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Original Research Paper | Clinical Laboratory

AWARENESS OF GOOD AND SAFE LABORATORY PRACTICE AMONG LABORATORY PERSONNEL DURING COVID 19 PANDEMIC.

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ABSTRACT The COVID-19 pandemic has highlighted the crucial role of laboratory medicine in the diagnosis and management of patients. However, there is a need to ensure that laboratory processes remain safe and effective, especially when handling potentially infectious samples. This study aimed to assess the awareness of laboratory personnel about safe laboratory practices during the COVID-19 outbreak. A cross-sectional study was conducted among laboratory personnel in a tertiary healthcare center in South Gujarat, India. A questionnaire based on guidelines from reputable institutes was used to collect data on demographics, knowledge about the virus and its transmission, and understanding of safe laboratory practices. The results showed that while there was generally good knowledge about the virus and its transmission, there were variations in understanding safe laboratory practices. For example, some participants were unaware of the recommended duration for handwashing or the need to change gloves regularly. The findings underscore the importance of continuous training and education to ensure that laboratory personnel have up-to-date information and adhere to best practices. It is crucial to develop harmonized indications for mitigating biohazard risks and enhance biosafety precautions without compromising efficiency in laboratory settings during the pandemic.

KEYWORDS : Covid - 19, Good lab safety procedures, standard practices

INTRODUCTION

Since December 2019, an outbreak caused by a novel coronavirus called SARS-CoV-2 (Severe Acute Respiratory Syndrome coronavirus 2) and causing the Coronavirus Disease 2019 (COVID-19) has emerged in China and has spread rapidly through the globe. It was classified as a pandemic by World Health Organization on 11th March, 2020.

Laboratory medicine is one of the most important front-line professions assisting the fight against the pandemic by producing test results that are crucial for the diagnosis and management of COVID-19 patients. [3], [4]. Potentially infectious samples are received routinely in the medical laboratory for analysis. Owing to the frequent contact with potentially infected biological material, it is crucial to ensure that laboratory processes remain safe and effective, and that laboratory test results can be always timely delivered during the pandemic.

There are few professional biosafety guidelines specifically focused on clinical laboratories, i.e. those with a general biosafety level ≤2 [5], [6], [7]. Nonetheless, there are important risks connected with some laboratory activities when performing analysis on uncapped clinical specimens, including the need to dispense, vortex and centrifuge clinical samples, and the need to manually handle samples on an open bench [8]. These procedures carry a risk of aerosolization, which is a minor but not meaningless source of potential SARS-CoV-2 contagion. Additionally, the high volume of samples and short turnaround time required for some critical test results put considerable pressure on the laboratory to adopt enhanced biosafety precautions without significantly compromising efficiency.

This study in laboratory personnel was planned to assess awareness about safe laboratory practices during the pre-analytical, analytical and post-analytical processes, with the final aim to have a clear picture of the current situation and develop harmonized indications for mitigating biohazard risks during the COVID-19 outbreak.

MATERIALS AND METHODS

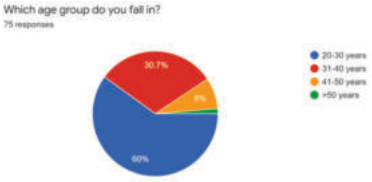
This was an institution based cross-sectional study of laboratory personnel which was conducted at tertiary health care center in South Gujarat.

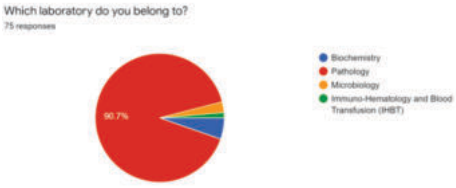
- **Study Population :** All laboratory personnel directly involved with the work in laboratories were included in the study.
- **Study Design:** This was an institution based cross sectional study which was conducted in a tertiary care center in South Gujarat.
- **Sample Size:** 75 Participants
- **Sampling Technique:** Purposive sampling technique. Data was collected with the assistance of well-structured questionnaire based on guidelines and other references from standard institutes like CDC, WHO and ICMR.
- **Sampling Method:** Eligible participants were selected and due consent was taken. Laboratory personnel absent during the study and incompletely or inappropriately filled form entries were excluded.
- **Assortment Of Data:** Data was collected with the assistance of a well-structured pretested self-administered questionnaire prepared by using guidelines on safe laboratory practices by WHO, CDC and ICMR. The questionnaire was divided into 4 parts each addressing a different aspect of the study. Before questionnaires were handed out to participants, the aims and objectives of the study were explained to them. Information was sought regarding socio-demographic characteristics such as age, sex, duration of working experience and background on biohazards. Questions will be aimed to assess their awareness regarding safe laboratory practices in the setting of a pandemic. The questionnaire is in English and will be explained in local language upon request.
- **Data Analysis:** The data was collected, collated and digitized data was analysed and conclusions drawn.

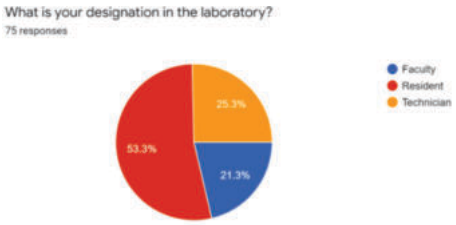
RESULTS

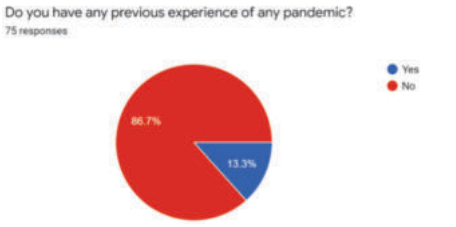
Analysis Of Individual Responses.

I. Demographic Data



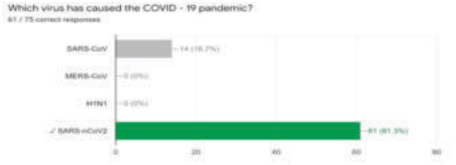


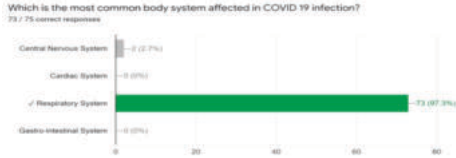


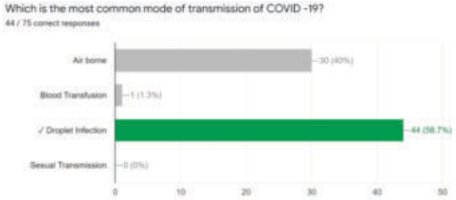


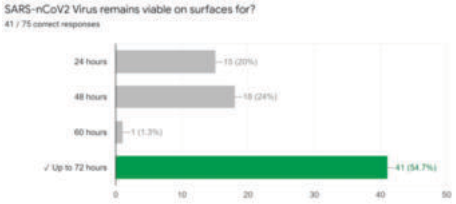
The first part of the survey collected data on the demographics of the participants and their professional roles and designations in the lab. The survey received 75submissions. More than half of the participants (60%) belonged to the 20-30 years age group. Most of the participants were residents(53%), followed by technicians(25%) and faculties(22%). The participants majorly (91%) belonged to the pathology section of the lab. Majority(87%) of the participants did not have any prior experience in a pandemic. Nearly half the participants reported having some training in COVID-19 protocols.

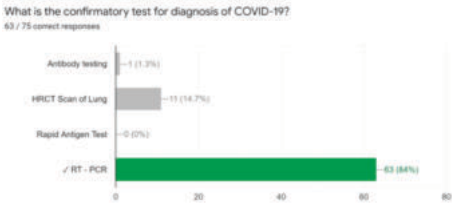
II. Virus and Transmission





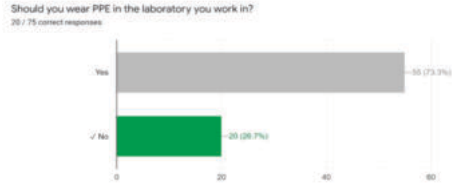


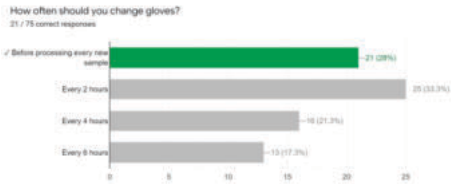


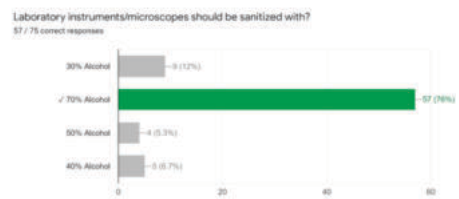


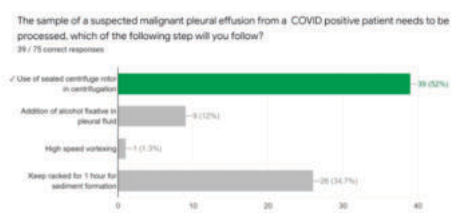
The second part of the questionairre dealt with questions on the knowledge of virus and its transmission. 81% participants correctly answered that the disease was caused by SARS nCoV 2 virus. 97% correctly identified that the virus primarily affects the respiratory system. The next question received dichotomous answers. While 59% believed the virus spread through dropets, 40% believed that the spread was airborne. Majority (86%) of the participants correctly identified that virus could be isolated from peripheral blood, urine and stool. There was considereble difference in the response to the next question. While 55% believed the virus stayed on surfaces for 72 hours, 20% and24% believed they are viable for 24 hours and 48 hours respectively. The last question of this section was answered correctly by majority(84%) of the participants who correctly answered that RT-PCR was the gold standard test for detecting the virus.

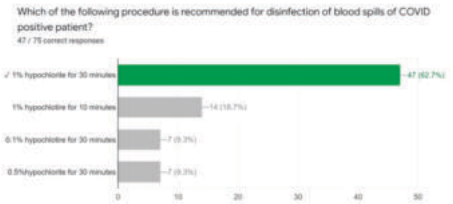
III. Tests, Practices and Risks

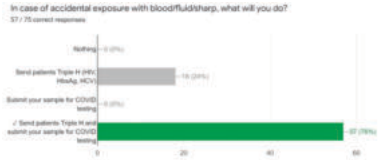


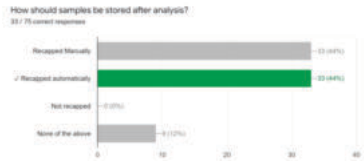






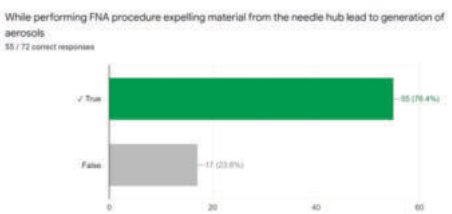


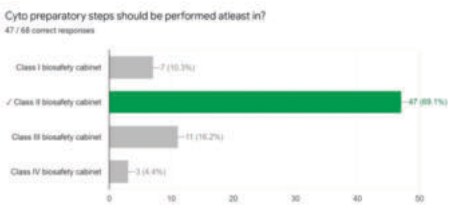


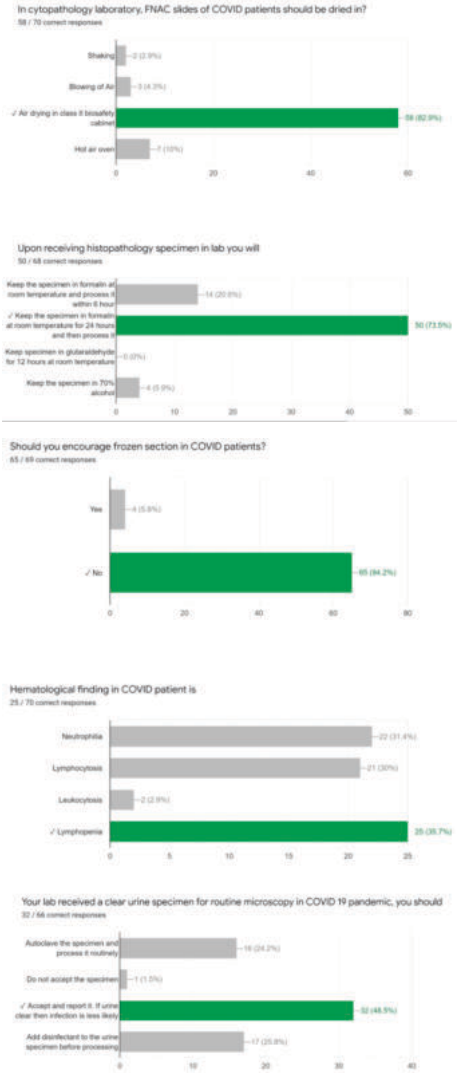


This section dealt with tests, risks and the knowledge about procedures practices to follow in the laboratory for safe handling and conduct of tests. On a question asking what they would advise a colleague who has a household contact of covid, majority (96%) correctly answered that they should advise the person to inform the lab in-charge and get quarantined. On asking if they should wear PPE kit in lab, 73% answered they should and 27% said they shoudnt. On asking the optimum duration for washing hands, 81% correctly answered that it should be done for >20 seconds. 28% believed they should change gloves before processin every sample while 33%, 21% and 17% believed it should be done every 2 hours, 4 hours and 6 hours respectively. Majority (91%) participants correctly answered that samples should be received in the lab in a transport box with biohazard label on it. Most (95%)participants correctly answered that sample tube and work surface should be disinfected with 0.1-1% hypochlorite solution.76% correctly answered that laboratory instruments and microscopes should be disinfected with 70% alcohol. Nearly half (52%) the participants answered that fluids from covid patient should be centrifuged in a sealed centrifuge rotor while others (35%)answered that it should be kept racked for 1 hour.62% answered that blood spills should covered by 1% hypochlorite for 30 mins. Majority(76%) of participants correctly answered that on accidental exposure, Covid test should be sent along with Triple H. 44% answered that samples should be recapped automatically while 44% believed it should be done manually. Most (77%) participants correctly answered that samples should be autoclaved before disposal.

IV. In the Pathology Lab.



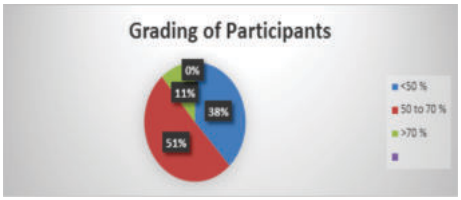




This section dealt specifically with pathologists and procedures in a pathology lab. Majority (76%)of theparticipants correctly identified that expelling material from needle hub after FNAC leads to aerosol generation. 69% correctly answered that cyto-preparatory steps should be performed in a Class II biosafety cabinet and 83% answered that FNAC slides should be also be airdried in a Class II biosafety cabinet. Majority(73%) of participants correctly identified the procedure for receiving and processing histopathology specimens. >94% participants answered that frozen section should not be performed in covid positive patients. There were varied answers about the hematological findings in covid patient and answers were evenly distributed. Majority participants correctly answered about urine processing and reporting.

Analysis of Collective Responses

Correct Responses	No. of Participants
<50 %	28
50 to 70 %	38
>70 %	09



Question Wise Responses:

Question No.	Correct Response (%)	Wrong Response (%)
Q1	82	18
Q2	97	03
Q3	60	40
Q4	87	13
Q5	53	47
Q6	84	16
Q7	98	04
Q8	28	72
Q9	80	20
Q10	26	74
Q11	90	10
Q12	95	05
Q13	88	12
Q14	76	24
Q15	51	49
Q16	63	37
Q17	76	24
Q18	42	58
Q19	77	23
Q20	75	20

DISCUSSION

The COVID-19 pandemic has put laboratories on the edge and has brought the labs in limelight, even if they are not testing for the novel corona virus. This is rightfully so as the virus is highly infectious and potentially fatal in a few. Lab safety should always be top priority but sometimes can get lax owing to many reasons. This can create a big potential safety problem for everyone working in the labs as well as those who come in contact with lab personnel.

One of the earliest challenges when facing this new pandemic was dealing with the fears who have to work with COVID-19 patients or specimens. This fear emanated from the novel nature of the disease and inadequate information regarding the natural history, route of transmission and pathogenicity of the virus which was yet to be established. This caused lab personnel to be afraid of working with such specimens and a few even refused to work for the same.

There was growing need to allay these fears and to provide the correct information to lab workers so as to improve the lab processes which would ultimately benefit the patients. Understanding that lab safety was a top priority for maintaining a conducive working environment in the lab, it was to imperative to ensure that every lab member knows the standard lab practices and understands all SOPs, guidelines and policies regarding lab safety.

So, the purpose of the present study was to first understand the current knowledge and training of the lab members so as to design a training programme to address the deficiencies in the same. This discussion includes the individual questions, the rationale for it and its implication in formulating a lab safety plan.

This study was undertaken in the laboratory personnel of a tertiary care center in South Gujarat. It is a NABL accredited lab and conducts many routine and specialized

investigations under pathology, biochemistry and microbiology. There is use of automated and semi-automated machines as well as manual conduction of tests. The participants included the staffie: faculty, resident doctors and technicians in the respective laboratories.

This survey reflected a snapshot of the operations and working of a high volume laboratory in a resource limited setting during a rapidly changing scenario of a novel virus pandemic. Considering the resource limited setting and limited adherence to health policies, it was imperative that the staff in our lab had useful information that is implementable and practicable to keep the laboratory staff safe while not compromising on the tests.

The demographic data was as follows. The survey received 75 submissions. More than half of the participants belonged to the 20-30 years age group which are overall more informed through rapid dissemination of data through various media sources. Most of the participants were residents, followed by technicians and faculties. Pathology section being the largest service of the laboratory, the participants majorly belonged to the pathology section of the lab. Majority of the participants did not have any prior experience in a pandemic. Nearly half the participants reported having some training in COVID-19 protocols. This training was at the current knowledge basis and was based on general lab safety guidelines and not specifically with respect to COVID pandemic. Information was still evolving and specific guidelines were yet to be published as we would discuss further.

The second part of the questionairre dealt with questions on the knowledge of virus and its transmission. 81.3% participants correctly answered that the disease was caused by SARS nCoV 2 virus. Others answered SARS CoV which though is the correct virus but not the correct species responsible for the current pandemic. Majority of the participants correctly identified that the virus primarily affects the respiratory system, that the virus could be isolated from peripheral blood, urine and stool and that RT-PCR was the gold standard for the diagnosis of the disease. The next question received dichotomous answers. While 59% believed the virus spread through dropets, 40% believed that the spread was airborne. The initial studies (6) indicated that the primary mode of transmission of the virus was droplet infection. WHO and CDC guidelines(4) also emphasised on mitigating these droplet infection spread. Further studies and meta analysis confirmed that there is an air-borne component to the spread of this virus.(7) There was considereble difference in the response to the next question. While 55% believed the virus stayed on surfaces for 72 hours, 20% and 24% believed they are viable for 24 hours and 48 hours respectively. Different studies gave different timings for this question. It ranged from 24 to 72 hours(8). This section of the questionairre underscores the rapidly evolving nature of the pandemic, the virus and the rapid pace with which guidelines were changing. It highlighted the importance of continuous updation of information and guidelines.

The third section dealt with tests, risks and the knowledge about procedures practices to follow in the laboratory for safe handling and conduct of tests. It included some hypothetical questions as well as some questions on the procedures one should follow in the lab. On a question asking what they would advise a colleague who has a household contact of covid, majority of the participants correctly answered that they should advise the person to inform the lab in-charge and get quarantined. This was a correct practice according to the prevailing guidelines (5). It was also in sthe guidelines suggested by ICMR (5) in their contact tracing and containment measures. On asking if they should wear PPE kit in lab, 73% answered they should and 27% said they shoudnt. On asking the optimum duration for washing hands, 81% correctly answered that it should be done for >20 seconds. 28% believed they should change gloves before processing every sample while 33%, 21% and 17% believed it should be done every 2 hours, 4 hours and 6 hours respectively. Majority (91%) participants correctly answered that samples should be received in the lab in a transport box with biohazard label on it. The clinical laboratory was at the forefront of the fight against COVID. Blood, fluid and tissue examination were routine during this period. With viral shedding and a high R value of the virus, the lab personnel were at a very high risk of infection. While we could aspire to follow idealistic guidelines, it was not always possible in the resource limited setting of the institute. According to IAPM guidelines, it is prudent to use PPE after proper risk assesment for aerosol generating procedures. PPE should include laboratory coats, surgical masks, face shield and gloves. In areas of high aerosol generation, it should be supplemented by fluid impervious gown or coveralls, double gloves, proper masks, head cover, leggings or shoe covers, goggles and face shield should be used. Whole-body suit should be used for high risk works.When samples are being transported they should be packed in triple layer: using primary container, secondary container and zip lock pouches. The collected samples should be placed in leak-proof bags followed by secondary containers to minimize any chances of breakage or spillage. The outer container should be disinfected, both at the time of packing as well as before taking them out of the transportation box during testing.(ijpm)With strict adherance to Good Laboratory Practices and adherence to protocols of Infection Prevention and Control policies, there is a high possibility of reducing information in a resource limited setting.

Most participants correctly answered that sample tube and work surface should be disinfected with 0.1-1% hypochlorite solution. 70% correctly answered that laboratory instruments and microscopes should be disinfected with 70% alcohol.63% answered that blood spills should covered by 1% hypochlorite for 30 mins. IAPM guidelines suggest that for small surfaces 62–71% Ethanol, while for bigger areas 0.5% Hydrogen peroxide, or 0.1-1% Sodium hypochlorite should be used. Only freshly prepared Sodium hypochlorite should be used. The disinfectant solution should be applied for at least 30 minutes.(IJPM)Nearly half the participants answered that fluids from covid patient should be centrifuged in a sealed centrifuge rotor while others answered that it should be kept racked for 1 hour. IAPM guidelines in this regard suggest that cytopreparatory steps performed by technicians leading to aerosol or droplet formation such as opening of containers and removing the caps of the tubes, blending, diluting, vigorous shaking or mixing of fluids, centrifugation and, discarding the supernatant should be performed in a class II BSC. Majority of participants correctly answered that on accidental exposure, Covid test ahould be sent along with Triple H. 44% answered that samples should be recapped automatically while 44% believed it should be done manually. Most participants answered that samples should be autoclaved before disposal.This is contrary to guidelines which do not suggest autoclaving of waste before disposal.The biomedical waste and general waste should be segregated at the point of generation and not in the collection or storage area so as to maintain complete safety. The general laboratory wastes should be collected separately as per the existing biomedical waste management (BMW) guidelines. The wet and dry solid waste bags should be tightly tied so as to prevent any leakage and sprayed with sodium-hypochlorite solution before handing over to the sanitary workers. Additionally, The bags used for collection of waste from COVID-19 patients should be double layered ensuring adequate strength and prevention of leakages. Biomedical waste should be collected and stored separately in a temporary storage room and shifted directly into the BMW collection van. (IJPM).

The fourth section dealt specifically with pathologists and

procedures in a pathology lab. Majority (76%)of the participants correctly identified that expelling material from needle hub after FNAC leads to aerosol generation. 69% correctly answered that cyto-preparatory steps should be performed in a Class II biosafety cabinet and 83% answered that FNAC slides should be also be airdried in a Class II biosafety cabinet. IAPM Cytopathology specific guidelines suggest thatthe number of fine needle aspiration cytology (FNAC) should be restricted to bare minimum and should be advised only if it truly alters the medical management of the patient.After aspiration, the material should be gently expelled and smearing should be made cautiously (preferably in a closed cabinet). While making a smear it is recommended that slides are held as far as possible from the personnel. Drying of the smears by shaking or blowing of air should not be done as it can lead to generation of aerosol and small droplets. Air-drying of the smears should be ideally performed in class II biosafety cabinets. (IJPM)

Majority(73%) of participants correctly identified the procedure for receiving and processing histopathology specimens and in line with IJPM guidelines which say that histopathology specimens should be properly fixed in 10% buffered formalin or Glutaraldehyde. Both these are reported to decrease the infectivity of coronavirus in a temperature and time dependent manner. Formalin inactivates the virus in a contact time of 24 hours if specimens are kept at a temperature of 37°C; at temperature of 56 °C for 90 min, 67 °C for 60 min, or 75 °C for 30 min.>94% participants answered that frozen section should not be performed in covid positive patients. The guidelines suggest that the use of fresh-frozen sections should be restricted to a strict necessity basis, as cryostat disinfection takes a long time and many laboratories have only one cryostat machine available. Only single personnel should operate the cryostat and wear protective gears including goggles, N95 mask and face shield. Immediately after the frozen section is prepared, the remaining tissue should be placed in formalin for fixation and routine processing. The cryostat and the grossing station should be thoroughly disinfected using 70% Alcohol solutions.(IJPM)

There were varied answers about the hematological findings in covid patient and answers were evenly distributed. Majority participants correctly answered about urine processing and reporting.

On overall analysis of the questionnaires, individual scoring was done. 11% participants answered >70% questions correctly, 51% answered 50 to 70% questions correctly and 38% answered <50% questions correctly. Most of the participants who had a score less than 50% were technicians. For these participants a training was organized which included varied topics on lab safety in liu of a pandemic. For all other participants a reinforcement training was conducted which included some updated SOPs and additional safety measures.

CONCLUSION

The survey responses to the questionnaire showed wide variation in knowledge, attitudes and practices of good lab safety procedures. It is more likely that many of the suboptimal biosafety practices are related to practical local factors and resource limitations. It is imperative that in spite of these shortcomings, labs adapt these guidelines to make sure there is a balance maintained between strict adherence to official guidelines and implementable local factors. The balance should be implementable, cost effective, adoptable, seamlessly blending with workflow and at the same time maintain the standards and rigors of a NABL accredited lab.

Labs should review their standard practices, SOPs and safety procedures periodically especially during a pandemic due to the rapidly evolving information and guidelines. It is the responsibility of the lab to routinely train the staff, test their competency, maintain records and monitor the implementation of these guidelines in daily workflow in the lab.

COVID was not the first and will not be the last pandemic to affect humanity. With rapidly evolving environment and mutations in respiratory viruses, we have to make sure that we remain ahead of any future pandemics. So, it is of utmost importance that lab safety guidelines are updated frequently and training provided to staff so that it keeps them safe, increases confidence in working and ultimately benefits the patients.

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