**WHITE PAPER**

# Drivers of improving cost-efficiency of COVID-19 testing in India


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# Table of Contents

# 1. Introduction

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[1] The disease was first identified in 2019 in Wuhan, China, and has since then spread worldwide. Globally, as of Jan 26, 2021, more than 100 million people have been diagnosed with the disease, and 2.1 million people have succumbed to it.[2] Widespread and equitable testing is an important method to reduce the spread and the impact of the disease.

The first case of COVID-19 in India was reported on January 30, 2020. India's initial response to the pandemic was decisive and swift – the Government of India imposed a nationwide lockdown on March 24, 2020 even before the cumulative cases crossed 500, and the lockdown was one of the most stringent across the globe.[3] India was one of the first nations to impose a mask mandate as well. The recent Supreme Court remark that "*Those people who do not wear masks are violating fundamental rights of other persons*" is indicative of the resolve of the administration and policymakers to control the epidemic.[4] As the nation started lifting the lockdown, the central and state governments continued to define containment zones and impose strict stay-at-home orders to curb any local hotspots. The government also upgraded healthcare facilities, spending INR 3 billion on 205 facilities, onboarding private sector facilities for COVID-19 treatment and constructing large, dedicated COVID care centers, including the world's largest care center in Delhi with 10,000 beds.[5]

Even after all these measures from the government, India is still one of the world's worst-hit nations. Currently, India has the second-highest number of confirmed cases in the world. As of Jan 26, India has more than 10.6 million confirmed cases, and 153,000 people have lost their lives because of the disease. The seroprevalence studies in India have shown the heterogeneous nature of the spread of the infection. While the Indian Council of Medical Research (ICMR) found a seroprevalence of 6.6% on September 22, the estimate varies widely from region to region – Odisha's Berhampur at 31%, Gujarat's Ahmedabad at 17%, and Delhi at 23%.[6] Within a city, the slum areas have shown a much higher prevalence of COVID-19 than the non-slum areas. A study in Mumbai indicated a seroprevalence of 55.1- 61.4% in slum areas compared to 12.0-18.9% in non-slum areas. These varying estimates indicate the importance of testing to understand the state of the epidemic in India and inform essential public health action to curb the epidemic. Previous studies have indicated that intensive testing and quarantine can curb the epidemic.[7] Nations including Taiwan, New Zealand and South Korea changed the epidemic's trajectories by increased testing and contact tracing. Even China, the epicenter of the outbreak, curbed the epidemic with intensive testing - sometimes testing entire cities within days of observing new cases.[8]

In this article, we (a) briefly highlight the COVID-19 testing landscape in India, (b) study the cost-effectiveness of various testing mechanisms for COVID-19, such as Real-time Polymerase Chain Reaction (RT-PCR), CBNAAT / TrueNAT, Rapid Antigen, and pooled testing, and (c) provide specific recommendations for reducing the unit cost of testing for COVID-19 applicable to both urban (densely populated) and rural (sparse demand) areas.

# 2. COVID-19 testing landscape in India

## 2.1 Testing numbers and infrastructure

With over 192 million tests, India ranks second highest globally in terms of the number of tests conducted. India's testing ability has increased substantially over the past few months. ICMR has led the testing scale-up since the beginning of the epidemic, and its active response has been crucial in increasing the testing 500 times in the past eight months from 1,800 tests per day before the lockdown (March 23) to over one million tests a day now. From the sole VDRL testing lab in Pune at the start of the pandemic, RT-PCR tests are available across 1,337 public and private sector labs today.[9] The inclusion of TrueNAT and CBNAAT facilities also helped. TrueNAT and CBNAAT tests were used by the Central TB Division for TB testing. 885 TrueNAT and 133 CBNAAT labs have been aptly roped in by ICMR for COVID-19 testing as well. While not used outside India, TrueNAT assays appear to detect COVID19 based on independent studies.[10] A similar approach was followed in the UK in its adoption of COVIDNudge. Further, ICMR devised a protocol for the inclusion of rapid antigen testing (RAT) for case detection in hotspots and containment zones. Also, ICMR has devised protocols for pooled testing and helped increase testing in low-prevalence regions. The number of empaneled private sector labs has increased from 153 in May to 1,147 in Jan 2021. Though the ICMR moved swiftly, there were regulatory hiccups including the accreditation of BSL-2 standards, initial procurement of Antigen test-kits and adoption of international agencies-validated RT-PCR kits. [11,12]

At 139 tests per 1,000 people, India's testing numbers seem low compared to more developed countries like the US, Germany, Italy, Australia etc. However, compared to other similar Developing countries, India's testing numbers per 1000 people are one of the highest in the world[13] (Fig. 1). Despite the progress in testing, India's scale and size require more to be done. E.g., if the state of Delhi were considered as a country, it would rank 20$^{th}$ in the number of new cases but only 79$^{th}$ in the number of tests per thousand. Also, the number of tests is not evenly spread across various states, with some states performing much better than others.

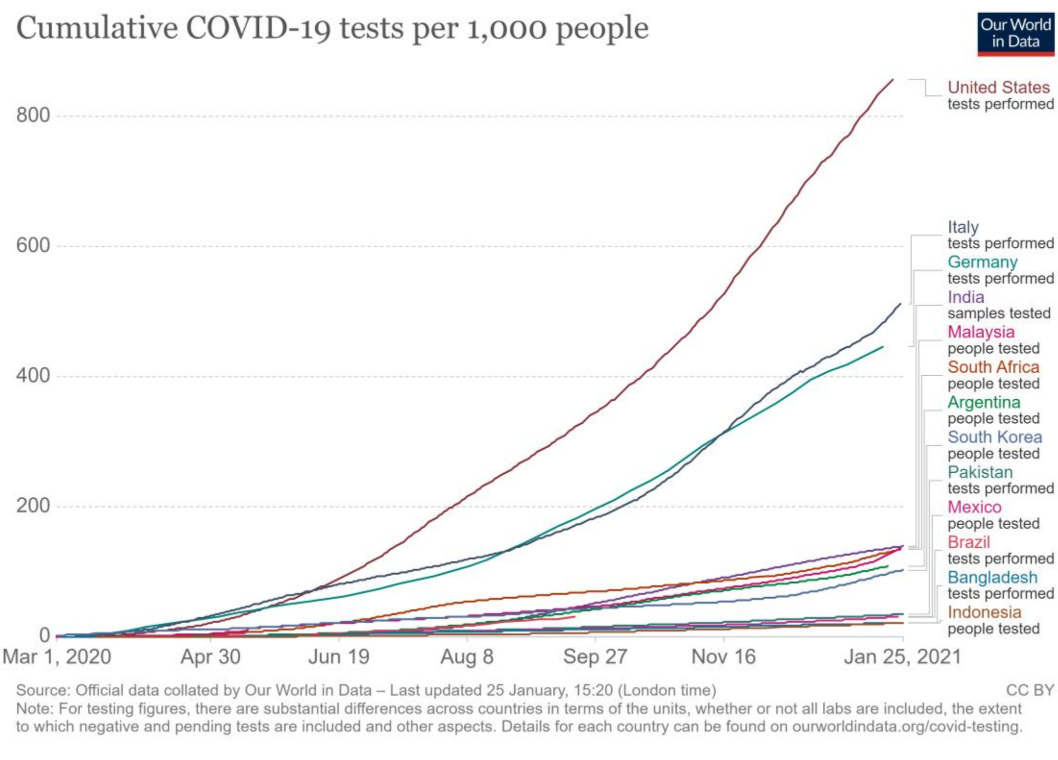



Fig 1: Number of COVID-19 tests per 1000 people for few selected countries

## 2.2 Testing policy and technology

Different options for COVID-19 testing, such as RT-PCR, Rapid Antigen, TrueNat, and CBNAAT have been explored, experimented with, and deployed in India. These tests vary based on their underlying testing principle, method, costing, infrastructure, sample analysis time (cycle time), etc. We show below a comparison among these 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<br>Xpert - 60 minutes | 8 – 10 hours |
| Infrastructure required | Dedicated lab with RNA Extraction and RT-PCR machine | Almost none | TrueNAT - portable and battery-operated<br>Xpert - dedicated labs required | Labs having RNA Extraction and ordinary PCR machine |
| Availability (as of Jan 25, 2021) | 1,337 labs | Data not available | 1,018 labs<br>Many labs were previously part of the government's TB infrastructure. | Data not available |
| Number of approved test kits | 144 | 24 | Not applicable | |
| Approved usage by ICMR | Diagnosis | Diagnosis in containment zones and serosurveillance | Diagnosis | Diagnosis |

Table 1: Summary of the three types of tests widely available in India

ICMR has laid down specific guidelines for the different testing mechanisms.[14] For instance, a single RT-PCR / TrueNat / CBNAAT / RAT positive test is to be considered confirmatory, without the requirement of any repeat testing. For those who test negative for COVID-19 by RAT, an RT-PCR needs to be performed for suspected individuals.[15] The guidelines dictate RAT's usage in containment zones, hotspots, and healthcare settings under strict medical supervision while maintaining the kit temperature between 2° and 30°C. RAT has a low sensitivity and, therefore, might not be effective in identifying active cases or inform quarantine decisions.[16] However, there is a gap between government guidelines and their implementation on the field. In Delhi, less than 85 % of symptomatic antigen negatives are tested again using RT-PCR.[17] Earlier, only 10-15% of such individuals were being retested. To make progress in curbing the epidemic, we need a widespread, equitable, and efficient testing strategy. It is important to have a robust testing infrastructure. However, it is equally important to have simple, clear, and transparent guidelines, which can be consistently followed.

## 2.3 Government's price policy and regulations

Testing is free in government establishments. Furthermore, to encourage people to get tested and to navigate through the public apprehensions toward testing price, Government of India has followed the practice of capping the price for the RT-PCR test for the private sector. On March 17, 2020, the central government capped the price of RT-PCR test at INR 4,500 for the private sector. The government's directive was met with criticism across the private sector. Private sector labs complained that the government had decided the ceiling price based on the kit cost and had not factored the high overhead costs. In May 2020, as the global supply chain for test kits had stabilized and indigenous kit production had started, the central government lifted the price cap. However, it delegated the responsibility of fixing the guidelines for testing and negotiating price caps with the private sector to the respective state governments. Ever since states have continued with the practice of price-capping and the ceiling price has been continuously reduced. As of Dec 2020, the price has dropped to INR 800 - 1000 for most states. While there is a lack of evidence in the context of COVID-19, ceiling prices have previously led to supply shortage and lack of innovation.[18,19] Private players find a workaround by either bundling the product with service where there are no price caps or there is an opacity on the processes so certifying the cost is hard. Price ceiling leads to inefficiencies, discourages private players, discourages innovations in technology, and creates a financial burden for the government. Unless a reduction in costs can support the price ceiling, both private and public players will have incentives not to increase high-quality RT-PCR testing.

## 2.4 Private sector engagement

The Indian private sector has ably supported ICMR's efforts. There are more than 140 approved RT-PCR kits and 20 RAT kits, the majority of which are produced in India.[20] Several private players have come up with innovative screening and diagnostic testing options. AnuPath, a strip-based, hand-held biosensor, uses the technology - initially built to measure vital parameters for diabetes, chronic kidney failure, anemia, and malnutrition with a finger-prick blood sample - for performing a sensitive antibody test using COVID-19 specific antibodies.[21] The TATA group has developed a CRISPR-based paper-strip test, which is reportedly as accurate as of the RT-PCR tests and requires less expensive ordinary PCR machines. ICMR has already laid out guidelines for the inclusion of CRISPR in the testing infrastructure.[22]

Over the last few months, India has significantly improved its testing capacity. The number of tests conducted has increased manifold and the price of a test is kept low. However, the price is low either because it is provided for free in the public sector or because of the price ceiling for the private sector. This leads to the financial burden, inefficiencies, and lack of incentives for innovation. To prevent these, the reduction in price needs to come from a cost reduction. In the next section, we conduct a cost analysis of COVID-19 testing in India and present possible measures to reduce cost.

# 3. Cost analysis of testing

In this section we (a) conduct a cost analysis of the RT-PCR test, (b) compare the cost of RT-PCR test with other tests, and (c) present possible measures to reduce the cost of RT-PCR (or alternatives with lower costs and similar test sensitivity). We first compute the unit cost of conducting RT-PCR and then compare it with the cost of conducting RAT, CBNAAT, TrueNAT, CRISPR + PCR tests and novel testing strategies.

## 3.1 Process and procurement for RT-PCR test

To understand cost distribution across the value chain for the RT-PCR test, we first study the process flow and the procurement process. The table below illustrates the Steps in RT-PCR test and corresponding procurement sources for the public and the private labs.[23]

<table>
<tr><th rowspan="2"></th><th rowspan="2">Step</th><th rowspan="2">Reagents required</th><th colspan="2">Procurement</th></tr>
<tr><th>Public lab</th><th>Private lab</th></tr>
<tr><td>Step 1</td><td>Sample collection</td><td>VTM for sample collection (2 swabs - throat and nasal - should be put in 1 VTM tube)</td><td>By state government</td><td rowspan="5">Private players</td></tr>
<tr><td>Step 2</td><td>RNA extraction</td><td>RNA extraction kit</td><td>By state government</td></tr>
<tr><td rowspan="2">Step 3</td><td rowspan="2">RT-PCR</td><td>Primers, probes, master mix, positive control, RNAseP</td><td>ICMR through resident commissioner and state nodal officer</td></tr>
<tr><td>Machine</td><td>Central government (for virus research and diagnostic labs)</td></tr>
</table>

Table 2: Sources of procurement for public and private labs

Even though the RT-PCR testing machines were allocated to government labs by the central government, all tender requests of consumables and reagents are currently submitted by each state independently. Moreover, the procurement of consumables and machines in the private sector is done independently from International and Indian manufacturers.

## 3.2 Unit cost of RT-PCR test

We divide the cost of a test into following categories; Collection and testing consumables (cost of VTM kits, reagents, testing kits, plate, etc.), personnel cost (for collection, and testing), transportation cost, and overheads (includes the cost of equipment, rent of establishment, IT cost, electricity etc.). The numbers were estimated by creating a costing model.*

We assume sample collection at the center. The cost for home collection or sample collection site is not included and will be extra.

The figure below represents the percentage contribution of different cost components across the value chain of RT-PCR testing for private and public labs, for May and Oct 2020.

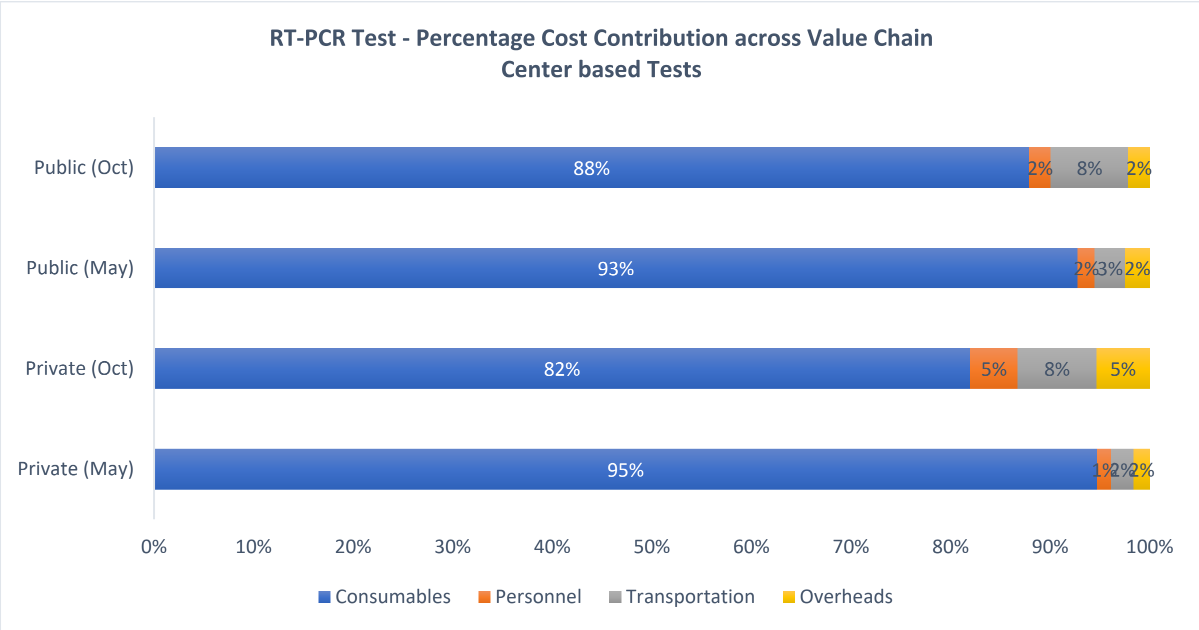


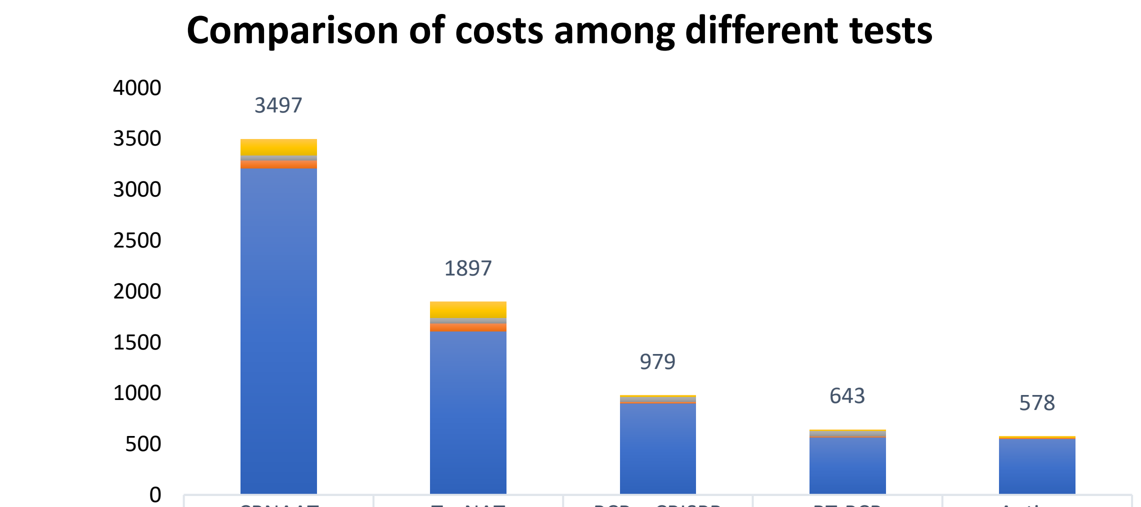

Fig 2: % contribution of different cost elements across the value chain in private and public labs

From the above graph, for both private and public labs, the cost of consumables (e.g., RT-PCR kit, RNA extraction kit, and VTM kit) constitutes ~82-95% of the total cost of an RT-PCR test. In our costing model, the consumables constitute a very large proportion of the cost, while the personnel, overheads, and transport constitute a very low proportion. This is because of three reasons, (1) In the initial phase of the pandemic the supply of testing kits might be limited and volatile, and therefore the kit cost might be very high compared to other costs in the value chain. (2) Even though personnel cost and overheads might be a large expense for a lab, these costs are spread over many tests and hence do not contribute much to the per-unit cost, and (3) In our model the transport cost is low because we assume samples are collected in the lab. We do not account for transport costs for home collection.

## 3.3 Cost comparison: RT-PCR vs other tests (public sector)

The below graph shows a comparison of cost for RT-PCR test with the cost for RAT, CBNAAT, TrueNAT and PCR + CRISPR tests.

* Total cost includes cost of test consumables, equipment, personnel cost, transportation costs, IT cost, Rent, Electricity and Managerial Staff. However, it does not include expenses such as administrative expenses, office expenses, marketing, and R&D expenses etc. Cost of consumables for the private sector was estimated to be equal to the maximum of the cost of procurement for any state.




| | CBNAAT | TruNAT | PCR + CRISPR | RT-PCR | Antigen |
|---|---|---|---|---|---|
| Overheads | 158 | 158 | 14 | 14 | 14 |
| Transportation | 50 | 50 | 50 | 50 | 0 |
| Personnel | 80 | 80 | 16 | 14 | 14 |
| Consumables | 3210 | 1610 | 900 | 565 | 550 |
| | 3497 | 1897 | 979 | 643 | 578 |

Consumables Personnel Transportation Overheads

Fig 3: Estimated average cost of different tests (in INR) in the public sector

We see that the unit cost of the Rapid Antigen Test (RAT) is comparable to that of an RT-PCR test. The reason for a significant decrease in RT-PCR test cost to the RAT level is the greater competition in the RT-PCR market. With ~450 players in the RT-PCR kit manufacturing market compared to ~50 manufacturers of RAT kits, indigenous kit manufacturers have driven down the cost of consumables, which constitutes the major portion of the testing cost. The lower number of players in the RAT market can be attributed to the test's lower sensitivity than the RT-PCR test. The cost of CBNAAT and TrueNAT tests were estimated using figures from our discussion with experts. From our discussions, we learnt that the costs of kits and consumables used in sample collection and testing are INR ~3210 and INR ~1610 for CBNAAT and TrueNAT tests respectively in comparison to INR ~565 for the kits and consumables in an RT-PCR test. Although the TrueNAT test cost is high relative to the RT-PCR test, TrueNAT is portable since its machine operates on battery. Also, the relative ease of TrueNAT testing along with its capability to function without an air-conditioner makes its use appropriate in an area with low demand, such as remote areas. TrueNAT can also be highly useful in scenarios requiring urgent results, such as checks at airports, where a high testing cost is typically not a major bottleneck. The countervailing concern is the limited capacity of the TrueNAT machine processing 4 per batch in 1.5 hours in comparison to 94 per batch processed in 6 - 8 hours in an RT-PCR machine. Due to the limited use of CBNAAT and TrueNAT tests in both public and private sectors, it is difficult to comment on the improvement in cost-effectiveness from scaling up of the testing using these technologies. Also, the technologies have existed for TB screening but haven't reduced in cost substantially. While we expect that its usage for COVID19 testing can reduce unit cost, we do not foresee the reduction of a similar magnitude to that observed for RT-PCR tests.

The emergent FELUDA test by the Tata Group is seen as favorable alternative to the RT-PCR test due to reduced infrastructure requirement. However, it is also important to note that PCR + CRISPR (FELUDA) test kit (~INR 550) costs higher than RT-PCR kits (INR 50 - 380). Below is a table evaluating the PCR + CRISPR (FELUDA) test on various measures.

| Sr. 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 an ordinary 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.<br>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.<br>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.<br>The manufacturer claims to have brought an automated, high throughput version that does not require skilled manpower. |
| 3 | High TAT | With a usual 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 in the base version, lab technicians might be willing to run each batch at a lower utilization, thus reducing the waiting time. |
| 5 | High cost of test | Approximately INR 808 – 1150 for public labs. |
| 6 | Price of test | Media sources report the price to be ~INR 500 |

Table 3: Evaluation of PCR + CRISPR (FELUDA)

## 3.4 Levers of cost reduction

Collection and testing consumables constitute around 88% of the total cost of the RT-PCR test. This implies the largest cost reduction can come from reducing the cost or usage of these consumables.

### 3.4.1 Reduction in kit cost due to increased and stable supply

Using our model and taking inputs from experts, we estimate that from May to Oct 2020 the cost of testing has reduced from approx. INR 1707 – 2185 to approx. INR 307 – 979 in the public sector, and from INR 3303 to INR 885 for the private sector. Much of the reduction in cost is due to a decrease in the cost of consumables. We estimate that from May to Oct 2020, the cost of consumables has decreased from approx. INR 1570 - 2040 to approx. INR 230 – 900 in the public sector. Cost reduction in the private sector is similar to the public sector. This reduction in the cost of consumables is due to increased competition, economies of scale, and an increase in procurement from indigenous manufacturers. These Indian kit manufacturers have driven down the price of kits by 90% in certain states. However, care must be taken to ensure that these kits are of high quality. Our analysis indicates that there is scope to further reduce the cost of consumables and thereby reduce the cost of testing.

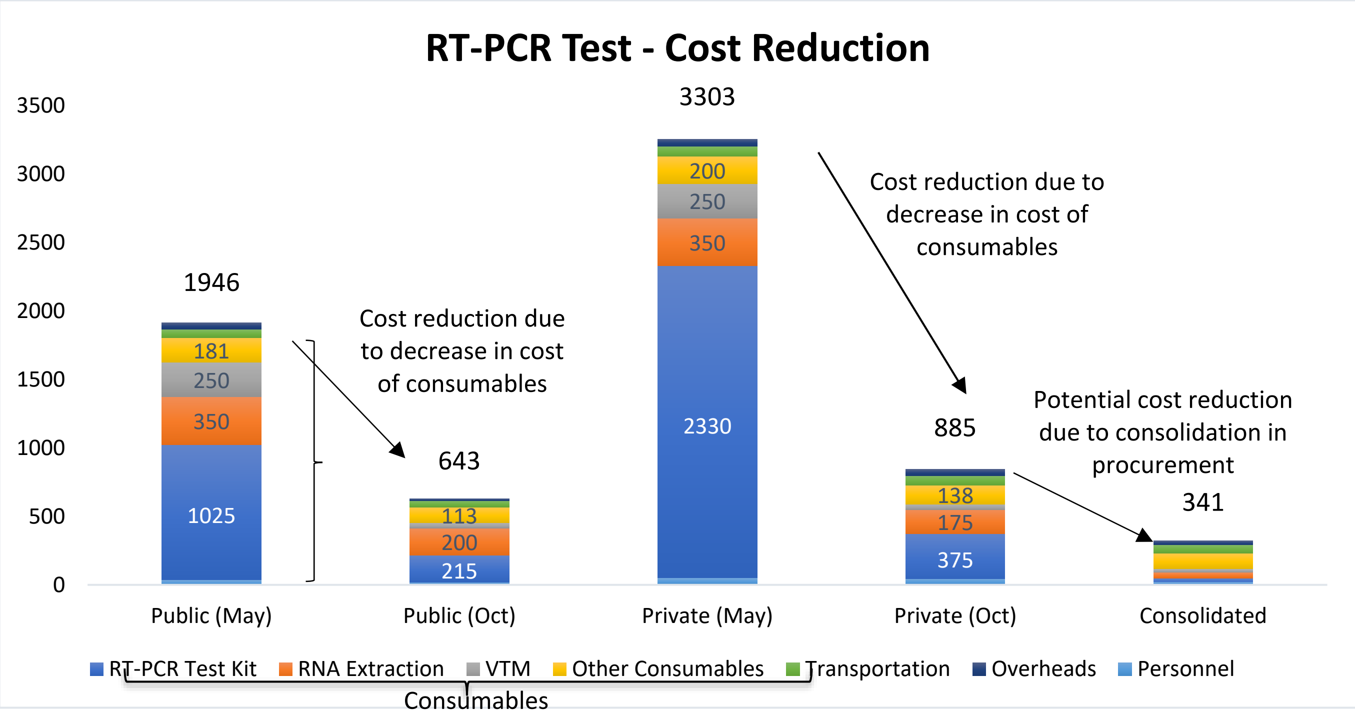



Fig 4: Average Cost of RT-PCR test (in INR) in different procurement scenarios

### 3.4.2 Reduction in kit cost through consolidated and pooled procurement mechanism

Other disease management programs have successfully leveraged pooled procurement to reduce the testing costs, improve the quality of testing, and increase the availability for the patients. Figure 5 below shows a simple representation of individual vs. pooled procurement mechanism. Under the individual procurement, each buyer has to individually negotiate with each seller. A single seller may sell the same product to different buyers at different prices. Under pooled procurement, a central agency negotiates with different sellers and provides the product to all the buyers at a uniform and much lower cost.

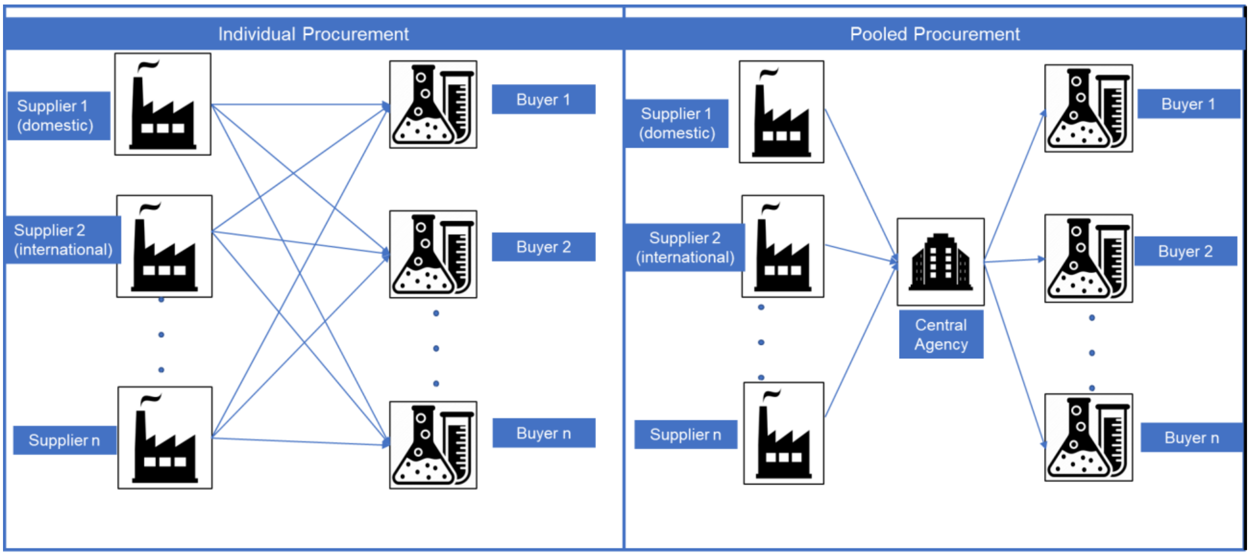



Fig 5: Individual vs. Pooled procurement mechanism

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 and lowered the cost of testing for the patients. Further, the IPAQT alliance took steps for demand generation which led to an increase in testing.[24] The pooled procurement mechanism is seen at a much larger scale in procurement by the Global Fund to fight malaria, AIDS and TB. Their central procurement measures have reduced the cost of an insecticide-treated malaria net and antimalarial treatment to less than $2 and $0.58, respectively, for partner countries. In India, the National AIDS Control Organization (NACO) has adopted a similar strategy for HIV test kits. The organization procures the kits centrally and distributes them to both the public sector and empaneled private sector labs.[25] Further, NACO and ICMR have created a consortium of labs for verifying HIV testing kit quality. It has enabled NACO to address the quality of tests and ensured faster onboarding of validated kits.[26]

Not-for-profit organizations such as Clinton Health Access Initiative (CHAI) and PATH have worked with the state governments to provide TB testing services free of cost to patients across public and private sectors. The government has onboarded labs based on pre-decided rate cards and reimburses the private laboratories based on the number of tests conducted. While tackling other diseases, these experiences are encouraging signs that similar measures could work for COVID-19 testing in India.

We observe that even in the public sector, a test kit's cost varies from state to state. Maharashtra, reportedly, procures the RT-PCR kits for less than INR 100 whereas Odisha procures them at INR 380.[27] Using our cost model, we estimated that procuring testing consumables through a consolidated and pooled procurement mechanism would reduce the unit cost of testing to as low as INR 341. Suppose the benefits of consolidated procurement were extended to the private sector labs as well. In that case, India could significantly reduce RT-PCR testing costs and make the testing affordable for a large section of the country. It is important to note that despite the cost reduction, the prices in the private sector will be higher than the public sector as the former needs to keep a profit margin for the viability of the business.

### 3.4.3 Cost reduction through pooled testing

Pooling samples involves mixing several samples in a batch (called a pool) and then testing the batch with a diagnostic test. In case a pool is tested positive, all samples in the pool are individually tested again. This approach increases the number of samples that can be tested using the same number of resources. However, caution needs to be exercised as the mixing of samples leads to dilution, causing a greater chance of false-negative results. ICMR guidelines allow pooled testing to be done for a maximum of five samples, and in areas with a positivity rate of less than 2%.

We estimate that pooled testing would reduce the cost of test by 40% - 54%, for a per-unit cost of test for public labs to be approx. INR 296. This cost can be further reduced to approx. INR 205 if we combine pooled testing with consolidated procurement. This reduction in cost is shown below through a simple illustrative example:

*Let 800 samples be processed in a day. This indicates that 160 pools of 5 samples each can be created. Assuming seropositivity of 2%, an average of 16 pools (80 individual samples) would be positive, leading to the testing of approx. 80 more samples. The total number of samples that have to be tested under pooled testing will be 240 (vs 800 under individual testing).*

Assuming 800 samples are to be tested, the table below presents the average cost savings in percentage for different combinations of positivity rate and numbers of samples in a pool.

| | Positivity Rate | | | |
|---|---|---|---|---|
| **Samples in a Pool** | **2%** | **3%** | **4%** | **5%** |
| 3 | 47% | 44% | 42% | 40% |
| 4 | 52% | 49% | 45% | 42% |
| 5 | 54% | 50% | 46% | 42% |

Table 4: Cost-saving in pooled testing for different positivity rate and the number of samples in a pool

From the above table, we infer that the cost per test increases when the positivity rate increases, and the pool's size decreases.

### 3.4.4 Antigen + RT-PCR Testing

Antigen + RT-PCR testing is a novel testing method that requires first an Antigen test on every individual. For the individuals who are found to be negative but show COVID-19 symptoms, a second confirmatory test is done using RT-PCR. This implies that the

*Cost of Antigen + RT-PCR Testing*
*= Cost of Antigen + (Proportion Antigen negative but have symptoms) * Cost of RT-PCR.*

From our discussions with experts, we learnt the costs of VTM and Antigen kit to be approx. INR 38 and INR 400 respectively. Given this, we estimate the cost of an Antigen test to be on average approx. INR 580. For Antigen + RT-PCR to be an economically viable option, the proportion of people testing negative but have symptoms should be less than 10%. Anything above that would make Antigen + RT-PCR more expensive than RT-PCR. One benefit of this method is that the antigen test is a point of care test and has a lower turn-around-time. Antigen + RT-PCR can be used in remote areas and in containment zones, where it can be used to control the spread of the disease.

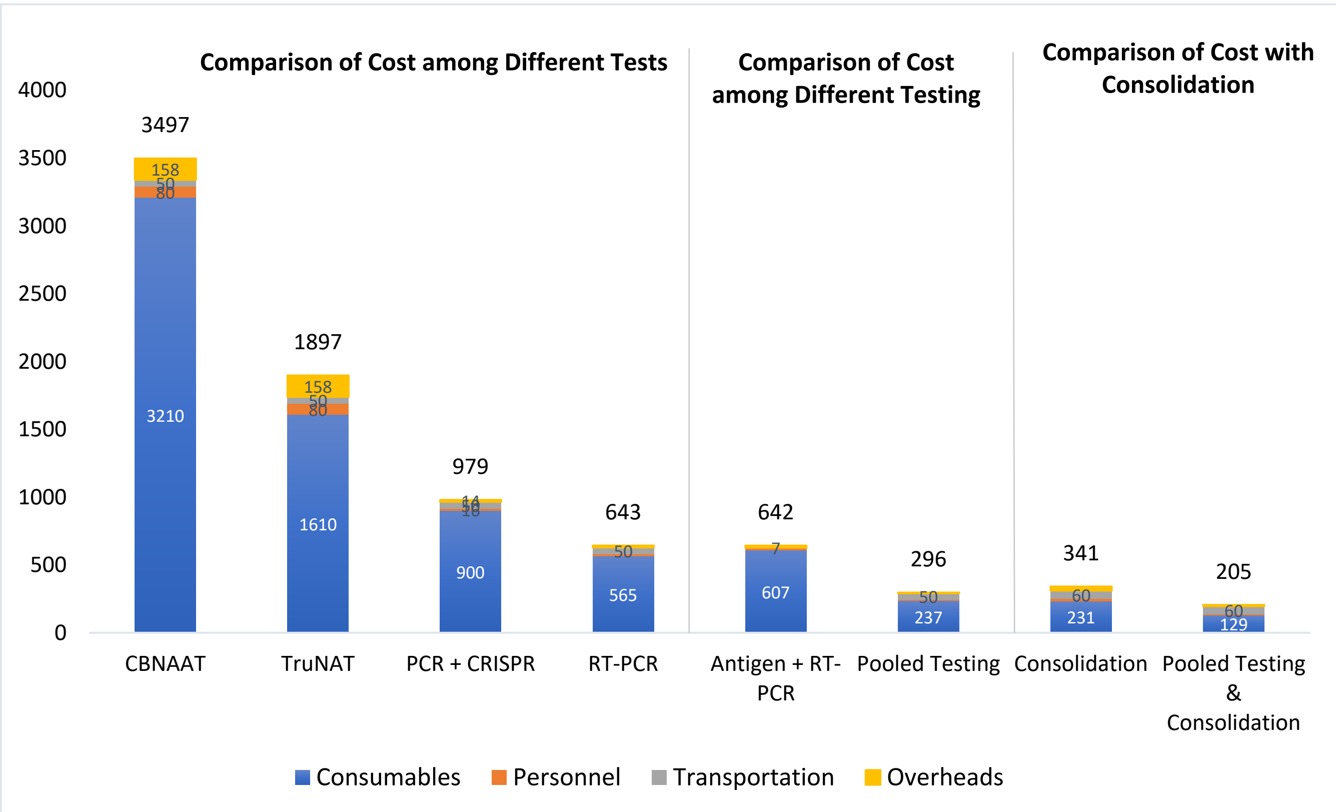


Fig 6: Comparison of cost among the different tests in the public sector

### 3.4.5 Serial Antigen Testing

We estimate the cost of an antigen test to be approx. INR 580. Conducting serial antigen tests, even at a minimum iteration count of two is not economically beneficial when compared with the unit cost of RT-PCR and other comparable substitutes. However, the government could explore serial antigen testing as a viable option in geographies with limited RT-PCR capacities, given the accuracy of a positive result in antigen testing.

### 3.4.6 Other ways to reduce cost

In the initial phase of the pandemic, consumables constitute the major proportion of the cost. Hence the major reduction in the cost of a test has to come from a reduction in the costs of the consumables. However, once these are accomplished and consumables cost is minimized, further cost reduction can come from process improvements, lab and network optimization, load balancing, etc. Also, in our model, we assumed the samples are collected at the lab. However, if the samples were collected at home and needed to be individually transported, the cost can be further reduced by optimizing sample collection and transport protocol.

# 4. Recommendations

*The cost of COVID-19 testing is determined by the dynamics at each step in the testing value chain, namely sample collection, sample transportation, sample testing, and result delivery. There is a need for a comprehensive understanding of the dynamics at each step for formulating a cost-effective testing strategy. For instance, the scope to leverage economies of scale varies across each segment in the value chain. While government policies on price capping play an important role, price reduction should flow from ironing out inefficiencies in the value chain. In our analysis above, we have analyzed the cost-effectiveness of COVID-19 testing in major cities and large laboratories that do not typically face the dearth of resources as faced by labs in small cities and rural areas. We identify several recommendations below in the context of the COVID-19 pandemic which can guide the private sector and the central and state-level governments to deter pricing surges flowing from future similar crises and build a sustainable, cost-effective testing protocol for both urban and rural areas.*

## 4.1 Aggregated procurement of testing consumables

Assuming the availability of adequate RT-PCR equipment capacity, there is room for improving the cost-effectiveness of testing by reducing costs of test kits (without adequate RT-PCR capacity, optimization of test kit costing will not lead to any significant impact on the overall test costing). A component of this test kit cost is procurement expenditure. As our analysis has indicated, we can achieve almost a threefold reduction in the cost of testing if the states procure kits and consumables through a consortium rather than independently. A government agency can facilitate the consortium. Establishing collaboration within such a consortium requires coordination among the various segments of the supply chain of consumables to achieve better demand forecasting for drafting volume contracts. While such coordination can easily be established at an intra-state level, the challenge is to facilitate information exchange and cooperation across states. It would also be useful to leverage the expertise within agencies such as NACO and CTD to leverage the best practices from procurement mechanisms for the HIV and TB program, respectively. Further, we should try to set up mechanisms to extend the benefits of such a pooled procurement to the private sector. This would enable (i) lower testing cost, and (ii) participation of more labs in COVID-19 testing - both of these will make tests more affordable and available to the general public.

## 4.2 Better utilization of RT-PCR test kits

Optimal use of different testing strategies will reduce the consumption of RT-PCR kits. Strategies such as pooled testing can result in a multifold decrease in test kits consumption. ICMR guidelines allow pooled testing to be done for a maximum of five samples, and in areas with a positivity rate of less than 2%.[28] For the pooled testing strategy to be commonly utilized in private and government labs, lab personnel training would have to be ramped up to ensure implementation at scale. Another strategy, especially in containment zones, could be the usage of rapid antigen tests at scale. While those who test negative for COVID-19 by an antigen test should be tested sequentially by RT-PCR for confirmation, a positive label can be considered a true positive and does not need reconfirmation by RT-PCR test, thereby reducing the burden on the RT-PCR infrastructure.[29] It is also important to note there is a multifold drop in testing turnaround time.

## 4.3 Efficient sample collection and transportation protocol

The important step in the COVID-19 value chain is the collection (and the transportation, if any) of COVID-19 samples from the patients. This can be achieved in multiple ways, but the goal should be to minimize ambulances' requirement since the availability of ambulances can quickly become an expensive bottleneck for testing volume during great demand.[30] This is especially the case for rural low-demand areas due to their small size and geographically fragmented characteristic.[31] Both adhoc-patient-visit-to-lab model and adhoc-home-testing model (Models on the left and the center in Figure 6) require a significant number of ambulances. In one of our studies, we propose an aggregation model of sample collection (model on the right in Figure 6) wherein multiple samples are collected in a single milk run and brought to the testing lab, thereby reducing the need for ambulances and skilled workforce by 4x.[32] The cost savings could be transferred to the patients through reductions in the testing price.

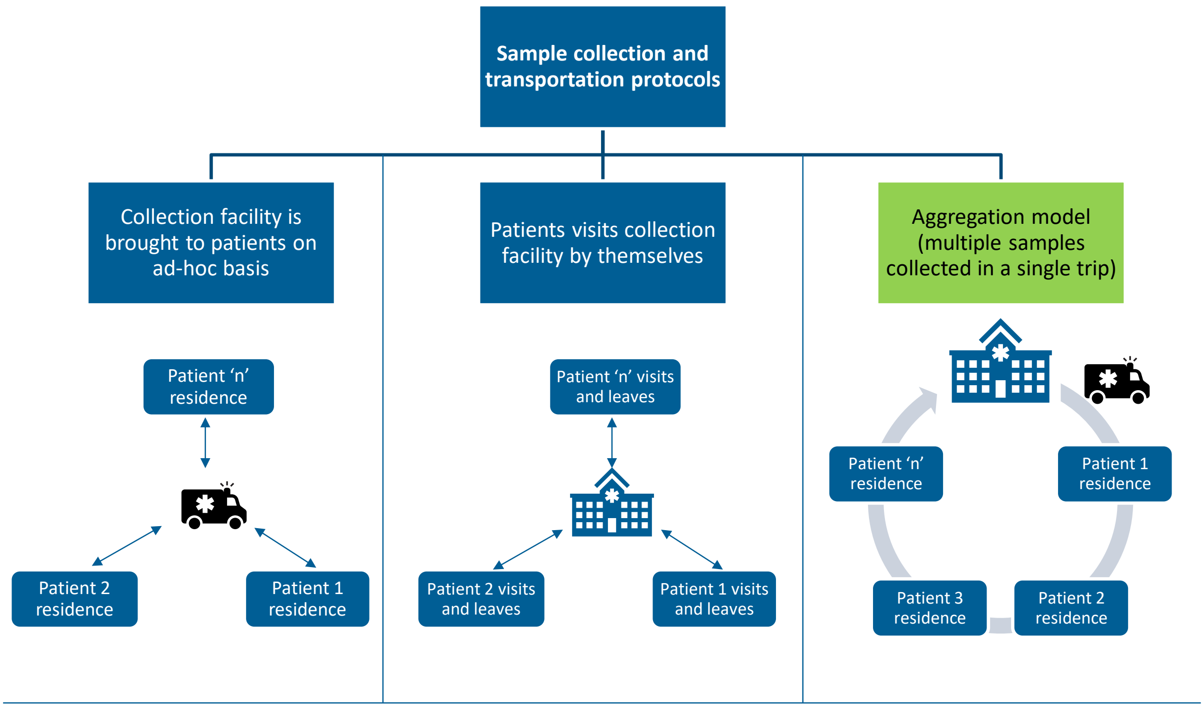



Fig 7: A visual representation of sample collection protocols

## 4.4 Lab network optimization to improve equipment utilization

There is a need for information exchange and planned coordination across labs, districts, and states to facilitate sample transfers within testing infrastructure networks, which will help drive down the cost of setting up new equipment and facilities. Setting up new infrastructure is expensive, and needs lots of planning, training, and approvals. The pressure to ramp up equipment capacity to meet the growing demand for testing to reach self-sufficiency could prove to be an expensive endeavor, whose pinch would eventually be borne by the patients. To cite a national-level example, we show in a study that states such as Uttar Pradesh, Bihar, Rajasthan, and Madhya Pradesh, which have weaker health systems compared to their adjoining states, may find it challenging to ramp up their testing capacity.[33] In such scenarios, sample transfers can be a beneficial strategy. Another strategy to reduce the burden on RT-PCR machines is to leverage other segments of the health system, but it might come with an increase in testing costs. For instance, tests for HIV and TB are conducted on CBNAAT and TrueNat, which have the same underlying technology as required for COVID-19 testing.[34] Channeling such testing capacities toward COVID-19 testing can help in areas with low availability of COVID-specific testing systems, albeit at a higher cost. Choosing such options requires careful evaluation of the necessity to shift to other machines and planned coordination across different healthcare verticals such that testing rates for other diseases (for which the machines were originally placed) are not impacted massively.

## 4.5 Coordination and partnerships between the private and public sector

The private sector is the predominant provider of healthcare in India, even for the poor strata of the Indian population.[35] Therefore, given the scale of the epidemic, the private healthcare sector's engagement in testing is of paramount importance, and the government's stepping in as a payer in this setting is highly crucial. For instance, The National Health Authority's (NHA) decision to formulate financial packages, such as covering the COVID-19 treatment cost for the poor population in private hospitals under Ayushman Bharat, serves both as a major relief and as a mechanism to improve testing volumes.[36] In addition, the government can explore opportunities to engage with the private sector in improving the supply dynamics for COVID-19 testing. First, collaborations such as the recent tie-up between CSIR Centre for Cellular & Molecular Biology (CCMB) and Apollo Hospitals for the development of rapid, safe and cost-effective DArRT-PCR tests and nationwide distribution through the extensive Apollo supply chain[37] must be explored. Bodies, such as the National Industrial Development Corporation of India (NIDC) and the Directorate General of Health Services (DGHS) can also work closely with government and private sectors to facilitate the development of efficient testing frameworks and to develop sufficient supply and efficient procurement systems. Second, there is a need for a careful analysis of the various cost items involved in testing through a detailed coordinated engagement between the private and public sector for ICMR to formulate testing price cap policies. A jointly decided price cap will not only prevent exorbitant test rates from being charged to the end customers but will also ensure incentive-compatibility for the private testing facilities for their active participation. The private hospitals in Karnataka complained of the state government's non-consideration of the costs associated with human resources in the transportation of samples in their pricing cap for COVID-19 tests;[38] such a mismatch could have been avoided through joint decision-making. Third, several private sector companies operate centralized models wherein samples are collected from collection centers from all parts of the country and are transported to a central testing facility via air-cargo logistics within 24 hours.[39] Outsourcing of inter-lab transportation (and testing, if needed) to such third-party private sector players can be explored for reducing costs otherwise associated with setting up new equipment and facilities. Fourth, rapid onboarding a large number of private players for test kit manufacturing and transportation would improve not only the supply dynamics but also create a competitive ecosystem, which would limit any coordination among suppliers to disproportionally pass through price increases to the patients.[40]

## 4.6 Inter- and intra-governmental coordination to accelerate cost reduction

High-throughput, accurate, cost-effective and rapid testing is the need of the hour to curtail the spread of the pandemic.[41] The various government agencies at the central and the state levels need to bring in their specific functional expertise and come together so that the levers of cost reduction can be pulled faster and efficiently. To obtain scale, there is a need for coordination among (a) the various departments and states/districts, and (b) across various government levels.

**Coordination across functional areas and states:** The governance and the service delivery systems must align seamlessly, with coordination across the various functional areas, such as surveillance, research and development, demand forecasting, procurement, and field operations. For each such function, there is a need to set up a dedicated body, whose expertise can be used in future pandemics or similar national-level emergencies. Assigning each task to a dedicated body (or department), as was done during COVID-19 in India, is necessary but not sufficient; an efficient pandemic control protocol also requires gathering information, coordinated monitoring and evaluation, and operational coordination among these different units. Besides, inter-state coordination to leverage manufacturing specialties of different states could assist in drastically bringing down the test kit manufacturing costs.

**Coordination across various government levels:** There is also a need for coordination across the different levels of the government. For instance, while the ICMR needs to prioritize its focus on central level policy-setting and guidelines-construction for COVID-19 testing, it can only do so if the state and the district governments take up the responsibility of ground-level management. The latter has the added advantage of drawing from their knowledge of their demographics how to make the last mile leg of the test kit supply chain efficient and cost-effective.[42]

Achieving a thoroughly cost-sustainable implementation-friendly pandemic management protocol is not an easy task but can be accomplished through establishing a coordination agency at helm consisting of members with expertise in pandemic and disaster management.

## 4.7 Healthcare innovations

Increase in testing capability and reduction in cost can be achieved through innovations in healthcare. It is important to note that healthcare innovations and new technologies can potentially disrupt the costing framework for COVID-19 testing in India. However, the analysis for the same is not covered in the scope of this article.

### 4.7.1 Indigenous manufacturing of kit components

Currently, hundreds of RT-PCR kits are being manufactured in India, which has contributed to a reduction in the unit cost of the kit. However, most of the components in the kit are imported. The Rockefeller Foundation has recently given a grant to C-CAMP to develop an MSME ecosystem to make probes and enzymes that go into RT-PCR kit.[43] It is important to note that the kit cost is already low; other countries already may have a comparative advantage and are leveraging economies to scale. Therefore, indigenously producing the kit components may not lead to a large reduction in cost. However, there are several advantages from indigenous production, such as the creation of a stable supply system. Going forward, the country must charter out a smart testing roadmap for urgent times similar to COVID-19; an indigenous production setup for testing kit components will not only make the supply chain more stable but also more sustainable and resilient to ensure consistent non-deficit of kits in the future. Such already-established systems would aid in similar situations in the future by acting as available capabilities.

### 4.7.2 Novel screening and testing methods

Investment from the government and the private sector in modern healthcare technologies that use state-of-the-art systems such as artificial intelligence and machine learning could help lower the burden on RT-PCR kits and equipment for the initial round of screening. For instance, Mumbai-based Qure.ai uses an artificial intelligence-powered solution to identify 24 different abnormalities in a chest X-ray, including the ones indicative of a COVID-19 infection.[44]

### 4.7.3 New tests

FELUDA is being mentioned in the media as a prospectively fast and cost-effective testing option. Other benefits associated with FELUDA being reported include: (a) it doesn't require a qPCR machine and can be carried out on ordinary PCR machines, which are already available in most areas of the country thus augmenting the testing capacity, (b) for remote areas, where currently the samples are sent to far off labs, FELUDA can reduce the turnaround time and the transportation cost, and (c) in places with insufficient demand, FELUDA may pose a lower unit cost than RT-PCR test.

As another example, a "probe-free" method of testing developed by Indian Institute of Technology, Delhi, identifies short stretches of RNA sequences, an exclusive characteristic of the COVID-19 virus.[45]

The benefits from tests go well beyond cost-effectiveness into an array of boons, such as indigenous production boost and supply chain efficiencies. However, several variables need to be assessed before a new testing system is rolled out at mass. First, there is a need to carefully evaluate available machines in various tiers (tier 1/2/3) of Indian cities. Second, there is a need to assess the availability of trained manpower to conduct novel tests across cities and rural areas. Operational mishappenings associated with testing, often due to lack of appropriately trained staff, more often than not result in media focus and doubts in the minds of the public on the testing mechanism itself. Third, any new test being considered for mass rollout must be incentive compatible for the sector it is being planned to be rolled out in (public or private). For instance, the private sector has shown reluctance to adopt FELUDA, as they have already found other, more profitable testing options.

*The lessons learnt from the COVID-19 pandemic can help construct pricing models to better detect, prevent, and combat future pandemics by aligning the demand dynamics, i.e., the paying capacity and the interests of the public at large with the supply-cost dynamics. Establishing such price-equitable and cost-sustainable models will be crucial in improving ease of access and affordability for the masses and, therefore, in managing future crises and reducing the national-level threat of emerging viruses.*

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