.26	18	0.18
Equipment malfunctioning	2	0.02	2	0.02	3	0.03	3	0.03
Reagent contamination	5	0.06	3	0.03	3	0.03	2	0.02
Total	**533**	**5.30**	**169**	**1.71**	**362**	**3.55**	**177**	**1.73**
Post-analytical errors observed								
Transcription error	78	0.76	25	0.24	56	0.55	21	0.21
Failure of reporting	99	0.97	36	0.35	66	0.65	22	0.22
Delay in reporting results	609	5.96	194	1.90	392	3.84	161	1.6
IT software problem	31	0.30	22	0.22	23	0.23	18	0.18
Physician not notified of problem	62	0.61	25	0.24	42	0.41	23	0.23
Total	**879**	**8.61**	**302**	**2.96**	**579**	**5.68**	**245**	**2.44**

The results from various studies on laboratory errors (pre-analytical, analytical and post-analytical errors) were tabulated along with our study. In this study samples considered from both OPD and IPD were compared before and after intervention for all the errors. It was observed that in OPD samples the errors got reduced to 1/3rd when compared to IPD samples in which errors got reduced to ½ after intervention (Table 3).

Table 3 Comparison of various study papers with this study on laboratory errors taking place during total testing process

Sr. No.	**Year**	**Author**	**Sample size**	**Duration of study**	**Sector of laboratory**	**Error type**	**Error in frequency (%)**
	1996	Plebani and Carraro [16]	40490	3 months	Stat laboratory	All phases	Pre-analytical-68.2 Analytical-13.3 Post-analytical-18.5
	2006	Plebani and Carraro [17]	51746	3 months	Stat laboratory	All phases	Pre- analytical-61.9 Analytical-15.0 Post-analytical-23.1
	2014	Fauzia Sadiq, et al. [18]	127500	6 months	Whole laboratory	All phases	Pre- analytical-70.4 Analytical-12.1 Post-analytical-17.5
	2009	Binita Goswami, Bhawna Singh [19]	67,438	1 year	Clinical chemistry	All phases	Pre- analytical-77.1 Analytical-7.9 Post-analytical-14.9
	2014	Pawan Toshniwal	10211	3 months	Clinical chemistry (Biochemistry)	All phases (Before intervention, OPD samples)	Pre- analytical-43.01 Analytical-5.30 Post-analytical-8.61
	2014	Pawan Toshniwal	10211	3 months	Clinical chemistry (Biochemistry)	All phases (After intervention, OPD samples)	Pre- analytical-14.66 Analytical-1.71 Post-analytical-2.96
	2015	Pawan Toshniwal	10211	3 months	Clinical chemistry (Biochemistry)	All phases (Before intervention, IPD samples)	Pre- analytical-37.9 Analytical-3.55 Post-analytical-5.68
	2015	Pawan Toshniwal	10211	3 months	Clinical chemistry (Biochemistry)	All phases (After intervention, IPD samples)	Pre- analytical-15.87 Analytical-1.73 Post-analytical-2.44

One of the renowned scientists, Westguard has come with a question in his mind that which error from pre-analytical, analytical and post-analytical to be considered worse that affects the patient's safety, as it could occur that sample collected doesn't comes to laboratory or wrong analysis of sample is done or wrong result given to the patient, all will lead to poor patient's health and their safety, that is why no error can be considered worse than other, but all errors have to be considered equally bad [13].

Similarly, others suggested that there are various consequences and degree of seriousness taking place due to errors in laboratory during TTP on patient's health and safety [14,15-19]. We also tried to highlight the possible consequences of laboratory error and degree of seriousness of all phases of TTP on patient safety and were tabulated in Table 4.

Table 4 Possible consequences and degree of seriousness on patient health and safety in all the errors of total testing process (TTP)

Pre-analytical errors		
Errors	**Possible consequences**	**Degree of seriousness**
Order of sample collection	Inappropriate sample-sample not clotted-delay in analysis/diagnosis/prognosis	Mild to moderate
Misidentification of patient	Wrong patient identification or wrong test - wrong diagnosis – wrong treatment	Moderate to life threatening
Incomplete test requisition form (TRF)	Wrong test analyzed, wrong interpretation, wrong treatment-increased TAT	Mild to severe
Container inappropriate	Repetition of sample-delay in diagnosis/prognosis	Moderate to severe
Sample quantity not sufficient	Repetition of sample-delay in diagnosis/prognosis, increased TAT	Mild to severe
Labeling error	Test not performed – delay in diagnosis-increased TAT Wrong test - wrong diagnosis – wrong treatment	Mild to life threatening
Illegible handwriting	Wrong test or analysis can't be done	Mild to severe
Prolonged tourniquet time	Effect on serum or plasma analyte, inappropriate sample, hemolysis of sample	Mild to severe
Blood collected without using of tourniquet	Hemolysis of sample, repetition of sample-delay in diagnosis and treatment	Moderate to severe
Improper mixing of sample	Proportion of chemicals not maintained	Mild to moderate
Antiseptic used before collection of blood	Mix-up of antiseptic with blood, interference	Mild to moderate
Fast pooling of blood sample	Hemolysis of sample	Mild to severe
Wrong capping of samples	Interference of additives on analyte concentrations	None to moderate
Loose capping of samples	Sample spillage, wrong analysis performed, analytes concentration changes-wrong interpretation-delay in diagnosis/treatment-increased TAT	Mild to severe
Sample collected rapidly without relaxation	Variation in test results - misinterpretation	Mild to severe
Sample collected from other vein	Variation in test results - misinterpretation	Moderate to severe
Samples not collected	Repeat sample- delay in results- increased TAT	None to mild
Sample lost	Repeat sample- delay in results- increased TAT	Moderate to life threatening
Repetition of sample	Delay in results – increased TAT	Moderate to life threatening
Interface problems+	Delay in reporting results	Moderate to severe
Transportation errors	Spillage of sample- sample lost-hemolysis-recollection-delay in results	Moderate to severe
Analytical errors		
Wrong entry	Wrong id-wrong test-delay in diagnosis/prognosis	Mild to life threatening
Delay in centrifugation	Variation in result-delay in diagnosis/prognosis	Moderate to severe
Random error	Variation in results-delay in diagnosis/treatment-increased TAT	Moderate to severe
Systemic error	Variation in results and delay in diagnosis/prognosis	Moderate to severe
Calibration drift	Delay in results- increased TAT	Mild to moderate
Non-conformity with QC	Delay in results-increased TAT	Mild to severe

Equipment malfunctioning	Delay in results-increased TAT	Moderate to life threatening
Reagent contamination	Wrong result-wrong interpretation-repetition of sample-delay in results-increased TAT	Mild to severe
Post-analytical errors		
Transcription error	Wrong interpretation-wrong diagnosis/treatment	Mild to severe
Failure of reporting	Delay in results-delay in diagnosis-increased TAT	Mild to moderate
Delay in reporting results	Delay in diagnosis/prognosis/treatment	Moderate to life threatening
IT software problem	Delay in diagnosis/prognosis/treatment	Moderate to life threatening
Physician not notified of problem	Delay in diagnosis/prognosis	Moderate to life threatening

CONCLUSION

This study has been carried out to observe, analyze and evaluate the errors that took place while performing test on the patient's sample. From the study, we came to conclude that a single intervention in terms of training has produce sustainable reduction in errors taking place during total testing process. Although the errors took place after intervention were reduced and not fully eradicated, it remained, so to have best results from intervention training, there should be periodic sessions and training using different methods to focus on the problems and to evaluated those problems. This periodic training will not only help old staff for remembrance of errors but will also aware new staff about the errors that could occur while performing duties. Moreover, errors will also teach how those errors leads to mild to life threatening conditions towards patient's health and safety. Thus, it will not only make improvement towards quality of work but also it will improve the work quality of individual person.

REFERENCES

[1] Chawla, Ranjna, et al. "Identification of the types of preanalytical errors in the clinical chemistry laboratory: 1-year study at GB Pant Hospital." *Laboratory Medicine* Vol. 41, No. 2, 2015, pp. 89-92.

[2] Toshniwal, Pawan, Seema Toshniwal and Rita Mahendra Shah. "An Insight View on Pre- and Post-Analytical Errors in Clinical Chemistry Laboratory of a Tertiary Care Super Specialty Teaching Hospital." *National Journal of Laboratory Medicine* Vol. 5, No. 4, 2016, pp. BO10-BO14.

[3] Lundberg, George D. "Acting on significant laboratory results." *Jama* Vol. 245, No. 17, 1981, pp. 1762-63.

[4] Plebani, Mario. "Exploring the iceberg of errors in laboratory medicine." *Clinica chimica acta* Vol. 404, No. 1, 2009, pp. 16-23.

[5] Piva, Elisa, and Mario Plebani. "Interpretative reports and critical values." *Clinica chimica acta* Vol. 404, No. 1, 2009, pp. 52-58.

[6] Da Rin, Giorgio. "Pre-analytical workstations: a tool for reducing laboratory errors." *Clinica chimica acta* Vol. 404, No. 1, 2009, pp. 68-74.

[7] Harrison, T.R. "The value and limitation of laboratory tests in clinical medicine." *Journal of the Medical Association of the State of Alabama* Vol. 13, 1944, pp. 381-84.

[8] Plebani, Mario, and Paolo Carraro. "Mistakes in a stat laboratory: types and frequency." *Clinical Chemistry* Vol. 43, No. 8, 1997, pp. 1348-51.

[9] Hawkins, Robert. "Managing the pre-and post-analytical phases of the total testing process." *Annals of Laboratory Medicine* Vol. 32, No. 1, 2012, pp. 5-16.

[10] Toshniwal, P., et al. "Test requisition form-A check point in pre-analytical phase for laboratory errors." *Asian Pacific Journal of Health Sciences* Vol. 4, No. 2, 2017, pp. 175-82.

[11] Reed, Marie C., and R.F. St Peter. "Satisfaction and quality: patient and physician perspectives." *Data bulletin (Center for Studying Health System Change)* 3 (1997): 1.

[12] Shindul Rothschild, J. Berry, D & Long-Middleton, E. Where have all the nurses gone? Final results of our patient care survey. *American Journal of Nursing* Vol. 96, No. 11, 1996, pp. 25-39.

[13] Westgard, James O. "Practicas basicas de control de calidad." *Edición Wallace Coulter. Madison WI: Westgard QC* 2013.

[14] Lundberg, George D. "The need for an outcomes research agenda for clinical laboratory testing." *JAMA* Vol. 280, No. 6, 1998, pp. 565-66.

[15] Toshniwal, Pawan, Seema Toshniwal and R.M. Shah. "A retrospective six months study on pre-analytical errors occurring in OPD in a tertiary care hospital: The first step for patient safety in clinical diagnostics and its impact." *European Journal of Biomedical and Pharmaceutical Sciences* Vol. 3, No. 6, 2016, pp. 637-41.

[16] Plebani, Mario, and Paolo Carraro. "Mistakes in a stat laboratory: types and frequency." *Clinical Chemistry* Vol. 43, No. 8, 1997, pp. 1348-51.

[17] Carraro, Paolo, and Mario Plebani. "Errors in a stat laboratory: types and frequencies 10 years later." *Clinical Chemistry* Vol. 53, No. 7, 2007, pp. 1338-42.

[18] Sadiq, Fauzia, et al. "Frequency of errors in clinical laboratory practice." *Iranian Journal of Pathology* Vol. 9, No. 1, 2014, pp. 45-49.

[19] Goswami, Binita, et al. "Evaluation of errors in a clinical laboratory: a one-year experience." *Clinical Chemistry and Laboratory Medicine* Vol. 48, No. 1, 2010, pp. 63-66.