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Clinical Laboratory

"CLINICAL TESTING AFFECTED FROM LABORATORY VARIABLES IN PRENATAL SCREENING"

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ABSTRACT In current scenario diagnostics is taking a wider curve as industry due to increased disease burden, population load, and strict legal implications on health system. Clinicians majorly depend upon the testings' whereas those may get influenced by several technical and environmental factors. Everyday many testing tools arising in the market with various attractive benefits, but their standards should not be compromised. So, all talent and supplement factors combine for societal health ultimately. This makes it a lot more important for laboratories to provide accurate results with greater sensitivity and specificity. Many factors beginning from patient information till outcome are linked with those variables to take note sincerely which affect the whole system. It impacts <1% in global testing but India has more deteriorating picture of reported errors and the studies on this topic are very limited. This needs a close observation, trained handling, and strict SOP for corrections in lacunae and more studies are required with a bigger data.

KEYWORDS : Diagnostic, Analytical, Errors, and Laboratory testing.

INTRODUCTION

Disease diagnosis is nowadays majorly depending upon the test results offered by the clinicians from the laboratory. Test involve many complex stages starting from patient visit in lab to result handover to doctor. This multistep process many times handled through the non-technical persons, untrained and non-professional involvement may induce some manual error during the procedure and these are termed as analytical errors/variables. Analytical variables are classified in three different groups for any test setting which are pre analytical, analytical and post analytical variables [1]. Errors from these steps has been studied since long, many times but still need consistence evaluation and rectification of process errors due to existing presence of 0.1-9.3% [2]. These laboratory errors affect 26-30% of patient care decisions [3]. This article accumulates all possible errors areas (**Table 1**) irrespective other studies as they target either side only, in addition it gives majorly all studies conducted in this process in India till date (**Table 2**). This area of focus will provide present system to make it an absolute error free environment.

Analytical Variables

Analytical phase is the core part of testing where most of technical staff is involved and this makes a sensitive issue to perform proper and declare results appropriately for the sake of laboratory. Initially few studies have shown <10% errors in analytical segment which later get fixed quite soon with the application of automation, improved technology, assay standardization, protocol follow ups, QCs, and core technical staff involvements [5]. However, recently collected data demonstrates that analytical quality standard majors an issue [3].

Pre and Post analytical Variables

These two phases have been considered as major error consisting sections by almost 43-71% [6]. All the steps before test comes in this criteria, and mostly non-technical and unprofessional individuals handles these activities. Some controllable and uncontrollable multifactorial, most erroneous variables are (**Table 1**); Age (Neonate, pubertal, adolescence, adult, elderly), sex, ethnicity, date, season, vital signs such as weight, height, body mass index (BMI), physiological status; pregnancy, diet type (vegetarian/non vegetarian, eggitarian, began), fasting or food ingestion time before test, smoking or alcoholic , caffeine intake, water intake, drug intake, in last 24 hrs, allergies, fever, blood pressure, socioeconomic status, stimulants, handling related; sample collection, sample handling, sample processing , sample storage, and entry related errors; such as waiting time for samples influences the individual risk results.

Laboratory logs, digital entries, physiological status of specimen, timing of collection, patient medical history, equipment's maintenance status, etc [7]. It needs to understand that each single step described through the guidelines is important to follow with defined protocol only for providing accurate results else it may cause huge error in diagnosing the wrong people. (Lima-Oliveira, Volanski *et al.,* 2017)

Table 1: Maximum possible error creating variable in laboratory which may affect test results

Sr no.	Phase	Factors	Variables	Influence
	Pre analytical	Error prone sections	46-68.2%	
1		Vital	Weight, Height, BMI measurements.	-
2		Physiological	Pregnancy, Fever, Obesity status of patients.	-
3		Age	Neonate, adolescence, adult, elderly, pubertal stage differentiation.	-
4		Sex	Female, male, transgender writing error.	-
5		Time	Time at sampling, transportation time, resting time for sample etc.	39%
6		Sample status	Heamolysed (60%) samples, insufficient amount, incorrect tube selection, clotted sample.	15-27% 3.91-13%, 0.91-11%
7		Central Coordination	Errors between different centers for sample and patient information sharing, lost prescription.	3%
8		Entry	Digital entry, lab catalog, receipt entry, sample form, sample description entries.	-
9		Diet	Vegetarian, non-vegetarian, fasting, last food intake time for patient.	-
	Analytical	-	-	15%
10		Chemicals	Expiry dates and company quality.	27%
11		Temperature settings	For machine, stored reagents and Room temperature.	
12		Technology used	New or old in machines, routine maintenance.	23%
13		Trained technicians	Valid license and mandatory qualifications, venipuncture error, tourniquet application time.	20.2%
14		Protocol follow-ups	According to manuals of kit.	
15		Lab manuals	For safety, hygiene and equip handling, phlebotomy.	24-30%

16		Report entry	With every detail in chronology.	
17		Reporting precautions	Verification of patient correctly.	
	Post Analytical Variables	-	-	23%
18		Report Entry	With every detail in chronology.	
19		Log Maintenance	Honest Entry in daily routine with transparency.	
20		Report Delivery	Verification of patient correctly.	

Table 2: Indian studies in comparative means of rectification of errors and observation.

Sr no.	Factors studied	studies from India	Result influence (%)	Sample Size	Study type	References
1	Preanalytical Errors	Gurgao, NCR, India	0.4%	104677	Not mentioned	Ashok Rattan, 2008
2	Specimen Collection Error	Mumba, India	70fold reduction in clotting by BD vacutainer	225623	Observational	Ashvaid, T F, 2009
3	Pre-post & Analytical Error reported	Pant hospital, Delhi	77.1%, 15%,7.9%	67438	Prospective	Goswami B, 2010
4	Preanalytical Errors	G B Pant Hospital	1.52%	96328	Retrospective	Chawla, R. 2010
5	Preanalytical Errors	New Delhi, India	0.65%	32589	Observational	Parul Singla, 2011
6	Preanalytical Errors	Meerut, UP, India	1%	135808	Retrospective	Upreti S. 2013
7	Pre analytical Errors	Karwar, Karnataka	5.20%	23680	Prospective	Bhuyar B. K, 2017
8	Preanalytical Factors	Ludhiana, Panjab	0.28%	471006	Retrospective	Narang V, 2015
9	Pre-Analytical and Post-Analytical Errors	Karad, Maharastra	1% & 0.18%	121470	Prospective	Dhiraj Kumar B, 2016
10	Prevalence and types of preanalytical errors	Tamil Nadu, India	0.43%	118732	Cross sectional	Pitchaikaran Arul, 2018
11	Pre analytical Errors	Surendranagar, Gujarat	1.05%	33679	Observational	Milav Bhavsar, 2016
12	Risk assessment of pre-analytical errors	Pondicherry, India	7.2%-27.7%	500	Descriptive	Venkat Raghavan A.T.M, 2020
13	Pre analytical Errors	New Delhi	2.11%	19002	Prospective Observational	Tapasyapreeti Mukhopadhyay, 2021

Estimate of monetary value of errors & post error losses

A study quoted a variation of 6% posttest risk due to pre analytical factors only where in 94 % of variation was coming from analytical variables [13]. One more study by Green SF 2013 has calculated the preanalytical errors costs' burdens 0.23-1.2% additional of total hospital expense [14]. Another study calculated additional costs of patient treatment found $208.00 USD and 157€ respectively, in North American hospital and European institutions due to the pre analytical errors which leads to $1,199,122 per year additional burden on hospitals [15].

MATERIAL METHODS

A study between a period of 2017 to 2018 on 519 patients had been conducted in the SGPGIMS, Lucknow, UP to evaluate the preanalytical errors in the serological samples of pregnant women. It is a tertiary care reference hospital in north India. Blood Samples studied were meant for routine testing of trisomy screening test in the laboratory drained by trained technicians through the vacutainer from the OPD (Out patients department) and IPD (in patients/ admitted ward patients). Samples were observed errored in six types (Haemolysed, insufficient, wrong tube, no label, no correct time (fasting, after 2 hr meal, along with ultrasound week or day specific in pregnancy), or storage temperature for sample (room temperature, fridge temperature maintaining etc.).

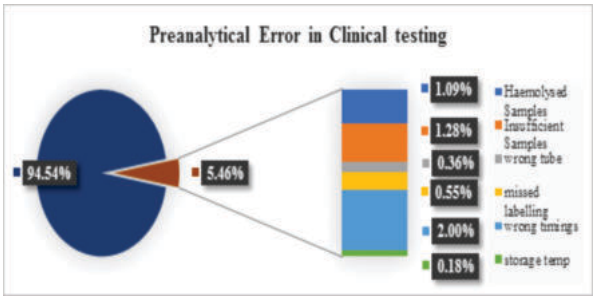

Figure 1: Preanalytical factor influenced serological testing in lab

RESULTS AND DISCUSSION

In the samples of this studies, total 30 (5.78%) have been found errored under the criteria: Haemolysed sample (1.16%), insufficient sample (1.35%), wrong tube selection (0.38%), missed or incomplete labelling (0.59%), wrong timing of sampling (2.12%) or inappropriate storage temperature (0.19%) (Table 3 & Figure 1). It's observed that most of the errors were due to unawareness of patients, their financial constraints which cause time gap between the testing of USG and serology. Sometime long queues of the patients in the laboratories causes extra ordinary delays in the sampling.

Other type of error was insufficient volume of sample due to multiple tests being conducted simultaneously. Missing labels were found in the cases when sample was collected outside the lab by the patients and the same reason may had caused wrong tube selection. However, this percentage could vary with the larger study size.

Table 3: Nature of errors in laboratory testing and their frequency

	OPD + IPD	% ERROR
Total Patients	519	
Haemolysed samples	6	1.16%
Insufficient Samples	7	1.35%
Wrong tube	2	0.38%
Missed labelling	3	0.58%
Wrong timings	11	2.31%
Storage Temp	1	0.19%
Errored samples	30	5.78%

CONCLUSION

Most of the reasons causing error can be reduced considerably by increasing the awareness among the stake holders. This article indicates the importance of need of more studies for improving the reliability of testing and for removing error in the non-technical segment for the overall benefit of the society.

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