The Road Ahead for Smart Covid-19 Testing and Tracing in India

Devising an equitable, cost-effective, and scalable Covid-19 response amid vaccinations and gene mutations

The Rockefeller Foundation

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FOREWORD

The development of innovative solutions for robust healthcare system, continuous improvement to adapt to the emerging variants of SARS-CoV-2 and targeting maximum immunization coverage remain the components of an effective fight against Covid-19. The recent emergence of new variants and their spread means we need to maintain testing and tracing to complement vaccination to control the transmission of SARS-CoV-2. This report very lucidly elucidates steps that India can take to step up preparedness to tackle this pandemic and ensure an equitable response.

Towards an equitable pandemic response: To ensure a uniform pandemic preparedness, the country needs to scale up testing and make it cost-effective too. Variability of prices of RT-PCR tests across states can be countered through price capping; thus, increasing affordability for consumers, and viability for the private sector. States with robust health systems should be encouraged to optimize lab networks for safe storage and transfer of samples by the states that have relatively less robust health systems.

Stocking test kits of global quality standards through imports and domestic production will be a short-term strategy but eventually, the focus must shift to attaining self-sufficiency in the production of reagents to ensure testing is unperturbed over medium- and long-term duration. Besides, a seamless pandemic response will require an effective ecosystem with the combination of genomic surveillance, R&D, demand forecasting, procurement, and field operations at different administrative levels.

Demand forecasting for better preparedness: The next facet of response is its robustness. Predicting the demand for SARS-CoV-2 tests will ensure the industry has steady supplies for the future. Raw material reserves should, thus, be maintained so that our testing capacity doesn't dwindle when faced with an elevated demand. Robustness should be complemented with financial security for the industry. Effective integration of Indian test kit makers with global supply chains can be done by incentivizing the former for stepping up production and ease export restrictions on them when the domestic demand for test kits is low.

Digitalization and manual intervention to reach the last mile: A balance of deployment of digital tools and involvement of trained frontline workers, and community self-help groups, is necessary to effectively implement tracing and tracking across the country. SARS-CoV-2 transmission through clusters is responsible for a large number of cases and integration of retrospective tracing in contact tracing programmes will be effective in the reconstruction of chains of transmission. Implementation of digital technologies, which got a shot in the arm last year with the introduction of the National Digital Health Mission, will be imperative to both these exercises. However, maximum public good and minimum privacy invasion should be kept front and centre while implementing technology-based solutions.

Data sharing, building trust, and the power of communication: data generated in laboratories was shared quickly and made freely accessible. The information generated by researchers fed into policy decisions of governments across the world. The partnership between the government and scientific community supported by other stakeholders is unprecedented and has resulted in increased trust and confidence. Going a step ahead, a dedicated campaign to communicate the benefits of testing and tracing and encourage their uptake among the masses, who are important stakeholders in any health system, will bear better results.

Preparedness and not panic were strongly advocated as an effective strategy when the Covid-19 pandemic was in its early stages. Close to one year later, we still need to step up testing, effectively trace contacts and isolate those who test positive, strengthen healthcare infrastructure, and increase emphasis on better communication pushing for Covid-19 appropriate behaviour. This report is timely as it goes on to touch upon these points that are related to testing and tracing primarily.

by Prof. K. VijayRaghavan

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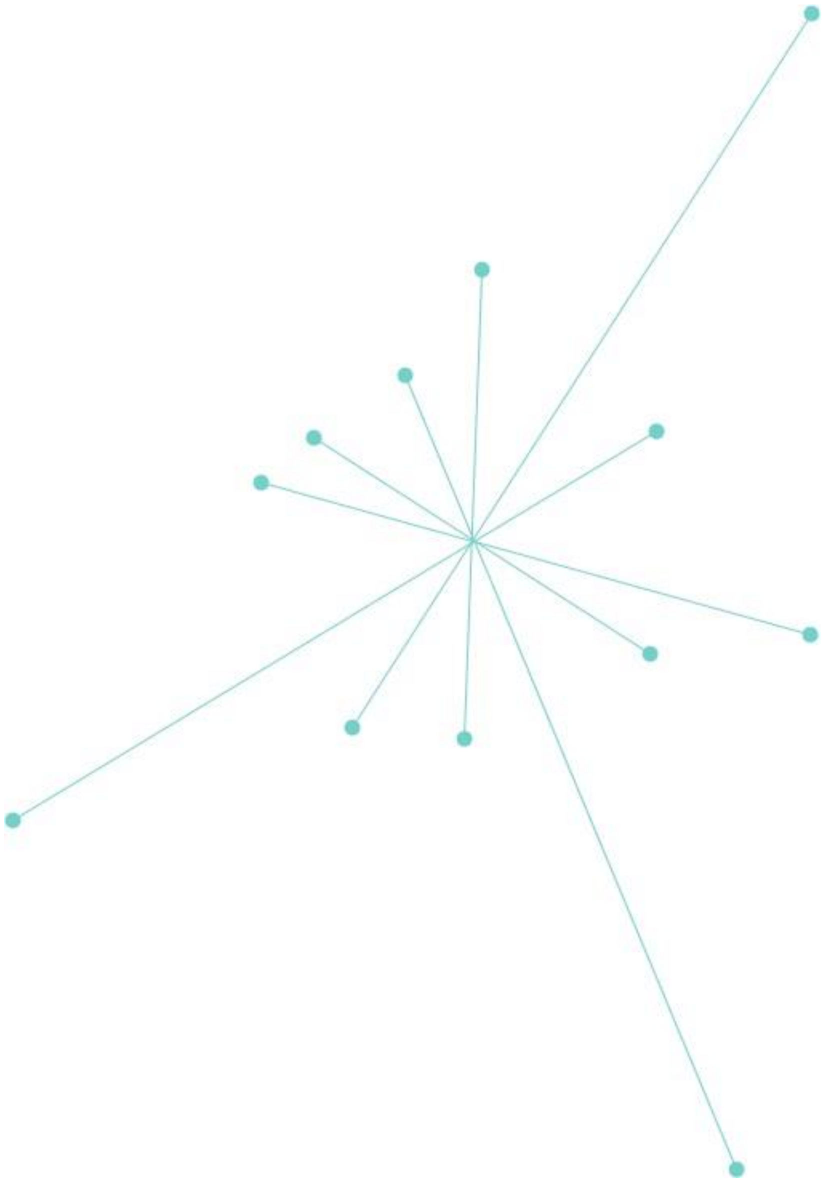

FOREWORD

Just over one year ago, Covid-19 caught fire, racing around the globe, taking lives, infecting communities, and shuttering schools and businesses in India and around the world. In the year since, the Indian government, The Rockefeller Foundation, and the rest of humanity have learned a great deal about the virus: who is most vulnerable, when to test, and how to inoculate against it. We've also learned what we can do when we act together.

India and its health system are now at a critical moment. Facing a staggering wave of infections and new Covid-19 variants, the weeks ahead will be some of the most challenging since the pandemic's start.

Although vaccinations are underway, inoculations will not be delivered fast enough to stop this pandemic any time soon. Until then, testing and tracing are essential tools to aid in the effective management and adaption of public health response.

As we have learned throughout this pandemic, none of us can fight this virus alone. The Rockefeller Foundation is privileged to work alongside the Office of the Principal Scientific Advisor and Centre for Cellular and Molecular Platform in their efforts to contain the Covid-19 pandemic. From October 2020 to February 2021, The Foundation held a series of virtual convenings with an expert advisory group of leaders from a wide range of disciplines central to India's response. This strategic roadmap for testing and tracing, which includes recommendations to fight the current wave as well as future waves with equitable, cost-effective, and scalable tactics, represents the next act in that partnership.

"The Road Ahead for Smart Covid-19 Testing and Tracing in India" will help the government meet this moment and stop the spread. The recommended steps here—leveraging different tests for different settings, pooling procurement, using demand forecasting, tracing in ways that do not contribute to stigmas, and building public collaboration and trust—will bolster India's Covid-19 strategy and improve health outcomes more broadly.

The recommendations here are also a reminder of the need to keep learning. Covid-19 has challenged every nation in some way, the key to success will be taking what's learned and applying it to improve public health. As it has over the last year and over the century, The Rockefeller Foundation will continue to learn and act alongside India and other countries until the pandemic is over for everyone.

by Dr. Rajiv J. Shah,

President of The Rockefeller Foundation

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AB-PMJAY	Ayushman Bharat Pradhan Mantri Arogya Yojana
AIIMS	All India Institute of Medical Science
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
AWW	Anganwadi Worker
CBNAAT	Cartridge-based Nucleic Acid Amplification Test
CHAI	Clinton Health Access Initiative
CHCs	Community Health Centres
Co-WIN	COVID Vaccine Intelligence Work
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CSIR	Council of Scientific & Industrial Research
CSR	Corporate Social Responsibility
DCGI	Drugs Controller General of India
FDA	Food and Drug Administration
FELUDA	FNCAS9 Editor-Limited Uniform Detection Assay
GDPR	General Data Protection Regulation
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Viruses
H1N1	Hemagglutinin Type 1 and Neuraminidase Type 1
iCART	India COVID Apex Research Team
ICMR	Indian Council of Medical Research
ICU	Intensive Care Unit
IDFC	Infrastructure Development Finance Company
IGIB	Institute of Genomics ad Integrative Biology
INSACOG	Indian SARS-CoV-2 Consortium on Genomics
IIT	Indian Institute of Technology
ITIHAS	IT-enabled Integrated Hotspot Analysis System
LAMP	Loop Mediated Isothermal Amplification
MERS	Middle East Respiratory Syndrome
NACO	National AIDS Control Organization
NCL	National Chemical Laboratory
PATH	Program for Appropriate Technology in Health
PHCs	Primary Health Centres
SARS	Severe Acute Respiratory Syndrome
SSE	Super Spreading Events
RAT	Rapid Antigen Test
RICH	Research and Innovation Circle of Hyderabad
RNA	Ribonucleic Acid
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
TB	Tuberculosis
VDRL	Viral Research and Diagnostic Laboratory
WHO	World Health Organization

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OVERVIEW

The Covid-19 pandemic has defined lives across the world. It has tested the resilience of every nation, monumentally influenced international politics and shaped new global orders. Within this scheme, India's vulnerabilities have been unique, given the inherent complexities of such a vast population. During the first wave (September 2020), the country had achieved significant success in containing the pandemic by launching dynamic responses. India weathered the storm by massively scaling up testing and contact tracing, reinforcing Covid-appropriate behaviour and deploying graded response measures.

Now, India and its health system are at a critical moment facing a second wave. Although the country has rolled out an expanded vaccination program, the tools of testing and tracing continue to be the mainstay in the effort to contain the pandemic. The present report makes a case for precisely this – smart testing and tracing measures to limit the ongoing pandemic and avert impending ones.

This report was developed before the second wave; however, its findings and recommendations continue to be relevant at this moment of crisis. The report draws from insights of a panel of experts convened by The Rockefeller Foundation and is supported by evidence from academics and public health leaders. It lays out actionable recommendations that can benefit the testing and tracing response architecture. This report aims to enable policymakers to craft equitable, cost-effective, and scalable testing and tracing measures.

To combat recurring waves of Covid-19 infection, the report proposes catalyzing the role of testing and tracing within the pandemic management system through:

- Strengthening Covid-19 testing by fortifying existing strategies and adopting some novel ones – To effectively protect the population from Covid-19: intensify testing for all populations, including the vaccinated; develop a cafeteria approach to testing; carve regulatory pathways to fuel testing innovations; undertake well-designed seroprevalence surveys; and expand genome sequencing efforts.
- Scaling up testing volumes through cost-effective models – To increase accessibility and affordability of testing: operationalize a pooled procurement mechanism to reduce testing costs for providers; enhance testing availability across states; stimulate inter-state coordination and optimize lab network capacity; and incentivize domestic production of testing kits and components.
- Undertaking demand forecasting for tests – To ensure testing suppliers are response-ready: undertake scientific demand projection of tests every quarter and pre-empt testing needs to prepare for recurring waves.
- Combining a mix of contact tracing measures – To ensure an effective and empathetic public health experience: employ digital resources to complement manual efforts of contact tracing; augment retrospective contact tracing capacity to bust clusters; provide dignified and destigmatized support to those that test Covid-19 positive.
- Encouraging data sharing and harnessing the power of communication – To instill trust among populations: create an enabling environment to motivate quick and quality research; engage with stakeholders to tailor technological deployment strategies; design a dedicated communications campaign to allay fears and misinformation.

While India perseveres to prevail over Covid-19, the lessons learnt have extended profound perspectives. The value of forging purposeful partnerships and igniting innovations has been pivotal during the pandemic. By leveraging individual and collective strengths, India can accelerate equitable and sustainable recovery and help populations guard against future pandemics.

I. RETHINKING AND SCALE UP OF TESTING AND TRACING

Infections are again rising in India and new concerning strains of the virus are emerging despite the roll out of Covid-19 vaccines. An official sero-survey in January 2021 estimated that less than a quarter of citizens in India have been infected with SARS-CoV-2, leaving much of the population still susceptible to the virus. India must continue its push for vaccines, testing, tracing, and behavioral modifications to build a smart and comprehensive Covid-19 response strategy. Only then can we mitigate public health risks and the various socio-economic challenges associated with this pandemic.

While the advent of effective vaccines adds new hope and strength to the fight against Covid-19, it is critical that testing and tracing remain at the core of the pandemic strategy. Though Covid-19 vaccines arrived earlier than initially anticipated, only 300 million of the 1.38 billion people in India were identified as priority group under Phase 1 of the vaccination programme [1].

The country's vaccination drive is expected to eventually reduce the need for other public health interventions but achieving 'herd immunity' is a challenging and elusive goal. It is unlikely that inoculation numbers alone will reach that evolving threshold this year. In addition, without conclusive studies on the longevity of immunity from a natural infection, any projections around herd immunity are speculations at best.

Scientists are also wary of using the concept of 'herd immunity' at a national or state level. 'Herd immunity' may be more fittingly applied to compact populations in communities, clusters, or cities. What is more, those who get vaccinated may gain protection from Covid-19, but there is little evidence to prove that they will not transmit the infection [2].

Questions also persist around the effectiveness of the vaccines against new SARS-CoV-2 variants, some of which are proving to be more infectious and potentially more deadly [3]. Increasingly, scientists are beginning to believe that the virus will become endemic. This means that despite the early entry of vaccines, there is no room for complacency at this very crucial moment in our fight against Covid-19.

A national sero-survey conducted by the Indian Council of Medical Research (ICMR) in January 2021 estimates that over three-quarters of the population has not been infected with SARS-CoV-2 [4]. With the rising infections due to the second wave, it is essential that testing and tracing remain one of the central pillars of the pandemic response.

With the increasing burden of cases, the fight against Covid-19 could be drastically weakened. The fresh wave and rising infection rate are a reminder to further strengthen our Covid-19 response and management mechanisms. This is key to effective disaster preparedness, anticipating and preparing ahead of the next crisis, and not waiting until it strikes to respond.

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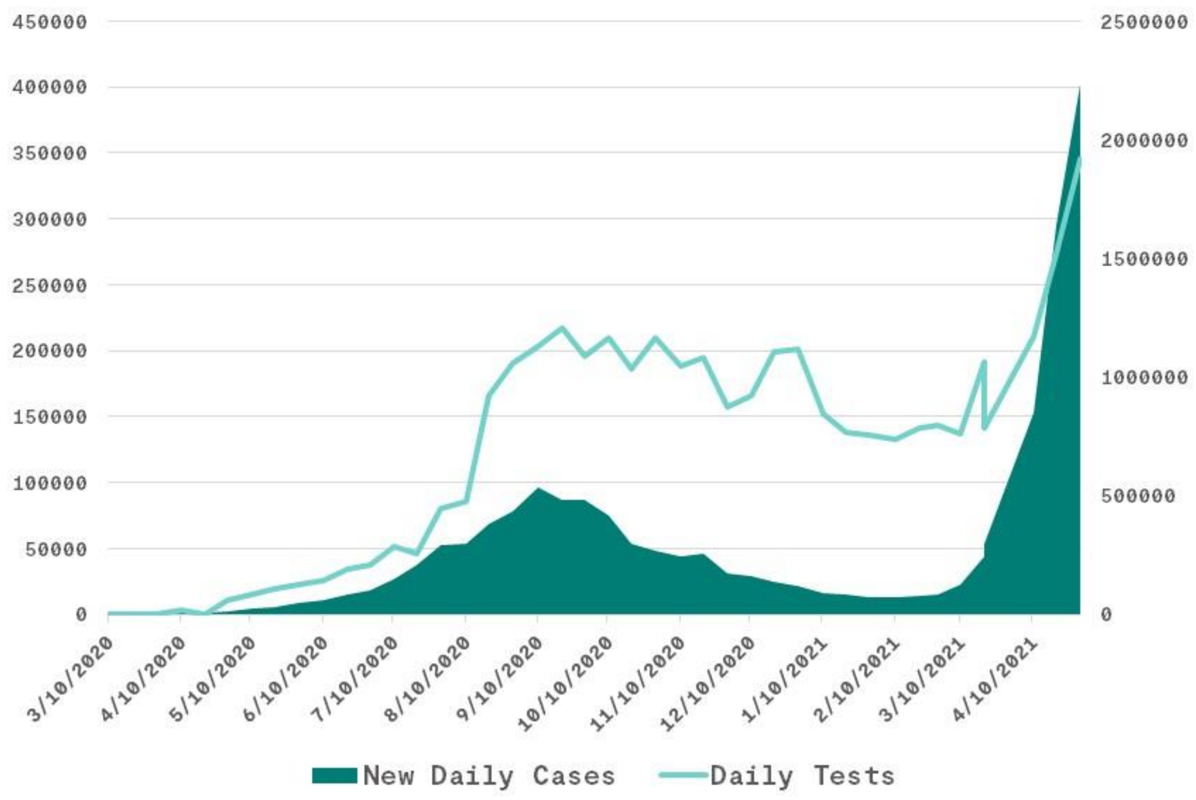
Considering SARS-CoV-2 mutations and the long road ahead to vaccinate a significant share of the country's population, India needs to further strengthen its testing and tracing strategy to effectively complement its vaccination strategy.

a. REVIEW TESTING STRATEGIES IN LIGHT OF VACCINATION ROLL-OUT

India overcame technological, regulatory, and logistical challenges to scale up its Covid-19 testing. By April 2021, testing had increased to 1400 times of March 2020 numbers, as indicated in Figure 1. Having conducted over 307.5 million tests as of early May 2021, India ranks second highest globally in the number of tests conducted. From a single lab at Pune, (Viral Research and Diagnostic Laboratory, VRDL) at the start of the pandemic, RT-PCR tests are available across 1,457 public and private sector labs. Meanwhile, 915 TrueNat, 131 Cartridge based nucleic acid amplification test (CBNAAT) and 6 labs offering Abbott ID NOW, RT-LAMP and CRISPR-Cas9 have been tapped by the Indian Council of Medical Research (ICMR) for Covid-19 testing as well. At over 200 tests per 1,000 people, India's testing rate is low when compared to countries like the U.S., Germany, and Australia, but when compared to lower-income countries, it is one of the highest [5].

However, according to official estimates, almost half of that testing has been through the less accurate rapid antigen test (RATs) [6]. This has been due to constraints in scaling up the more accurate and expensive RT-PCR test, which remains the gold-standard for diagnosing Covid-19. These two types of tests — RT-PCR and RAT — were the predominant tests available in the country from June to March 2021.

FIGURE 1: DAILY COVID-19 TESTS VS. DAILY CONFIRMED CASES (MARCH 2020 TO APRIL 2021)



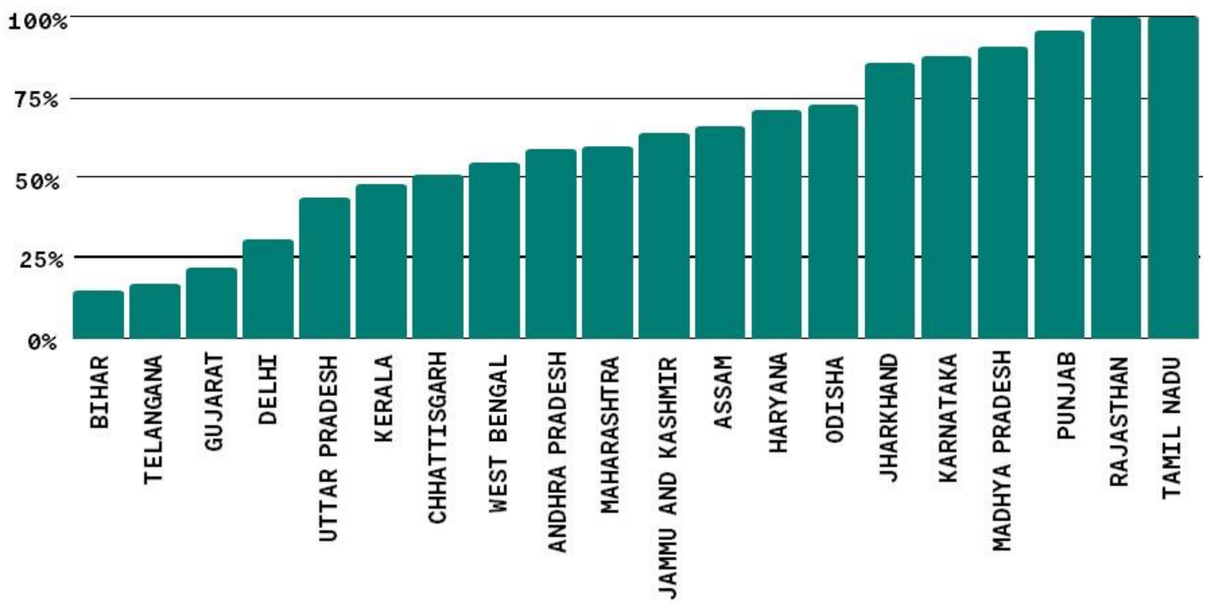
Source: www.ourworldindata.org

Despite a commendable escalation in testing, the quantity and type of tests used have remained uneven across states and rural-urban contexts. For instance, Goa tested at a rate of 150 thousand per million, while states like Madhya Pradesh, West Bengal, and Chhattisgarh tested at a rate one-fifth of that, as of January 2021 [7].

As indicated by Figure 2, the share of RT-PCR usage ranged from 15% to 100% between states, which demonstrates the variability of testing approaches and capacity across the country.

Covid-19 testing continues to be more readily available in larger urban centres, representing a broader historical skew of health infrastructure in favor of cities. A parliamentary panel noted in November 2020 that "testing facility is only limited to bigger cities and towns. Lack of testing facilities in rural areas has also resulted in the under-reporting of cases. The Primary Health Centres (PHCs) and the Community Health Centres (CHCs) are still largely devoid of any testing facilities and the required technical workforce" [8]. Even where tests were available, did the attributes of accessibility and accuracy converge?

FIGURE 2: STATE-WISE PERCENTAGE OF RT-PCR TESTS IN OVERALL COVID-19 TESTS



Source: Collation of various media reports, November 2020 [9]

RATs, which are less accurate but more accessible than the RT-PCR tests in parts of the country, have a false-negative rate of up to 50% but have been used widely for confirmatory diagnosis [10]. It was thus a challenge to determine whether India's steadily declining Covid-19 positivity rate was accurate.

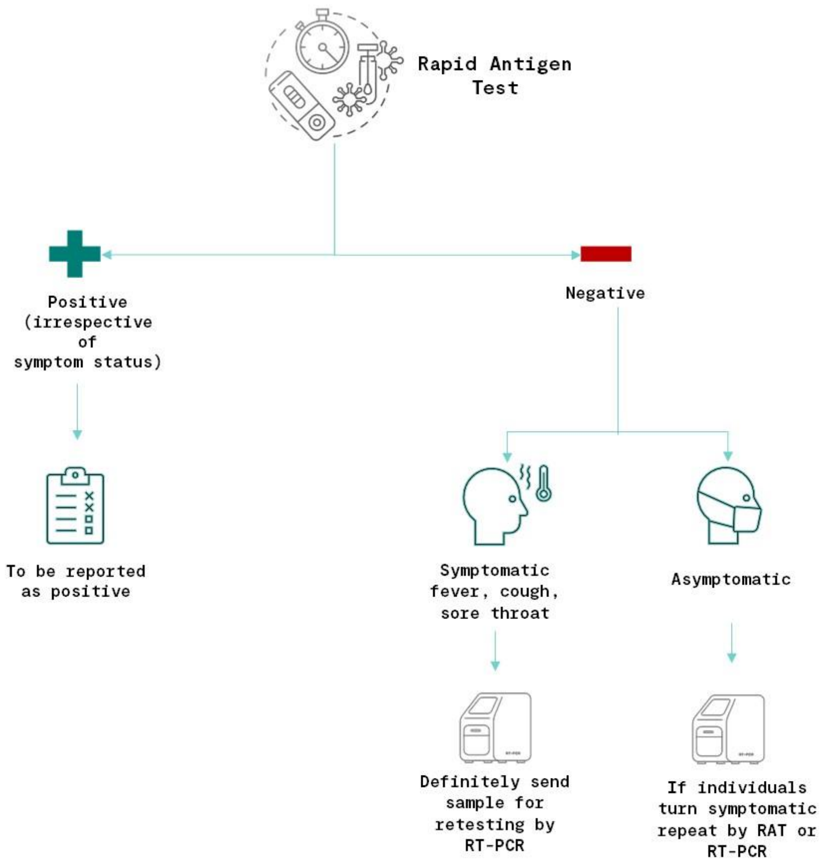
The testing algorithm updated by ICMR in September 2020 did not mandate asymptomatic individuals testing negative on RAT to repeat any test if they did not develop any symptoms (see Figure 3). This was presumably done to optimize resources in a constrained setting and ensure that symptomatic patients could access testing when they needed it the most. However, many states have used a single RAT test as a confirmatory diagnostic tool in all types of cases, allowing Covid-19 cases to go undetected.

Testing and tracing will continue to be relevant at least until the second wave tides over during which hundreds of millions are likely to remain unvaccinated. A third wave of Covid-19 and the prospect of more infective and deadly mutations cannot be ruled out either. Thus, all appropriate Covid-19 interventions – physical distancing, masks, hand-hygiene, and most importantly testing and tracing – should continue to be an integral part of the pandemic response to boost the ultimate goal of vaccination: to control Covid-19.

As the vaccination programme expands under Phase 3, the testing and tracing strategy should be recalibrated keeping in mind key questions, such as:

- Which groups are most likely to be infected but will remain unvaccinated?
- How should the vaccinated be treated under the testing algorithm?
- Considering Covid-19 testing options remain less than perfect, which types of tests should be used in which contexts?
- How can we ensure that emerging virus variants do not escape the testing system?
- Which set of workers should be tested with regular periodicity to keep the economy running close to normal?
- How can the cost of testing be optimized to ensure that testing remains a priority even as vaccines are rolled out in a resource limited context?

FIGURE 3: ALGORITHM FOR COVID-19 TEST INTERPRATATION USING RAPID ANTIGEN POINT OF CARE TEST



Source: ICMR advisory on Strategy for Covid-19 Testing in India, September 2020

1. STUDY THE VACCINATED AND NATURALLY INFECTED THROUGH CONTINUOUS TESTING

As the vaccination drive progresses, it remains unclear whether those vaccinated also need to be tested if they show symptoms or come into contact with a Covid-19 positive person. It is critical for technical expert groups of the country to review the role of and strategy for testing and tracing during and after mass vaccination efforts.

Until strong evidence supports that vaccination will curb transmission, it is prudent to test any individual who develops Covid-19 symptoms or has been in contact with a Covid-19 positive person. If found to be Covid-19 positive without symptoms, the individual should be treated as an asymptomatic carrier. Testing should also be encouraged as part of general pandemic surveillance, such as during travel or as part of 'assurance' testing in offices and schools.

Apart from confirming individual infection status and informing appropriate personal health interventions, this testing approach could also provide insight into the kind of protection offered by different vaccines both in the general population and specific subgroups. As different vaccines are rolled out across the world on varying timelines and in various populations, studying the growing body of global research on the impact of different vaccines will be key to keeping India's pandemic response strategy effective.

It is important for the technical expert group to periodically review evidence from around the world and India to determine the need for antibody testing for individuals before vaccination.

It is also crucial for the technical expert group to monitor clinical trial data and other emerging evidence regarding the duration of Covid-19 immunity from a natural infection as well as Covid-19 immunity from vaccination. Some hospitals in New Delhi are already reported to be considering tests for antibodies before vaccination [11].

Several global studies are assessing the duration of protection after a natural infection. Among these, a recent pan-Indian sero-survey by the CSIR Institute of Genomics and Integrative Biology (CSIR-IGIB) has found that the persistence of antibodies is likely to confer protection against reinfection from the same variant for at least six months [12]. Evidence such as this, and those emerging from ongoing clinical studies, should inform policies on whether those recently recovered from Covid-19 should be deprioritized for vaccines or should be advised to delay registering on the Co-WIN app for vaccination.

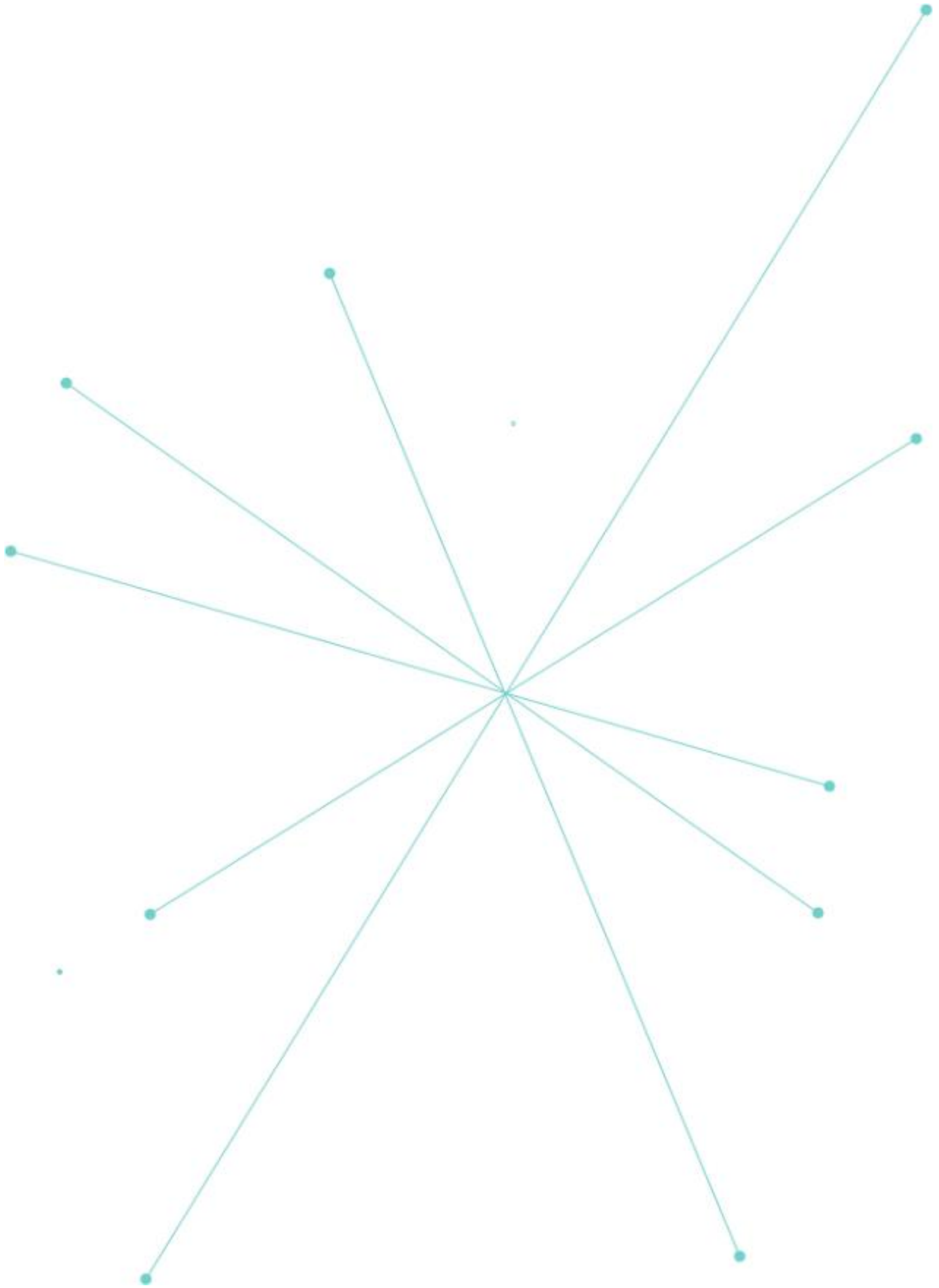
1.1. DESIGN A STUDY-PROTOCOL OF A SUB-GROUP OF VACCINATED PEOPLE FOR UNANSWERED QUESTIONS

Significant questions remain regarding the protection granted by Covid-19 vaccines:

- How long does the immunity generated by different vaccines for Covid-19 last?
- If and by when would a booster dose following vaccination be needed?
- Does the duration of immunity vary by age, sex, or pre-existing disease profile, and if so, which populations may need a booster dose before others?
- How well will the current vaccines work against new variants?
- What are the types and quantities of antibodies formed by vaccination?

To address these questions, the country can design and plan a nation-wide study and database to monitor immune responses in a subset of vaccinated populations. The study can, through immunophenotyping, compare the samples of those naturally infected against those vaccinated, to understand the differences in immune response between the two groups over time and develop a database of the same. This should be done for all vaccines being used in the country for different demographic groups such as those above fifty years of age, those with and without co-morbidities, and people under fifty years of age with and without co-morbidities, with adequate representation of both sexes and regions in the samples.

This type of study will help glean insights on how best to tailor our vaccine response strategies for different sets of people in a highly heterogeneous population. Vaccination prioritization for different segments of the population has thus far been based mainly on ethics and the impact of Covid-19. However, as the understanding of differential immune responses to the virus and vaccines evolves through studies such as these, we can build a graded, calibrated, and targeted vaccine strategy against Covid-19, and even other viral infections going forward. Studies along these lines are already being planned by the Pune-based CSIR-National Chemical Laboratory (NCL) with the help of the Pune Knowledge Cluster [13].



2. ASPIRE FOR A CAFETERIA APPROACH TO COVID-19 TESTING

India needs to develop effective and diverse Covid-19 testing pathways to enable a "cafeteria approach to testing" – i.e., making available a diverse portfolio of tests with clear guidance. Given the heterogeneity and socio-economic diversity of the country, different tests would be more suitable in different contexts.

- For some, the goal is to test individuals to confirm the presence of infection and prescribe health interventions.
- For others, it may become necessary to prove that one is not carrying the virus even in the absence of symptoms for businesses to return to normalcy.

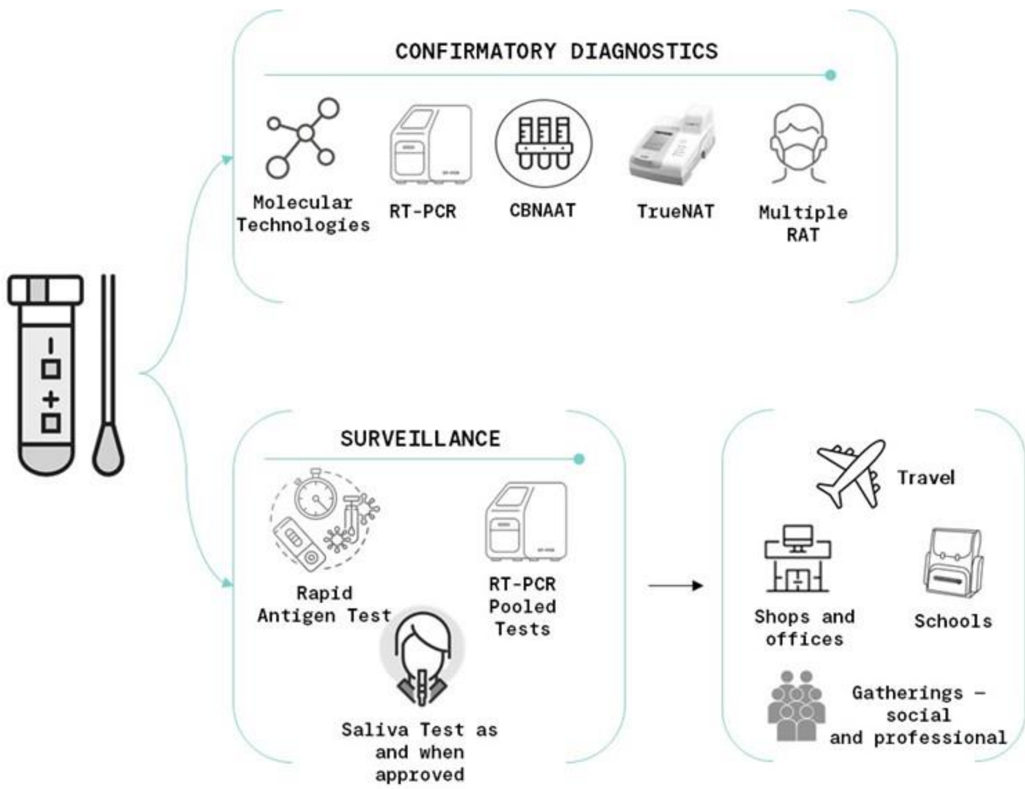
Several workplaces in India have already voluntarily chosen their testing strategies - some administering random rapid tests, others conducting antibody tests to keep their employees safe [14].

As Covid-19 peaks at different times in different regions within states, tests are being mandated for interstate travel. Witnessing an upsurge of cases under the second wave, a majority of states directed travelers to carry a negative RT-PCR test report not older than 72 hours for interstate travel [15]. In early May 2021, however, ICMR relaxed the need for RT-PCR test in healthy individuals undertaking inter-state domestic travel in a bid to reduce the load on laboratories [16].

Creating a choice of tests and specifying their mode of delivery to cater to different sets of the population in various situations and settings is crucial.

Considering the current landscape of imperfect testing technologies for Covid-19 and limited supplies of testing resources, two distinct types of testing pathways can be implemented in the immediate future: one for confirmatory diagnosis, and one for an effective surveillance regimen of mass-testing termed as assurance testing (see Figure 4). Under the two testing pathways, different types of tests should be validated and made available to people.

FIGURE 3: CAFETERIA APPROACH TO COVID-19 TESTING



Source: Illustrated by Chase India

3. TWO DISTINCT PATHWAYS FOR TESTING

It is important for the Indian government to provide clear guidelines stating that either PCR tests or another accurate molecular diagnostic technology should be used for confirmatory diagnosis of Covid-19. This will be critical until either an assortment of accurate tests is readily available, affordable, and accessible to all or vaccines grant sufficient protection to a large section of the population.

If PCR-based technology is not accessible, then RATs could be repeated (about three to four days apart) for confirmatory diagnosis. This is to ensure that those missed by the first RAT because of a low viral load will be confirmed as positive in subsequent tests. A field test can also be conducted to assess effectiveness of this strategy. This may be particularly helpful in contexts where, in contradiction to ICMR guidelines, a single RAT is being used for confirmatory diagnosis.

All other surveillance testing regimens that can interrupt transmission chains and reduce community spread should complement, not replace, confirmatory diagnostic tests. For assurance testing purposes, such as in case of domestic travel and keeping shops, offices, and schools running, easy to use rapid tests with the highest specificity and sensitivity may be promoted.

Even among rapid tests, automated options should be preferred over manual options to reduce error rates. The specificity and sensitivity rates of these tests should not be lower than that of currently permitted RATs.

In Australia, mass-testing regimes in offices based on easy-to-use saliva tests are already being piloted, and their results will shed light on the feasibility and efficacy of these regimens [17]. Saliva-based tests are seeking validation and approvals in India as well. If commercialized, these have the potential to offer cheaper and more convenient Covid-19 testing options.

Frequent use of affordable, simple-to-use rapid tests at scale for populations without symptoms will mitigate outbreak, even if their analytic sensitivities are inferior to those of benchmark tests [18]. A different regulatory pathway may be considered for such tests, which would act as a 'Covid-19 filter' to reduce transmission in communities.

As schools plan their reopening without vaccines being an option for children, these tests may become commonplace as periodic checks to ensure safety from the virus. Periods of lull for an unpredictable virus such as SARS-CoV-2, should not be mistaken for a pandemic in retreat.

4. A FORMAL MECHANISM TO PROACTIVELY VALIDATE NEW INNOVATIONS IN TESTING TECHNOLOGIES

Innovations in the Covid-19 testing space have been evolving at a rapid pace. Given how disruptive the Covid-19 testing technologies space has become, accuracy and accessibility are likely to converge, resulting in the emergence of affordable, accurate, and scalable options for testing.

Till such convergence, it is crucial for the government to implement a formal mechanism with clear regulatory pathways to proactively invite, transparently assess and validate, new testing technologies from across the world. At present, new test developers are required to negotiate two simultaneous approvals from the ICMR and Drug Controller General of India (DCGI), which causes confusion and delays. Rather than a case-by-case approach, clear broad guidance on key parameters such as type of system (open or closed), cost, and weightage given for approval by other regulators such as the US Food and Drug Administration (US FDA) may help test developers understand broad expectations of the regulatory system. Minimizing the time for test approvals during a pandemic is important, similar to how accelerated regulatory pathways have been created for vaccines. In an ideal regulatory ecosystem, agencies evaluating testing innovations would not be competitors themselves.

Until such highly accurate tests which are also easy-to-use are validated and commercialized, it is essential for India to build capacity in accurate and scalable PCR technologies and explore the feasibility of scaling up other emerging accurate technologies, including the FELUDA test that uses the Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology.

4.1. NEW TESTING TECHNOLOGIES ON THE BLOCK

As it stands, CRISPR FELUDA, despite being a highly specific and sensitive test, does have a scalability challenge because of the many steps involved in testing. Compared to RT-PCR however, it may be much more scalable (see discussion in Section II).

Other technologies that should be proactively explored include home-based tests, like the lateral flow antigen test first approved in the US in December 2020 [19].

Lateral flow antigen tests can potentially halve the quarantine period from 14 days to 7 days, or further cut it to 5 days for those exposed to confirmed cases [20].

Another technology deserving attention is Loop-mediated Isothermal Amplification (LAMP). After initial setbacks in experimentation with tests using LAMP technology, which can potentially improve access to testing in tier-2 and 3 cities and rural areas, approvals have finally come through [21]. The first set of RT-LAMP-based tests was approved by ICMR in November 2020, and the states of Kerala and Gujarat, among others have already commenced using them [22][23].

Saliva-based, non-invasive PCR tests are also awaiting regulatory approval. These have the potential to significantly drive down the cost of test processing.

In most cases, RT-PCR tests fail due to faulty sample collection, and not the inherent technology. The swab must go through the nostril to the back of the nasal cavity, which is uncomfortable for patients and cumbersome for untrained lab technicians. This leads to mistakes or improper swabbing, causing inconsistency between field sensitivity and theoretical sensitivity (claimed to be 95%). In view of these complexities, it is important that saliva-based tests are validated on priority.

4.2. POST-MARKETING SURVEILLANCE IN FIELD CONDITIONS TO VALIDATE NEW TECHNOLOGIES

In crises brought about by pandemics, accelerated regulatory pathways have been used for health interventions, including diagnostics. This necessitates special follow-up monitoring of tests and technologies to ensure that the tests are living up to their promises and claims on the field and among a larger population base. For all new technologies that are being commercialized, a post-marketing surveillance mechanism should be available for companies to submit data from the field periodically. The data can then be assessed to determine the performance of tests in real-life conditions. Based on the evidence gathered, these categories of tests should be allowed to prevail - the most accurate ones for diagnosis, and the fast, affordable, easy-to-use, and scalable ones for assurance testing.

4.3. MOVING BEYOND THE EMERGENCY MINDSET, TESTS MUST PASS QUALITY NORMS

It is essential that the country now aspires to secure more than just the availability of tests. Test kit manufacturers can be made to pass periodic quality checks for the diagnostic tests produced. In some instances, a quality failure or misdiagnosis can do more harm than a lack of diagnosis.

During phases when the country's requirement for testing dips, indigenous Covid-19 testing kit players should be allowed to export and compete in the global markets to evolve and conform to international standards.

5. WELL-DESIGNED SERO-SURVEYS ARE NEEDED TO UNDERSTAND EPIDEMIOLOGICAL TRANSMISSION PATTERNS

While RT-PCR tests check the infection status of the individual, sero-surveys help diagnose the infection status of an entire population. With the pandemic having peaked and ebbed in parts of the country, meticulously planned sero-surveys — either based on antibodies or sewage water systems — can be performed in different contexts as part of well-designed studies to glean epidemiological insights. In areas where the pandemic is just starting, or prevalence is low, pooled RT-PCR tests can also be useful.

Until now, sero-surveys have not followed a design or periodicity that can help states understand epidemiological insights about Covid-19 spread in their regions.

At the national level, ICMR has completed three sero-surveys: the first from April to May 2020, the second from August to September 2020, and the third from December 2020 to January 2021. The results show a sero-prevalence of 0.7%, 6.6%, and 21%, respectively, underscoring the fact that a vast majority of the population is still susceptible to infection [24]. As predicted, dense urban slums had 14% sero-prevalence and urban areas had 10%, while rural areas had the lowest rates 4% in the last round of the national sero-survey. States also conducted their own sero-surveys, and some of their results painted a differed picture from national surveys [25]. For instance, in September 2020 the Delhi government found that a quarter of its population had been infected (see Table 1) while a sero-survey in Assam by a charity and a group of clinics found that 23% of its population may have contracted the virus [26]. The Uttar Pradesh state government's sero-survey results suggest a fifth of the population had been infected by November 2020. In Karnataka, a study by IDFC Foundation indicated that almost 47% of the state's population may have had the infection between June to August 2020 [27][28].

These variations in findings of various sero-surveys may be attributed to several factors (see box).

Why do results of Sero-surveys vary?

Second-round surveys in the same population might show lower numbers because:

i. Some people might be reluctant to give blood again after knowing results from the previous time;

ii. Decline of antibodies over time.

Different studies from the same state or city show inconsistent numbers on prevalence because studies often use distinct sampling and testing methods. Using tests of different sensitivity also offers contrasting results.

Apart from indicating general trends, sero-surveys have not yet efficiently guided policy, either independently or when combined with other data sets such as those from contact tracing or sequencing. Despite the delay, the central government can support states in planning sero-surveys that help explain transmission patterns in real-time and inform policymaking at regional and national levels to mitigate the impact of outbreaks.

TABLE 1: SERO-SURVEYS CONDUCTED IN DELHI

DATES OF SERO SURVEYS	SAMPLE SIZE	KIT USED FOR TESTING	OVERALL SERO PREVALENCE
June 27 - July 10, 2020	21,387	ELISA (COVID Kawach sensitivity: 92.1% specificity- 97.7%)	22.8%
August 01 - August 07, 2020	15,239	ELISA (COVID Kawach sensitivity: 92.1% specificity- 97.7%)	28.3%
September 01 - September 05, 2020	17,409	ERBALISA Covid-19 kit (sensitivity- 99.12%; specificity- 99.3%)	25.1%
October 15 - October 21, 2020	15,015	ERBALISA Covid-19 kit (sensitivity- 99.12%; specificity- 99.3%)*	25.5%
January 15 - January 23, 2021	28,000	ELISA (COVID Kawach sensitivity: 92.1% specificity- 97.7%)*	56.13%

* Based on media sources pending confirmation from official sources.

6. TESTING FOR AN EQUITABLE PANDEMIC RESPONSE

Covid-19 testing will be truly equitable when citizens across income groups can access tests at affordable rates when they need them. Creating conditions that restrict middle-income and economically privileged citizens from accessing Covid-19 testing in the private sector may prompt them to delay testing. Such conditions also tend to place a greater burden on already overstretched public health resources as more people shift to public sector for testing.

In India, citizens across economic strata access 70% of their healthcare needs in the private sector [29]. Anyone willing to pay extra for home-based testing should be allowed to access it for a premium. Factors such as variable price-caps and mistrust between stakeholders – the state, public, and private sector – could lead to parts of the private sector withdrawing from Covid-19 testing. It is critical to monitor that in a zeal of state governments to cut prices of Covid-19 tests, the availability and accessibility of tests are not curtailed. This can be corrected through a comprehensive and unified approach to testing policies at the national level, with state-level inputs and decentralized implementation allowing flexibility to account for local needs (see discussion in section II).

While planning for equitable testing, special provisions need to be made for socio-economically disadvantaged groups. Having faced job losses, reduced income, and minimized access to health services, these groups have been disproportionately affected by the pandemic. Vulnerable populations from socio-economically disadvantaged backgrounds also have low risk-perception and high-risk tolerance. Anecdotal experiences of non-profit organizations working on the ground in different states support this finding and have reported low demand for Covid-19 testing and high complacency among economically marginalized communities. In September 2020, almost half of all Indians knew of one or more people who had dodged testing despite symptoms of Covid-19, according to Local Circles, a community-led social media engagement platform [30].

FIGURE 4: TESTING STRATEGIES FOR VULNERABLE POPULATIONS

TESTING PHASES	Pre-test	Testing	Post test
SOCIO-ECONOMIC VULNERABILITIES AND LACK OF ACCESS TO HEALTHCARE	Public information campaign to understand when, why and how to access testing	Cover cost of test, make access to test easy, incentivize testing	Monetary, essential items and psychological support
HIGH SUSCEPTIBILITY, LOW-THRESHOLD SETTINGS (FOR VULNERABLE POPULATION)	Identification of individuals through registry of comorbidities, tele-triage, behavioural phenotyping	Integrated mobile diagnostic and imaging	Teleconsulting and daily monitoring of symptom

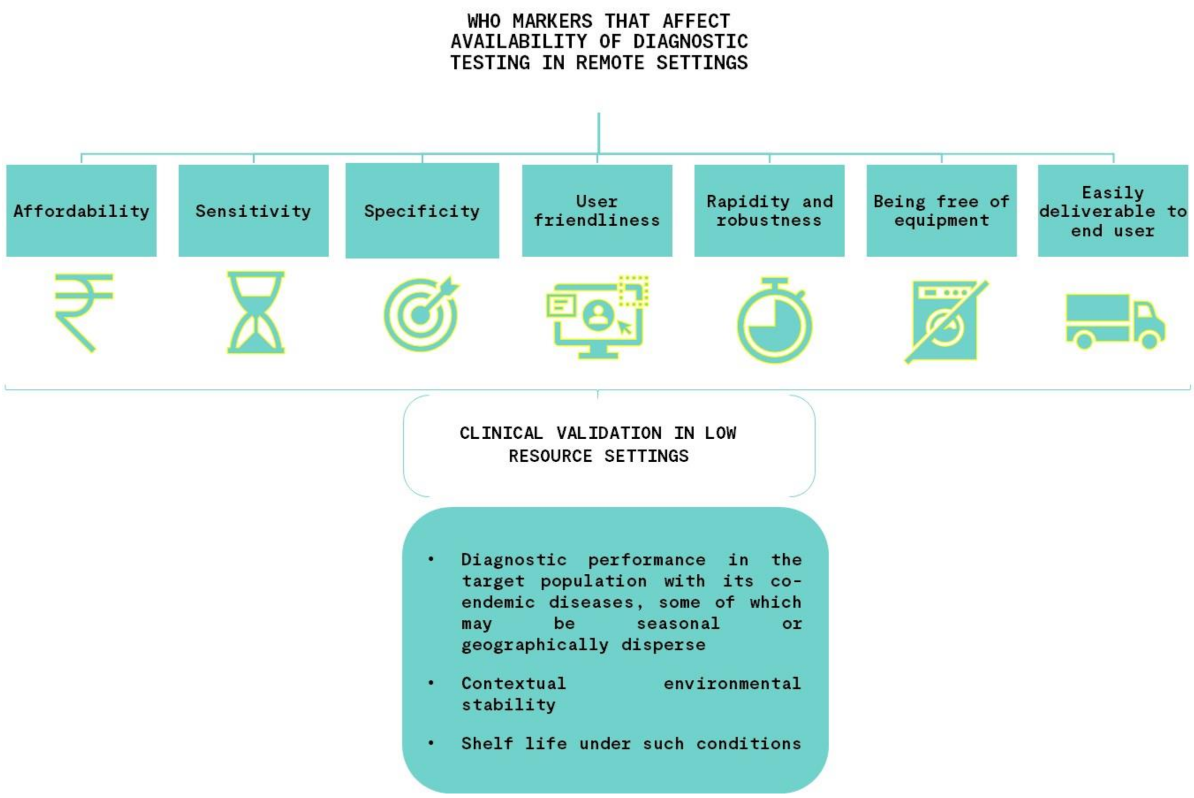
Source: Adapted from the study on optimal options for a national testing strategy to ensure fair and equitable testing, ETI

For disadvantaged groups to benefit, tests must reach them where they are. Before the need to test arises, they must have access to information about when, how, and why they need to get tested. Further, if they need to be quarantined or hospitalized, it is necessary that assurance be given about food, wages, and other essentials during recovery. Counseling will allay fears, and provisioning will improve compliance with rules (see Figure 5).

6.1. LAYERING COVID-19 TESTING IN SOCIAL PROTECTION SCHEMES OFFERS A SEGUE INTO EQUITABLE TESTING FOR THOSE UNDERSERVED BY THE STATE

For socioeconomically disadvantaged groups, the cost of the test should be covered by the government, irrespective of whether they access it in the government or private sector. One-way equitable testing can reach urban and rural poor is to merge testing for Covid-19 into current disease control programs and integrated service delivery models. This will help to absorb the cost of infrastructure and utilize existing databases that have identified vulnerable populations. It was a well-intentioned move to offer Covid-19 testing for free under Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) since early in the pandemic [31]. However, according to media reports and government submissions to Parliament, only 400,000-500,000 Covid-19 tests had been done through this program until early January 2021, which is less than half of the number of tests performed daily during India's peak period of testing in 2020 [32][33]. This seems low for a program that covers 131.3 million families. It could be because not enough people were aware of this provision under AB-PMJAY or because they were already being offered free tests and treatments by the state governments [34].

FIGURE 5: COVID-19 TESTING IN LOW-RESOURCE SETTINGS



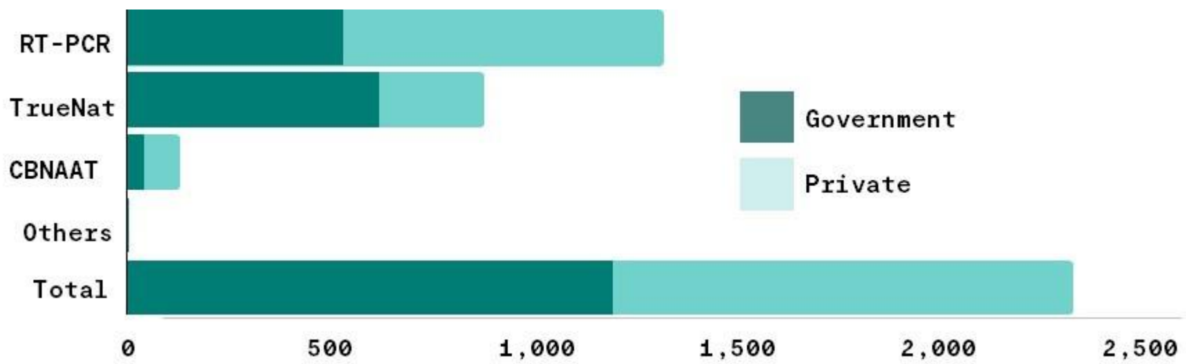
6.2. DISTRICT HOSPITALS AS HUBS FOR TESTING IN RURAL AREAS

In the medium term, every district should have a lab to turn out results faster to the catchment area it serves. Along with equipping district-level hospitals with a lab, infrastructure, and technicians, CHCs should also be armed to serve as testing centres. In November 2020, a parliamentary panel observed that the PHCs and CHCs are still largely devoid of any testing facilities or the required technical workforce. Lack of testing facilities in rural areas has also resulted in the under-reporting of cases [35].

For rural areas, a hub and spoke model can be explored for testing, using mobile-based labs to reach inaccessible areas and expand testing. The operation of mobile labs at scale will require an army of trained technicians and quality and compliance protocols. Training people to collect samples and run tests on various platforms is one of the foremost challenges to be addressed. Public-Private Partnership (PPP) models and pooling Corporate Social Responsibility (CSR) funds can be explored for running the mobile testing vans.

As tests become common at subdistrict levels, protocols around storage, supply chain, training technicians, and quality control will have to be paid more attention. The WHO has identified markers to strengthen the availability of diagnostic testing in remote areas (see Figure 6). Private medical establishments can also be identified in smaller centres for testing purposes to fill in the gaps in public health systems.

FIGURE 6: TEST LABS IN INDIA



Source: Drivers of improving cost-efficiency of Covid-19 testing in India, ISB/Max Institute of Healthcare Management

7. AS THE VIRUS MUTATES, IT IS CRITICAL TO REVIEW EFFECTIVENESS OF CURRENT TESTING TECHNOLOGIES

As the virus changes its form, it is critical to scale up genome sequencing to understand how the virus is mutating for the country to adapt mitigation strategies. As of March 2021, India had about 771 reported cases that carried the variant that originated in UK (B.1.1.7), South Africa (B.1.351) and Brazil (P.1). Variants of double mutant (B.1.617) and triple mutant (B.1.618) category were also reported in India in March [36].

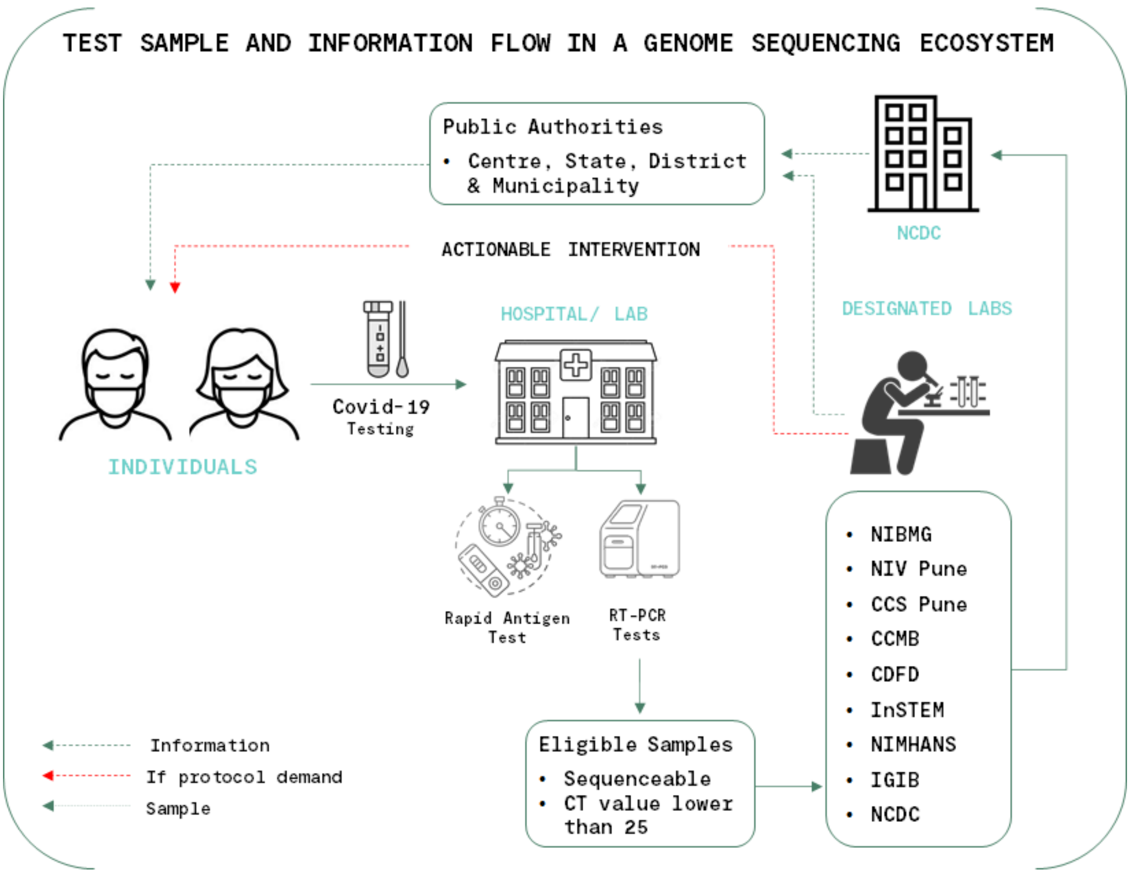
7.1. INDIA ACTED SWIFTLY TO MONITOR B.1.1.7; WE NEED STRONG SYSTEMS TO DETECT DOMESTIC VARIANTS

The UK informed the WHO in December 2020 that the strain identified in September 2020 was found to be spreading faster than the parent Covid-19 variant. India acted swiftly to counter the impact of this variant [37]. Private labs and testing centres were advised to preserve samples of all those who entered India after 23rd November 2020 in ultra-cold storage and transport them to designated labs for gene sequencing [38]. Some logistical issues, however, persist. Stakeholders working on the ground reported that in some northern states, medical colleges struggled to determine who would arrange and pay for transport services of samples to the designated labs.

It is important to have similar pathways to systematically test for potential variants originating within the country, especially B.1.617.

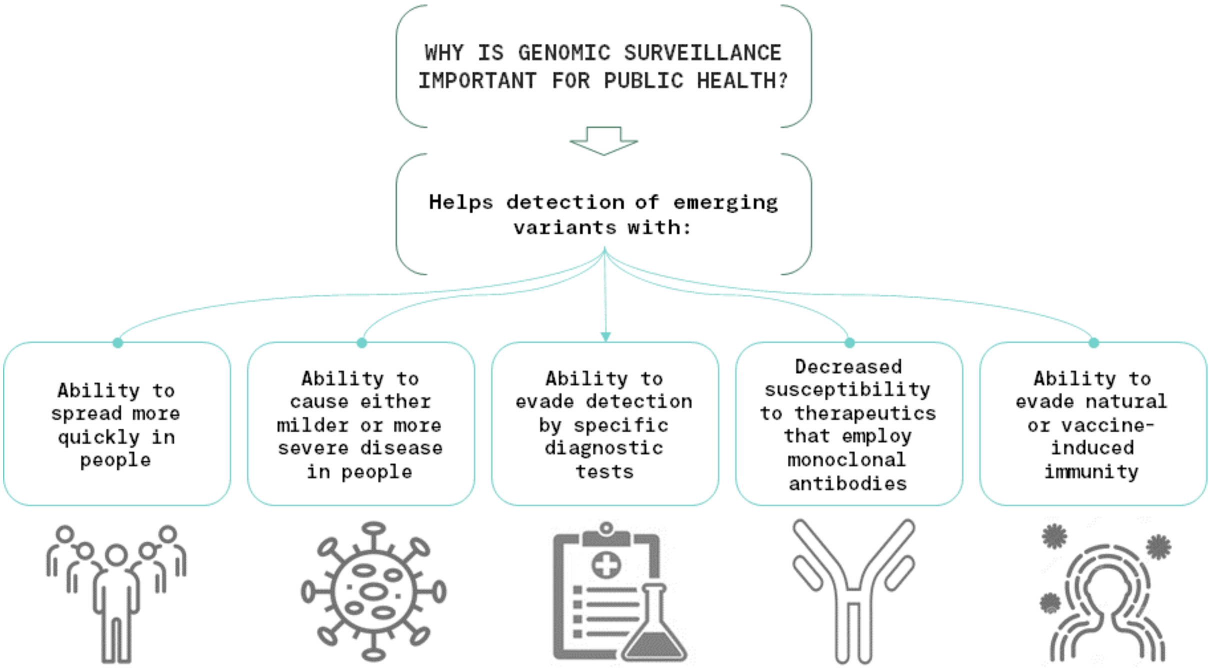
Hospitals and large testing centres across the country should be advised to regularly preserve and ferry RT-PCR samples to designated labs in their regions. After sequencing, the information could flow to central level policymakers and state/district level authorities in charge of pandemic response, accompanied by actionable insights. When virus mutations show evidence of higher severity which demands modified clinical protocol and health interventions, the patient and physicians also need be informed (see Figure 8).

FIGURE 7: GENOME SEQUENCING ECOSYSTEM



Source: Illustrated by Chase India

FIGURE 8: IMPORTANCE OF GENOME SURVEILLANCE

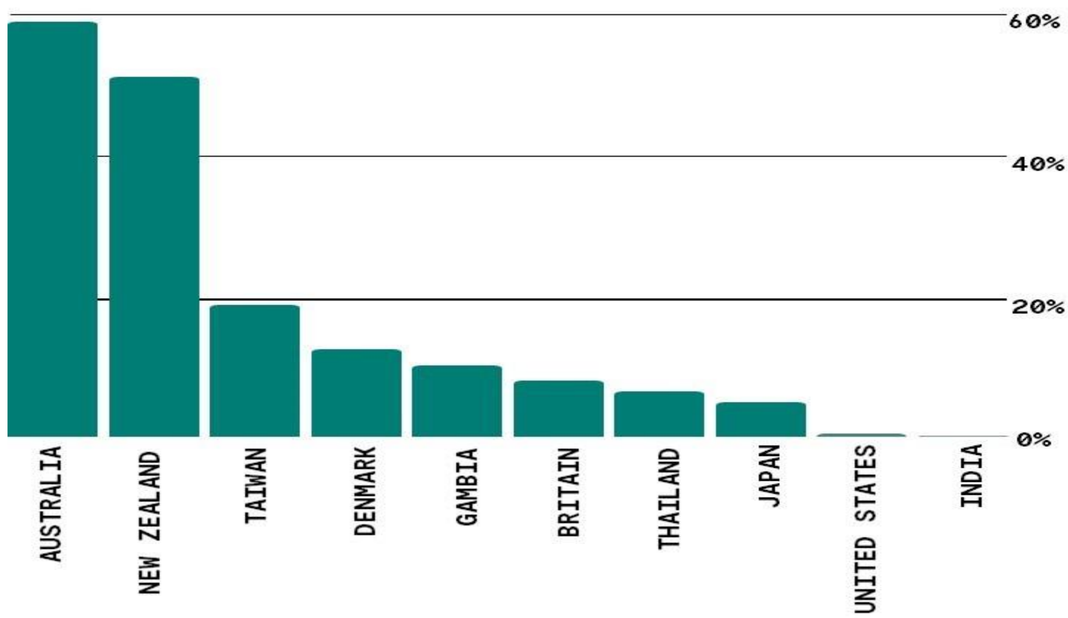


Source: CDC, US

7.2. STEPPING UP SEQUENCING WILL BOLSTER THE BATTLE AGAINST COVID-19

It is important for India to sequence domestic samples at an adequate rate to catch variants in time and design public health interventions for testing, vaccines, and other responses such as intensive and advanced contact tracing (see Figure 9). The UK, which has been at the forefront of genetic sequencing, was sequencing at a rate of over 6% when it identified the B.1.1.7 variant. Similarly, South Africa was sequencing at 0.3% when it identified its own variant (see Figure 10). The WHO calls for at least 0.3% sequencing of the total number of Covid-19 infections [39].

FIGURE 9: PERCENTAGE OF COVID-19 CASES SEQUENCED



Source: www.washingtonpost.com and www.newindianexpress.com

Until December 2020, India had submitted only 5,000 sequences for over 10 million confirmed infections, as part of the Global Initiative on Sharing All Influenza Data (GISAID) [40]. By these figures, India appears to be sequencing at a rate 8 to 10-fold lower than what is prescribed by WHO.

However, as of mid-March 2021, the country had sequenced 13,614 samples, which is more than what was deposited in GISAID [41]. Not all that was sequenced in India was being deposited in GISAID for multiple reasons — such as lack of dedicated skilled human resources in frontline labs to do the deposition, unavailability of meta-data, and the deposition itself being accorded low priority.

The country declared its commitment in December 2020 to scale up sequencing to 5% of positive cases from all states and union territories [42]. This seems to be a steep target and a hundred-fold increase against the current 0.05% estimate. Many frontline labs are working towards sequencing not 5% of positive infections, but 5% of samples that can be sequenced. This excludes a large share of Covid-19 cases, including samples tested on RATs and those RT-PCR which have a higher than prescribed cycle threshold (CT) value. At the current rate, India aims to sequence between 2 to 2.5% of positive cases, according to an estimate by scientists. At this rate, the country should manage to catch emerging domestic variants of the virus.

To be sure, India has adequate sequencing capacity: CSIR-IGIB, one of India's top public sector labs alone, has the capacity to sequence about 10,000 samples monthly. At a time when daily cases are hovering over 400,000, public labs should be capable of carrying out the sequencing target when supported with resources and funding.

7.3. PRIMERS FOR TESTS NEED TO BE DESIGNED AND UPGRADED CONTINUOUSLY

For dangerous mutations to be detected, sequencing rates in countries must be scaled up and primers used in testing should be designed and upgraded continuously.

Notably, the issue of SARS-CoV-2 mutations escaping testing occurred with B.1.1.7 in the UK. The RT-PCR testing protocol being followed was testing for three genes – spike gene [S], nucleocapsid [NC], and Envelop [E]. The sample was labeled as Covid-19 positive if two of these three genes came back positive. When the UK mutation started missing one gene (spike gene [S]), and another was missed due to a problem in the sample, there was a likelihood that positive samples could be falsely labeled negative.

The WHO has recommended an approach of using different assays in parallel, or multiplex assays targeting different viral genes that allows the detection of potential arising variants [43]. In its December 2020 meeting, the National Task Force on Covid-19 in India concluded that as "ICMR has always advocated use of two or more gene assays for testing SARS-CoV-2, it is unlikely to miss infected cases using the current testing strategy" [44].

New primers have now been recommended for testing B.1.1.7. according to experts. However, it is critical that these primers be designed and updated continuously to ensure that no variant of concern escapes detection in the testing system.

It is also important for regulators to be in constant dialogue with test developers and marketers to assess whether the existing technologies are able to detect new strains effectively. Already, some international regulators such as the US FDA have been consulting with test developers to assess the effectiveness of current testing technologies on emerging strains [45]. They have also established direct channels with stakeholders, like healthcare providers and lab clinicians, to report aberrations in test results [46]. It is critical for Indian regulators to establish processes to assess whether current testing technologies can detect new strains, and update testing guidance accordingly.

7.4. ADD STRAIN PICKING TESTS AND POINT-OF-CARE SEQUENCING MODELS TO COVID-19 ARSENAL

At present, patients are not informed of the variant they have contracted, even if their samples have been sequenced as part of genomic surveillance. This is partly due to lack of consensus among scientists and doctors on whether informing the patients has any intrinsic value in the pandemic response, considering clinical protocols for all mutations remain the same. Also, genome sequencing could take place weeks after the sample has been taken, likely after the disease outcome has passed, rendering the information futile for prescribing health interventions. However, should mutations demand modified medical protocols, or a different public health response – such as variation in quarantine period – it should become mandatory for such information to flow to patients and their clinicians directly from sequencing labs in time. Protocols for such information flow need to be designed and tested before the pandemic requires such a situation.

It is vital for some tests to be designed to report about the SARS-CoV-2 variant to the patient on the spot. A team of researchers from CSIR-IGIB, which developed the FELUDA test, is in the process of seeking approval for FELUDA-RAY tests which claim to identify variants faster than genome sequencing. Scientists claim they can develop strip tests for emerging variants within two to three weeks. Such tests may become crucial to the pandemic response once more severe variants emerge. Such tests will also allow countries with limited to no genomic sequencing capabilities to detect variants once they become known.

In another initiative, CSIR-IGIB started a micro lab in partnership with SpiceHealth at Delhi Airport to carry out on-the-spot genome sequencing for samples of all international passengers who undergo RT-PCR test on arrival at Delhi airport and are found positive [47]. If the top five mega-labs in each corner of the country are strengthened, and about one hundred micro-labs are strategically located across India, this could inform pandemic policy response effectively in a rapidly evolving context.

7.5. HASSLE-FREE CLEARANCES FOR IMPORT AND BUILDING CAPABILITIES IN REAGENTS

The amended import regulations, in view of policies promoting the Atmanirbhar Bharat initiative, caused unintended hindrances to companies supplying sequencing reagents until exemptions were allowed in January 2021. Many manufacturers were asked to show proof of 20% manufacturing in India [48]. In the current situation, there must be a clear distinction in import rules for public health-related or pandemic priority products and other products. According to scientists, there have been instances where government Covid-19 sequencing labs have had to wait for over four months for reagents. At this juncture, bottlenecks of genome sequencing related products need to be identified and resolved urgently. To aim for Atmanirbhar Bharat, the making of highly sophisticated ingredients for genome sequencing needs to be incentivized at home.

8. THE ROLE OF GENOME SEQUENCING IN THE ERA OF COVID-19 VACCINATION

Viral genomic surveillance allows new mutations to be identified as they emerge and provides crucial intelligence about when, where, and how the virus is spreading. Genomic surveillance is used routinely in parts of the world to track influenza and predict which flu vaccines will work best during a given season in a particular place. Genome sequencing is of special relevance when it comes to coronaviruses, which are known to mutate frequently.

As vaccines roll out to a large number of people in 2021, it is critical to accelerate genomic sequencing to track the emergence of mutations that could impact vaccine effectiveness.

Evidence indicates that mutations of SARS-CoV-2 are likely to emerge and must be detected in time before they spread widely. In view of the same, continuous monitoring and updating of vaccination strategy will be necessary [49]. The first steps toward setting up a robust genomic surveillance network have been taken, with the formation of a national network of labs - Indian SARS-CoV-2 Consortium on Genomics (INSACOG). This initiative should be funded adequately.

In the past 15 years, efforts to co-analyze viral genomic sequencing data, clinical data and epidemiological data have proved their usefulness in transforming responses in other infectious disease outbreaks.

- Sequencing of Severe acute respiratory syndrome coronavirus (SARS-CoV) in 2002-03 helped develop diagnostic responses rapidly. Hospitals in East Asian countries were identified as a source of mutation and spreading of the disease.
- During the Ebola virus epidemic in West Africa, co-analysis of genomic and epidemiological data established that transmission was possible through breast milk and sexual transmission for asymptomatic survivors even after they had recovered.

Researchers involved in genome sequencing also need to be supported with rich datasets, both clinical and epidemiological, to fully harness the power of genomic surveillance for effective pandemic planning and mitigation.

INSACOG - A GENOMIC SURVEILLANCE CONSORTIUM

A consortium formed for epidemiological surveillance of circulating strains of SARS-CoV-2 with a network of 10 labs:

1. National Centre for Disease Control, Delhi
2. CSIR-Institute of Genomics and Integrative Biology, Delhi
3. CSIR- Centre for Cellular and Molecular Biology, Hyderabad
4. DBT- Institute of Life Sciences, Bhubaneshwar
5. DBT-National Institute of Biomedical Genomics, Kalyani
6. DBT-InStem and National Centre for Biological Sciences (NCBS), Bengaluru
7. National Institute of Mental Health & Neurosciences (NIMHANS), Bengaluru
8. National Institute of Biomedical Genomics, Kolkata
9. Centre for DNA Fingerprinting and Diagnostics, Hyderabad
10. National Institute of Virology, Pune

Besides access to basic data such as geographical origin of the samples, it is important for researchers to have access to anonymized details of patients' medical records. This will help to answer questions about whether a new variant can be linked to different disease symptoms, severity, or outcomes, and whether a variant is more infectious or deadly.

Sequencing can also help answer questions about whether recovered Covid-19 patients are still susceptible to the virus, patterns of reinfection rates, and which Covid-19 vaccines work against emerging variants.

Sequencing databases can also help answer questions around the relevance of diagnostic tests against emerging variants. When genomic, clinical, and epidemiological data analyses are integrated, they can provide a real-time picture of an outbreak that is more nuanced and precise than the same data sets if considered in isolation (see Table 2). Genomic epidemiology can inform the rapid deployment of targeted interventions to protect the public as an outbreak unfolds [50].

The National Task Force on Covid-19 has selected ten front-line labs with diverse geographic distribution. Geographic diversity should also be represented in pathogen samples, as well as demographic attributes such as age, gender, and comorbidity profile.

Different labs in the network have different capacities when it comes to genome sequencing. While the top labs may easily meet the set target for genome sequencing, smaller labs may struggle to do so. To optimize efficiencies, it is prudent to give more responsibilities to labs with higher capacities in a short-term pandemic response while strengthening the overall lab infrastructure for other labs in the long-term.

The government needs to invest in infrastructure to develop the requisite systemic capabilities to accurately and safely link genomic, clinical, epidemiological, and other relevant data, across multiple sources that can strengthen public health responses to Covid-19 and successfully manage future outbreaks.

Making genome sequencing a mainstay in pandemic response is imperative so that India can effectively use the power of real-time sequencing to successfully shape the trajectory of the pandemic to minimize its impact.

TABLE 2: CONSIDERATIONS FOR TRANSMISSION, EVOLUTION, AND CLINICAL DISEASE

Goal	Question	Viral Genomic Sequence Data Needs	Clinical and/or Epidemiological Data Needs
Transmission patterns	Is the outbreak due to multiple introductions? Where is the virus coming from?	Pathogen samples from individuals who represent broad diversity from outbreaks and many regions/countries.	Time and place of virus isolation and travel history of cases
	Is the outbreak due to local spread? How and/or where is the virus being transmitted?	Sequences from local groups/areas with increased incidence rates	Local population-based information on sites of exposure, gatherings, isolated communities, and congregate living (long-term care facilities, hospitals, prisons)
	Severity of symptoms, ICU, ventilation, mortality, length of hospitalization, coinfections	Sequences of the virus from groups of people infected in the same setting.	Information on sites of exposure, gatherings
Evolution/ influence of selective pressures	Is the virus changing in transmissibility?	Changes in viral genome sequence associated with increased spread.	Calculations of R0 (contact tracing data– number of people infected)
	Is resistance to antiviral drugs or other treatments changing?	Changes in the viral genome associated with failure to respond to treatment.	Hospital or health care center data on patients who do not respond to therapy or show failure of treatment.

	Is there an altered escape from the host immune response/ within host evolution?	Changes in the viral genome associated with persistence.	Hospital data on patients who show prolonged shedding.
	Is there changed protection from vaccine-induced immunity?	Changes in the virus that affect epitopes important for protective immunity and sequences of viruses associated with vaccine failure.	Vaccine trial databases and post-marketing vaccine failures
	Are there strains/mutations associated with changes in disease severity?	Sequences of viruses from patients with different disease severity	Severity of symptoms, ICU, ventilation, mortality, length of hospitalization, coinfections
	Are there strains/mutations that affect virus loads or clearance?	Sequences of viruses from patients with viral load data	RT-PCR data to measure the viral load of respiratory secretions, blood, and feces over time.
Clinical disease	Are there strains/mutations that affect response to different treatments?	Sequences of viruses from before and after treatment	Treatment type, duration, and outcome
	Are there strains/mutations that are associated with response to different treatments?	Sequences of viruses from different body sites and patients with and without specific complications	Clinical data on complications related to different organ systems (e.g., kidney, liver, nervous system)
	Are there strains/mutations that predispose to MIS-C?	Sequences of viruses from children in the same community/family with and without MIS-C	Clinical data over time on immune response, viral load, treatment, and response

Source: Genomic Epidemiology Data Infrastructure Needs for SARS-CoV-2: Modernizing Pandemic Response Strategies (2020)

ACTION STEPS

1. REVIEW TESTING STRATEGIES IN LIGHT OF VACCINATION ROLL-OUT

- Testing and tracing must remain relevant as hundreds of millions of people in India are likely to remain unvaccinated by the end of 2021. New waves of Covid-19 and more transmissible and deadly mutations cannot be ruled out. Testing strategies need to be calibrated to the pace of vaccination, and the evolution of the virus.

2. STUDY THE VACCINATED AND NATURALLY INFECTED THROUGH CONTINUOUS TESTING

- Until evidence shows that vaccination will curb transmission, test individuals when they develop Covid-19 symptoms or come in contact with a Covid-19 positive person.
- If found to be Covid-19 positive without symptoms, individuals should be treated as asymptomatic carriers.
- Design studies to seek answers to questions around the immune response in vaccinated people.
- Periodically review evidence from around the world to determine the need for antibody testing for individuals before vaccination.

3. ASPIRE FOR A CAFETERIA APPROACH TO COVID-19 TESTING

- Create a choice of tests to cater to different sets of the population in various settings.

4. PLAN TWO DISTINCT PATHWAYS FOR TESTING

- Prescribe PCR tests or another accurate molecular diagnostic technology for confirmatory diagnosis. If PCR test is not available, then use serial antigen tests to confirm infection status.
- For purposes of assurance testing, such as domestic travel and keeping shops, offices and schools running, consider easy to use rapid tests with the highest specificity and sensitivity.

5. BUILD A FORMAL MECHANISM TO PROACTIVELY VALIDATE NEW INNOVATIVE TECHNOLOGIES IN TESTING

- Set clear regulatory pathways for proactive and transparent assessment, validation, and invitation of new testing technologies from across the world.

- Lateral flow antigen tests, saliva-based PCR tests, Loop-mediated Isothermal Amplification technologies, are point-of-care technologies worthy of attention.

6. PLAN POST-MARKETING SURVEILLANCE TO VALIDATE NEW TECHNOLOGIES

- Develop a monitoring mechanism to ensure that approved tests work in real-life conditions as per their stated claims.
- Arrange for tests to pass periodic quality checks.

7. DESIGN PERIODIC SERO-SURVEYS THAT CAN ASSIST POLICY MAKING

- Plan regular sero-surveys based on antibody tests, sewage water systems, pooled RT-PCR technologies in different contexts to glean epidemiological insights.

8. ENSURE TESTING IS EQUITABLE

- For socio-economically disadvantaged groups, cover the cost of the test, regardless of whether testing is accessed in the government or private sector.
- Consider merging Covid-19 testing into current disease control programs and integrated service delivery models.
- Resolve the variability of RT-PCR pricing across states.

9. REVIEW POTENCY OF CURRENT TESTING SYSTEM IN LIGHT OF MUTATION OF SARS-COV-2

- Improve & ramp up sequencing of samples adequately to catch more infectious and severe variants in time.
- Design and upgrade primers for tests to not let mutants escape the testing system.
- Seek information from test developers and marketers to assess whether the existing testing technologies are detecting new strains effectively.
- Establish direct channels with stakeholders, healthcare providers, and lab clinicians to catch aberrations in testing results.
- Add a new point of care tests to detect more infectious variants.

10. ACCELERATE GENOME SEQUENCING TO ENSURE COVID-19 VACCINATION EFFECTIVENESS

- Track virus mutations through genome sequencing that could impact vaccine effectiveness.
- Invest in infrastructure to develop the requisite systemic capabilities to accurately and safely link genomic, clinical, epidemiological, and other relevant data across multiple sources.

II. COST-EFFECTIVE AND SCALABLE TESTING THROUGH CENTRALISED POOLED PROCUREMENT

There are established ways to scale-up RT-PCR tests, make them affordable, and increasingly available if costs-structure for the private sector can be reduced significantly. These mechanisms including centralized procurement have been used effectively in global settings before – for vaccines, and in India, for HIV and TB tests – to cut the price of testing and to make these health interventions more accessible.

The pricing of RT-PCR tests has emerged as a point of contention in India throughout the pandemic. On one side, there is the question of affordability of these tests if market forces are allowed to prevail in a pandemic. On the other side, when states and courts cap prices at levels, the private sector find unviable to sustain services, the availability of these tests will be jeopardized.

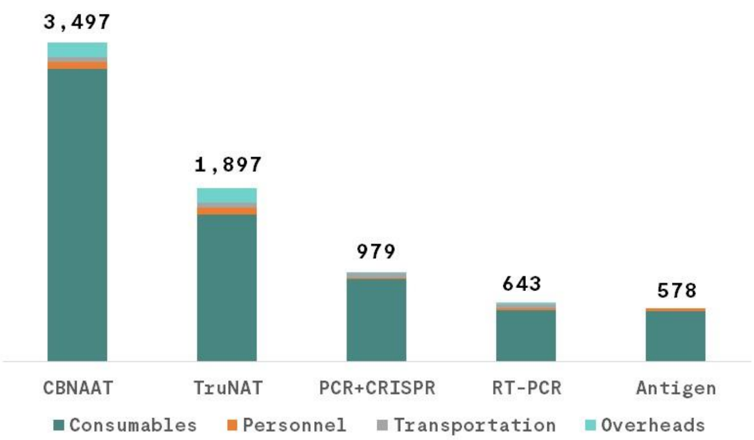
It was a 'catch-22' situation from March 2020 to December 2020, during which the price point of RT-PCR tests fell from over INR 4500 (USD 61.73) to INR 400 (USD 5.49) in parts of the country, prompted partly by fluctuating supplies of components for testing kits and price caps determined by states. While the upper end of the price spectrum was comparable to the per capita monthly income of some of India's poorest states, the lowest end of the price spectrum meant unviability of business to some private players. As a result, many private players had either stopped offering Covid-19 testing or deprioritized it by only using their marginal capacity before the second wave.

If more private players withdraw from Covid-19 testing, this will cause a difficult situation for all stakeholders: public, government, and private sector. The section of the population that can afford and prefers to use healthcare services in the private sector will have fewer choices and may be left with no option but to get tested in public healthcare facilities.

One major reason prices of testing kits, both RT-PCR and RAT, remained high is due to fragmented procurement by central and state agencies without a commonly agreed upon price structure. If the country uses pooled procurement for RT-PCR test kits, it can make available the most accurate Covid-19 tests for one third of current prices, allowing more private labs to offer the test. This will, in turn, ensure tests are more accessible and affordable on a sustainable basis.

As newer, more effective, and easy-to-use testing tools replace RT-PCR tests as the preferred choice to confirm a positive diagnosis, the pooling platform could also be adapted to procure these new testing kits centrally.

FIGURE 10: ESTIMATED AVERAGE COST OF DIFFERENT TESTS (IN INR) IN THE PUBLIC SECTOR

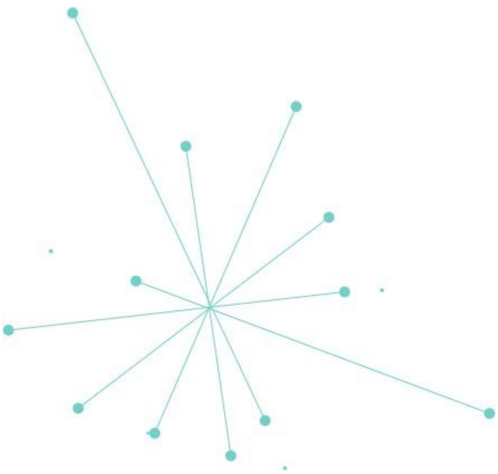


Source: Drivers of improving cost-efficiency of Covid-19 testing in India ISB/Max Institute of Healthcare Management

TABLE 3: COMPARISON AMONG TESTING VARIANTS

	RT-PCR	Rapid Antigen Test (RAT)	CBNAAT	PCR+CRISPR
Principle	Detects the presence of SARS-CoV2 genome	Detects antibody indicating the body's immune response to Covid-19	Detects the presence of SARS-CoV2 E- gene	Detects the presence of SARS-CoV2 genome
Sample required	Throat or nasal swab	Nasal swab	Throat or nasal swab	Throat or nasal swab
Sample preparation	Reverse Transcriptase to create DNA out of RNA	None	Automated	Reverse Transcriptase to create DNA out of RNA
Sample analysis time	6-8 hours	30 minutes	TrueNat – 90 Minutes; Xpert - 60 minutes	8-10 hours
Infrastructure required	Dedicated lab with facility for RNA extraction and RT-PCR machine	Almost none	TrueNat – portable and battery-operated; Xpert – dedicated labs required	Labs that can perform RNA extraction and manual PCR machine
Availability (as of Jan 25, 2021)	1337 labs	Data not available	1,018 labs; Many labs were previously part of the government's TB infrastructure	Data not available
Number of approved test kits	144	24	NA	NA
Approved usage by ICMR	Diagnosis	Diagnosis in containment zones and sero surveillance	Diagnosis	Diagnosis

Source: Drivers of improving cost-efficiency of Covid-19 testing in India ISB/Max Institute of Healthcare Management



1. SUBSTANTIALLY REDUCING RT-PCR COST

For a large part of the pandemic, many states in India over-relied on less accurate RATs because they were cheaper and easier to use compared to more accurate RT-PCR tests. However, an ISB-Max Institute of Healthcare Management (MIHM) model on cost of testing shows that if a pooled procurement mechanism is used to procure RT-PCR test kits, the cost of RT-PCR testing can be reduced by up to one- third, bringing it down to INR 341 per unit (USD 4.68) (see Figure 12).

The world and India have already seen the benefits of pooled procurements. Other disease management programs have successfully leveraged pooled procurement to reduce the cost, improve the quality, and increase the availability of tests.

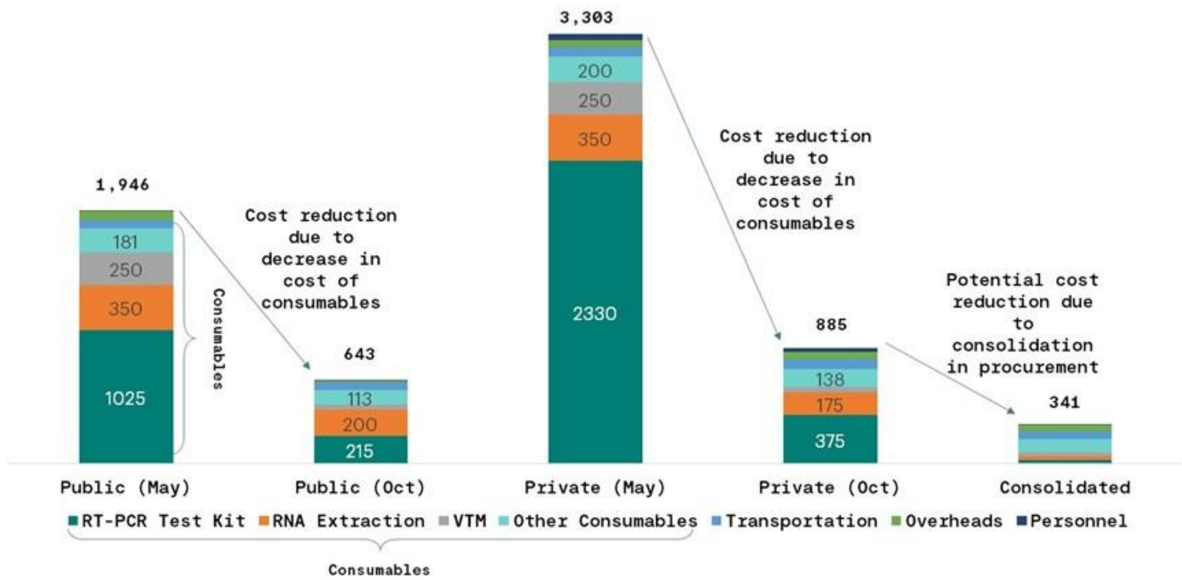
In the case of TB, laboratories partnered with each other and formed the IPAQT (Initiative for Promoting Affordable and Quality TB Tests) alliance. The alliance negotiated lower prices for equipment and reagents, which lowered the cost of testing for patients. Further, the IPAQT alliance helped to generate demand, which led to an increase in testing.

In the past, not-for-profit organizations such as PATH and Clinton Health Access Initiative (CHAI) have worked with state governments to provide TB testing services free-of-cost to patients across public and private sectors. The government onboarded labs based on pre-decided rate cards and reimbursed private laboratories based on the number of tests conducted. During 2011-2018, this initiative resulted in a 10-fold increase in the uptake of tests (Xpert) and a 30% - 50% reduction in price [51].

The Global Fund to fight Malaria, AIDS and TB uses pooled procurement at a much larger scale. Their central procurement measures have reduced the cost of an insecticide-treated malaria net and antimalarial treatment to less than USD 2 and USD 0.58, respectively, for partner countries [52].

In India, the National AIDS Control Organization (NACO) has adopted a similar strategy for HIV testing kits. The organization procures the kits centrally and distributes them to both public sector labs and empaneled private sector labs. NACO and ICMR have created a consortium of labs for verifying HIV testing kit quality, enabling NACO to address the quality of tests as well as ensuring faster onboarding of validated kits [53]. These are encouraging signs that similar measures could work for Covid-19 testing in India.

FIGURE 11: AVERAGE COST OF RT-PCR TEST (IN INR) IN DIFFERENT PROCUREMENT SCENARIOS

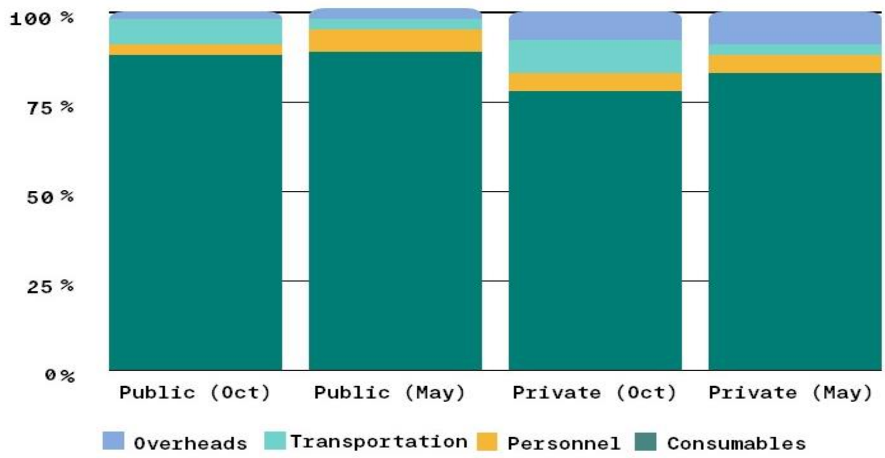


Source: Drivers of improving cost-efficiency of Covid-19 testing in India ISB/Max Institute of Healthcare Management

1.1. PROCURING KITS AND CONSUMABLES THROUGH A CONSORTIUM

To attain this three-fold reduction in the cost of Covid-19 testing, states should procure kits and consumables through a consortium rather than independently. This consortium can be facilitated by the central government to ensure states can exchange information seamlessly with counterparts. It can use expertise gained from HIV and TB programs, which have used pooled procurement effectively in India and around the world.

FIGURE 12: PERCENTAGE COST CONTRIBUTION ACROSS THE VALUE CHAIN

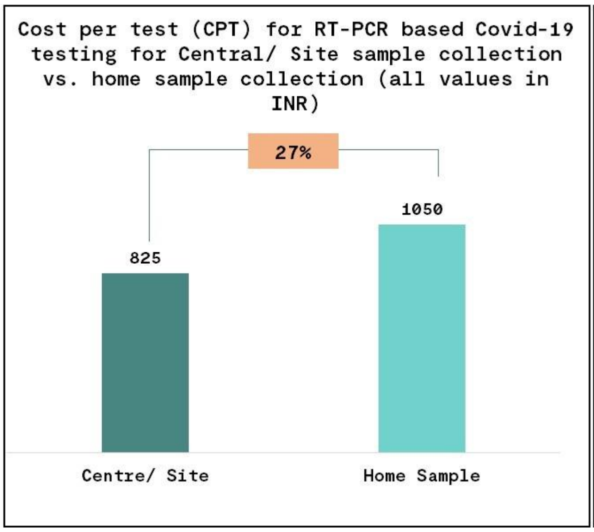


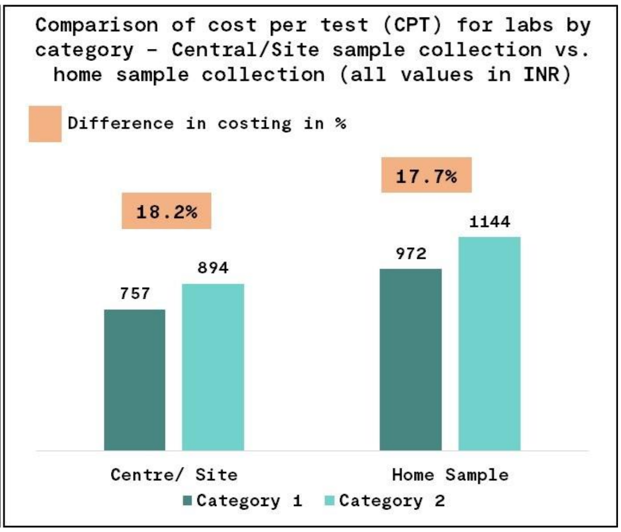
Source: Drivers of improving cost-efficiency of Covid-19 testing in India ISB/Max Institute of Healthcare Management

1.2. EXTENDING COST BENEFITS TO THE PRIVATE SECTOR

Extending the benefit of pooled procurement kits to the private sector may encourage many more labs to opt to offer RT-PCR testing, increasing testing capacity and reach. In the cost-structure of RT-PCR, consumables still account for a large share (see Figure 13). Therefore, if consumables are procured at scale, and made available at cheap prices to private labs, offering RT-PCR tests at a low cost would become viable. This finding was validated by an analysis of NATHEALTH (an industry grouping of private healthcare players) done in December 2020 (see Figure 14).

FIGURE 13: CENTRAL/SITE SAMPLE COLLECTION VS. HOME SAMPLE COLLECTION





Source: NATHEALTH Report, 17th December 2020

2. BALANCING PRICE AND ACCESS TO ENHANCE TESTING AVAILABILITY ACROSS STATES

The imposition of variable price-caps by states, without driving down the cost of tests, may discourage the private sector from offering RT-PCR tests. Anecdotal evidence suggests that this may already be happening in parts of the country, where mid- to small-sized labs are finding it unviable to offer RT-PCR tests [54]. Almost 60% of private-sector diagnostic services are rendered by stand-alone labs or regional chains comprising of a few labs. The private sector diagnostic industry in India is highly fragmented, with pan India diagnostic players only accounting for 6% of the total market. The remaining market-share in the diagnostic sector is comprised of hospitals.

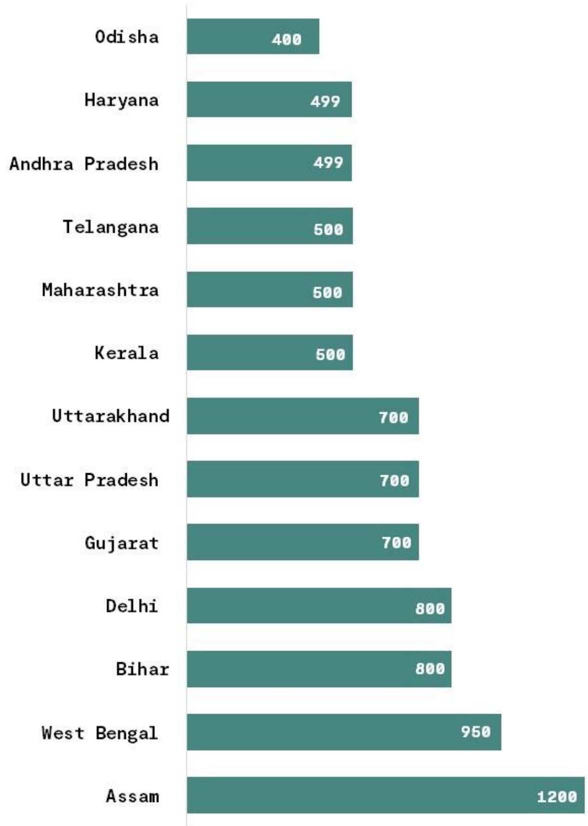
Right before the second wave hit India, some large labs had deprioritized Covid-19 testing in favor of non-Covid-19 testing, which has a steadier demand, and better margins, according to industry insiders [55]. The private sector's daily Covid-19 testing for the entire state of Punjab stood at half of what a medical college in Patiala did in February 2021, according to stakeholders working on the ground.

This shift of Covid-19 testing to public sector has consequences, including limiting choices of accurate tests for citizens and adding additional resource and financial burdens on health systems that are already overstretched.

The wide range of price-caps on RT-PCR tests across states indicates that the cost-structure of tests was not fully taken into consideration while fixing the price. For example - one state has capped prices at INR 1200 (USD 16.34), while another state has capped it at INR 400 (USD 5.49) (see Figure 15). A significant amount of price decline in RT-PCR tests in last few months is due to cost reduction in raw material and competition among an increasing number of testing kit makers. However, according to industry insiders, the price of Covid-19 tests also became a victim of populism, with each state trying to outdo the other without fully factoring in repercussions associated with such price-caps.

States should cap prices only after a careful analysis of the various cost elements involved in testing, with a view to keep it viable for the private sector to continue testing for Covid-19.

FIGURE 14: PRICE CAPS (IN INR) FOR RT-PCR TESTS ACROSS STATES (AS OF APRIL 2021)



Source: Various Media Reports

3. MAKING RT-PCR PRICE COMPETITIVE WITH RAT FOR A CONFIRMATORY DIAGNOSTIC TEST

A single rapid antigen test (RAT) is more affordable than RT-PCR. However, due to its low sensitivity in comparison to RT-PCR, if the first RAT result comes out negative, one has to repeat the test on RT-PCR or do a second RAT to confirm the result.

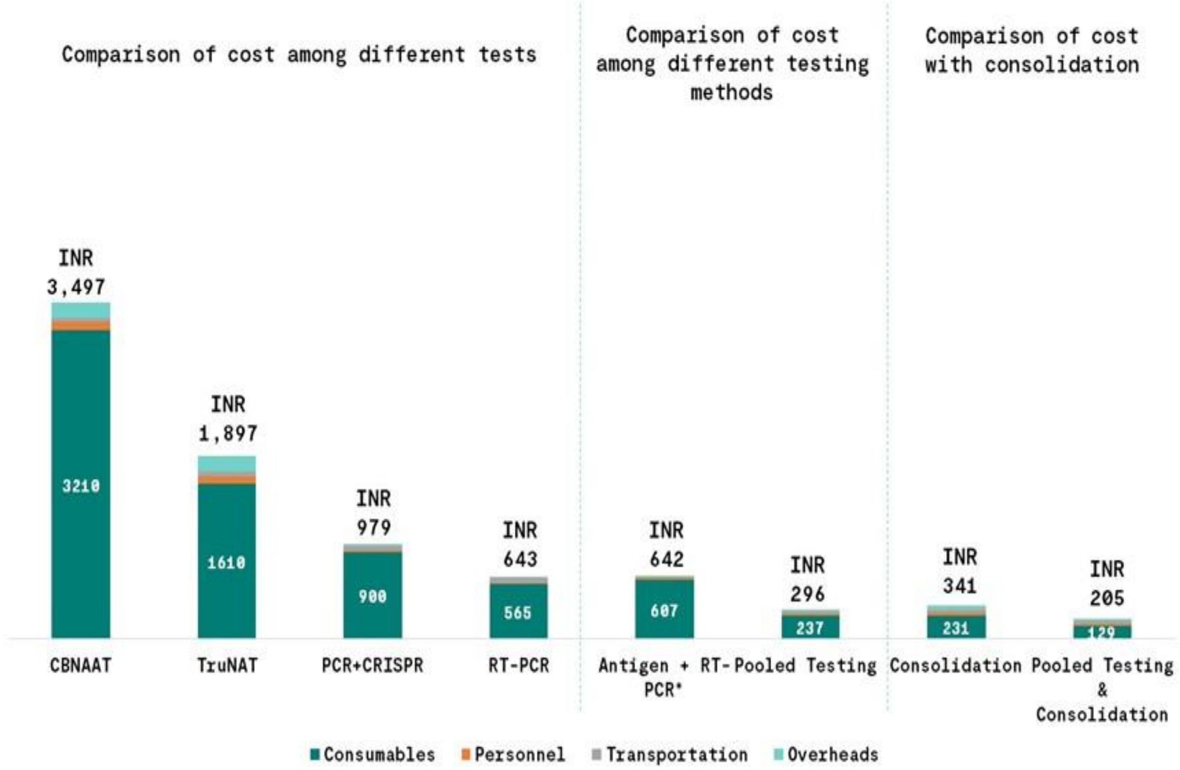
According to the ISB-MIHM cost model, undertaking two RATs is more expensive than conducting one RT-PCR or other comparable substitutes (see Figure 16). Therefore, it makes sense to restrict the serial antigen testing only to contexts where RT-PCR or other accurate tests cannot be made available.

3.1. POOLED RT-PCR TESTING CAN FURTHER DRIVE DOWN THE COST

If pooled RT-PCR testing with five samples can be used in low-prevalence settings with a positivity rate of less than 2%, (as recommended by ICMR) at scale, centralized procurement can drive down costs of tests to INR 205 per test (USD 2.81 per test), according to the ISB-MIHM cost model [56].

However, for the pooled testing strategy to be commonly utilized in both private and public labs, the government must invest in ramping up lab personnel training. This pooled RT-PCR testing strategy can be an effective part of the mass-surveillance in the future.

FIGURE 15: PRICE CAPS FOR RT-PCR TESTS ACROSS STATES (IN INR)



* Cost of Antigen+ RT-PCR was calculated by assuming 10% of people tested using Antigen were found negative and had symptoms.

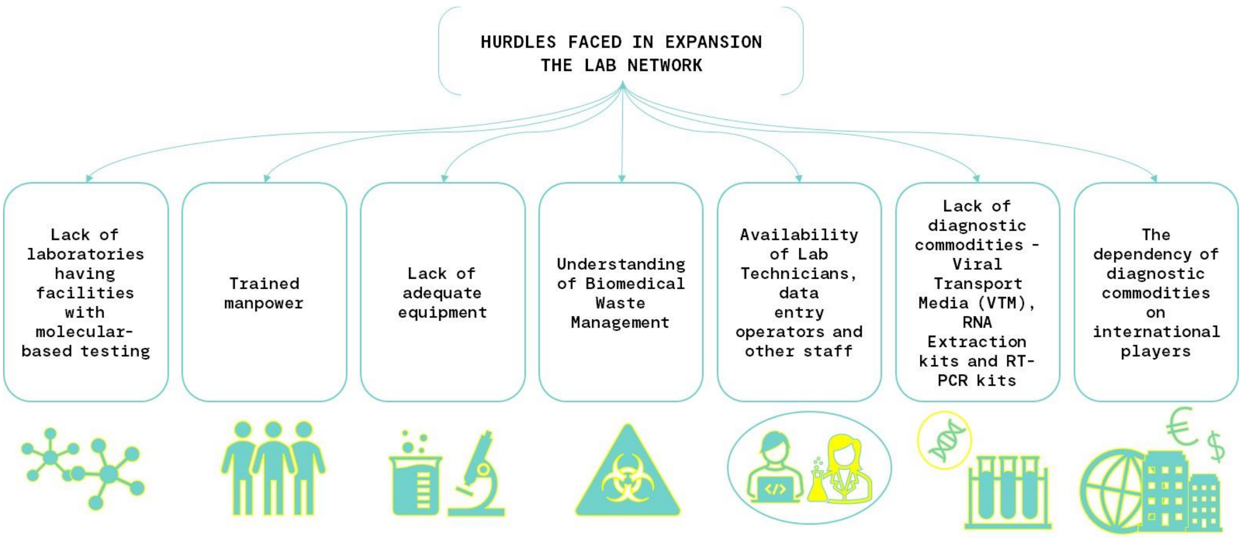
Source: Drivers of improving cost-efficiency of Covid-19 testing in India ISB/Max Institute of Healthcare Management

4. OPTIMIZING THE LAB NETWORK ACROSS STATES

Since the distribution of laboratory infrastructure is not uniform across the country, coordination between adjoining states to transfer test samples could be beneficial for the states with less robust health systems (see Figure 17). This would enable efficient sharing of resources between the states without compromising on the number and type of tests.

Several private sector companies operate centralized models where samples are collected from centers across the country and are transported to a central testing facility via air-cargo logistics within 24 hours. Outsourcing of inter-lab transportation (and testing, if needed) to third-party private sector players is an area for exploration to reduce costs associated with setting up new equipment and facilities in public sector.

FIGURE 16: HURDLES IN LAB NETWORK EXPANSION



Source: Management of Covid-19 pandemic and related issues, 229th report, Department-related Parliamentary Standing Committee on Home Affairs, Rajya Sabha

The following measures were taken to address the hurdles faced in expanding the lab capacity:

- The ICMR increased its efforts by adding private testing RT-PCR laboratories, expedited approval mechanisms by NABL, and initiated TrueNat/CBNAAT based testing in district-level hospitals and other testing facilities.
- The Government of India identified 14 Centre of Excellence Institutes as a Mentor Institute for mentoring all government and private medical colleges in their catchment area.
- The testing was increased by the introduction of rapid antigen-based testing (by ICMR).
- The ICMR purchased and deployed 57 RT-PCR machines and 125 RNA Extraction machines in various laboratories across the country. ICMR also supported the laboratory network w.r.t VTM, RNA Extraction kits and RT-PCR kits.
- Ministry of Electronics and Information Technology deployed data entry operators through Common Service Centres in the states.
- Owing to the sudden and unprecedented nature of the pandemic, initially, India completely relied on the import of testing kits and polymer swabs primarily from the United States, Germany, China

Source: Management of Covid-19 pandemic and related issues, 229th report, Department-related Parliamentary Standing Committee on Home Affairs, Rajya Sabha

5. ENCOURAGING DOMESTIC PRODUCTION FOR TEST KITS IS STRATEGICALLY IMPORTANT

At the start of the pandemic, India depended on imports for RT-PCR testing kits from the United States, Germany, and China. This has now changed, with close to 450 India-based players making RT-PCR kits. Local manufacturing of RT-PCR kits has contributed to a reduction in the unit cost of these kits. However, many of the components in the kit are still imported. Since some other countries are already leveraging economies of scale and have a comparative cost advantage, indigenously producing the kit components may not lead to a significant cutting of cost for the country [57]. However, domestic production will create a steady supply of test kits which is absolutely essential in pandemic outbreaks.

In November 2020, a parliamentary panel underscored the need to encourage the domestic medical device manufacturing industry to minimize the import of diagnostic kits from other countries [58]. This would improve supply dynamics and create a more competitive ecosystem.

In the short-term, ensuring availability of testing kits that meet quality standards is critical. In medium to long term, self-sufficiency in components like primers and probes for RT-PCR should be the focus for strategic reasons. Depending on imports for critical health products used in emergencies can expose the country to risks of shortages based on supply constrains in source countries. Further, products developed in other countries fail to perform well here many times due to climatic conditions, and other logistical challenges typical to the country.

For this, homegrown testing kit makers need to be incentivized. They should also be allowed to export their products and compete in the global market when India's need for testing reduces. This will encourage them to match global quality standards and keep them ready to respond if there is a sudden surge in domestic demand for testing.

5.1. NOVEL TECHNOLOGIES MAY HELP TO SCALE UP TESTING

The Covid-19 testing technologies space is in the middle of huge disruption, and the search for an accurate, affordable, point-of-care or home-based, easy-to-use test that can be used frequently is still underway. It is possible that in India, or in overseas markets, such a test may revolutionize Covid-19 testing soon.

Until such a test is developed and brought to scale, other scalable and affordable, easy-to-use alternatives to RT-PCR can be proactively pursued. CRISPR FELUDA's accuracy has been hailed as comparable to that of the RT-PCR test. Even though FELUDA does not offer much cost advantage over RT-PCR tests, there are other benefits associated with it (see Figure 17 & Table 4). Another potential alternative to RT-PCR could be, RT-LAMP tests which can be used in places where use of RT-PCR may prove challenging [59].

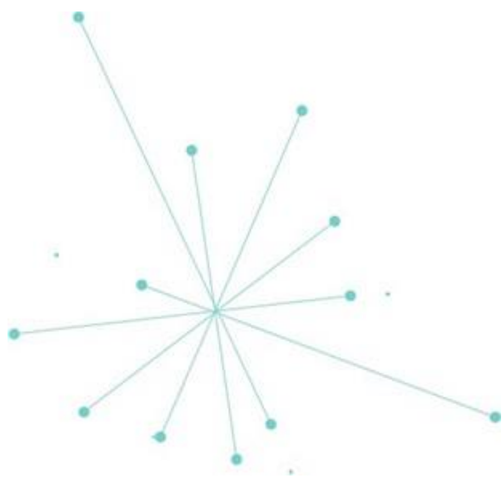
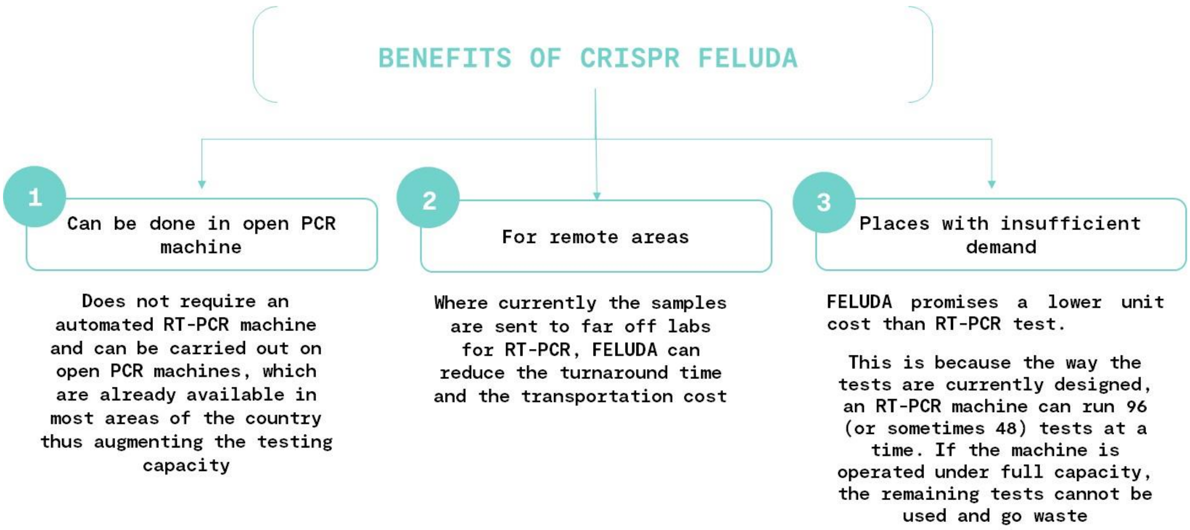


FIGURE 17: BENEFITS OF CRISPR FELUDA



Source: Illustrated by Chase India, adapted from Drivers of improving cost-efficiency of Covid-19 testing in India, ISB/Max Institute of Healthcare Management

TABLE 4: EVALUATION OF PCR + CRISPR (FELUDA)

S. No.	Measure	PCR + CRISPR (FELUDA) test
1	Availability of equipment	A popular belief is that the adoption of PCR + CRISPR technology will increase testing capacity, as it needs a manual PCR machine vs an automated PCR for RT-PCR test. According to the manufacturer, this test can also be deployed in a real mobile vans in a line.
2	Quality concerns	Greater training and skills are required for FELUDA test in comparison to RT-PCR test. 1. Lab technicians are required to manually dip 96 individual strips in the PCR machine to test the results of the amplification process. In our interactions with experts, we found that the test strips of the FELUDA test are susceptible to contamination, given the high degree of manual intervention. 2. Since the last process step in the FELUDA test requires the lab technician to visually interpret the fluorescent color's darkness, lab technicians are required to be careful. The manufacturer claims to have brought an automated, high throughput version that does not require skilled manpower.
3	High turnaround time (TAT)	With a capacity of 94 blocks per PCR machine, all these amplified samples are processed using FELUDA kit, which takes additional 2 hours. Thus, increasing the TAT to 8 – 10 hours. The fully automated version is claimed to have a much lower TAT of 2-3 hours
4	Decreased waiting time	Due to lower Capex investment, lab technicians might be willing to run each batch at a lower utilization, thus reducing the waiting time.
5	High cost of test	INR ~808 – 1150 (USD 11.14 -15.85) for public labs
6	Price of test	Media sources report the price to be ~INR 500 (USD 6.89)

Source: Drivers of improving cost-efficiency of Covid-19 testing in India, ISB/Max Institute of Healthcare Management

PCR + CRISPR (FELUDA) test kit (~INR 550/ USD 7.55) costs higher than RT-PCR kits (INR 50 - 380/ USD 0.69 - USD 5.21)

6. EFFECTIVE VERTICAL AND HORIZONTAL COORDINATION

Coordination among the various departments and states/districts, and across various levels of the government is necessary to implement cost reduction measures quickly and effectively. First, effective coordination across various functional areas, including surveillance, research and development, demand forecasting, procurement, and field operations will be necessary. An efficient pandemic control protocol must go beyond assigning each task to a dedicated department, as was done during early days of Covid-19 in India (see Table 5). It requires effective information gathering, coordinated monitoring and evaluation, and operational coordination among these different units.

Further, inter-state synergies that leverages different states' manufacturing specialties could assist in significantly bringing down testing kit manufacturing costs. Establishing a coordination agency at the helm, consisting of members with expertise in pandemic and disaster management, is necessary.

While ICMR prioritizes its focus on central level policy-setting for Covid-19 testing, state and district authorities must continue to take up. States and local administrations have the added advantage of drawing on knowledge from their constituents making the last mile leg of the test kit supply chain efficient and cost-effective.

Establishing such price-equitable and sustainable models will be crucial to managing future crises and reducing the national-level threat of emerging viruses - whether from the next wave of Covid-19, emerging variants, or a completely new pathogen.

TABLE 5: SOURCES OF PROCUREMENT FOR PUBLIC AND PRIVATE LABS

Steps	Reagent required	Procurement	
		Public Lab	Private Lab
Sample collection	VTM for sample collection (2 swabs throat and nasal- should be put in 1VTM tube)	By state government	Private players
RNA extraction	RNA extraction Kit	By state government	
RT-PCR	Primers, probes, master mix, positive control, RNAseP	ICMR through resident Commissioner and state nodal officer	
	Machine	Central government (for virus research and diagnostic labs)	
RT-PCR testing machines allocated to government labs by the Centre but tender requests for consumables and reagents are submitted by each state independently. Procurement of consumables and machines in the private sector done independently from International and Indian manufacturers.			

Source: Drivers of improving cost-efficiency of Covid-19 testing in India ISB/Max Institute of Healthcare Management

ACTION STEPS

1. USE POOLED PROCUREMENT MECHANISM TO BRING DOWN RT-PCR TEST COST TO A THIRD

- Encourage states to procure kits and consumables through a consortium rather than independently.
- Extend the benefits of pooled procurement to the private sector to increase testing capacity and reach.

2. RESOLVE PRICE VARIABILITY OF RT-PCR TESTS ACROSS STATES

- Determine price caps after factoring in cost elements involved in testing to keep it affordable for consumers and viable for the private sector.

3. OPTIMIZE LAB NETWORKS ACROSS STATES

- Ensure coordination between adjoining states to transfer test samples from states with less robust health systems to states with additional capacity.

4. CREATE INCENTIVES FOR DOMESTIC PRODUCTION OF TEST KITS

- In the short-term prioritize the availability of testing kits, that meet quality standards through imports and domestic production.
- In the medium to long term, focus on self-sufficiency in components like primers and probes for RT-PCR for strategic reasons.

5. ENSURE EFFECTIVE VERTICAL AND HORIZONTAL COORDINATION FOR SEAMLESS PANDEMIC RESPONSE

- Ensure collaboration across various functional areas: surveillance, research and development, demand forecasting, procurement, and field operations and as well as across administrative levels for an effective testing ecosystem.

III. DEMAND FORECASTING FOR TESTS

Given the evolving nature of the Covid-19 pandemic, demand for testing will fluctuate based on many variables — new variants, vaccination rates and efficacy, seasonal changes, uptake of a mass-testing or surveillance regimen, and more. Under such circumstances, maintaining a reliable and well-managed supply of testing resources is critical. Industry estimates indicate that some states take two to four weeks to place procurement orders when demand for testing kits rises, while testing kit makers claim that they require two to six weeks of advance notice to ramp up manufacturing and delivery. Given this, investing in demand forecasting will help set purchasing expectations for manufacturers, secure sustainable and predictable supplies without gaps, and ensure that tests reach states in a timely and reliable manner. This will also ensure that testing kit makers do not sit on the idle capacity for too long.

a. VACCINATIONS MAY DRIVE DOWN COVID-19 TESTING DEMAND

According to January 2021 estimates from the Research and Innovation Circle of Hyderabad (RICH), vaccination roll-out and declining Covid-19 caseloads were expected to drastically reduce testing in 2021. However, the estimates also predicted that need for Covid-19 testing may suddenly increase for a variety of reasons - the appearance of a new and more virulent variant of the virus that is undetectable through the present testing system or causes less effective vaccine performance. Demand for Covid-19 testing may also rise if immunity from natural protection and vaccination is found to be short-lived or there is a sudden resurgence of Covid-19 cases.

b. BEFORE THE SECOND WAVE, COVID-19 TESTING WAS ESTIMATED TO DECREASE BY UP TO 70% IN 2021

Overall, demand for all types of Covid-19 testing — RT-PCR, rapid antigen, CBNAAT as well as TrueNat was predicted to dip by 55% to 70% in 2021 compared to 2020. This estimate followed the trend of December 2020, which saw a 23% month-on-month dip in Covid-19 tests after November 2020. Testing numbers in January and February 2021 was expected to remain almost on par with December 2020, mainly because people were likely to confuse common cold symptoms with Covid-19. This means if not for the winter season and the overlap of seasonal flu and Covid-19 symptoms, declining caseloads would have further reduced Covid-19 testing at the start of the year.

In December 2020, Covid-19 testing was anticipated to further decline by up to 60% between March and June 2021. This downward trend was likely to continue between July to September 2021, with another 10% reduction in testing. The projections by RICH indicated that number of Covid-19 tests in 2021 was expected to be in the range of 76 million to 128 million (see Figure 19).

These forecasts for testing demand were not without limitations. For instance, they did not account for testing increases, in the following instances:

- If a new variant or a next wave causes a surge in cases, like in the current situation of the second wave;
- If vaccine options are not as effective as expected;
- If immunity after natural Covid-19 infection or after vaccination is not long-lasting;
- If a very convenient, accurate, cheap point-of-care test is commercialized and scaled-up;
- If routine testing in offices, schools, and colleges, picks up as public spaces reopen.

c. COVID-19 TESTING KIT MAKERS SHOULD NOT GO ON SLEEP MODE YET

According to industry experts, if the trajectory of the virus shifts in one or more ways and the demand for testing soars abruptly, testing kit makers, particularly Indian suppliers, could take two to six weeks to deliver the kits. This is partly because Indian Covid-19 test makers are still dependent on imports for important ingredients in the kits. Domestic players claim they lack the cash reserve to buy and stock up RT-PCR tests ingredients long-term, which can ultimately set back shipping timelines. For instance, if testing kit makers obtained their validation based on imported ingredients, it could take six weeks or more to ship those into India and deliver the kits.

The most vulnerable ingredients that go into making an RT-PCR kit, the enzymes, and the master-mixes, have a shelf life of nine to ten months. These are also the ingredients for which the country is most dependent on imports. Thus, if the industry needs to scale up testing significantly, it will need advance notice of four to eight weeks, according to estimates.

The industry experts explain that RT-PCR kits cannot be made based on a 'switch-on/switch-off' model. Developing RT-PCR kits require a long runway and coordination between multiple stakeholders, which makes scaling up quickly difficult if test kit makers relax production. It is a process that will have to 'restart' if it goes into 'sleep' mode. This could imply that without scientific predictions on demand for tests, test makers would sit on idle capacity and incur losses. Alternatively, if cases escalate rapidly in multiple parts of the country, tests may not timely reach people in need.

d. DEMAND PROJECTION OF COVID-19 TEST KITS WILL PRE-EMPT SHORTAGES

One of India's most pressing needs is to appoint a capable agency to scientifically forecast testing demand on a quarterly basis, if not more frequently. Such forecasts should also simulate indicators reflecting the emergence of a more infective variant, impact of vaccination on testing, a lower-than-expected vaccine efficacy, the effect of allowing exports of test kits, the need for importing test kits and any other identified factors that threaten to increase infections. The country must also stress-test its testing ecosystem to measure how prepared it is to quickly respond to unexpected demand situations, including the potential threat of variants escaping detection. At a policy level, India could also decide to maintain a reserve of raw material for testing capacity to preempt shortages of tests in the foreseeable future.

e. STEPS TO KEEP TEST MAKERS RESPONSE-READY

Easing export restrictions on Indian testing kit manufacturers could help keep the testing industry response-ready for the future. This will ensure that the industry can become part of the global supply chain and remain functional even at a time when India does not need its full test kit making capacity. Additionally, this would enable Indian test kit makers to meet the quality standards mandated by other international regulators such as US FDA or CE mark. At the same time, if the domestic need arises, these manufacturers will be able to quickly respond to the demand. This will also continue to promote the vision of 'Atmanirbhar Bharat'.

Sound and scientific projections along with centralized procurement, as discussed in previous sections, can bring efficiencies, scale capacity, and ensure cost-effectiveness to a testing system.

Two scenarios have been modelled to estimate the overall demand between Jan 2021 to Dec 2021:

- Scenario 1: Forward-looking demand based on country-level testing volume for the last few months and overall population coverage at the country level.
- Scenario 2: Individual state projections for states that have higher testing coverage and testing volume (sum-of-the-parts estimate with individual projections for certain states and blanket assumptions for rest of the country).

The states for individual demand modelling have been selected based on potential impact on overall demand estimate (high population coverage and testing volume). Covid-19 Diagnostics: Demand Estimation Study 1 conservative estimate and factors in lower testing volume due to certain states already having testing >15% of their population or having relatively lower level of testing as compared to the national average. Higher RAT % has been assumed in certain states individually modelled if historical testing trends (from secondary research) indicated use of higher levels of RAT.

The amount of testing done in the country until December 2020 was 168.8 million tests. Based on decline noted in testing volume in the months of November and December 2020 in most states, declining incidence and impending vaccine roll-out, and progressively continuing decline in testing volume through 2021 is anticipated. The testing volume that was estimated under both scenarios is summarized below:

Scenario – 1 (Testing Volume estimate for January 2021 to December 2021):

Segment	**Total no. of Tests**	**RT-PCR**	**RAT**	**CBNAAT/ TrueNAT tests**
Public & Private Sector	11,71,43,320	4,68,57,328	4,68,57,328	2,34,28,664
Hospitals in Public & Private Sector	67,04,244	20,11,273	46,92,971	-
Total	12,38,47,564	4,88,68,601	5,15,50,299	2,34,28,664

Scenario – 2 (Testing Volume estimate for January 2021 to December 2021):

Region	**Total no. of Tests**	**RT PCR**	**RAT**	**CBNAAT**
Delhi	50,52,532	10,10,506	30,31,519	10,10,506
Karnataka	50,27,518	20,11,007	20,11,007	10,05,504
Tamil Nadu	47,47,452	35,60,589	2,37,373	9,49,490
Maharashtra	33,12,574	11,59,401	16,56,287	4,96,886
West Bengal	30,49,938	12,19,975	12,19,975	6,09,988
Andhra Pradesh	28,99,098	11,59,639	11,59,639	5,79,820
Kerala	23,49,584	9,39,833	9,39,833	4,69,917
Haryana	15,54,398	3,10,880	9,32,639	3,10,880
Rest of India	3,94,24,844	1,57,69,937	1,57,69,937	78,84,969
Hospitals in Public & Private Sector	67,04,244	20,11,273	46,92,971	-
Total	7,41,22,182	2,91,53,042	3,16,51,181	1,33,17,959

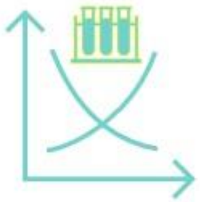
- Composition of platforms for testing (RT-PCR, RAT and CB-NAAT/TrueNat is in the ratio of 40:40:20 based on current use pattern.
- Any RT-PCR or RAT testing done at airports is included in reported national volumes. The current practice at both public and private hospitals to perform RT-PCR based Covid-19 tests for any procedures performed and RAT tests for any admissions for in-patient and emergency cases has been considered for the analysis.

** These projections were made in January 2021 and would be revised periodically.*

Source: Research and Innovation Circle of Hyderabad (RICH) for C-CAMP in January 2021

ACTION STEPS

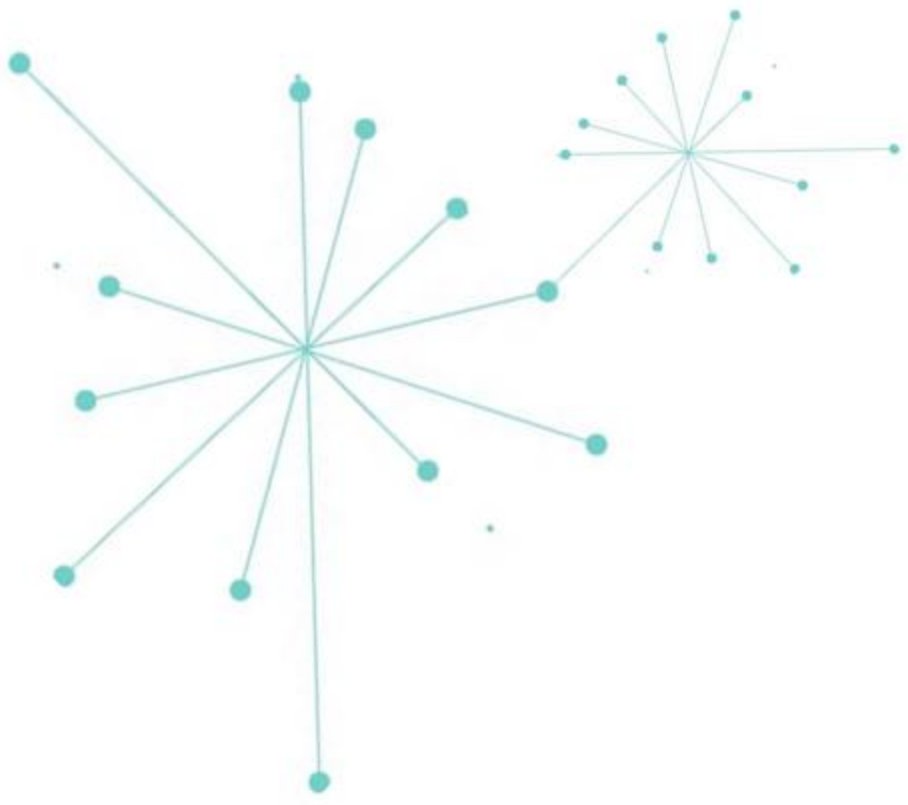
1. PREDICT DEMAND OF COVID-19 TEST TO ENSURE STEADY SUPPLIES



- Make demand projections for tests periodically to keep the testing industry response-ready for the future.
- Maintain a reserve of raw material for testing capacity to preempt shortages of tests in the foreseeable future.

2. PREVENT DOMESTIC KIT MAKERS FROM GOING INTO SLEEP MODE

- Incentivize test kit makers for domestic production.
- Ease export restrictions on Indian testing kit manufacturers when domestic demand for test kits is low as a strategy to effectively integrate Indian test kit makers in the global supply chain.



IV. TRACING AND TRACKING STRATEGY

Comprehensive contact tracing has been an enormous and complicated task for India with the country's heterogeneous and dense population. In the absence of any pharmaceutical cure, the choices of infection control strategies are limited for an outbreak like Covid-19; therefore, it is necessary to build a detailed tracing and tracking protocol that leverages an optimal combination of both manual and digital practices, delivered by a pool of trained healthcare workers. Tracing and tracking also need to be refined and practiced in times when infections are low. This will ensure better preparedness for recurring waves of the pandemic and future infectious disease outbreaks.

Most countries that have managed to flatten the curve and successfully sustain low infection rates in the initial months of their Covid-19 outbreaks—such as South Korea, Taiwan, Hong-Kong, Germany, and New Zealand—used contact tracing effectively [60]. Barring Japan, which mostly relied on manual efforts, most of these countries have turned to digital technologies in one or multiple ways to support their tracing efforts [61].

In other East Asian countries celebrated en bloc for their response to the pandemic, citizen's collectivist spirit, a willing compliance with governments' infection control measures, and openness to using technology for public health surveillance have also enabled the containment efforts [62]. In addition to cultural elements, a collective memory of experiences with other deadly viruses like SARS and MERS, likely spurred this public cooperation with state measures.

Testing and tracing are both critical to flatten the curve: when a country manages to trace potential infection carriers effectively through tracing, such efforts can ensure its testing strategy is focused and well-targeted. In India, the tracing policy guidance released by the government at the Centre was in line with WHO recommendations calling for tracing of at least 80% of contacts of those infected within 72 hours of symptom onset [63][64].

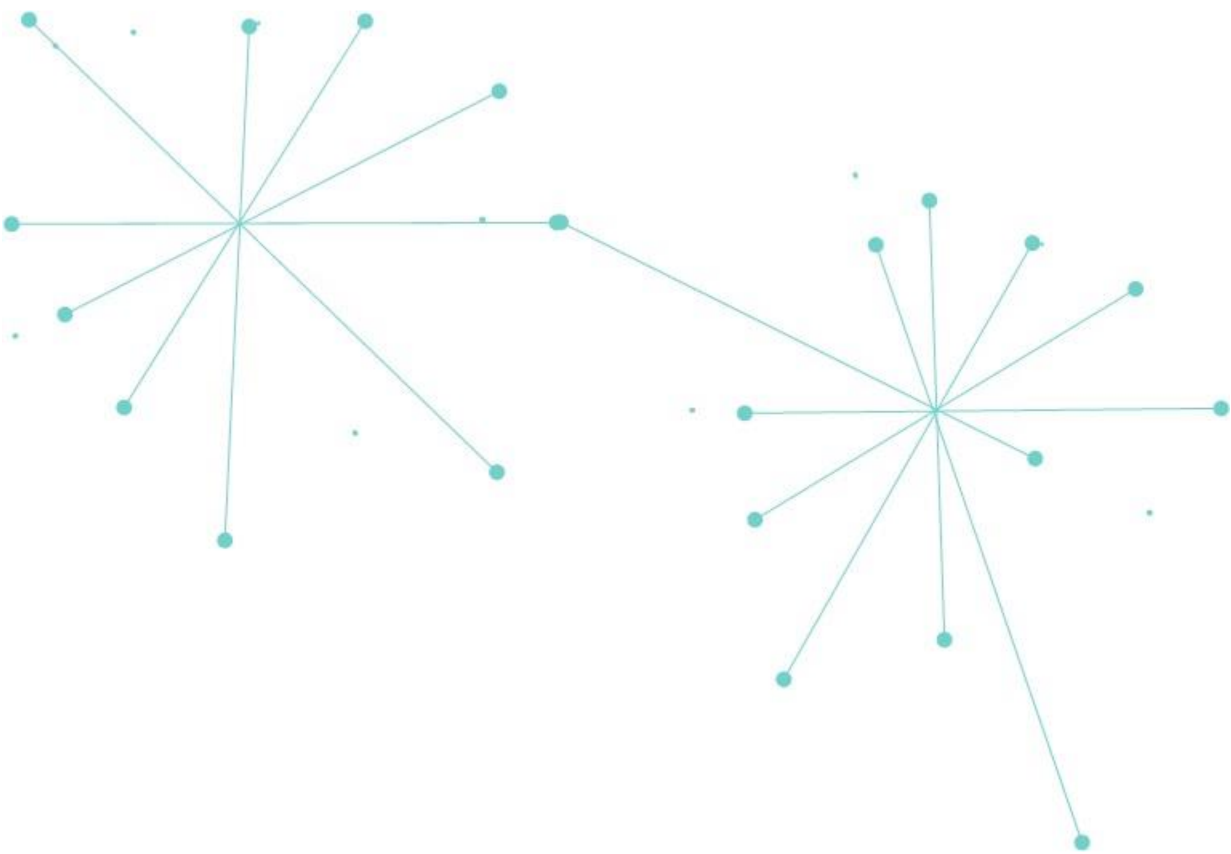
However, this guidance has not been uniformly implemented across states. In the initial phase of the pandemic, most Indian states attempted to trace contacts, and some saw success. Kerala, for instance, used tracing effectively in the first wave to keep infections under control. As cases surged, however, most states' tracing efforts became overwhelmed [65]. In December 2020, a parliamentary panel noted the need to train community healthcare workers in contact tracing skills [66]. The skills required for front-line contact tracing are significantly different from those of advanced contact tracers, such as "cluster-busters" [67]. It is crucial that contact tracers with each of these skill sets are present at the state level. These contact tracers can be activated, depending on the threat perception indicated by test positivity rate, the gradient of the caseload, and alerts of dangerous variants through genome sequencing data (see Table 6).

To track infections digitally, the Centre released the Aarogya Setu app in April 2020. However, after an initial spurt — in 40 days post-launch the app had seen over 100 million installations — Aarogya Setu struggled to expand its user base further by adding a little over eighty-five million in the next thirteen months until May 2021. Nevertheless, within the sample of operation, its target for testing recommendation to users served as a trailer of the potential of digital technologies in contact tracing.

TABLE 6: TARGETED APPROACHES TO CONTACT TRACING ACCORDING TO SARS-COV-2 TRANSMISSION PATTERNS

Epidemiological Scenario	
No cases	A well-trained contact tracing workforce should be identified and ready to deploy and scale up (i.e., have the required tools) to respond to first cases.
Sporadic cases	Exhaustive contact tracing and case investigation for all cases is essential for rapidly suppressing transmission.
Clusters	Contact tracing is essential to reduce transmission within clusters and to identify events that have led to high levels of virus transmission. Public health and social measures can then be implemented to reduce the occurrence of such events.
Community transmission (including four sub-categories of increasing incidence)	Contact tracing remains an important activity in high incidence scenarios where the capacity to trace and follow-up all contacts may be at the breaking point. Contact tracing activities should be targeted rather than abandoned. It is possible to prioritize tracing of higher-risk exposure contacts based on capacity.

Source: Contact tracing in the context of Covid-19, Interim guidance, WHO 1st Feb 2021



1. MANUAL AND DIGITAL TECHNOLOGIES ARE BOTH ESSENTIAL FOR EFFECTIVE CONTACT TRACING

While the outbreak persists, it is important for India to continue to combine manual contact tracing with new and advanced digital tools, targeting relevant populations for quarantining and testing while minimizing privacy concerns. Experience shows that manual contact tracing might work in the very early stages of an outbreak. However, as cases surge, digital solutions are needed to accelerate efforts to track, trace, isolate, and quarantine virus carriers in a timely manner.

For digital tracing efforts to be successful, winning the trust of the public is essential so that they willingly participate in the process. This requires a human-centred approach to tracing, and clear communication about the digital public health surveillance methods that will be used. Demonstrating how digital tracing is being used effectively for the larger public interest will also support in building public confidence.

1.1 ENSURE MANUAL TRACING EFFORTS COMPLEMENT DIGITAL TRACKING TOOLS

While digital tools are important, not everyone can be reached through these tools alone. Only half of the country has internet access of some kind, and less than a quarter of Indians use a smartphone [68]. Those without access to digital technologies also tend to be the most marginalized, with limited access to health services [69]. This digital divide within India makes it imperative for policymakers to ensure that marginalized and vulnerable population receive access to the care they need during a pandemic. Many women, children, and adolescents do not own their devices, which makes them more likely to be overlooked by digital tracing mechanisms. Other populations, such as the elderly, may find smartphones cumbersome and difficult to use.

As the pandemic penetrates deeper into rural and peri-urban areas where internet access is poor and unreliable, diligent manual contact tracing efforts are necessary to contain the transmission of Covid-19. Contact tracers are effective when they approach the potential Covid-19 carriers with empathy and patience. They tend to inspire trust when they are drawn from the community, they are tracing. In Bhilwara, Rajasthan, the administration set up 2,000 contact tracing teams. Their model engaged Accredited Social Health Activists (ASHA) workers, village elders, panchayat leaders, and grassroots health workers. Thanks to their efforts in building trust with local communities, the program was able to screen roughly 92% of the population within nine days.

1.2 SUPPORT AND MAINTAIN A CONTACT TRACING COMMUNITY CADRE

The million-plus all-women army of ASHA, Auxiliary Nurse Midwives (ANMs), and Anganwadi workers (AWWs) have played a crucial role in contact tracing and door-to-door surveillance during the pandemic. While the contribution of ASHAs to contact tracing has been commendable in the initial phase, many reported feelings overburdened with their existing responsibilities. Protests broke out, as many of them felt inadequately compensated and reported a lack of access to masks and other protective gear, making their jobs riskier [70]. As the pandemic dragged on, many frontline health workers experienced tremendous stress due to consistent heavy workloads with no breaks, leading to fatigue, reduced productivity, and low morale.

A parliamentary panel in November 2020 found that many healthcare workers lack the specialized skills required for tracing, counseling, home care, contact mobilization, and epidemic outbreak investigation [71]. The panel recommended strengthening the network of ASHAs, ANMs, and other community health workers and sought an improvement in the quality of training to ensure effective and efficient delivery of health services.

Enlisting local self-help groups can help relieve the pressure on ASHAs and other frontline health workers. India has nearly 60 million women organized into over 5 million self-help groups that can become formidable contact tracers with appropriate training. Students and non-medical volunteers around the country could also be enrolled for the task. In addition, digital tools can be used to improve efficiency and reduce the burden on health workers.

In rural areas, IVRS-based call-in/call-out approaches can be leveraged to map, list, and trace individuals by syndromic surveillance or active surveillance depending on the feasibility, according to iCART, which is building an award-winning digital tool for ASHAs [72].

1.3 DEPLOY DIGITAL TOOLS WIDELY IN A PANDEMIC, BUT WITH CONSENT AND CAVEATS

Digital tools can make contact tracing more agile, efficient, and accurate. They can dramatically lessen the workload of overburdened human contact tracers, reduce the time it takes to trace cases, and allow quick responses to control the outbreak. In South Korea, tracing the contacts of a single case manually may have taken officials 24 hours, but with automatic tracing this task was accomplished in ten minutes [73].

Countries have also used digital tools to gauge proximity between users and alert them if they may have been exposed, monitor symptoms, and check compliance with quarantine and social distancing guidelines. In India, the Aarogya Setu app was deployed at a national level to alert users if they came in close contact with other users of the app who could have been carrying the infection.

Though uptake of the app soared after immediate release, its popularity waned after privacy concerns were raised around who designed it, how the captured data would be stored and processed, and the possibility of the data being repurposed for other uses the user had not explicitly consented to, according to a CDPP whitepaper [74].

Despite this, Aarogya Setu gave a glimpse of the potential of technology driven targeted interventions. As of November 2020, amongst those who had been advised by the app to be tested, 27% had tested positive at a time when the overall positivity rate hovered around 7% [75].

The willing participation of the public is essential for the successful use of these technologies. Therefore, governments must make concerted efforts to improve the social acceptability of digital tools in pandemic response. Broad uptake of digital apps and privacy-protected tracking software facilitates more comprehensive contact tracing. This requires informing citizens about the nature of data that is being collected, how it is being used, and what their rights are in case of misuse. Strong legislative protection for citizens' data will help make sure that data captured will not be repurposed for commercial interests or state surveillance outside of public health measures. This will also enhance the willingness of people to participate in such interventions.

An IT-enabled Integrated Hotspot Analysis System (ITIHAS), for surveillance and containment strategies to supplement manual contact tracing was developed. Once a patient tests positive, this tool takes data from two channels — one from ICMR, the agency which is notified of positive cases tested in labs, and the Aarogya Setu application depending on the declaration and self-assessment by the user. The tool then traces the movement of the patient over the past 20 days based on the duration spent at a location, calculated by mobile pings sent to the mobile network tower. Based on this, an exposure score is calculated, which is fine-tuned and mapped geographically to undertake surveillance activities. Using this, Gujarat identified 4,696 hotspots as of August 2020 and its Principal Secretary, Health and Family Welfare, called the tool a "game-changer in surveillance activities" [76]. However, privacy concerns remain a barrier to uptake of this tool.

Mobility Reports

Mobility data with privacy-preserving aggregation has been used by governments and health authorities that quantify and track people's movements in specified regions. Mobility reports help evaluate the effectiveness of physical distancing rules and lockdowns in place. Such data is collected by smartphones via GPS, cellular networks, and Wi-Fi.

They also help track population flows and identify potential spots for fresh outbreaks. Monitoring of physical distancing measures is crucial in predicting future health system demands and assessing when to lift restrictions. In China, health officials use daily aggregated travel data from Baidu to measure effectiveness of travel curbs. Google also releases weekly Community Mobility Reports with subnational granularity data that are publicly available. (Budd, J., Miller, B.S., Manning, E.M. et al, 2020).

TABLE 7: DIGITAL TECHNOLOGY FOR PANDEMIC MANAGEMENT

Uses	Functional Categories
Epidemiological surveillance	Proximity and contact tracing: Gauges spatial proximity between users and tracks their interactions. E.g., TraceTogether (Singapore).
Early and timely detection	Syndromic surveillance: Symptom monitoring, and collection and analysis of reported health data. E.g., CoronaMadrid (Spain).
Interruption of the chain of disease transmission	Quarantine compliance: Ensures compliance of suspected patients with quarantine regulations by monitoring them in real-time. E.g., Electronic Fence (Taiwan).
Communication of healthcare information to the public	Flow modeling: Mobility reports that quantify and track people's movements in specified regions, thereby gauging the effectiveness of public health measures already taken. E.g., Google's Community Mobility Reports.

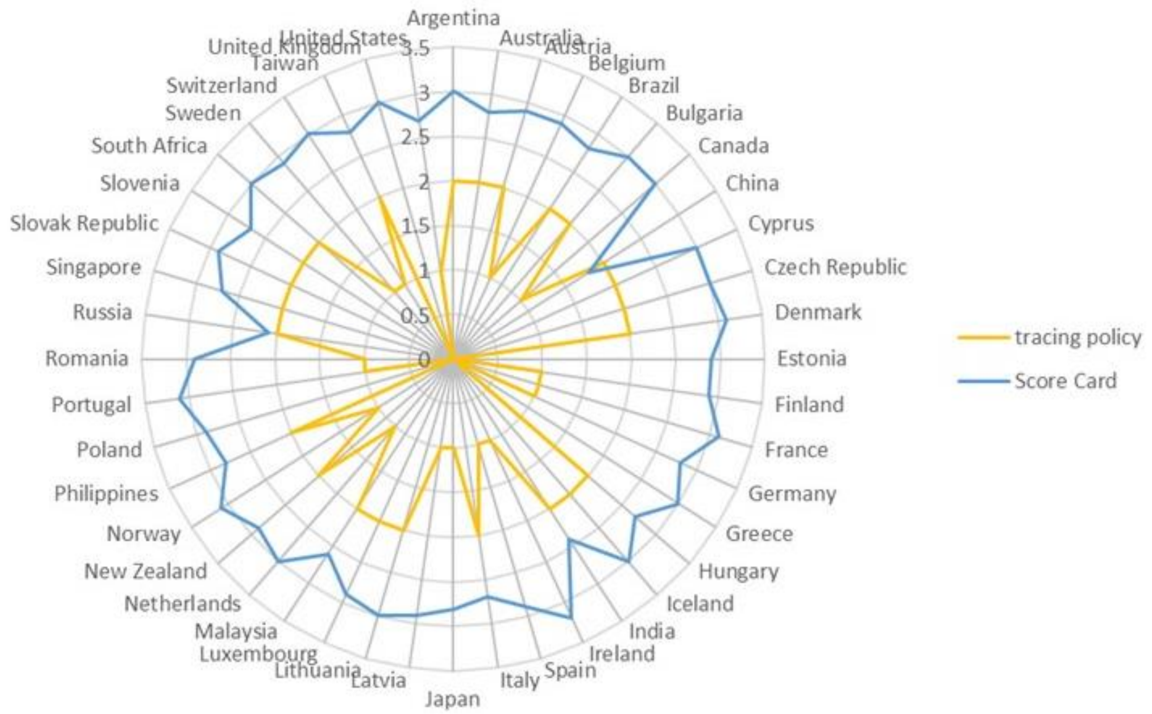
Source: Gasser, Ienca, Scheibner, Sleigh and Vayena, (2020)

1.4 HOW INDIA COMPARES WITH OTHER COUNTRIES ON TRACING POLICY AND PRIVACY PROTECTION

Comparitech assessed privacy protection and the state of surveillance in 47 countries to see where governments are failing to protect privacy and/or are creating surveillance states. The index covers aspects such as statutory protection, privacy enforcement, identity cards and biometrics, data sharing, visual surveillance communication, interception, workplace monitoring, government access to data communication, data retention, surveillance of medical, financial and movement, border and trans-border issues, leadership, and democratic safeguards.

As depicted in Figure 20 below, the trends in tracing and privacy protection are plotted for a select batch of countries. The scorecard represents the country's commitment to and effort at protecting individual freedom and respect for privacy [77]. Tracing policy adopted by each country is also marked in the graph [78]:

FIGURE 19: TRACING POLICY VS. PRIVACY PROTECTION SCORE



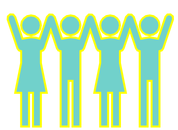
Source: Technology-aided models for effective tracing and tracking of Covid-19, and potential data collection modes, Centre for Development Policy and Practice (CDPP).

Scoring system

4.1-5.0 = Upholding privacy standards on a consistent basis
3.6-4.0 = Significant safeguards and protections
3.1-3.5 = Adequate safeguards against abuse
2.6-3.0 = Some safeguards but weakened protections
2.1-2.5 = Systemic failure to maintain safeguards
1.6-2.0 = Extensive surveillance
1.1-1.5 = Endemic surveillance

India scored 2.4 on this index, indicating a systemic failure in maintaining privacy safeguards. The country fared particularly low on measures such as statutory protections and privacy enforcement. Going forward, when adopting digital tools to track and trace health officials must also address privacy concerns and adhere to principles for data protection (see Table 8).

TABLE 8: BASIC PRINCIPLES FOR MODELS THAT COMBINE TRADITIONAL AND DIGITAL TECHNOLOGY FOR TRACKING AND TRACING



Public Benefit

Developers and policymakers must ensure public benefit outweighs the risks associated with deploying any digital technology for tracking or tracing Covid-19.

Garnering Public Trust

Public messaging by political leaders, health authorities, media, and others on disease control measures should be congruent and unified, especially to gain public trust and ensure voluntary use of digital health tools.

Regular communication and realistic offers of support will help ensure quarantine compliance and motivate individuals to be responsible for reporting suspected symptoms (Woolliscroft, Shaif, Jackson, Pagden, Redgrave and Heller, 2020).

Ensuring Efficacy and Scientific Validity

Considering there is not enough consensus among members of the scientific community about the efficacy of digital technology for tracking and tracing, the pandemic should not be a reason to lower scientific standards. Validation tests and protocols must be developed to assess the efficacy and accuracy of the technology in use.

Time Limit

Time-boundedness requires that any restrictions on rights and freedoms are temporary and will be lifted within a designated timeframe. The principle of time-boundedness ensures that while some rights may be harmed now, they will not last forever. There is the concern that right-infringing policies may continue past their usefulness. One of the common criticisms of digital surveillance tools is that it will lead to a permanent change in societal habits and behaviors, with people and governments becoming dependent on them. Therefore, all measures taken for heightened surveillance using digital health technology should have an expiration date.

Users must be informed of the reason and duration for which data is collected. These dates of cessation could be based on specific timelines, a predetermined threshold for number of new cases, number of new deaths and total number of active cases.

Digital contact tracing should be regularly evaluated to determine if the threat is still credible or if the potential (and actual) infringements on rights are excessive, compared to the benefits derived from it. This has already been done in Norway, where they abandoned digital contact tracing because the low case numbers and potential privacy infringements outweighed its benefits.

Privacy Protection

Spatial proximity tracking tools among phone users are, less privacy-invasive than personal contact tracing or quarantine enforcement apps. Tools using aggregate mobile phone tower data are, on average, less privacy-invasive compared with tools based on Global Positioning System data and sensor tracking for individual users

Preserving Autonomy

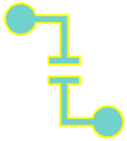
It is important for individuals to make the choice themselves to use digital health tools, as opposed to making them mandatory. Moreover, individuals need access to information about how their data will be stored and shared in order to make informed choices about using these technologies

Avoiding Discrimination

Digital tracing and tracking tools carry an inherent risk of discrimination. Safeguards must be put in place to ensure the large amounts of health and demographic data collected through these apps and tools are not used to further stigmatize underserved populations. Instead, such data should be contextualized and utilized for evidence-based action to bridge persistent health inequities

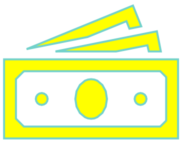
Preserving Repurposing

There is an overarching risk of data collected by digital health tools being repurposed for commercial gains and other forms of surveillance in the absence of robust safeguards against third-party sharing



Avoiding Digital Inequality

Considering that only one-third of the world's population had access to a smartphone in 2019, and the same proportion lacked access to any mobile phone, digital health technology used during the pandemic must not exclude marginalized communities and deepen health inequities. For this, digital tracing and tracking efforts must be carried out alongside traditional interventions such as door-to-door, telehealth, and other in-person monitoring measures

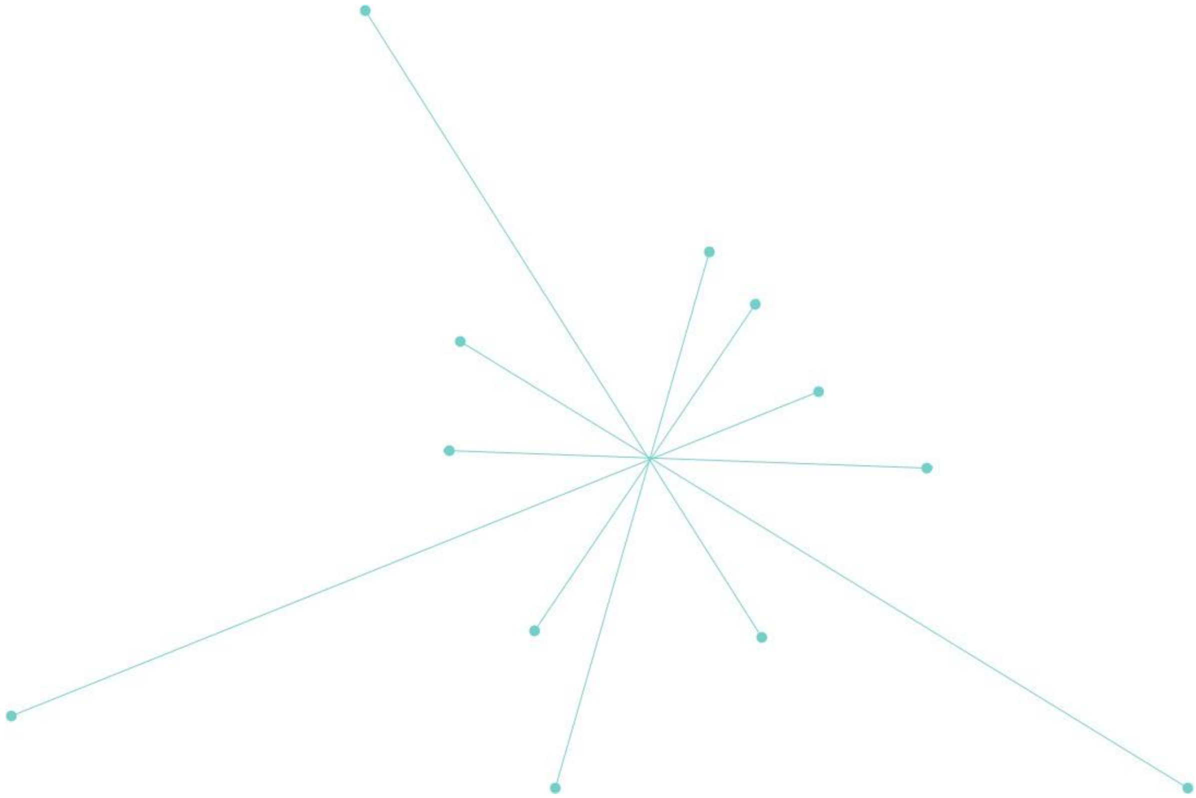


Investment in Contact Tracing

Studies suggest that incremental increases in levels of contact tracing are likely to bring in diminishing benefits in disease control (Armbruster and Brandeau, 2007).

Simulation models and cost-effectiveness analysis can be used to determine the optimal level of investment in contact tracing.

Source: Technology-aided models for effective tracing and tracking of Covid-19, and potential data collection modes, Centre for Development Policy and Practice (CDPP)



2. BUILD RETROSPECTIVE TRACING CAPACITY TO BUST CLUSTERS

2.1. FEW CASES CAUSE MANY, MANY DO NOT CAUSE ANY

A growing body of emerging evidence, both global and regional, is now indicating that a minority of infections is causing most Covid-19 transmissions [79]. This means super-spreading events (SSE) or 'clusters' disproportionately contribute to the spread of the virus. At present, India's limited contact tracing program has largely focused on forward tracing, i.e., to trace all contacts of an identified case to quarantine all possible secondary cases. However, this evidence highlights the importance of backward or retrospective tracing.

Retrospective contact tracing strives to find when and where the person was infected and identify who else might have been infected simultaneously as part of a cluster [80].

While this will require adequate capacity building for the tracers, the yield of the contact tracing program is likely to improve significantly if retrospective tracing is added as a supplement to the traditional approach.

2.2. GLOBAL EVIDENCE SUPPORTS CLUSTER BUSTING

Analysis of transmission patterns from Japan, China, and Hong Kong have established that during the spread of Covid-19, SSEs contributed significantly to the spread of the virus. This led authorities in Japan to conclude that if there is no cluster or SSE, there is no sustained outbreak. Though exact numbers have not been analyzed, a senior health official was quoted estimating that the Japanese contact tracing program identified half of the cases through this process of cluster busting. In Japan's cluster-focused contact tracing system, officials trace contacts up to 14 days before symptom onset, rather than the usual 48 hours [81]. South Korea and Australia have also used this approach to effectively control infection transmission [82]. In mid-November 2020, with the guidance of the European Centre for Disease Prevention and Control, backward tracing was added as an option for enhanced contact tracing citing the same rationale [83].

2.3. INDIAN STUDIES BACK THE NEED TO BUST CLUSTERS

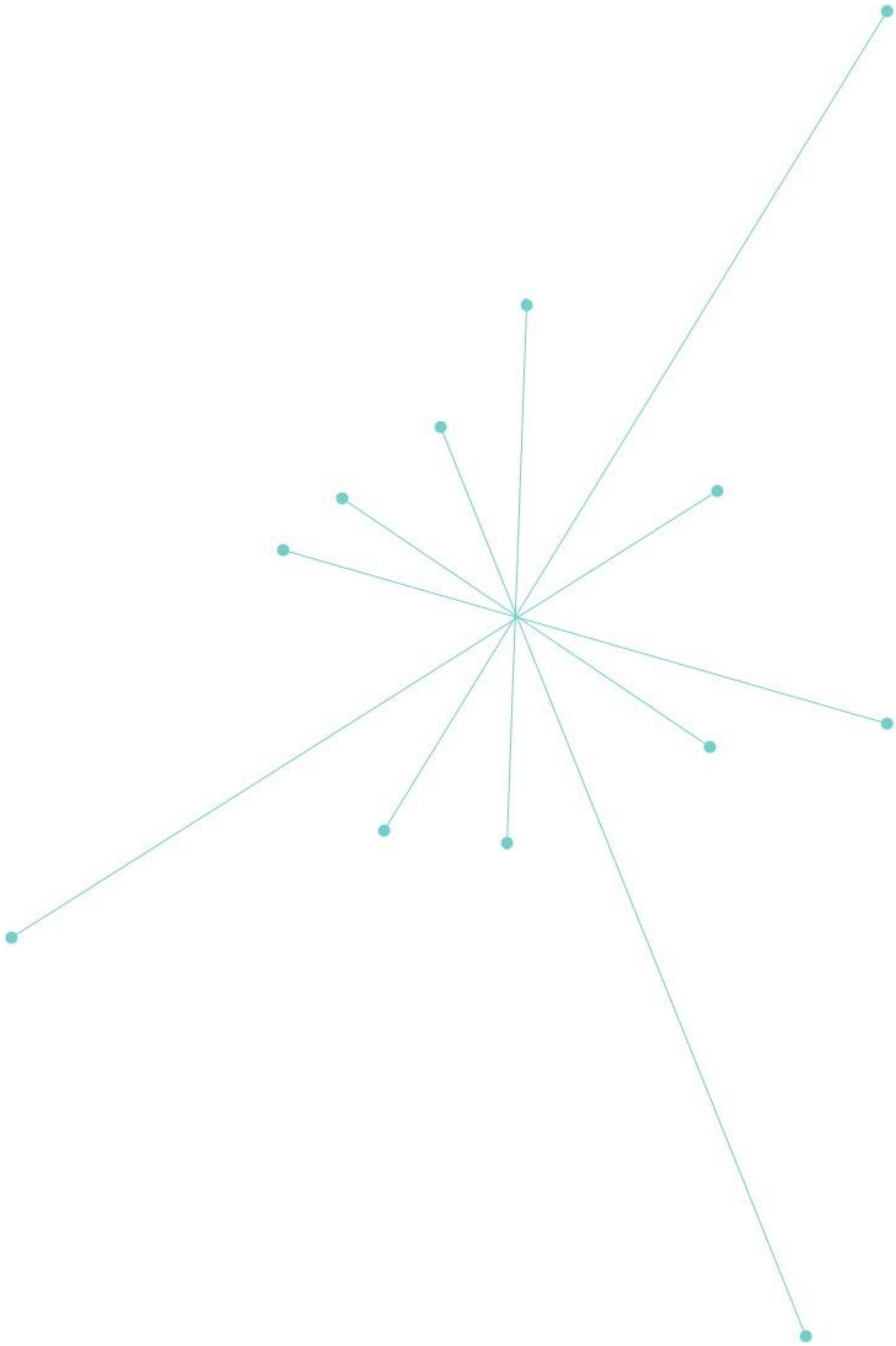
Recent evidence emerging from India has also indicated that clusters might have played a significant role in transmitting the virus. A recent study from Karnataka, yet to be peer-reviewed, suggests that patients who caused most secondary cases did not have a concurrent larger share of total contacts (8.7% of infectious cases had 14.4% of contacts but caused 80% of transmission) [84]. These findings are congruent with a larger study from Andhra Pradesh and Tamil Nadu, which found that 71% of traced cases were not linked to any secondary infections [85]. Backward tracing yields actionable health intelligence to identify high-risk settings and prevent onward transmission. This gives policymakers an insight into high-risk activities in their geographies that would not be possible with prospective tracing alone.

At a micro-level, retrospective tracing can alert officials about high-risk activities within their own communities, such as a market failing to enforce social distancing or sites ignoring indoor capacity requirements. At a macro-level, health officials might uncover activity patterns or types of venues that are consistently leading to cluster formation throughout their state. In response, state authorities can engage with identified communities locally and take action to keep their populations safe.

2.4. CLUSTER MAPS OF CASES

A three-tier integrated contact tracing program involving district, state and national levels will allow professional teams of contact tracers to interview infected individuals and collect data on where they were infected and who else might have been exposed. It is also necessary for contact tracing programs to have state-wide data sharing on cases to reconstruct the chains of transmission. By piecing together, the connections between cases, gleaned through prospective and retrospective contact tracing efforts, officials can build "a cluster map" of cases.

Such a system would require specialized skill-sets different from frontline tracers. In addition, officials would need to implement safeguards to ensure that those identified as the source of infection are not discriminated against or stigmatized in any manner.

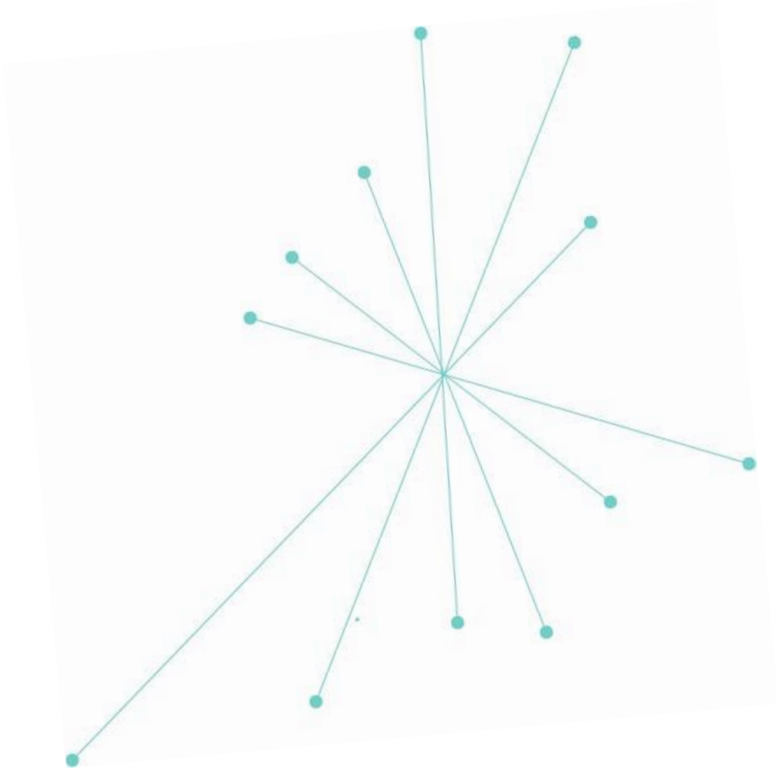


3. CONTACT TRACING ALONG WITH SERO-SURVEILLANCE AND SEQUENCING DATA CAN INFORM POLICY MAKING

The true picture of epidemics can be comprehensively understood by analyzing contact tracing, serological, and phylogenetic data together, which can help plan adequate and effective control measures. Serological testing detects people with a mild or asymptomatic Covid-19 infection who have already recovered, allowing for a more accurate determination of the number of people infected in a cluster or the overall population.

This means an antibody test can trace the links in the chain of asymptomatic transmitters that may have been missed during contact tracing. Such well-designed sero-surveys can be used to link the chain of disease transmission in and between clusters and prove useful in detecting asymptomatic carriers who silently spread the disease [86]. Similarly, combining contact tracing and sequencing data can provide insights to understand disease transmission patterns (see discussion in Section I).

The intensity of contact tracing should be calibrated based on data from genetic sequencing, test positivity, the gradient of the caseload, and the guidance of sero-surveys.



If a new highly transmissible or dangerous variant is found to be circulating, or caseloads and test positivity rates are seen to be rising, contact tracing can be intensified. Contact tracing should be a graded response continuously adjusted to the threat perception.

4. MAKE TRACING A HUMAN-CENTRED AND EMPATHETIC PUBLIC HEALTH EXPERIENCE

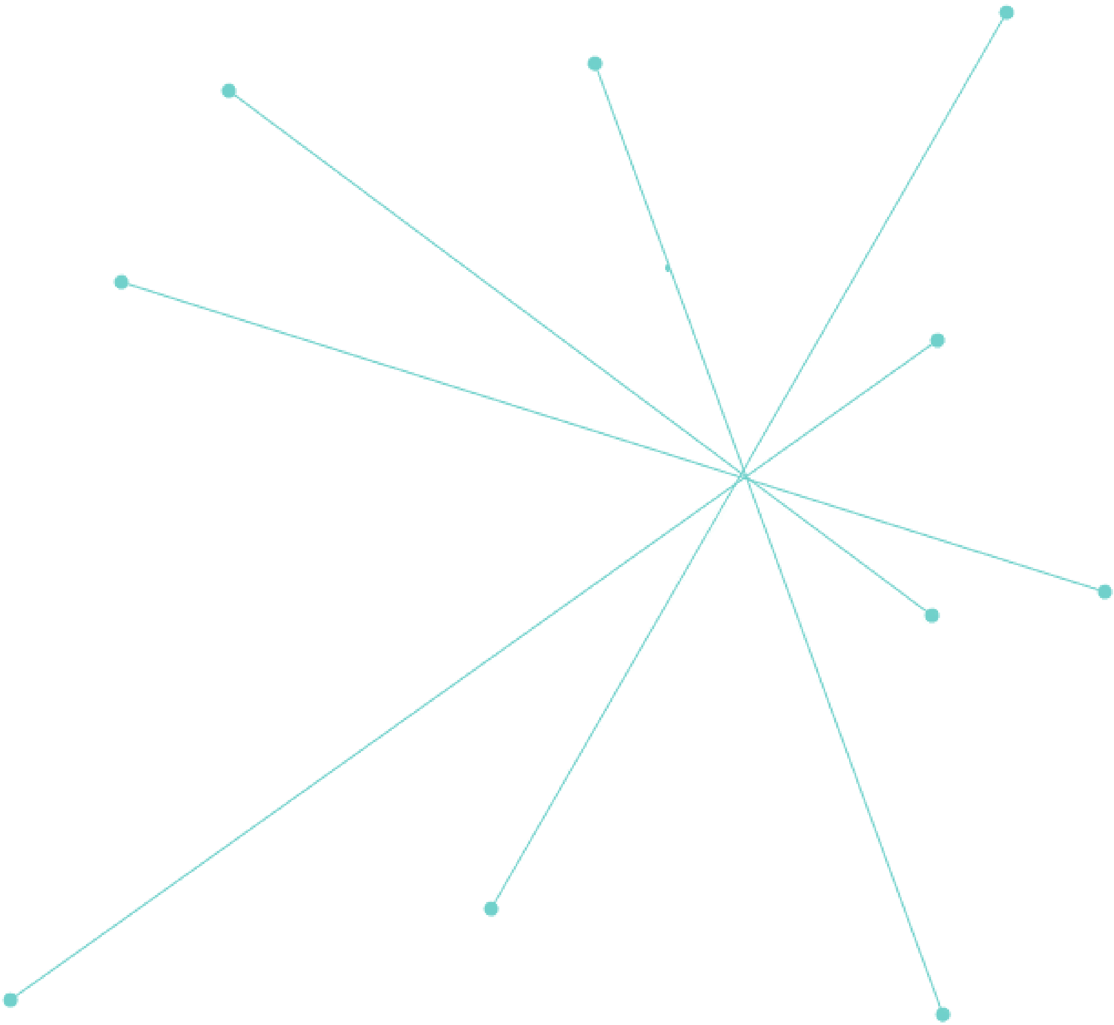
The success of a tracing programme is dependent on the willing participation of the public. If individuals perceive tracing as an infringement upon their privacy and freedom, or a coercive detective action by the state, they will not be inclined to share truthful information about their activities, contacts, and probable conditions under which they may have contracted Covid-19, and the program will be unproductive.

No manual contact tracing program can succeed without active support and participation of the community.

Many contact tracing programs in and outside of India have struggled as those identified as Covid-19 positive have attracted stigma and discrimination. Once this happens, other people who are suspected to be infected may become reluctant to reveal their infection status [87].

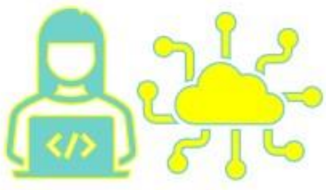
People also have practical and logistical concerns about being quarantined. In India, food and other essential items were not fully coordinated at many places, after people were asked to home quarantine [88]. It is important for contact tracers to have a public health approach rather than a law-enforcement approach. Tracers preferably also need a set of community networks so that they can provide quarantined contacts with means to access food, essential items, and other means of support.

Finally, home-quarantine is simply not a solution for homeless or single room dwellers, and states need to consider planning for dignified living in quarantining facilities for those who may need to move out of their dwelling or living space if found positive.



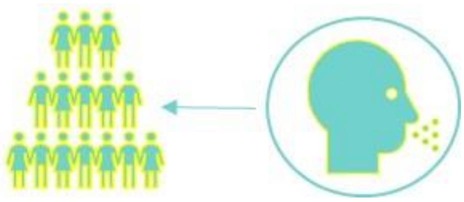
ACTION STEPS

1. USE A MIX OF MANUAL AND DIGITAL TECHNOLOGIES FOR EFFECTIVE TRACING AND TRACKING



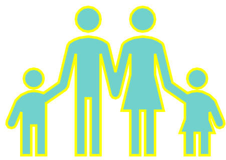
- Focus on manual tracing methods in early stages of outbreak when infections are low and in contexts where digital tools are unavailable.
- Build a frontline contact tracing community cadre by imparting necessary skills.
- Acknowledge the role of frontline workers in tracing.
- Explore other resources like local self-help groups which can be quickly trained to supplement ASHA workers.
- Ensure wide deployment of digital tools for tracking but with consent and caveats.

2. INTEGRATE RETROSPECTIVE TRACING IN THE CONTACT TRACING PROGRAM TO BUST CLUSTERS

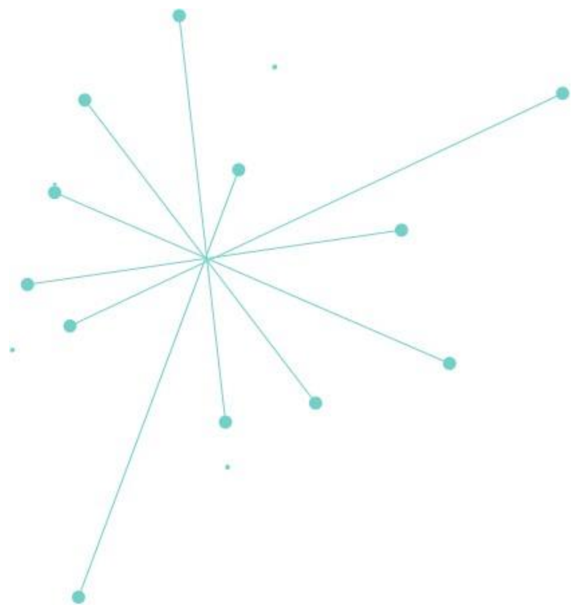


- Impart specialized skills to a cadre of professional contact tracers required for retrospective tracing and cluster busting.
- Build a three-tier tracing program to reconstruct the chains of transmission.

3. MAKE TRACING A HUMAN-CENTERED AND EMPATHETIC PUBLIC HEALTH EXPERIENCE TO ENSURE THAT PEOPLE SUFFERING WITH COVID-19 ARE NOT STIGMATIZED



- Involve members from the community in contact tracing.
- Focus on training contact tracers in soft skills like empathy and patience.
- Provide quarantined individuals with means to access food, essential items, and other means of support where necessary.
- Plan dignified living in quarantining facilities for homeless or single room dwellers



V. SHARING DATA, BUILDING TRUST, AND THE POWER OF COMMUNICATION

In India, the public health and research communities have reported their struggles with both the quality and quantity of data during the pandemic. Scientists and public health experts found it difficult to conduct real-time research without access to official Covid-19 data from the government. Even broad state-level data about the breakdown of RT-PCR tests and RATs was not officially available in most cases. Some states reported the share of tests, but with a significant time lag that made using that information for policymaking almost impossible given the rapidly evolving situation.

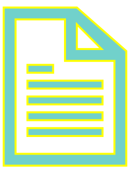
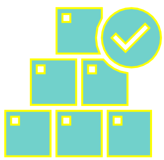
a. DATA-DRIVEN EVIDENCE IS KEY FOR PANDEMIC COMMUNICATION AND POLICYMAKING

Capturing, maintaining, and sharing quality data on every possible aspect of the pandemic enables doctors, scientists, and policymakers to find a way out of the crisis. Timely access to data was acknowledged as a critical global health priority by WHO after deficiencies in data-sharing mechanisms were highlighted during the 2013-2016 Ebola virus outbreak in West Africa [89]. In September 2015, at a WHO consultation, it was affirmed that timely and transparent sharing of data during public health emergencies must become the global norm (see Table 11) [90].

When a new or re-emergent pathogen causes a major outbreak, rapid access to both raw and analyzed data is critical to developing a timely and effective public health response. Without the timely exchange of information on clinical, epidemiologic, and molecular features of infectious diseases, informed decisions about appropriate responses cannot be made.

This is especially important for decisions about implementing new interventions or adapting existing ones. Failure to share information promptly can have disastrous public health consequences, leading to unnecessary suffering and death [91]. However, when such information is collected and shared consistently in an organized format, independent research outfits are able to offer valuable support to policymakers in making decisions.

TABLE 9: ACTIONS AGREED TO AT THE WHO CONSULTATION ON DATA AND RESULTS SHARING DURING PUBLIC HEALTH EMERGENCIES

	During public health emergencies, public disclosure of relevant information should not be delayed by biomedical journal publication timelines and early disclosure should not and will not prejudice later journal publication.
	Researchers should be responsible for the accuracy of shared preliminary results, ensuring that they have been subjected to sufficient quality control before public dissemination.

Opting-in for data sharing should be the default practice, and the onus should be placed on data generators and stewards at the local, national, and international levels to explain any decision to opt-out from sharing data and results during public health emergencies.

Incentives for sharing data should be created and tailored for each type of data generator and steward, while data management and analysis expertise is enhanced in under-resourced settings.

In India's own experience, external and independent agencies have played a crucial role in spotting, documenting, and validating of evidence around major indicators such as falling infant mortality rates and flattening HIV infection rates. Going forward, India must prioritize collecting and sharing appropriate data on the pandemic response at the district or sub-district level for open, meaningful collaboration among top data scientists, epidemiologists, and other public health experts. Such openness fosters trust and creates efficiencies required for effective pandemic management.

b. COUNTRIES THAT USED DATA MEANINGFULLY HAVE SUCCEEDED IN SUSTAINING LOW INFECTION RATES

This pandemic has shown two clear approaches: The first one, favored by East Asian countries, relied on deploying advanced technology to collect data on the progress of the virus. The second approach was adopted predominantly by Western democracies, with deeply entrenched liberal values, which found the adoption of these privacy-compromising technologies unacceptable.

The lesson from this pandemic experience is that developing effective technological solutions that preserve privacy while permitting effective tracing and related health interventions is critical. In the Bloomberg Covid-19 resilience ranking of 21st December 2020, 8 of the 14 top-performing countries during the pandemic emerged from East Asia.

It is clear from the health outcomes of these countries in 2020 that technologies save lives in a pandemic but may harm personal freedom. What is remarkable is that these actions of the government in countries like South Korea, China, and Hong Kong received widespread public support [92][93]. Citizens in some of these East Asian countries believed that 'public health and public good should take precedence over individual rights' [94].

Approximately 80% of Koreans said that they would accept some privacy infringements to fight the epidemic [95]. The government also promoted transparency during Covid-19, publishing their findings and sending text notifications about how citizens can protect themselves. It led some academics to conclude that the transparency with which the government has adapted its surveillance practices inspired public trust in an endeavor that would otherwise have aroused suspicion [96].

South Korea's surveillance practices are mandated by a legal regime tailored to the demands of modern epidemics which were implemented in the aftermath of the MERS outbreak in 2015. The country's lawmakers swiftly moved to amend the Infectious Disease Control and Prevention Act (IDCPA), which granted health authorities the right to collect data of confirmed and potential patients during infectious disease outbreaks while granting the public a "right to know." The patients have the option to directly petition review of their logs, a process that allows for correction on a case-to-case basis. South Korea's success with the Covid-19 response reflects the lessons learned from its experience with MERS, when experts had criticized the government for its lack of transparency [97].

South Korea's experience offers lessons on how surveillance technologies may be controversial tools to pandemic response but can be deployed successfully. Establishing the legal boundaries of surveillance and developing best practices through public interactions are two ways in which democratic governments can strive to create a balance between public safety and individual privacy [98].

It is critical that India begins this conversation with its people on technologies that can save lives, and how they should be deployed so that public good can be maximized without invading privacy. It is equally important for stakeholders in media and research to understand that in a pandemic, the government cannot be held responsible for all of what frequently changing numbers depict. Besides the government, success of a pandemic response is also determined by the collective responsible behavior demonstrated by the citizens of a nation.

Putting in place a transparent data collection and sharing policy is the first step towards creating an environment where more researchers can access data, quickly understand the virus, find methods to reduce transmission, and develop interventions to make humanity safe from future epidemics.

c. DIGITAL ARCHITECTURE FOR COVID-19 AS A SUBSET OF A LARGER HEALTH INFORMATION SYSTEM

Efforts that are focused on strengthening technologies in different healthcare verticals alone will not be sufficient to track the full spectrum of the pandemic's impact. Instead, a cross-cutting technology that can integrate community data with laboratory and hospital data can assist policymakers to plan and visualize the real-time burden of disease and launch an effective response.

It is crucial for the epidemic response to be data-driven and locally owned. Granular data from the block level and data sharing across administrative levels would enable surveillance data to be used for management decisions, including planning for testing capacities, personal protective equipment, medicines, supplies, ICU capacity, and healthcare personnel.

For data to be interoperable, government needs to imagine a cross-cutting digital architecture after building a consensus among all stakeholders on principles, ease of operations, and process flow. Such data need to be released in real time. It should be designed to assist policymakers to understand the burden of the disease and take the necessary steps for its control.

Had India maintained fully operational parallel data on intensive contact tracing and seroprevalence, it could have monitored how many individuals are under-quarantine and how many more should be under quarantine. This could have particularly identified those individuals who may have received the virus through asymptomatic carriers and may have been missed getting identified during contact tracing.

With seroprevalence data, targeting the timing of a test for an individual can be more precise, leading to improved results even from the less accurate RATs. This is just one way to use data to ensure that the right tests are reaching the right individuals at the right time. At an aggregated population level, policymakers would be informed through this dataset about pockets where communities need to be supported and prioritized.

d. LEVERAGING A MULTI-STAKEHOLDER APPROACH TO BUILD TECH SOLUTIONS

Collaboration among diverse experts is key to building the technology architecture that can generate real-time data and develop a sustainable and workable model to fight the pandemic. These experts need to be drawn from multiple disciplines, including medicine, public health, epidemiology, software engineering, disaster management, GIS mapping, and app development. A cookie-cutter approach cannot be applied across different areas given the heterogeneity of contexts in which disease transmission is taking place.

The involvement of community health workers is also critical given the stark socio-economic disparities between and within rural and urban areas. Community health works can offer insight on how reliable data can be collected on disease prevalence, syndromic surveillance, or active surveillance. Digitization of health systems to create a single platform for all health programs can save a lot of time for community health workers and enable them to utilize their time more fruitfully in delivering health services, rather than filling records and registers manually. The National Digital Health Mission initiated by the Indian Government is a step in the right direction.

e. SHARING DATA WITH PUBLIC TO ARM THEM FOR INFORMED DECISION-MAKING

Government can empower the public to make informed decisions by sharing targeted public health messaging as well as information on real-time caseloads, bed occupancy, ventilator occupancy, testing availability, and location of nearby labs and hospitals. These datasets, if owned locally under a transparent and robust data sharing policy, can build public confidence in health measure, and encourage people to voluntarily participate in surveillance programs, leading to more efficient and targeted pandemic responses.

Without real-time data and monitoring, health systems are left in the dark, unable to respond effectively to the pandemic.

f. TRUST IS CURRENCY, AND COMMUNICATION IS KEY IN A PANDEMIC

In the hyperconnected world of the 21st century, misinformation and disinformation have the power to kill before they can be corrected. Early in the pandemic, hundreds of people died in Iran after drinking toxic Methanol following widespread rumors that it could cure Covid-19 [99].

In March 2020, the WHO coined the term 'infodemic' which refers to false or misleading information in digital and physical environments during a disease outbreak. It causes confusion and risk-taking behaviors that can harm health. It also leads to mistrust in health authorities and undermines the public health response [100]. In this light, all communication on Covid-19 is crucial whether it be from the government, media, health professionals, or friends and family members. Effective communication emphasizes the importance of content, accuracy, even signs, symbols, language, culture, and semiotic rules [101]. Communication is received well only when there is an environment of trust or the source is judged by people as trustworthy.

Trust has repeatedly emerged as one of the most critical currencies in epidemics and has determined whether the public complies with the rules set by the authorities. An Italian study from 2011 showed that people who trusted the health ministry and the media were more likely to adopt recommended behaviors during the H1N1 influenza outbreak compared to those who lacked trust in those agencies [102]. More recently, early in the Covid-19 pandemic, countries with higher trust in institutions reported lower fatalities [103].

g. SYNCING COMMUNICATION ON TESTING WITH THE SPEED OF POLICY CHANGE

As the pandemic unfolded, policy measures were frequently fine-tuned to manage the crisis. The Covid-19 testing strategy was kept dynamic and testing algorithms underwent several changes. But the absence of a parallel information campaign to demystify the scientific language led to confusion among the public about the type of tests that were available at different stages of the outbreak. Particularly when there are multiple testing options with different attributes in a pandemic, the Centre needs to collaborate with states to promote health-seeking behaviors through an easy-to-understand information campaign tailored towards different constituencies.

This lucid, targeted information campaign for people to be informed is crucial, particularly when widespread, voluntary testing (without requiring a prescription) becomes the norm. Voluntary testing for Covid-19 was introduced at a late stage (in September 2020) and it merited adequate publicity to enable people to access testing facilities when in need. Such campaigns become even more crucial when many of the available test choices are less than accurate.

h. A DEDICATED COMMUNICATION CAMPAIGN FOR TESTING

Dispensing information on the type of tests available and modalities around the process can help people make informed choices. In many states, citizens did not have access to relevant information, such as where they were offered, how much they cost, and when they could expect results, making it challenging for them to opt for the right tests.

Lack of information creates a vacuum which then becomes a breeding ground for rumors and misinformation on testing. This has led to stigma towards the identified cases of Covid-19, ultimately resulting in an inflated sense of fear and reduced appetite for testing [104].

In India, many people chose not to get tested even when they were symptomatic [105]. This has the potential to lead to an exponential increase in undetected cases and uncontrolled spread of the disease. Building public confidence in testing and tracing is critical, including by emphasizing how testing at the right time has benefits at the individual, household, and community levels.

A parliamentary panel in December 2020 noted that measures should continuously be taken to avoid social stigma and fear of isolation and quarantine, including efforts to raise general awareness about the virus and treat patients with respect and empathy. The panel proposed that an interdisciplinary team of public health specialists, grassroots political and social leaders, and volunteers should raise awareness about modes of transmission and methods of prevention of Covid-19 in the community. This can be done by adopting emergency risk communication methods and broad-based community engagement strategies.

i. PROFESSIONAL COUNSELING

Good communication lets people know how they can protect themselves and others and helps them balance their fears with concrete information they can use. Provision of professional counseling services at the points of testing both in public and private sector institutions could have helped in alleviating people's fears about the disease and encouraging caution and positive behaviors, such as masking and distancing. In the National AIDS Control Programme, counseling greatly facilitated access to testing and promoted health-seeking behavior. India can, thus, look at training its cadre of health care professionals and make counseling an integral part of testing protocols for Covid-19.

ACTION STEPS

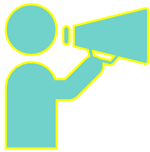
1. IMPLEMENT A TRANSPARENT DATA COLLECTION AND SHARING POLICY FOR RESEARCHERS AND CITIZENS

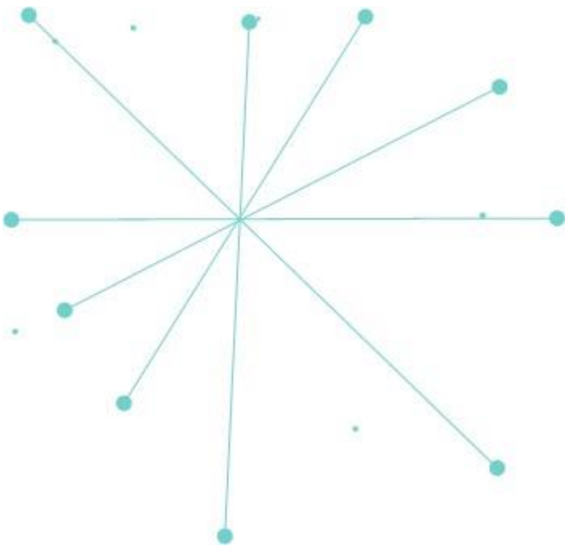
- Create an environment where independent researchers can quickly access authentic data and analyze it to offer valuable insights for policymakers.
- Devise an information sharing policy to ensure citizens have access to relevant data around venue, cost, waiting period and turnaround time of test.

2. INITIATE PUBLIC CONSULTATION ON HOW TECHNOLOGIES CAN BE DEPLOYED TO MAXIMIZE PUBLIC GOOD WITH MINIMUM PRIVACY INVASION

- Involve multiple stakeholders drawn from the field of medicine, public health, epidemiology, software engineering, disaster management, GIS mapping, and app development and community health workers to build technology platforms which are strongly rooted in their contexts of application.

3. DESIGN A DEDICATED CAMPAIGN TO COMMUNICATE THE BENEFITS OF TESTING AND TRACING AND ENCOURAGE UPTAKE





REFERENCES

1. https://www.pib.gov.in/PressReleasePage.aspx?PRID=1687305
2. https://www.nature.com/articles/d41586-021-00450-z; https://www.bloombergquint.com/quicktakes/can-a-vaccinated-person-still-spread-the-coronavirus-quicktake
3. https://www.thenationalnews.com/world/europe/uk-covid-strain-is-30-deadlier-than-original-virus1.1151818
4. https://www.bbc.com/news/world-asia-india-55945382
5. Das Hemanshu et al [2021], *Drivers of improving cost efficiencies in COVID testing in India*, ISB MIHM; https://www.isb.edu/en/research-thought-leadership/research-centres-institutes/max-institute-of-health-care-management/Grants/cost-effectiveness.html
6. https://timesofindia.indiatimes.com/india/Covid-19-india-conducts-46-pc-of-rt-pcr-49-pc-antigentests-so-far/articleshow/79155723.cms
7. Estimates from covidindiaupdates.in, as of 23rd January 2021
8. https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/14/142/123_2020_11_15.pdf
9. https://www.ndtv.com/india-news/why-official-Covid-19-numbers-are-misleading-2329668; https://theprint.in/health/how-many-rat-rt-pcr-tests-has-india-conducted-dont-have-data-ask-states-says-icmr/538513/
10. https://theprint.in/india/why-indias-rapid-antigen-tests-for-coronavirus-are-like-flipping-a-coin/483203/
11. https://theprint.in/health/how-effective-are-covid-vaccines-delhi-centres-to-test-for-antibodiesbefore-after-shot/589653/
12. https://www.medrxiv.org/content/10.1101/2021.01.12.21249713v1.full.pdf
13. https://timesofindia.indiatimes.com/city/pune/immune-response-study-of-covid-shots-likely-soon/articleshow/80592291.cms
14. https://timesofindia.indiatimes.com/life-style/health-fitness/health-news/my-covid-story-a-rapid-testat-my-husbands-workplace-showed-a-positive-report/articleshow/79941484.cms
15. https://www.outlookindia.com/outlooktraveller/travelnews/story/71431/updated-list-of-statewise-travel-rules-and-restrictions-for-air-passengers
16. https://www.icmr.gov.in/pdf/covid/strategy/Advisory_COVID_Testing_in_Second_Wave_04052021.pdf
17. https://www.nationalheraldindia.com/international/workplace-Covid-19-saliva-testing-pilot-program begins-in-australia
18. https://www.nejm.org/doi/full/10.1056/NEJMp2025631
19. https://www.fda.gov/news-events/press-announcements/coronavirus-Covid-19-update-fdaauthorizes-antigen-test-first-over-counter-fully-home-diagnostic
20. https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667(20)30308-X/fulltext
21. https://www.sciencedirect.com/science/article/pii/S266605392030014X
22. https://www.deccanherald.com/national/south/new-rt-lamp-based-test-kits-rolled-out-for-Covid-19-cleared-for-use-by-labs-913956.html
23. https://www.newindianexpress.com/states/kerala/2020/dec/31/kerala-to-use-rt-lamp-test-forspeedy-confirmation-of-covid-2243352.html
24. https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(20)30544-1/fulltext?dgcid=raven_jbs_etoc_email
25. https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/14/142/123_2020_11_1 5.pdf
26. https://economictimes.indiatimes.com/news/politics-and-nation/assams-sero-survey-found-23-7per-cent-seroprevalence-in-the-state/articleshow/78606153.cms?from=mdr
27. https://www.newindianexpress.com/states/karnataka/2020/nov/10/46-of-karnataka-was-covidinfected-byaugust-sero-survey-report-2221732.html

28. https://www.hindustantimes.com/india-news/Covid-19-up-sero-survey-reveals-1-in-5-peopledeveloped-antibodies/story-1gRi4Ly1QIyjTPo6oaHEeO.html
29. https://timesofindia.indiatimes.com/blogs/voices/role-of-private-sector-towards-universal-healthcoverage-in-india/
30. https://qz.com/india/1901171/india-increases-Covid-19-tests-but-indians-hesitant-to-get-tested/
31. https://pmjay.gov.in/sites/default/files/2020-05/4th-OM-COVID-19.pdf
32. https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/14/142/123_2020_11_15.pdf
33. https://www.thehindubusinessline.com/money-and-banking/ayushman-bharat-crosses-15-crmark-in-hospital-admissions-as-non-COVID-19-treatments-resume/article33495653.ece
34. https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/14/142/123_2020_11_15.pdf
35. https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/14/142/123_2020_11_15.pdf
36. https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1707177
37. https://www.hindustantimes.com/india-news/centre-identifies-10-labs-in-india-for-monitoring-genomic-variations-in-sars-cov-2/story-1a4hiaVuOFkYFsiqRMMfzJ.html
38. https://www.mohfw.gov.in/pdf/IndianSARSCoV2PDFGenomicsConsortiumGuidanceDocument.pdf
39. https://www.indiatoday.in/coronavirus-outbreak/story/Covid-19-india-mutant-coronavirus-variant-1753752-2020-12-28
40. https://science.thewire.in/the-sciences/india-sars-cov-2-genome-sequencing-roadblocks-resources-b117-n440k-variants/
41. https://pib.gov.in/PressReleasePage.aspx?PRID=1712312
42. https://www.mohfw.gov.in/pdf/IndianSARSCoV2PDFGenomicsConsortiumGuidanceDocument.pdf
43. https://www.who.int/emergencies/disease-outbreak-news/item/2020-DON304
44. https://pib.gov.in/PressReleasePage.aspx?PRID=1683835
45. https://www.medtechdive.com/news/fda-tracks-impact-Covid-19-mutations-on-tests/592970/
46. https://www.fda.gov/news-events/press-announcements/fda-issues-alert-regarding-sars-cov-2viral-mutation-health-care-providers-and-clinical-laboratory
47. https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/coronavirus-spicehealth-csir-igib-launch-genome-sequencing-lab-at-delhi-airport/articleshow/80268024.cms?from=mdr
48. Special input from science experts in the group
49. https://www.nature.com/articles/d41586-021-00396-2
50. https://www.ncbi.nlm.nih.gov/books/NBK562776/
51. https://gh.bmj.com/content/4/6/e001539
52. Das Hemanshu et al [2021], *Drivers of improving cost efficiencies in COVID testing in India*, ISB MIHM; https://www.isb.edu/en/research-thought-leadership/research-centres-institutes/max-institute-of-health-care-management/Grants/cost-effectiveness.html
53. ICMR (n.d.) Consortiums of NRLs for Kit Quality. ICMR, Government of India
54. https://www.business-standard.com/article/current-affairs/labs-find-lower-covid-rt-pcr-testpricing-unviable-some-may-opt-out-120120100758_1.html
55. Based on inputs from industry executives and not-for-profit organizations working on the ground
56. The ISB costing model has assumed the cost of Viral Testing Medium at Rs 100 and antigen test kit at Rs. 75
57. https://www.ft.com/content/de3114a2-8b97-4d95-a55c-0a9d72dfa1ea
58. https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/14/142/123_2020_11_15.pdf
59. https://www.thehindu.com/sci-tech/science/rt-lamp-a-new-technology-for-detecting-Covid-19/article33201609.ece
60. https://www.nature.com/articles/d41586-020-03518-4

61. https://hbr.org/2020/04/how-digital-contact-tracing-slowed-COVID-19-in-east-asia
62. https://hbr.org/2020/04/how-digital-contact-tracing-slowed-COVID-19-in-east-asia
63. https://www.mohfw.gov.in/pdf/ContainmentandSurveillanceManualforSupervisorsincontainmentzones.pdf
64. https://pib.gov.in/PressReleasePage.aspx?PRID=1637024
65. https://scroll.in/article/967223/Covid-19-as-cases-surge-in-india-most-states-abandon-contact tracing
66. https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/15/143/229_2020_12_18.pdf
67. https://www.abc.net.au/radio/programs/am/japan-attributes-corona-containment-to-cluster-buster-network/12310268
68. https://datareportal.com/reports/digital-2020-india
69. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6859513/
70. https://www.thenewleam.com/2020/08/asha-workers-protest-at-jantar-mantar-against-low-salaries-and-lack-of-access-to-protective-gear-for-fight-against-COVID-19/
71. https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/14/142/123_2020_11_15.pdf
72. i-Cart, India COVID Apex Research Team is a volunteer research and development group that comprises professionals and students from AIIMS, IISER, IIIT among other institutes who came together during the pandemic to build evidence with an intent to assist policy-makers.
73. https://www.emerald.com/insight/content/doi/10.1108/IJPCC-07-2020-0081/full/html#ref091
74. Roser, M., Ritchie, H., Ortiz-Ospina, E., and Hasell, J. (2020). Coronavirus Pandemic (COVID-19). OurWorldInData.org. Retrieved from: https://ourworldindata.org/coronavirus
75. Khan A et al, [2021], *Technology-aided models for effective tracing and tracking of Covid-19, and potential data collection modes*, Centre for Development Policy and Practice
76. https://cyber.harvard.edu/events/retrospective-contact-tracing-how-states-can-investigate-COVID-19-clusters
77. https://www.livemint.com/news/india/now-you-can-understand-how-aarogya-setu-app-works-11605928716781.html
78. Roser, M., Ritchie, H., Ortiz-Ospina, E., and Hasell, J. (2020). Coronavirus Pandemic (COVID-19). OurWorldInData.org. Retrieved from: https://ourworldindata.org/coronavirus
79. https://indianexpress.com/article/india/itihas-tracks-covid-cases-using-mobile-network-artificialintelligence-algorithm-6563546/
80. https://www.nature.com/articles/d41586-021-00460-x
81. https://www.nature.com/articles/d41586-020-03518-4
82. https://www.bbc.com/news/health-54648734
83. https://www.financialexpress.com/opinion/remove-stigma-associated-with-coronavirus-not-posters/2142898/
84. https://www.medrxiv.org/content/10.1101/2020.12.25.20248668v1
85. https://www.thehindu.com/news/cities/Delhi/ensure-food-water-provided-separately-to-coronavirus-patients-at-quarantine-facilities-hc-to-aap-govt/article31694193.ece
86. https://www.ecdc.europa.eu/sites/default/files/documents/Covid-19-contact-tracing-public-healthmanagement-third-update.pdf
87. https://www.medrxiv.org/content/10.1101/2020.12.25.20248668v1
88. https://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099(20)30273-5.pdf
89. https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001935
90. https://www.who.int/medicines/ebola-treatment/blueprint_phe_data-share-results/en/
91. Developing Global Norms for Sharing Data and Results during Public Health Emergencies, KayvonModjarrad, Vasee S. Moorthy, Piers Millett, Pierre-Stéphane Gsell, Cathy Roth, Marie-Paule Kieny, Published: January 5, 2016, https://doi.org/10.1371/journal.pmed.1001935

92. https://asia.nikkei.com/Spotlight/Coronavirus/Singapore-urges-citizens-to-sign-up-for-COVID-19tracking-app

93. https://www.economist.com/china/2021/01/16/many-in-china-are-strikingly-accepting-of-harshvirus-controls

94. https://www.emerald.com/insight/content/doi/10.1108/IJPCC-07-2020 0081/full/html#ref075

95. Pietrewicz, O. (2020), “Preparedness and surveillance: South Korea’s response to COVID-19

96. https://www.emerald.com/insight/content/doi/10.1108/IJPCC-07-2020-0081/full/html

97. https://www.nytimes.com/2015/06/14/world/asia/experts-fault-south-korean-response-to-mersoutbreak.html

98. https://thediplomat.com/2020/04/south-koreas-experiment-in-pandemic-surveillance/

99. https://www.aljazeera.com/news/2020/4/27/iran-over-700-dead-after-drinking-alcohol-to-cure-coronavirus

100. https://www.who.int/health-topics/infodemic#tab=tab_1

101. Importance of effective communication during COVID-19 infodemic, B Venkatashiva Reddy, Arti

102. https://pubmed.ncbi.nlm.nih.gov/21957983/

103. https://www.researchgate.net/publication/347893014_Acceptance_and_adoption_of_protective_measures_during_the_COVID-19_pandemic_The_role_of_trust_in_politics_and_trust_in_science

104. https://www.newindianexpress.com/cities/kochi/2020/aug/05/contradicting-results-cause-confusion-2179107.html

105. https://qz.com/india/1901171/india-increases-Covid-19-tests-but-indians-hesitant-to-get-tested/

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