

FELUDA Diagnostic Test for COVID-19

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Abstract: *Testing capacity has been the achilles heel for most of the low- and low-middle income countries responding to the current COVID-19 pandemic. This has led to a number of innovations in health technology globally and India has been no exception. In this study, a Health Technology Assessment (HTA) was done on the recently indigenously developed innovative FELUDA test for SARS-CoV-2 diagnosis in India. The HTA shows that at the current price of INR 500 (USD 6.8), FELUDA is a cost effective test as compared to RT-PCR and Rapid Antigen Test (RAT). Since, field sensitivity and specificity is unknown for this test, it is recommended that the test be first piloted and monitored for field sensitivity and specificity before roll out. This is the first HTA on a COVID-19 related health technology from India and future HTA's at different points in the life cycle of FELUDA is recommended to guide policy.*

Keywords: Innovation, policy, testing strategy, entrepreneurship, India, sensitivity, specificity, cost effectiveness, SARS-CoV-2.

1. Introduction

From the very early days of the Novel Corona Virus disease (COVID-19) pandemic, the World Health Organization (WHO) has been emphasizing the importance of testing as one of the key strategies in addressing the spread of the virus.¹ Test-isolate-track/treat has been the golden rule but its implementation has been constrained by availability of resources (financial, skilled human resources, infrastructure) and dependency on imports, especially in the low-and low-middle income countries. India has been no exception and while ranked second globally in terms of number of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) cases, it is ranked 105th in the world (as on October 12, 2020) in global comparison of its population testing rate.²

It is in times like these that innovation and entrepreneurship can play a key role and COVID-19 has opened a window of opportunity for innovations across multiple sectors. One of the biggest drivers of this innovation is health technology³ which by definition includes interventions (like a test) developed to diagnose a medical condition. Health technology Assessment (HTA) is a multidisciplinary process that uses explicit methods to determine the value of a health technology to inform decision-making for promoting an equitable, efficient, and high-quality health system.⁴ While the use of HTA to inform policy decisions is well established in the high income and upper middle income countries, its use and application in health systems has been limited in low- and low-middle income countries.^{5,6} With a plethora of technologies being developed to address the COVID-19 situation, the role of HTA in addressing medical, ethical, economic and social implications of a policy decision becomes even more important. In this context, this study is the first HTA of a recent indigenously developed health technology called the FNCAS9 Editor-Limited Uniform Detection Assay (FELUDA) diagnostic test to provide recommendations for India's COVID-19 testing policy.

2. Methodology

This is a study based on secondary data available open access in the public domain. Testing guidelines, costs and effectiveness (sensitivity and specificity) data reported

regarding current COVID-19 diagnostic tests have been used for comparative analysis. The market price of the test has been used to calculate the direct testing costs from the societal perspective. Media reports and official government web sites have been used to identify the price and sensitivity and specificity parameters of the tests in the Indian context. Data on new tests per day smoothed, based on official Indian data, available from our world in data database (www.ourworldindata.org) has been used for the analysis. A Health Technology Assessment (HTA) was done to assess the implications of FELUDA test on India's testing strategy.

3. Results

India's current testing strategy permits the use of two types of tests for diagnosing SARS-CoV-2.

The two diagnostic tests are Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) and Rapid antigen test (RAT). The RT-PCR is currently considered as the gold standard with high sensitivity and specificity but the sensitivity of RAT is only moderate resulting in higher chances of false negatives. Hence, the testing strategy advisory issued on June 23⁷ and subsequent advisories^{8,9} insist on a RT-PCR follow up test for those symptomatic testing negative by RAT to rule out false negatives. Studies and reports have shown that the implementation of this follow up testing has been weak by the states/union territories (UT), since RT-PCR is a cost and skill intensive exercise.¹⁰

The market price of RT-PCR had initially been capped to INR 4500 (USD 61) across India and subsequently the cap was removed and states were asked to negotiate and decide on the price of this test. With the better availability of reagents for RT-PCR and personal protective equipment (PPE), the price of RT-PCR has been reducing. The current market price (October 12, 2020) of RT-PCR test for COVID-19 varies across states and is in the range of INR 1200 to 2750 (USD 16 – 37.5). The current market price of RAT is in the range of INR 450-700 (USD 6 - 9.5). The Drug Controller General of India (DCGI) recently (September 2020) approved a novel indigenously developed paper based diagnostic test named 'FELUDA'.¹¹ This test is based on Clustered Regularly Interspaced Short Palindromic

Repeats (CRISPR) technology and was successfully innovated to be used as a diagnostic tool for SARS-CoV-2.¹² While the method of swab collection in this test remains the same as that of RT-PCR and RAT, the results of this test can be read with the naked eye like a pregnancy test within 45 minutes. This innovative diagnostic test has been

reported to be 96% sensitive and 98% specific.¹¹ It has a much quicker turnaround time than RT-PCR and requires less expensive equipment. The FELUDA test is being considered to be marketed at a price of INR 500 (US\$ 6.8). Table 1 shows key differences between these three tests.

Table 1: Key differences between COVID-19 diagnostic tests currently used in India

Test	Cost (INR)	Time taken to give results	Sensitivity and Specificity (Lab data)	Additional findings
RT-PCR	1200-2750 Average cost: 1975	90 minutes	Sensitivity- 95% Specificity-99%	Requires expensive equipment and reagents, skilled personnel and specialized laboratories. Imports involved.
RAT	450-700 Average cost: 575	30 minutes	Sensitivity- 50-84% Specificity- 99-100%	Requires less specialized chemicals, equipment and skills. Imports involved. Field sensitivity reported to be 50-60%. Adjunct RT-PCR required to rule out false negatives
FELUDA	500	45 minutes	Sensitivity- 96% Specificity- 98%	Quicker turnaround time, less expensive equipment and reagents involved. Does not require specialized lab or skilled personnel Not dependent on imports. Can also detect other viruses (e.g. SARS-1) and can be developed to detect more.

4. Discussion

The implications of this HTA on testing policy is discussed through the following three comparative scenarios.

Scenario I: Earlier testing strategy through RT-PCR

Scenario II: Current testing strategy (RAT + RT-PCR)

Scenario III: FELUDA as a testing strategy

The RAT test used in India has an analytical (lab) specificity of 99%-100% and sensitivity in the range of 50%-84%¹³, implying that the false negative rates are in the range of

16%-50%. Considering that this proportion of people would require adjunct RT-PCR as per current testing strategy, the mean value of this range (33%) was selected for the proportional calculation of costs for RT-PCR in scenario II. Using the data on simple exponential smoothing (SES) forecast on new tests conducted per day on October 12,¹⁴ the existing average market prices of these tests and sensitivity and specificity values (table 1); the cost implications and associated issues of these three scenarios are presented in table 2.

Table 2: Implications for testing policy

Testing scenarios	New Tests/day (Smoothed) (As on Oct 12, 2020)	Average Cost (INR)	Cost of testing/ day	Issues	Comparative Analysis
I (RT-PCR) Previous testing policy	1127100	1975	2226022500 (INR 2.2 Billion) (USD 30 million)	Need for specialized labs and skilled human resources	High on cost and high on effectiveness
II (RAT+ RTPCR) Current testing policy	1127100	575 (RAT) and 1975 (RT-PCR)	1382669925 (INR 1.3 Billion) (USD 17.7 million)	Poor compliance leading to increased societal costs due to false negatives. Field sensitivity reported to be lower.	High on costs and low on effectiveness
III (FELUDA)	1127100	500	563550000 (INR 0.5 billion) (USD 6.8 million)	Field sensitivity and specificity not known.	Low on cost and high on effectiveness

5. Conclusions

The HTA shows that the FELUDA test at the price of INR 500 per test, is the most cost-effective testing strategy currently among these three diagnostic tests and has the potential to improve India's testing capacity. At the current rate of testing and market price, it would bring down the testing cost in the country by almost a third and save around INR 800 million (approximately USD 11 million) per day. In addition, the added benefits of shorter turnaround time, ease of doing the test and interpretation would increase accessibility of testing and enhance the testing rates in India. FELUDA test also address the social and ethical dimensions associated with the improper implementation of the current testing strategy. However, it is important to monitor the field sensitivity and specificity of this test.

Based on this HTA, it is recommended that the FELUDA test be first piloted in those districts/states having the lowest compliance to RT-PCR and monitored to analyse the field effectiveness data. If field sensitivity and specificity are similar to the RT-PCR, it can be rolled out across the country at the current price. If the field sensitivity is moderate (like the current RAT), then adjunct RT-PCR will need to be done. Future HTA's at different points in the life cycle of FELUDA is recommended. With the DCGI already approving FELUDA for commercial launch, it is important that the testing strategy aligns itself to this reality at the earliest to facilitate a smooth convergence of science, technology, innovation and policy.

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