Vibriocidal serum responses to oral cholera vaccine (Shanchol) when the second dose is delayed 6 months

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Rationale for Delayed Second Dose

• Single doses have been shown to stimulate protection for months → years

• 2015 study from Kolkata compared immune responses following 14 days and 28 days.
  – Seroconversion rates and GMT vibriocidal responses were similar between the two groups.

• Outbreak response campaigns with delayed 2\textsuperscript{nd} dose schedule
  – Zambia in 2016 with a 6-8-month time between doses

• Study purpose: to compare the vibriocidal responses if a second dose of OCV is given after 6 months rather than the “standard” 2 weeks.
Study site

Lusaka
Lukanga Swamps
Study Site: Lukanga Swamps

Floating Reed Island in Lukanga Swamps

Nurse drawing blood pre-vaccination

Centrifuge run on car battery
Vaccination & Blood Draw Schedule

OCV dose 1 given at baseline (Day 0)
OCV dose 2- Given at 14D or 6M post dose 1
Blood draw
Blood Draw at 14D post Dose 2
Assessed for eligibility (n=174)

DIG1 (n=87)

Received 1st dose OCV: n=87
- < 5yrs: n=33
- 5-14yrs: n=29
- > 15 yrs: n=25
Received 2nd dose OCV: n=87
- < 5yrs: n=33
- 5-14yrs: n=29
- > 15 yrs: n=25

DIG1: (n=81)
- < 5yrs (n=29),
- 5-14yrs (n=28)
- > 15 yrs (n=24)

Included in Analysis n=157

Excluded (n=2)

DIG2 (n=85)

Received 1st dose OCV: n=84
- < 5yrs: n=31
- 5-14yrs: n=28
- > 15 yrs: n=25
Received 2nd dose OCV: n=79
- < 5yrs: n=29
- 5-14yrs: n=26
- > 15 yrs: n=24

DIG2: (n=76)
- < 5yrs (n=26)
- 5-14yrs (n=26)
- > 15 yrs (n=24)
Overall vibriocidal GMTs for Inaba and Ogawa

Inaba

Ogawa
Primary Outcome: GMT vibriocidal titers 2 weeks after 2nd dose

**Inaba**

**Ogawa**

![Graphs showing GMT vibriocidal titers for Inaba and Ogawa strains before and after doses.](image-url)
GMT vibriocidal titers two weeks after 2nd dose by age group

(Inaba)

(Ogawa)
Comparison of Vibriocidal Inaba and Ogawa Response Rates 2 weeks after second dose
Conclusions

• Vibriocidal titers 2 weeks after 2\textsuperscript{nd} dose similar regardless if OCV is given 2 weeks or 6 months after first dose

• A second dose given 2 weeks after first dose maintained higher titer briefly, but by 3 months, there was no difference between DIG1 and DIG2

• All follow-up GMTs were higher than baseline through 9 months
Additional Analyses

- Very similar study in different setting: Douala, Cameroon
  - Large urban area (v. rural Lukanga)
    - Major center of trade
  - No cholera since 2012 (no confounding with intercurrent infections)
- Cameroon analysis will include groups at
  - 2 weeks (DIG1)
  - 6 months (DIG2)
  - 11.5 months (DIG3)
- Preliminary analyses (Inaba)
  - DIG2 and DIG3 may be superior to DIG1
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