

**4<sup>th</sup> HEPATITIS C**  
TECHNICAL ADVISORY  
GROUP  
**TAG Meeting**

**INTEGRATING HCV SCREENING AND SIMPLIFIED  
TREATMENT SERVICES IN PRIMARY HEALTHCARE**

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# Background

- Over the first three years of Georgia's HCV elimination program, more than 50 thousand persons initiated treatment, achieving >98% cure rates.
- Patient enrollment in treatment has been slowing down in recent months, most likely because of deficiencies in HCV testing and linkage to care.
- HCV screening and linkage modality currently used creates unnecessary barriers that negatively impacts pace of treatment uptake.
- Integration of screening and treatment services in primary healthcare offers opportunity to eliminate barriers and to improve engagement in the entire continuum of HCV care from testing through cure.
- Integrated models of care are effective ensuring high diagnosis, treatment and cure rates.

Nasrullah M, et al. MMWR Morb Mortal Wkly Rep 2017;66:773-6.; Arora S, et al. N Engl J Med 2011;364:2199-207.  
Cachay ER, et al. Hill L, et al. AIDS Res Ther 2013;10:9. Coyle C, et al. MMWR Morb Mortal Wkly Rep 2015;64:459-63.  
Kattakuzhy S, et al. Ann Intern Med 2017;167:311.

# Objectives

The objective of the proposed project is to assess effectiveness of integrated HCV screening and treatment model in primary healthcare settings.

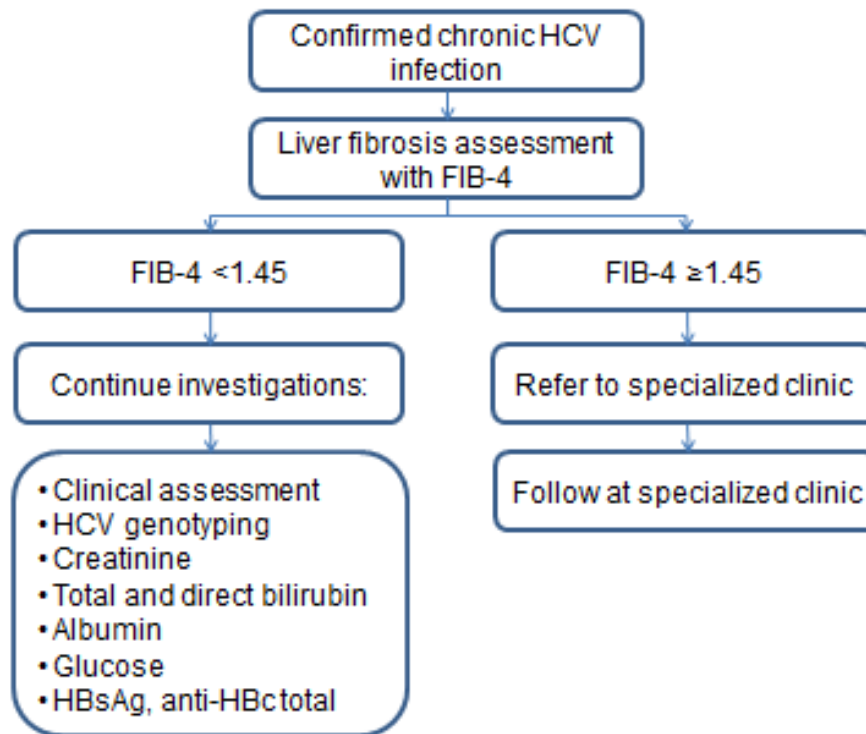
Specific aims include:

- Quantify engagement in the HCV care continuum (cascade) from screening through cure
- Assess efficacy and safety of simplified diagnostics and treatment monitoring procedures in primary healthcare settings
- Compare key project monitoring and evaluation indicators with national data

# Methods: Design

- Prospective evaluation of integrated screening and treatment program in primary healthcare settings.
- A total of 4 primary healthcare clinics (PHCs), including 1 in the capital city of Tbilisi and 3 in non-urban regional locations involved in the program.
- “One stop shop” approach used - patients will receive all HCV screening and care services in selected PHCs, without need for going to other locations.
- A total of 12,500 persons will be screened in 4 selected PHCs
- Estimated 963 persons will be positive for anti-HCV and 675 will have chronic hepatitis C.
- PHCs will provide care to **HCV treatment-naïve patients with mild fibrosis** using simplified diagnostics and treatment monitoring approach, while persons with more advanced liver damage will be referred to specialized clinics in close proximity.

# Pre-treatment evaluation



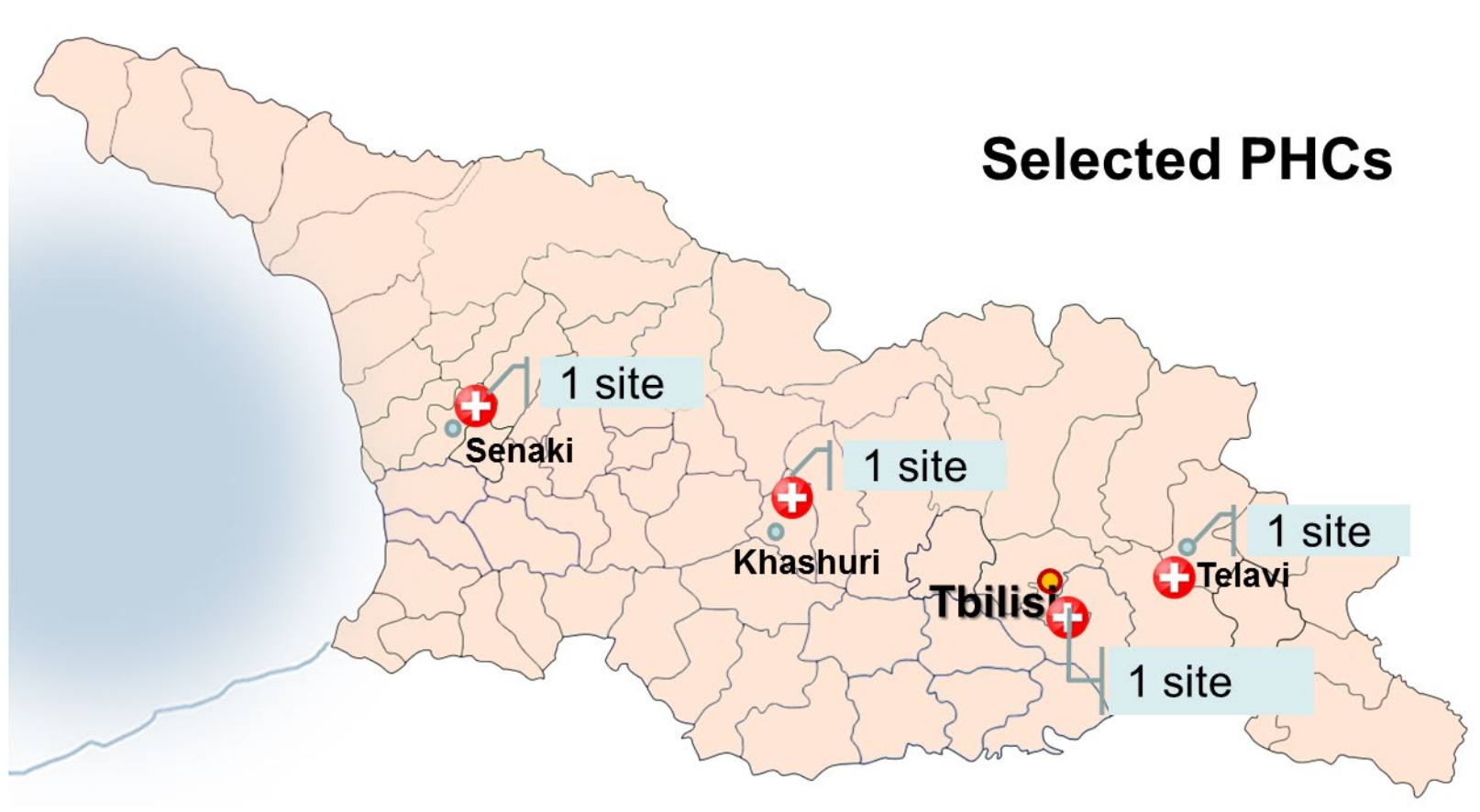
In case Sofosbuvir/Velpatasvir is introduced in Georgia, HCV genotyping testing will be also removed from pre-treatment evaluation algorithm.

# Monitoring during antiviral therapy

Simplified treatment monitoring procedures				
Measurements	Treatment Duration (weeks)			After treatment completion (weeks)
	4	8	12	
				<b>12 or 24</b>
Clinical assessment	X	X	X	X
HCV RNA quantitative				X
Complete blood count	X*	X*	X*	
ALT	X	X	X	

\* only for patients receiving Ribavirin containing regimens

# Completed activities





# Completed activities (cont.)



- A special CME training program for primary care physicians developed and already approved by MoLHSA
- Trainings for physicians from all 4 PHCs were conducted in Tbilisi in March 2018
- Tele ECHOclinics will be implemented in these centers in nearest future.



# Completed activities (cont.)

- HCV diagnostics, treatment and care protocol specially prepared for this project.
- Integration of the project activities into national HCV elimination program approved by a Government decree.
- IT unit at MoLHSA created a separate module in national HCV elimination program database which will collect data on patients receiving diagnostics, treatment and care services at PHCs within this pilot project.

# Preliminary Results from Senaki PHC

- Number of screened on anti-HCV: 1415
- Anti-HCV+: 154 (10.9%)
- 135 specimens sent for confirmation using HCV Core Ag
- Chronic infection was confirmed in 131 cases. 124 persons returned for pretreatment evaluation.
- 40 Persons had FIB4 score  $<1.45$ . Of them 23 persons already started HCV treatment at Senaki PHC.
- 48 patients with FIB4 score  $\geq 1.45$  were referred to specialty hepatology clinics
- 36 persons are under pretreatment evaluation

# Preliminary Results from Telavi PHC

- Number of screened on anti-HCV: 163
- Anti-HCV+: 13 (7.9%)
- Specimens of 13 patients were sent for confirmation using HCV Core Ag
- Chronic infection was confirmed in 10 cases. All 10 persons returned for pretreatment evaluation. Three persons are under evaluation
- Five persons had FIB4 score  $<1.45$ . Their paperwork is under review by social service agency and they will start treatment nearest future at Telavi PHC.
- Five patients with FIB4 score  $\geq 1.45$  were referred to specialty hepatology clinics

# Future Plans

- Continuation
  - Proposal submitted to Gilead's Conquering Hepatitis via Micro-Elimination (CHIME) Program
  - 2-year period
  - Enroll additional 1,350 HCV-infected persons

# Acknowledgement

- Funding: CDC; L.I.F.E.R.
- Primary care centers

