GLOBAL TASK FORCE ON
CHOLERA CONTROL

CHOLERA MOLECULAR DIAGNOSTICS: RESEARCH TO OUTBREAK CONFIRMATION

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1. CURRENT STATE OF MOLECULAR DIAGNOSTICS

CURRENT OBJECTIVES FOR THIS MEETING

- Review previous guidance
- Review new surveillance guidelines
  - Implementation
- Reagent supply, logisitics
- Training, Proficiency testing and EQA

RECAP: EXISTING GUIDANCE

- 2017 technical note
  - DNA-based techniques for identification and characterization of *V. cholerae* strains: PCR tests
    - Conventional
    - qPCR
  - . DNA-based techniques for advanced genotyping of *Vibrio cholerae* strains
    - MLVA
    - WGS
  - Shipment and Storage of samples
    - Depends on sample type
    - Job aid to be completed

PCR: GUIDANCE AS OF FALL 2021

- Following the last meeting, it was decided to adapt to the laboratory equipment
- Methods of sharing equipment and working together may be the subject of future recommendations (*Real time equipment, supplied for Ebola and COVID, tend to be located and fixed in flu labs and thus unavailable for other uses or transfer to bacterial/enterics labs*).

➢ Both conventional and Real Time methods should be part of GTFCC recommendations

2. NEW SURVEILLANCE GUIDELINES

GOLD STANDARD COMBINATION

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In surveillance units where there is no confirmed cholera outbreak

- Any person infected with Vibrio cholerae O1 or O139 identified by presumptive identification (culture/seroagglutination) or PCR.
    - The strain should also be demonstrated to be toxigenic (by PCR) if there is no concomitant confirmed cholera outbreak in other surveillance unit(s) of the country and there is no established epidemiological link to a confirmed cholera case/ source of exposure in another country.

In surveillance units where there is a confirmed cholera outbreak

- Any person infected with Vibrio cholerae O1 or O139 identified by presumptive identification (culture/seroagglutination) or PCR.

https://www.gtfcc.org/wp-content/uploads/2023/02/gtfcc-public-health-surveillance-for-cholera-interim-guidance.pdf

Specifically recommend PCR for tox testing in very specific situations

- Review settings where different PCRs are recommended
  - Toxigenicity testing
  - species identification (Vibrio cholerae)
  - serogroup identification (O1/O139)

IMPLEMENTATION

- COUNTRY PREPAREDNESS
  - Currently practiced bacterial molecular biology?
    - Pathogens
    - Research or Public Health Practice
  - Equipment
    - Type?
    - Availability by Admin level
    - Used for bacterial, viral, parasites?
  - Training GAPS

FURTHER REFINE/IMPROVE PCR RECOMMENDATIONS

- Any thoughts on PCR recs in current 2023 testing strategy
  - Timeline to implementation?
  - Enhance understanding of cholera disease burden?
    - elimination

- Are there additional PCR suggestions for the new recommendations?

2. MOLECULAR TESTING STRATEGY

CONVENTIONAL VERSUS Q-PCR

- Post-covid, are qPCR machines more widely available?
  - Available for cholera?
- Are commercial kits required for cholera PCR?
  - Versus in-house?
  - Pros v. Cons

IN-HOUSE?

- primer / probe sequence standardized?
  - Ctx
  - O1?
  - ompW
  - 16S?
- WHO standard?
  - Facilitate comparison/reporting of findings with in-house or commercial kits
  - Should we create?

COMMERCIAL KITS

- Experience with any?
- LifeRiver Biotech, China
  - Gene target: ctx, O1,
- Creative Biogene, USA
  - Gene target: ctx, O1, O139
- BioPerfectus, China
  - Gene target: ctxA, ctxB, ompW, O1, O139

  - Experience with others

3. SUMMARY

SUMMARY

- Molecular Diagnostics added to Testing Strategy
- Need to work with country partners to help establish PCR capacity
  - Training
  - Supply chain
  - Equipment
- TPP and independent validation

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THANK YOU