Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Original Research Article

Indian microbiology EQAS registered laboratory's capacity building and infection control practices during the COVID-19 pandemic in India: Lessons learnt and gaps identified

Malathi Murugesan [a,1], Reena Raveendran [b,1], Rajesh Kannangai [c], Jagadish Ramasamy [d], Pallab Ray [e], Mallika Gope [f], Venkateswaran Natarajan [f], Kamini Walia [g], Chand Wattal [b,**], Balaji Veeraraghavan [a,*]

[a] Department of Clinical Microbiology, Christian Medical College, Vellore, Tamil Nadu, India
[b] Institute of Medical Microbiology and Immunology, Sir Ganga Ram Hospital, New Delhi, India
[c] Department of Clinical Virology, Christian Medical College, Vellore, Tamil Nadu, India
[d] Department of Biochemistry, All India Institute of Medical Sciences, Madurai, Tamil Nadu, India
[e] Department of Medical Microbiology, Postgraduate Institute of Medical Education and Research, Chandigarh, India
[f] National Accreditation Board for Testing and Calibration Laboratories, Gurugram, Haryana, India
[g] Indian Council of Medical Research, New Delhi, India

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ABSTRACT

Purpose: The COVID-19 pandemic was unique in the history of outbreaks because of the massive scaling up of resources related to diagnostics, treatment modalities, and vaccines. To understand the impact of the pandemic among laboratory professionals, we aimed to conduct a survey to assess the improvement in the lab capacity post-covid in terms of infrastructure and accreditation status across various levels of hospitals and to determine the changes in the practice of infection control precautions during the pandemic.

Methods: This was an anonymous, online-based survey (using 58 item questionnaire) conducted between July 09, 2021, and August 07, 2021. The survey targeted all EQAS registered diagnostic laboratories located in India.

Results: The survey reached out to 1182 participants, out of which 721 (61%) laboratories completed the questionnaire. During pre-COVID times, only 39% (282/721) of the laboratories had an RT-PCR facility. Among these 721 labs, 514 used open system RT-PCR assay, 217 labs used Truenat assay, 188 labs used GeneXpert assay, 31 used Abbott ID Now and 350 labs performed rapid antigen tests. During the pandemic, 55.3% got NABL accreditation and 7.4% were in the process of applying for COVID-19 molecular testing. In this, 80.7% of the laboratories participated in the ICMR – COVID quality control assessment. It was estimated that 41.4% of the laboratory professionals were re-using N95 masks. Overall, the infection prevention and control practices varied across each laboratory and hospital.

Conclusion: These survey findings helped us to understand the strength and efficiency of laboratories in India in setting up new assays during a crisis time. Based on our findings, we propose to connect this network in a sustained manner to efficiently utilize the existing platforms to adapt to future pandemics.

1. Introduction

COVID-19 pandemic had been declared a public health emergency of international concern by the World Health Organization in March 2020 [1]. Even though epidemics and pandemics had occurred in the past, a massive scaling up of resources related to diagnostics, treatment modalities, and vaccines that occurred during the COVID-19 pandemic was unique. In India, a network of virus research and diagnostic laboratories (VRDLs) was initiated by the Indian Council of Medical Research (ICMR) to scale up the testing capacity, thereby facilitating early detection, early

* Corresponding author. Department of Clinical Microbiology, Christian Medical College, Vellore, 632004, India.
** Corresponding author. Institute of Clinical Microbiology and Immunology & EQAS (North), Sir Ganga Ram Hospital, New Delhi, 110060, India.
E-mail addresses: chand.wattal@sgrh.com (C. Wattal), vbalaji@cmcvellore.ac.in (B. Veeraraghavan).
[1] Shared first authorship.

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containment, and prevention of larger outbreaks [2]. As per the ICMR data, around 1320 Government and 1548 private laboratories conducted diagnostic tests for COVID-19 all over India in August 2021 [3]. During any epidemic outbreaks, laboratories played a key role in strategic testing for early diagnosis and containment of infection [4].

The National Accreditation Board for Testing and Calibration Laboratories (NABL), India, with a mission of initiating new programs supporting accreditation activities, stepped in by pacing up the accreditation process for COVID-19 molecular testing without compromising the quality [5]. As there were newer diagnostic platforms introduced in most of the laboratories during the pandemic, an accreditation process helped in improving the quality of management, reduced the cost, and aided in better control of the operation system.

With this sudden system change in the laboratories, the clinical microbiology laboratories were overwhelmed with respect to laboratory personnel, work timings, infrastructure, and sample overload during the COVID-19 pandemic [6]. The laboratory health care workers (HCW) were at higher risk of acquiring the infection if the infection control practices and disinfection protocol were not followed appropriately. While there was a rampant increase in the number of testing laboratories in India in a year, learning lessons from the pandemic will help us to sustain the practices and be prepared for the future outbreaks. Hence we aimed to conduct an online questionnaire-based survey to understand the perceptions of microbiologists or laboratory HCW during the COVID-19 pandemic. The objectives of this survey were to assess the improvement in the lab capacity post covid in terms of infrastructure and accreditation status across various

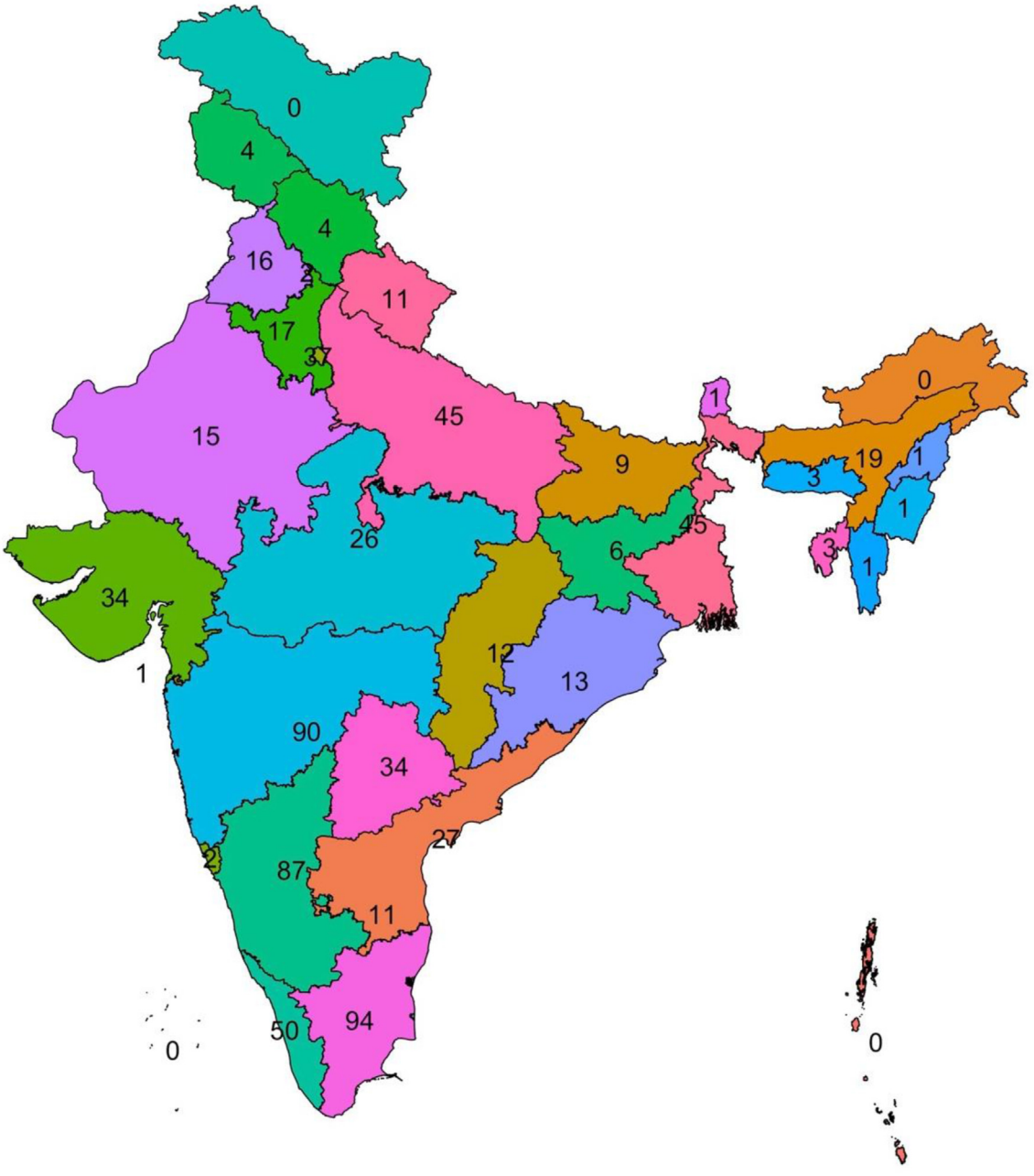

Fig. 1. State wise distribution of EQAS participating laboratories in the survey.

levels of hospitals and to determine the changes in the practice of infection control precautions during the pandemic.

2. Material and methods

2.1. Survey conduct

This was an anonymous, online-based survey (using SurveyMonkey®) conducted between July 09, 2021, and August 07, 2021. The participants were invited to take part in the survey through an email with an invitation message and a web link for the survey. The contact details of the laboratories were accessed from the NABL website and the Christian Medical College, Vellore – Sir Ganga Ram Hospital, New Delhi IAMM EQAS program. The survey was accessible only to the participants who gave informed consent. Only one completed response was accepted from each center.

2.2. Questionnaire design

A 58 item questionnaire (Appendix A) was developed and reviewed by all the authors. The majority of the questions were set as closed-ended (yes or no and multiple choice) except for a few open-ended questions. The survey was conducted only in English.

2.3. Statistical analysis

Data were exported to MS Excel® using the SurveyMonkey® platform. The quantitative data was represented in descriptive statistics and all the analyses were done using Microsoft Excel and R programming language.

3. Results

3.1. Demographics

The survey reached out to 1182 participants, out of which 721 (61%) laboratories completed the questionnaire. The average time taken to complete the survey was 11 min. The locations of the participating centers mapped and shown in Fig. 1. Among the laboratories that participated, 75.3% were located in urban, 16.4% in semi-urban and 8.3% were in the rural area. The laboratories were predominantly affiliated with the private sector (73.9%), followed by the Government (24.2%) and a few NGO/mission networks (1.9%). Most of the laboratories were associated with a tertiary care hospital (67.4%), whereas 23.8% were standalone diagnostic centers. The demographic details of the hospitals that participated in the survey shown in Table 1.

Table 1
Demographic details of the participating laboratories.

Demographics	Number	Percentage
Location of the laboratories		
Urban	543	75.3%
Semi urban	118	16.4%
Rural	60	8.3%
Affiliation		
Government	174	24.2%
Private	533	73.9%
NGO/Mission network	14	1.9%
Type of laboratory set up		
Standalone diagnostic facility	172	23.8%
Laboratory associated with a primary care hospital	17	2.4%
Laboratory associated with a secondary care hospital	46	6.4%
Laboratory associated with a tertiary care hospital	486	67.4%
Bedded facility of hospital to which laboratory provides service		
<100 beds	28	3.9%
101–250	134	18.6%
251–500 beds	135	18.8%
501–1000 beds	161	22.3%
>1000 beds	92	12.7%
Not associated with a single hospital	171	23.7%
Radius covered by laboratory services		
<10 kms	197	27.4%
10–50 kms	303	42.1%
>50 kms	219	30.5%

3.2. Laboratory capacity and infrastructure

Overall, 82.3% of the laboratories had a computerized laboratory information system and automation facility. During pre-COVID times, only 39% (282/721) of the laboratories had an RT-PCR system being used for routine diagnostic purposes. The remaining 61% (439/721) of the labs set up an RT-PCR testing facility during the pandemic. The COVID-19 testing platforms were newly set up in 535 laboratories by using institutional funding (409/535, 76.45%) and by Government/other grants (126/535, 23.55%). In 186 laboratories, an existing platform was used for COVID-19 testing. Overall, the majority of them reported COVID-19 results within 24 h of turnaround time.

3.3. Diagnostic assays

Overall, 696 out of 721 laboratories responded to the question that aimed to distinguish the type of platform used for COVID-19 testing. 292 (41.9%) laboratories used only one platform for COVID testing, 236 (33.9%) labs used two platforms, 129 (18.5%) labs with three different methods, and 39 (5.7%) labs had more than three methods. Among the diagnostic methods used, 514 labs used open system RT-PCR assay, 217 labs used Truenat® assay, 188 labs used GeneXpert® assay, 31 used Abbott ID Now® and 350 labs performed rapid antigen tests. In these, 54 labs performed only rapid antigen assays. The data on number of samples from rapid antigen assay sent for any confirmatory PCR test was not available. Among these centers, 435 out of 696 (62.5%) of the laboratories performed COVID antibody testing. The most common assay used was CLIA (62.5%) followed by ELISA (31.3%) and the remaining performed other methods.

3.4. NABL accredited medical testing laboratories

Overall, 33.6% of the laboratories were NABL accredited prior to COVID-19 pandemic. When COVID-19 molecular testing accreditation was questioned, 55.3% got accreditation and 7.4% were in the process of application. Among the remaining 37.3% of non-accredited COVID-19 molecular testing labs, 52.1% were private labs, 46.8% were Government institutions and 1.1% were NGO/mission hospital labs. When COVID-19 serological testing accreditation was questioned, 76.1% responded that they did not have accreditation. Owing to an increasing number of mucormycosis cases during the COVID-19 pandemic, a question on fungal testing capability was added, which showed that 81.7% of the labs did not have accreditation for the same.

3.5. Laboratory quality control and assessment

Among the laboratories that participated in the survey, 88.9% used an IVD/FDA-approved diagnostic assay. Of them, 92.4% performed an internal evaluation before implementing the assay in the lab. Most of them (83.6%) performed precision and accuracy testing of their diagnostic method as a part of their routine internal quality assessment. Around 66% of the laboratories were a part of the external quality assessment (EQAS) program run by Christian Medical College Vellore and Sir Ganga Ram Hospital, New Delhi in bacteriology and virology. During the pandemic, 80.7% of the laboratories participated in the ICMR – COVID quality control assessment.

The testing capacity, platforms used, details of accreditation, the impact of the pandemic on these parameters and the lessons learnt had been mentioned in detail in Table 2.

Table 2
Impact of COVID-19 pandemic in laboratory capacity building and accreditation.

Parameters	Pre COVID	Post COVID	Observation	Insights
Availability of RT PCR testing facility in laboratories	39%	61% (Newly added)	Molecular testing was made available in most of the teaching hospitals and secondary care hospitals during the pandemic	As laboratory personnel are trained to perform molecular testing, the platform can be utilized to diagnose other bacterial and viral diseases on a routine basis.
SARS-CoV2 platform set up	NA	NA	25.1% used old platform 57.3% bought new equipment by institutional funding 17.6% bought new equipment funded by Government/other grants	During a short span of time, it was noted that adequate funding was allocated for COVID-19 both from national level and each institutional level. In future, special budget to be allotted for infection control and outbreak management in national level and in each hospital.
SARS-CoV2 diagnostic assays	NA	NA	Real time PCR (open) – 41.9% 2 platforms – 33.9% 3 platforms – 18.5% >3 platforms – 5.7% Platforms like Real time RT-PCR (open), True Nat assay GeneXpert assay, Abbott ID Now, Agappe RT-LAMP assays, Tata MD Check CRISPR assays were used (in the order of highest usage).	Even though multiple methods are available, the cycle threshold (ct) value for reporting positivity differs across each platform which makes the comparability and accuracy of results debatable. Assessing the infectivity of the patient based on the ct values is in practice which is not acceptable because of various pre-analytical and analytical factors that affect the ct values. Hence appropriate guidance based on clinical correlation and lab results to be considered. With increase in caseloads, point of care assays need to be considered in future for rapid turnaround time, reduced cost, and ease of usage.
SARS-CoV2 antibody tests	NA	NA	Most of the labs used CLIA (62.5%), ELISA (31.3%) and remaining performed other methods Lack of standard cut offs Antibody targeting the antigens differs across each kits used the labs	Lack of standardized quantitative titers makes comparability of test results difficult. With duration and protection of antibodies against SARS-CoV2 still under research, utility of antibody tests needs guidance and regulations through national authorities.
NABL accreditation for COVID-19 molecular testing	NA	55.3%	Among the 37.3% laboratories not accredited yet, 140/269 (52.1%) were private labs, 126/269 (46.8%) were Government centers, and 3/269 (1.1%) were NGO/Mission centers.	The importance of accreditation and quality of testing to be promoted and guidance to be given to Government and private standalone laboratories.
NABL accreditation for COVID-19 serological testing	NA	14.7%	Only 14.7% of the labs performed serological testing.	
NABL accreditation for fungal testing	15.0%	3.3% (Under process)	Due to increased reporting of mucor cases during COVID-19 pandemic, mucormycosis was included in the notifiable diseases list. Hence resources to identify mucor was made available in laboratories.	Training of clinicians in sample collection and processing of samples and identification of fungi for laboratory professionals to be promoted through educational sessions from expert centers.

NA – Not applicable.

3.6. Infection control practices

When the N95 respirator usage policy was questioned, around 58.6% of the labs followed a single usage policy, 22.5% reused after 72 h of drying, 10.5% reused after 48 h of drying, 5.3% reused after sterilization, and 3% used other methods (Table 3). Most of the laboratories (89.2%) used biosafety level 2 or higher-level safety cabinets for processing COVID-19 samples. As per the biomedical waste management guidelines, around 97.28% had an autoclaving facility to treat the laboratory wastes by themselves. When looking at the concentration of sodium hypochlorite used to disinfect COVID-19 wastes, 76.9% used the standard recommendation of 1%, whereas the remaining used varying concentrations in the range of 0.01–5% (Table 3).

The policy of pre-operative screening for COVID-19 varied across the nation, wherein 32.2% performed screening 24 h before surgery, 24.6% used 48 h policy, 21% used a more than 72 h policy and the remaining 22.2% were standalone labs and hence it was not applicable. During the second wave of the pandemic, 19.16% of the hospitals still performed repeat swabbing for discharging the COVID-positive patients. Among the participating centers, 57% of the laboratories followed a one-week quarantine policy after one week of work during the first and second waves. If any exposure occurred for a health care worker, 39.5% of the laboratories followed quarantine for 14 days and testing before joining duty and 24.2% without testing; 19.5% followed 7 days quarantine and testing; 12.4% followed 10 days quarantine and testing and 4.5% followed other policies (Table 3). When asked about COVID-19 vaccination, 74.9% of the laboratories had a mandatory vaccination policy.

4. Discussion

This survey results captured the experience of laboratory professionals during the COVID-19 pandemic in India. It has been observed in our survey that only 8.3% of the participating labs were located in rural areas. Even though the testing facilities were widespread and built up faster in cities, rural parts of India need further improvements in the health care delivery and laboratory infrastructure capacity [7]. 75% of the rural labs were private, 23.33% belong to Government and 1.67% were NGO/mission hospital affiliated labs. In these labs from rural areas, 58.33% got NABL accreditation for COVID molecular testing. Among the diagnostic methods used, 48 labs used open system RT-PCR assay, 20 labs used Truenat® assay, and 34 labs performed rapid antigen tests. This showed that molecular level diagnostic assays can be set up in rural laboratories with appropriate training and infrastructure assistance. As we have a three-tier system in rural India that includes primary health centers, sub-centers, and community health centers, basic laboratory setup and training of technicians in these areas will prepare us for future pandemics.

COVID-19 pandemic has taught us that clinical laboratories and molecular testing play a crucial role in early diagnosis, thereby controlling the spread of cases and the management of the disease [8]. Almost all the laboratories used guidance released by the ICMR in procurement,

Table 3
Impact of COVID-19 pandemic in IPC practices.

IPC measures	Observation among laboratories/ hospitals	Impact	Lessons learnt
N95 mask policy	Single usage policy was observed in 58.6%. Re-use after drying for a period of 48–72 h was observed in 33%. Re-use after sterilization in 5.3%	Re-use policy was advised only for FDA approved N95 masks which cannot be made applicable for other varieties of masks. Effectiveness of sterilization for different quality of masks was questionable.	Manufacturing units can be scaled up in India Quality of N95 masks to be tested and certification should be made mandatory Fit testing kits and rationale usage of masks should be emphasized
Validity period of COVID-19 for pre-operative screening	24 h before surgery – 32.2% 48 h before surgery – 24.6% >72 h before surgery – 21.1% Not applicable – 22.1%	No standardized national guidelines for universal screening of patients before surgery during the first wave and second wave of pandemic Financial burden for patients due to repeated screening without appropriate rationale and evidence	Nationwide guidelines were released by ICMR during the third wave stating that pre-operative screening for asymptomatic patients is not needed
Repeat COVID-19 testing for discharging patients during the second wave	19.16% repeated COVID-19 test for discharging the patients	Based on the available evidence, the viral shedding has been shown for a prolonged period which will give the test result as positive even if non-infectious. Prolonged period of hospital stay can lead to other complications and secondary infections if COVID negativity is considered as a discharge criterion	ICMR has released guidelines that the repeat COVID testing is not needed for discharging patients. Hospitals and public should be aware of the national policies and strict adherence to the policies can be promoted through training sessions and effective communication.
Quarantine of health care workers after COVID-19 exposure	Quarantine for 7 days and testing is compulsory before joining duty – 19.5% Quarantine for 10 days and testing is compulsory before joining duty – 12.4% Quarantine for 14 days and testing is compulsory before joining duty – 39.5% Quarantine for 14 days, no testing, can join duty if asymptomatic – 24.2% Others – 4.5%	Due to manpower constraints, the policy differed across institutions in India.	Judicious use of testing and manpower allocation to be foreseen and strengthened in future pandemics.
Vaccination policy among health care workers	74.9% of the laboratories had mandatory vaccination policy	Overall, the percentage of vaccination was more than 90% among the laboratory professionals	Due to high-risk exposure among laboratory professionals, vaccination should be promoted among all the categories of health care workers.
Disinfection of COVID-19 areas	76.9% used 1% sodium hypochlorite Remaining labs/hospitals used varying concentrations between 0.01% and 5%	Long term usage of sodium hypochlorite is found to be corrosive to few surfaces.	Appropriate/equivalent disinfectants that can disinfect COVID-19 can be tested and certified by national authorities. Surface compatibility need to be checked and alternate equivalent disinfectants should be added in the policies.

redeployment, and usage of point of care tests. To cope with the increased number of samples per day, increased manpower, adequate quality testing kits and commodities should be made available in an uninterrupted manner. When large-scale testing is done as a part of public health measures, a validated test kit that is used uniformly across the nation will help in reproducibility and reliability of the results. This has been promising in India as all the testing platforms were validated and approved by the ICMR (Table 4) [9]. Although serological testing was done in many centers, the interpretation of protection from reinfections based on the antibody titres was questionable as this is still a grey area under research.

The use of molecular diagnostic assays helped in early detection of the disease thereby containing the spread by means of home isolation or by triaging the patients in hospital setting. Routinely, molecular diagnostic techniques were not widely used in all tiers of health care set up. COVID-19 pandemic paved a way to equip the laboratories and helped to train the technicians in molecular diagnostics especially PCR. In a study published by Gupta et al., 2020, it has been shown that all the virus research and diagnostic laboratories (VRDLs) who shared their samples for quality control with NIV, Pune had 100% concordance with negative results and low concordance with borderline positive samples (ct value between 33 and 35 cycles) [2]. Although very helpful in triaging or early detection, the variations in the reporting of positive samples based on the cycle threshold (ct) values makes it difficult to compare the results and hence standardization of ct values for kits manufactured in India is the need of the hour.

Accreditation is a process in which an accreditation body (Eg: NABL) awards formal recognition that a body or a person is competent to carry out the scope of diagnostic assays [10]. This accreditation process during the COVID-19 pandemic has helped to improve the accuracy and precision of the reports (Table 4). This will also help to sustain the practices of timely delivery of reports, following SOPs/protocols, adequate training of staff, and practicing quality checks by participating EQAS program. In the remaining non-accredited labs, the importance of accreditation needs to be strengthened through education and awareness.

Even though the Ministry of Health and Family Welfare, India constantly updates the guidelines based on the new evidence related to SARS-CoV2, the practices differed across each laboratory/institution based on their availability of resources, manpower, and cost. Ideally, N95 mask is defined only for single use; but in this pandemic crisis, it was noticed that 41.4% of the laboratory professionals were re-using N95 masks (even in July 2021). This has also been seen in an observational study that showed that only 64% of the HCWs used masks rationally [11]. This can be avoided by maintaining uniformity in the quality and the cost of N95 masks/PPE supply across the country through a testing and certifying body like the FDA [12]. A national-level occupational health and infection control expertise with certification can be enforced in each

Table 4
National Initiatives during the COVID-19 pandemic.

Organization	Events/Initiatives during the COVID-19 pandemic
Indian Council of Medical Research	Identification of SARS-CoV2 in January 2020 as in the very early phase of the first wave
	Initiation and validation of indigenous test kits
	Setting up VRDLs
	Testing advisories and guidelines
	National task force for COVID-19 was established
	Surveillance of asymptomatic cases and research on community prevalence
	National policies on COVID-19 along with the Ministry of Health and Family Welfare, India
	Collaboration with the private laboratories for COVID-19 testing
	Quality control program for COVID-19 testing by setting up regional QC labs for each state.
	Introduction of digital platform for COVID-19 testing (RT-PCR app and ICMR portal) and maintaining database of all COVID-19 tests
	Setting up National Clinical Registry for COVID-19, special registry for pregnant women with COVID-19
	Funding and assistance for COVID-19 related research activities across India
	Clinical trial of COVAXIN in partnership with Bharat Biotech
National Institute of Virology, Pune	SARS-CoV2 isolation and sequencing for the first time in India (5th in the World – March 2020)
	Laboratory set up in Iran by NIV scientists
	Training and capacity building all over the nation
	Genome sequencing and characterization
	Setting up genomic consortium (INSACOG)
	Isolation of new variants and strains (VUI-202012/01 of the B.1.1.7 lineage, SARS-CoV-2 V501Y·V2 variant (B.1.351)
	Study on neutralization of variant under investigation B.1.617 with sera of BBV152 vaccinees
	Animal studies and various research projects in COVID-19
National Accreditation Board for Testing and Laboratories, India	Links to obtain ISO Standards free of cost to combat COVID-19 crisis was published by NABL
	NABL has introduced separate application process for laboratories testing RNA viruses using RT-PCR technique testing
	NABL accredited molecular testing labs were empaneled in accordance with the ICMR requirements
	NABL used ICT tools and worked round the clock to assess the competence of applicant laboratories before granting accreditation

hospital/lab to protect the health care workers from communicable diseases in workplace settings.

4.1. Gaps identified in pandemic control measures

The nation-wide network of laboratories helped in predicting the surge through mathematical modelling using the confirmed cases reported to ICMR during the first and the second wave of the pandemic. It was well documented that the SARS-CoV-2 virus can rapidly evolve and mutate so that it can maintain its virulence and can escape from pre-existing immunity obtained from prior infection or vaccination [13]. In this situation, the genomic surveillance played an important role in constantly being vigilant for new strains that evolve in the community. The Indian SARS-CoV-2 Genomic Consortium (INSACOG) launched in 2020 had 10 national laboratories which further expanded to 28 more labs to monitor the genomic variations all over the country [14]. When the highly infectious Omicron (B.1.1.529) wave hit India in late 2021, it was noted that only 2–3% of the positive samples were subjected to sequencing. As Omicron presented as a mild disease, there was no major impact on mortality and hospital admissions. But keeping in mind future respiratory outbreaks, more centers need to be strengthened with whole genome sequencing (WGS) facilities. This will help to predict a future wave and to determine the efficacy of COVID-19 vaccination.

4.2. Limitations of the study

Firstly, this survey was conducted before the third wave caused by Omicron strain in India. Hence the results do not reflect the preparedness of laboratories to tackle the enormous testing capacity that was needed during the third wave. Secondly, this study was an invited voluntary survey and hence it did not cover the entire COVID laboratory network in India. Most of the participating laboratories were from Tamil Nadu, Karnataka, Maharashtra followed by Kerala, Uttar Pradesh, Telangana, and West Bengal.

5. Conclusion

The global threat raised by the COVID-19 pandemic had created a high-quality standard molecular laboratory network in India. The lessons learnt during the first wave of the pandemic have made a great difference in operationalizing and managing the second wave in India. These survey findings helped us to understand the strength and efficiency of laboratories in India in setting up molecular assays during a crisis time. This helped in early detection, containment, isolation and management of the patients. Based on our findings, we propose to connect this network in a sustained regular manner for routine diagnostic molecular services and also to efficiently utilize the existing platforms to adapt to future pandemics.

CRediT author statement

Malathi Murugesan: Conceptualization, Methodology, Resources, Validation, Formal analysis, Data Curation, Writing- Original draft & Editing. **Reena Raveendran:** Conceptualization, Methodology, Resources, Validation, Formal analysis, Writing - Review & Editing. **Rajesh Kannangai:** Conceptualization, Resources, Validation, Writing - Review & Editing. **Jagadish Ramasamy:** Conceptualization, Methodology, Formal analysis, Data Curation, Writing - Review & Editing. **Pallab Ray:** Conceptualization, Validation, Writing - Review & Editing. **Mallika Gope:** Conceptualization, Resources, Writing - Review & Editing. **Venkateswaran Natarajan:** Conceptualization, Resources, Writing - Review & Editing. **Kamini Walia:** Conceptualization, Writing - Review & Editing. **Balaji Veeraraghavan:** Conceptualization, Methodology, Resources, Validation, Data Curation, Writing - Review & Editing, Supervision, Project administration. **Chand Wattal:** Conceptualization, Methodology, Resources, Validation, Data Curation, Writing - Review & Editing, Supervision, Project administration.

Ethics approval

The EQAS activity was granted exemption from ethical clearance by "Institutional Review Board" from Christian Medical College, Vellore, India and granted ethical clearance from Sir Ganga Ram Hospital, New Delhi.

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Conflicts of interest

None.

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Appendix A. Supplementary data

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