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Original Research Article

Testing guidelines and strategies by ICMR: a roadmap to handle COVID-19 pandemic in India

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ABSTRACT

Background: Since the inception of the COVID-19 pandemic, the cases are continuously increasing in India. Though this growth of the cases was relatively slower during the initial phase of the pandemic, now the cases are increasing rapidly and positioned the country at third place in the world in the COVID-19 tally. This study was done to review all the guidelines and strategies released by the ICMR and MoH and FW, Government of India, in regard with the testing of COVID-19 in the country and to collate them with timelines.
Methods: Country-level data was retrieved from the crowdsourced database and was analyzed descriptively to calculate the cumulative and per day test positivity rates.
Results: A sharp rise in the test positivity rate was observed until the first week of April, which declined slightly during the next month. After that, the test positive rate is found to be continuously increasing. At the same time, the testing capacity of the country has also increased from about 250 tests per day at the beginning of March to 6.42 lac per day by the end of July. ICMR put a lot of effort into the expansion of the laboratory network to ramp up the COVID-19 testing capacity in the country. Without having any delay, dynamic guidelines, and strategies for testing with a lot of innovations were developed and implemented maintaining all the quality and safety parameters.
Conclusions: ICMR worked tirelessly on the forefront to devise a roadmap to handle the COVID-19 pandemic in India through the development of testing strategies and guidelines.

Keywords: COVID-19, Laboratory, Pandemic, Testing

INTRODUCTION

The world is striving to fight against COVID-19 by adopting different dynamic strategies for detection, prevention, and management. Similar to other countries, guidelines were evolved in India since the inception of this pandemic. Though this pandemic was quite slower in India in the initial phase which may be due to early and strict government interventions (especially lockdown) and fear among people.[1] But post lockdown, the cases increased rapidly and positioned the country at third place in the world in the COVID-19 tally.

As of 31st July 2020, India accounts for around 9.9% of the global caseload, despite having 17% of the world's population.[2] At the same time, the testing capacity of the country has also increased exponentially. A total of 1,93,58,659 tests have been conducted for SARS-CoV-2 till 31st July 2020 in the country.[3] This study was done to assess the trends of COVID-19 testing in India and review the existing testing guidelines and strategies.

METHODS

A descriptive study was conceptualized on the evolving guidelines developed by the indian council of medical research (ICMR), the apex body in India for the formulation, coordination, and promotion of biomedical research. During the pandemic, ICMR attempted to address itself to the growing demands of finding practical solutions to health problems in the country. Reporting was done according to STROBE guidelines.

Secondary data analysis was performed on all the available raw data from the inception of the COVID-19 pandemic till 30th July 2020 , retrieved from the crowd sourced database, which includes the reporting from state and central Government agencies in India.[3] Further, Cumulative and per day test positivity rates were calculated and their trends were plotted with the trend of the testing capacity of the country. To avoid the extreme variations in test positivity rates, due to spikes on particular days, a seven-day moving average was taken. All the available guidelines and circulars related to the COVID-19 testing in the country were retrieved from the Indian Council of Medical Research (ICMR) and Ministry of Health and Family Welfare (MoH&FW) websites and reviewed.[4,5]

RESULTS

The testing capacity of the country has increased from about 250 per day at the beginning of March to 6.42 lac per day by the end of July. A sharp rise in the test positivity rate was observed until the first week of April, which declined slightly during the next month. After that, the test positive rate is found to be continuously increasing (Figure 1). Indian council of medical research (ICMR) worked tirelessly on the forefront to develop the testing strategies and guidelines for the country. Those efforts are broadly categorized into the following domains.

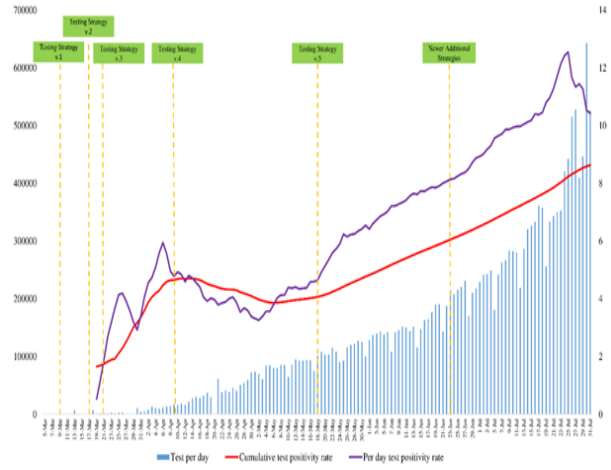

Figure 1: Trends of tests per day and test positivity rate in India.

Expansion of laboratory network

At the outset, state nodal and testing viral research diagnostic laboratories (VRDLs) were identified as the state nodal laboratories for noble coronavirus (nCoV) testing. A state-wise list of laboratory networks (VDRLs) was released on 12th Mar, in which a total of 106 VDRLs were identified for COVID-19 testing in the country. To strengthen the testing across the country, 25 government VRDLs were provided with RT-PCR machines to enable testing at those labs. To expand the testing capacity further, it was decided to involve the private labs for COVID-19 testing. A proforma for the requisite information from interested private labs was circulated for this purpose. Till 5th April, more than 200 laboratories were approved across the country for COVID-19 testing. Based on the requests from several districts of India for the initiation of COVID-19 testing, the guidelines were formulated for the establishment of new testing laboratories in the districts. Applications were also invited from the interested government and private medical colleges in the country for establishing a COVID-19 testing facility. In this regard, the guidelines for minimum infrastructure and expertise were given to all medical colleges. To further ramp up the testing, ICMR expressed its no objection to the adoption and establishment of convenient sample collection sites by the state Governments.

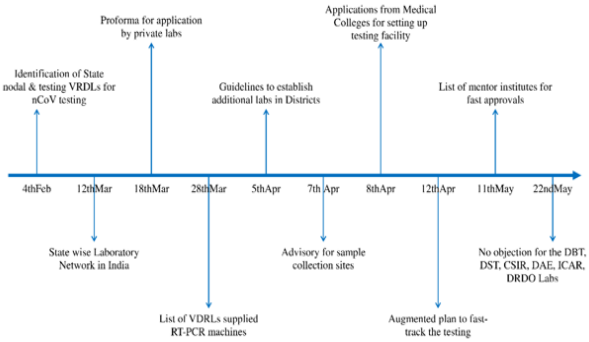

Figure 2: Milestones of strategies to expand the labs for COVID-19 testing in India.

Further, to fast-track the testing laboratory scale-up process, a proactive search of potential laboratories in the country was done. Fourteen centers of excellence were identified and designated with the responsibility of mentoring all the government & private medical colleges in their catchment areas and eventually creating state-of-art molecular virology setups. To hasten this process, a list of mentor institutes along with allocated states was released to review the requests for approving any new laboratory for COVID-19 testing. ICMR also expressed no objection to the initiation of COVID19 testing in Government laboratories operating under the Department of Biotechnology (DBT), Department of Science & Technology (DST), Council of Scientific & Industrial Research (CSIR), Department of Atomic Energy (DAE),

Indian Council of Agricultural Research (ICAR) and Defense Research and Development Organization (DRDO) (Figure 2).

Quality assurance and safety

A detailed guideline to ensure the proper collection, packaging, and transport of clinical samples of 2019-nCoV to ICMR-National institute of virology (NIV), Pune for diagnosis was released on 24th January 2020. Standard operating procedures (SOPs) were devised for the NIV, Pune for the detection of 2019-nCoV by RT-PCR in first-line screening as well as confirmation assay. The SOPs for the manufacturer of RT-PCR kit (BGI) was also put in place. To maintain the uninterrupted testing in the country, a memo was released to all the notified COVID-19 testing labs to remain open for all 7 days in the week. To ensure an uninterrupted supply of reagents for COVID-19 testing, states were given guidelines to procure the reagents for labs doing RT-PCR.

A notification was given for private laboratories in India to ensure about NABL accreditation and to follow the national testing guidelines for COVID-19, along with an addendum instructing them not to amplify the virus by culture or sequence from any positive sample. In all the circulars, GoI had given the advisory to ensure the use of recommended Personal Protective Equipment (PPE), regular disinfection, and implementation of biosafety and biosecurity precautions. On 29th March health ministry also came up with an SOP for transporting suspect/confirmed case of COVID-19 using all the safety precautions. Sample collection sites were also advised to maintain proper cold-chain conditions while transporting the samples to the nearest COVID-19 testing laboratory. Though, Government of India decided not to conduct any site assessment or accord approval for initiation of testing at government laboratories operational under DBT, DST, CSIR, DAE, ICAR, and DRDO but recommended them to ensure minimum safeguards before initiation of COVID-19 testing. ICMR also designed a prototype of the mandatory specimen referral form (SRF) for collection centers/labs to enter details of the samples being tested for COVID-19.

In the initial phase, all the designated labs were assigned the responsibility of ensuring the collection and transportation of suspected samples to ICMR-NIV, Pune. But, considering the surge in testing across the country with time, it was advised to store the positive samples by ICMR approved labs instead of sending all of them to NIV, Pune. The guidelines were also released for the storage of respiratory specimens collected for COVID-19 testing in government labs for various purposes such as performing additional tests, quality control, research, and assessing newer diagnostic tests. All the COVID-19 testing labs were mapped with different quality control labs to ensure the QC activities. They were instructed to send 5 random positives and 5 negative samples per month to QC labs for quality assurance purposes. A letter was sent to all the states to encourage private labs /hospitals to immediately apply for NABL. A mapping of COVID-19 RT-PCR testing laboratories with QC labs for Inter Lab Quality Control (ILQC) activity was also done (Figure 3).

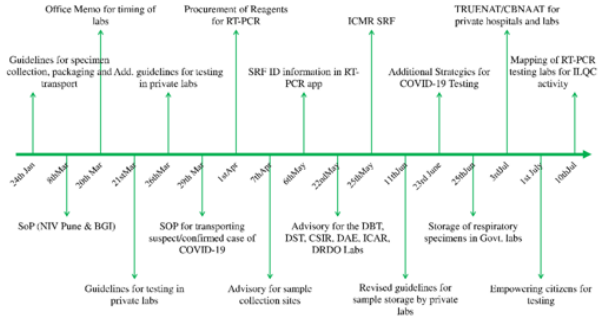

Figure 3: Proposed guidelines to maintain quality assurance in COVID-19 testing.

Dynamic testing strategies and guidelines

In the initial phase of this pandemic, it was considered that the disease was primarily reported in individuals with travel history to the affected countries (in the last 14 days) or close contacts of positive cases. Therefore, it was decided to send them for home quarantine for 14 days, and to perform testing on the development of respiratory symptoms within the quarantine period. After one week of the first version, on 17th Mar, the second version of the testing guidelines was released. In this along with the previous two strategies, it was also decided that all the health care workers who were managing respiratory distress/severe acute respiratory illness (SARI) would be tested when they become symptomatic. The symptoms were detailed as fever, cough, difficulty in breathing, etc. Positive cases were decided to be isolated and treated as per the standard protocol. On the same day, the discharge policy for COVID-19 patient was devised along with the case definitions for COVID-19. In this policy, the discharge criteria were based on two negative tests within 24 hours along with the radiographically clear chest.

The next version of the testing strategy was released immediately (20th March) after the second version. This time it was decided to test all the symptomatic individuals who had undertaken international travel in the last 14 days, who had h/o contacts of laboratory-confirmed cases, and who were health care workers. All hospitalized patients with SARI (fever AND cough and/or shortness of breath) were also decided to test. Asymptomatic direct and high-risk contacts of a confirmed case were decided to test once between day 5 and day 14 of coming in contact.

Health ministry released guidelines for quarantine facilities for COVID-19 on 5th April. According to this, the people on quarantine were decided to undergo testing at baseline and the end of 14 days of the incubation period. Negative test result at resampling was considered as

discharge criteria from quarantine. In the same week, ICMR released an advisory to start rapid antibody-based blood test for COVID-19 for large migration gatherings/ evacuees centers, in which all symptomatic persons having Influenza-Like Illness (cough, cold, low-grade fever, sore throat) were decided to be tested with a rapid antibody-based blood test during their home quarantine for 14 days. Later on, this guideline was modified and adopted in version four of the testing strategy which was released on 9th April. Along with all the criteria of v.3, it was decided that in hotspots/clusters and large migration gatherings/ evacuees centers all symptomatic ILI (fever, cough, sore throat, runny nose) will be tested by RT-PCR within 7 days of illness. For illness detected after 7 days, the antibody test would be conducted and followed by RT-PCR in case of a negative result. On 17th April, ICMR released a protocol for using rapid antibody tests in hot spots for epidemiological studies and surveillance purposes. This was denoted as a supplementary tool to assess the prevalence of the diseases within a specific area/perimeter. In this direction, ICMR also arranged and made available rapid antibody test kits (Guangzhou Wondfo Biotech and Zhuhai Livzon Diagnostics) to all the states and sent instructions to reinforce its use for surveillance purposes only. But, after raising the issue regarding the performance of those kits by certain states, ICMR tested them in field conditions and found wide variation in their sensitivity. So, ICMR had to direct the states to immediately stop using those kits.

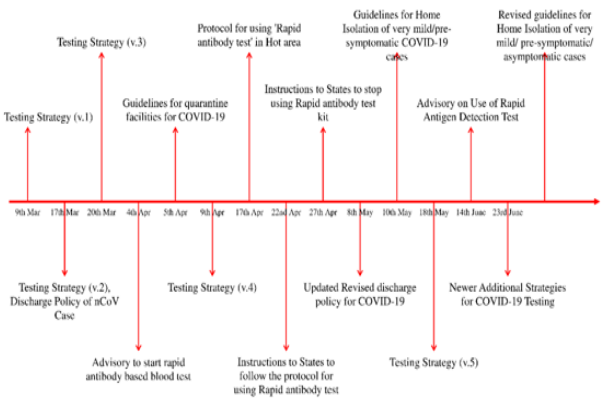

Figure 4: Dynamic COVID-19 testing strategies and guidelines for the country.

The discharge policy for COVID-19 patient was updated on 8th May. This time only severe cases including immune-compromised patients (HIV positive, transplant recipients, having malignancy) were decided to test after the resolution of symptoms at the time of discharge, and pre-symptomatic, very mild, mild, and moderate cases were advised to discharge after the resolution of symptoms without undergoing testing. After 2 days (on 10th May) the guidelines were also revised for home isolation of very mild/pre-symptomatic COVID-19 cases, and decided not to conduct any test after the home isolation period is over. This was again revised on 2nd July maintaining the same policy to declare the completion of the home isolation period for very mild/ pre-symptomatic/ asymptomatic COVID-19 cases.

The fifth version of the testing strategy was released on 18th May 2020 with precise definitions of ILI and SARI cases. Along with all symptomatic (ILI symptoms) health care workers, symptomatic frontline workers involved in containment and mitigation of COVID19 were also decided to test. Asymptomatic direct and high-risk contacts of a confirmed case were decided to be tested once between day 5 and day 10 (instead of 14) of contact. Besides having all the guidelines of v.4, it was also decided to test the hospitalized patients who develop ILI symptoms and the symptomatic ILIs among returnees and migrants within 7 days of illness. It was clearly instructed that no emergency procedure (including deliveries) should be delayed for lack of test.

In view the high specificity and relatively low sensitivity of 'Standard Q COVID-19 Ag detection kit', ICMR recommended the use of a rapid antigen detection test for COVID-19 as a point of care diagnostic assay for testing in the containment zones or hotspots and healthcare settings in combination with the gold standard RT-PCR. Despite all these strategies, the accessibility and availability of testing were a big challenge for the country. To address this issue, ICMR decided to increase the outreach of testing by introducing rapid point-of-care (POC) antigen detection test for diagnosis (along with RT-PCR) and IgG based antibody tests for surveillance as newer additional strategies for COVID-19 testing along with the existing strategies (RT-PCR, TrueNat and CBNAAT) (Figure 4).

Innovations in testing

Though the country was in lockdown during April 2020, the COVID-19 cases were continuously rising. At that time, it was essential to increase the testing capacity of the laboratories. So, based on the feasibility study conducted at King George's Medical University (KGMU), Lucknow, ICMR released an advisory on the feasibility of using pooled samples on 13th April. The objective was to increase the capacity of the laboratories for screening the increased numbers of samples using molecular testing for COVID-19. This was approved for surveillance in areas with a low prevalence of COVID-19 (positivity of ≤5%), and five were the maximum number of samples recommended to be pooled (except for research). Given this, the health ministry recommended using pooled samples (25 numbers) in district-level facilities for the surveillance of COVID-19 on 11th May. Guidelines regarding RT-PCR-based pooled samples were also released on 14th May.

ICMR proposed the detection of SARS-CoV-2 in human clinical specimens using TaqPath™ COVID-19 Combo Kit, and develop an SOP in this regard. Besides expanding the horizon of the testing through implementing antibody assay and antigen detection tests along with RT-PCR,

ICMR validated the TrueNat™ beta CoV test on the Truelab™ workstation and recommended it as a screening test with a detailed guideline for its proper implementation. Later on, the TrueNat system was declared as a comprehensive assay for screening and confirmation of COVID-19 cases without confirmation by RT-PCR. Further, an advisory for the use of Cartridge Based Nucleic Acid Amplification Test (CBNAAT) using Cepheid Xpert Xpress SARS-CoV2 for use under an emergency use authorization was also released. On 3rd Jul a letter was sent to all the states to expedite the approval of TrueNat/CBNAAT for COVID-19 testing in private labs/hospitals (Figure 5).

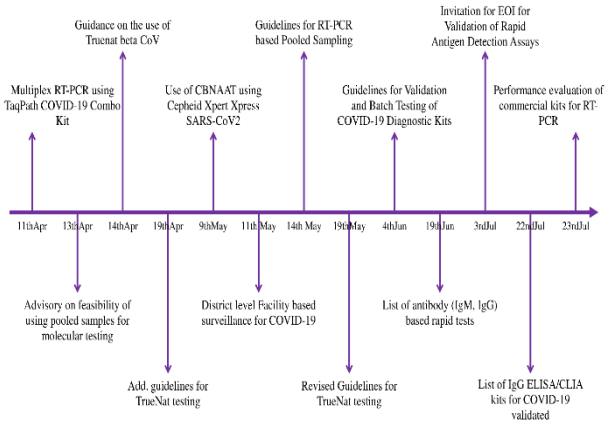

Figure 5: Innovative strategies to expand COVID-19 testing in the country.

As India started lifting lockdowns in a phased manner, an upsurge in cases was expected after June. In view of this, it was important to scale up the testing capacity to the maximum possible levels. ICMR released guidelines for validation and batch testing of COVID-19 diagnostic kits (other than US-FDA approved). A total of 24 institutes (9 ICMR, 5 DBT, 3 CSIR, and 7 others) across the country were identified for this purpose.

ICMR released a list of 56 validated antibody-based rapid test kits. They also invited applications for the validation of rapid antigen detection tests for COVID-19 and identified 9 sites for such a validation process. Reports on performance evaluation of commercial kits for RT-PCR IgG ELISA/CLIA for COVID-19 from those identified sites were released on 23rd July. Besides all these efforts to upsurge the testing capacity in the country, ICMR also advised performing antibody-based testing among all government and private hospitals, offices, and other public sector units, so that the fear and anxiety of health care workers and office employees could be alleviated.

A letter was sent to chief secretary/ administrator/ advisor to governor/ advisor to Lt. Governor for empowering citizens for testing of SARS-CoV-2 virus to save precious lives and contain the virus.

DISCUSSION

ICMR stood as a dynamic regulatory body in the formation of different strategies for the detection, prevention, and management of COVID-19 in the country. The prime effort was to identify and establish the potential laboratory network in various states to fast-track the COVID-19 testing. This paper has tried to assess and summarize the guidelines issued by the Indian council of medical research (ICMR) for the country to handle the COVID-19 pandemic.

At the inception of this pandemic, the whole world was struggling to find out the ways to manage this pandemic. As the disease was new to the world, there was a huge shortage of the lab facilities for the detection of COVID-19 in all the countries including India. ICMR released various guidelines in different timelines for the expansion of laboratory networks for COVID-19 testing in the country.[6] Besides providing the guidelines, the resources were also mobilized to the identified laboratories. With these efforts to ramp up the laboratory network, by 30th July Government of India (GoI) had approved a total of 1331 COVID-19 testing labs in the country in both public (911) and private sector (420).[5]

Along with the expansion of the laboratory network, the Government of India strived to maintain the quality and standards for COVID-19 testing in India since the inception of this pandemic. In this regard, various guidelines were released to assure the quality of testing by laboratories.[6,7] Besides maintaining the quality control, ICMR also focused on research initiatives to explore the newer diagnostic modalities for COVID-19. Safety of the health care workers was also ensured in all the circulars and guidelines released by GoI.

The first case of the COVID-19 in India was reported on 30th January 2020, and another two cases were reported on 2nd and 3rd February. For the next month (3rd Feb to 1st Mar), no case was reported in the country. From 2nd March onwards, the cases started increasing, and till 9th March there were 48 cases of COVID-19 in India[3] when the first version of the testing strategy for COVID-19 was released for the country. As the understanding of the disease increased with time, these testing strategies and guidelines were frequently changed by Government of India and kept them dynamic.[8] Along with the testing and other guidelines, discharge policies for the COVID-19 patients from hospitals were also released time to time.

Along with those efforts, Government of India was also proactive in developing innovations in the testing strategies and methods to increase the capacity of the laboratories for testing and maintain the surveillance mechanism. Guidelines about pooling the samples, using the rapid test kits for detection are some of the examples of those innovations.[6,8] (Table 1) depicts the comparison of those various testing methods. One of the study limitation is inability to acquire critical data during lockdown. The secondary data used for analysis may have some bias and prevent control over data.

Table 1: Comparison of various testing methods for the diagnosis of COVID-19 approved by the ICMR, India.

Variables	Molecular tests			Rapid tests	Antibody detection
Methodology	RT-PCR[9,10]	CBNAAT[11]	TrueNat[12,13]	Card tests[5]	ELISA/ CLIA[14]
Purpose	Diagnostic	Diagnostic	Diagnostic	Screening/ Diagnostic	Epidemiological
Recommended laboratory containment level	BSL-2	BSL-2	BSL-2	Bedside	Benchtop/ BSL-2
Specific target	Viral RNA (N, RNase P, RdRp, Orf 1a/b genes etc)	Viral RNA (N2 and E gene)	Viral RNA (RdRp gene)	Spike protein antigen/ Ab	IgG, IgM, IgA Abs against N, S1/S2 Ag
Test Format	Real Time quantitative PCR	Cartridge-based Real Time qualitative PCR	Chip-based Semi-quantitative Real Time PCR	Nitro-cellulose strip-based lateral flow assay	ELISA/ CLIA
Turn-around time[5]	4-5 hrs	1-2 hrs	1-2 hrs	Within 30 minutes	3-4 hrs
Sample	Nasal/Nasopharyngeal / Throat swab	Nasopharyngeal nasal, or mid-turbinate swab and/or nasal wash/aspirate specimens	Nasal/Nasopharyngeal / Throat swab	Nasopharyngeal swab(Ag)/ Serum or plasma (Ab)	Serum/ Plasma
Testing significance	Current infection	Current infection	Current infection	Current infection	Past infection
Sensitivity	71-98%[15]	PPA – 97.8% [11]	~100% (based on 18 samples)[16]	66% [17]	84.3% - 94.8% [12]
Specificity	>95% [10]	NPA- 95.6% [11]	~100% (based on 18 samples) [16]	96.6% [17]	97.6- 97.8% [17]
Detection time	At any stage/ asymptomatic	At any stage/ asymptomatic	At any stage/ asymptomatic	2-5 days post symptoms	5-20 days post symptoms

CONCLUSION

ICMR stood as a dynamic regulatory body in the formation of different strategies for the detection, prevention, and management of COVID-19 in the country. The prime effort was to identify and establish the potential laboratory network in various states to fast-track the COVID-19 screening. Further, the availability of quality testing kits and reagents maintaining the safety parameters were marked. The guidelines were reformed continuously on quarantine facilities including the International passengers to contain the spread of virus. Also, research and development was boosted in all spheres to handle the COVID-19 pandemic in the country by improving the surge of testing, and by developing innovative and dynamic testing strategies.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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