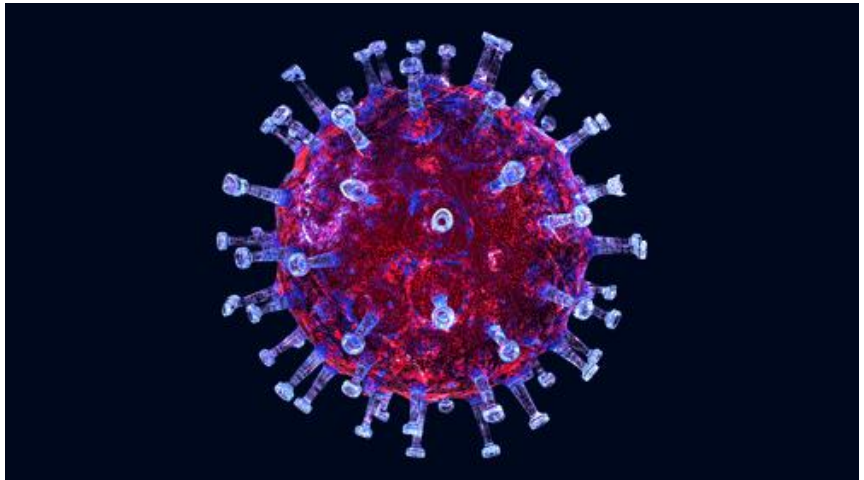
Testing Strategies and Lessons learned

Dr Sarada Devi K.L



Objectives

- The backdrop of testing strategies
- Covid 19 testing strategies in India from 2020 till March 2022
- Covid 19 testing strategies of Kerala from 2020 to 2022
- An insight into the test biology
- Test positivity rates – Kerala
- Serosurveys
- Lessons learned from the pandemic

Testing strategies- A backdrop

- Key public health policy:
- Diagnostic testing: plays a critical role in addressing pandemics
- How rapid and accurate diagnostic tests help?
  - Identifying and managing infected individuals
  - Contact tracing
  - Epidemiologic characterization
  - Public health decision making
  - Conducting a rapid situation analysis
  - Surveillance.

Testing strategies- A backdrop

Comparison of testing strategies across the world

1. No testing policy

2. Testing only for those who both (a) have symptoms AND (b) meet specific criteria (e.g. key workers, admitted to hospital, came into contact with a known case, returned from overseas)

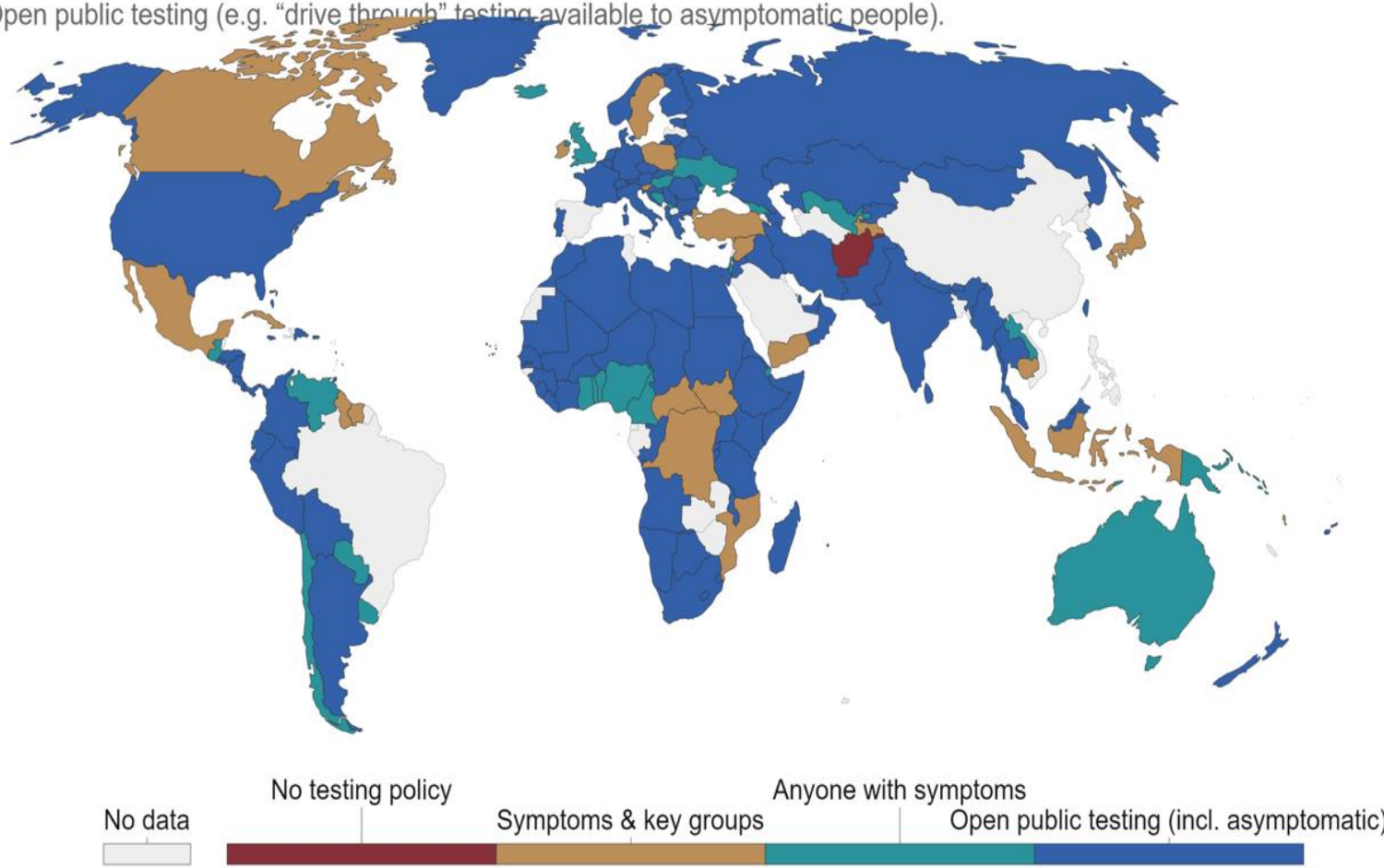
3. Testing of anyone showing COVID-19 symptoms

4. Open public testing (eg “drive through” testing available to asymptomatic)

COVID-19 Testing Policies, May 2, 2022

Our World in Data

– No testing policy.
– Only those who both (a) have symptoms and also (b) meet specific criteria (e.g. key workers, admitted to hospital, came into contact with a known case, returned from overseas).
– Testing of anyone showing COVID-19 symptoms.
– Open public testing (e.g. "drive through" testing available to asymptomatic people).



Source: Oxford COVID-19 Government Response Tracker, Blavatnik School of Government, University of Oxford – Last updated 3 May 2022
OurWorldInData.org/coronavirus • CC BY

Covid 19 testing strategies in India from 2020 till March 2022

- 2009 H1N1 pandemic
- set up a network of COVID-19 testing labs
- accredited laboratories for testing
- formulated the testing strategies from time to time incorporating the newer and available tests
- issued guidelines for the use of these tests
- the sole authority in India for approving testing kits.

Covid 19 testing strategies in India from 2020 till March 2022

Establishment of mentor institutes for upscaling the testing capacity

- These centres mentored the Govt and private MCs to set up a molecular virology network across the country.
- The network of laboratories have grown since February 2020 and this network maintains the data of individuals tested for Covid 19 in ICMR approved laboratories across the country

Covid 19 testing strategies in India from 2020 till March 2022

By June 2020, along with real time RTPCR, PoC molecular tests CBNAAT , TrueNat and RAT were given authorization as diagnostic strategies in the country.

According to NMC (2020) regulations for recognition of MBBS course in Medical Colleges - Molecular diagnostic service lab attached to Microbiology dept as an additional specific requirement. It shows the extent to which the Central Govt also supported the drive for testing.

By September2020, ‘on demand testing’ was authorized in the country and RAT positivity alone was enough to declare a person as COVID-19 positive.

Covid 19 testing strategies of Kerala from 2020 to 2022

- Kerala has been alive to the threat of Covid 19 due to its huge expatriate population and started preparation to identify and isolate cases by the middle of January 2020 itself.
- Kerala has successfully integrated the local governments to the public health system. Evidence based guidelines and evolving protocols made the process more scientific.
- Two Nipah outbreaks gave Kerala health system valuable training and confidence to handle COVID-19.

Covid 19 testing strategies of Kerala from 2020 to 2022

- When the epidemic was reported in China & SEA in the middle of Jan
- GOK took numerous steps to strengthen the guidelines, emergency preparedness, diagnostics & categorization of risks involved in reducing the transmission of the virus
- First positive case in India – reported from Kerala- **Jan 30, 2020**

Tested at NIV Pune

- 2 more cases reported –NIV Pune
- Foll the detection of cases, GOK declared a health emergency warning
- Feb- No cases Health emergency withdrawn on Feb 12

Covid 19 testing strategies of Kerala from 2020 to 2022

- 8th March – 5 cases tested positive
- 9th March -1 more case tested positive
- **10th March- 5** labs of Kerala started RT-PCR testing (3 Govt Medical Colleges, NIV unit & SPHL)
- Permission was granted by third week of March 2020 for independent release of SARS-CoV2 results by respective labs
- RT- PCR machines identified all over the State & redistributed to all the GMCs, Research Institutes and Veterinary Colleges
- HR- provided by **National Health Mission-**to all .Research Scientist, Lab techs, Lab assistants, DEOs, cleaning staff. Thus, human resources were well managed in all govt testing labs.
- Simultaneously training also imparted

- **KMSCL** provided best healthcare infrastructure services- kits, equipment's & all other consumables to all the Govt institutions
- KMSCL provided Automated Nucleic acid extractors and the results were released faster, two hours earlier after five months of initiating RTPCR

❖Each district of Kerala was allotted labs where the samples have to be sent, for eg from Trivandrum district samples to be send to GMCT, SCTIMST and IISER.

❖To begin with Kerala started testing about 200 samples per day and reached about 2 lakhs.

❖All GMC labs are conducting in addition to RTPCR, PoC molecular tests like CBNAAT, TrueNat, RATs, and antibody tests for retrospective diagnosis of MIS-C, MIS-A and other post sequelae of Covid-19

Covid 19 testing strategies of Kerala from 2020 to 2022

- According to revised NMC regulations 2020 for recognition of MBBS course in any MC there should be a BS-L2 Molecular lab attached to MICRO Dept
- All the **private MCs as well as private labs** across the State-set up labs
- ICMR insisted NABL accreditation also for them- to ensure quality of results
- Training was given to the newly established labs both private and government by VRDLs &adjacent Govt MCs.
- Thus, to start with 5 labs the state ended up with 173 labs (govt-50) (private -123) fully functional to do RTPCR testing
- Mobile testing booths

Diagnostic approaches to COVID-19

- Rapid & early lab diagnosis-is critical to diagnose infection & control transmission
- Clinical diagnostics include symptoms, biomarkers related to inflammation, and imaging tests which helps formulating patient management decisions.
- In vitro diagnostics - NAATs – gold std test- RT-PCR
- TrueNaT and CBNAAT have widespread availability even at district and primary health center level as these platforms are widely used for diagnosis of TB and other IDs.
- Serology - antibody and antigen based assays, which are specific to SARS-CoV-2
- Applicable in the different settings of clinical care, public health,

or epidemiologic investigations

Sample collection

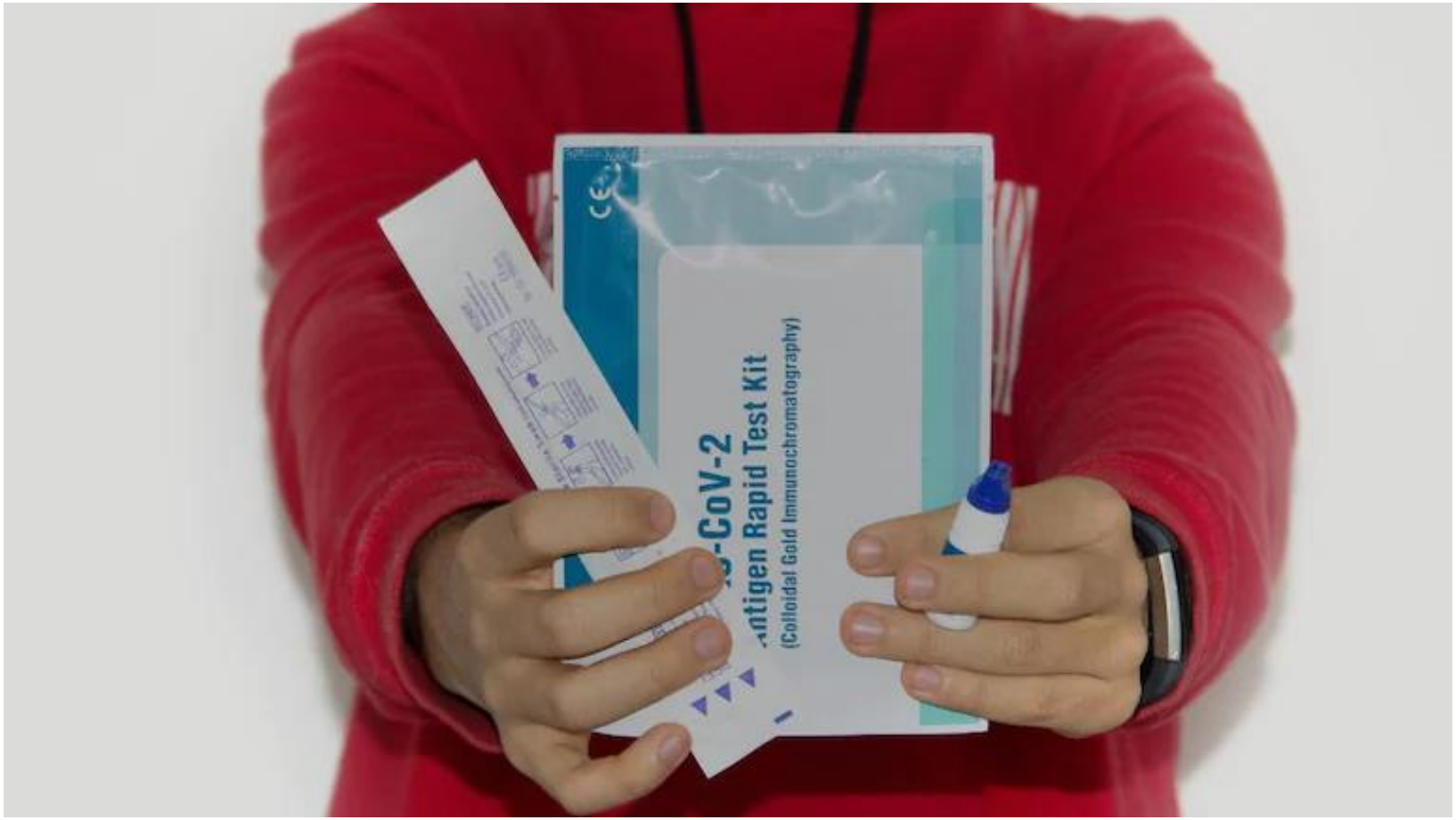
RT-PCR-March 10 ,2020

automated nucleic acid extractor-july20

CBNAAT- April 2020

TrueNat- May 2020

RAT-June 2020



Abbott ID NOW-rapid PCR-airport screening of samples-June2021

Accula –airport screening of samples June2021

Antibody detection by CLIA- serosurvey -Jan 2021 & retrospective diagnosis

Setting up of quality control processes to safeguard quality assurance

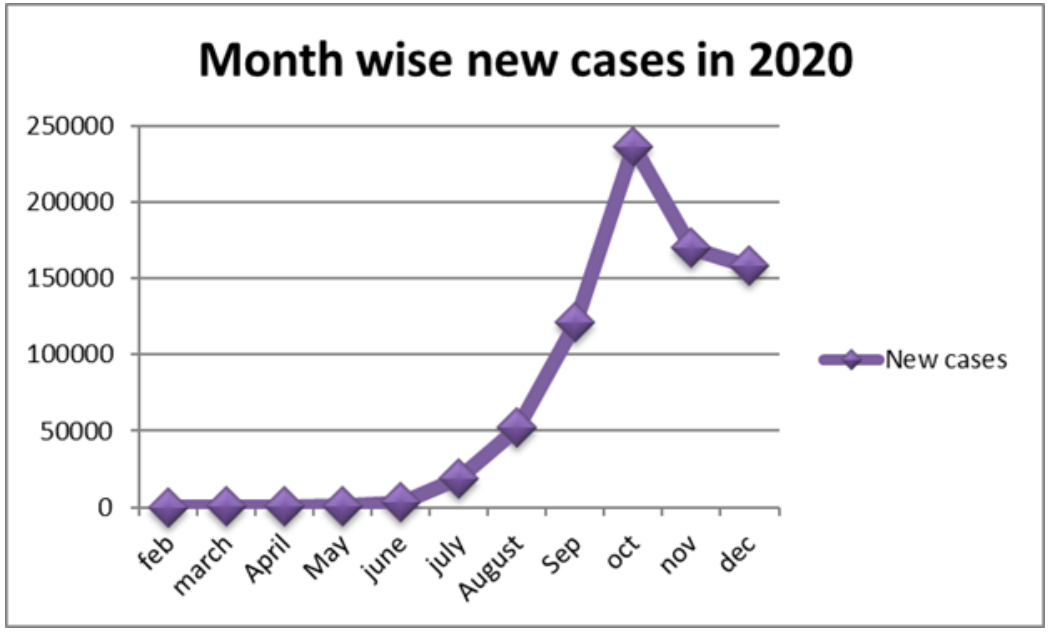
- ICMR selected 2 QC labs in Kerala to do Inter lab quality control(ILQC)
- NIV unit Alappuzha & GMC Trivandrum
- Started in Jan 2021
- All testing labs are asked to send 5pos & 5neg to QC labs twice a yr
- ICMR has launched an online portal for ILQC activity. ILQC activity started in January 2021
- QC labs also have to send samples to NIV Pune for Quality checking

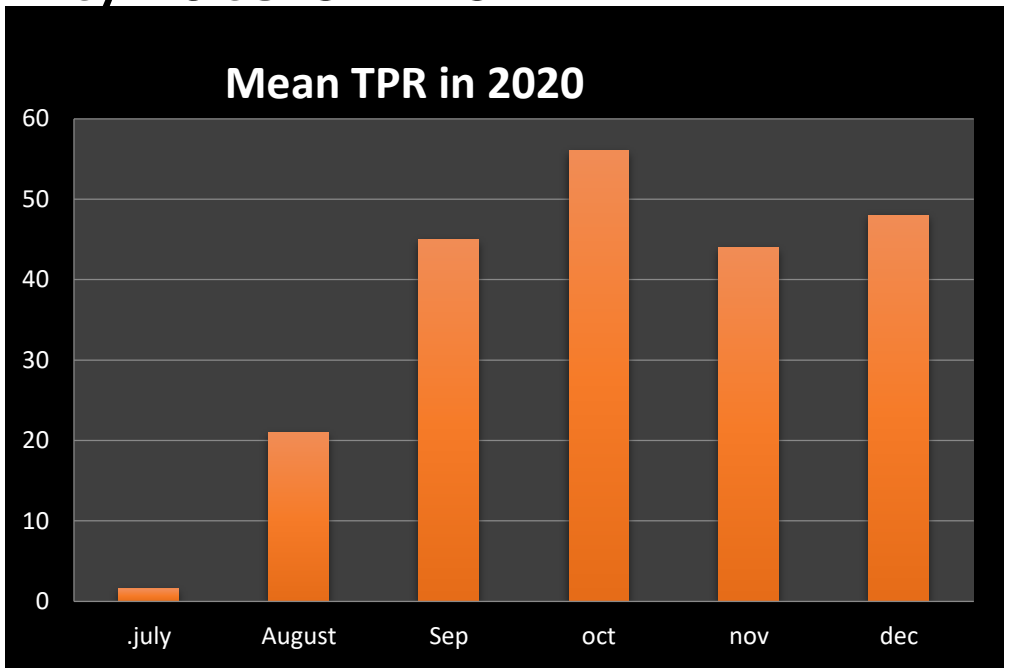
Covid-19 genomic surveillance

- INSACOG (Indian SARS-CoV2 genomics consortium)
- To understand the landscape of genetic epidemiology of SARS-CoV2 across the State- surveillance spanning all 14 districts of Kerala- Dec2020
- Every month 100-175 samples will be collected from each of the 14 districts by CSIR- IGIB New Delhi on a preplanned date -
- Sequence analysis updates- GOK on a weekly basis
- Summaries of the analysis & key observation- available in the web portal (GENESCoV2) specially developed for the project.
- Over the two yrs (20-22)identified VOC: Alpha, Beta, Gamma, Delta, Omicron,B.1.617.1 & B.1.617.3, AY series

Test positivity rates – Kerala

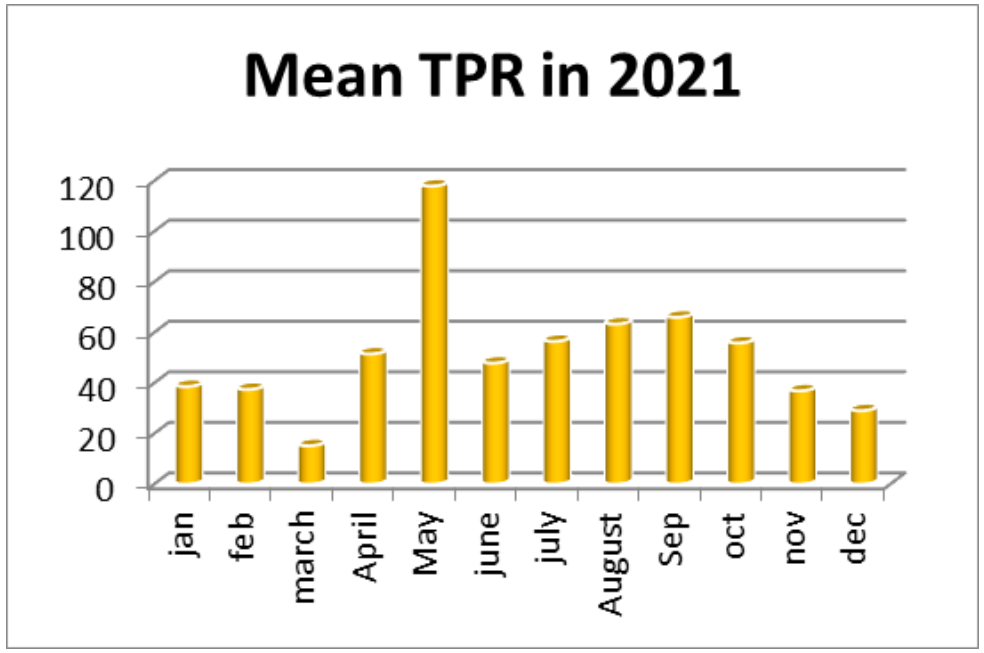
- After the start of the pandemic in India, there was a gradual increase in cases in Kerala and by June 2020, test positives were 20,889 with a mean test positivity rate of 2.62.

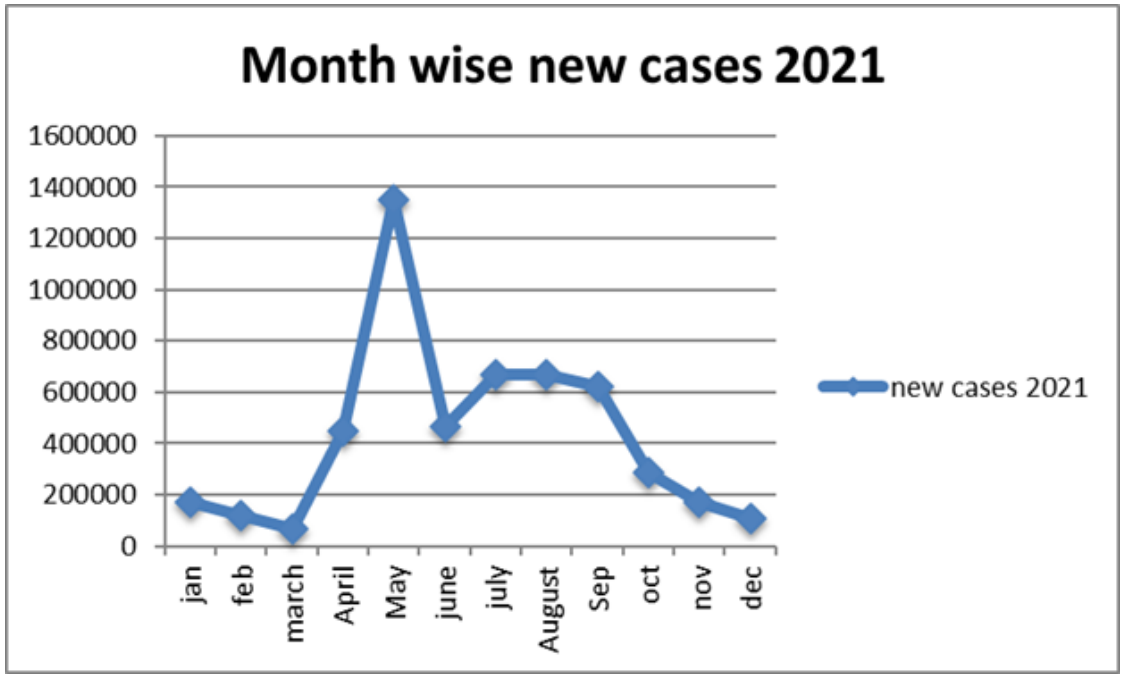




Test positivity rates – Kerala

- In 2021, by second week of April, Kerala started showing signs of the second wave rampaging across the state shown by the mean TPR per week crossing the 20 mark.





Trends of test positivity across Kerala

- Analysis of trends of testing strategies and test positivity across the state shows that at the start of the pandemic when test positivity rates were low, the testing strategy was very stringent.
- The state made timely changes in testing strategies based on ICMR guidelines.
- Initially the positives were located to specific places with a history of either an international travel or very close contact to positive cases.
- Even with a high testing rate (>1,00,000 per week) during July to September 2020, TPR was around 4-9.

Trends of test positivity across Kerala

- This was the time when the test positivity also showed a peaking with rates reaching 13 and more.
- During most of 2021, even on weeks with less number of tests the test positivity remained high.
- Relaxation in testing strategies were responsible for an initial rise in TPR but later the increase in TPR was due to an actual increase in cases rather than on the number of tests performed.
- During the last week of September and initial part of October 2020, the per week new tests performed were around 4,00,000.

Serosurveys

- Seroprevalence surveys are required to estimate the disease burden in a community.
- Such surveys can bring insights into disease epidemiology and can provide vital inputs to policy decisions for optimizing prevention and control activities.
- H&FWD, GOK had conducted three rounds of COVID-19 serosurveys till date.

Serosurveys:1st round: May 2020

A community based sero-surveillance using rapid antibody test among special groups was conducted in Kerala during May 2020, after the first wave of cases of the pandemic in the state.

Samples were collected from 14 districts among specific groups based on the guidelines issued by H&FWD.

Analysis based on data from 9483 individuals in specific groups with varying levels of risk was done.
Seroprevalence of 0.13 %.

During the same time **ICMR** had also conducted a serosurvey in three districts in Kerala and the **seroprevalence obtained was 0.33%.**

Serosurveys: 2nd round: February 2021

The second round of serosurvey was conducted by the H&FWD using a cross-sectional design applied on a representative adult population of Kerala during February 2021.

The objective was to estimate the seroprevalence of SARS CoV-2 IgG antibodies (ELISA) among the adult population of Kerala as well among specific high-risk groups in Kerala namely HCWs and frontline workers.

The survey also estimated the seropositivity among the residual serum samples in designated laboratories and blood banks.

The overall seroprevalence of COVID-19 (SARS CoV-2 IgG) antibodies among the adult population of Kerala was found to **be 10.76%.**

Seropositivity among the HCWs in Kerala was **10.5%.**

Serosurveys: 2nd round: February 2021

The overall seropositivity among the front-line workers was **12.0%** (Police personnel 15.3 and Local Self Government personnel 8.8)

The seropositivity among the residual samples from blood banks was 11.0% and among the taluk level designated laboratories was 12.2% giving an overall seropositivity among the residual samples as **11.7%.**

The case to infection ratio was estimated to be approximately 1:4 at that time.

The seroprevalence survey conducted by ICMR during December 2020 in three districts of Kerala obtained a seroprevalence of **11.6%.**

Serosurveys:3rd Round: September 2021

- The objective of the population based cross-sectional survey was to estimate the seroprevalence among 6 categories of the population in the state namely,

community ≥18 yrs,

antenatal women,

children aged 5-17 yrs,

tribal population ≥18yrs,

coastal population ≥18 yrs

& urban slum population aged ≥18 yrs.

- The antibodies measured were SARS CoV-2 IgG Nucelocapsid antibody (anti nucleocapsid antibody) and SARS CoV-2 IgG Spike -S1 RBD antibody (anti spike antibody) by CLIA in the same samples.

Serosurveys: 3rd Round: September 2021

- Seroprevalence was estimated based on an individual's positivity if any of the 2 types of antibodies was positive.
- The seroprevalence estimates obtained for the general community ≥18 yrs was 82.6%,

Coastal community 87.7%,

Urban slums 85.3%

tribal population 78.2%.

Children 5-17 yrs was 40.2%

Antenatal women was 65.4%.

Lessons learned

- Mapping of molecular diagnostic facilities so that within no time we could expand from five labs to 173 labs (50 Govt, private-123)
- Hub and spoke model for **AMR** converted to hub and spoke model for molecular diagnostics at EKM
- LDMS portal entry
- How we could shorten TAT in comparison to developed nations
- Mobile testing labs
- RAT for triaging and mass testing to identify the infective cases
- Focussed testing strategies so that even though number of tests were low…Kerala picked up one out of four cases compared to one out of 28 (national average) during first and second wave based on seroprevalence data
- Scaling up of activities in VRDL-Sequencing
- Kerala puts forth a model of evidence based action through a robust public health system with good community participation & intersectoral collaboration

References

- https://www.heritage.org/public-health/report/comparative-analysis-policy-approaches-covid-19-around-the-world
- Stephen Engelberg, Lisa Song, and Lydia DePillis, “How South Korea Scaled Coronavirus Testing While the U.S. Fell Dangerously Behind,” Pro Publica, March 15, 2020.
- Ponnaiah M, Suliankatchi Abdulkader R, Bhatnagar T, Thangaraj JWV, Santhosh Kumar M, Sabarinathan R, et al. (2021) COVID-19 testing, timeliness and positivity from ICMR’s laboratory surveillance network in India: Profile of 176 million individuals tested and 188 million tests, March 2020 to January 2021. PLOS ONE 16(12): e0260979. https://doi.org/10.1371/journal.pone.0260979.
- Indian Council of Medical Research. Testing strategies published from time to time
- https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/Inclusion%20of%20BSL-2%20Le.Lab.pdf
- https://dhs.kerala.gov.in. guidelines and technical reports published
- USFDA In Vitro Diagnostics EUAs - https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas
- Abduljalil J. Laboratory diagnosis of SARS-CoV-2: available approaches and limitations. New Microbes New Infect. 2020; 36: 100713. https://doi.org/10.1016/j.nmni.2020.100713 PMID: 32607246.
- Sharma K, Aggarwala P, Gandhi D, Mathias A, Singh P, Sharma S, et al. (2021) Comparative analysis of various clinical specimens in detection of SARS-CoV-2 using rRT-PCR in new and follow up cases of COVID-19 infection: Quest for the best choice. PLoS ONE 16(4): e0249408. https://doi.org/10.1371/journal.pone.0249408.


Thank you