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Original Research Paper

Microbiology

EFFECT OF INTERVENTIONAL STRATEGIES ON THE SAMPLE REJECTION RATE OF COVID-19 SAMPLES

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ABSTRACT **Background and objectives-**Preanalytical errors constitute major sources of error among all the parts of total testing process (TTP). This study was aimed to assess the effect of timely interventional strategies on sample rejection rate of Covid-19 samples at Department of Microbiology, MGMMC, Indore. **Methods-** This is a prospective study conducted from July2021 to September2022in which a total of 3,86,871 samples were analyzed. **Result-** In the post-intervention period, the sample rejection rate was reduced to 0.48%. Conclusion- Preanalytical errors are unavoidable sources of errors, but their frequency can be reduced by continuous monitoring and prompt intervention.

KEYWORDS : Covid-19, Sample compliance, Sample rejection rate, Pre analytical errors.

INTRODUCTION:

Laboratory error is defined as any defect from ordering tests to reporting results and appropriately interpreting and reacting to these. Laboratory errors have a reported frequency of 0.012–0.6% of all test results which in turn has huge impact on diagnosis and patient management [1].

Laboratory procedures are divided into 3 phases:
1. Preanalytic.
2. Analytic.
3. Post analytic.

1.1 Pre-analytic errors [2],[3],[4]:
1. Pre-pre-analytic phase:
a. Initial procedures usually performed neither in the clinical laboratory nor undertaken, at least in part, under the control of laboratory personnel, includes test requesting, patient and sample identification and sample collection.

2. True pre-analytic phase: Involves the steps required to prepare samples for analysis:
a. Opening
b. Sorting.

It has been shown that pre-analytic errors are an inevitable source of laboratory errors and with regard to SARS-CoV-2 identification these factors are more significant [2],[3].

While the pandemic has highlighted the significance of laboratory medicine in healthcare setups, laboratory testing is altogether an intricate process [2]. Each of the various steps involved in the total testing process can result in errors and they can have a huge impact on patient prognosis [3]. In laboratory practice, the total testing process is divided into three crucial steps: pre-analytical, analytical and post-analytical [4]. Laboratory specialists have demonstrated that 70% of errors occur in the preanalytical phase which is a critical component of laboratory medicine[2].

MATERIAL AND METHODS:

This study was undertaken at the Department of Microbiology, M.G.M. Medical College, Indore. This Prospective study includes a Baseline period from July2020 to June 2021, Intervention period from July 2021 to September 2021and Post intervention period from October 2021 to September 2022. All Covid-19 samples received during the period of study were analysed and included in the study with no exclusion criteria. All the samples received at VRDL, M.G.M. Medical College were thoroughly assessed according to the checklist during the baseline period and the postintervention period and the areas of maximum rejections are identified and analysed. In this study, during the interventional phase of 3 months from july2021 to September 2021, there was daily updating and informing the concerned authorities of rejected samples-including all non-complaint samples and request for repeat sampling in case of major non complaint samples.

Quality indicators for SARS Cov-2 samples (approved in 2020):

Rejection Checklist:
i. Unlabeled sample ii. Mislabeled sample iii. Missing sample iv. No triple layer packaging v. Improper storage conditions vi. Insufficient quantity (QNS) vii. No swab inside VTM vial.

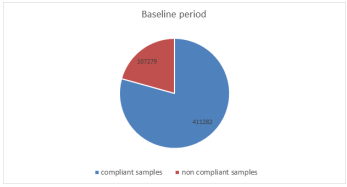
RESULT:

Table 1: Comparative sample compliance proportion:

In baseline period,107279 samples were recorded to be noncompliant (no. of samples received-518561) as compared to postintervention period, 2265 samples were observed to be noncompliant (no. of samples received-386871).

	Sample received	Compliant samples	Non-compliant samples
Baseline period	518561	411282	107279
Post intervention period	386871	384606	2265
Total	905432	795888	109544

Chart 1: Comparative sample compliance proportion:



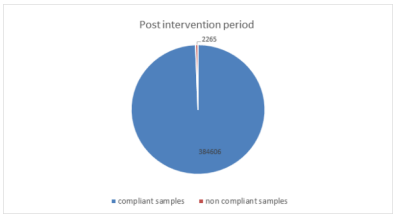
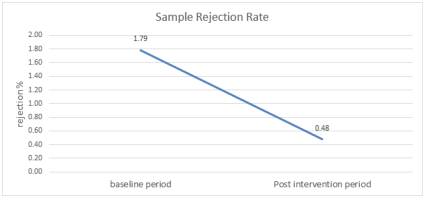


Table 2: Effect of intervention on sample rejection rate:

	Sample received	Sample rejected	Rejection %
Baseline period	518561	9267	1.79
Postintervention period	386871	1839	0.48

Chart 2: Effect of intervention on sample rejection rate:



DISCUSSION:

Identification and analysis along with documentation of any problem is a major contributing factor in improving the Quality of Clinical Laboratory. As per the study of G. Lippi et al,2011[7]- the preanalytical errors contribute about 70%of the total errors in clinical laboratory.

A total of 905432 samples were received and processed at VRDL, Department of Microbiology, M.G.M. Medical College, Indore (M.P), 109544 samples were non-compliant samples of preanalytical phase (Table 1). In the baseline period- 518561 samples were received, among which 107279 were noncompliant samples. Whereas in the postintervention period, 386871 samples were received, out of which only 2265 were non-compliant samples. The noncompliance % decreases from the baseline period to postintervention period from 20.6% to 0.59% respectively.

This change can be attributed to:
1. Interventional activities
2. Experienced staff working in postintervention period.
3. Decrease in sample load in postintervention period.

Effect of intervention on sample rejection rate (Table 2) shows decrease in sample rejection rate of baseline period to postintervention period from 1.79% to 0.48%. This change is attributed to regular follow-up and evaluation of errors on a day-to-day basis and continuous error targeted solutions provided for decreasing the sample rejection rate.

Irrespective of the general importance of defining appropriate preanalytical requirements for all clinical diagnostic testing, no guidelines on how to manage preanalytical variability in clinical studies are available to the best of our knowledge. In our laboratory, day to day follow-up of rejected samples was done along with weekly analysis of problematic areas.

CONCLUSION:

The errors are always unavoidable, and the pattern also remains same. There are several studies which mention that the errors were more frequent in the preanalytical phase. Great effort should be made after identification of errors for corrective and preventive action, so that these errors are not repeated in future and even if the errors are unavoidable, corrective action are already in place which increases our laboratory performance and hence effective clinical decision-making process.

A delay in diagnosis is considered misdiagnosis in high pressure setting of pandemics. In developing countries like ours, financial constraints play a major role in laboratory investigations. Therefore, conserving resources by Continuous interventions, analysis, assessment, training and re-assessment which leads to decrease in resource wastage.

FUTURE PROSPECTS: This study will be further expanded to factors of noncompliance and the development of quality indicators.

CONFLICTS OF INTEREST: None

ETHICAL CLEARANCE: This study was started on 25 September 2021 after ethical approval from Institutional Ethics Committee, M.G.M. Medical College & M.Y.H. Indore, Madhya Pradesh.

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