# Cholera Detection: Gaps and Aims

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- Diseases evolve and so should diagnostics
  - With continuous and real time data analysis, our diagnostics would mold to changing disease landscape

- Rapid Diagnostic Tests (RDTs) should be "rapid"
  - Ours is a fast one test confirmatory approach

- Cost of the test should not be prohibitive
  - Our approach, being molecular instead of antibody based, is cost effective

- Accuracy should not be limited to clinic
  - Our methods are designed to be equally robust in the field

- Execution and interpretation of the test should be simplistic and dilemma free
  - Our platform is simple and easy to follow

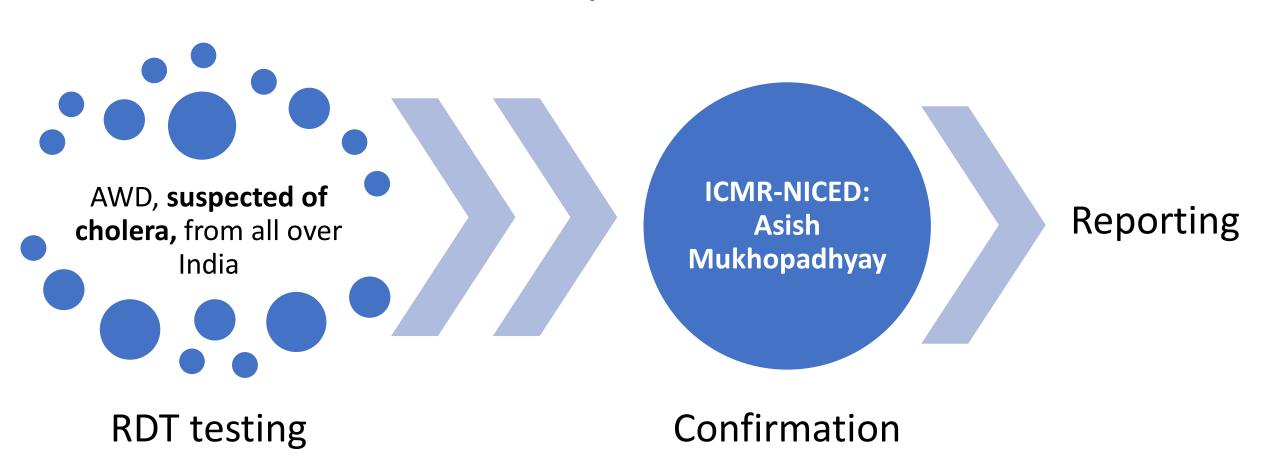
- Test result should be actionable
  - Our diagnostic results guide public health decision making

### Rapid Detection Test

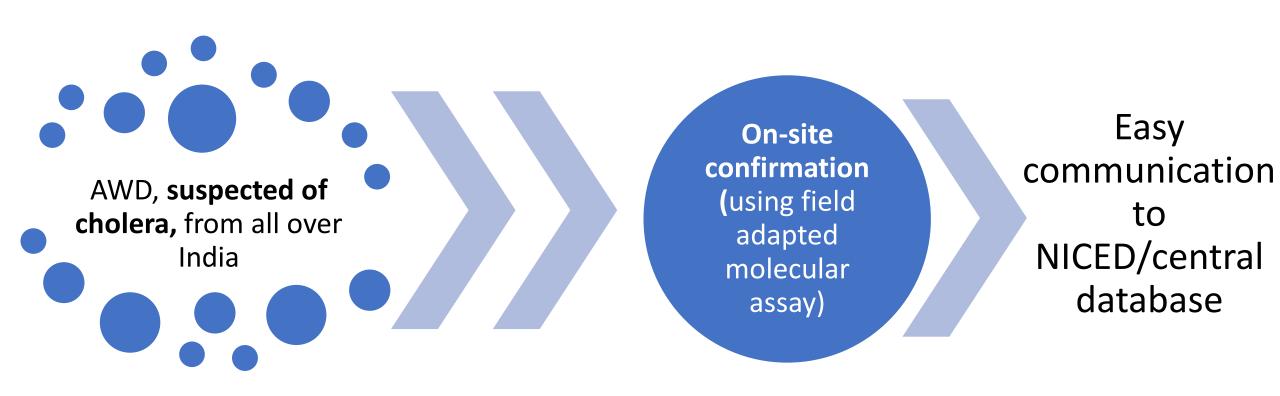
or

Rapid Detection Confirmatory Test

## In India - the process - how it is



### In India - the process - how it should be



RDT testing

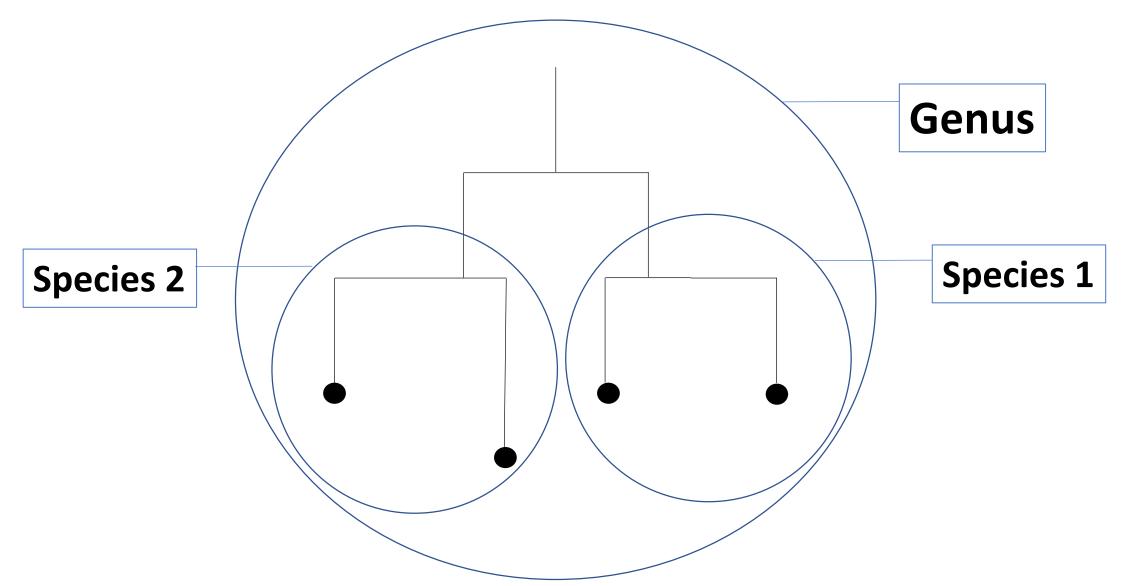
Confirmation

### PPC and TPP: Areas

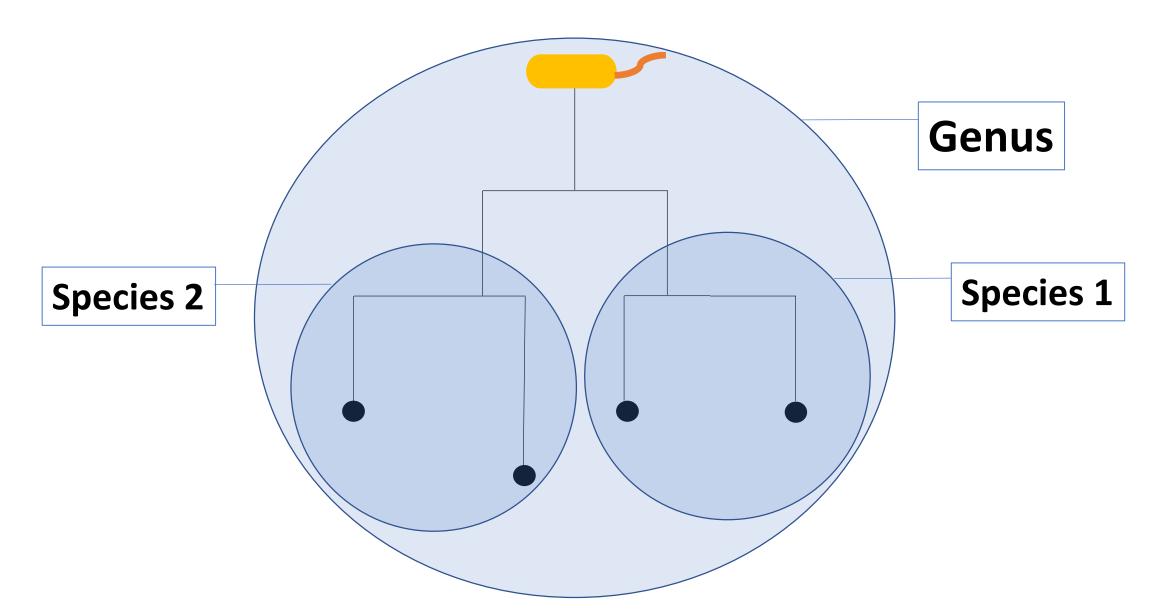
### Resolution and Throughput

- AWD Cholera vs other enterics?
- Toxic vs Non Toxic?
- 01 vs 0139?
- Pandemic vs Sporadic?
- Multiple answers in one test?
- Multiple sample tests in one assay?

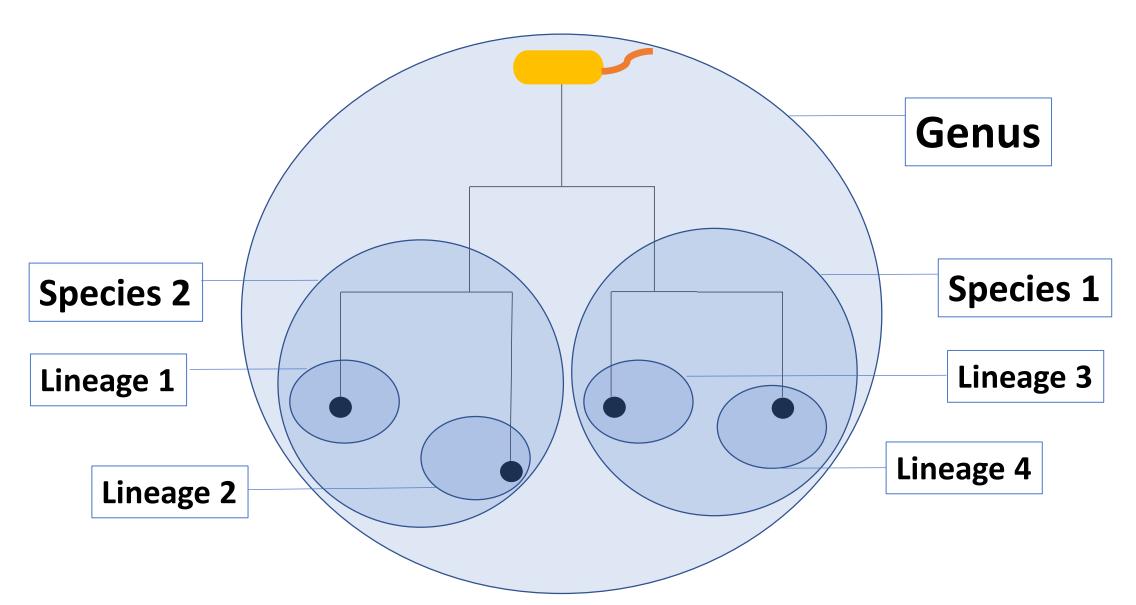




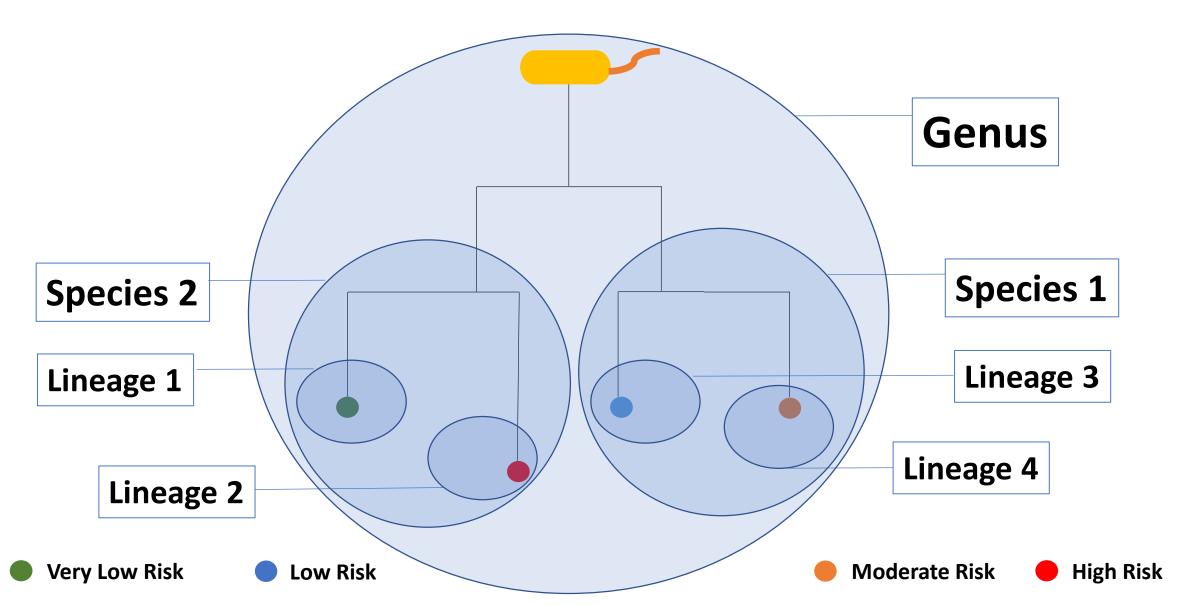
### Pathogen – as detected by current molecular tests



### Pathogen – there is more to it



### Pathogen – there is <u>even</u> more to it



### Sensitivity and Specificity

- Sensitivity as high as possible better than current antibody dipstick tests
- Specificity 100% should be the mandate

### Actionable Outcome

- One test confirming or rejecting the disease
- No need for further culture confirmation
- Generate reliable results that are easy to communicate/share
- Advises vaccine programs/drives

### Cost

As low as possible without compromising on quality

### Speed

- As fast as possible ideally in a couple of hours before the camp set up is folded for the day
- Data communication speed very important

## Portability and Deployability

- Should be easy to stockpile
- Should be easy to deploy on an urgent basis
- Reasonable shelf life
- Thermostability
- PHCs (in India) or equivalent one PHC per 30,000 population
  - Each PHC has 5-6 sub centres for easy accessibility
- Alignment with surveillance (both clinical and environmental)
- Alignment with WASH and vaccination programs
- AC power independent

### Skill set

- Requirement of minimum training
- Easy to follow universal language SOPs
- Video based guide(s) for process flow and troubleshooting

### Disposal of kits and contents

- Health risk free disposal on site or off site
- Easy defusal
- No amplification of actual bacteria (the problem pathogen)

# DIAGNOSTIC PRODUCT SPECIFICATIONS TPP CHOLERA

### TARGET POPULATION GROUP/PATIENT:

Patients clinically suspect of cholera

### **HEALTH FACILITY WHERE THE TEST WILL BE USED:**

Primary health care level with no access to standard laboratory facility or settings and no access to electricity. Community settings outside health facilities where cholera outbreak is suspected

ATTRIBUTES definitions	DESIRED	ACCEPTABLE
Priority features		
Intended use of the test	Early detection, declaration, and monitoring of outbreak without need for cholera confirmation First intention test to be used on a predefined number of cholera suspect cases	Test to declare a cholera alert, to be confirmed by culture and/or PCR



**Only Molecular Test can achieve this** 

### Poll workers journey to reach India's most remote voters



In this April 10, 2019, photo, Indian election officials and paramilitary soldiers with election materials walk along the river Brahmaputra to board on a country boat on the eve of the first phase of general election in Majuli, Assam, India. (Anupam Nath, File/Associated Press)

### **Thanks**