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Assessment of biosafety implementation in clinical diagnostic laboratories in Pakistan during the COVID-19 pandemic

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1. Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has spread worldwide with 237,630,439 confirmed cases of coronavirus disease 2019 (COVID-19) and 4,851,252 COVID-19-related deaths reported by the World Health Organization (WHO) as of October 8, 2021.1 On February 26, 2020, the government of Pakistan confirmed the first 2 cases of COVID-19 in Karachi and Islamabad, which had increased to 20 cases by March 12, 2020.2 All of these patients had a history of a recent visit to Iran, Syria, or London. On October 8, 2021, the number of confirmed COVID-19 cases surged to 1,256,233, with 28,058 deaths registered and 1,184,527 recoveries.2

The International Health Regulations (IHR), which came into force in 2007, call on all countries to strengthen their capacity to prevent, detect, and respond to public health emergencies such as the COVID-19 pandemic.3 For preparedness and response to a Public Health Emergency of International Concern (PHEIC) or pandemic, laboratory detection capacity plays a crucial role because symptomatic and asymptomatic patients are identified via laborator-

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tory detection, which also allows for contact tracing and guides public health response measures by providing much-needed data. The laboratory core capacity should allow for the provision of quality services that also rely on the implementation of a robust biosafety management (BRM) system covering preanalytical, analytical, and postanalytical activities. In view of findings of the Joint External Evaluation (JEE) report on Pakistan’s IHR core capacities released by the WHO in 2017, considerable gaps were reported in laboratory preparedness in terms of biosafety and biosecurity. In this report, biosafety and biosecurity systems in Pakistan received a score of 2 (limited capacity), and development and implementation of the national public health emergency preparedness plan received a score of 1 (no capacity). However, the JEE report noted the presence of a draft national epidemic and pandemic preparedness response and substantial development toward improving its position through actions taken by the government of Pakistan such as placement of trained biosafety officers in a few national and provincial laboratories, and establishing a functional biosafety level (BSL)-3 facility at the national level.

By May 2020, the government of Pakistan had equipped more than 15 laboratories to conduct no-cost COVID-19 PCR-based diagnostic testing. In addition, only a few private facilities were doing testing for profit at the onset of the pandemic. The government aimed to increase this number to expand the national testing capacity. This number has grown to 45 facilities in the federal region, 96 in Punjab, 49 in Sindh, 30 in Khyber Pakhtunkhwa (KP), 6 in Balochistan, 4 in Azad Jammu and Kashmir, and 3 facilities in Gilgit-Baltistan (GB) as of December 2, 2021. In terms of human resources, this capacity enhancement was made possible by hiring laboratory technicians and providing them with the required technical training. The provincial health care commissions visited each laboratory before authorizing it for COVID-19 testing and conducted an evaluation based on set parameters. Provincial governments in Pakistan established these authorization requirements for COVID-19 testing laboratories. However, whether the authorization criteria included all components of a BRM system, validated using BRM standards or international guidelines that are unbiased toward certain aspects of biosafety and biosecurity owing to limited awareness of the individuals concerned, is an important question that deserves attention. The successful operation of a BRM system necessitates a skilled, well-trained, and knowledgeable team. COVID-19 diagnostic testing facilities hired additional employees to meet the growing demand for staff who could conduct PCR testing. The laboratory authorization criteria mandated training in BRM but failed to mandate measurement of the efficacy of training and competency assessment. This could have led to engaging a workforce that was not competent in handling biorisk issues. Keeping in mind the considerable gaps in the BRM systems of organizations in Pakistan during the pre-COVID-19 era and gaps in specific aspects of knowledge and practices related to COVID-19, it is important to assess the BRM situation in authorized COVID-19 testing laboratories to see whether these laboratories have a good BRM system in place to protect their workers, the environment, and the community. It is also important to assess the biosafety and biosecurity situation in sections other than the COVID-19 diagnostic testing area of a laboratory as well as in laboratories that are not performing COVID-19 testing. This assessment is important because of the close proximity to COVID-19 testing areas of these sections/laboratories, their potential engagement with COVID-19 testing owing to increased workload, and the possibility of specimen contamination with samples taken for different kinds of tests from patients with suspected and confirmed COVID-19. It is important to note that no laboratory-acquired infections have been reported to date in COVID-19 diagnostic testing laboratories in Pakistan.

The aim of this study was to assess the situation in laboratories in Pakistan with regard to biosafety and biosecurity during the COVID-19 pandemic. We assessed the perceptions, knowledge, and preparedness of LPs to tackle risks associated with the handling and testing of specimens and the role of laboratory management in the implementation of best biosafety and biosecurity practices. Our survey will help identify gaps and develop plans for improvements to enhance the laboratory response to the current pandemic and PHEICs in the future.

2. Materials and methods

This was a cross-sectional study designed to assess the biosafety and biosecurity situation of clinical diagnostic laboratories in Pakistan during the COVID-19 pandemic.

Inclusion criteria: This study targeted laboratory professionals (LPs) working in public and private sector laboratories during the COVID-19 pandemic and LPs conducting COVID-19 diagnostic testing. LPs working in all sections (molecular biology, microbiology, hematology, biochemistry, and histopathology) of these laboratories in Punjab, Sindh, KP, GB, and Islamabad were targeted. Only 168 of 205 respondents were included based on the inclusion criteria.

Exclusion criteria: We excluded all professionals who were not working in a clinical diagnostic laboratory at the time of the survey.

Questionnaire: A structured, self-report, anonymous questionnaire was developed in English language with an introduction and description of the survey objectives. The survey included questions to assess basic knowledge and perceptions of LPs, resource availability, and commitment by top management regarding biosafety and biosecurity. Data were collected using an online form between March and April 2020. The form was distributed via the Internet and specifically throughout the targeted regions of Pakistan to focus on LPs in different laboratories. To maintain anonymity of responses and eliminate bias, the survey did not query the names of laboratories. Informed consent was obtained from the survey respondents. IBM SPSS Statistics for Windows (Version 24) was used for the statistical analysis (IBM Corp., Armonk, NY, USA).

3. Results

Fifty-eight of the 168 LPs whose responses were included in this study on the basis of the inclusion criteria were involved in diagnostic testing for COVID-19 infection in authorized laboratories across Pakistan. Most respondents were from Punjab (76.79%), followed by Sindh (10.12%), KP (8.33%), GB (3.57%), and Islamabad (1.19%). Public and private sector diagnostic laboratories represented 49.4% and 50.6% of survey respondents, respectively, with 62.1% and 37.9% conducting COVID-19 diagnostic testing. A total of 53.4% and 43.1% of the LPs conducting COVID-19 testing were 18–30 and 31–40 years old, respectively, with 1–5 years (44.8%) and 6–10 years (32.8%) of laboratory experience (Fig. 1). This shows that most (96.5%) LPs performing COVID-19 testing were less than 40 years old and nearly half (44.8%) had up to 5 years of laboratory experience. Fig. 2 presents the experience of LPs performing routine diagnostic testing in private and public laboratories. Most LPs involved in COVID-19 testing were laboratory technologists (53.4%) followed by researchers (20.7%), laboratory technicians (12.1%), pathologists (10.3%), and laboratory managers (3.4%).
3.1. LPs’ knowledge, perceptions, and preparedness

Table 1 presents the results regarding LPs’ knowledge, perceptions, and preparedness during the COVID-19 pandemic. According to the data, 32.8% of LPs said they did not have the necessary training to handle samples from patients with suspected or confirmed COVID-19 infection. More private sector LPs (95.45%) were trained in biosafety and biosecurity than public sector LPs (66.67%). Private sector LPs were more confident in handling COVID-19 samples (86.36%) than public sector LPs (55.55%) and were more often trained (77.27%) specifically in handling emergencies than public sector LPs (41.6%).

Most LPs performing COVID-19 testing (75.9%, n = 43) and routine diagnostic testing (59.1%, n = 62) said they knew that the N95 mask can be reused in certain situations, as per CDC recommendations. However, knowledge about the number of times the N95 mask can be reused varied greatly between professionals. Even LPs who claimed that they knew about reusing the N95 did not have the correct information, reflecting unconscious incompetence in the use of personal protective equipment (PPE). Only 14% of LPs who claimed that they knew about N95 reuse were aware that...
these masks can be reused up to five times in the absence of specific manufacturer instructions on reuse. Only 31% of LPs performing PCR-based COVID-19 testing knew that this can be performed at BSL-2 facilities, as per WHO interim biosafety guidelines. A certain number of LPs believed that PCR should be conducted at BSL-3 (53.4%) and BSL-4 facilities (15.5%).

Panic owing to the COVID-19 pandemic was reported by 70.7% of LPs conducting COVID-19 testing and 50% of LPs conducting routine diagnostic testing. This reflects that LPs considered themselves at risk in their laboratories during the pandemic. A total of 71.8% of LPs who were not involved in COVID-19 testing at the time of the survey reported that they were willing to volunteer for COVID-19 testing. A few of these individuals (20.9%) were unable to volunteer owing to a lack of relevant expertise.

### 3.2. Practices, availability of resources, and commitment

Analysis of the availability of resources and commitment by laboratory management during the COVID-19 pandemic indicated a lack of adequate PPE (43.1%), absence of standard operating procedures (SOPs) for best biosafety and biosecurity practices specific to the COVID-19 pandemic (32.8%), and initiation of COVID-19 testing without a prior risk assessment (41.4%) in COVID-19 testing facilities (Table 2). In the private sector, LPs were found to be conducting COVID-19 testing with a larger supply of PPE than LPs in the public sector. Private sector laboratories performing routine diagnostic testing also had an abundant supply of PPE (72.7%) compared with public sector laboratories (47.2%).

### 4. Discussion

In this study, a high percentage of LPs conducting COVID-19 testing did not feel confident in the safe and secure handling of COVID-19 samples (32.8%), spills (43.1%), or other accidents (32.8%). These findings reflect gaps in the preparedness of LPs to handle emerging pathogens such as SARS-CoV-2, forecasting errors and poor practices that can result in laboratory-acquired infections. This lack of confidence may have several contributing factors, some of which we identified in this study, as discussed below.

#### 4.1. Experience and training

The data obtained from this survey showed that more than half of the LPs (53.4%) conducting COVID-19 diagnostic testing were under the age of 30 years and had between 1 and 5 years of experience (44.8%). This can be owing to the emergency recruitment of laboratory technologists by the Pakistani government, which in most cases resulted in the hiring of unemployed and/or recent medical laboratory technology graduates with minimal experience. The involvement of early career staff in COVID-19 testing has some benefits, such as increased testing capacity by engaging a larger workforce, but this significantly increases the risk level associated with this testing. The risks associated with an inexperienced workforce can be lowered by ongoing training in biosafety and biosecurity. In collaboration with Health Security Partners (HSP), the Pakistan Biological Safety Association (PBSA) conducted virtual training of more than 150 LPs who were involved in COVID-19 testing between July and December 2020; this training comprised all relevant aspects of biosafety and biosecurity to address this important gap.

In the present study, 77.6% of LPs conducting COVID-19 testing had previously been trained in BRM. However, the lack of confidence among trained workers could be owing to ineffective training modes and limited hands-on exercises. Skryabin et al. reported that even with operation-based/functional exercises, long-term retention of the acquired skills is limited (50%), which highlights the need for continuing education on BRM and refresher training as per training needs assessment. Adult learners’ needs and the tasks they will perform should be carefully considered when selecting training methods. The authors propose small-group training with each participant performing hands-on exercises. Participants should be able to apply what they have learned in their organizations, which can be made possible with proper follow-up and ongoing assistance. Many national and international organizations are supporting BRM training for LPs in Pakistan and playing a visible role in their capacity building. However, these programs have a more generalized theme and thus fail to address facility-specific issues in most cases.
Resource availability and administrative risk control measures in Pakistani laboratories during the COVID-19 pandemic.

Table 2

| No. | Questions                                                                 | % of LPs conducting COVID-19 testing | % of LPs conducting routine diagnostic testing |
|-----|----------------------------------------------------------------------------|-------------------------------------|----------------------------------------------|
| 1   | Did you ever receive a biosafety training (before the onset of COVID-19 pandemic)? | Yes: 45 (77.6%) No: 13 (22.4%)     | Yes: 65 (59.1%) No: 45 (40.9%)               |
| 2   | Were you previously trained by your organization to specifically handle samples from suspected/confirmed cases of emerging infections like COVID-19? | Yes: 32 (55.2%) No: 26 (44.8%)     | Yes: 41 (37.3%) No: 69 (62.7%)               |
| 3   | Are people testing for COVID-19 in your organization have enough personal protective equipment (PPE) to handle samples from cases with suspected or confirmed COVID-19 infection? | Yes: 33 (58.9%) No: 25 (41.4%)     | Yes: 36 (32.7%) No: 74 (67.3%)               |
| 4   | If your laboratory is performing testing for COVID-19 infection, did your laboratory performed a risk assessment before starting it? | Yes: 34 (58.6%) No: 24 (41.4%)     | Yes: 51 (46.4%) No: 59 (53.6%)               |
| 5   | Do you have standard operating procedures (SOPs) in your lab for biosafety and biosecurity specific to this pandemic? | Yes: 39 (67.2%) No: 19 (32.8%)     | Yes: 59 (53.6%) No: 51 (46.4%)               |
| 6   | Are you doing work more than your duty hours during this pandemic?          | Yes: 43 (74.1%) No: 15 (25.9%)     | Yes: 66 (70.0%) No: 30 (30.0%)               |

LP, laboratory professional.

Most LPs conducting COVID-19 testing reported that they knew about the possibility of reusing the N95 mask (excluding situations where reuse is not recommended, such as contamination of the mask, and improper storage). However, only 10% of LPs knew the correct number of times the mask can be reused, per CDC recommendations and provided this is not specified by the manufacturer. Additionally, 68.9% of LPs assumed that COVID-19 PCR-based diagnostic testing should be conducted in a BSL-3 or BSL-4 laboratory and were unaware that WHO interim biosafety guidelines allow for PCR testing in BSL-2 laboratories. This lack of knowledge raises questions regarding LPs’ level of awareness, ability to implement best biosafety and biosecurity practices based on risk assessment, and failure to update their knowledge to the latest information for COVID-19 testing. This also showed that the perceived risk was greater than the actual risk in these facilities. This could lead to LPs feeling under-resourced, which could eventually influence their behavior and conduct. This situation can be remediated by having a biosafety officer or dedicated staff member give a daily or weekly safety and security update briefing. These sessions can help keep personnel up to date on any new guidelines or revisions to existing guidelines or policies as soon as they become available.

A total of 41.4% of LPs indicated that their laboratory began COVID-19 testing without performing a risk assessment. These findings are in agreement with previous studies that reported a trend of conducting diagnostic testing without prior risk assessment in 98% and 30% of diagnostic laboratories. This finding highlights the need for extensive training to build the capacity of LPs in conducting risk assessment before starting new or changing routines and specific testing procedures. This gap also reflects a lack of commitment from top management and the failure by management to define risk assessment as a BRM objective. To address this critical knowledge and implementation gap, the PBSA has hosted risk assessment webinars for LPs, assessors, and policymakers across Pakistan, in collaboration with HSP (July–December 2020) and the Fogarty International Centre, National Institutes of Health, USA (June 2021). In a follow-up personal communication with LPs working in COVID-19 testing facilities, the authors discovered that risk assessment is conducted during the evaluation process for the purpose of authorization. While this is preferable, it is not mandatory for a laboratory to perform a risk assessment. LPs also mentioned that not all staff from the health care commissions who assess laboratories are familiar with biosafety and biosecurity guidelines and standards. We propose that further work is needed among those who develop the authorization criteria and evaluate these laboratories for authorization to emphasize the necessity for risk assessment and make this a requirement rather than a preferential criterion. LPs conducting COVID-19 testing (94.8%) and routine diagnostic testing (96.4%) felt that biosafety is more important than biosecurity during the COVID-19 pandemic. This finding indicates that biosecurity measures are undervalued in these facilities, which can have immediate and unforeseen consequences. This also concerns the potential relaxation of biosecurity measures owing to panic and increased workload during the pandemic. This perception must be addressed to ensure the security of COVID-19 samples by implementing security management measures to prevent samples from falling into the hands of people with harmful intentions during and after the pandemic. This finding is consistent with a study conducted in Peshawar in 2017, which
reported easy accessibility to pathogens in diagnostic laboratories.22

4.2. Unavailability of resources

In total, 43.1% of LPs conducting COVID-19 testing reported a lack of sufficient PPE in their laboratory. This finding is in agreement with another study19 reporting that 60% of laboratories did not possess active PPE programs with defined SOPs for routine diagnostic testing.

4.3. Other factors

Studies conducted in Karachi (2012) reported an absence of commitment toward BRM by laboratory management in 75%19 and 43.33%18 of diagnostic laboratories.

A total of 32.8% of LPs indicated the absence of SOPs for good biosafety and biosecurity practices specific to COVID-19 testing in their laboratory, which is related to the findings of another study18 that emphasized commitment by top management as one key to a successful BRM system.

The WHO’s strategic preparedness and response plan23 calls for strengthening the diagnostic capacity for SARS-CoV-19 testing, where infection prevention and control and biosafety are included as key performance indicators to monitor implementation of the plan. The government of Pakistan has taken many steps to ensure the safety of LPs during the pandemic, but a lack of preparedness before the pandemic is evident from the findings. This demonstrates that emergency preparedness not only involves developing plans for emergency situations, such as the COVID-19 pandemic, but also strengthening and developing a culture of safety within the existing systems. A laboratory that has a good BRM system in place under normal circumstances will be able to deal with emerging pathogens safely and securely during emergency situations. Therefore, it is necessary to find gaps in the existing BRM systems and to fill those gaps through effective and sustainable interventions. In addition to the government, many other organizations have helped in the capacity building of LPs across Pakistan. The PBSA and HSP have supported the implementation of a BRM program tailored to COVID-19 testing facilities across Pakistan to address gaps, with a focus on capacity building of LPs in performing, for example, risk assessment, safe and secure sample handling, good laboratory practices, proper use of PPE, and biosecurity.

The authors put forward the following recommendations on the basis of our study findings.

1. The government should provide support and mandate laboratories to actively develop and execute BRM capacity strengthening programs for employees. These BRM capacity strengthening programs must be developed for all pathogens using an all-hazards approach rather than focus only on a specific pathogen because future outbreaks are likely to involve different pathogens with different routes of transmission.

2. A renewed focus on the value of risk assessment before starting work, together with appropriate training, dissemination of information, and conclusions from risk assessment such as regarding the use of PPE, biosafety cabinets, and containment required for testing, are needed during the roll out of any new, outbreak response testing.

3. There is a need to engage BRM experts in the process of establishing authorization and licensing requirements for laboratories in the local context.

4. There is a need to go beyond training and implementation of best biosafety and biosecurity practices using a narrow approach. Organizations in Pakistan should start implementing biosafety programs as described in the WHO Biosafety Programme Management Monograph.24

The weakness of biosecurity and biosafety practices has been documented in recent publications, including the JEE assessment in 2017. The present paper could serve as the foundation for a more focused investigation that results in actions and initiatives to improve biosafety and biosecurity practices during public health emergencies.

5. Conclusion

The COVID-19 pandemic should be taken as an opportunity to review existing BRM systems. It is important to learn from the experience gained during this pandemic, document such knowledge, and plan for the future accordingly. This can only be done with ongoing commitment from top management, capacity building through external and in-house training, and competency assessment of LPs.

CRediT authorship contribution statement

Samreen Sarwar: Writing – review & editing, Project administration. Faheem Shahzad: Formal analysis. Ayesha Vajeeha: Writing – review & editing, Investigation. Rimsha Munir: Writing – review & editing, Investigation. Amina Yaqoob: Conceptualization, Writing – review & editing, Project administration. Aniqa Naeen: Investigation. Mamoona Sattar: Investigation. Sheereen Gull: Investigation.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Statement of informed consent

The participants in the study gave their informed consent.

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