



**POINT INFO**

Jeudi 13 juin  
2024

# **CATALYSE THE UPTAKE OF UNDER- UTILISED TOOLS FOR PREVENTION OF HEPATITIS C - CUTTS HEPC**

**A UNITAID FUNDED PROJECT**

# SNAPSHOT

## DATES

January 2023 – March 2027

## COUNTRIES

Armenia, Georgia, Tanzania

## OBJECTIVE

Contribute to closing the HCV prevention and testing gap: through increased access to new / underused tools for prevention, enhanced simplified testing protocols and through 'treatment as prevention' approach, in marginalized populations in LMICs

## CONTRIBUTION

\$9,363,092

## DONOR

 **Unitaid** (hosted partnership of the  
World Health Organization)



# CUTTS HEPC CONSORTIUM APPROACH



**GENERATE EVIDENCE ON  
FEASIBILITY, (COST) EFFICIENCY  
AND COMMUNITY VALUES AND  
PREFERENCES**

**ASSESS DEMAND, SUPPLY &  
COSTING**

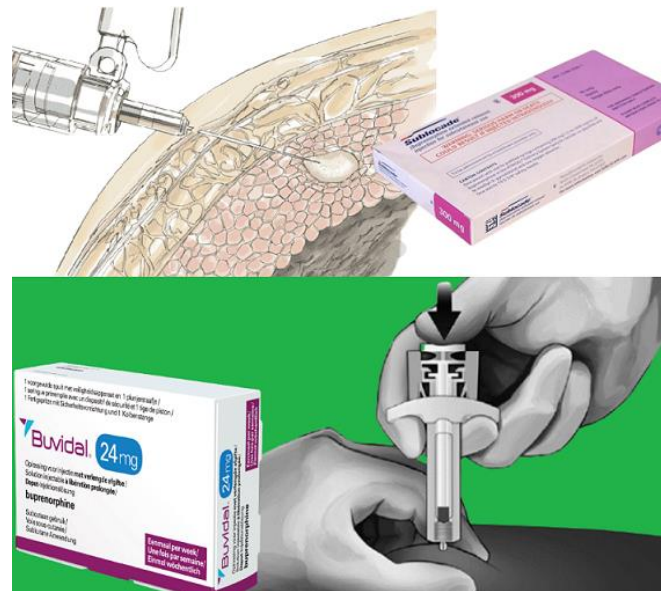
**ENGAGE COMMUNITIES**

**ENABLE EFFECTIVE TRANSITION  
AND SCALE UP**

# 3 STUDIES

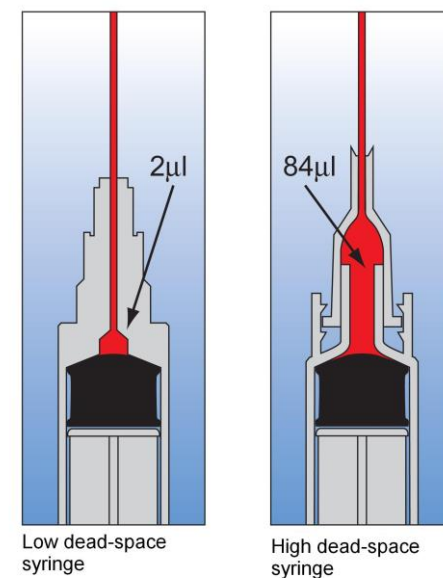
## INTRODUCTION OF NEW / UNDERUSED TOOLS FOR HEPC PREVENTION

### 1 Long-Acting Depot Buprenorphine (LADB)



### Low Dead Space Syringes and Needles (LDSS/N)

Figure 1: Mean Volume of Fluid Retained with Plunger Depressed



## IMPLEMENT A SIMPLIFIED TESTING PROTOCOL AND INTEGRATION OF HCV CARE

3



- To evaluate community values and preferences (acceptability)
- To determine the feasibility, effectiveness and cost-effectiveness
- To model the potential public health and budgetary impact in case of scale up

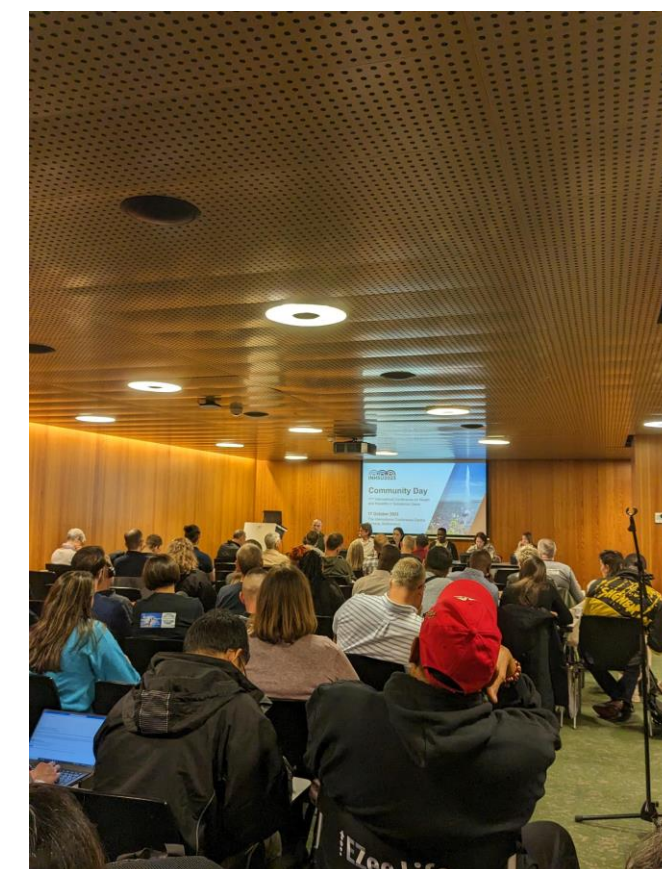
# UNITAID FUNDED 3 CONSORTIA





# KEY OVERALL ACHIEVEMENTS

- 3 “master” protocols fully approved by WHO Ethics Review Committee + 7 country protocols developed, reviewed by WHO and under review by national and institutional ethics committees
  - Additional level of complexity, still to be (partly) structured, BUT a significant leverage effect
- Interest from the HCV international community: 1 pre-conference event at HRI23 conference in Melbourne, 2 sessions + 1 poster at INHSU23 conference in Geneva, 1 session at INHSU24 conference in Athens
- A functional Community Advisory Board made up of representatives from all the target countries and regions
- Structuring our consortium with a first consortium agreement signed



# FOCUS TANZANIA

## ALL 3 STUDIES IMPLEMENTED

1

Long-Acting Depot  
Buprenorphine (LADB)

2

Low Dead Space Syringes  
and Needles (LDSS/N)

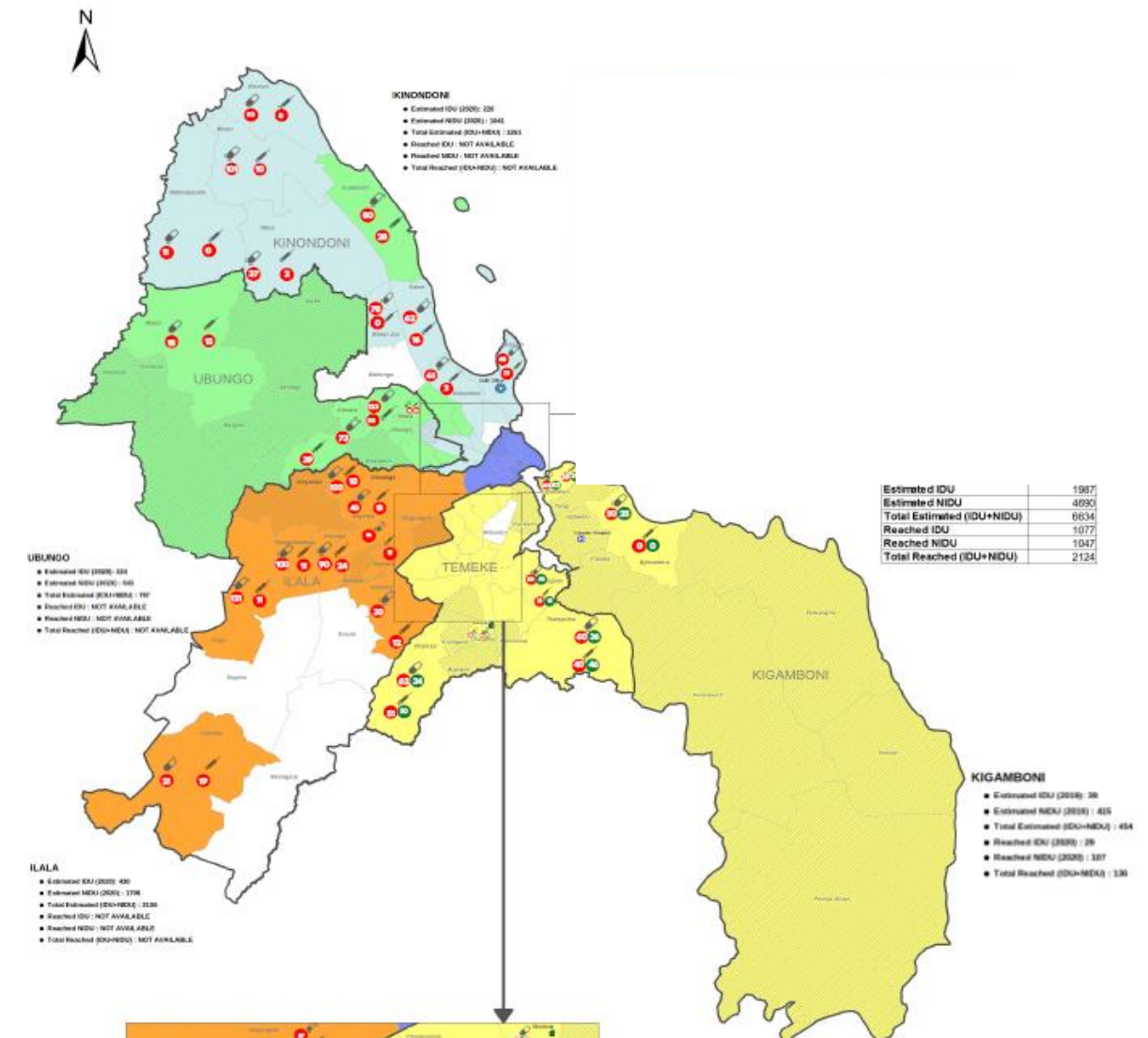
3

Simplified HCV model of  
care

## STUDY SITE

Dar es Salam

### HARM REDUCTION NEEDS AND INTERVENTIONS FOR PEOPLE WHO USE DRUGS IN DAR ES SALAAM



# WHAT IT MEANS TO MDM TANZANIA

A research project differs from classic MDM interventions (service delivery, advocacy) – it requires:

- A structured, systematic methodology
  - Ethical approvals from relevant bodies
  - Detailed documentation and quality data for replicability and analysis
- Stakeholders need to be people with capacity and allowance
  - Participants need to be extensively informed and give informed consent
  - Research protocols: highly technical, need to be simplified for correct information to beneficiaries



# ACHIEVEMENTS

## ENGAGEMENT WITH AUTHORITIES

- Introduction of the project to the Authorities (MoH, Drug Control and Enforcement Authority / DCEA)
- MDM received commitment letters from our partners Temeke Regional Referral Hospital, TanPud and DCEA, which is a plus for ethical clearance
- 14 healthcare workers from Temeke hospital's MAT clinic, TB clinic and emergency department and MDM staff were trained on the LADB study

## WHERE WE ARE

- The CUTTS research project team is identified and recruited (Principal Investigator / PI, study coordinator, site investigators, study nurses and outreach workers)
- MoU signed (April 2024) with 5 implementing partners / local civil society organizations (MUKIKUTE, MEFADA, STEPS, YOVARIBE and PEER to PEER) – MoU with hospital and DCEA in preparation

# CHALLENGES

1. Long processes of applying for and receiving ethical clearance
2. Research project being new to the Tanzania mission, it needs some adaptation and some training in research skills
3. Long processes for registration of new medicines and medical devices in the country; processes that are new to the mission

# NEXT STEPS

- Submission of protocols to NIMR (National Institute for Medical Research)
- Signing MoU with DCEA and Temeke Regional Referral Hospital
- Training the research team
- Introduction (2<sup>nd</sup> time) of the project to authorities after the ethical clearance
- Registration and importation of all medicines and medical devices

# FOCUS ARMENIA

## 2 STUDIES IMPLEMENTED

2

Low Dead Space Syringes  
and Needles (LDSS/N)

3

Simplified HCV model of  
care

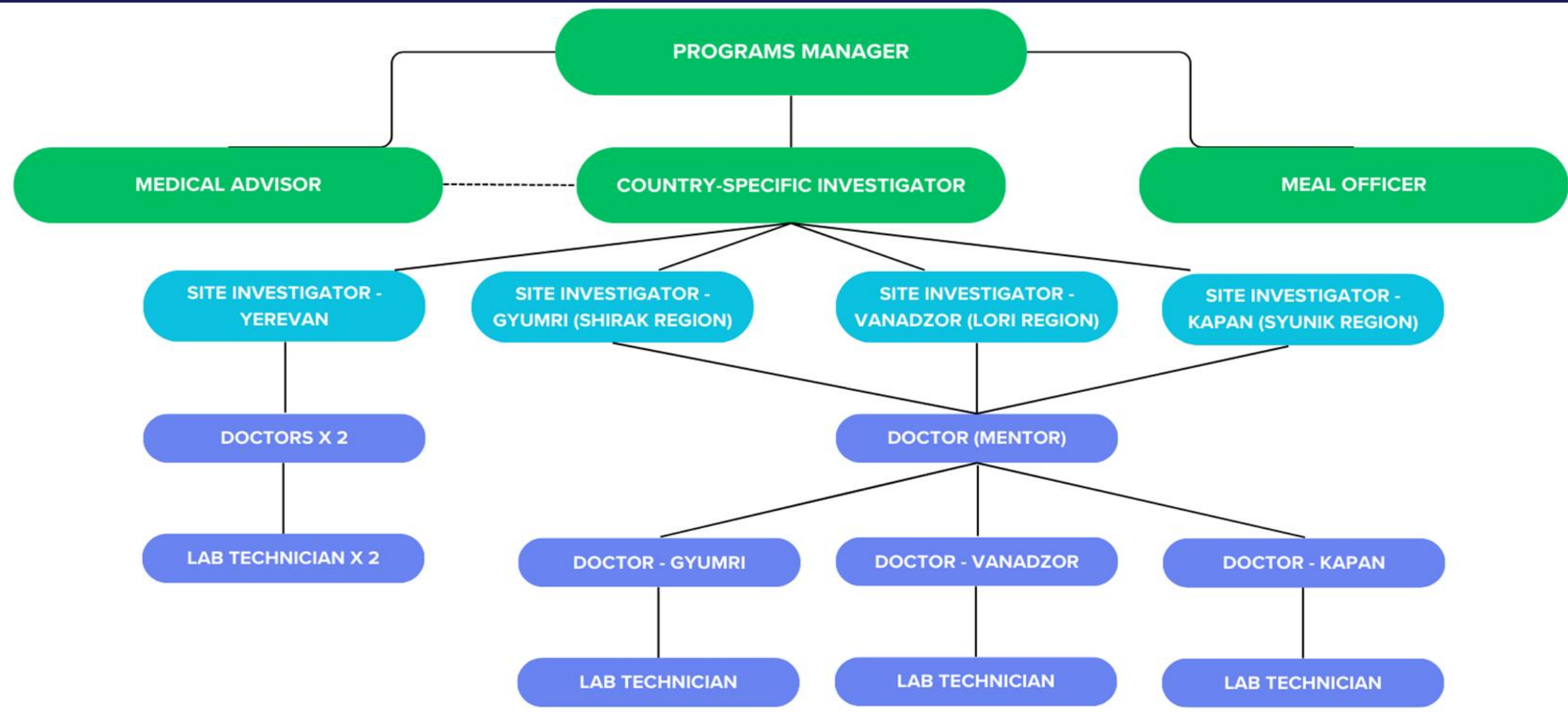
## STUDY SITES

Yerevan  
Shirak  
Lori  
Syunik





# ORGANISATIONAL CHART / STUDY TEAM



# OUR PARTNERS



# ACHIEVEMENTS

- Identifying the study partners and HR set-up (study doctors, nurses, peer workers, and other staff) + on-the-job training for doctors and nurses
  - All protocols are finalized and submitted to WHO IRB, Alfred HREC, and NCID EC
  - Cooperation with MSF on referral of beneficiaries falling under exclusion criteria
  - Partnership agreements & budgets finalized and signed
  - Procurement of HCV rapid diagnostic tests and LDSS/N in progress
- 
- The MoH has requested MDM to assist with the HCV treatment decentralization process in Armenia through our study: 3 medical centers were included so that their doctors are trained for the full HCV treatment decentralization process after the study
  - The MoH will provide free-of-charge HCV treatment (SOF/VEL) for study participants, as a result of our advocacy efforts.
  - NCID will provide free-of-charge HBV vaccination for our study beneficiaries.

# CHALLENGES

There are no challenges for us 😎💪



# CHALLENGES

## WELL, HERE ARE ACTUAL CHALLENGES))

- Unstable political & economic situation in Armenia – risk of war or military conflict
- Frequent changes in the management of medical partners
- Potential impact on the studies due to the replacement of the Minister of Health & associated changes in the HCV National Strategy
- Lack of complete and accurate official statistics on HCV in the country
- Drug use is criminalized, as in Georgia and Tanzania
- Lengthy internal processes at MDM... increased by the multi-layer configuration