TAKSHASHILA INSTITUTION

Analysis of COVID-19 Serosurveys in India

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Executive Summary

The Union and various state governments have conducted seroprevalence surveys at national and city/state levels to study the spread of COVID-19. We argue

1. The disparity in estimated cases as per seroprevalence studies and actual detected cases is a result of limited testing capacity and flawed testing strategy.
2. City level sero-surveys can help understand testing demand and should be used to tailor testing capacity at the local level.

Introduction

According to official reports, COVID-19 has infected 8.41 million people as of 6 November 2020. Molecular diagnostics tests (RT-PCR/TruNat/CBNAAT) and rapid tests (antigen) have so far been used for testing active infections. However, experts have critiqued that this number may be an under-reporting of the true disease burden.[1] Majority of COVID-19 infected individuals are asymptomatic and therefore, might have not been tested. It is essential to determine the spread of COVID-19 to design better public health measures. Beginning May, the union and state governments have been conducting serosurveys to assess the extent of the true spread of COVID-19. The serosurvey results have indicated a serious gap between the estimated number of cases and reported number of cases, which reflects shortcomings in India's active testing. For instance, Bihar's serosurvey, conducted in May, showed a prevalence of 0.7% which roughly equates to 0.75 million cases. However, it had reported only 1,391 cases at the time. India must scale up its testing capacity and adopt aggressive testing and contact tracing strategy to limit the spread of COVID-19.

What are serosurveys?

Serosurveys involve collection and testing of serum specimens from a sample of a defined population, over a given period of time to detect the presence of antibodies against a particular infectious pathogen. [2] High-quality serosurveys require that samples be collected from individuals that accurately represent the target population and that testing kits used, have high sensitivity and specificity. The presence of antibodies in the tested individuals indicate that they had been infected within a limited time period preceding the survey.

In the past, serosurveys have been used to design elimination programs for poliomyelitis, measles, and rubella "by informing estimates of the required population immunity thresholds for elimination". [3] Although, serosurveys that are being conducted for COVID-19 in India are not able to detect neutralising antibodies (which are actually responsible for fighting the virus),[4] they are a good way of identifying gaps in terms of testing across various states/cities of the country.

Why do sensitivity and specificity of the testing kit matter?

No test is 100% accurate (both 100% sensitive and 100% specific) and the test may erroneously detect people who do not have the disease as positive (false positive) and people who have the disease as negative (false negative).[5] This leads to misrepresentation of the disease burden.

The sensitivity of the test is defined as the ability of the test to correctly identify those who have the disease (true positives). If 100 COVID-19 positive people are tested, and the kit identifies all 100 people, the kit will be 100% sensitive. The specificity of a kit is its ability to identify only COVID-19 antibodies[6]. Thus, if a kit identifies 100 positive cases and all 100 only have antibodies against COVID-19, and no other disease, it means the kit is 100% specific. Some kits have been shown to have cross-reactivity with antibodies against dengue or other coronavirus-inflicted diseases[7]. Kits with lower sensitivity can mark samples, which are not COVID-19 positive, as positive cases.

Table 1: Calculating sensitivity and specificity

	Condition according to gold standard test	
Screening test result	Positive	Negative
Positive	True Positive (TP): Have the disease and test positive	False Positive (FP): Do not have the disease but test positive
Negative	False negative (FN): Have the disease but test negative	True Negative (TN): Do not have the disease and test negative

$$\text{Sensitivity} = \frac{TP}{TP+FN} \qquad \text{Specificity} = \frac{TN}{TN+FP}$$

To calculate sensitivity and specificity of a testing kit, the kit is first tested on a known diseased and healthy population. However, in the case of COVID-19, it is difficult because no 'gold standard' antibody test exists yet that can confirm if an individual has developed an immune response. Hence, most kit manufacturers use the next best option – the RT-PCR test, to calibrate their kits.[8] RT-PCR by itself is also not 100% sensitive,

but it the best technical and universally accepted option currently available to compare the antibody tests.

Table 2: Examples of some of the tests used for serosurveys in India

Test	Sensitivity	Specificity
COVID Kavach IgG ELISA	92.3%	97.9%
RBD ELISA[9]	84.7%	100%

Sensitivity and specificity numbers as given out by the developers of the testing kits

For SARS-CoV-2, the US Centres for Disease Control and Prevention recommends using antibody tests that have specificity ≥ 99.5%, to reduce the potential for false positive results.[10] Where the seroprevalence is low, it is even more important for the testing kits to be highly specific. If kits with low specificity are used, there is a high chance that the number of false positives is inflated which can lead to misrepresentation of the burden of the disease.[11] ICMR has stated that the specificity of the Covid Kavach (ELISA IgG) test used in the national serosurvey is less than 99.5%. However, a subsequent study carried out by the Department of Biotechnology estimated that the specificity of the Covid Kavach test is 99.5%.[12] If the tests being used in the field are actually 99.5% specific, the results may be deemed to be an accurate representation of true disease burden.

This paper recognises that there are caveats in the extrapolation of results of serosurveys, dependent on the characteristics of the kit and sampling technique for the serosurvey. However, we argue that even with potential discrepancies, the serosurvey results demonstrate a wider spread of the disease and the failure of aggressive RT-PCR based testing to be able to keep pace with this spread.

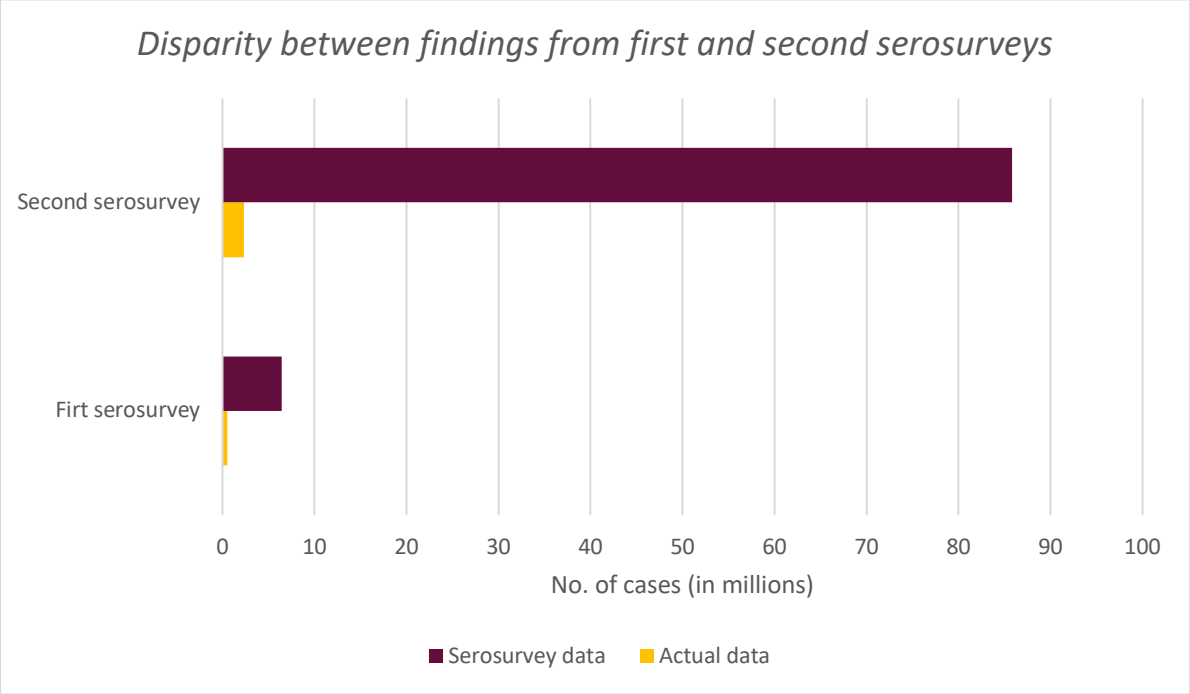
Findings from serosurveys

First national serosurvey – The first national serosurvey was conducted between May 11 and June 4. A sample size of 28,000 individuals was tested from over 80 districts, using the COVID Kavach Elisa kit. A seroprevalence of 0.73% was observed which equates to 6.4 million infections.[13] The cumulative caseload on 7th May was 52,592 which was much lower than the estimated number of cases. According to the survey, for every individual who tested positive through RT-PCR, 81 to 130 cases were missed.[14] Importantly, the serosurvey found COVID-19 spread in districts that were thought to be COVID-19-free.[15]

Second national serosurvey – The number of estimated cases based on the seroprevalence of the second round was 35 times more than the number of reported cases at the time. The second serosurvey was conducted between August 17 and September 22 and 29,082 people (from the same districts as covered in the first survey) were surveyed. A

seroprevalence of 6.6% was observed, up from 0.73% in May, which indicates that a large section of the population is still susceptible to the infection.[16] The seroprevalence roughly equates to 85.8 million infections. However, on 12th August, the reported number of cases was 2.3 million . The disparity here is much lesser than the first serosurvey which may be attributable to increased testing.

Fig 1: Differences in reported and estimated cases, based on the results of first and second national serosurveys



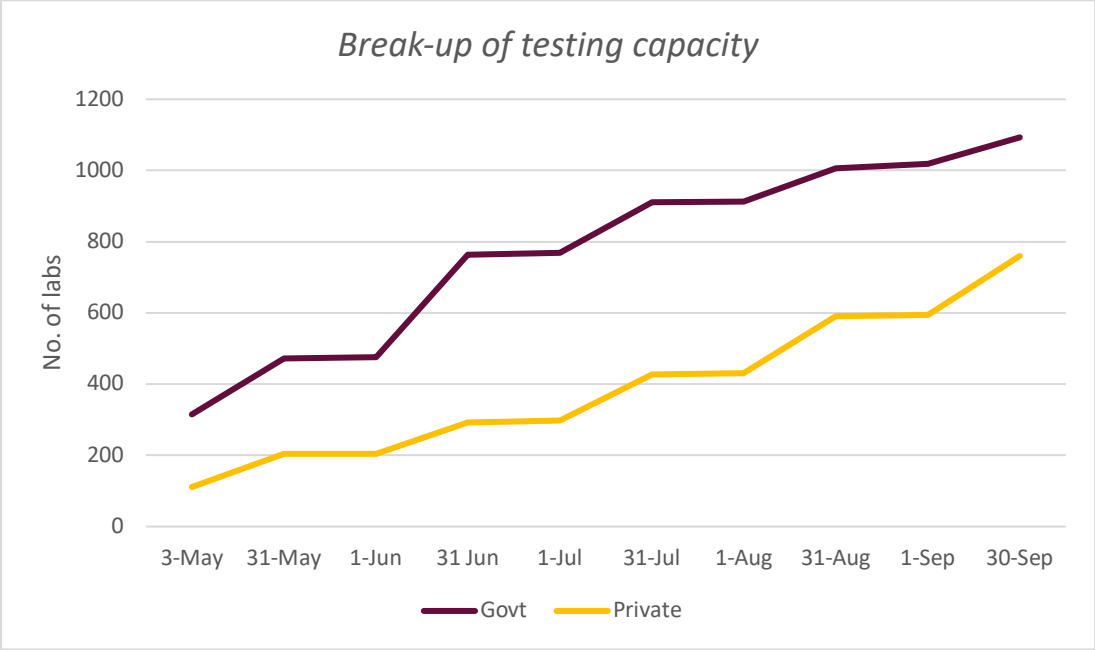
The findings from the first serosurvey show a considerable disparity in the number of cases estimated on basis of seroprevalence and those actually reported through molecular and rapid tests. We suggest that there are two possible reasons for this disparity:

1. **Inadequate RT-PCR-based testing capacity** – At the onset of the COVID-19 outbreak, testing for COVID-19 was limited to only designated government laboratories. In March, India was conducting only 10 tests per million whereas countries like South Korea and Italy were conducting 5,500 and 2,500 tests per million respectively.[17]

   Private labs were allowed to start testing for COVID-19 only from March 23. Moreover, the government imposed price caps on testing at private laboratories. The price cap on testing disincentivised the entry of private players in the market.[18] At the beginning of May, private labs accounted for just 26.05% of the total testing capacity. The late entry of the private sector and price caps on testing led to the under-utilisation of the potential testing capacity, preventing India from aggressively testing the population. As is evident from Figure 2, the share of

private laboratories contributing to COVID-19 testing is still much lesser than that of government laboratories.

Fig 2: No. of Government and private labs involved in COVID-19 testing

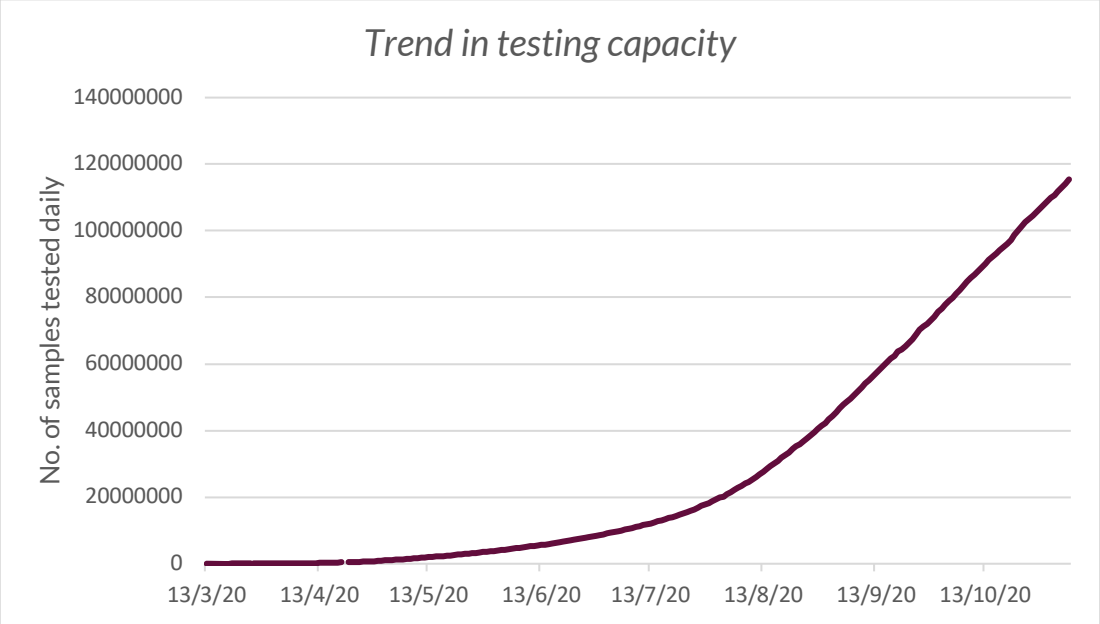


Source: ICMR Archive Reports on Total Operational Laboratories

India has increased its testing capacity from 1000 tests per day in March to 12 lakhs per day in September.[19] However, it is essential to look at the break-up of what kind of tests are being used. Many states have opted for Rapid Antigen Tests (RATs), to boost the testing capacity in a shorter period of time. Currently, Bihar is conducting 80% RATs and 20% RT-PCR tests.[20] About 90% of Odisha's testing capacity is facilitated by RATs.[21] The states of Andhra Pradesh, Karnataka, West Bengal, and Delhi tested a total of 1,034,537 samples in the second week of August and a majority (50.3%) were RATs.[22]

Although RATs give faster results when compared with RT-PCR tests, they are not as sensitive. Hence, it is necessary that those who tested negative in RAT should undergo an RT-PCR test for confirmation, especially if the result is inconsistent with the clinical context. [23] Although the ICMR has made it mandatory for suspected individuals who test negative in RAT to undergo RT-PCR test, in a few states only 30-35% of negatives are following the same. This means that as many as 70% of those negatives are still spreading the infection.[24]

Fig 3: Number of samples tested daily for COVID-19 across India



Source: COVID-19 India Org Data Operations Group, https://api.covid19india.org/csv/latest/tested_numbers_icmr_data.csv, Accessed on 6 November 2020

The above figure shows that a steep increase in testing has been observed since June. However, till May end, the increase in testing capacity was very low. The period from January, when the first COVID-19 case was detected in India, till May should have been used by the government to ramp up its testing capacity to aggressively test and trace individuals. Since there was no community transmission in the initial months, it would have been easier to test and trace individuals and control the spread of the disease. The initial passivity in testing may have contributed to the spread of the disease.

India's second serosurvey suggests a reduction in the disparity between seroprevalence-based case estimation and actual cases. The increased testing capacity, the inclusion of RATs, and increasing involvement of the private sector may have fed into improved coverage of active testing. However, sustained, aggressive testing and contact tracing need to be performed over the next few months to prevent the further spread of the disease.

2. **Conditional testing regime** – ICMR's testing strategy in the initial phases of the response was extremely stringent and precluded people from testing, even if symptomatic.

Table 3: India's COVID-19 testing strategy

Date	Testing strategy
17 March	All asymptomatic people who have undertaken international travel (to quarantine themselves at home for 14 days and to be tested only if they turn symptomatic), all contacts of laboratory confirmed positive cases, healthcare workers managing respiratory distress/SARI* when they are symptomatic
20 March	All symptomatic individuals who have undertaken international travel in last 14 days, all symptomatic contacts of laboratory confirmed cases, all symptomatic healthcare workers, all hospitalised patients with SARI*, asymptomatic direct and high-risk contacts of a confirmed case
9 April	All symptomatic individuals who have undertaken international travel in last 14 days, all symptomatic contacts of laboratory confirmed cases, all symptomatic healthcare workers, all hospitalised patients with SARI*, asymptomatic direct and high-risk contacts of a confirmed case, all symptomatic individuals with influenza-like illness (hotspots and large migration gatherings)
18 May	All symptomatic individuals who have undertaken international travel in last 14 days, all symptomatic contacts of lab-confirmed cases, all symptomatic healthcare/frontline workers, all patients of SARI, asymptomatic direct and high-risk contacts of a confirmed case, all symptomatic within hotspots/containment zones, all hospitalised patients who develop ILI** symptoms, all symptomatic ILI** among returnees and migrants within 7 days of illness

Source: ICMR advisories on strategy of COVID-19 testing in India (https://www.icmr.gov.in/cteststrat.html)
*Severe Acute Respiratory Illness
**Influenza like Illness

The first advisory recommended for all asymptomatic individuals who had undertaken international travel to quarantine themselves for 14 days and to be tested only if they showed symptoms in that period. After three days, it was narrowed down to only symptomatic individuals with international travel history. Ideally, all people with international travel history should have been tested, as those were the first source of the spread of infection. On April 9, the testing strategy was expanded to include all symptomatic individuals with influenza-like illness. However, it was limited only to those from hotspots and large migration

gatherings. Up until 18 May, the narrow testing strategy excluded a large number of people from getting tested, even when symptomatic. Testing on demand, without requiring a doctor's prescription was introduced only in September, removing barriers on testing and opening a pathway to an aggressive testing regime.[25]

We believe that the limited testing regime and capacity in the initial phases have contributed to the spread of the disease. An aggressive testing strategy accompanied with a ramping of testing capacity would have aided in curbing this spread.

In the next section, we discuss that serosurveys can now be used to build or divert capacity locally to facilitate aggressive testing over the next few months.

State/city serosurveys - Starting from May, states have started conducting their own serosurveys as well. The serosurveys have shown prevalence ranging from 0.25% to 51%.

Table 4: Disparity between estimated no. of cases and reported cases

State/City	Time period	Sample size	Sero-prevalence	Estimated no. of cases	Actual no. of cases reported before the survey	No. of cases missed per confirmed case
Chennai[26]	Jul 18 – Jul 28	12,045	22%	1,022,281	10th July – 73,728	13.87
Indore[27]	Aug 11 – Aug 23	7,103	7.75%	1,74,813	5th Aug – 7,735	22.6
Pune[28]	Jul 20 – Aug 5	1,664	51.5%	1,798,969	14th July – 35,000	51.4
Mumbai[29]	First half of July	6,936	~ 40%	5,564,229	24th June – 69,625	79.91
Delhi (1st round)[30]	Jun 27 – Jul 10	21,387	23.4%	5,573,412	20th June – 53,116	104.92
Delhi (2nd round)[31]	Aug 1 – Aug 7	15,289	29.1%	6,931,038	25th June – 70,390	98.46
Delhi (3rd round)[32]	Sept 1 – Sept 5	17,000	25.1%	5,978,318	24th Aug – 1,61,466	37.02
Andhra Pradesh[33]	Aug	65,000	19.7%	17,916,953	25th July – 88,671	202.06
West Godavari[34]	Aug	5000	12.3%	5,20,565	27th July – 8,820	59.02
East Godavari[35]	Aug	5000	14.4%	7,97,885	25th July – 12,391	64.39

Bihar[36]	May	2400	0.7%	7,58,604	19th May - 1391	545.36
Punjab[37]	Aug 1 - 17	1250	27.7%	8,337,977	25th July – 12,684	657.36
Amritsar[38]	Aug 1 - 17	250	40%	5,03,104	25th July – 1,491	337.42
Ludhiana[39]	Aug 1 - 17	250	35.6%	6,25,308	25th July – 2,327	268.7
SAS Nagar[40]	Aug 1 - 17	250	33.2%	3,58,285	25th July – 679	527.66
Patiala[41]	Aug 1 - 17	250	19.2%	3,94,909	25th July – 1,294	305.18
Jalandhar[42]	Aug 1 - 17	250	10.8%	1,01,821	25th July – 1,937	52.56

The estimated number of cases was calculated on the basis of the seroprevalence and 2020 projections of state-level populations.

Among the states where serosurveys were conducted, Punjab had the highest disparity with 657.36 cases being missed per confirmed case. By the end of June, the government of Punjab had decided to ramp up its testing capacity to 20,000 tests per day. However, up until the second week of July, Punjab was conducting only 3000-8000 tests per day.[43] The low testing rate could be the reason behind such high disparity. Bihar showed a considerably low seroprevalence (0.7%) which can be attributed to a low RT-PCR testing rate. As of May 13, Bihar was one of the states with the lowest testing rates (2,000 samples per day).[44] This time period also coincided with the return of migrant labourers. Hence, this implies that there is a high probability that the prevalence was more than 0.7%. One of the reasons for Punjab's disparity being higher than Bihar, despite doing more testing, could be the level of urbanisation. Punjab is more urbanised than Bihar and urbanisation indicates higher population density which can facilitate the spread of respiratory diseases like COVID-19.[45]

At the city level, Mumbai and Pune showed disparities of 79.91 and 51.4 respectively. Chennai and Indore showed considerably less disparity. The lower disparity could indicate a more aggressive testing strategy. Chennai, for example, has been aggressively testing from the beginning, being the first city to test 5 lakh individuals.[46] In the case of Indore, the testing capacity has gone up by 1300%, in the time period between April (214 samples per day) and September (2816 samples per day). At present, it has seven labs out of which five labs have the RT-PCR testing capacity.[47]

In Delhi, three rounds of serosurvey have been conducted so far and the disparity seems to have reduced over time. The reason behind the decrease in disparity could be attributed to the increase in Delhi's testing capacity. On 26th August, an emergency meeting was conducted by Delhi's government, wherein it was decided that the testing

capacity will be ramped up from 20,000 to 40,000 weekly. Following the meeting, the working hours of primary health centres were extended and testing at interstate bus terminals was also started.[48]

The findings from state/city serosurveys can be helpful in designing localised testing strategies. Therefore, periodic serosurveys should be performed to understand the spread of the disease, and tailor testing and contact tracing capacities, to respond to the increase in disease incidence. Data on the disparity between estimated number of cases and reported cases can be used to determine how many testing kits will be needed and which geographical areas should be tested aggressively. Local efforts in increasing capacity suggest that ramping up testing, contact tracing, and access to health care may help curb the disease spread. Serosurveys can guide in estimating the disparity in testing supply and demand and calibrating capacity building in an evidence-based manner.

Conclusion

The findings from serosurveys could be instrumental in managing the COVID-19 crisis. They can help in identifying the gap in testing capacity, building the capacity of health resources according to the prevalence in different demographic settings. However, there should be no complacency under the misbelief that India is moving towards attaining herd immunity. The proportion of neutralising antibodies among the detected antibodies from serosurveys is not known. Hence, it will be difficult to determine if India's population has developed herd immunity and the threshold for the same. The focus should be on increasing the RT-PCR based testing capacity, to have more reliable results and more accurately determine the burden of COVID-19. Serosurveys can be used as crude tools to determine local capacity disparities and respond with capacity building/redistribute to ensure enough testing capacity is available where required.

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