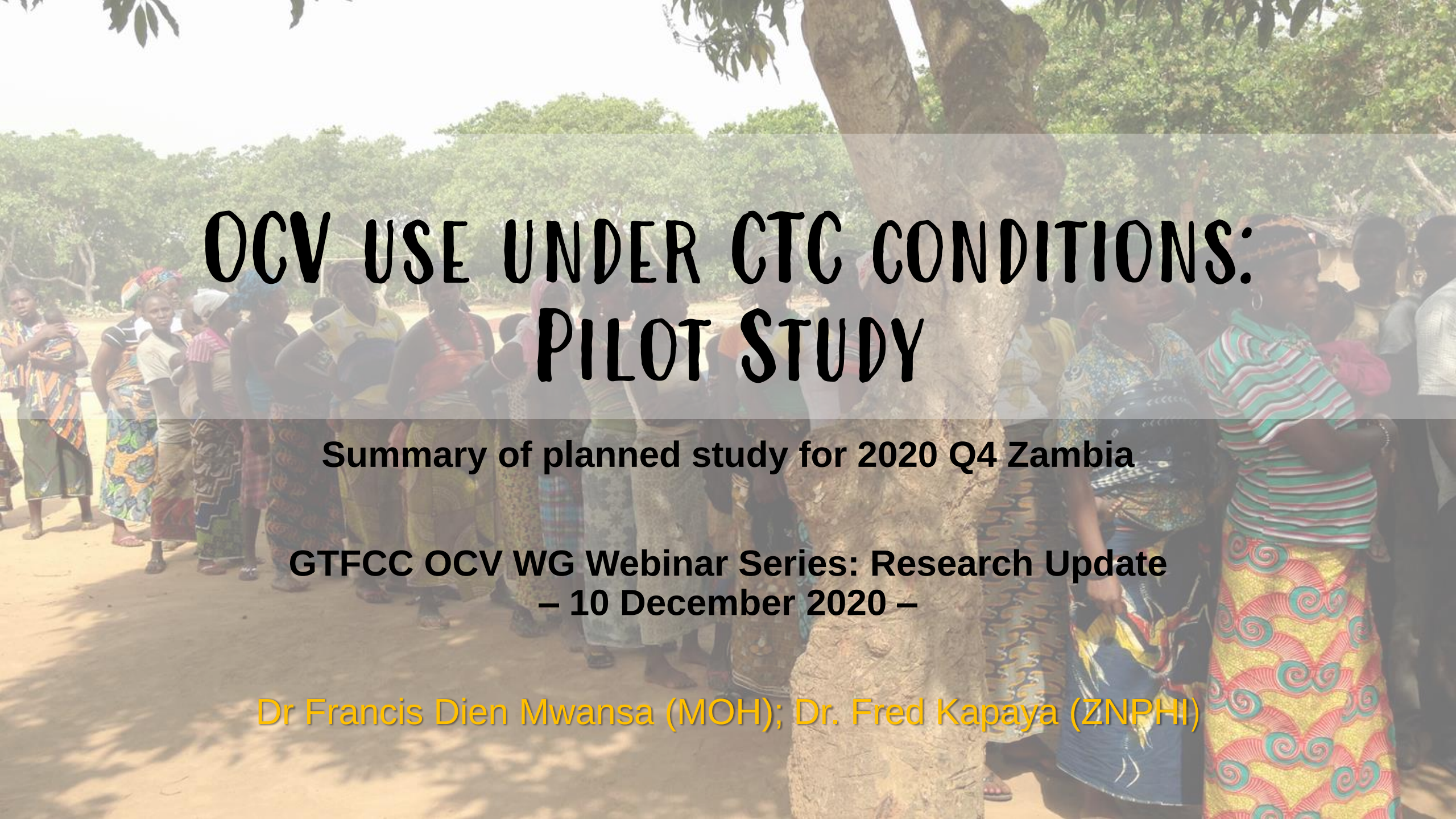

OCV use under CTC conditions: Pilot Study

Summary of planned study for 2020 Q4 Zambia

GTFCC OCV WG Webinar Series: Research Update
– 10 December 2020 –

Dr Francis Dien Mwansa (MOH); Dr. Fred Kapaya (ZNPHI)

Study Overview

Title:	Performance of a vaccination campaign using oral cholera vaccine with and without a controlled-temperature chain (CTC)
Study Site:	Zambia – Nsama and Shibuyunji districts
Primary sponsor:	WHO IVB/PDR
Study Type:	Pragmatic cluster randomized interventional trial
Principal Investigator (PI) :	Dr Victor Mukonka (ZNPHI)
Co-PI (National):	Dr. Kennedy Malama (MOH),Dr Patricia M Bobo (MOH), Dr. Nathan Bakyaita (WHO); Dr. Nathan Kapata (ZNPHI), Ms Mazyanga Liwewe (ZNPHI), Dr. Andrew Silumesi (MOH), Dr. Abel Kabalo (MoH), Dr. Nyambe Sinyange (ZNPHI), Mr. Belem Matapo (WHO), Dr. Fred Kapaya (ZNPHI), Ms. Angela Gama (ZNPHI), Dr Kayeyi Nkomba (ZNPHI), Ms. Hannah Mzyece (ZNPHI), Dr Paul Zulu (ZNPHI), Mr. William Ngosa (ZNPHI), Ms. Albertina Ngomah-Moraes (ZNPHI), Dr Raymond Hamoonga (ZNPHI), Dr. Penelope Masumbu (WHO), Dr. Otipo Shikanga (WHO), Mr. Orbrie Chewe (ZNPHI), Dr. Francis Dien Mwansa (MoH), Mr. Abrahams Mwanamwenge (WHO), Ms. Constance Sakala Banda (MoH), Mr. Guissimon Phiri (MoH), Ms. Princess Kayeye (MOH) Mr. Elesan Mshanga (MoH), Dr. Chikama Mukwangole (MoH), Mr Mumbi Chola (UNZA), Maricel Castro (WHO HQ), Anna Lea Kahn (WHO HQ)
Study Supervisor:	Dr Francis Dien Mwansa (MOH), Dr Fred Kapaya (ZNPHI)
Collaborating institutions:	Ministry of Health, Zambia, World Health Organisation, Zambia National Public Health Institute (ZNPHI), Global Task Force for Cholera Control (GTFCC)
Study product:	WHO prequalified Oral Cholera Vaccine (Shanchol)
Vaccine Manufacturer:	Shantha Biotechnics Private Limited (A Sanofi Company), India
Study timing:	December 2020
Approvals:	National IRB + WHO Ethics Review Committee

What is Controlled Temperature Chain (CTC)?

- CTC use of vaccines allows for a **planned removal of the vaccine from the standard 2-8°C cold chain into ambient temperatures** typically up to +40°C for a limited period of time, under monitored and controlled conditions.
    - Heat-stable vaccines differ in the length of time they can be stored in a CTC and the maximum temperature they can endure while remaining stable and potent.
    - ✓ ***Shanchol™ is labelled for storage and transport at up to 40°C for a single period of time up to 14 days just prior to administration.***
    - CTC qualification involves regulatory approval and prequalification by WHO.
    - Key time/temperature monitoring tools = Vaccine Vial Monitor (**VVM**) + Peak Threshold Temperature Indicator (**PTTI**)
- **EXPECTED BENEFITS OF CTC** → Increased vaccine delivery efficiencies, reduced burden on HCW, reduced delivery costs, **increased vaccination coverage and equity** → especially beneficial in campaign and special strategy contexts
- **IMPLEMENTATION OBJECTIVES** → Ensure high quality implementation effort which optimizes the flexibility and benefits offered by CTC and minimizes any associated risks.

Study Objectives

Primary:

- To demonstrate the **superiority of the CTC strategy** in terms of the average number of people vaccinated per day by a vaccination team compared with the standard cold chain (SCC) strategy holding all other resources constant

Secondary:

- To compare the vaccine wastage using CTC and standard cold chain.
- To compare the cost per dose delivered using CTC and standard cold chain.
- To compare the vaccine coverage achieved in areas vaccinated using CTC with the vaccine coverage achieved in areas vaccinated using the standard cold chain.
- To assess the perceptions of the CTC strategy among vaccination teams
- To assess the knowledge, attitudes and practices towards vaccination among vaccinators and vaccine supervisors.
- To compare the average number of individuals vaccinated, the cost and the vaccine coverage between the outreach (including door to door strategy) strategy and the fixed site (static) strategy if both strategies are used to implement the vaccination campaign.

Method

- open-label, cluster randomized (at vaccination team level) controlled, superiority trial (comparing no. of people vaccinated per day by a vaccination team between CTC and SCC)

+ KAP survey (sub-study)

Study population: vaccinators and vaccine supervisors (intervention arm will receive additional training on use of OCV under CTC conditions.)

- 2 study arms: (a) control arm: applying standard cold chain strategy
  (b) intervention arm: applying CTC strategy
- no blinding
- all data will be anonymized

Sample size: 30 clusters (sub-districts) per group

Study team: 1x PI + 3x co-Pis + 1x Study Coordinator + 30x surveyors (+ remote support from WHO-HQ)

Data Collection – Data

1. Average number of people vaccinated per team in one day (with the working time per day fixed and constant between study teams.)
2. * Proportion of vaccine wasted
3. * Average operational cost (total vaccination cost minus the direct vaccine cost) per dose delivered
4. Appreciation of the CTC strategy among vaccination teams in the intervention arm
5. Knowledge, attitudes and practices towards vaccination and CTC strategy among vaccination teams in the control and intervention arms
6. * Proportion of individuals reporting adverse events following immunisation (AEFIs) – via passive surveillance
7. * Vaccination coverage in the target population
8. Proportion of individuals reporting AEFI through active screening among the population-based coverage survey participants

*Data collected systematically during vaccination campaigns.

Data Collection – Process

- Before the start and after the end of the first round of vaccination we will collect information among study participants by using the **KAP questionnaire**.
- Daily during the vaccination session: **Tally sheets** and a **supervisory check list** to monitor daily the vaccination session and obtained estimates of the number of people vaccinated per day and per team, the vaccine wastage in respect to the cold-chain procedures.
- IVI's **CholTool costing tool** will be used to estimate the vaccine cost associated with the vaccine.
- A vaccine **coverage survey** will be conducted following the second vaccination round if it is implemented within 28 days following the first round, or following the first round otherwise using the standard vaccine coverage survey protocol developed by the GTFCC.

Thank you

Questions?