

Georgia HCV Elimination Spring Workshop

7 & 9 March 2018

Venue: National Center for Disease Control and Public Health (NCDC), Tbilisi, Georgia

Participants: Approx. 100

SUMMARY

- Organized by: The Georgia Ministry of Labour, Health, and Social Affairs (MoLHSA) and the Georgia NCDC.
- Objective: To bring local stakeholders and program implementers together to discuss program progress, successes, and challenges and to review TAG recommendations and how best to implement the recommendations.
- Challenges remain to reach the 2020 HCV elimination goals. Decentralization of screening, care, and treatment services will play a key role in achieving the goals and Georgia is investing greatly in this strategy.
- Diversity of services is critical: Although decentralization will play a key role in reaching the goals, other service models, i.e. the existing treatment centers will continue to play an important role in guiding care and treatment services nationally and in providing care to more severely ill patients.
- Decentralization workgroups: Overall, Primary Care/Hospital, and Harm Reduction will play a critical role. Key tasks include:
 - Workgroups meet monthly and urgently develop implementation plans
 - Ensure quality monitoring and evaluation/data collection
 - Ensure lessons learned from the model/pilot programs are considered when developing National implementation plans
 - Simplified care and treatment regimens are critical. Pangenotypic regimens will play a major role in simplification
 - Partnerships will be critical to successful National implementation
- Infection prevention and control in healthcare settings is making progress and there may be opportunities to collaborate with other efforts.
- Research efforts will continue to inform the National Program, both in primary care and in harm reduction
- A need to develop policies for testing for re-infection in harm reduction settings. This requires viral core antigen or PCR testing and is not currently covered by the program. It was recommended that a free of charge annual test could be included for beneficiaries.
- Decreasing time from screening to confirmation to returning results could improve linkage to care. Efforts should be made to decrease this timeframe. Making services available to all who are confirmed with infection without committee review was recommended as a solution.
- It was recognized that drug security can be deemphasized, as drug prices have dropped greatly throughout the world.
- Information technology needs to be responsive to the program and incorporate decentralized services.
- Laboratory services need to be expanded to accommodate decentralized services.
- Decentralization of services needs to be sensitive to potential unanticipated costs such as the need for doctors in harm reduction sites.
- Decentralization to harm reduction sites could lead to more accurate data regarding numbers of PWID receiving services; however, ensuring confidentiality remains a significant barrier.
- To the degree possible, co-locating or coordinating care and treatment services between harm reduction and primary healthcare could alleviate costs and other barriers.

The 5th National Hepatitis C Elimination Workshop

Day 1 – March 7

Time	Topic	Speaker
09:30-10:00	Welcome/Introduction	David Sergeenko , Minister of Labour, Health and Social affairs Elisabeth Rood , Deputy Chief of Mission, Embassy of the US in Georgia Dr. Beth Skaggs , CDC
10:00-10:15	Media Coverage	
10:15-10:40	Review Progress of Elimination Program	Amiran Gamkrelidze, NCDC
10:40-11:00	Brief overview of agenda and purpose of the meeting	Francisco Averhoff, CDC
11:00-11:30	Coffee Break	
11:30-11:50	Decentralization HCV treatment access through decentralization of screening, care and treatment services	Eka Adamia, MoLHSA Philippa Easterbrook, WHO
11:50-12:00	- Protocol of implementation - Lessons learned from HIV scale up	
12:00-13:00	Guided Discussion to develop plan for way forward timeline for activities	MOLHSA Francisco Averhoff, CDC
13:00-14:00	Lunch	
14:00-14:20	Introduction and progress update from Primary Care and Hospitals Decentralization Workgroup	Tengiz Tsertsvadze, Infectious Diseases, AIDS and Clinical Immunology Research Center (IDACIRC) Tengiz Tsertsvadze, IDACIRC Jaba Zarqua, Mrcheveli Irma Khonelidze, NCDC
14:20-14:35	Introduction and progress update from Primary care and Hospitals W/G	
14:35-14:50	Updates on projects	
14:50-15:05	- Integrating HCV screening and simplified treatment services in primary healthcare - Simplification of pretreatment diagnostic evaluation and on-treatment monitoring procedures within HCV Elimination Project (Mrcheveli) - HIV, TB, and HCV at primary healthcare settings—A pilot project in Samegrelo-Zemo Stvaneti	
15:05-16:05	Guided Discussion to develop plan for way forward timeline for activities	Tengiz Tsertsvadze, IDACIRC
16:05-16:20	Coffee break	
16:20-16:30	Infection Control	Marina Darakhvelidze, MoLHSA Giorgi Chakhunashvili, NCDC Meghan Lyman, CDC
16:30-16:40	Improving IPC in Georgia, Future activities, gaps	
16:40-16:50	- MOLHSA Activities - NCDC Activities - CDC Activities	
16:50-17:30	Guided Discussion to develop plan for way forward timeline for activities	Marina Darakhvelidze, MoLHSA Paata Imnadze, NCDC
17:30-18:00	WHO guidance on viral hepatitis surveillance	Antons Mozalevskis, WHO
18:00-18:15	Closing Remarks	Francisco Averhoff, CDC

Day 2 – March 9

Time	Topic	Speaker
09:30-09:45	Opening/Welcome remarks	Francisco Averhoff, CDC
09:45-10:05	Integration of HCV treatment Services in Harm reduction Centers Introduction and progress update from Harm Reduction Decentralization Workgroup	Maia Butsashvili, HRU
10:05-10:20	Updates on projects Implementing HCV treatment in harm reduction centers in Georgia (HRU Project)	Maia Butsashvili HRU
10:20-10:35	FIND "HEAD-Start project in Georgia"	Francois Lamoury, FIND
10:35-10:50	Barrier Study in HR Centers	Maka Gogia, Harm Reduction
10:50-11:10	Coffee Break	
11:10-12:20	Guided Discussion to develop plan for way forward timeline for activities	Francisco Averhoff, CDC Irma Khonelidze, NCDC
12:20-13:20	Lunch	
13:20-13:40	HCV Laboratory Diagnostics Quality of HCV testing in Georgia through National External Quality Assurance Program	Dr. Beth Skaggs, CDC
13:40-14:00	Confirmation of HCV infection by Core Ag using a centralized laboratory approach	Dr. Nazi Chitadze, NCDC
14:00-14:25	Simplified diagnostics and treatment monitoring of HCV infected patients	Karla Thornton, Project ECHO
14:25-15:25	Guided Discussion to develop plan for way forward timeline for activities	Beth Skaggs, CDC Maia Alkhazashvili, NCDC
15:25-15:40	Coffee Break	
15:40-16:00	Scientific Committee Progress	Tatia Kuchuloria, CDC
16:00-16:15	Introduction of Cured Hepatitis C Patients' Association	Temur Radiani, Cured Hepatitis C Patients' Association
16:15-16:40	Blood Safety Status of blood safety program in blood banks, successes, challenges, and plans to address challenges	Eter Kipiani, NCDC
16:40-17:30	Guided Discussion to develop plan for way forward timeline for activities	Marina Darakhvelidze, MoLHSA Khvicha Getia, NCDC
17:30-18:00	Closing Remarks	David Sergeenko Francisco Averhoff

Decentralisation of HCV testing, care and treatment: Lessons learned from HIV

Dr. Philippa Easterbrook
**Global Hepatitis Programme
and HIV Department**



**5th National Hepatitis C
Elimination Workshop**
Tbilisi, Georgia
7-9 March 2018



Outline of presentation

- **HIV and HCV: Similarities and differences**
 - Common barriers to increasing treatment access
 - Common features and differences - epidemiology and treatment approach
- **Progress in global hepatitis C and HIV response**
- **Key lessons learnt from HIV/ART scale-up**
 - Testing
 - Linkage to Care
 - Treatment and Service Delivery
- **What is next?**

Common initial barriers to increasing testing and treatment access

Barrier	HIV	HCV	HBV
Limited data on epidemiological situation	✓	✓	✓
High stigma and discrimination	✓	✓	✓
Lack of political and financial commitment	✓	✓	✓
Complexity of drug regimens, high pill burden Side effects that complicate adherence	✓	✓	
Complexity of screening, treatment and follow-up monitoring	✓	✓	✓
High cost of drugs and tests	✓	✓	✓
Patenting of drugs approved and in pipeline	✓	✓	✓
Highly specialized vertical services	✓	✓	✓
Limited patient and community engagement	✓	✓	✓

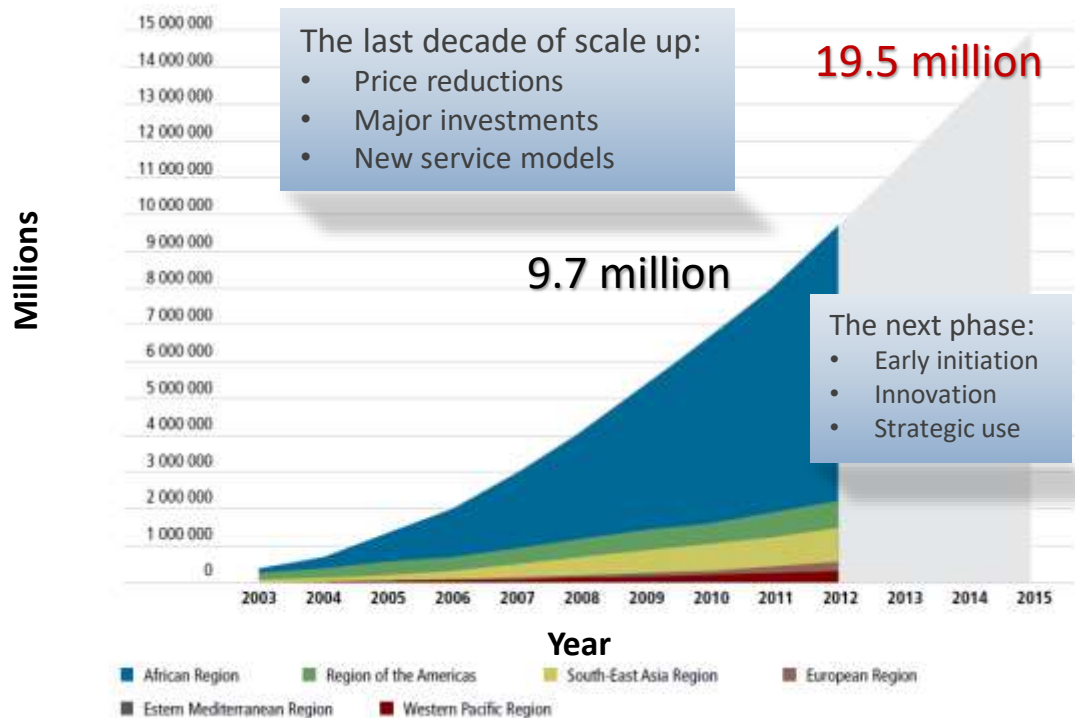
Similar, yet different....

Epidemiology and Treatment

2016/2015	HIV	HCV
Main transmission routes	Sexual IDU	Unsafe healthcare injections IDU
Burden of infection	36.7 million (HIV Ab)	71 m (HCV RNA)
Deaths per year	1 million	399,000
New infections per year	1.8 million	1.75 million
% infected requiring treatment	Treat All All HIV Ab positive	Treat All All HCV RNA positive
Treatment duration	Lifelong	12 weeks
Treatment response	70-80% HIV RNA undetectable (1yr)	>95% Cure HCV RNA undetectable (SVR12)
Numbers treated	19.5 million	3 million
% diagnosed/%treated	70%/53%	20%/7%
Funding	Global Fund/PEPFAR \$19 billion per year	Domestic

Progress in ART and DAA scale-up

ART scale up over the last decade

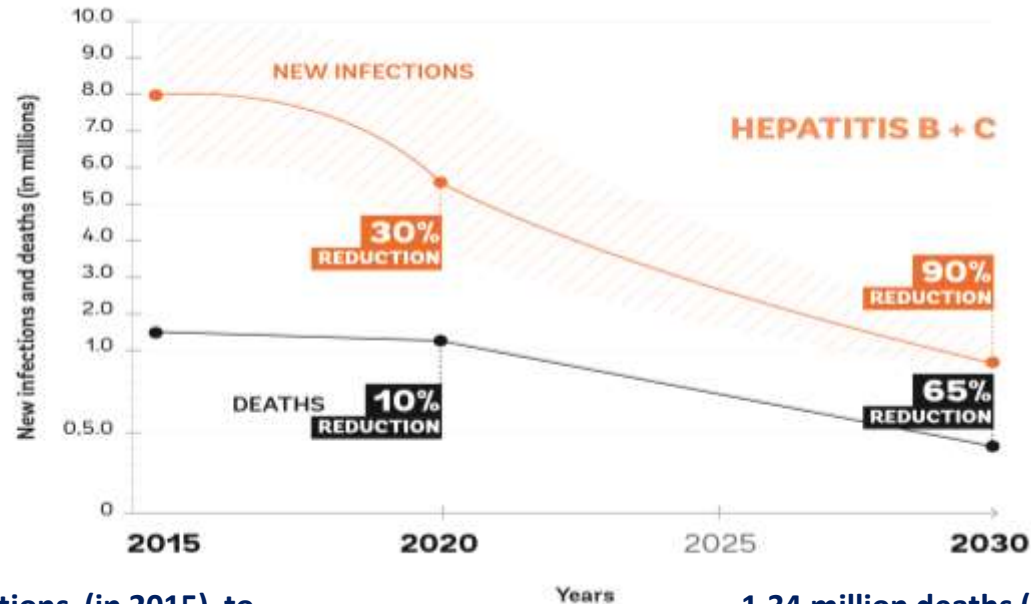


Persons starting curative HCV treatment with DAAs

- **2014:** < 200 000
- **2015:** 1.1 million
- **2016:** 1.7 million
- **TOTAL:** ~ 3 million

Source: WHO, work conducted by CDA/Polaris

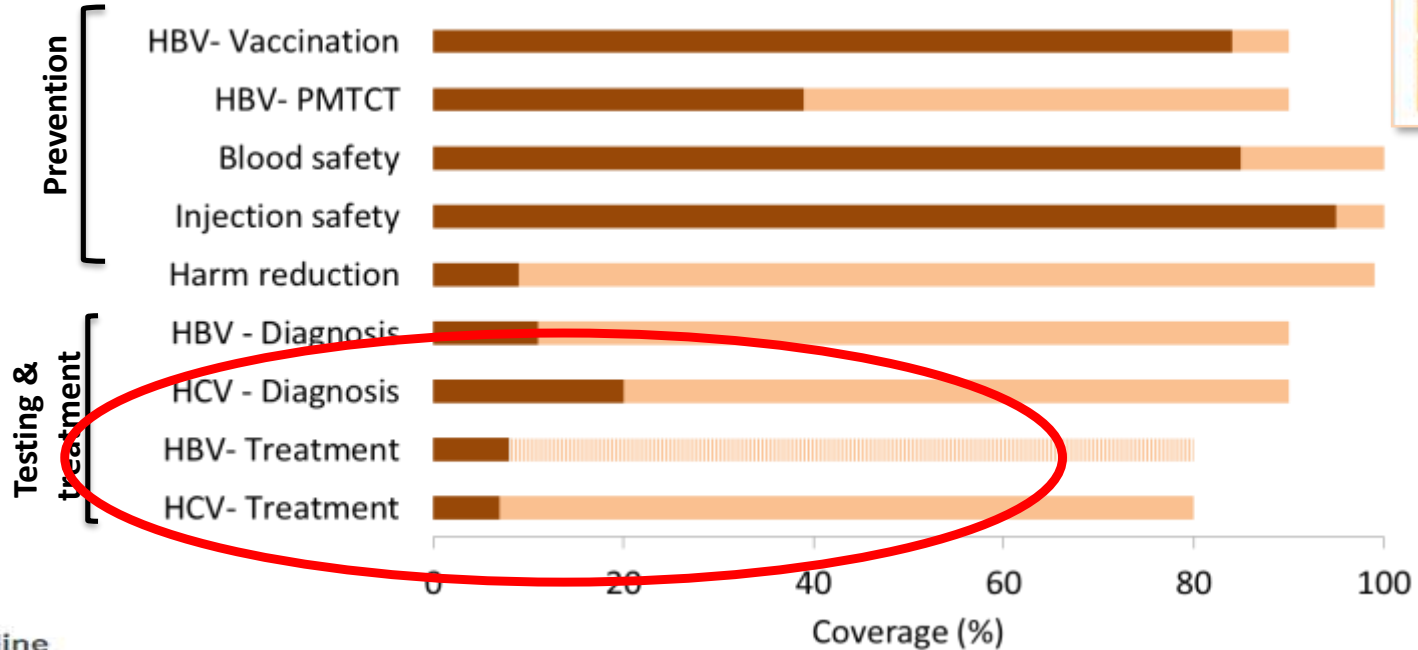
Eliminate viral hepatitis as a major public health threat by 2030, as defined by:



6-10 million infections (in 2015) to
900,000 infections (by 2030)

1.34 million deaths (in 2015) to
under 500,000 deaths (by 2030)

Global elimination 2030 targets and Where are we at now?



Global Hepatitis Report, WHO 2017

Key lessons learnt from HIV/ART scale-up

- I. The “Public health approach” to HIV care and treatment
- II. Strategies to reduce drug costs and increase access
- III. Success is possible: increasing HIV testing access/uptake
- IV. Where to test? Learning from evolution in HIV testing approaches
- V. Simplified diagnostic and management algorithms
- VI. Linkage to Care is key
- VII. Simplified drug regimens and WHO treatment guidelines
- VIII. Evolution in “when to start” ART to “treat all” in HIV care
- IX. Service delivery: Decentralization of testing + treatment and Task shifting to support decentralization
- X. Differentiated care
- XI. Integration
- XII. Tracking progress: the cascade of care

Lessons on Expanded Access to Testing

Viral hepatitis testing is at core of entry to treatment and prevention cascade

LESSON 4

Where to test? Learning from evolution in HIV testing approaches

TESTING SITES	TESTING APPROACHES	
	Routinely offered	Focused (Risk-based)
HEALTHCARE FACILITY TESTING		
Primary care settings	X	
Antenatal clinics	X	
HIV clinics	X	
TB clinics	X	
STI clinics	X	
Drug treatment and harm reduction services	X	
Inpatient and outpatient hospital settings	X	
Paediatric and adolescent clinics	X	
COMMUNITY-BASED		
Mobile/outreach testing for priority populations		X
Mobile/outreach for the general population (for example young people)		X
National testing campaigns/camps	X	X
Testing of family members		X
Partner testing (for all partners of people with viral hepatitis)		X
Mass media and social media	X	X
Home-based/ door-to-door testing	X	X
Workplace testing		X
School/educational institution testing		X

- **Health provider Focussed testing in health facilities/outreach**

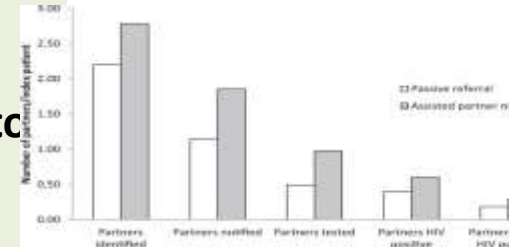
- High acceptance (HIV, antenatal & TB)
- But still many missed opportunities for testing
- Partner testing

- **Moving Testing Out of Health Center into community**

- Home-based (house to house), Campaigns, Outreach (mobile), partner, workplace

- **Lay provider testing** (already policy in 64% of SSA countries)

- **Self-testing**



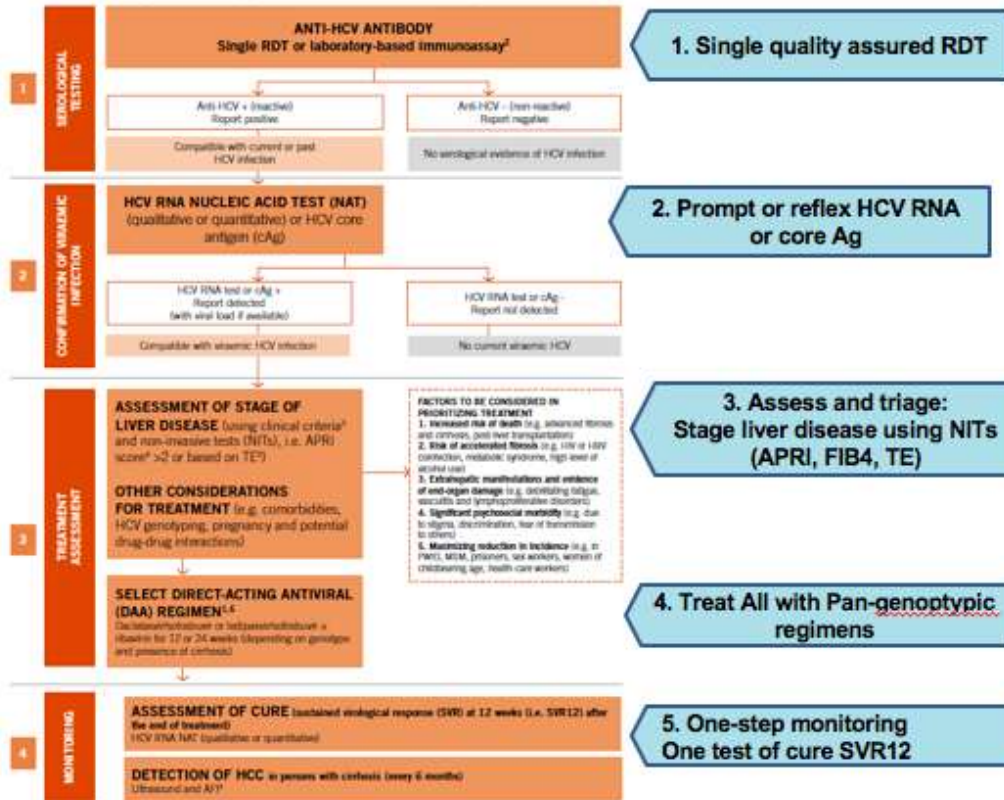
General pop testing: Egypt (village based programme), Mongolia and Georgia (PHC)



LESSON 5

Simplified testing and management algorithm

FIG.3. Summary algorithm for diagnosis, treatment and monitoring³ of chronic HCV infection



Five key steps



TESTING GUIDELINES
FOR HEPATITIS IN
MYANMAR

Lessons on promoting Linkage to Care

High rate of loss to follow up after positive serology, and low uptake of HCV RNA and access to treatment

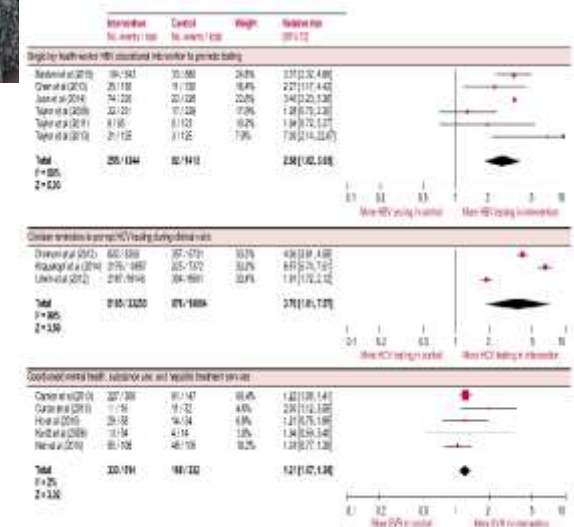
LESSON 6

Linkage to care is key (HIV and HCV)

Strategies to consider for improving linkage

Evidence is limited, but promising

- **Integration of services (testing/treatment)** at a single facility, especially within mental health/drug treatment services
- **On-site or immediate RDT testing** with same day results
- **Trained Peer and lay health worker support** to identify and reach people lost to follow-up
- **Clinician reminders** to prompt provider initiated, facility-based testing plus **reflex NAT**
- **DBS specimens** for NAT $\pm$ serology in some settings



For the future...

Decentralised viraemic testing and treatment

Lessons on Expanded Access to Treatment

LESSON 8a: - Evidence for clinical impact

Starting earlier reduces mortality and morbidity

The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 **AUGUST 27, 2015** VOL. 373 NO. 8

Initiation of Antiretroviral Therapy in Early Asymptomatic HIV Infection

The INSIGHT START Study Group*

ABSTRACT

BACKGROUND: Data from randomized trials are lacking on the benefits and risks of initiating antiretroviral therapy in patients with asymptomatic human immunodeficiency virus (HIV) infection who have a CD4+ count of more than 500 cells per cubic millimeter.

DESIGN: We randomly assigned HIV-positive adults who had a CD4+ count of more than 500 cells per cubic millimeter to start antiretroviral therapy immediately (immediate-initiation group) or to defer it until the CD4+ count decreased to 350 cells per cubic millimeter or until the development of the acquired immunodeficiency syndrome (AIDS) or another condition that dictated the use of antiretroviral therapy (deferred-initiation group). The primary composite end point was any serious AIDS-related event, serious non-AIDS-related event, or death from any cause.

RESULTS: A total of 4445 patients were followed for a mean of 3.8 years. At study entry, the median HIV viral load was 12,759 copies per milliliter, and the median CD4+ count was 671 cells per cubic millimeter. On May 15, 2015, on the basis of an interim analysis, the data and safety monitoring board determined that the study question had been answered and recommended that patients in the deferred-initiation group be offered antiretroviral therapy. The primary end point occurred in 42 patients in the immediate-initiation group (1.8%; 0.00 events per 100 person-years), as compared with 76 patients in the deferred-initiation group (4.2%; 1.28 events per 100 person-years), for a hazard ratio of 0.43 (95% confidence interval [CI], 0.30 to 0.62; $P<0.001$). Standard ratios for serious AIDS-related and serious non-AIDS-related events were 0.28 (95% CI, 0.15 to 0.50; $P<0.001$) and 0.61 (95% CI, 0.38 to 0.97; $P=0.04$), respectively. More than two thirds of the primary end point (66%) occurred in patients with a CD4+ count of more than 500 cells per cubic millimeter. The risks of a grade 4 event were similar in the two groups, as were the risks of unscheduled hospital admissions.

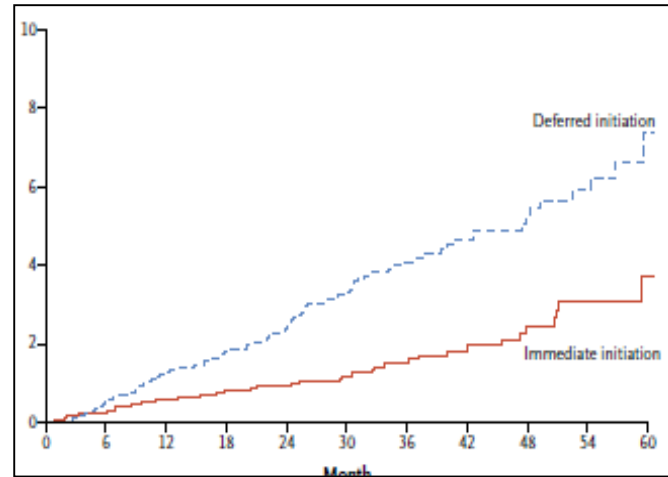
CONCLUSIONS: The initiation of antiretroviral therapy in HIV-positive adults with a CD4+ count of more than 500 cells per cubic millimeter provided net benefits over waiting such therapy in patients until the CD4+ count had declined to 350 cells per cubic millimeter, (funded by the National Institute of Allergy and Infectious Diseases and others; START ClinicalTrials.gov number: NCT00067048).

The members of the writing group (Jens D. Lundgren, M.D., Jonathan Abdo G. Babiker, M.D., Jonathan, Fred Sautin, M.D., Jonathan, Scott Henry, M.D., David Grant, M.D., Hilda Sharma, M.D., Anshu Aralingam, M.D., David A. Cooper, M.D., David H. Richman, M.D., Joseph M. Wilson, M.D., Jean-Marie Mouton, M.D., Hilda Mouton, M.D., Martin Schuster, M.D., Robert Wood, M.D., Marc J. Alagaras, M.D., Simon Collins, M.D., David A. Cooper, M.D., David A. Cooper, M.D., and James D. Nease, M.D.) received no financial support for the overall content and integrity of this article. The affiliations of the members of the writing group are listed in the Appendix. Address reprint requests to Dr. Lundgren at the Department of Infectious Diseases, Karolinska Institutet, University of Stockholm, Stockholm, S-141 86, Sweden (jens.lundgren@ki.se).

*A complete list of authors in the Study Group of Antiretroviral Therapy (START) Study Group is provided in the Supplementary Appendix, available at nejm.org.

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LESSON 8b: - Evidence for public health impact

HIV viral suppression reduces incidence

Community viral load, antiretroviral therapy coverage, and HIV incidence in India: a cross-sectional, comparative study

Sand Shrien Selvaraju, Shree HM Bhat, Aileen M McFall, Ajay K Selvaraju, Shreeganes Saravanan, Oliver Laeyendecker, Panchanan Bhatia, David D Galantzin, Suniti Selvaraju, Gregory M Luzzi

Summary

Background HIV incidence is the best measure of transmission-programme effectiveness, but its measurement is difficult and expensive. The concept of community viral load as a modifiable driver of new HIV infections has attracted substantial attention. We set out to compare several measures of community viral load and antiretroviral therapy (ART) coverage as correlates of HIV incidence in high-risk populations.

Methods We analysed data from a sample of people who inject drugs and men who have sex with men, who were participants of the baseline assessment of a cluster-randomised viral in progress across 22 cities in India (ClinicalTrials.gov number NCT01836756). We recruited the study population by use of respondent-driven sampling and did the baseline assessment at 27 community-based sites (12 for men who have sex with men and 15 for people who inject drugs). We estimated HIV incidence with a multi-step algorithm and calculated five community-based measures of HIV control: mean log₁₀ HIV RNA in participants with HIV in a community either engaged in care (in-care viral load), aware of their status but not necessarily in care (aware viral load), or all HIV-positive individuals whether they were aware, in care, or not (population viral load); participants with HIV in a community with HIV RNA more than 150 copies per mL (prevalence of viraemia); and the proportion of participants with HIV who self-reported ART use in the previous 30 days (population ART coverage). All participants were tested for HIV, with additional testing in HIV-positive individuals. We assessed correlations between the measures and HIV incidence with Spearman correlation coefficients and linear regression analysis.

Findings Between Oct 1, 2012, and Dec 19, 2013, we recruited 26 503 participants, 12 022 men who have sex with men and 14 481 people who inject drugs. Median incidence of HIV was 0.87% (95% CI 0.40–1.17). In men who have sex with men and 1.43% (95% CI 0.60–4.06) in people who inject drugs. Prevalence of viraemia was more strongly correlated with HIV incidence (correlation 0.81, 95% CI 0.42–0.93; $p < 0.0001$) than all other measures, although correlation was significant with aware viral load ($p = 0.59$, 95% CI 0.27–0.79; $p = 0.001$), population viral load ($p = 0.51$, 95% CI 0.16–0.74; $p = 0.007$), and population ART coverage ($p = 0.54$, 95% CI 0.20–0.88; $p = 0.004$). In-care viral load was not correlated with HIV incidence (0.29, 95% CI 0.10–0.40; $p = 0.14$). With regression analysis, we estimated that to reduce HIV incidence by 1 percentage point in a community, prevalence of viraemia would need to be reduced by 4.34%, and ART use in HIV-positive individuals would need to increase by 19.5%.

Interpretation Prevalence of viraemia had the strongest correlation with HIV incidence in this sample and might be a useful measure of the effectiveness of a transmission programme.

Funding US National Institutes of Health, Elton John AIDS Foundation.

Introduction

Compelling evidence of HIV transmission as prevention from clinical studies¹ and spending its highly variable global antiretroviral therapy (ART) coverage^{2,3} has focused attention on the need to monitor community-level effectiveness of ART. HIV incidence is the best possible measure of the effectiveness of transmission-prevention programmes. However, measurement of HIV incidence is difficult and expensive, and rarely done outside a research context.⁴ Researchers have proposed the measures of community viral load⁵ and population ART coverage⁶ as reporting a causal association between community-level effectiveness of HIV treatment and HIV transmission.

Community viral load, a family of measures derived from HIV RNA measurements in subgroups of individuals with HIV, has been temporally correlated

with HIV incidence or new HIV diagnoses from administrative databases in ecological studies.^{7,8} However, these measures have limitations. Community viral load data derived from administrative databases do not represent individuals who are one of care or unaware of their status—a population that has been proposed to account for a large proportion of HIV transmission.⁹ Community viral load measured in the context of a cohort study might represent individuals one of care, but it is unlikely to adequately account for individuals who are unaware of their status, because seronegative cohort participants are usually routinely tested for HIV at study visits. Some researchers have argued¹⁰ that overall tendency measures of community viral load among people with HIV do not account for HIV prevalence, which can vary widely by community.



Lancet HIV 2015; 5: e515–e524

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See Comment page e525

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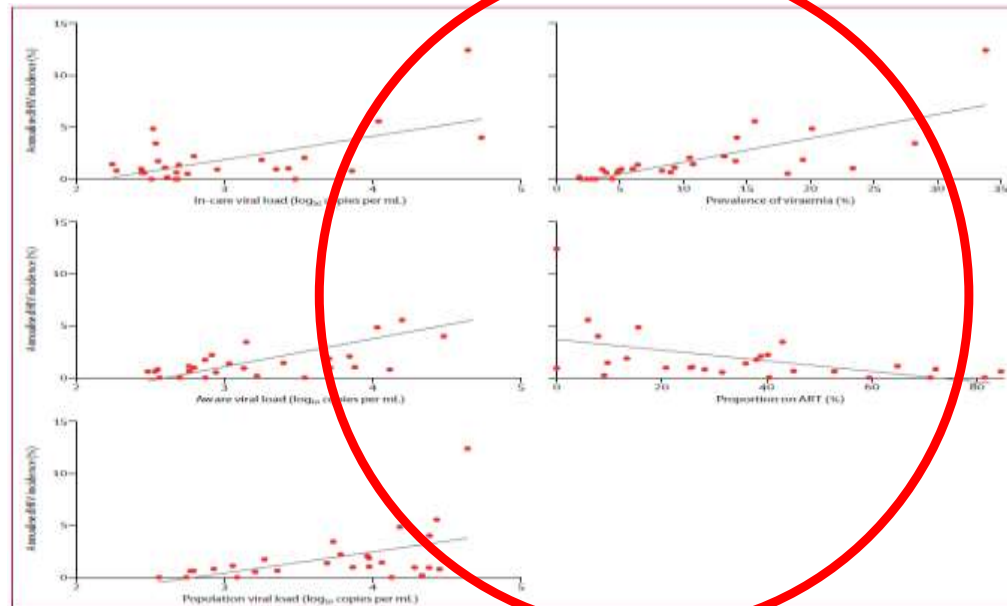
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LESSON 8c: - Evidence for programmatic impact

High rate of loss to follow up if not treated

New studies show that ART can be started on same day as HIV diagnosis

PLOS | MEDICINE

RESEARCH ARTICLE

Initiating Antiretroviral Therapy for HIV at a Patient's First Clinic Visit: The RapIT Randomized Controlled Trial

Sydney Rosen^{1,2*}, Mhairi Maskew³, Matthew P. Fox^{2,3}, Cynthia Nyoni⁴, Constance Mongwenyana³, Gliven Maletle³, Ian Sanne³, Dorah Bokaba³, Celeste Sauls³, Julia Rohr⁴, Lawrence Long⁴

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OPEN ACCESS

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Data Availability Statement: Data will be made publicly available in the Dryad repository (<http://www.dryad.org>) after the protocol has been closed (anticipated closure June 2018). Until then, data will remain under the supervision of the University of the Witwatersrand Human Research Ethics Committee (HREC). Requests should be sent to the HREC Research Administrator at: research@hrc-wits.ac.za or research@hrc-wits.ac.za.

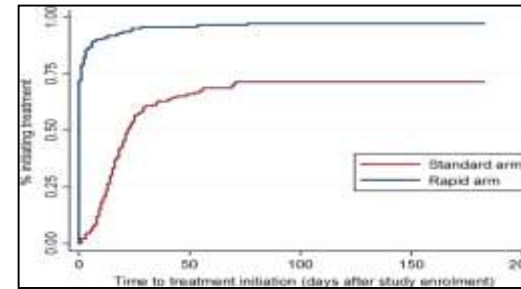
Funding: Funding for this study was provided by the U.S. National Institutes of Health (National Institute of

Abstract

Background
High rates of patient attrition from care between HIV testing and antiretroviral therapy (ART) initiation have been documented in sub-Saharan Africa, contributing to persistently low CD4 cell counts at treatment initiation. One reason for this is that starting ART in many countries is a lengthy and burdensome process, imposing long waits and multiple clinic visits on patients. We estimated the effect on uptake of ART and viral suppression of an accelerated initiation algorithm that allowed treatment-eligible patients to be dispensed their first supply of antiretroviral medications on the day of their first HIV-related clinic visit.

Methods and Findings
RapIT (Rapid Initiation of Treatment) was an unblinded randomized controlled trial of single-visit ART initiation in two public sector clinics in South Africa, a primary health clinic (PHC) and a hospital-based HIV clinic. Adult (>18 y old), non-pregnant patients receiving a positive HIV test or first treatment-eligible CD4 count were randomized to standard or rapid initiation. Patients in the rapid-initiation arm of the study ("rapid arm") received a point-of-care (POC) CD4 count if needed; those who were ART-eligible received a POC tuberculosis (TB) test if symptomatic, POC blood tests, physical exam, education, counseling, and antiretroviral (ARV) dispensing. Patients in the standard-initiation arm of the study ("standard arm") followed standard clinic procedures (three to five additional clinic visits over 2–4 wk prior to ARV dispensing). Follow up was by record review only. The primary outcome was viral suppression, defined as initiated, retained in care, and suppressed (<400 copies/mL) within 10 mo of study enrollment. Secondary outcomes included initiation of ART <90 d of study enrollment, retention in care, time to ART initiation, patient-level predictors of primary

PLoS Medicine | DOI:10.1371/journal.pmed.1002015 May 10, 2016 1/19



WHO recommendation (July 2017)

Start within 7 days of an HIV diagnosis •

Consider same day start •

Lessons on Service Delivery approaches to expand access to testing and treatment

Simplified HCV Service Delivery for a Public Health Approach

Good service delivery health practice principles

1. **Simplified and standardized algorithms**
2. **Strengthen Linkage** from testing to care, treatment and adherence
3. **Integrated** testing, care and treatment
4. **Decentralisation of care** to promote access
5. **Differentiated care** to address diverse health care needs of those with HCV
6. **Engagement with Community** and peer support
7. **More efficient procurement + supply management**

Service delivery in specific populations

- Persons who inject drugs
- People in prisons and other closed settings
- MSM and sex workers
- Adolescents and Children
- Migrant/indigenous populations
- Pregnant women

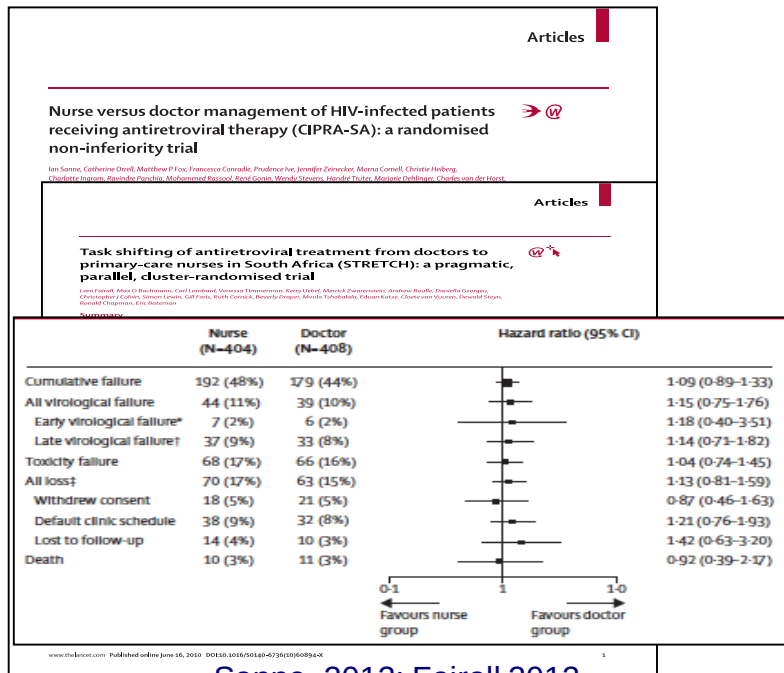


LESSON 9

Decentralization of testing and treatment supported by Task shifting

ART initiation and prescribing by nurses can be done safely, and improve health outcomes and quality of care

Time to ART initiation decreased from nearly 100 days in 2003 to less than 3 weeks in 2009



Sanne, 2012; Fairall 2012

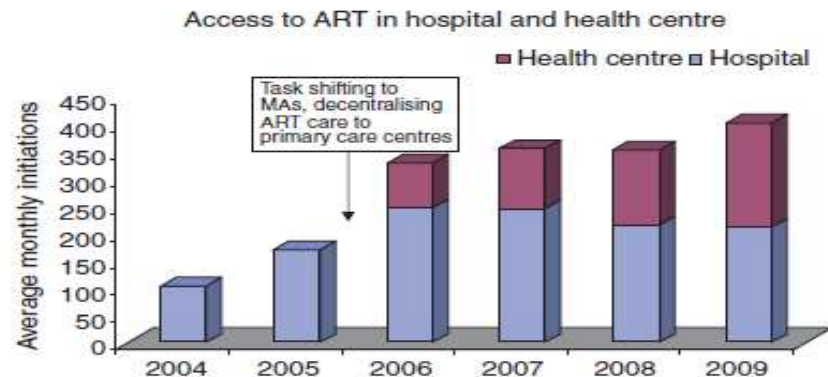
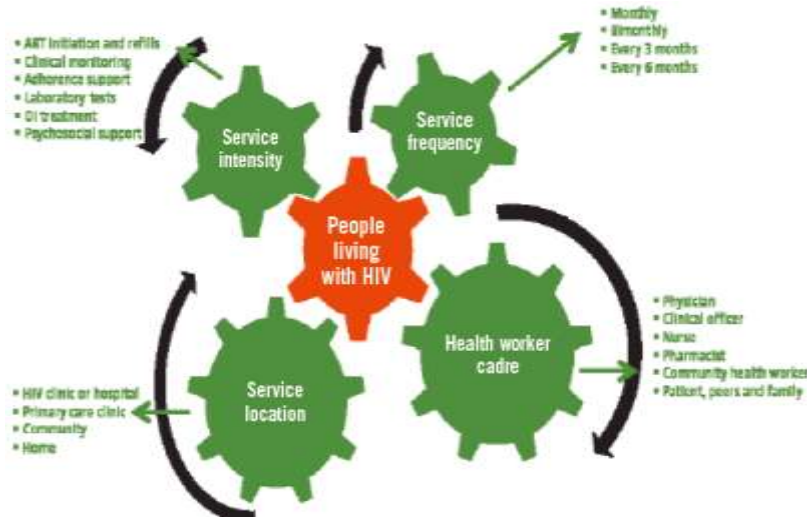


Figure 2 Access to antiretroviral therapy in Thyolo district; MA, medical assistant.

LESSON 10: - Differentiated care

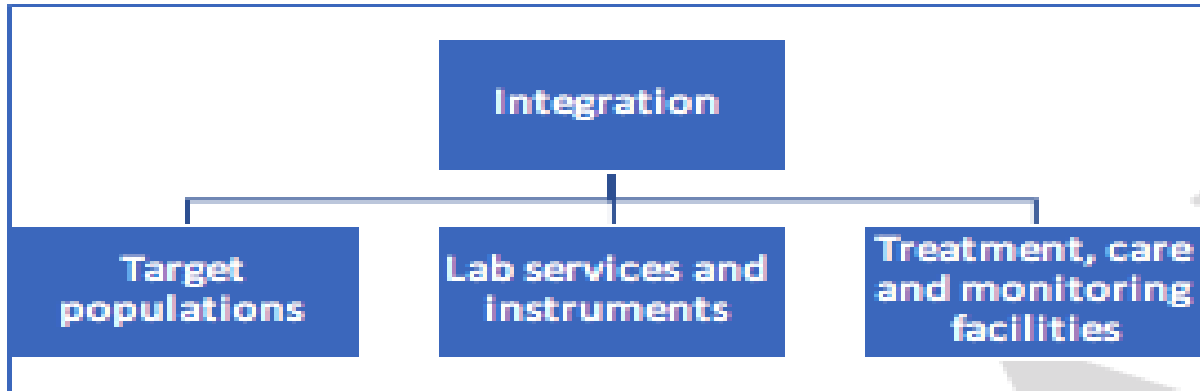
(based on evolving HIV care and treatment principles)



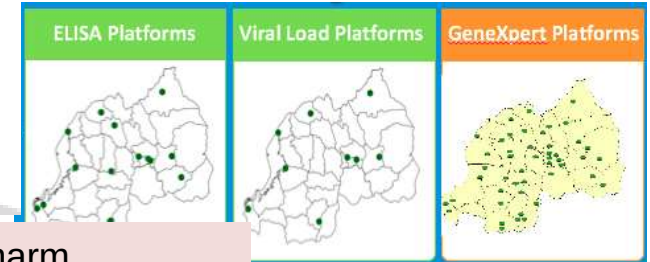
Who? HCV infected persons category	What? Care needs	Where? Site	By Whom? Care-giver
Persons clinically well and stable	Standard care package: Counselling, adherence support, treatment initiation and monitoring	Facility-based including primary care or community-based settings, including mobile/outreach	Physician or ?nurse
Advanced liver disease or serious co-morbidities, HCC, previous treatment failure	Requiring more intensive clinical support and follow-up: Management of liver related complications (eg. variceal bleed, ascites, encephalopathy, HCC treatment, genotyping)	Facility-based - hospital	Physician
Mental health issues, active injecting drug users, alcohol misuse, adolescents	Requiring more intensive psychosocial/mental health support	Can be Facility-based or Community-based, Harm reduction site	Physician and counsellor/peer support

LESSON 11

Integration



Build on substantial existing lab and diagnostics capacity: Multiplatform testing



Integration with other testing settings or opportunities eg. HIV, antenatal or TB

Integrated combo serology (HIV/HCV RDTs), including self-testing

Use of integrated multi-disease platforms for HCV RNA (centralised or decentralised)

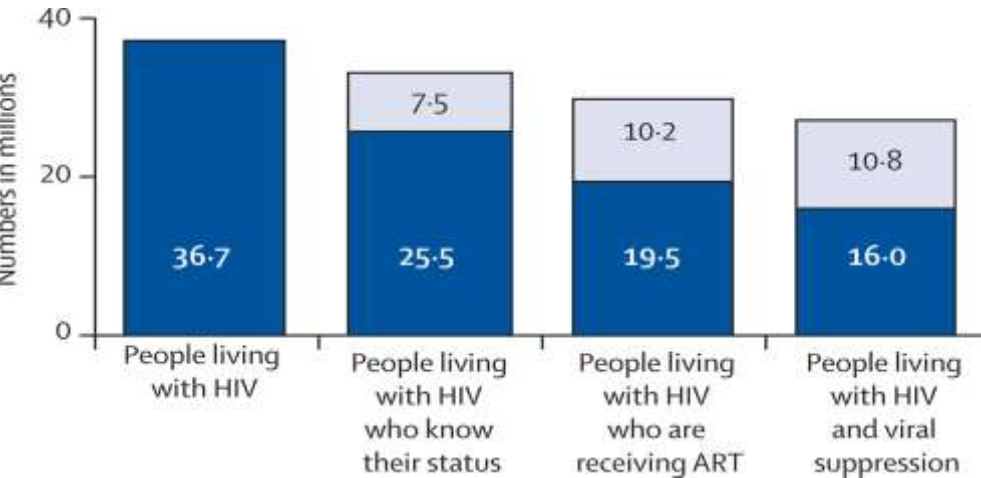
HCV care at harm reduction sites

HCV care at HIV, STI, TB clinics

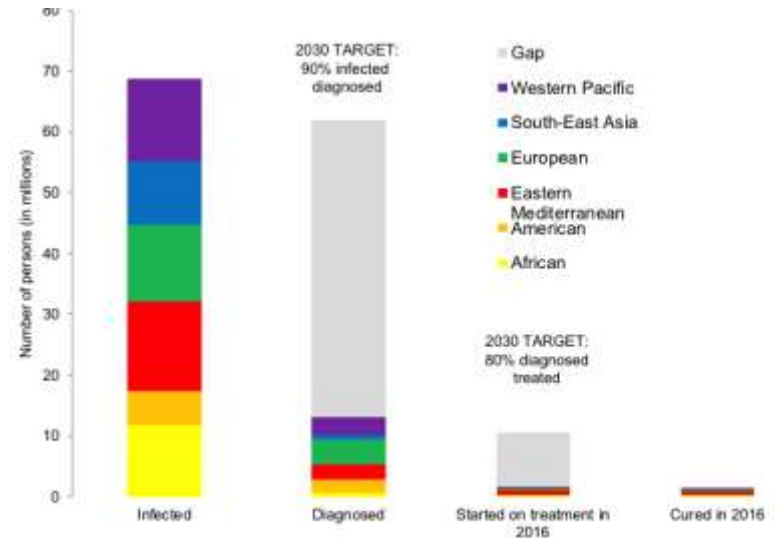
HCV care in prisons

LESSON 12

Tracking progress: the cascade of care



Cascade of care for HCV infection by WHO region, 2016



Source: WHO on the basis of Center for Disease Analysis / Polaris



Next steps

- **What more can we learn from HIV?**
 - Differentiated care, decentralization and task-shifting approaches
 - Self-testing
- **What can HIV learn from hepatitis?**
 - Demonstration projects and operational research on different models of care
- **How can we integrate better?**
 - When and how to share technologies

Thank you + Acknowledgements

Global Hepatitis Programme

Nathan Ford

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Meg Doherty

Michel Beusenbergh

Rachel Baggaley

The 5th National Hepatitis C Elimination Workshop
Tbilisi, Georgia

Introduction and Progress Update from Primary Care and Hospitals Working Group

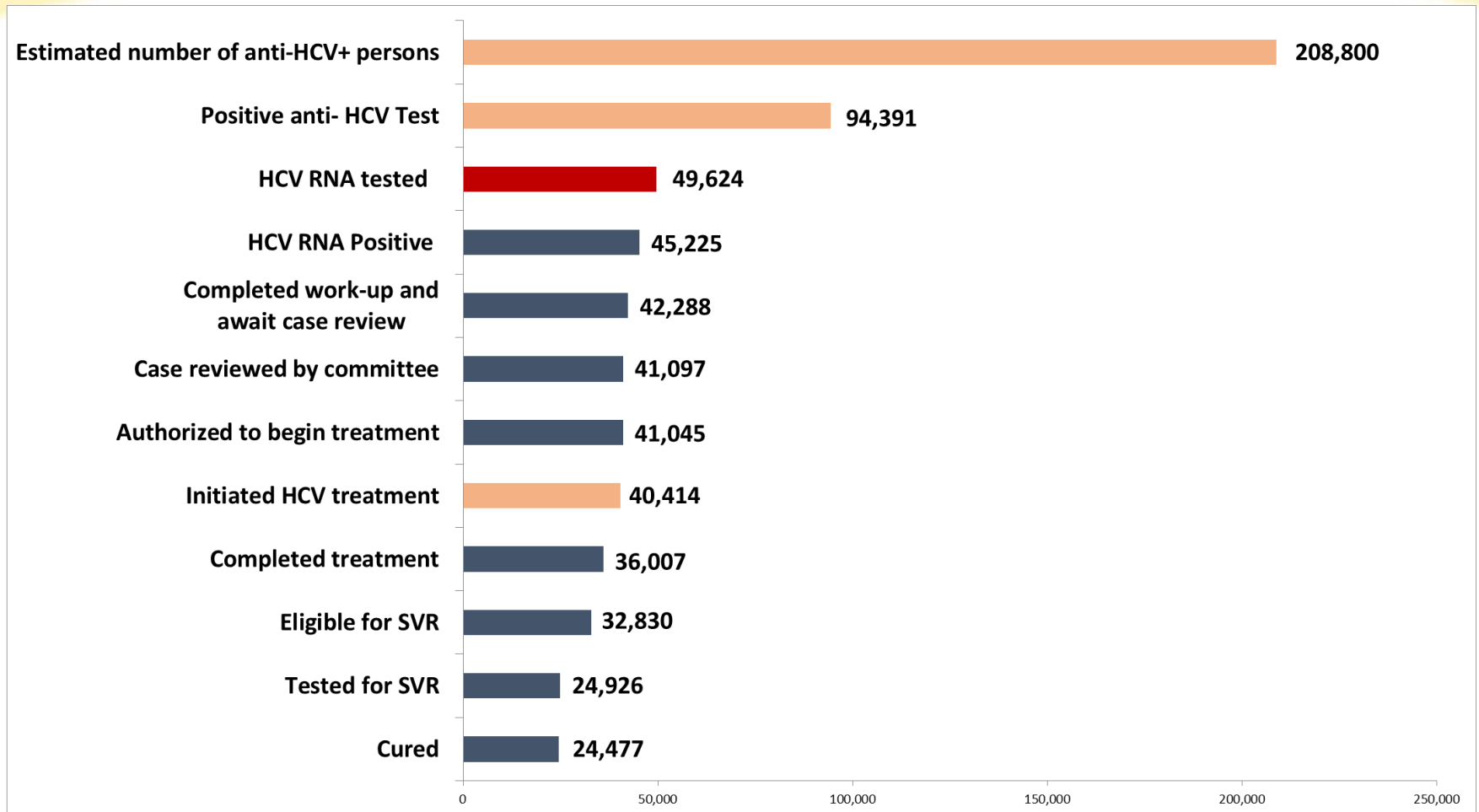
Tengiz Tsertsvadze MD, PhD

**Director General, Infectious Diseases, AIDS and Clinical
Immunology Research Center**

Professor, Tbilisi State University

Georgia Hepatitis C Elimination Program Care Cascade

April 28, 2015 – October 31, 2017



Source: Georgia's HCV Elimination Program Treatment Database

Rationale

- Increasing HCV treatment uptake is needed to achieve ambitious elimination goal
- Integrating screening and simplified treatment services in primary healthcare offers opportunity to eliminate barriers and to improve engagement in the entire continuum of HCV care
- Integrated and simplified models of care are effective in ensuring high diagnosis, treatment and large number of persons achieving SVR

First Georgia Meeting on Decentralization held at MoLHSA on December 8, 2017

Primary care /hospitals working group established

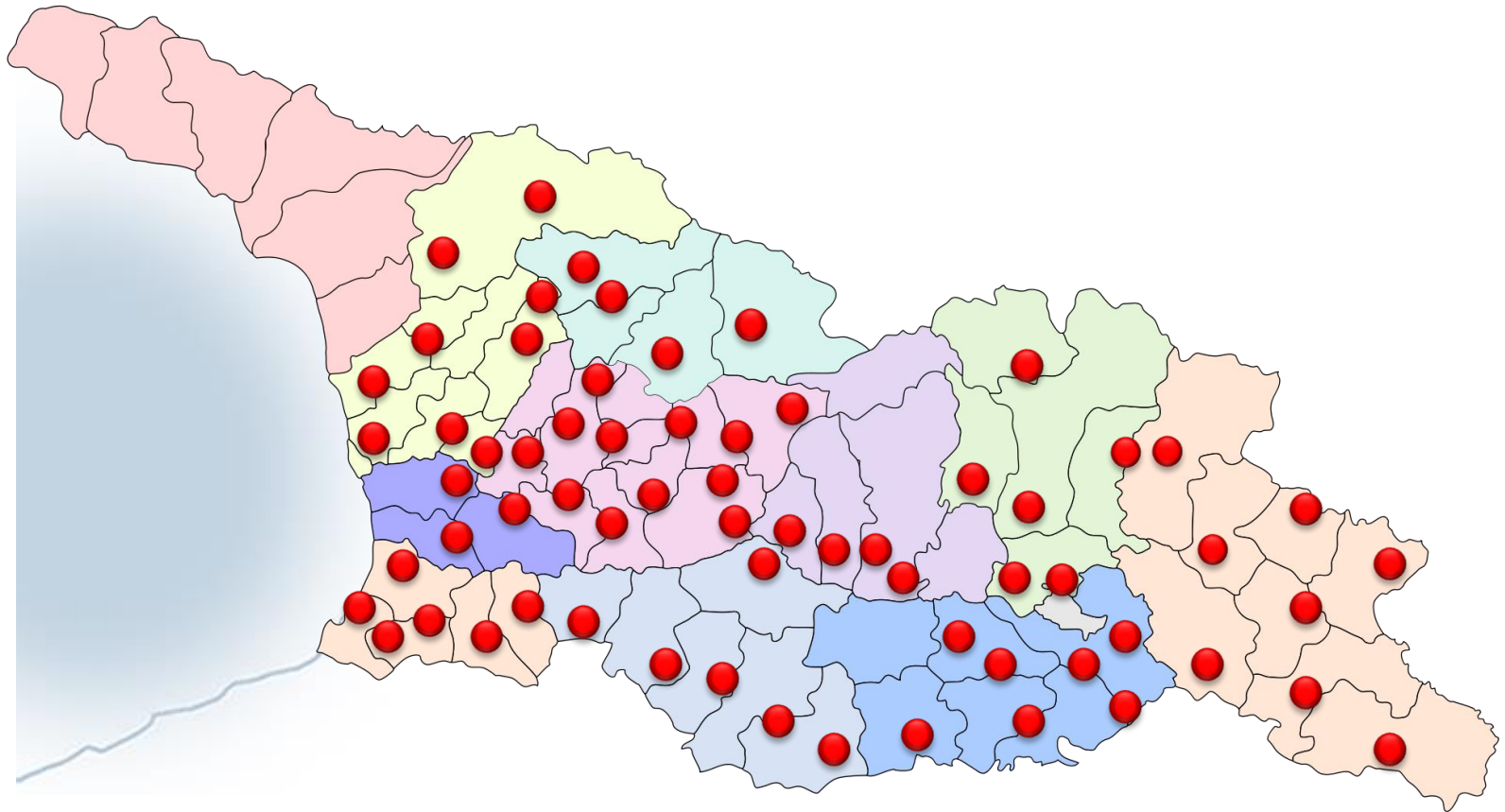
Objective

Develop a practical model of care to be implemented for HCV screening and treatment in primary health care centers and district hospitals that maximizes HCV screening, enrollment, and retention in the HCV program of the general population.

Roles and Responsibilities of Primary healthcare /hospitals working group

- Meet as a group as recommended by the oversight committee
- Adhere to timeline of task completion
- Selection of primary healthcare facilities across the country
- Develop an action plan for decentralization at PHCs and district hospitals that addresses the challenges
- Adhere to expectations of meetings, communication, documents/products set by the oversight workgroup

Decentralization of HCV treatment and care at PHCs



Major challenges

- **Simplified Treatment and Diagnostics guidelines/algorithms**
 - Necessary tests for screening; confirmatory testing; simplified pre-treatment; monitoring and follow-up diagnostics; location of testing; consolidation of testing
 - National standardized treatment guidelines; standardized medication supply chain
- **Ensure laboratory and diagnostics integration**
 - screening; confirmation; pre-treatment; monitoring and follow-up diagnostics; standardized interpretation of results
- **Develop and disseminate SOPs**
 - using simplified diagnostics plans and simplified treatment regimens

Major challenges (cont.)

- **Develop Curriculum for PHC/hospitals**
 - curriculums/training in screening, confirmation, pre-treatment, treatment and monitoring diagnostics

- **Initial and Continued training (CME) for PHC and Hospital staff**
 - areas of potential initial training; continued education/support/mentorship; in-person and teleconference modules

- **Use of ECHO platform to facilitate training**
 - curriculum development; initial training; continued education

Major challenges (cont.)

- Develop necessary information systems/modules
 - method of data collection and storage; integration into national Elim-C database; standardized data collection
- Elaborate the concept of treatment in rural areas (i.e. 69 districts)
- Incorporate lessons, findings from PHC/hospital related pilot projects into practical model/action plan



Pilot project

Integrating HCV screening and simplified treatment services in primary healthcare

This model will provide the basis for the decentralization of treatment and care in PHCs and hospitals nationwide

Completed activities

- A special accredited CME training program and curriculum for PHCs created initially for the pilot project to support training of primary care/hospitals providers countrywide
- Simplified HCV diagnostics and treatment protocols developed for the pilot project to be applied for primary care on national level
- Established ECHO telemedicine model to train and provide primary care providers and hospital staff with advice and clinical mentoring

Timeline of activities

- Simplified HCV diagnostics and treatment guideline/algorithms developed by April, 2018
- Primary care providers and hospital specialists under accredited CME training program are trained countrywide by June 2018
- ECHO telemedicine platform is expanded as a national model for using telemedicine for HCV treatment and care in rural areas by June 2018
- Laboratory diagnostics SOPs are develop and disseminated by June 2018

The 5th National Hepatitis C Elimination Workshop
Tbilisi, Georgia

Integrating HCV screening and simplified treatment services in primary healthcare

Tengiz Tsertsvadze MD, PhD

**Director General, Infectious Diseases, AIDS and Clinical
Immunology Research Center**

Professor, Tbilisi State University



Pilot project

Integrating HCV screening and simplified treatment services in primary healthcare

Objectives/specific aims

To assess effectiveness of integrated HCV screening and treatment model in primary healthcare settings

Specific aims:

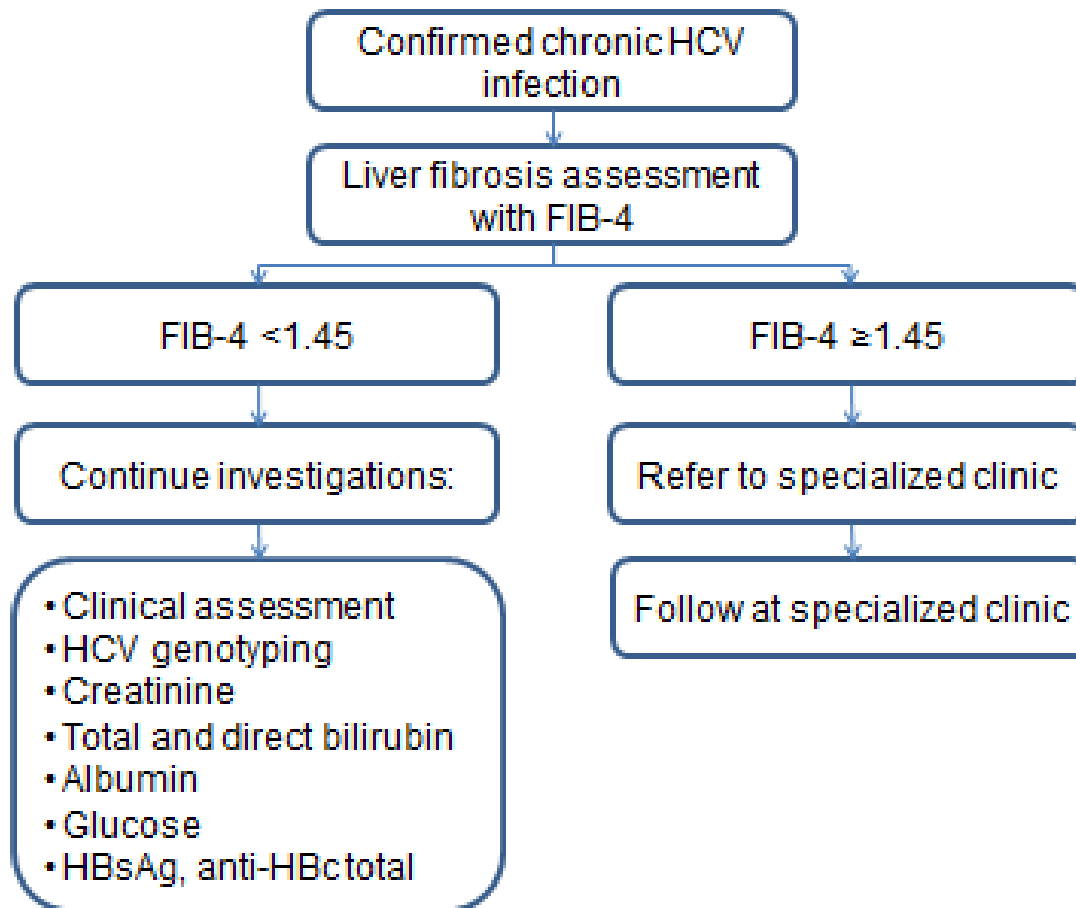
- Quantify engagement in the HCV care continuum (cascade) from screening through cure
- Assess efficacy and safety of simplified diagnostics and treatment monitoring procedures in primary healthcare settings
- Conduct cost-analysis of achieving sustained virologic response (SVR) with simplified approach and current standard of care
- Compare key project monitoring and evaluation indicators with national data

Methods

- Prospective evaluation of integrated screening and treatment program in PHCs
- Total of 4 PHCs will be selected, including one in Tbilisi and three in non-urban regional locations
- HCV screening and care services using “One stop shop” approach
- Patients will be offered anti-HCV test using an opt-out model. Same specimen will be used for confirmatory analysis
- Paperwork and registration with the MoLHSA will be completed by case managers at PHCs.
- Registered patients will be treated by primary care providers under the supervision of IDACIRC and HEPA clinic.

Pre-treatment evaluation

Algorithm for pre-treatment evaluation



Monitoring during antiviral therapy

Treatment monitoring approach will be simplified for PHCs

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

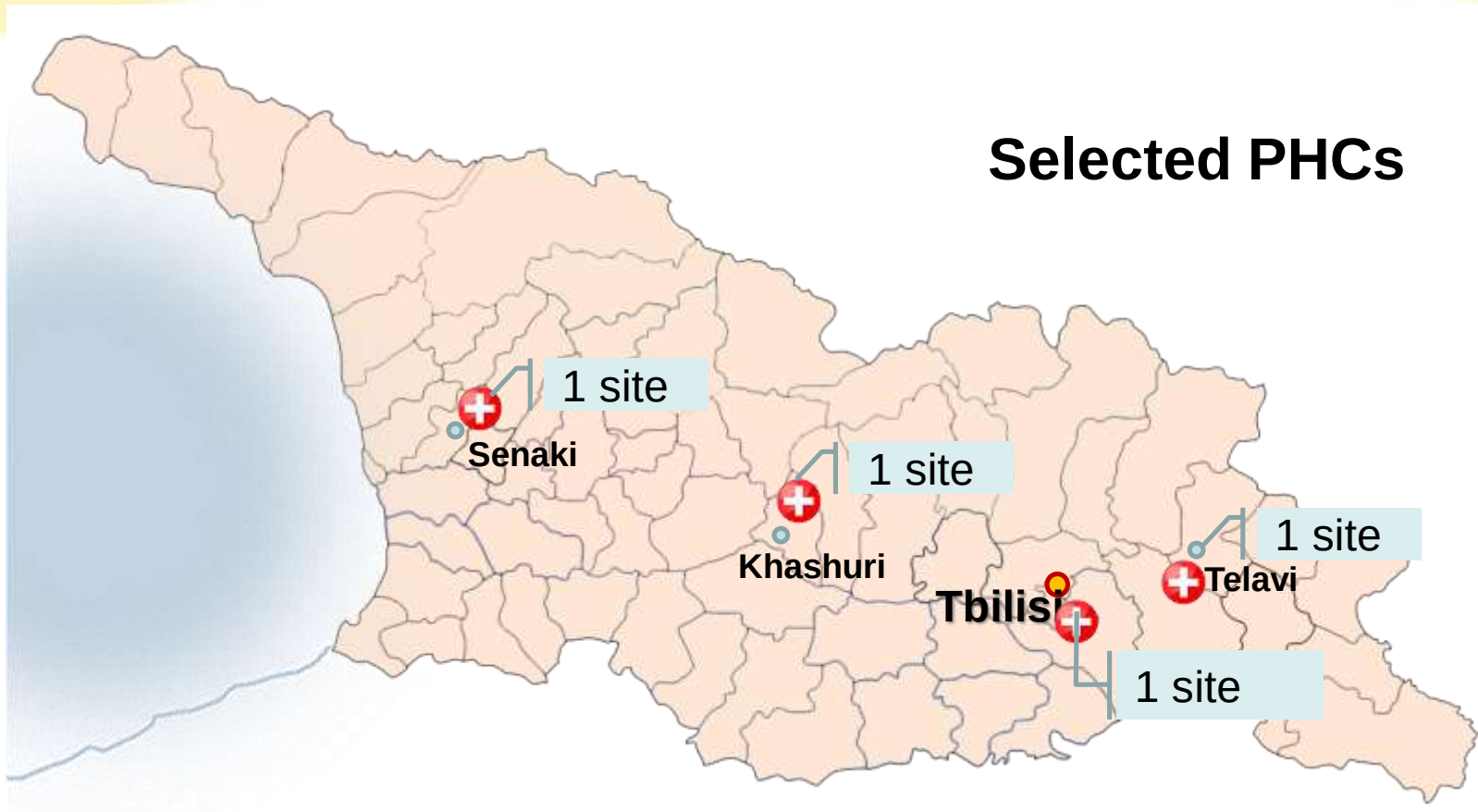
* only for patients receiving Ribavirin containing regimens

Guidance/supervision on integrated model implementation

IDACIRC and HEPA clinic together with other partners will provide guidance and supervision on integrated model implementation, including:

- Training on PHC personnel on hepatitis C related issues using
- Training on HCV rapid antibody testing
- Training on information system
- Utilizing the ECHO telemedicine model to train and support primary healthcare providers.
- Establishing M&E framework for assessing program effectiveness.

Completed activities



Completed activities (cont.)



- A special CME training program for primary care physicians developed and already approved by MoLHSA
- First training was conducted at the Family Medicine Training center in Tbilisi on March 5th.

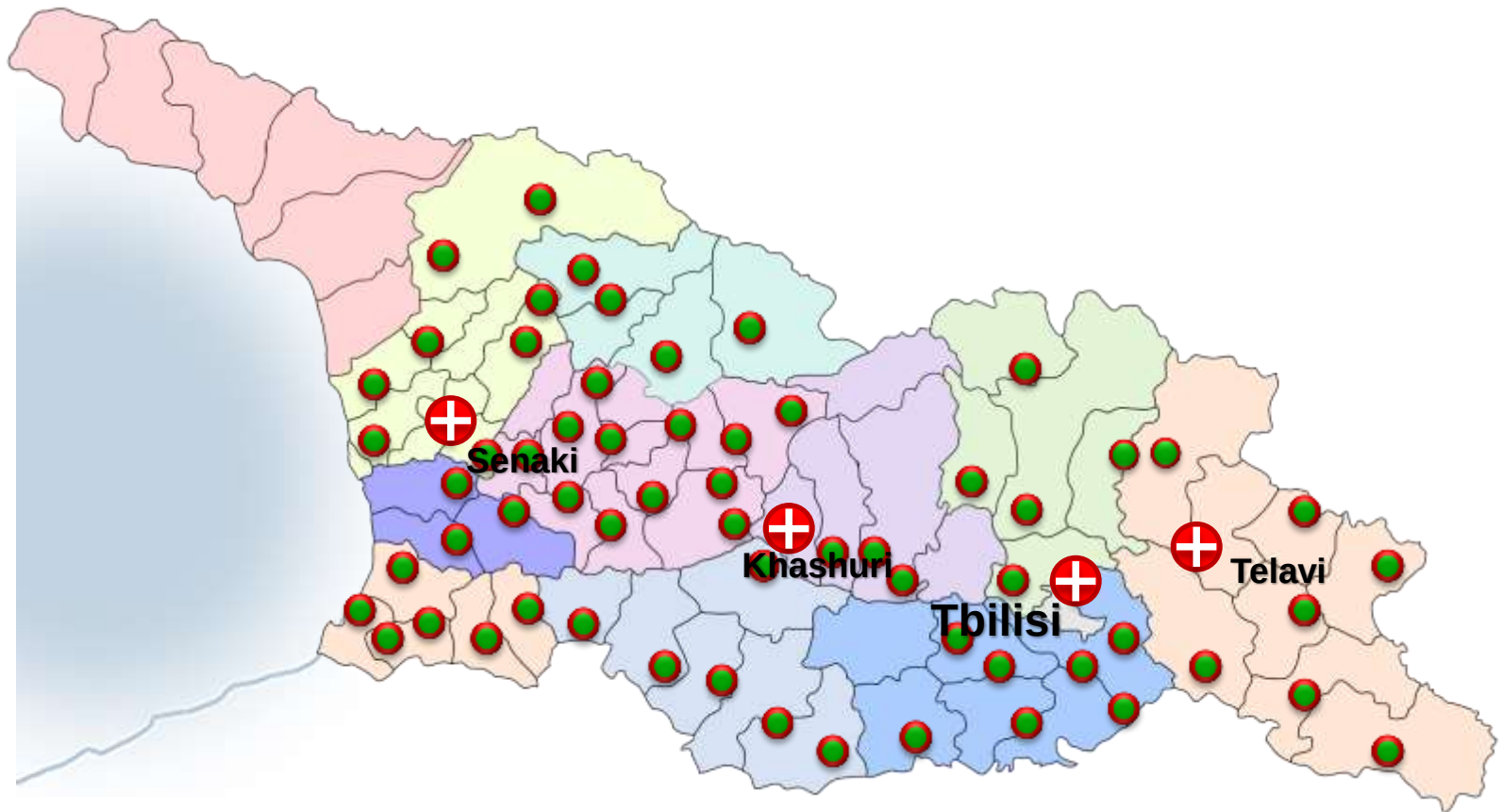
Completed activities (cont.)

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

Future plans

- Training of PHC personnel will continue
- Implementation of integrated model of HCV diagnostics and simplified treatment in PHC
- Implementation of ECHO telemedicine

Decentralization of HCV treatment and care at PHCs



Acknowledgements

Technical Advisory Group (TAG)



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John Martin, Greg Alton, Graeme Robertson



Nezam Afdhal, Stefan Zeuzem, Geoffrey Dusheiko



Sanjeev Arora, Karla Thornton



David Sergeenko, Valeri Kvaratskhelia, Multisectoral
Commission on Hepatitis C



Amiran Gamkrelidze

All HCV Clinical Care Provider Clinics

Simplification of pretreatment diagnostic and on-treatment monitoring procedures within HCV Elimination Project

The 5th National Hepatitis C Elimination Workshop

Tbilisi, Georgia, 2018

Dr. Jaba Zarkua, Medical Center Mrcheveli



Background

- From June 2016 – Treatment for all HCV infected patients!
 - Main type of patients – w/o advance liver disease.
 - Drugs available – Sofosbuvir/Ledipasvir (Harvoni) +/- Ribavirin.
 - Treatment duration – 12 or 24 weeks.
- Main problem – decreasing number of patients.
 - Screening activities (challenge for 2017, activities are on-going)
 - Linkage to care (challenge for 2018)
 - Costs
 - Low motivation of patients
 - Low level of awareness
 - Disinformation about new drugs
 - Many mandatory procedures within project, discomfort

Standard of care procedures

- 1 Step: anti-HCV(+) patient's visit to Hub, perform confirmatory test (HCV RNA PCR/HCV core AG).
- 2 Step: Patient's first appointment to physician for diagnostics. Fasting state mandatory for lab. Investigations (glucose, ALP).
- 3 Step: Second visit to physician with lab. and imaging results. Final consultation before treatment. Complete clinical records and referral to service center.
- 4 Step: Start of treatment. Visit in every 2 weeks for drug control. Monthly for lab. tests.
- 5 Step: Follow up visit after 12 weeks from completing the treatment.

12 week regimens - schedule

Procedures	Pretreatment	2	4	6	8	10	12	Follow Up
Drug Control		X	X	X	X	X	X	
Physicians Consultation	XX		X		X		X	X
HCV RNA PCR	X		X					X
HCV Genotype	X							
CBC	X		X		X*		X	
ALT	X		X		X		X	
AST	X							
Creatinine	X						X	
Bil (tot., dir.)	X						X	
Albumin	X							
PT, INR	X							
ALP	X							
GGT	X							
Glucose (f.)	X							
HBsAg, anti-HBc (tot)	X							
Ultrasound	X							
Fibroscan	If needed							

* RBV containing regimens only

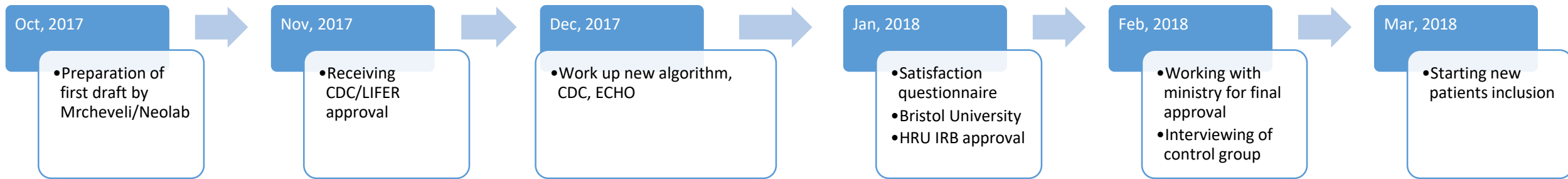
24 week regimens - schedule

Procedures	Pretreatment	2	4	6	8	10	12	14	16	18	20	22	24	Follow Up
Drug Control		X	X	X	X	X	X	X	X	X	X	X	X	
Physicians Consultation	XX		X		X		X						X	X
HCV RNA PCR	X		X											X
HCV Genotype	X													
CBC	X		X		X*		X						X	
ALT	X		X		X		X		X**		X**		X	
AST	X													
Creatinine	X						X		X*		X*		X	
Bil (tot., dir.)	X						X						X	
Albumin	X													
PT, INR	X													
ALP	X													
GGT	X													
Glucose (f.)	X													
HBsAg, anti-HBc (tot)	X													
Ultrasound	X													
Fibroscan	If needed													

* RBV containing regimens only

** RBV free regimens only

Pilot study by Mrcheveli/Neolab



Aims of the project

- **Primary aims:**

- Reduce the patient's unnecessary clinical visits.
- Reduce the patient's unnecessary visits to HCV Elimination Service Center.
- Remove the unnecessary laboratory investigations.
- Reduce the financial expanses per patient.
- Reduce the budget of the Project.

- **Secondary aims:**

- Simplified algorithm should not influence on the treatment outcome.
- Decrease the lost to follow up rates.
- Make participation in HCV Elimination Project more comfortable.

12 week regimens - Simplified

Procedures	Pretreatment	2	4	6	8	10	12	Follow Up
Drug Control		✗	X	✗	X	✗	X	
Physicians Consultation	XX		X		X		X	X
HCV RNA PCR/HCVcAg	X		✗					X
HCV Genotype	X							
CBC	X		✗		✗		✗	
ALT	X		X		✗		X	
AST	X							
Creatinine	X						✗	
Bil (tot.)	X						✗	
Bil (dir.)	X							
Albumin	X							
PT, INR	X							
ALP	X							
GGT	X							
Glucose (f.)	X							
HBsAg, anti-HBc (tot)	X							
Ultrasound	X							
Fibroscan	If needed							

24 week regimens - Simplified

[illegible]

Where are we now?

- From 1st march, 2018 – started inclusion of new patients.
- No preliminary data available for today.
- First results of project will be available for TAG-2018.

Thanks for Attention!



The 5th National Hepatitis C Elimination Workshop

HIV, TB, and HCV at Primary Healthcare Settings Pilot Project in Samegrelo-Zemo Stvaneti

Irma Khonelidze

NCDC

7 March, 2018

HIV, TB, and HCV at Primary Healthcare Settings Pilot Project Activities

Objective: To improve case detection of Hepatitis C, Tuberculosis and HIV infection at the primary healthcare settings

- Pilot Project
- Samegrelo-Zemo Stvaneti Region
- Program Launching - 25 November, 2017



HCV,TB,HIV in Samegrelo-Zemo Svaneti Region

- **HCV Prevalence** – 10.9% (Anti-HCV+) 7,27% (HCV RNA+)

Population - 330,761
≥ 18 Population - 213,194

[Georgia: 7,7 Anti-HCV+; 5,4 HCV RNA+]

- Estimated number of HCV RNA+ 15,458 (23,238 Anti-HCV+)

- **TB Prevalence*** - 113 (100,000 population)

[Georgia 77,9 (100,000 population)]

- Number of notified cases – 373 (estimated undetected cases 75(20%))

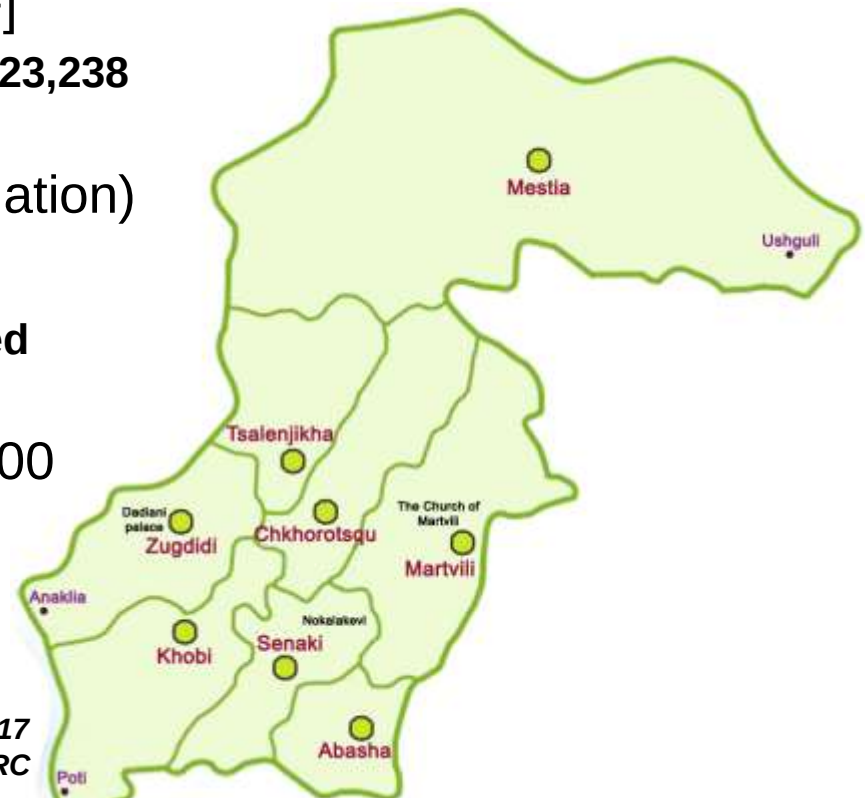
- **HIV/AIDS Prevalence**** – 208 (100,000 population, estimated)

[Georgia:145 (100,000 population)]

- Number of cases - 868

**Database, National Center for Tuberculosis and Lung Diseases, 2017*

***Database, IDACIRC*



Need for Change

Challenges

- Significant burden of three diseases TB, HIV, HCV
- Low early detection rate and screening coverage
- Weak linkage to care and retention on treatment
- Fragmentation of services and lack of coordination

Opportunities

- Universal Health Care Program
- Universal coverage of all three diseases
- High political commitment to Hep C Elimination
- Available resources to support innovations

Strategies

- Integration of Services
- Create demand – educate people, rise awareness, spread information on services
- Supply side interventions – strengthening capacity of PHC service providers, community organizations to respond to challenges
- Putting right incentives for better performance

Underlined Assumptions and Key Considerations

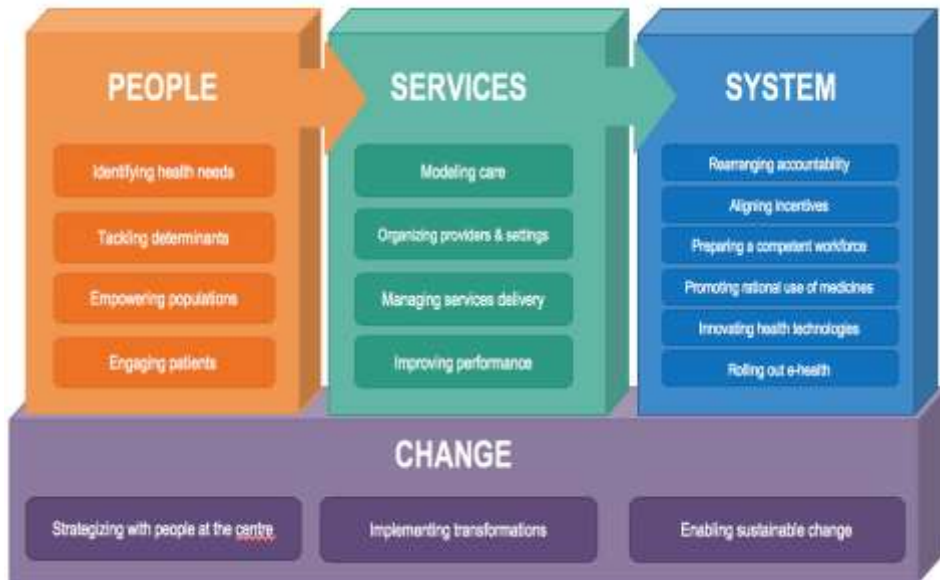


- Disease Interactions-infection with “one” makes a person more susceptible to “other”
- Transition roots, common behavioral risk factors
- Social and economic conditions - poverty, unemployment, substance use, mental illness, incarceration, social stigma, level of education
- Shared services at local level – the same providers, PH, PHC, treatment sites, shared capacity
- **Program Collaboration and Service Integration**

CDC, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention: Strategic Plan through 2020.

Strategic Framework

A people-centred approach to care WHO

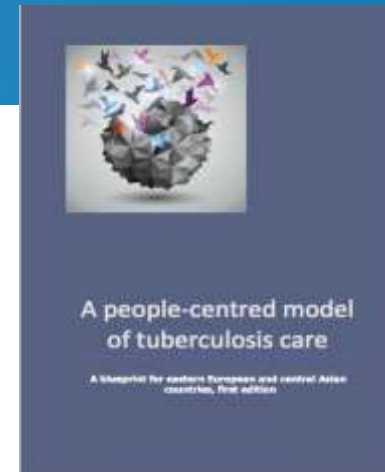


«People-centred care is focused on and organized around the health needs and expectations of people and communities rather than on patients or diseases»

Strategic Framework

A people-centred model of TB care

“An efficient and integrated set of affordable, accessible and acceptable health services, provided in a supportive environment to prevent, diagnose and treat TB”



HIV differentiated service delivery models

A client-centered approach that simplifies and adapts HIV services

“A differentiated care, is an approach that simplifies and adapts HIV services to better serve the needs of people living with and at risk of acquiring HIV and reduce unnecessary burdens on the health system”

Strategic Framework



Global health sector strategy on viral hepatitis 2016-2021



São Paulo Declaration on Hepatitis World Hepatitis Summit 2017

7. Emphasize the importance of a comprehensive, integrated and multisectoral approach that includes implementation of high-impact viral hepatitis prevention and control measures as outlined in the Global health sector strategy on viral hepatitis 2016-2021;

Need to strengthen health systems, new models of people-centered service delivery, integrated collaborative approaches and synergies between prevention and control measures for : viral hepatitis, HIV, STIs,

HIV, TB, and HCV at Primary Healthcare Settings Pilot Project Activities



- To Develop the sustainable local public-private partnership for effective integration of TB/HIC/HCV screening and early disease detection

HIV, TB, and HCV at Primary Healthcare Settings Pilot Project Activities (cont.)

- To raise awareness among all stakeholders including general public on all three diseases in the region

აივ ინფექცია და ჰილსი
გამოავლინა უმჯურნაღა შეიძლება

საპატრულო პირი აივ/რდსის მქონე ტერიტორიებში ადგილობრივად ვრცელდება არ იმის საპატრულო სტატუსი

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დღეს აივ/რდსის მკურნალობა შესაძლებელია!

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www.ncdc.ge

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საპატრულო პირი ც პეპსიტიმდებელი ინფექციის მქონე პაციენტებისა და სხვა პირების საპატრულო სტატუსი

➔

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დღეს ც პეპსიტი იკურნება!

მისამართი მონიტორინგი: 1505 16 116001 www.moh.gov.ge
www.ncdc.ge

ტუბერკულოზი **UNITE TO END TB**
გამოავლინა უმჯურნაღა შეიძლება

საგანგებო შემთხვევაში აივ/რდსის, ც პეპსიტიმდებელი და ტუბერკულოზის გამომწვევის ხელშეწყობა პირველად განხილვისთვის

➔

დღეს ტუბერკულოზი იკურნება!

საინფორმაციო ცენტრი: 1505 16 116001 www.moh.gov.ge
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HIV, TB, and HCV at Primary Healthcare Settings Pilot Project Activities (cont.)

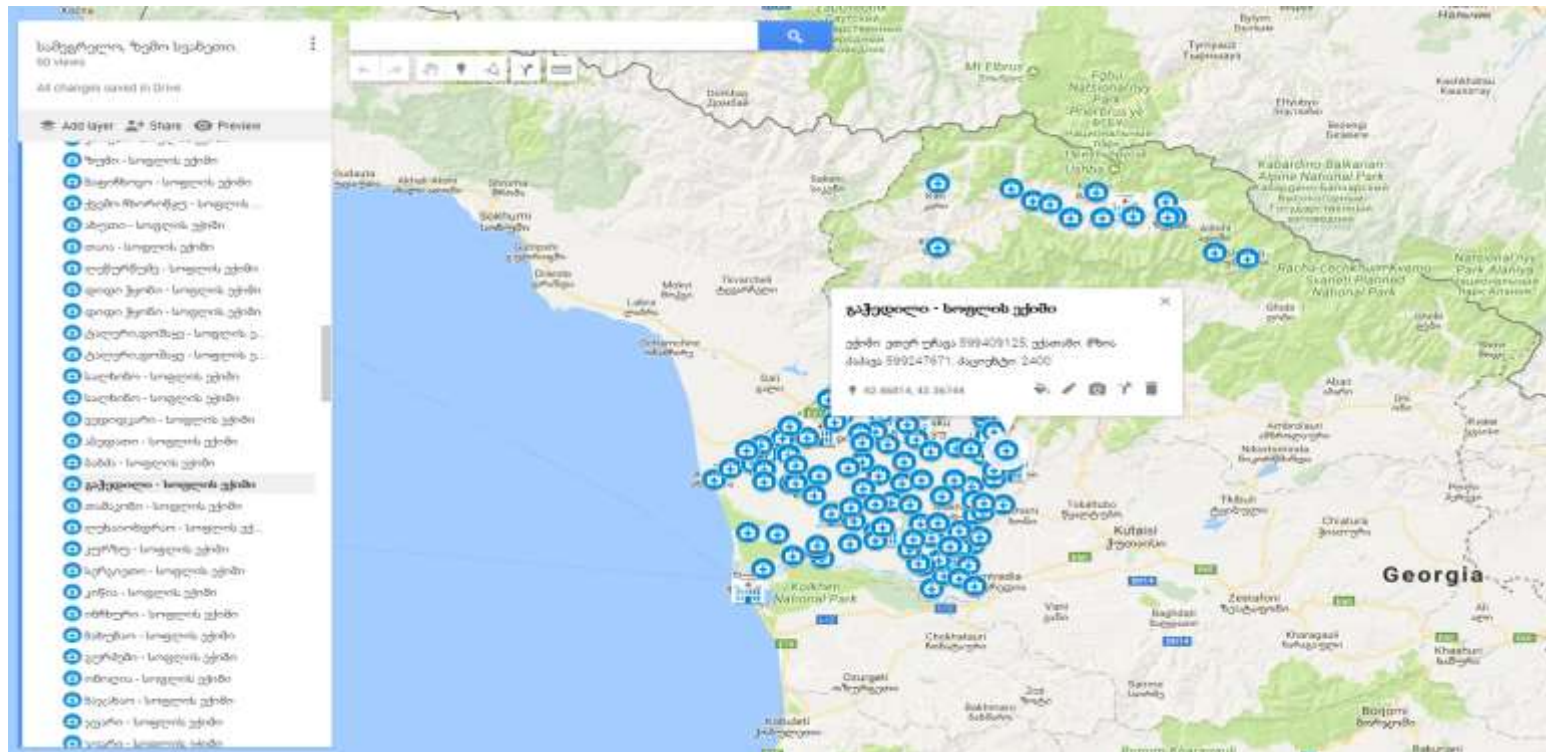
- To strengthen PHC through development of integrated TB/HIV/HCV screening model with detailed protocol

[illegible]

HIV, TB, and HCV at Primary Healthcare Settings

Pilot Project Activities (cont.)

- To map the service providers at the regional level and establish effective referral systems to specialized clinics
- 200 doctors and 200 nurses, local health managers
- MoUs with private service providers



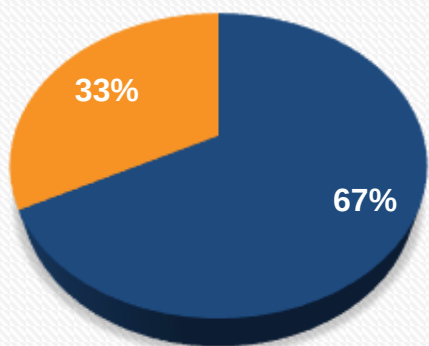
HIV, TB, and HCV at Primary Healthcare Settings Pilot Project Activities (cont.)

Ongoing activities

- Building the providers' capacity and increase the stakeholders' engagement in service quality monitoring;
- Meeting individually with established groups and initiate active implementation of integrated screening protocol;
- Visiting sites (including village level) for supportive supervision, individual needs assessment and additional training;
- Training of 200 doctors and 200 nurses;
- Developing municipal programs to incentivize service providers;
- Testing – from April, 2018

HIV, TB, and HCV at Primary Healthcare Settings Pilot Project Activities (cont.)

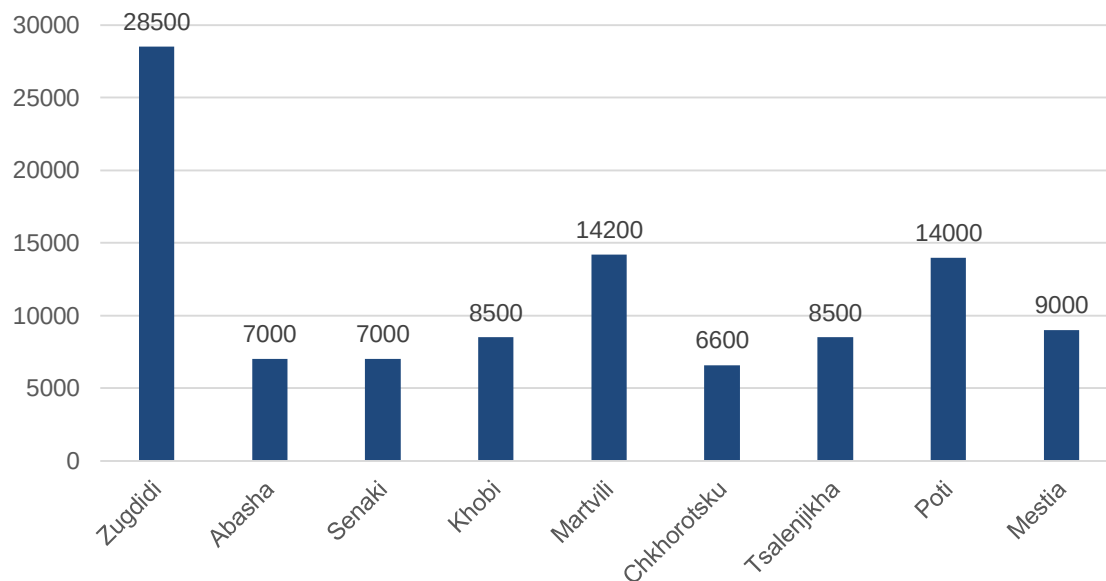
Regional Targets



■ Population above 18 ■ Pilot target

April –October, 2018

Screening Targets by Districts



Partners

- *Ministry of Labour, Health and Social Affairs*
- *National Family Medicine Training Center*
- *National Center for TB and Lung Diseases*
- *Infectious Diseases, AIDS and Clinical Immunology Research Center*
- *Local governments*
- *Private service providers*

Thank You!





საქართველოს შრომის,
ჯანსაღობისა და
სოციალური დაცვის
მინისტრეტი

Infection Prevention and Control in Healthcare facilities

Ministry of Labour, Health and Social Affairs of Georgia



Marina Darakhvelidze
Head of Health Care Department



Infections Control Regulating Documents

- "On approval of the rules for surveillance, prevention and control of nosocomial infections" - Decree of the Minister of Health №38 of September, 2015
- „On Approval of Technical Rules of Disinfection and Sterilization in Medical, Public Health and Institutions of public importance” - Governmental Decree №185 of April, 2015
- Technical regalement - “Management of medical waste”, Governmental decree №294, 16th of June, 2017
- “National strategy on antimicrobial resistance for 2017-2020”- Governmental decree №29, 11th of January, 2017
- National guideline on infection control in medical institutions (Approved by decree of the Minister of Health №148 /o of 2009)



საქართველოს შრომის, ჯანმრთელობისა და სოციალური დაცვის სამინისტრო

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MINISTRY OF LABOUR HEALTH AND SOCIAL AFFAIRS OF GEORGIA

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შრომა

ანგარიშები

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ცხელი ხაზი



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ცვლილებები
"სამედიცინო
მიმწოდებლების
შესახებ"

პასპორტიზაციის
შესახებ"

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რეცეპტის სისტემა

დედათა და ბავშვთა
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ძუძუს კიბოს გავრცელება
პერსპექტივით



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Guidelines



Classifiers

Professional competences of medical specialties

საანგარიშგებო მართლმსაჯულებრივ მენეჯერულ და სოციალურ სფეროში, სამსახურში

Legislation

Projects



Infection control in health facilities

Normative base

Requirements

Infection control in health facilities

Normative base

Requirements

Methodology

Administration

Reports

Disinfectants



SOCIAL SERVICE AGENCY



LEPL STATE REGULATION AGENCY FOR
MEDICAL ACTIVITIES



STATE FUND FOR PROTECTION AND
ASSISTANCE OF (STATUTORY) VICTIMS
OF HUMAN TRAFFICKING



SOLIDARITY FUND

Differential packages have been
launched in the universal health

launched in the universal health

www.moh.gov.ge



Recent legislative changes

- “On approval of assessment tool for monitoring infection control system of in-patient hospitals” - Decree of Minister of Health №01-9/o, 18th of January, 2016
- “On approval of first stage plan and assessment tool for monitoring infection control system of in-patient hospitals” - Decree of Minister of Health №01-45/o, 15th of February, 2017
- “On approval of second stage plan and assessment tool for monitoring infection control system of in-patient hospitals”- Decree of Minister of Health №01-173/o, 3rd of August, 2017.
- “On Approval of the First Round Implementation Plan of Infection Control Monitoring System in Inpatient Medical Institutions in 2018”
Decree of Minister of Health №01-54/o, 22nd of February, 2018
- *Update of infection prevention and control guideline is under development*



IPC legislative Requirements Administration and enforcement mechanism

- “On Approval of the Regulations on the Rules and Conditions of Issuance of Licenses for Medical Activities and Permits of Inpatient Institutions” -Decree No. 385 of the Government of Georgia of December 17, 2010.
- “On approval of the Regulations on the Rules for High Risk Outpatient Medical Activities” -Decree No. 359 of the Government of Georgia of November 22, 2010 .

It is administered by the State Regulation Agency for Medical Activities by selective control of permit/license conditions. The process also provides for the imposition of a penalties, if permit/license/high risk medical activities conditions are not satisfied



IPC legislative Requirements Administration and enforcement mechanism

- "On some measures to be taken for the purpose of transition to universal healthcare"- Decree No. 36 of the Government of Georgia of February 21, 2013
- "On Approval of Rules for Evaluation of Infection Control System in Inpatient Medical Institutions within the State Program of the Universal Health Care" -Decree of Minister of Health №01-5/n, 7 of February, 2018

The subjects, participating in the program, are obliged to take into account the recommendations issued during the monitoring of the infection control system, otherwise the participant status will be stopped



Monitoring of IPC Systems Functioning in inpatient Health Care Facilities

- Since 2016 monitoring in medical institutions of the country is conducted in the mode of assessment of the functioning of the IPC system in inpatient medical institutions. Monitoring is coordinated by the Health Care Department at the Ministry and in conjunction with the NCDC. Monitoring is carried out by the method of Supporting Supervision
- Monitoring area
 - ✓ Inpatient Medical Facilities ≥ 150 beds in Tbilisi
 - ✓ Inpatient Cardiac Surgical Service providers in Tbilisi
 - ✓ Third level perinatal service providers
 - ✓ With the permission of Reanimation of Tbilisi Facilities ≤ 40 beds
 - ✓ Inpatient medical facilities in Kutaisi and Batumi



Goals of Monitoring

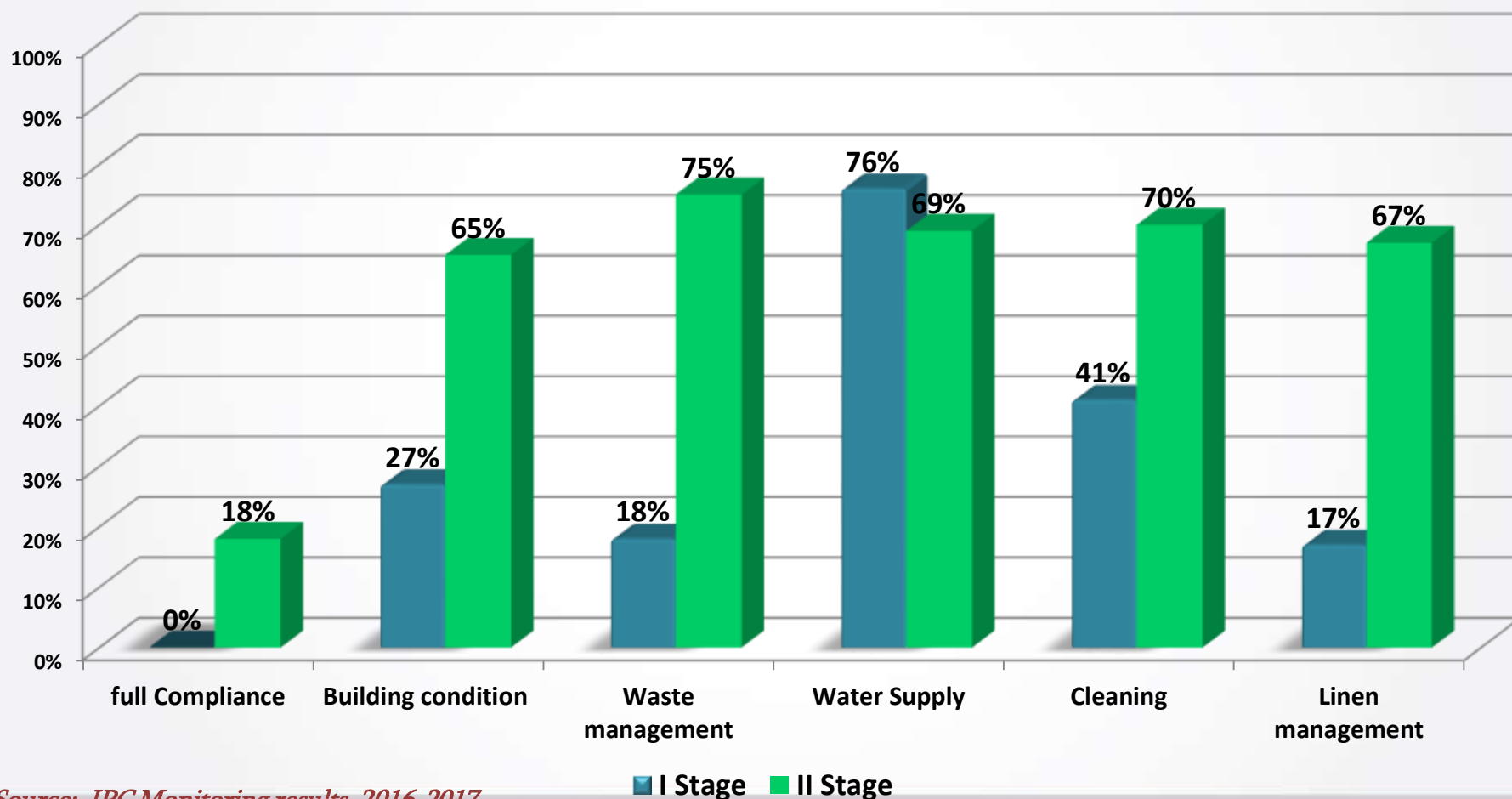
On each institution level the infection prevention and control system

- Evaluation of capabilities and support supervision
- Evaluation of the necessary infrastructure and supplies for functioning
- Discover strongholds and follow it further
- Increase awareness of the requirements within the national regulations
- Find disadvantages and develop recommendations, methodological assistance in place
- Identify systemic problems and plan activities to eradicate them



IPC Monitoring results

I-II Stage (Environmental Assessment Component) 66 Establishment

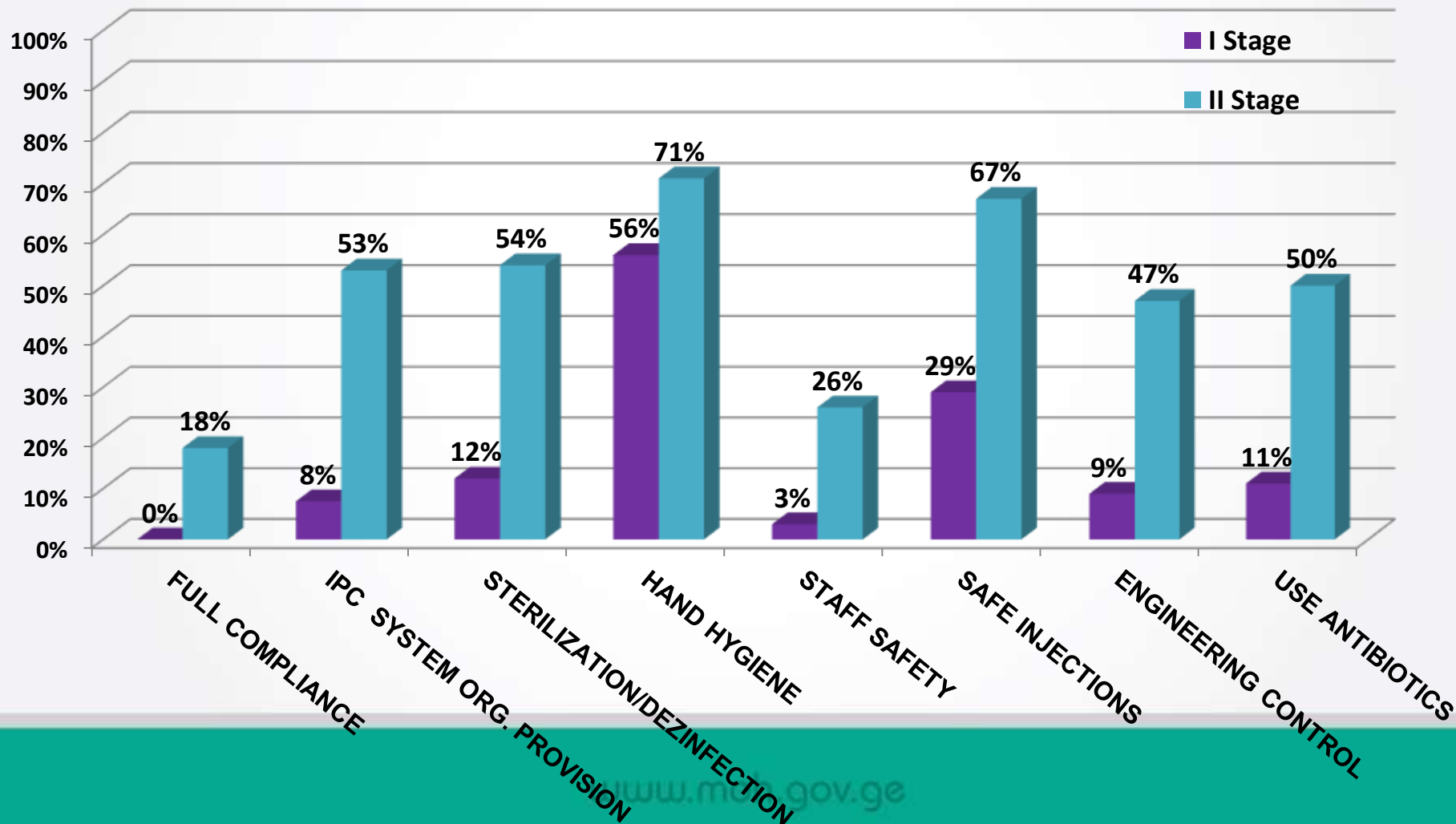


Source: IPC Monitoring results, 2016-2017



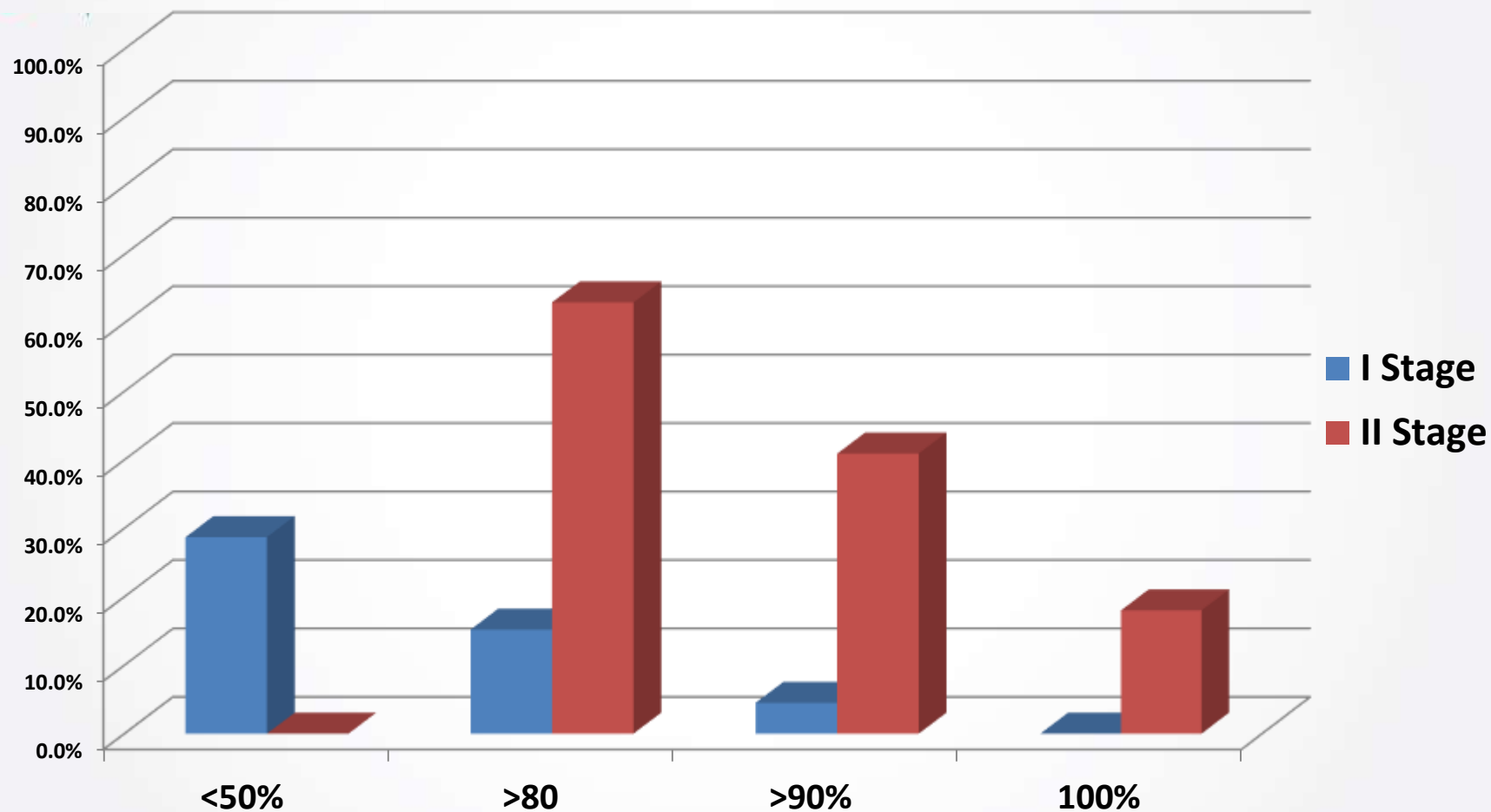
IPC Monitoring results

I-II Stage (component of IPC measurement assessment) 66 Establishment





Conformity indicator with the criteria for infection prevention and control measures





Healthcare settings - Gaps

- Although regulations are in place to mandate IPC in health-care facilities, these regulations are not well enforced
- Most hospitals have no internal policy on the safety and hepatitis B vaccination for high-risk groups of HCWs (only 26% of institutions in the second stage of the monitoring have satisfied these criteria fully)
- At the second stage of the monitoring, 33% of the institutions do not meet the safeguards of safe injection practice
- The problem still remains to identify, register and report nosocomial infections by institutions, more than 50% of institutions fail to fulfill this obligation



Priorities for 2018

Improving of legal and regulatory framework:

- Develop/update the healthcare workers and **patients safety policy** (screening, immunization, post-exposure prophylaxis), review, recognition and implementation
- Revision and modification of the acts regulating the infection control and prevention measures in a medical institution
- Acceptance and Implementation of New Guidelines for Infection Control and Prevention
- Development of educational materials on IPC-related topics for medical personnel training of medical personnel on IPC-related topics
- In 2018, will be continue **Supportive Supervision** Monitoring of inpatient medical institutions in the country

Thank you for your attention!



Infection Prevention and Control in Georgia: Current and Future Activities

Giorgi Chakhunashvili MD, PhD

National Center for Disease Control and Public Health
Georgia



National Guideline on Infection Prevention and Control (IPC)

- In 2009, the first National Guideline on “Infection prevention and Control in Healthcare Facilities” was then developed and published in 2009. Currently, it is being updated with the support of US CDC
- Guideline on “Infection prevention and Control in Dental Settings” was then developed and published

National AMR Strategy: Strengthening IPC

Activity	Anticipated Outcome	Indicator
Establishing infection control committees at hospitals and strengthening surveillance of their performance; Updating documents and preparing protocols, guidelines and other information material, regulating infection prevention and control at health-care facilities and ensuring their communication	Effective organizational control systems for infections at inpatient health-care facilities will be ensured	Infection control committees are established at hospitals and their adequate performance is ensured Documents, protocols, guidelines and other information material, regulating infection prevention and control at health-care facilities are in place

Previous Awareness Campaigns on IPC

Healthcare workers

- 320 nurse received trainings on IPC (short-term)
- 40 hospital-epidemiologist received trainings on IPC (short-term)
- Long-term post-graduate educational course on IPC has been developed



Non-healthcare workers

- Training of non-medical facility staff on IPC-related topics

General population

- Mass media campaigns

IPC in Dental Settings

- Guideline on “Infection prevention and Control in Dental Settings” has been developed and implemented
- Strengthening of IPC programmes in dental settings
- About 5,000 personals of dental settings received trainings on IPC



Collaboration with Sanford Guide

- Sanford Guide to Hepatitis Therapy Android app and website in Georgian language
 - Disease characteristics
 - Information on drugs
 - Prevention
 - Dosage calculation
- Sanford Guide to Antimicrobial Therapy in Georgian language (hardcopy and web-edition) will be updated in 2018



Non-traditional healthcare and other community settings – M & E indicators and targets

- Activities to improve IPC in non-healthcare settings:
 - State regulations and policies of IPC during aesthetic and cosmetic procedures are updated and published online
 - SOPs on sterilization, disinfection, and waste management available in non-medical facilities
 - Number and percentage of non-medical facility staff trained
 - Degree to which sterilization, disinfection, and waste management SOPs are followed

The following activities are planned

- Strengthening IPC programmes in hospitals
- Surveillance of the antibiotic use
- Promotion of antibiotic stewardship
- Update National IPC guideline
- Development of IPC standard operation procedures
- Participation in media campaigns on IPC-related topics
(Antibiotic awareness day, TV programs, etc.)

Implementation TAG Recommendations for Infection Prevention and Control

5th National Hepatitis C Elimination Workshop

Tbilisi, Georgia

March 7, 2018

Meghan Lyman, M.D.

International Infection Control Program

CDC Division of Healthcare Quality Promotion

CDC International Infection Control Program



Provide rapid assistance for outbreaks and other adverse events related to healthcare delivery



Reduce the global burden of antimicrobial resistance associated with healthcare delivery



Improve country Infection Prevention & Control capacity to prevent and control healthcare-associated infectious disease outbreaks and device-associated HAIs



Core Components of IPC



TAG IPC Recommendations

-
- 1. Create multidisciplinary **IPC central authority** or structure (IPC unit or department) accountable for implementation of IPC all over the country.
 - 2. **Decrees** are needed to approve the country IPC structure (National, facility and primary health care levels) with **clear roles and responsibilities**.
 - 3. The central IPC authority should develop a **national IPC strategy** and plan to achieve implementation of IPC standards at all healthcare facilities by December 2020 (including detailed activities and timeline for implementation).
 - 4. Completion of the **national IPC guidelines** and making them accessible to all healthcare providers.
 - 5. Develop a standardized **national IPC training program** using the national IPC guidelines as the basis.
 - 6. Develop a **training strategy** with the aim of targeting all healthcare providers (clinicians, nurses, others) by December 2020.
 - 7. Develop and implement a **communication strategy** to promote behavior change of healthcare providers and non-traditional healthcare providers to ensure safety of practices
 - 8. **Monitor implementation of IPC** at facility level by auditing IPC practices using available IPC tools to monitor progress of implementation of IPC.
- IPC Program
- IPC Guidelines
- IPC Training & Education
- IPC Monitoring & Evaluation

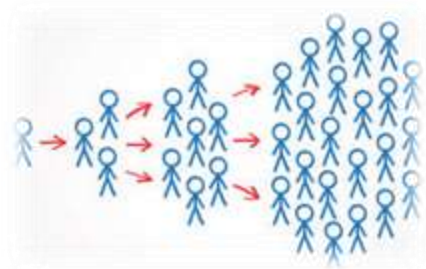
IPC Program

- Progress
 - Leadership support for strengthening IPC
 - National IPC Focal Person identified
 - National action plan under development

- Challenges
 - Decentralized national IPC structure
 - Limited IPC enforcement and accountability
 - Limited resources allocated for IPC

IPC Guidelines

- Progress
 - National IPC Guidelines being developed
 - Guidelines on priority topics already approved
 - Standard and transmission-based precautions
 - Environmental cleaning
 - Equipment decontamination and sterilization
- Challenges
 - Roll-out and implementation



IPC Training

- Progress
 - Motivated IPC focal persons
 - Trained IPC champions
- Challenges
 - Limited IPC expertise
 - No IPC training strategy



IPC Monitoring & Evaluation (M&E)

- Progress
 - IPC assessments (MoLHSA)
 - Situational analysis (MoLHSA, CDC, and partners)

- Challenges
 - Lack of M&E strategy
 - Evaluating IPC implementation
 - 'Punitive' perception



Core Components of IPC

Important next steps

- Establish a strong national IPC unit with sufficient resources and authority
- Mandate IPC activities at the facility level
- Effectively roll out and implement guidelines
- Provide sufficient training to all healthcare workers
- Monitor IPC practices to guide improvement

Thank you

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

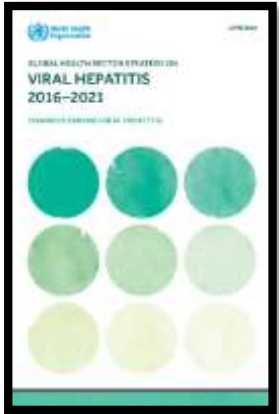
The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



WHO GUIDANCE ON HEPATITIS SURVEILLANCE

Antons Mozalevskis, WHO Regional Office for Europe
Yvan Hutin, Global Hepatitis Programme

THE GLOBAL HEALTH SECTOR STRATEGY ON VIRAL HEPATITIS



5 STRATEGIC DIRECTIONS

1. Information for focused action
2. Interventions for impact
3. Delivering for equity
4. Financing for sustainability
5. Innovation for acceleration

7th

leading cause of
death globally
(2013)

FOUR MAIN HEPATITIS VIRUSES

A.

E.

B.

C.

95%
of burden

Faecal oral route

Exposure to blood / body fluids

Acute hepatitis

Chronic infections

Sequelae

HAV

HEV

HBV

HCV

DATA SYSTEMS NEEDED

A | HEPATITIS SURVEILLANCE

1. Acute hepatitis that reflect new infections
2. Chronic infections
3. Sequelae

B | PROGRAMME DATA

- Prevention indicators
- Patient registries for the cascade of care and cure

CHALLENGES IN VIRAL HEPATITIS SURVEILLANCE

- Multiple disease outcomes
 - 👉 Consider acute hepatitis, chronic infection and sequelae
- Similar clinical presentation
 - 👉 Use in-vitro diagnostics
- Asymptomatic nature of most infections
 - 👉 Plan biomarker surveys
- Multiple modes of transmission / persons at risk
 - 👉 Tailor response to national situation

TERMINOLOGY

DISEASE

- Acute
- Chronic

INFECTION

- New
- Old
- Resolved

SEQUELAE

- Cirrhosis
- Hepatocellular carcinoma

DIFFERENTIATING INCIDENCE AND PREVALENCE

INCIDENCE

- New infections among susceptible persons
- May lead to acute hepatitis
 - Known referent exposure period (incubation)
 - Investigation of risk factors
 - Direct prevention activities

PREVALENCE

- Current infections, usually acquired in the past
- Usually asymptomatic
 - Timing of exposure unknown:
 - Investigation of risk factors limited
 - Possible to examine factors associated with prevalent infection
 - Plan testing and treatment

HAV

HEV

HBV

HCV

VIRAL HEPATITIS SURVEILLANCE

1. Detect outbreaks, monitor trends in incidence and identify risk factors for new, incident infections

2. Estimate the prevalence of chronic infections and monitor trends in sentinel groups

3. Estimate the burden of sequelae

Surveillance for acute hepatitis

Surveillance for chronic infections

Surveillance for cirrhosis and HCC

HCC: Hepatocellular carcinoma

HAV

HEV

HBV

HCV

ACUTE HEPATITIS SURVEILLANCE

1. Detect outbreaks, monitor trends in incidence and identify risk factors for new, incident infections

Surveillance for acute hepatitis

2. Estimate the prevalence of chronic infections and monitor trends in sentinel groups

Surveillance for chronic infections

3. Estimate the burden of sequelae

Surveillance for cirrhosis and HCC

HAV**HEV****HBV****HCV**

ACUTE HEPATITIS SURVEILLANCE

	Syndromic surveillance	Enhanced case reporting
Scale	Nationwide	Mostly sentinel
Implementer	Communicable disease surveillance	Centres of excellence
Case definitions	Clinical – No in vitro diagnosis	Type specific – IgM in vitro diagnosis
Data collection	Basic demographics	Risk factors
Objectives	Detect outbreaks	Describe trends Identify risk factors

CASE DEFINITIONS FOR ACUTE HEPATITIS

Level	Acute hepatitis			
Suspect case: Clinical criteria	Discrete onset of an acute illness with signs or symptoms of (a) acute viral illness and (b) hepatic injury (liver enzymes)			
Confirmed case: Clinical criteria AND epidemiological criteria or biomarker criteria	HAV	HEV	HBV	HCV
	IgM anti-HAV + OR	IgM anti-HEV + OR	IgM anti-HBc +	Anti HCV + AND All IgM – for HAV, HEV, and anti-HBc OR
	Epidemiological link with a confirmed case	Epidemiological link with a confirmed case		RNA +/- Anti-HCV – OR
				Sero-conversion Anti-HCV

Acute hepatitis less common than chronic hepatitis:
Definitions must be as specific as possible

SPECIFICITY KEY FOR ACUTE HEPATITIS

- Chronic hepatitis is more common than acute
- Only acute hepatitis can inform about risk factors
- Inclusion of cases of chronic hepatitis among cases of acute hepatitis is misleading
 - Over-estimate incidence
 - Misrepresent risk factors
- ✓ Prefer quality to quantity
 - ✓ Smaller number of sentinel sites with good diagnosis

HBV

HCV

SURVEILLANCE FOR CHRONIC INFECTIONS

1. Detect outbreaks, monitor trends in incidence and identify risk factors for new, incident infections

Surveillance for acute hepatitis

2. Estimate the prevalence of chronic infections and monitor trends in sentinel groups

Surveillance for chronic infections

3. Estimate the burden of sequelae

Surveillance for cirrhosis and HCC

HBV

HCV

SURVEILLANCE FOR CHRONIC INFECTIONS

A | BIOMARKER SURVEYS

- Reference method
 - General population
 - High-risk groups

B | DATA MINING

- Search for existing information (Gray literature)

C | REPORTING OF CHRONIC CASES

- Only estimates the quantity of cases diagnoses
- Best directed to patients registries
- Not to be mixed up with acute hepatitis surveillance

CASE DEFINITIONS FOR CHRONIC HEPATITIS

Type of criteria	HBV	HCV
Clinical criteria	Person not meeting the case definition for acute hepatitis	
Biomarker criteria	HBsAg +	Serological evidence of past or present infection
		Anti HCV +
		Chronic HCV infection
		HCV RNA + OR HCV Ag +

Chronic infections are common:
Definitions do not need to be as specific as for acute hepatitis

HBV

HCV

04 | THREE PURPOSES – THREE DOMAINS

1. Detect outbreaks, monitor trends in incidence and identify risk factors for new, incident infections

Surveillance for
acute hepatitis

2. Estimate the prevalence of chronic infections and monitor trends in sentinel groups

Surveillance for
chronic infections

3. Estimate the burden of sequelae

Surveillance for
cirrhosis and HCC

HCC: Hepatocellular carcinoma

HBV

HCV

ESTIMATING MORTALITY

1. **Assess quality** of the vital registration system
2. **Group deaths directly associated** with HBV or HCV infections
ICD-10 codes
3. Estimate cirrhosis and HCC deaths (**Mortality envelope**)
ICD-10 codes
4. Estimate HBV/HCV **attributable fraction** of HCC and cirrhosis:
 - Centre of excellence
 - Prevalence of HBV and HCV infections in sequelae patients
5. **Apply** attributable fractions to HCC and cirrhosis envelope
6. **Compile data and break down** by acute / chronic and by virus

USING SURVEILLANCE TO EVALUATE PROGRAMMES

Levels	Interventions	Domain
1. Prevention of new infections	Vaccination	Surveillance for acute hepatitis that reflect new infections
	Food water safety	
	Blood safety	
	Condoms	
	Harm reduction	
	Infection control	
2. Management of chronic hepatitis	Testing and treating	Surveillance for chronic, prevalent infections
3. Reduction of mortality	Hepatocellular carcinoma screening	Surveillance for sequelae

Hepatitis Surveillance Workshop

6 March 2018
Tbilisi, Georgia

What questions need to answered/addressed for HCV elimination?

1. Monitor the trends;
2. Identify the risk factors for incident infections;
3. Monitor the cascade of care;
4. Evaluate the impact of interventions.

Discussion/Considerations

- **EIDSS:**

- Centralized system for reporting cases of notifiable conditions, including hepatitis A and hepatitis B cases
- Currently **does not collect** acute HCV cases

- **Harm Reduction**

- Incidence study /PWID cohort
- Linking harm reduction data base through unique ID with the treatment database planned

- **Blood Program**

- Possibility for surveillance of incident infections
- Query to reveal seroconversion in the screening D/B

Discussion/Considerations

- **Dialysis**

- HD units screen the patients, however are not mandated to report to the screening data base

- **Pediatric and ANC**

- 2016-2017, 88,689 pregnant women tested, 437 – HCV+ (0.5%)
- From 2015, 103,399 children under 18 tested, 322 – HCV+
- Of 107 HCV+ children below 2, 54 children's mothers (50%) tested HCV- (diagnostics quality??)

Recommendations

- Strengthen human resources for hepatitis surveillance
- Establish acute hepatitis C surveillance:
 - Integrate reporting of acute HCV to EIDSS?
 - Establish sentinel surveillance in 3 ID hospitals?
- Conduct retrospectively review of ID hospitals records of acute hepatitis cases
- Link harm reduction data base with the treatment databased through unique ID, ensuring personal data protection

Recommendations

- Conduct case investigation for each HCV+ child and repeat testing at 18 months
- Ensure quality of screening tests
 - Enforce limited list of quality assured test-kits
 - Centralized provision of tests-kits
- Modify the decree to mandate HD units to report and enter all cases tested HCV+
- Use eHealth database, cancer registry and vital statistics for sequelae surveillance

Overview and Progress of the HCV Elimination Program in Georgia

Amiran Gamkrelidze, MD, PhD, Professor

Director General

National Center for Disease Control and Public Health

March 7, 2018

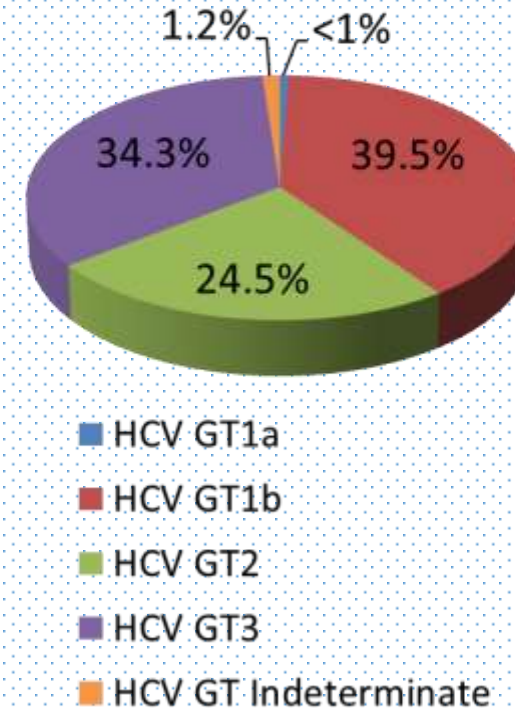


Nationwide HCV prevalence

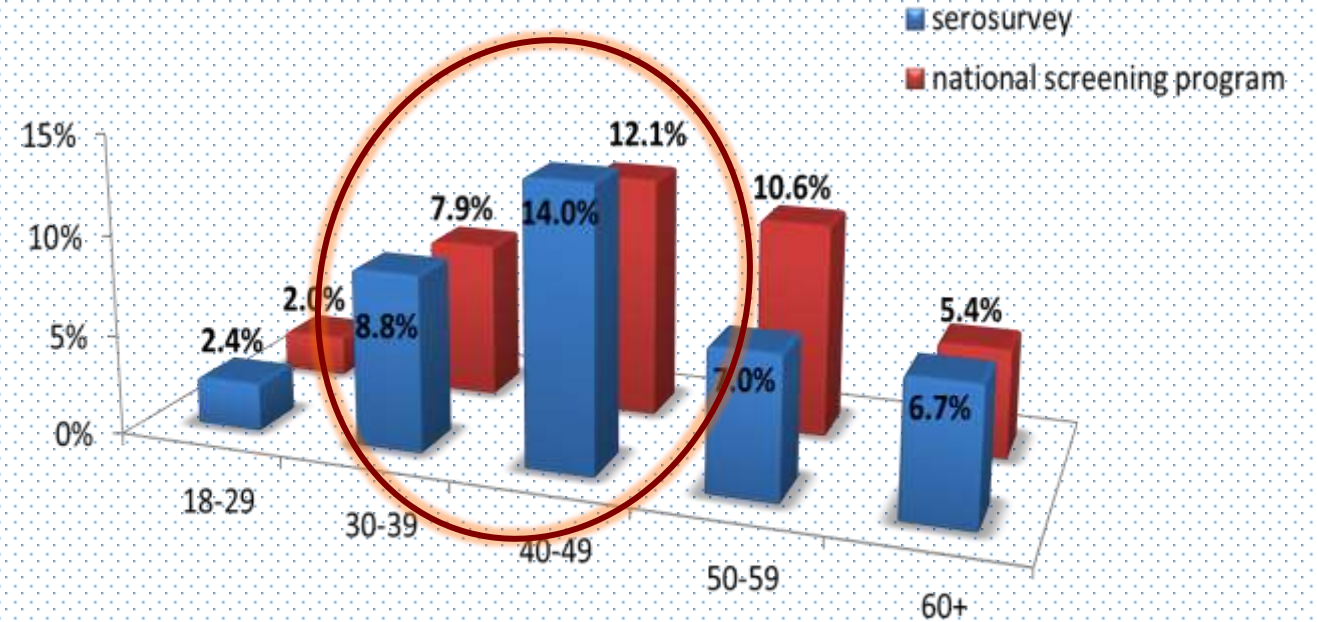
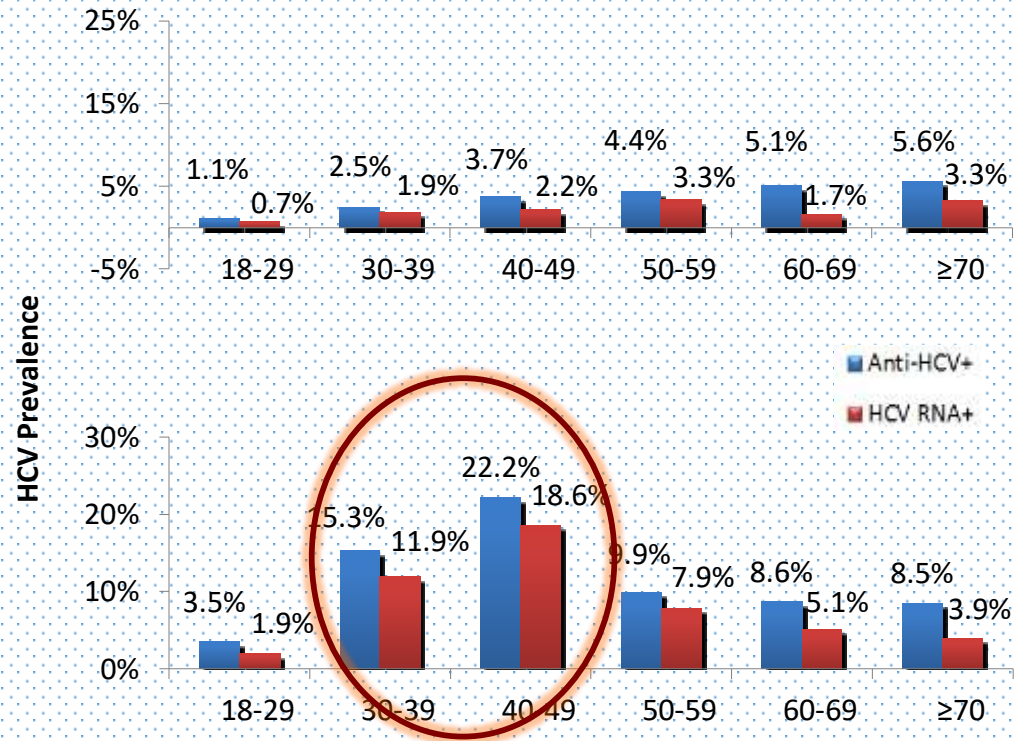
- ✓ Total number of interviews – **6330** (90% response rate)
- ✓ Total number of blood samples – **6010** (86% response rate)

Characteristic	n	%	Estimated # nationwide ≥18 years
Anti-HCV+	433	7.7%	215,000
HCV RNA+	311	5.4%	150,000

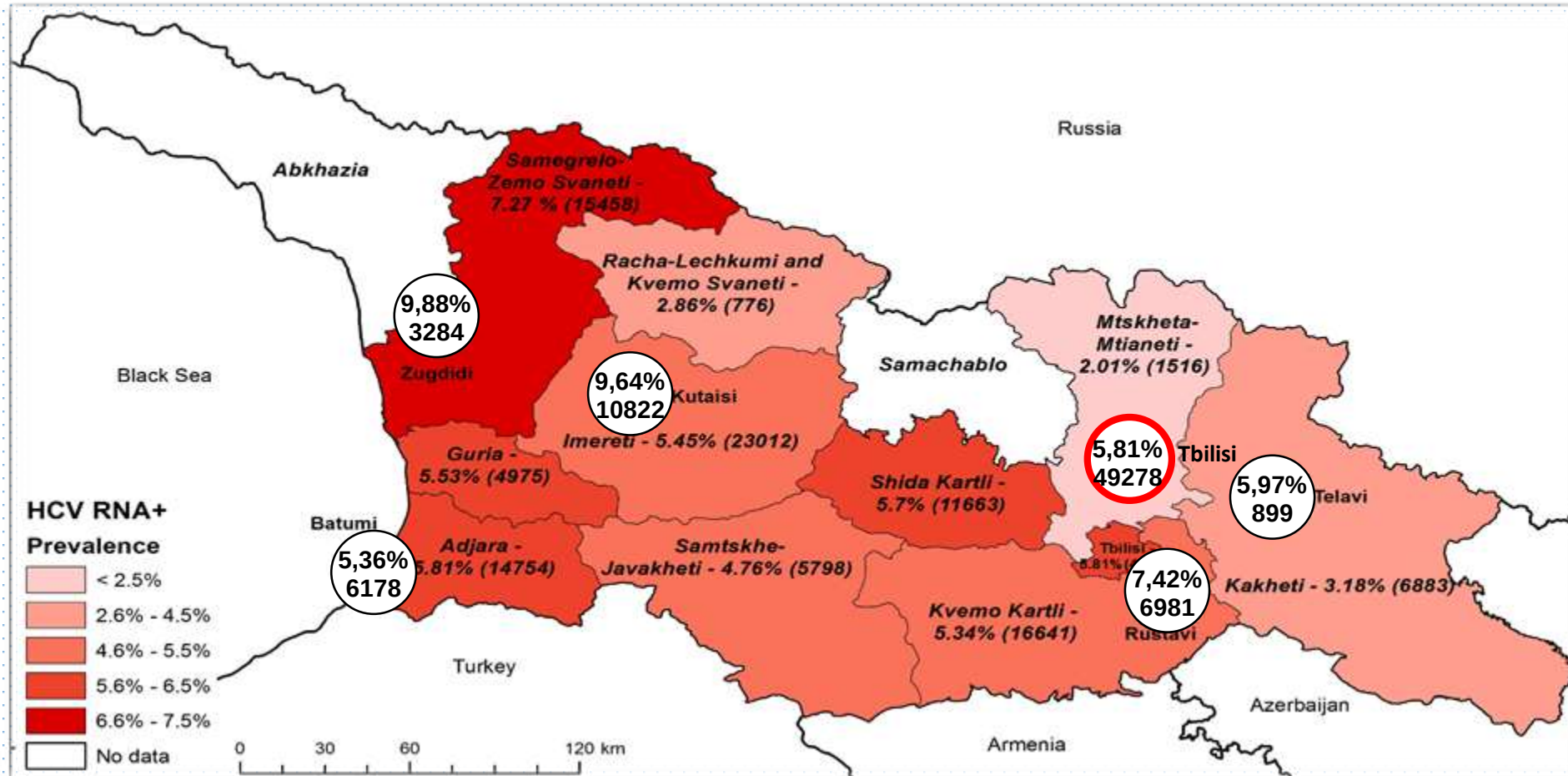
HCV Genotype Distribution



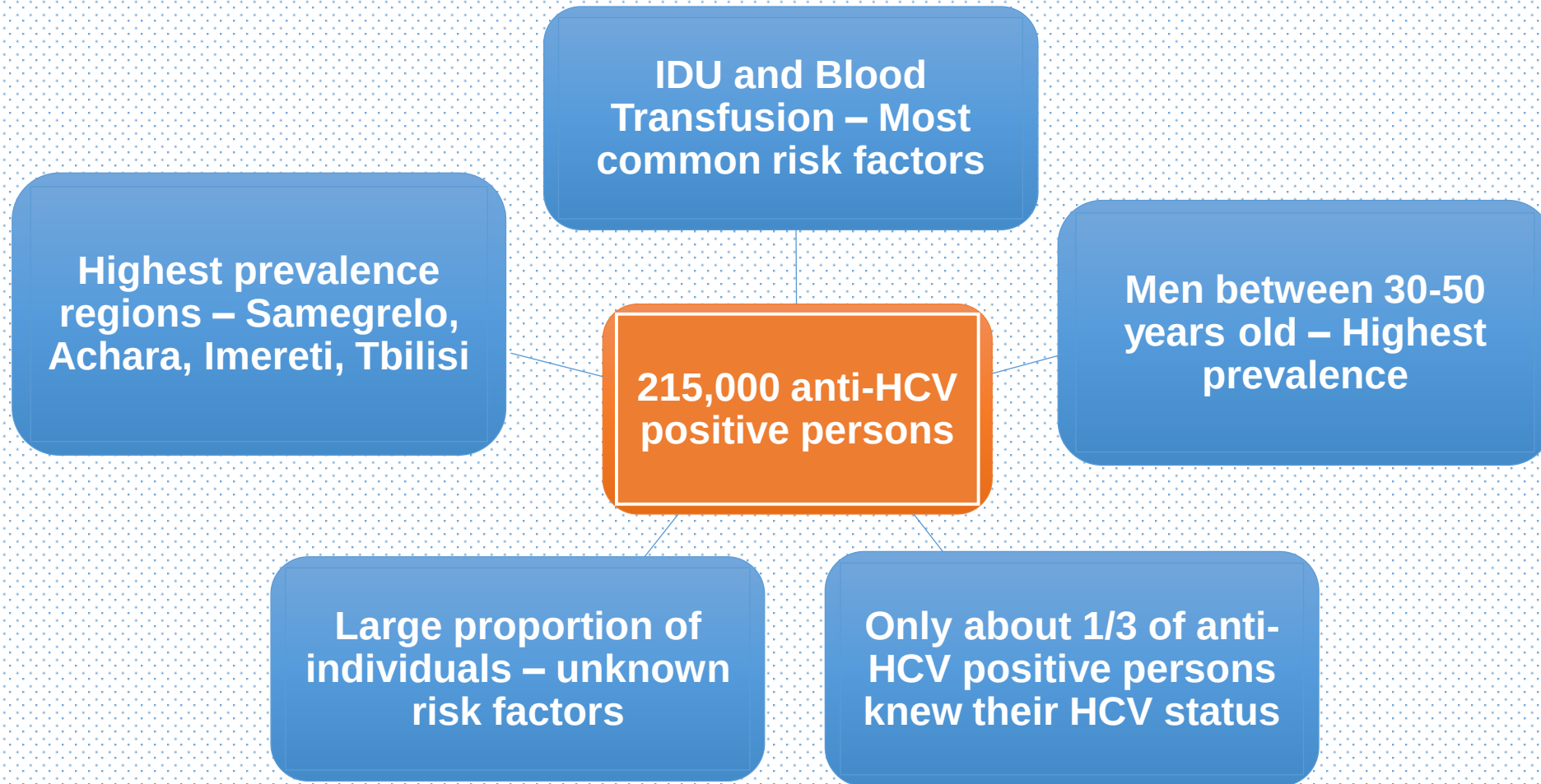
HCV Prevalence by Age and Gender



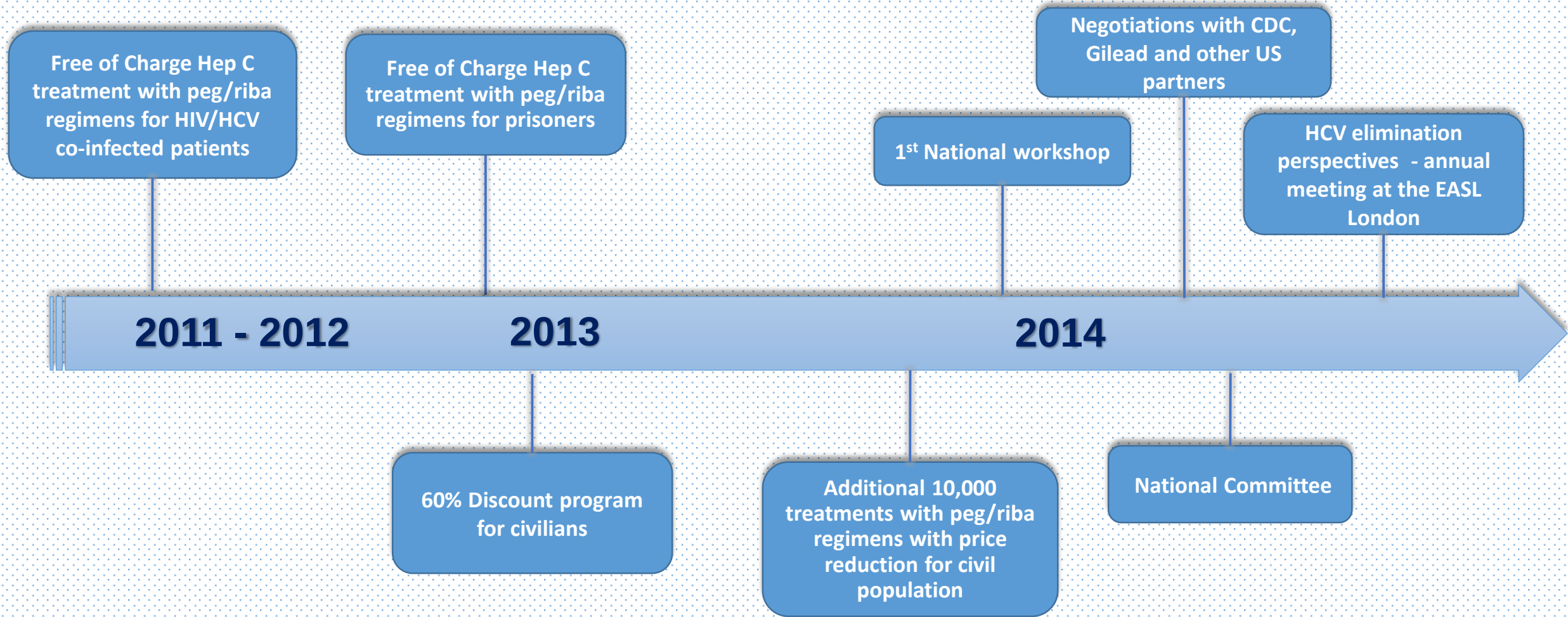
Prevalence and Estimated Number of HCV RNA+ Individuals by Regions and Cities



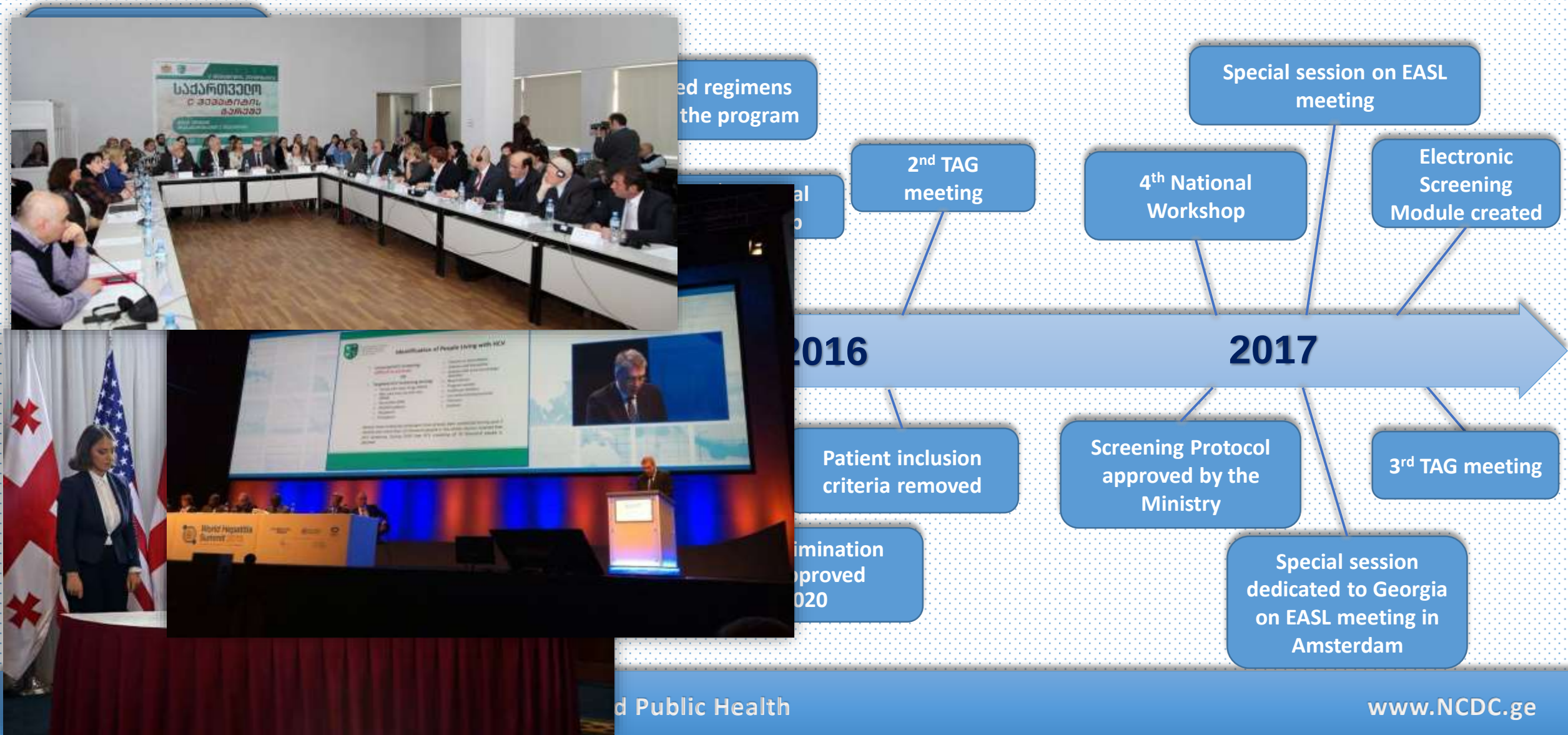
Main Findings



Road towards HCV Elimination



Road towards HCV Elimination (2)



Why Georgia?



- ▶ Small size of the country (69,700 km²) with population of **3.7 million** people
- ▶ High prevalence of HCV infection in general population
- ▶ Strong Governmental commitment towards elimination of HCV
- ▶ Availability of all modern HCV diagnostic and treatment methods
- ▶ Strong human resource capacity in the field of viral hepatitis, and particularly in hepatitis C
- ▶ Adherence to principles of evidence-based medicine for hepatitis C
- ▶ Existence of effective systems for implementing large-scale national and international health programs, including through multi-sectoral approach
- ▶ Availability of logistic and control mechanisms within existing national HIV/AIDS, Tuberculosis and hepatitis C treatment programs

Public/private partnership

MoHLSA

NCDC

CDC

- South Caucus Office (DGHP)
- Division of Healthcare Quality Promotion (DHQP)
- Division of Cancer Prevention & Control (DCPC)

Gilead Sciences

Others

- Abbott Diagnostics
- Becton Dickinson (BD)
- University of Bristol, UK
- Extension for Community Healthcare Outcomes (ECHO)
- Liver Institute & Foundation for Education and Research (LIFER)
- Global Fund for AIDS, TB & Malaria

NOhep

HCV treatment provider clinics

- Division of Global HIV & TB (DGHT)
- Division of Health Informatics and Surveillance (DHIS)
- Division of Viral Hepatitis

WHO-HQ, WHO-EURO

- Foundation for New Innovative Diagnostics (FIND)
- Blood Systems Research Inst.
- CDC Foundation
- Training Programs in Epidemiology and Public Health Interventions Network (TEPHINET)
- ENABL-ED



Goal

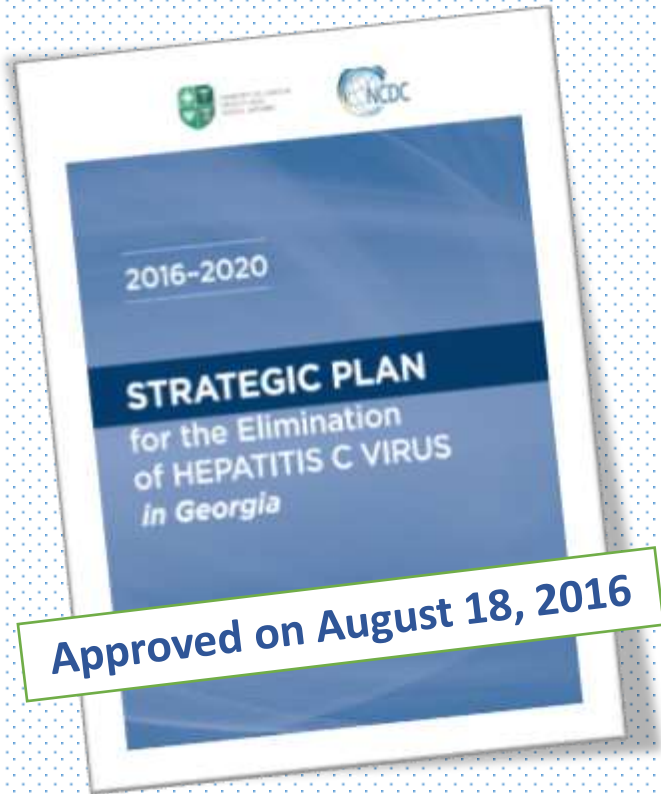
Elimination of HCV by ensuring prevention, diagnostics and treatment of the disease

Targets

90-95-95

By 2020

- ✓ **90%** of people living with HCV are diagnosed
- ✓ **95%** of those diagnosed are treated
- ✓ **95%** of those treated are cured



Strategic plan for the elimination of HCV

Recent progress

Promote advocacy, awareness and education, and partnerships for HCV associated resource mobilization

- Massive awareness raising campaigns
- Short text messages (SMS) regularly sent to the population to invite them to the HCV screening
- HCV Hotline established at NCDC

Prevent HCV transmission

- Infection control and prevention monitoring and evaluation in medical and non-medical facilities
- Regular screening activities among PWID and their sexual partners
- Improved quality control mechanisms for blood banks

Identify Persons Infected with HCV

- Enhancement of screening through extending it to the more than **600 centers** countrywide, including inpatient and outpatient settings, pharmacies, Public Health Centers, Harm Reduction Cites, etc.
- Development of unified electronic screening module that combines screening data from all sources

Improve HCV Laboratory Diagnostics

- Research activities for the simplification of HCV diagnostics, including studies on HCV cAg and various PCR approaches
- Introduction of external quality assessment in NCDC referral laboratory (Lugar Center)

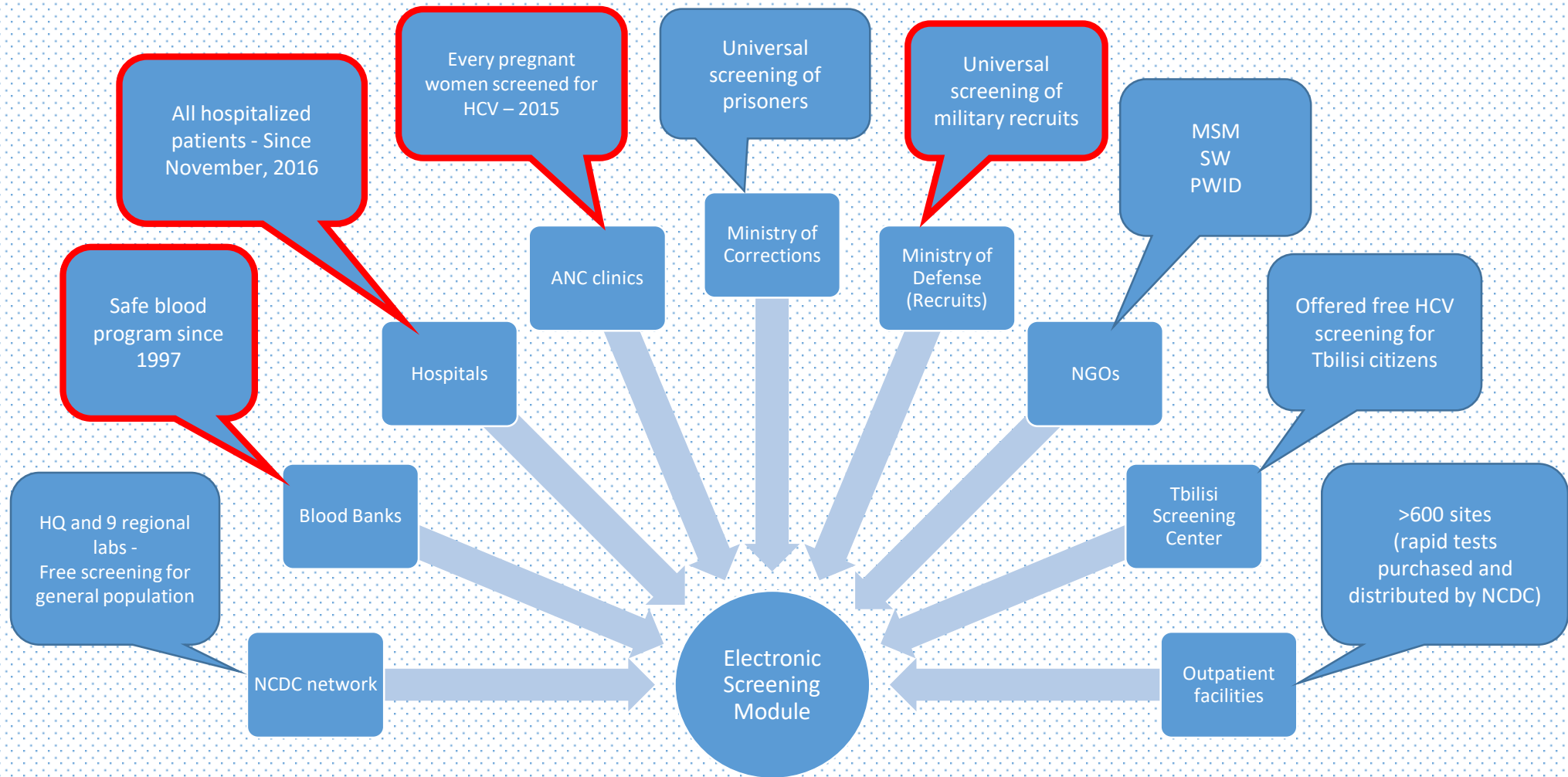
Provide HCV Care and Treatment

- 32 medical facilities providing treatment services countrywide
- Overall SVR rate – 98%

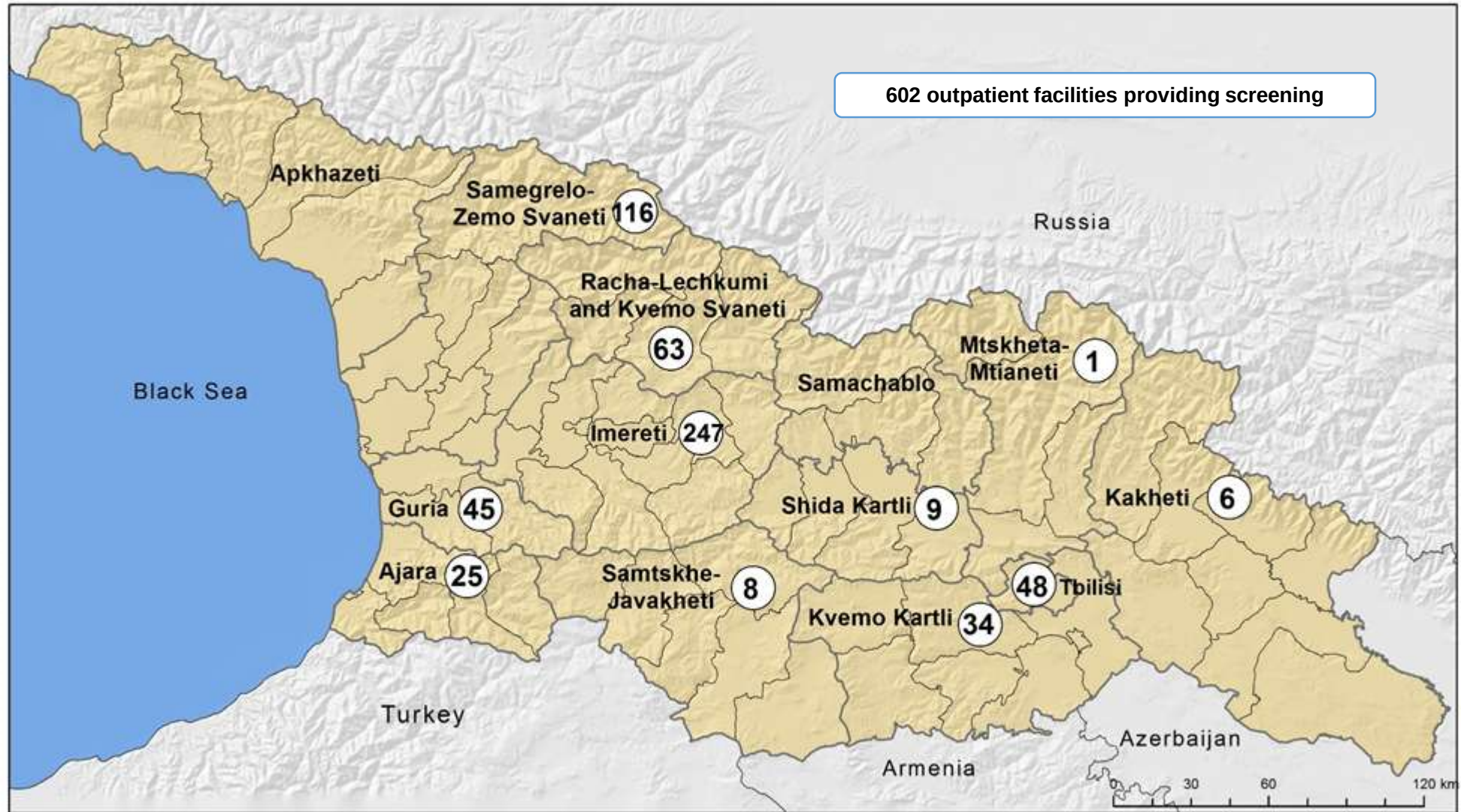
Improve HCV Surveillance

- Identification and Characterization of HCV-Attributable Hepatocellular Carcinoma – in collaboration with US CDC
- Survey to find the barriers and facilitators to enroll in the HCV treatment program
- HCV seroprevalence survey to be repeated in 2019

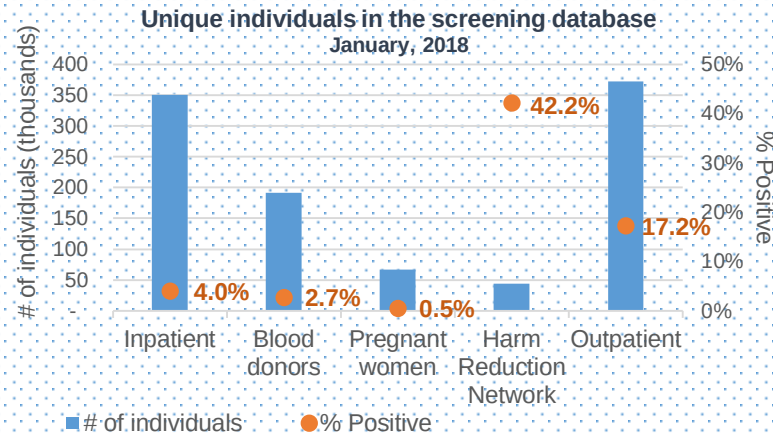
Sources of HCV screening data



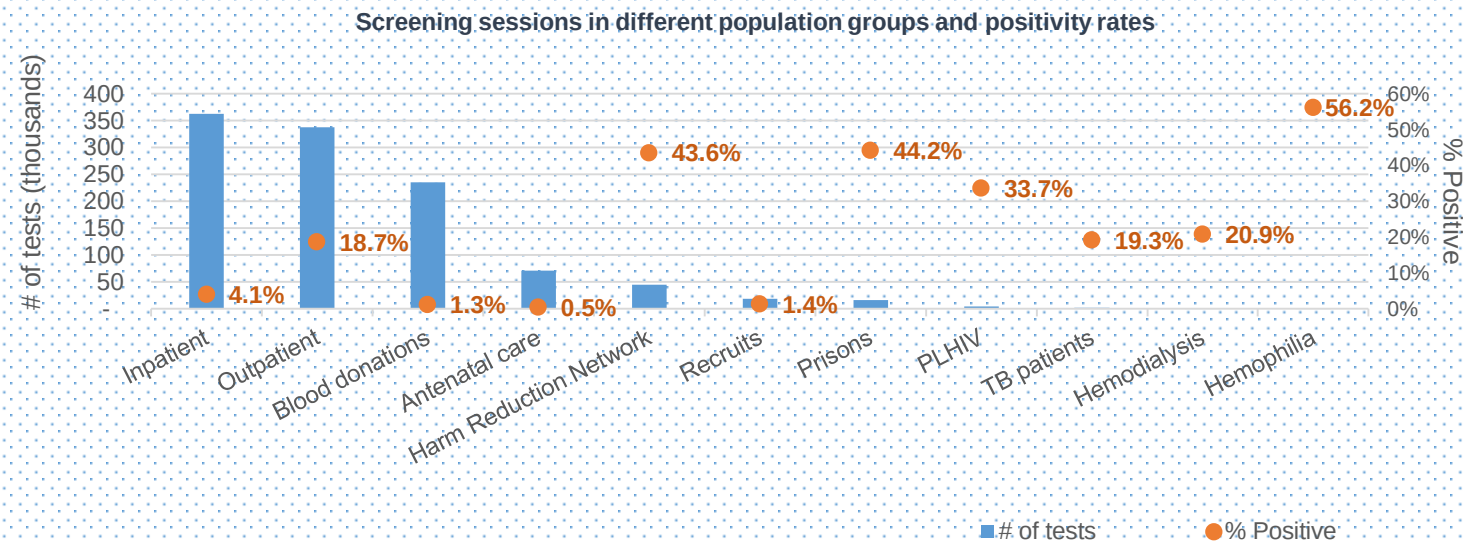
HCV screening providers



HCV Screening Among Different Target Groups



Since 2015, more than **1,5 million** persons have been screened among which **~974,000** were unique individuals with positivity rate **10.6%**



Unified Electronic Screening Module

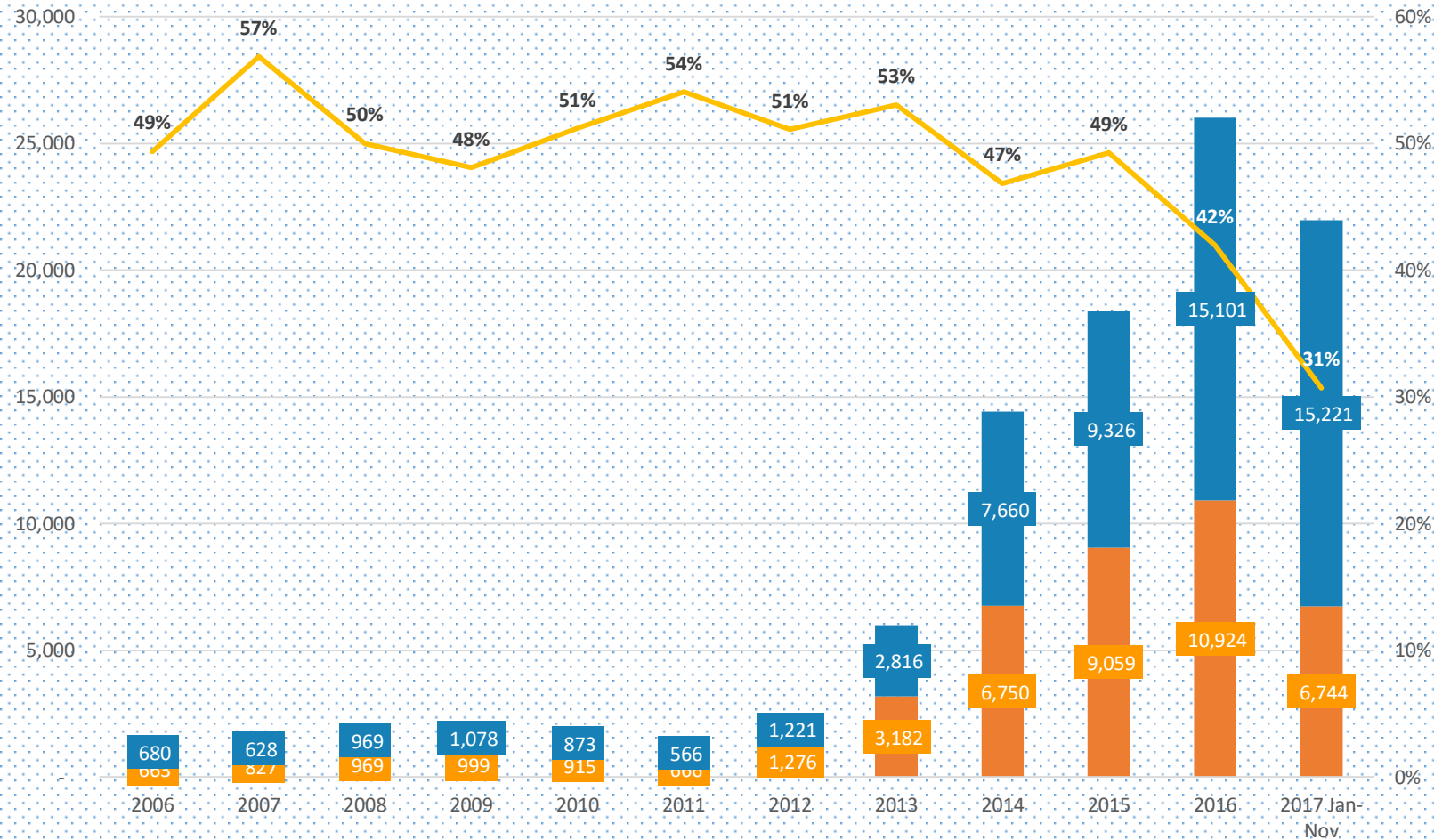
- Real time monitoring of screening progress and data linkage with other databases
- Simplified process of getting medical services
- Easy data exchange capabilities for validation of different results
- Data standardization for better analysis
- Proper and effective validation mechanisms to avoid mistakes in business rules and data entry
- Notification and reminder systems
- Robust reporting capabilities
- Comprehensive data for improved policy making process

Blood Safety

2017 progress

- Since July 2017, participation in the Unified Electronic Donor Database became mandatory for all blood banks irrespective of their involvement in the State Safe Blood Program and for all hospitals performing blood transfusion
- Confirmatory Core-Ag testing by the Lugar Center became mandatory for all HCV screening positive blood donations
- Referral of hepatitis C screening-positive samples to the Lugar Center for confirmatory testing became mandatory for all blood establishments
- Modernization of the Donor Database has been finalized through the addition of an advanced modules to the existing core variables and linkage with the hepatitis C screening modules has been established
- An additional external quality control mechanism has been added to the existing quality control system through the professional testing by the Lugar Center
- Blood banks not involved in the State Safe Blood program were given the opportunity to participate in the program's component providing external quality control mechanism
- For the first time, mandatory voluntary donations and mandatory nucleic acid testing was introduced for blood donors with high behavioral risk

Number of HCV testing sessions among PWIDs by years



14 Harm Reduction Centers



6 Mobile Units



>80 Harm Reduction Workers

☐ Period: 2017 As of November 1st
☐ Number of RDTs
☐ Source: GHRN Data

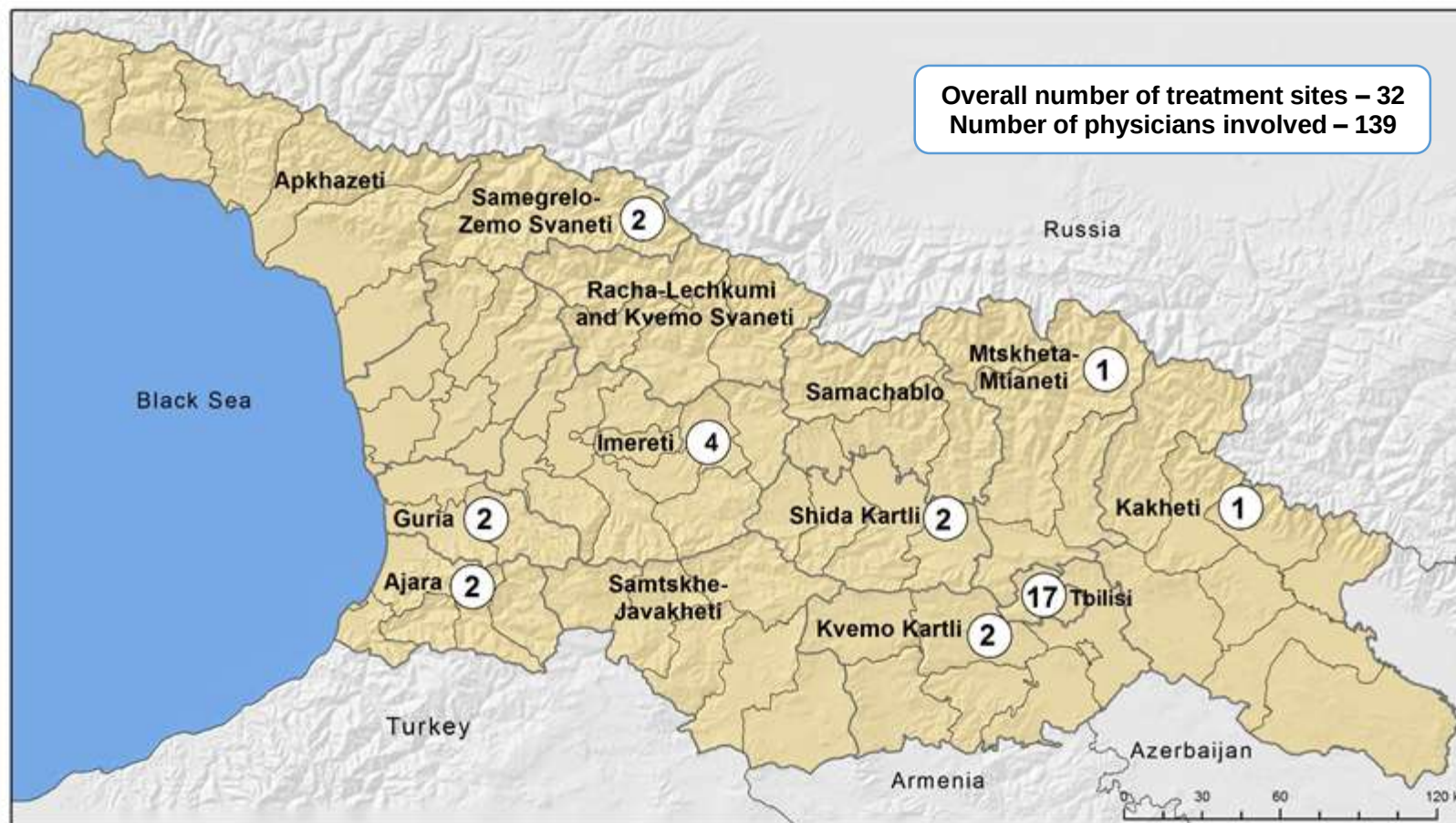
☐ Poitive ☐ Negative ☐ AB Positive %



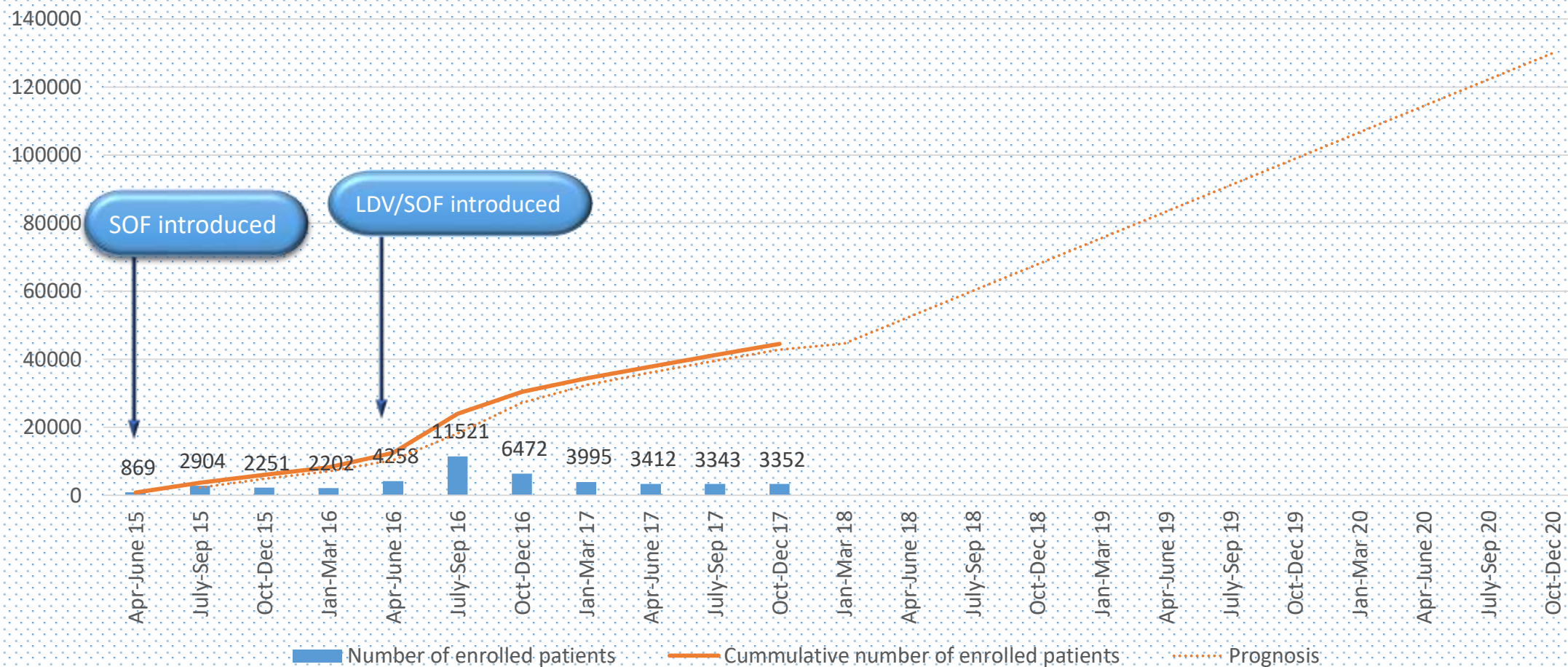
National Center for Disease Control and Public Health

www.NCDC.ge

Treatment providers

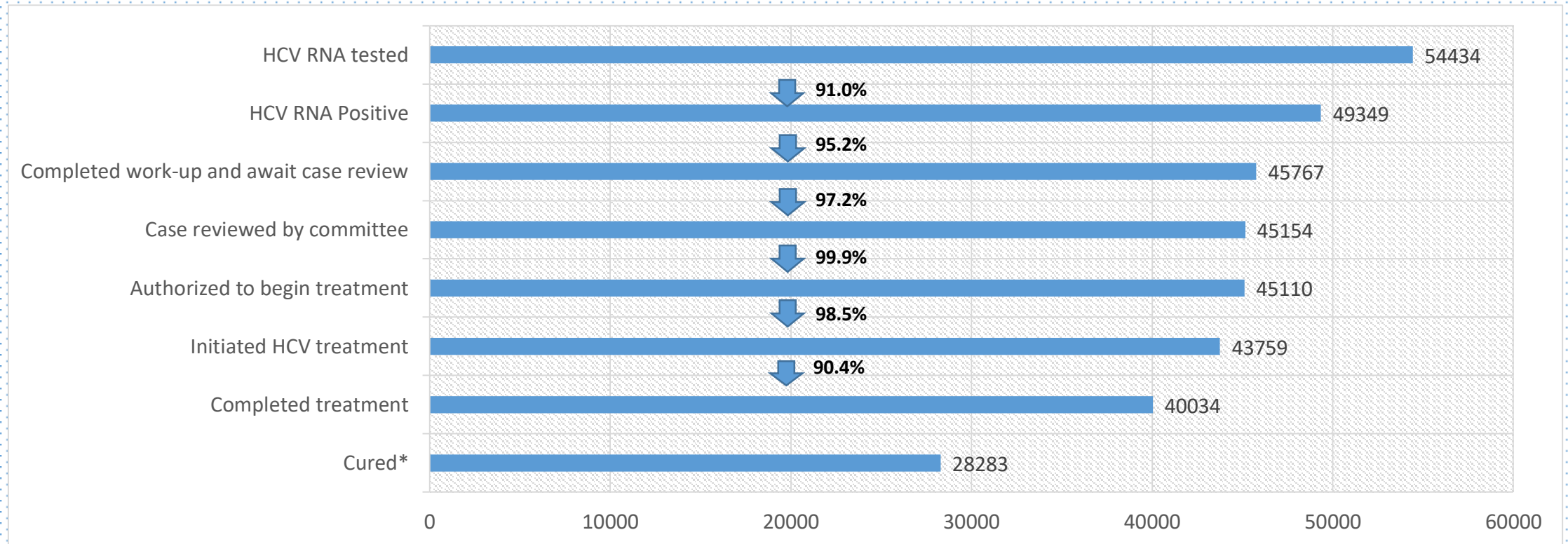


Enrollment in the HCV treatment program



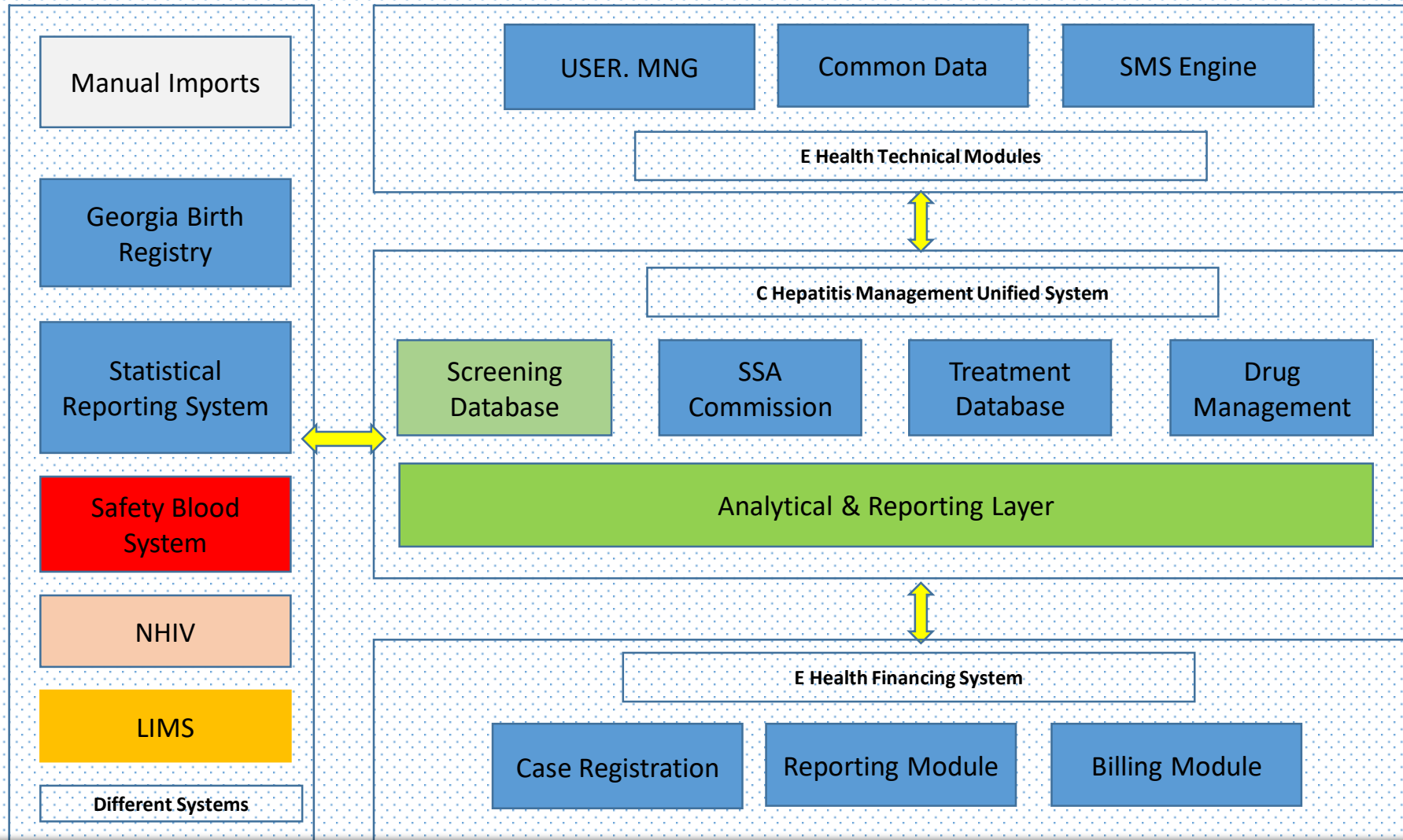
Georgia Hepatitis C Elimination Program Care Cascade

April 28, 2015 – February 28, 2018



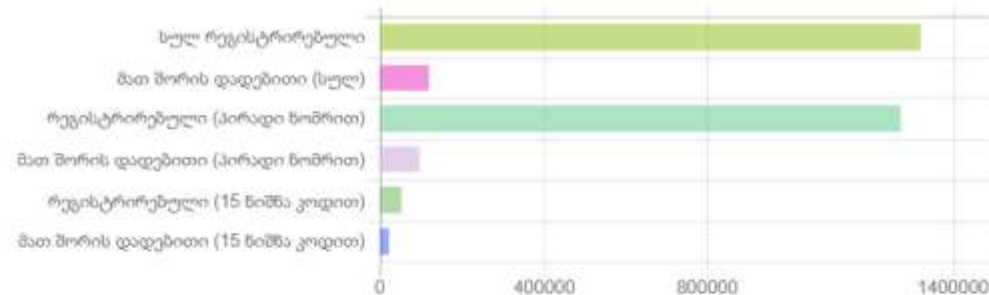
** Of 37,500 patients eligible for SVR assessment, 28,806 were tested, 28,283 (98.2%) achieved SVR, 8,694 (23.2%) missing data*

System Future Architecture



Dashboard Example from Hepatitis C Analytical Layer

1. რეგისტრირებული სკრინინგები



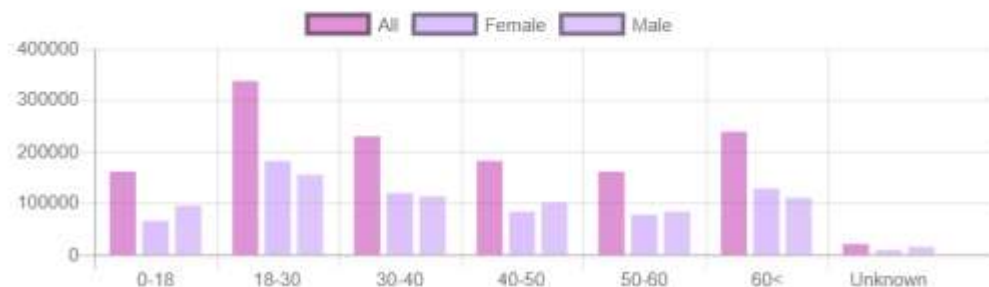
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3. სკრინინგები პერიოდის მიხედვით

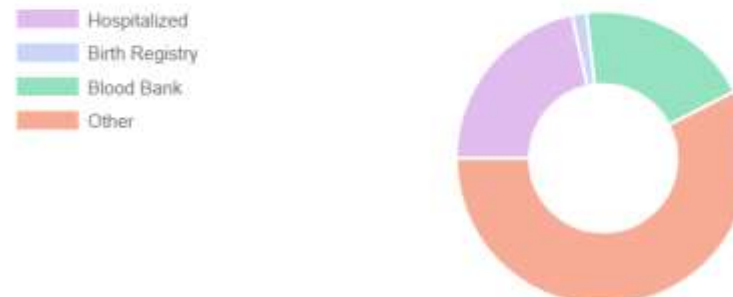


Description: რეგისტრირებული სკრინინგები პერიოდის მიხედვით

8. სკრინინგები ასაკის და სქესის მიხედვით (ყველა)

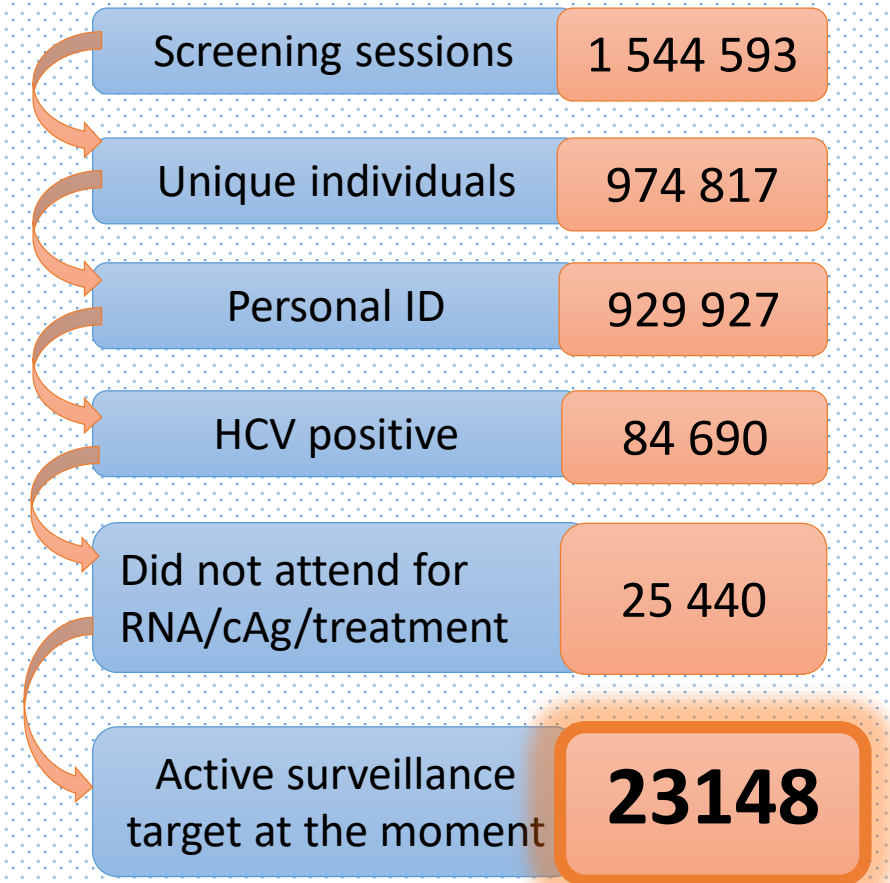


9. წყაროებად სტრუქტურირებული სკრინინგები



Recent update in the HCV Elimination State Program

- HCV active infection confirmation testing becomes free-of-charge
- Screening providers, including inpatient clinics, blood banks, NCDC labs and public health centers will prepare venous blood samples after HCV screening positive result. NCDC will organize the transportation of the blood samples to the Lugar Center
- NCDC/Public Health Center epidemiologists commit to find and follow-up all persons with probable HCV infection



Integration of HCV, TB and HIV Detection at PHC level

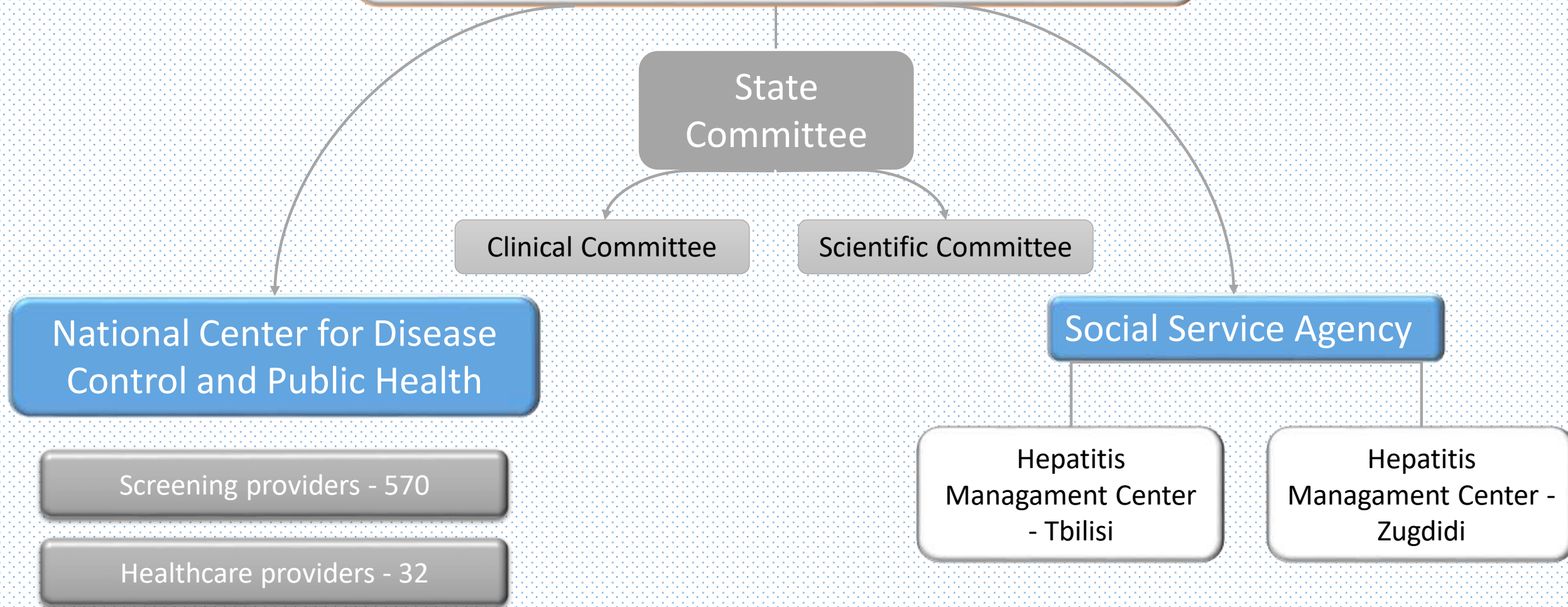
«People-centred care is focused on and organized around the health needs and expectations of people and communities rather than on patients or diseases»



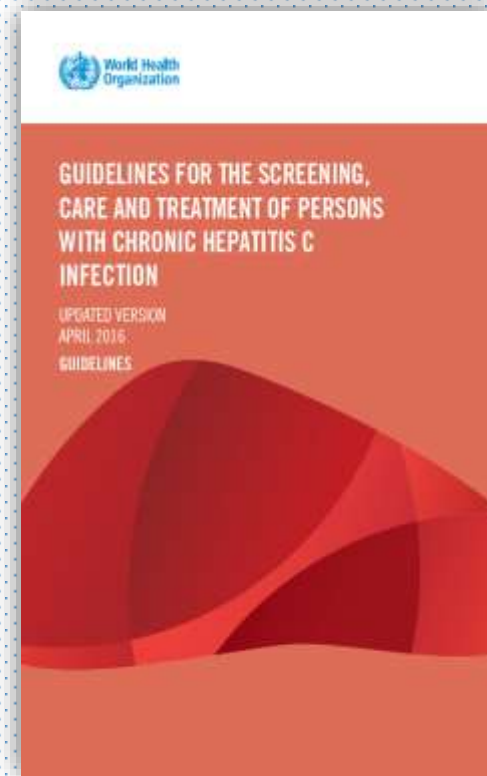
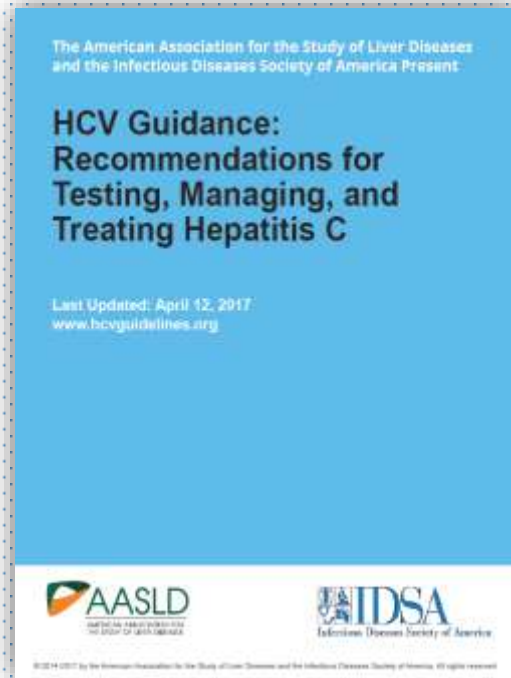
Pilot project in Samegrelo-Zemo Svaneti Region was launched in September, 2017

- To raise awareness among all stakeholders including general public on all three diseases in the region;
- To Develop the sustainable local public-private partnership for effective integration of TB/HIC/HCV screening and early disease detection;
- To strengthen PHC through development of integrated TB/HIC/HCV screening model with detailed protocol;
- To map the service providers at the regional level and establish effective referral systems to specialized clinics;
- To build the providers' capacity and increase the stakeholders' engagement in service quality monitoring;
- To generate the evidence-based recommendations for program expansion to promote service integration nationwide

HCV Elimination Program Management
Ministry of Labour, Health and Social Affairs of Georgia

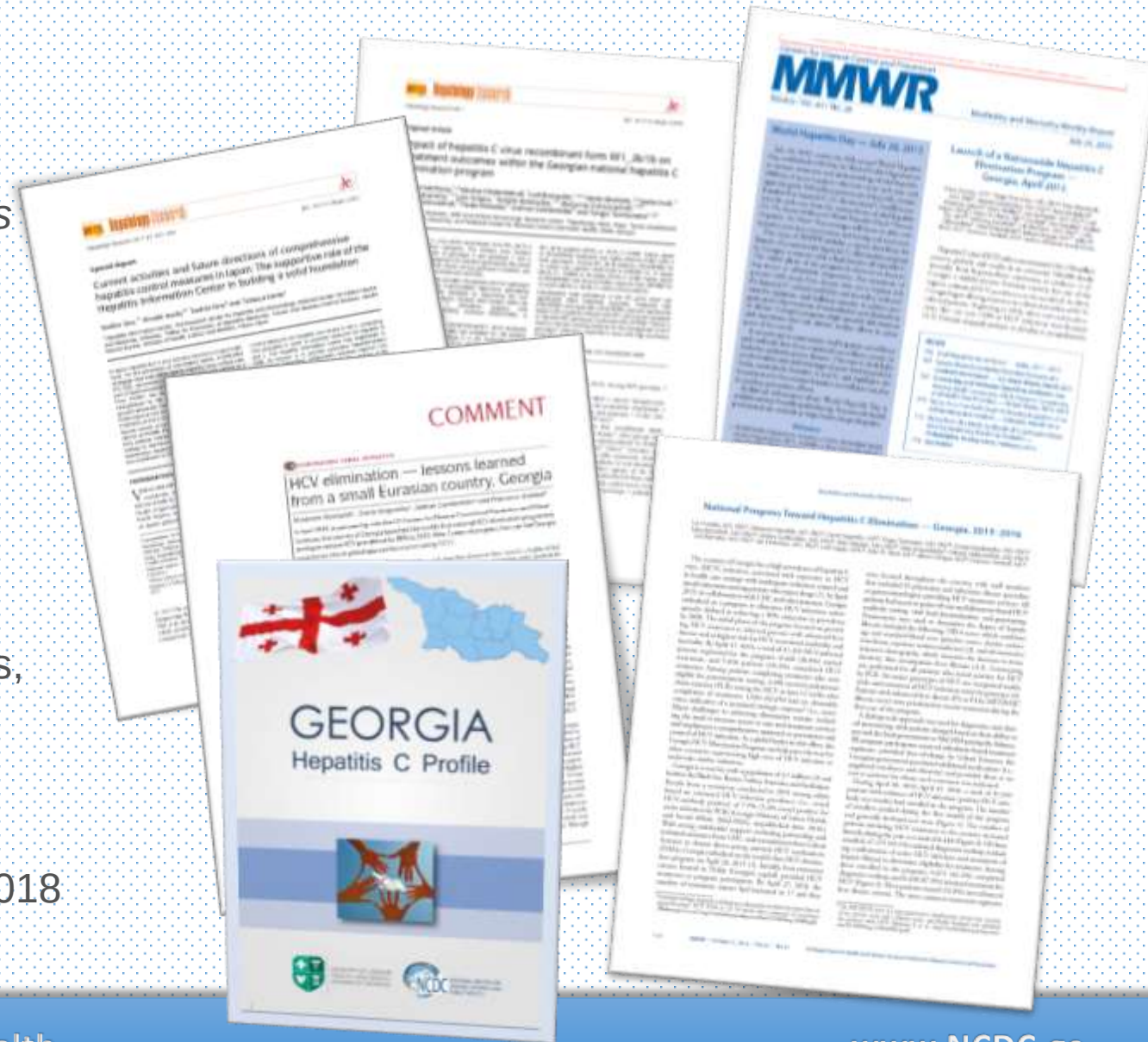


Georgia HCV Elimination Clinical Committee



Georgia HCV Elimination Scientific Committee

- **Established in August, 2016**
- **Membership**
 - *Ministry of Labour, Health and Social Affairs*
 - *NCDC,*
 - *Infectious Diseases, AIDS and Clinical Immunology Research Center,*
 - *Clinic “Hepa”,*
 - *Clinic “Neolab”,*
 - *Clinic “Mrcheveli”*
 - *US CDC*
- **Open to non-members (e.g.: NGOs, Universities, other)**
 - **Requires member sponsorship**
 - **Bristol U, FIND, Boston U**
- **Received 40 proposals from Aug 2016 to Feb 2018**
 - **40 reviewed, 32 approved**



Project ECHO to Regional Facilities

(About 20 TeleECHO clinic sessions conducted through 4 hubs,
June 2016 – June 30, 2017)

TBILISI

ECHO Hubs

Infectious Diseases and AIDS Center; Clinic HEPA; Clinic
NeoLab; Clinic Mrcheveli

Tbilisi

3 sites

Batumi

1 site

Kutaisi

3 sites

Zugdidi

1 site

Rustavi

1 site

Gori

1 site

Expert Panel:

Tengiz Tsertsvadze (Head of Clinical Group)

Vakhtang Kerashvili (ID Center), Elza Vashakidze (Tbilisi State Medical University),

Lali Sharvadze (Hepa), Maia Butsashvili (NeoLab), George Kamkamidze (NeoLab),

David Metreveli (Mrcheveli), Maia Zhamutashvili (Mrcheveli), Jaba Zarkua (Mrcheveli), Mamuka Zakalashvili (Mrcheveli)

Important events

- National Hepatitis C Elimination Workshops - 2014, 2015, 2016, 2017, 2018
- Technical Advisory Group meetings –2015, 2016, 2017



- EASL side meetings dedicated to Georgian HCV Elimination Program
 - 2014 – London
 - 2015 – Vienna
 - 2016 – Barcelona
 - 2017 – Amsterdam
 - 2018 – Paris

Study tours

Study tours organized by NCDC with a focus on HCV elimination.

- Introduction to the State HCV Elimination program, its management and organization
- Discussion about the steps taken to achieve the progress towards the elimination goals



Delegation from Egypt



Delegation from Post-Soviet countries

Meetings with all stakeholders:

- Ministry of Labour, Health and Social Affairs
- NCDC
- HCV Management Centers
- HCV screening and treatment provider clinics
- NCDC Referral laboratory (Lugar Center)
- Public Health Centers

NOhep Visionaries Programme



Georgia was awarded the title of NOhep Visionary for the European Region at the World Hepatitis Summit in Sao Paulo, Brazil, on November 1st, 2017.

■ Six countries were selected to launch the NOhep Visionaries Programme worldwide:

- Brazil,
- Bangladesh,
- Egypt,
- Gambia
- Mongolia, and
- Georgia



The NOhep Visionaries Programme is a global campaign which engages governments to scale-up successful approaches to elimination and share key learnings, accelerating progress towards eliminating viral hepatitis by 2030.

Acknowledgements



Ministry of Labour, Health and Social Affairs



US Centers for Disease Control and Prevention (CDC)



Gilead Sciences, Inc.



WHO, WHO Euro



TAG Members



LIFER



ECHO



World Hepatitis Alliance



Nohep Movement



National Center for Disease Control and Public Health

Thank you!





Management of HEPC

Decentralization

Ekaterine Adamia

Head of Health Care Programs Division
March 2018

Goal

Goal Elimination of HCV by ensuring prevention, diagnostics and treatment of the disease

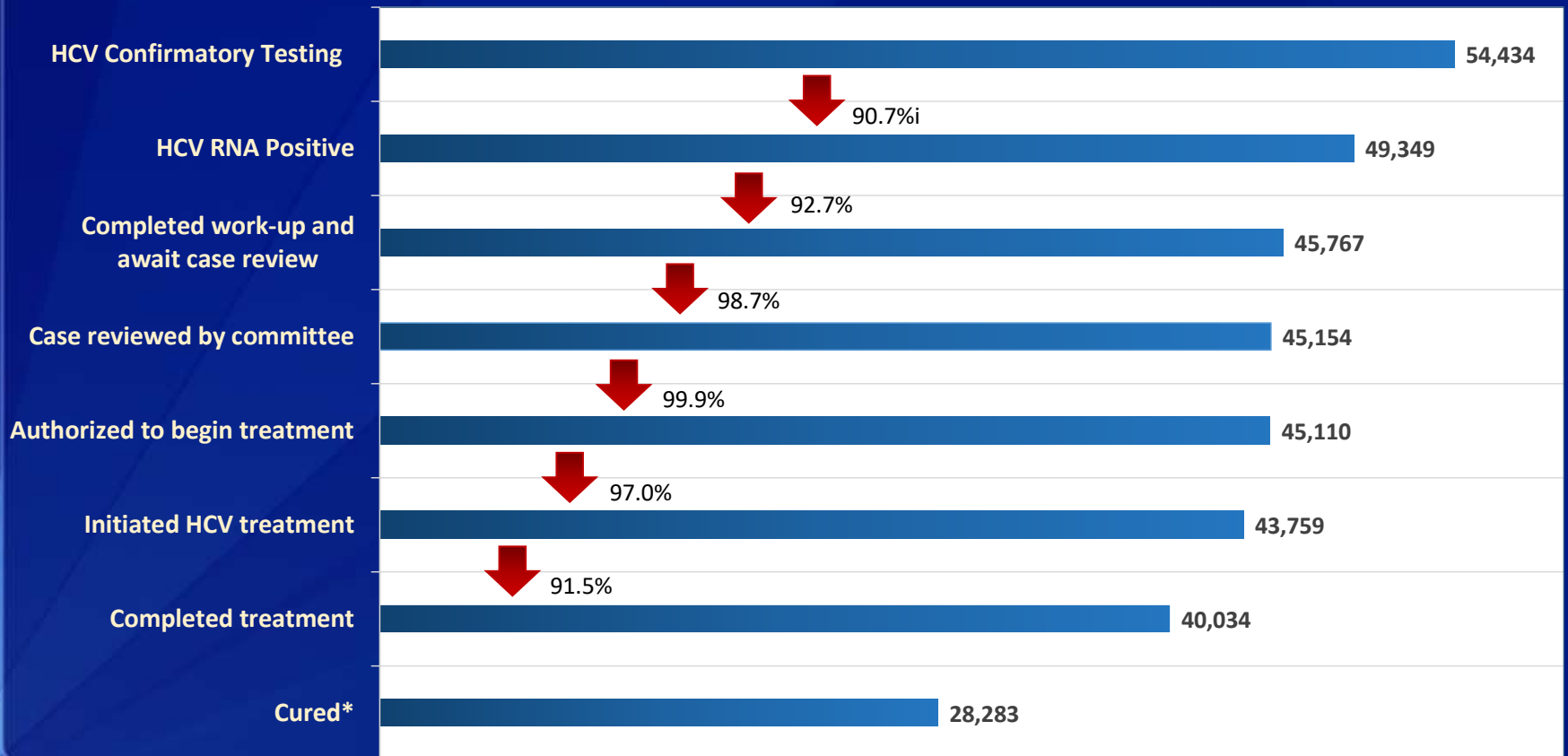
Targets

90-95-95

By 2020

- ❖ **90%** of people living with HCV are diagnosed
- ❖ **95%** of those diagnosed are treated
- ❖ **95%** of those treated are cured

Georgia Hepatitis C Elimination Program Care Cascade April 28, 2015 – February 28, 2018

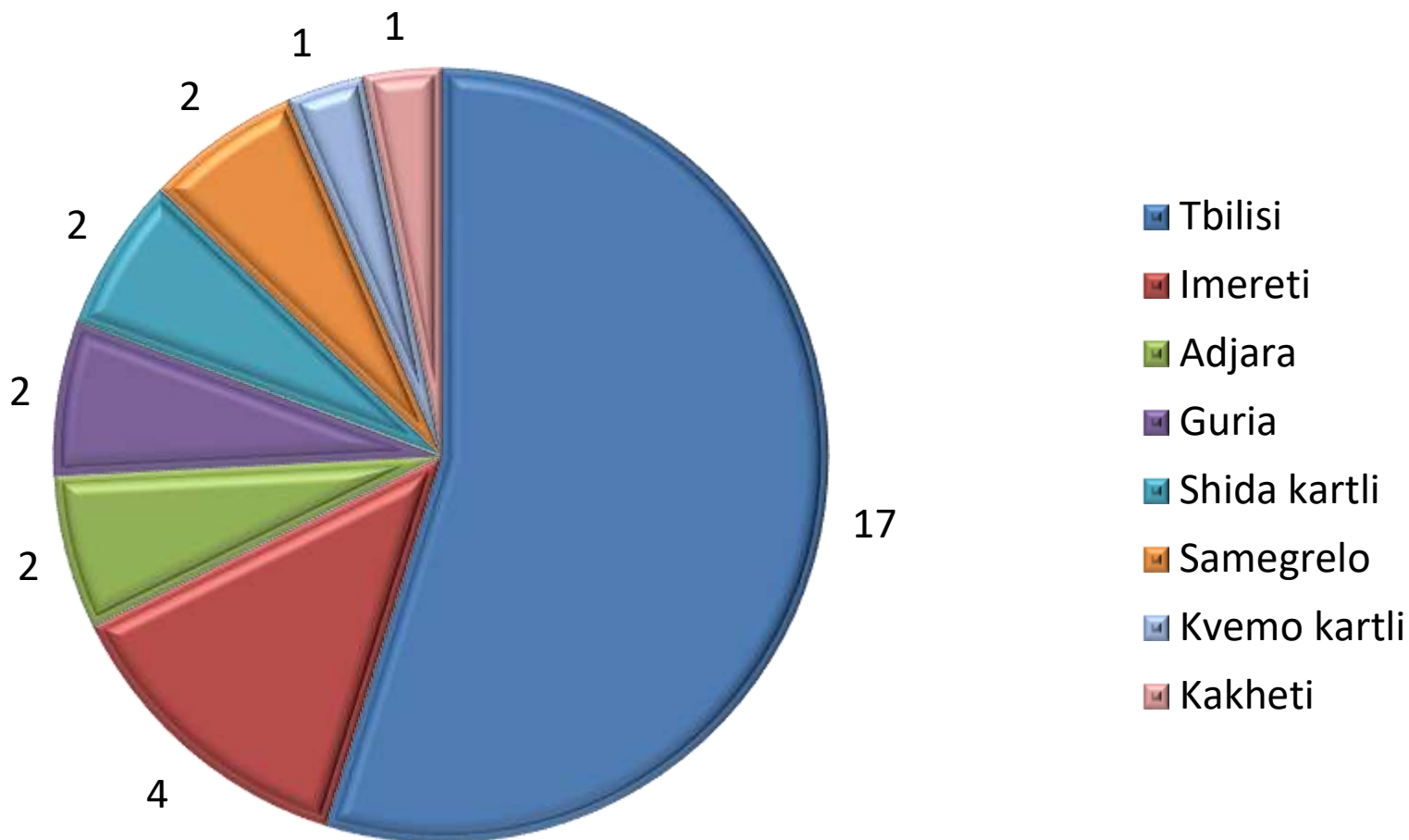


* of 37,500 patients eligible for SVR assessment, 28,806 were tested, 28,283 (98.2%) achieved SVR, 8,694 (23.2%) missing data

Challenges

- Declined enrollment in the treatment program
- Limited provider capacity and a scarcity of treatment centers in some geographic and especially in rural areas
 - Increase from 4 sites (launch of the program in April 2015) to 31 sites by October, 2017

Service provider



Objectives

- **Increase geographical accessibility**
 - decentralization of screening, care and treatment services
- **Increase financial accessibility**
 - simplified diagnostics algorithms
 - Minimize cost of diagnostic

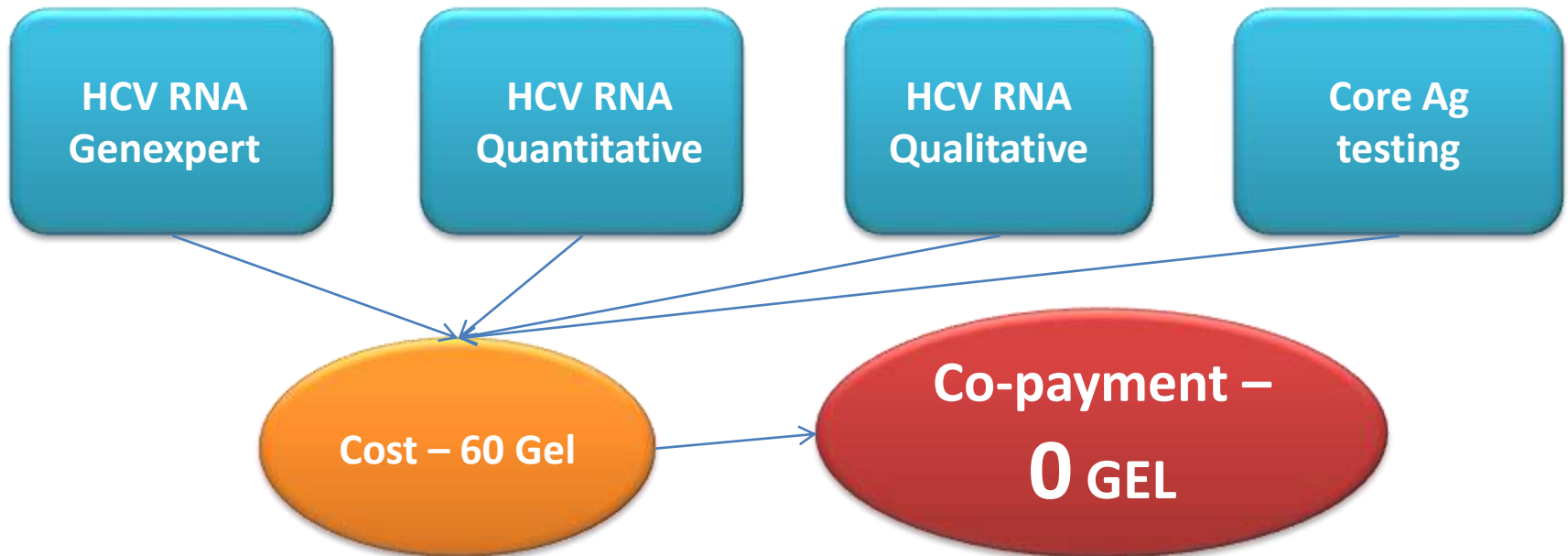
Diagnostic algorithm

First confirmatory test

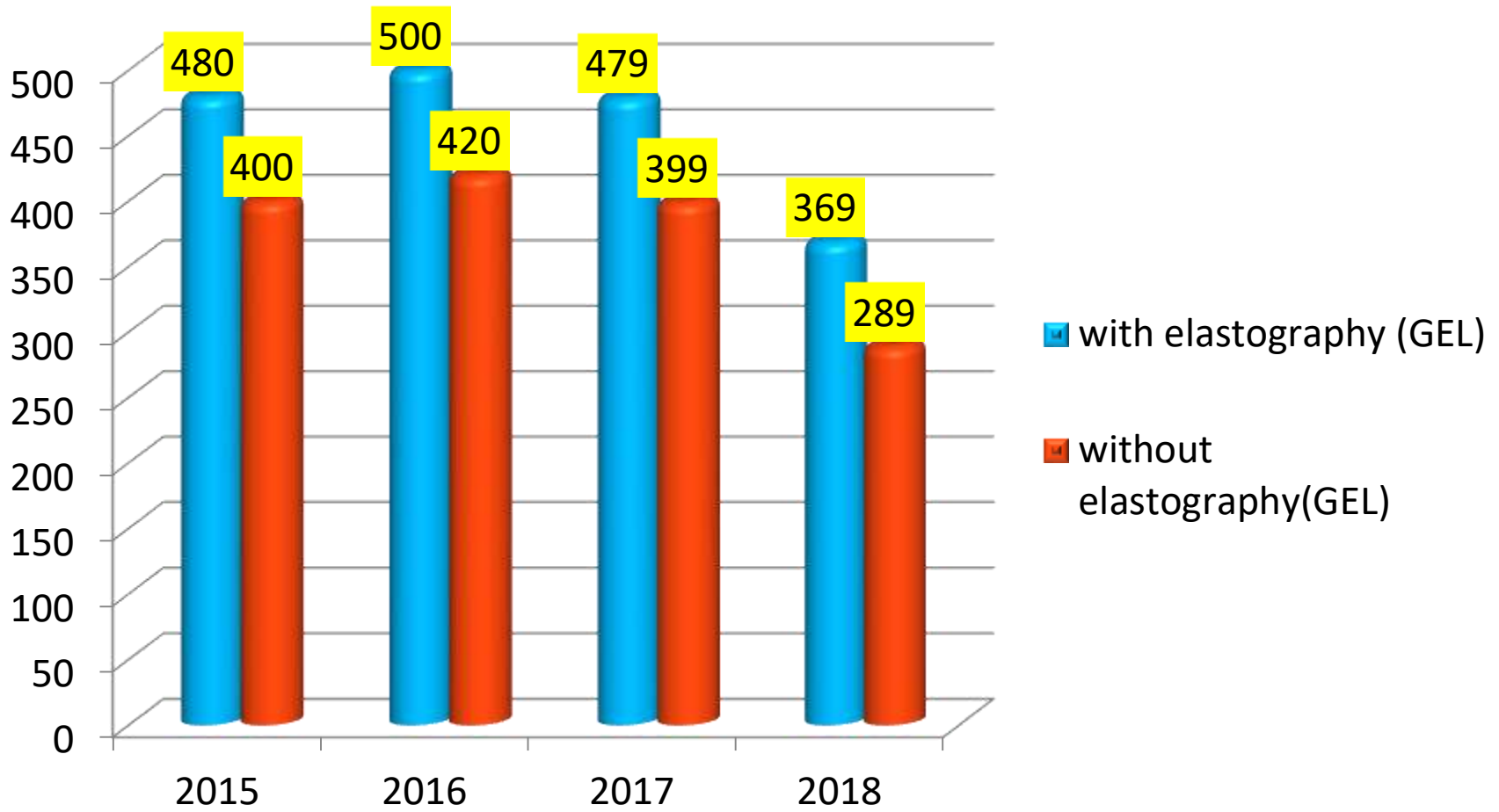
Before 1.12.17



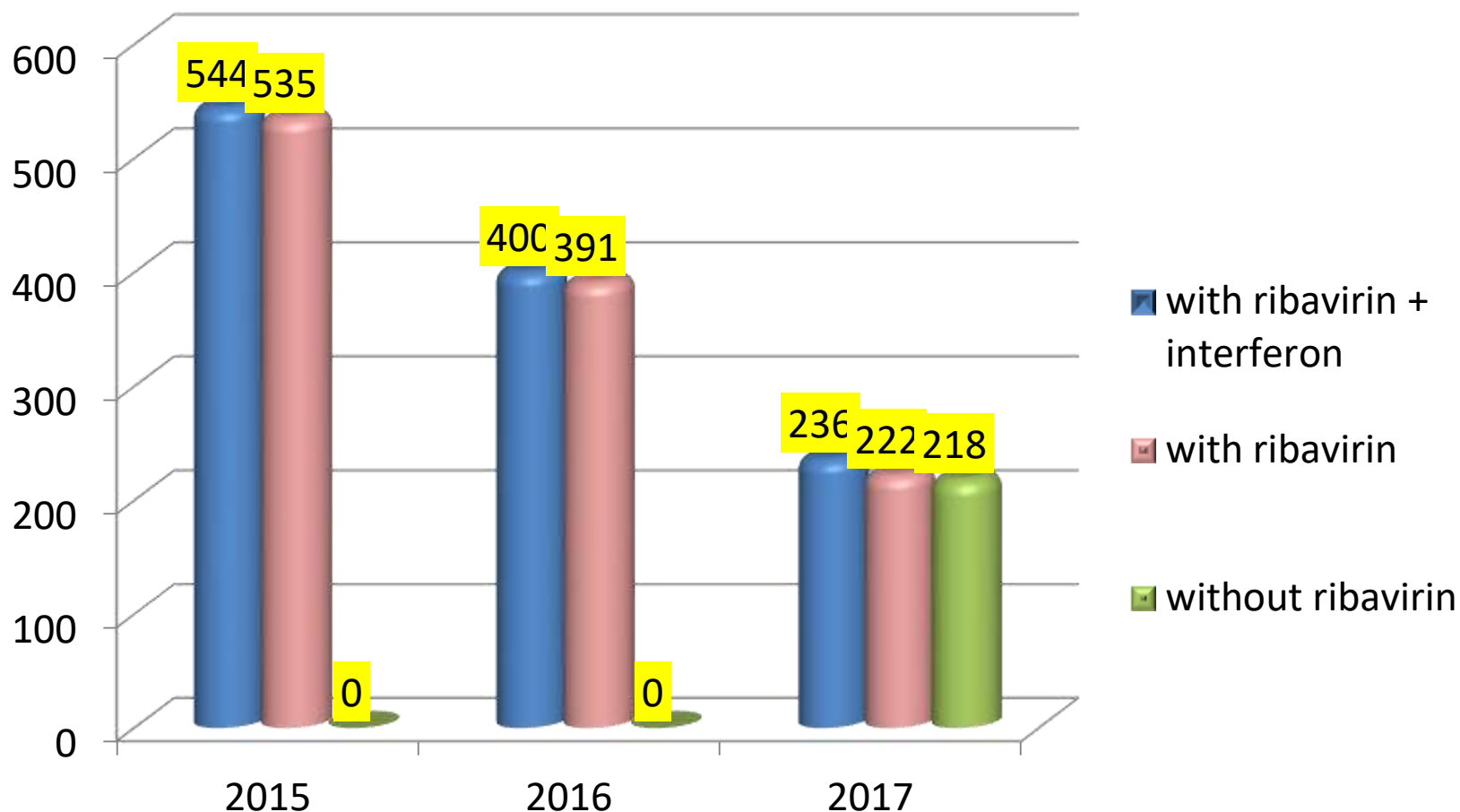
After 1.12.17



Diagnostic before treatment

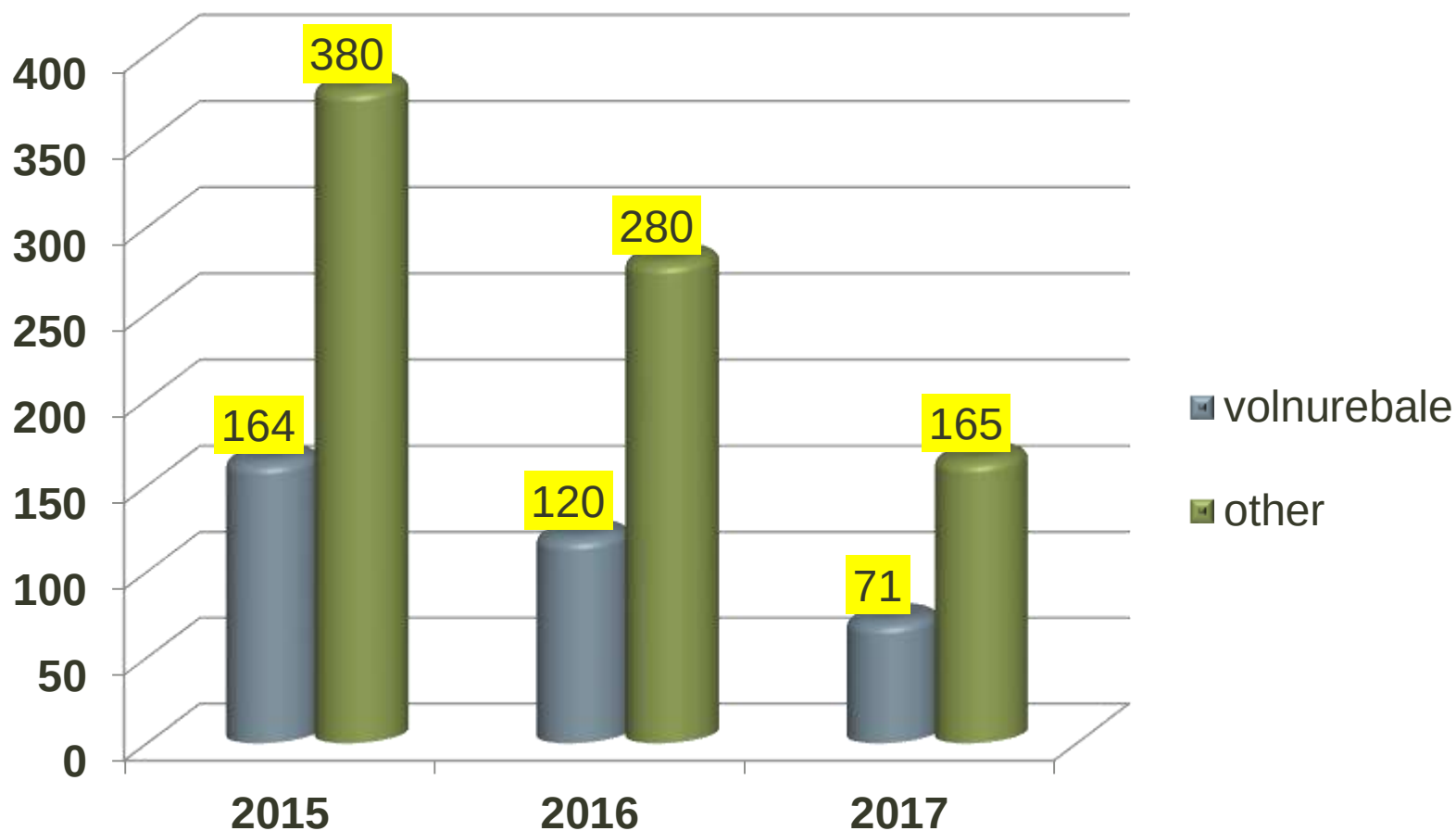


Diagnostic for **12 week** treatment monitoring



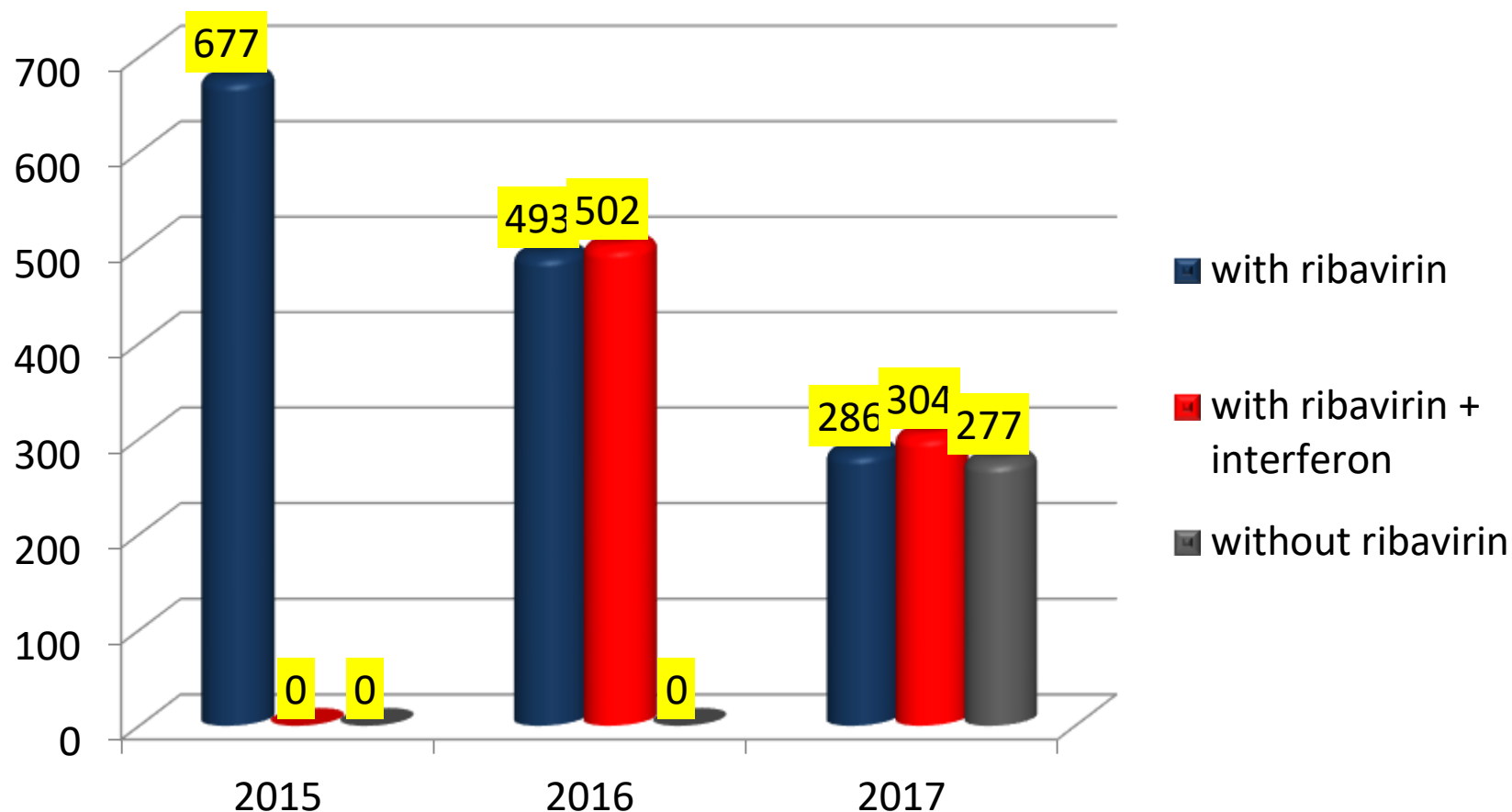
Diagnostic cost for patient

Diagnostic for **12 week** treatment monitoring



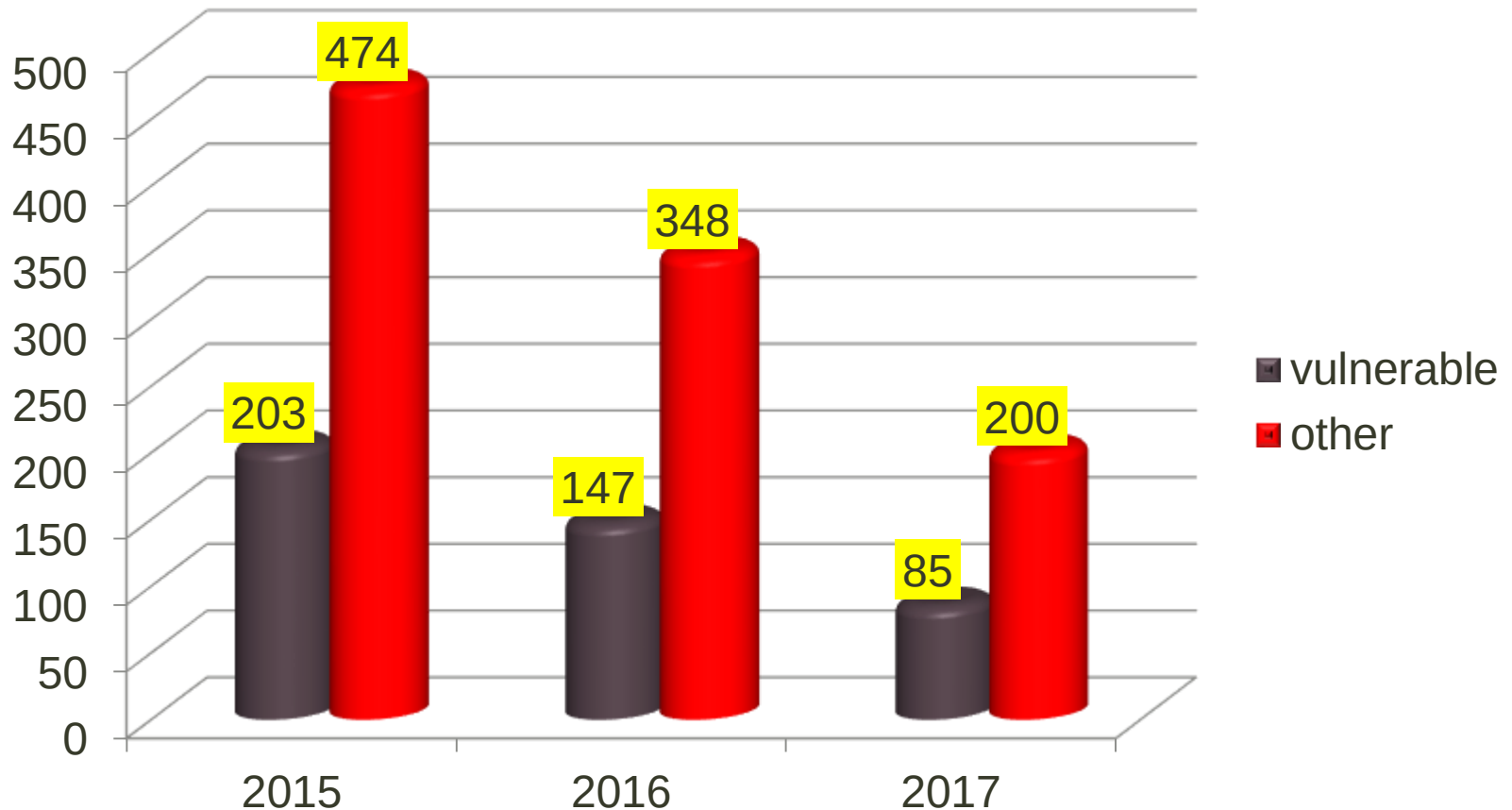
Diagnostic cost

Diagnostic for **24 week** treatment monitoring



Diagnostic cost for patient

Diagnostic for 24 week treatment monitoring



Diagnostic cost

❖ **SVR test (HCV RNA + Physician consultation) = 130 GEL**

Fully Funded by Government

Decentralization

First Steps

- existing regulations - all in-patient facilities are conducting **HCV screening** of hospital patients.
- After 10 of march, they will have an obligation to **conduct confirmatory testing** to all HCV positive patients.



Decentralization

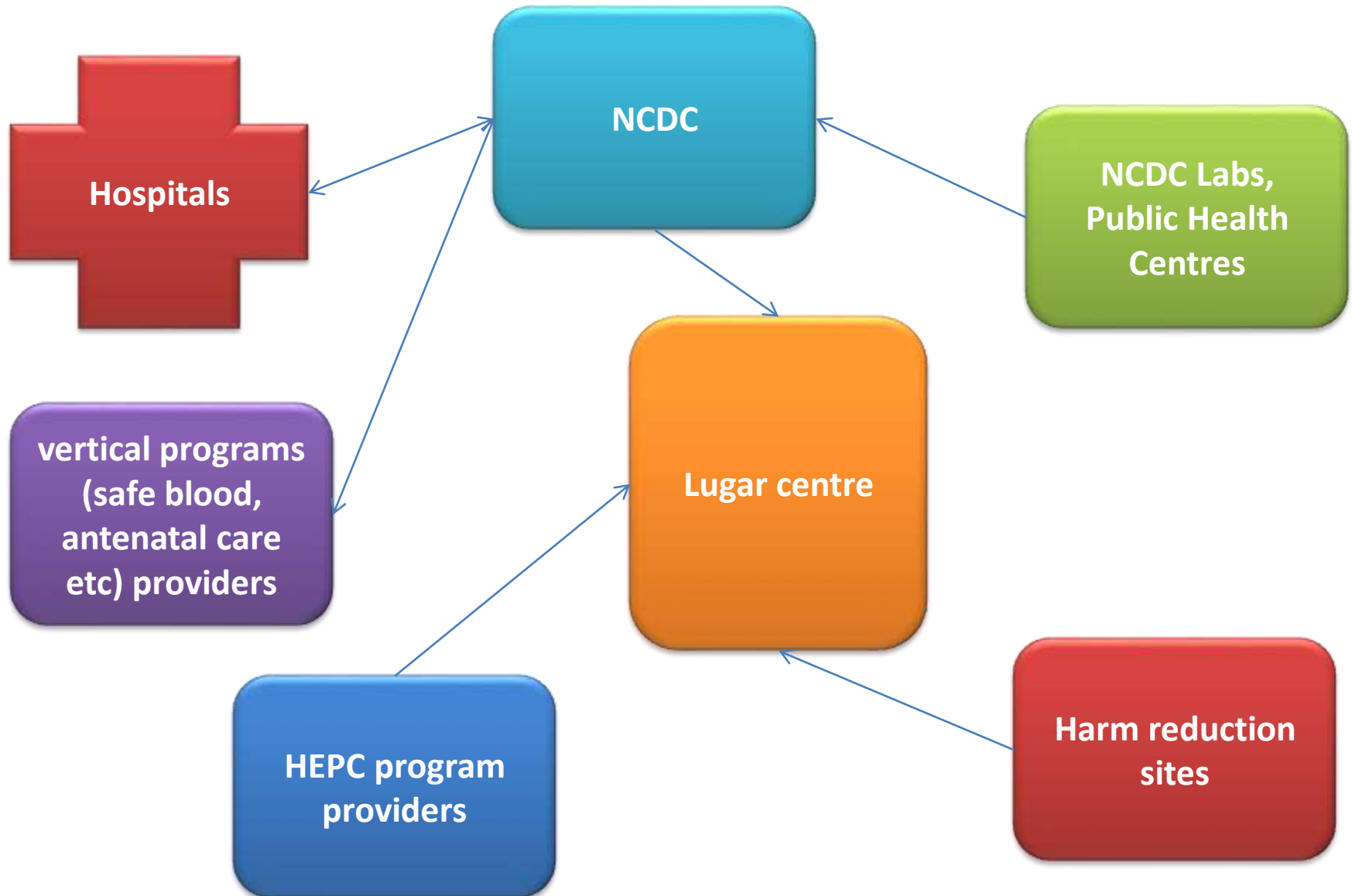
First Steps

- The regional laboratories of the NCDC;
- The regional units of the NCDC;
- Public Health Centers;
- Harm reduction sites;



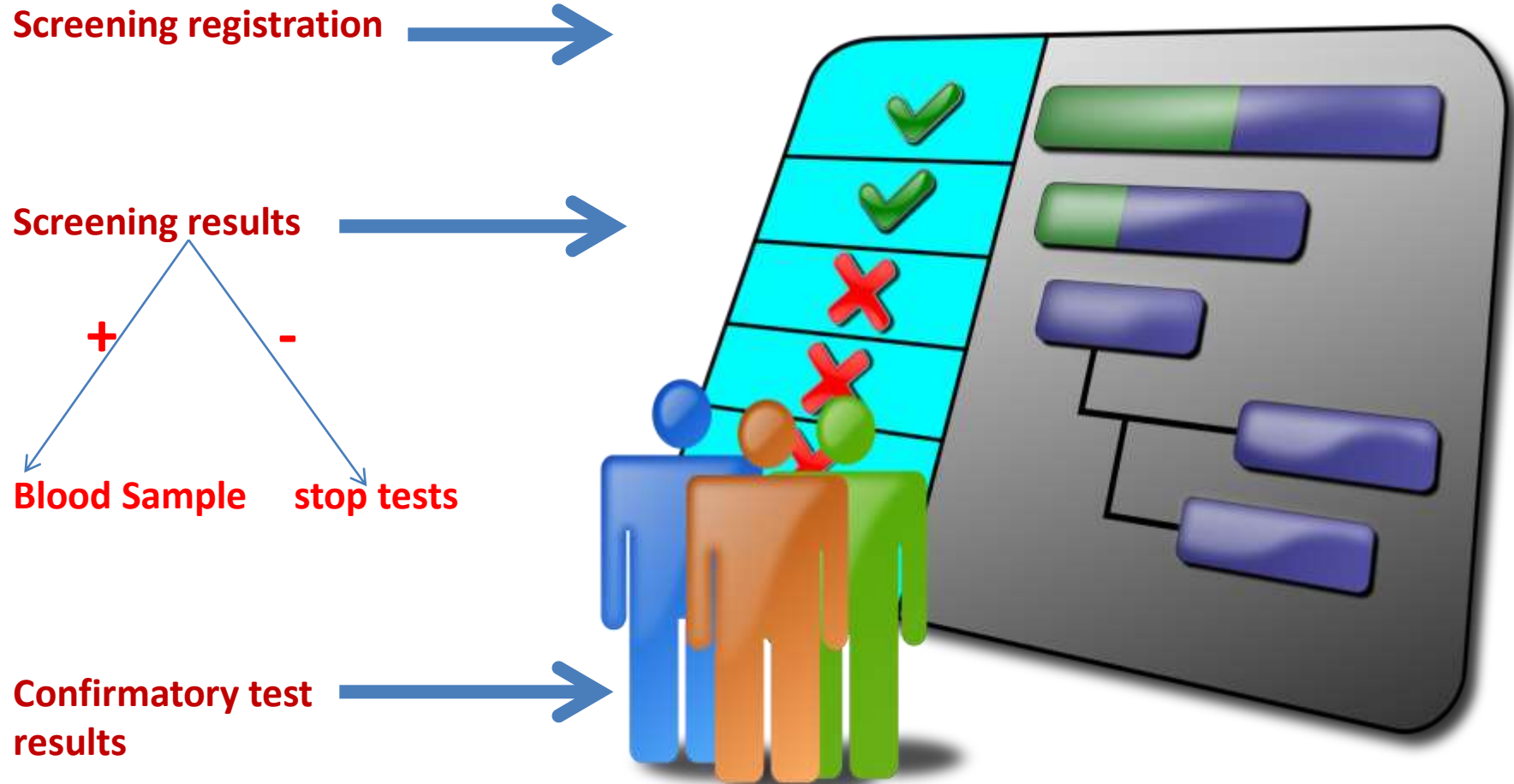
are obliged to **conduct confirmatory testing** of HCV positive patients;

Blood Samples Transportation



Information Flow

SCREENING MODULE!



Patient Surveillance

- **From 1 of march 2018**, The relevant units of the **NCDC** and **Public Health Centers** are obliged to ensure surveillance of HCV positive patients revealed by confirmatory testing and other needed diagnostic tests

Pilot Projects (1)

- **“Integrating HCV screening and simplified treatment services in primary healthcare”** – project of the Infectious Diseases, AIDS and Clinical Immunology Research Center, which aims to eliminate barriers and improve engagement in the entire continuum of HCV care;

Pilot Projects (2)

- „Simplifying pre-treatment diagnostic tests and treatment monitoring process in the Hepatitic C Elimination Project” - Project of Clinics “Mrcheveli” and “NeoLab”

Pilot Projects (3)

- **FIND's Head Start Project**, which aims to scale up effective diagnosis and linkage to care of PWIDs through harm reduction sites.

Pilot Projects (4)

Integration of HCV, TB and HIV Detection at PHC level

- ✓ To Develop the sustainable local public-private partnership for effective integration of TB/HIC/HCV screening and early disease detection;
- ✓ To strengthen PHC through development of integrated TB/HIC/HCV screening model with detailed protocol;
- ✓ To map the service providers at the regional level and establish effective referral systems to specialized clinics;

Main principles/tasks of decentralization

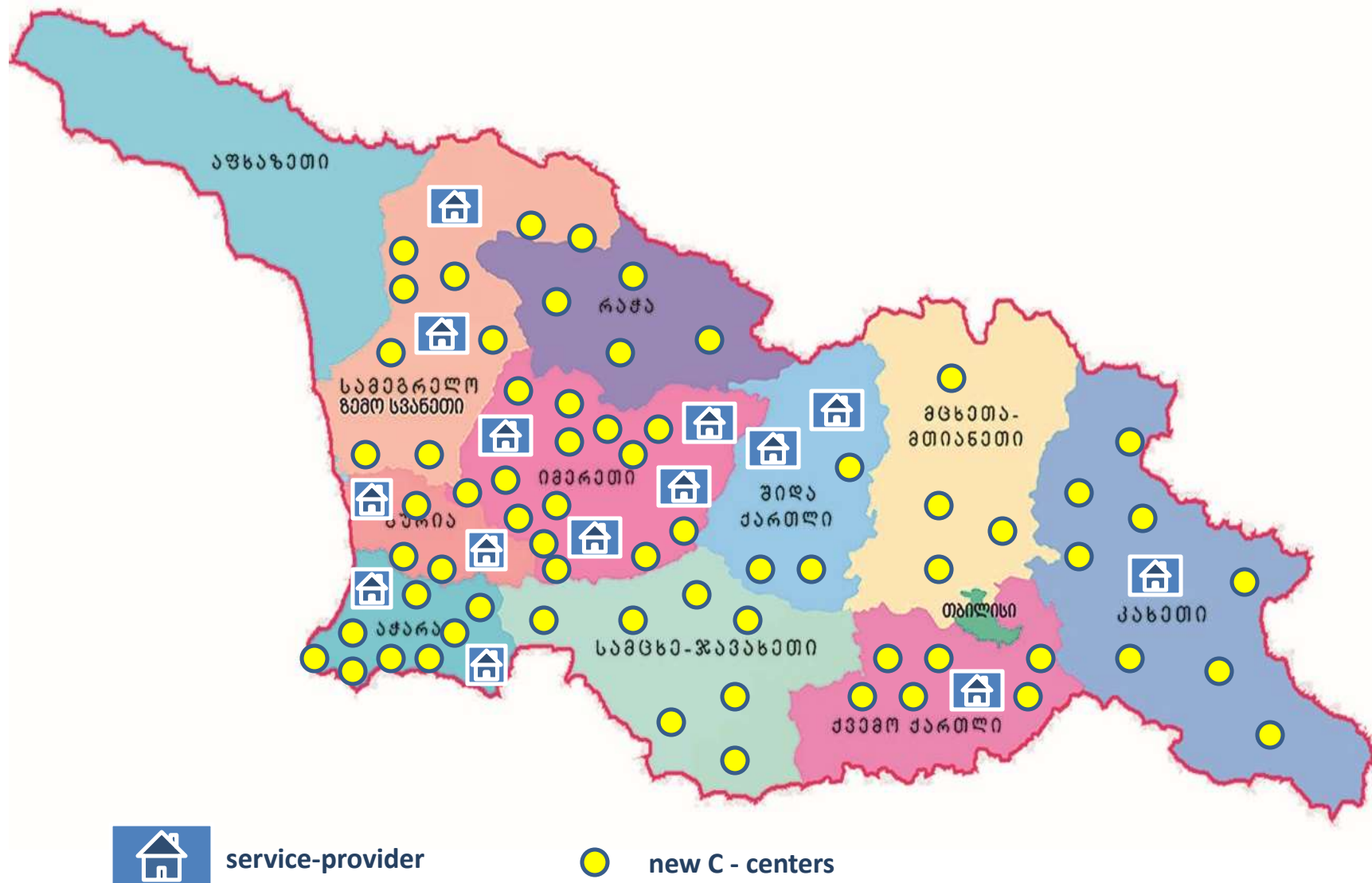
Integrating HCV screening and simplified treatment services in:

- **Primary healthcare centers (minimum one on each municipalities)**
- **Harm reduction centers (minimum one in Tbilisi, one in Batumi and one in Zugdidi)**
- **Hospitals**

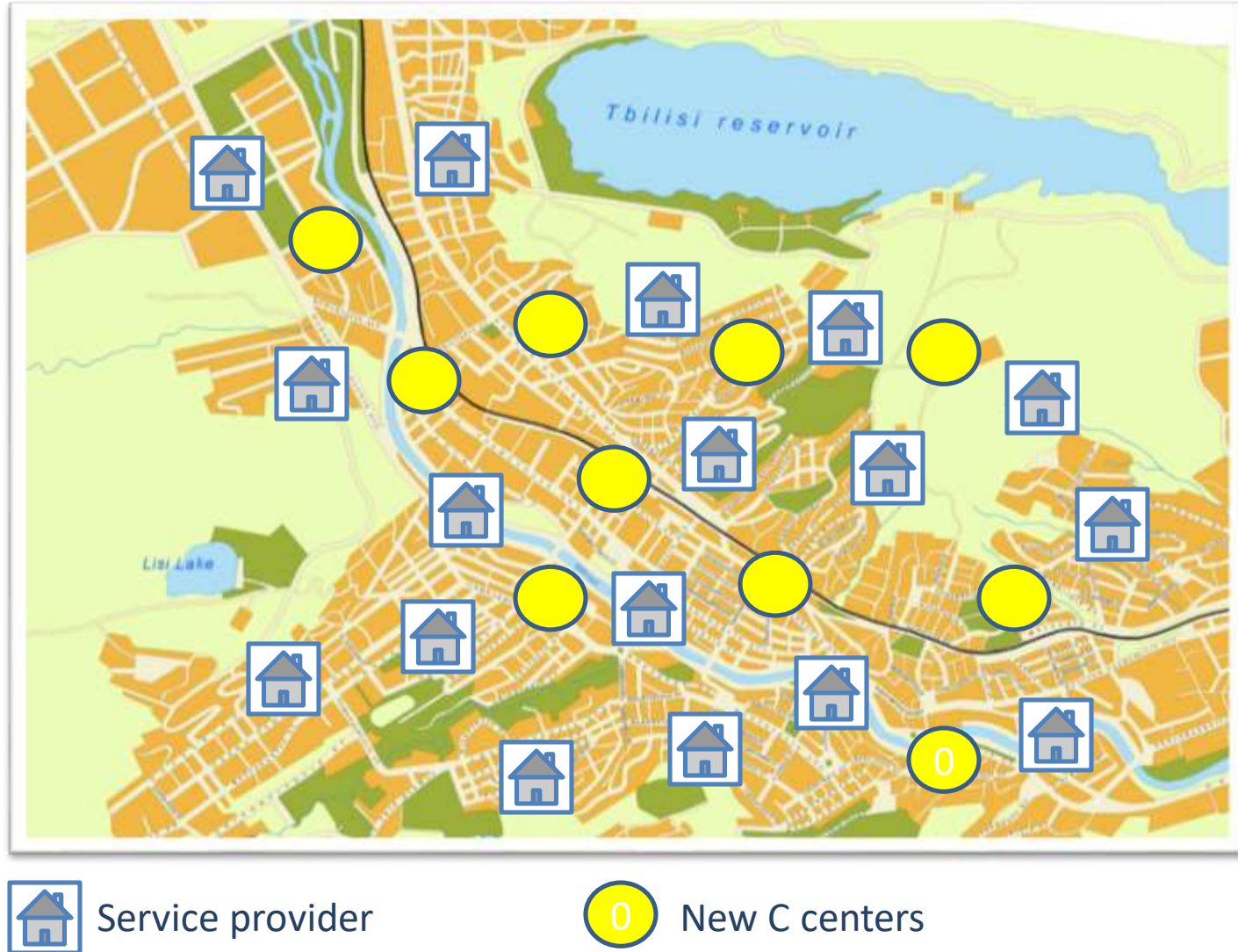
Main principles/tasks of decentralization

- Simplified Treatment and Diagnostics guidelines/algorithms
- Develop reasonable minimum criteria required for facilities to provide services to HCV patients
- Initial and Continued Training for PHC, Hospital staff
- Develop necessary information systems or modules to support decentralization projects (harm reduction sites, PHC etc.) into Elim-C data base

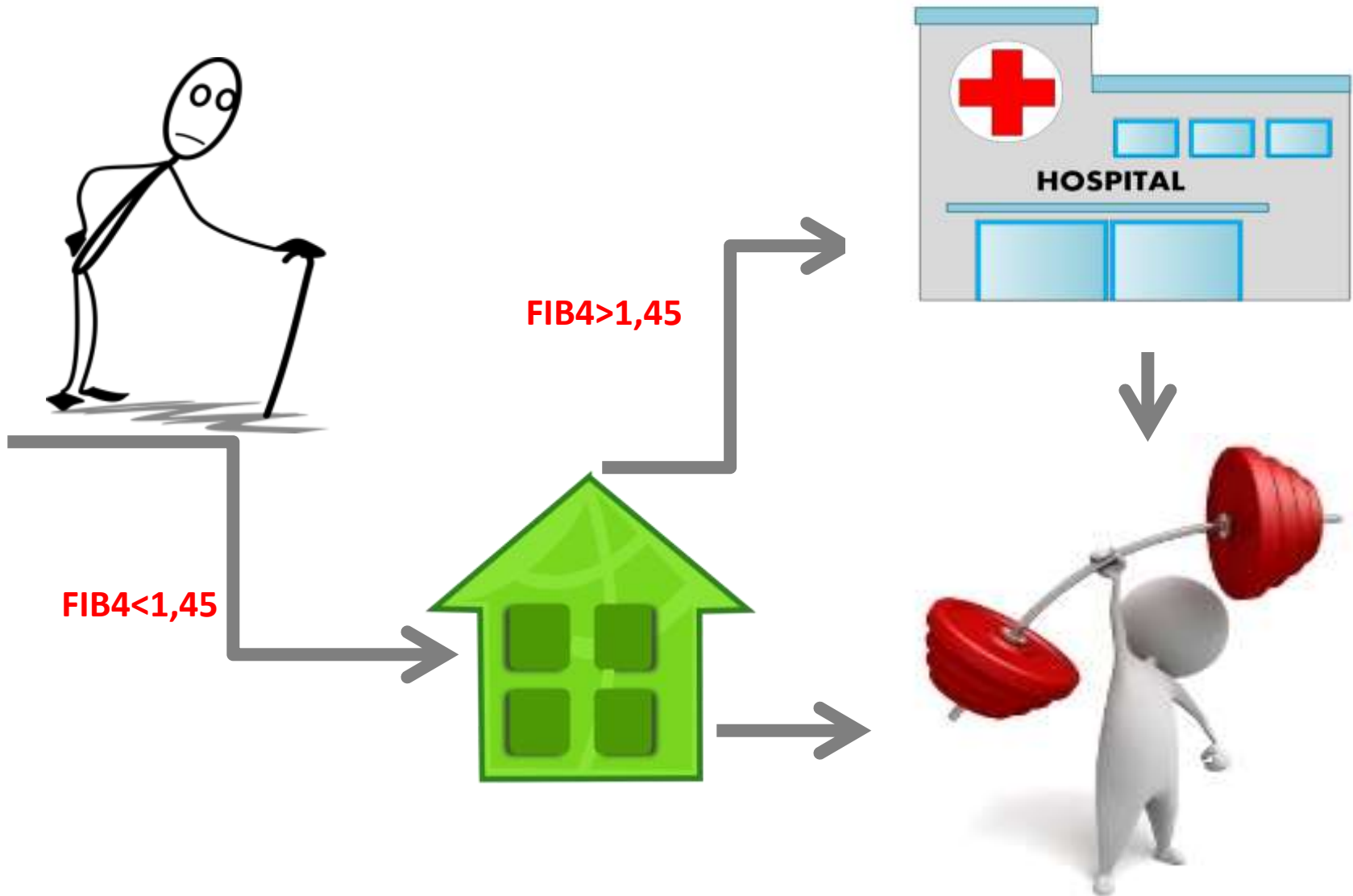
Decentralization Project (Regions)



Decentralization Project (Tbilisi)



Patient referral system



Thank you for your attention!

Implementing HCV treatment in harm reduction centers in Georgia

Health Research Union

Maia Butsashvili



Background

- **HCV treatment was integrated with OST services at one center in Tbilisi**
- **Enrollment of other HR sites is necessary to treat more PWID and improve linkage to care in this high-risk group**
- **Technical support is necessary to facilitate the process of application to MOH for being enrolled in HCV elimination program and provide HCV diagnostic and treatment services for their beneficiaries.**



Background

- From January 2018, FIND will launch the project “Feasibility, acceptability, effectiveness and cost-effectiveness of models of HCV viremia testing for confirmation and cure among people who inject drugs in Georgia”
- In arm one of this study, several HR centers will start on-site HCV RNA testing using GeneXpert platform to improve linkage to care among PWID



Pilot project

Integration of HCV treatment with harm reduction services

Funded by CDC



Goal and Objectives

The goal of this project is to integrate HCV treatment with harm reduction services at four OST/NSP sites in different regions of Georgia

Objective 1

To provide three NSP sites with security equipment to meet the MOH requirements to the facility for enrollment in HCV treatment

Objective 2

To train personnel of NSP/OST sites enrolled in HCV treatment

Objective 3

To introduce simplified testing algorithm among patients treated at harm reduction sites

Objective 4

To monitor diagnostic and treatment process and to establish ECHO teleconsultations with the Hub



Activities

Facilitate enrollment in treatment program for 4 sites with different services:

- **2 sites in western Georgia (in Zugdidi and Batumi) having on-site RNA testing (FIND study site, arm 1)**
- **1 site in Tbilisi (FIND study site, arm 1)**
- **One private OST site (using suboxone and not being FIND study site) with low linkage to HCV care rate**



Activities

- 3 NSP sites will be provided with security equipment to meet the MOH eligibility requirements
- 1 private OST center is already equipped with security equipment
- Trainings at selected 4 sites will be conducted



Activities

- We plan to train physicians, nurses and social workers before the sites start treatment
- Each site will become the spoke of the ECHO system and will be connected to one of ECHO hubs to provide continuous teleconsultations for physicians



Simplified regulation

- This project needs simplified regulations from MOH to make possible treatment integration at HR centers
- The basic security measures (camera, security system, lockers) is necessary
- Physician on site (contracted)
- Simplified diagnostic and monitoring algorithm
- Contract with elimination program provider clinic





FIND HEAD-Start project in Georgia

François Lamoury
Senior Laboratory Expert
FIND

The 5th National Hepatitis C Elimination Workshop
Tbilisi, Georgia
NCDC, 7-9th March 2018



Outline

FIND HEAD-Start project

FIND activities in Georgia

- ✓ Validating new technologies for HCV diagnosis
- ✓ Pilot project with different testing pathways
- ✓ Study nested within the pilot project:

Evaluation of HCV viremia testing approaches among PWID in Georgia

- ✓ Cost analysis of testing pathways



Hepatitis c Elimination *through* Access to Diagnostics (HEAD) - Start project

Goal:

Support and build efficient and long-lasting public health response to HCV by driving policy change and accelerate access

Objectives:

- Accelerate the development of new HCV diagnostics
- Establish innovative approaches for HCV testing [screening and diagnosis]
- Assess feasibility and effectiveness of HCV service delivery approaches
- Provide evidence to scale-up differentiated HCV diagnostic services
- Contribute to global normative guidelines & national policies to support a global ***HCV elimination pathway***





HEAD-Start: Country projects

Georgia:
Provide confirmatory
testing for 10,500

Total Dx
Confirmatory testing: ≈36,000

Rx Targets
Treatment: ≈7,200 (FIND), ≈20,500 (Partners)

Myanmar

Vietnam

Malaysia

Cameroon

India:
Delhi
Manipur
Punjab

WHO region	Map key	Incidence of HCV infection			
		Incidence rate (per 100 000)		Total number (000)	
		Best estimate	Uncertainty interval	Best estimate	Uncertainty interval
African Region		31.0	22.5–54.4	309	222–544
Region of the Americas		6.4	5.9–7.0	63	59–69
Eastern Mediterranean Region		62.5	55.5–65.2	409	363–426
European Region		61.8	50.3–66.0	565	460–603
South-East Asia Region		14.8	12.5–26.9	287	243–524
Western Pacific Region		6.0	5.5–6.5	111	104–124
Global		23.7	21.3–28.7	1 751	1 572–2 120

Source: WHO, work conducted by the Center for Disease Analysis. See Annex 2.

* These deaths exclude those from the extrahepatic complications of HCV infection and background mortality from other causes among HCV-infected patients.



Expanding new technologies for HCV testing Validation project - Georgia

- **Xpert HCV VL FS assay**

Easier blood collection by fingerstick

Result in one hour

Study closing @ Lugar Center & Hepa+, recruited 400 participants.

Other countries: Cameroon, Malaysia, Greece, Denmark



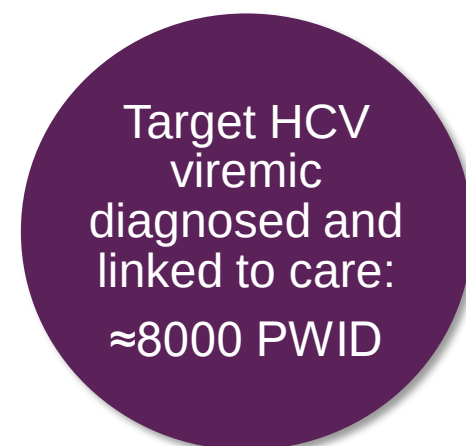
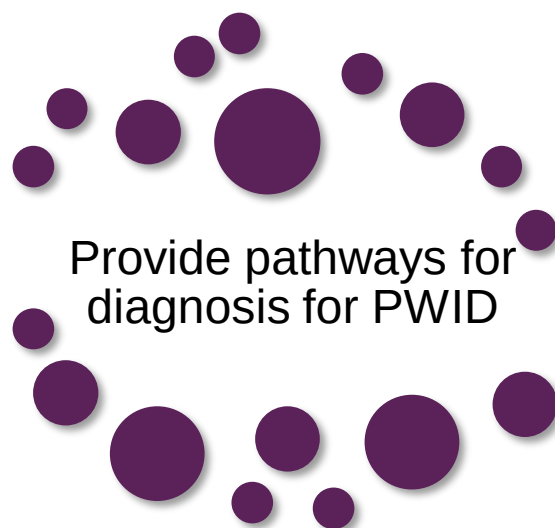
- **Future potential projects:**

Use of Dried Blot Spots for HCV RNA testing

Rapid Diagnostic Test evaluation for more quality assured products



Pilot project - Georgia



Increase linkage
between screening
and confirmatory
testing

Help move
elimination of HCV in
Georgia forwards



FIND pilot project- scope

ACTIVITY

Decentralization of HCV confirmatory testing at HRS using **GeneXpert plasma** cartridges



OUTCOME

HCV confirmatory at HRS increases linkage to care and reduces loss-to-follow up between screening and confirmatory



POTENTIAL

- Support the integration of HCV RNA testing in TB GeneXpert

Decentralization of HCV confirmatory testing at HRS using **Abbott cAg assay** at Lugar Centre



Effective sample referral mechanism and efficient pts workflow increases access to HCV confirmatory and decreases TAT



- One testing approach in high prevalence setting (modelling)



Overview FINDs contribution

≈ 10,500 PWID will
undergo confirmatory
testing within pilot
PROJECT

**1,860
of those will
undergo
confirmatory
testing
within the
STUDY**

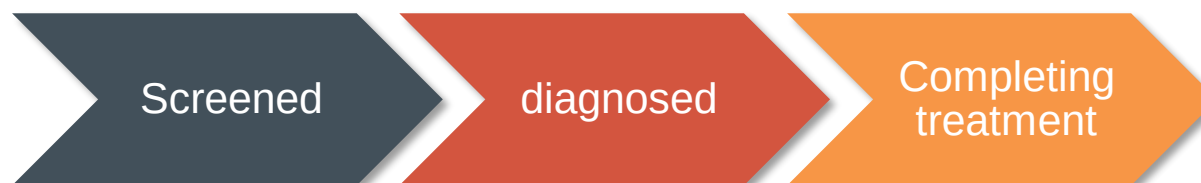


STUDY - portion of pilot project

Evaluation of HCV viremia testing approaches among PWID in Georgia

Goals

- Service delivery approaches to provide confirmatory testing for a greatest number of PWID being:



- Use of cAg for test of cure (SVR 12)
- Cost of the service delivery approaches; core antigen and point of care RNA



HRS sites included in the pilot project



Point of Care at HRS



cAg, samples collected at HRS and transported to Lugar Center



Standard of Care, patient referred for dx and tx



Study methods

Harm Reduction Sites



Non randomized assignment

Arm 1 - POC



620 beneficiaries who screen HCV+

- Blood draw
- HCV RNA testing
- Results to PWID

Arm 2 - cAg



620 beneficiaries who screen HCV+

- Blood draw
- Blood sample shipped to Lugar
- HCV cAg test
- Results to PWID

cAg as test of cure

Arm 3 - SOC



620 beneficiaries who screen HCV+

- Current practice

Costing of pathway

LTFU rate along care cascade



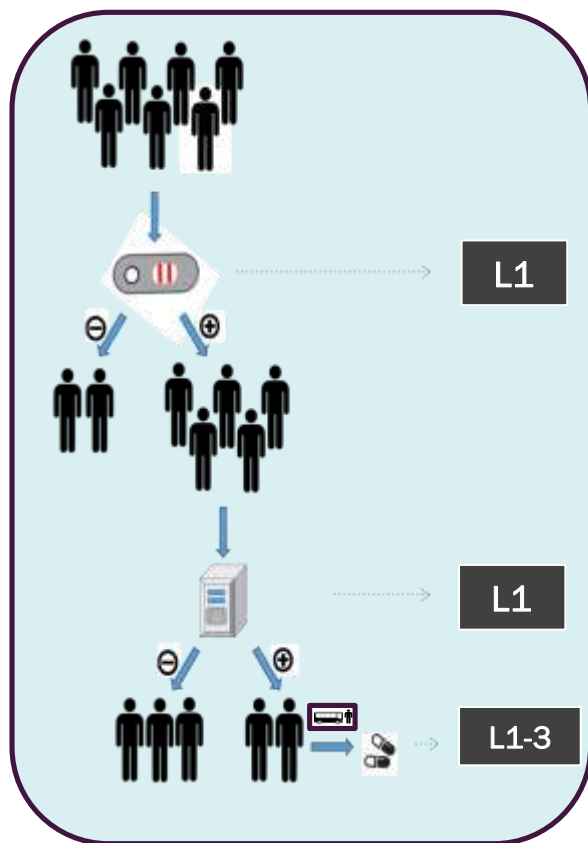
Substudy: Evaluation of the diagnostic performance of HCVcAg as test of cure in for hepatitis C among PWID in Georgia

- **HCVcAg:** highly **sensitive** and **specific** in the diagnosis of **active HCV infection** in different populations.
- **HCVcAg confirmatory testing** already approved by the **Georgian** government
- **Limited data** on its clinical utility to confirm sustained virologic response (**SVR**) in people who have completed therapy for hepatitis C.
- **Hypothesis:** The use of HCV cAg assay may present an **alternative** to confirming **SVR**.
- **1st objective:** To estimate the **diagnostic accuracy** of **HCVcAg** assay in differentiating patients who have **achieved** sustained virological response (**SVR**) from those who **fail SVR** among those who have completed treatment for hepatitis C.
- **Analysis plan:** The performance of the HCV cAg Assay to confirm SVR will be evaluated in comparison with Abbott *RealTime* HCV viral load assay HCV. (sensitivity, specificity, PPV, NPV. Subgroup analyses will include performance of HCV cAg by: HIV status, HBV status, HCV genotype)

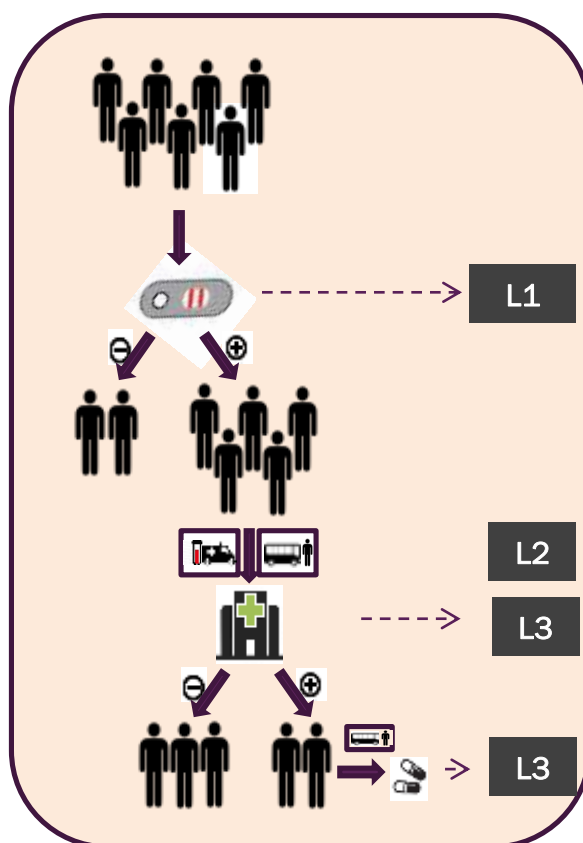


Cost analysis of testing pathway

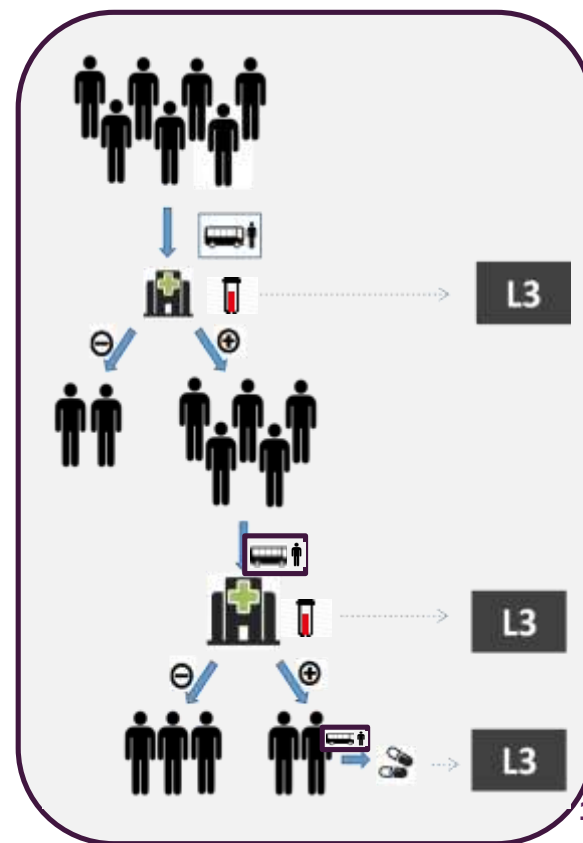
Arm 1 - POC



Arm 2 - cAg



Arm 3 - SOC



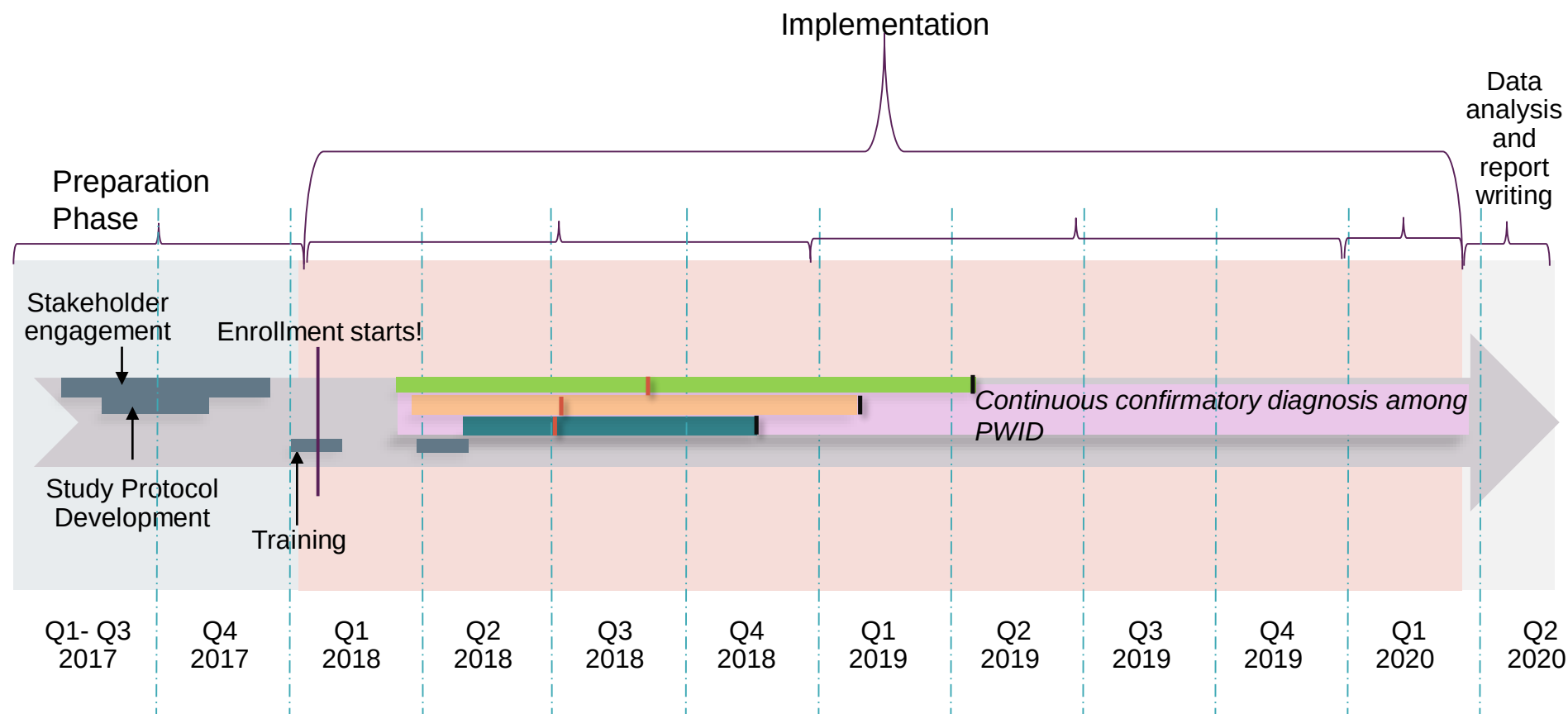
L1: primary health care

L2: Secondary health care

L3: Tertiary Health Care



Georgia pilot project timelines



Study portion of pilot project

- POC RNA
- cAg
- Standard of Care
- Last study enrollment per group
- Last study SVR12 per group



THANK YOU!

Special thanks to our partners in this endeavor!



We are grateful for the input and feedback of many of the organizations also doing great work in the area of HCV elimination in Georgia



Study of Barriers for HCV treatment involvement in Harm reduction Centers

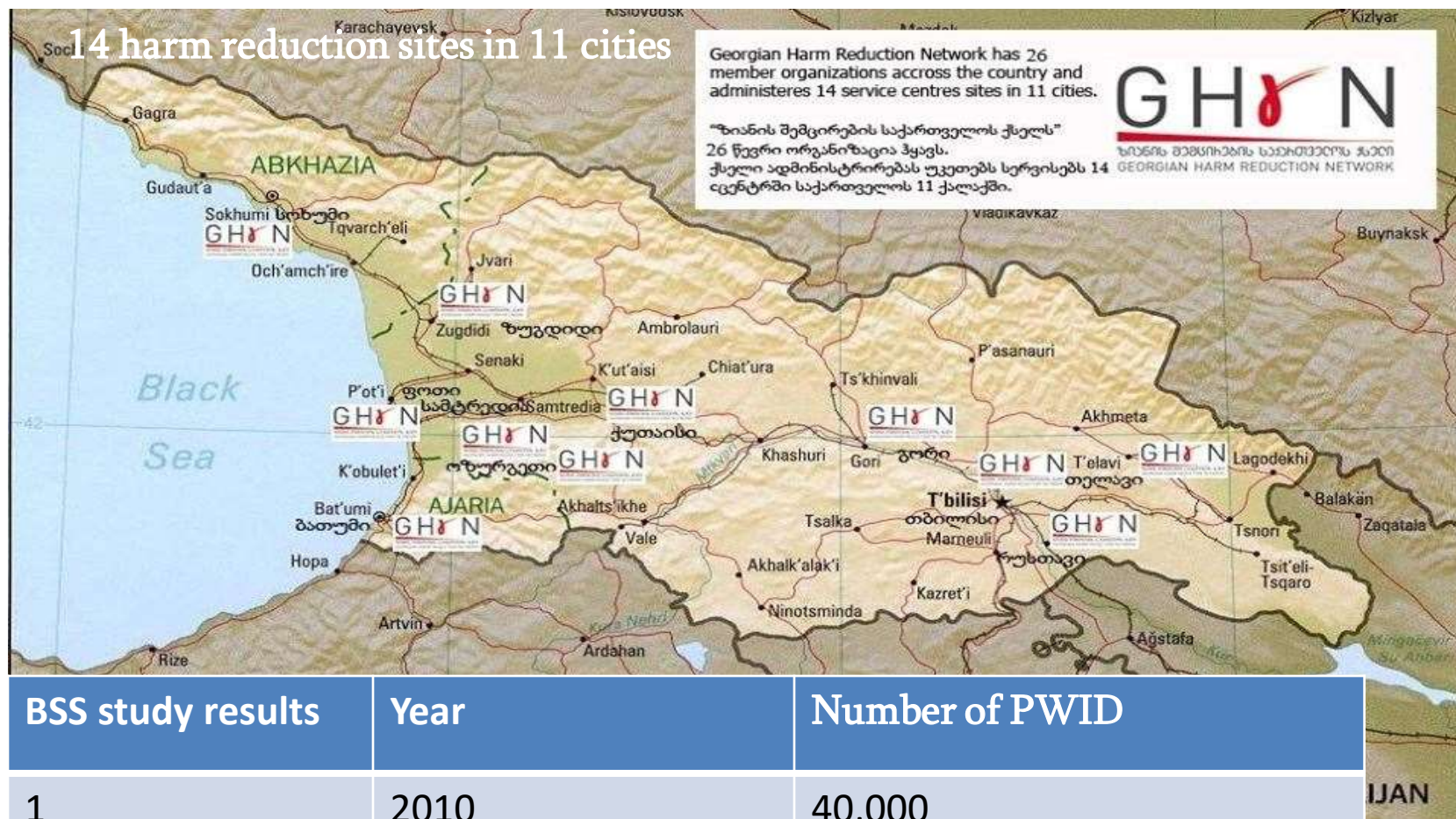
Maka Gogia

Georgian Harm Reduction Network

March 9, 2018

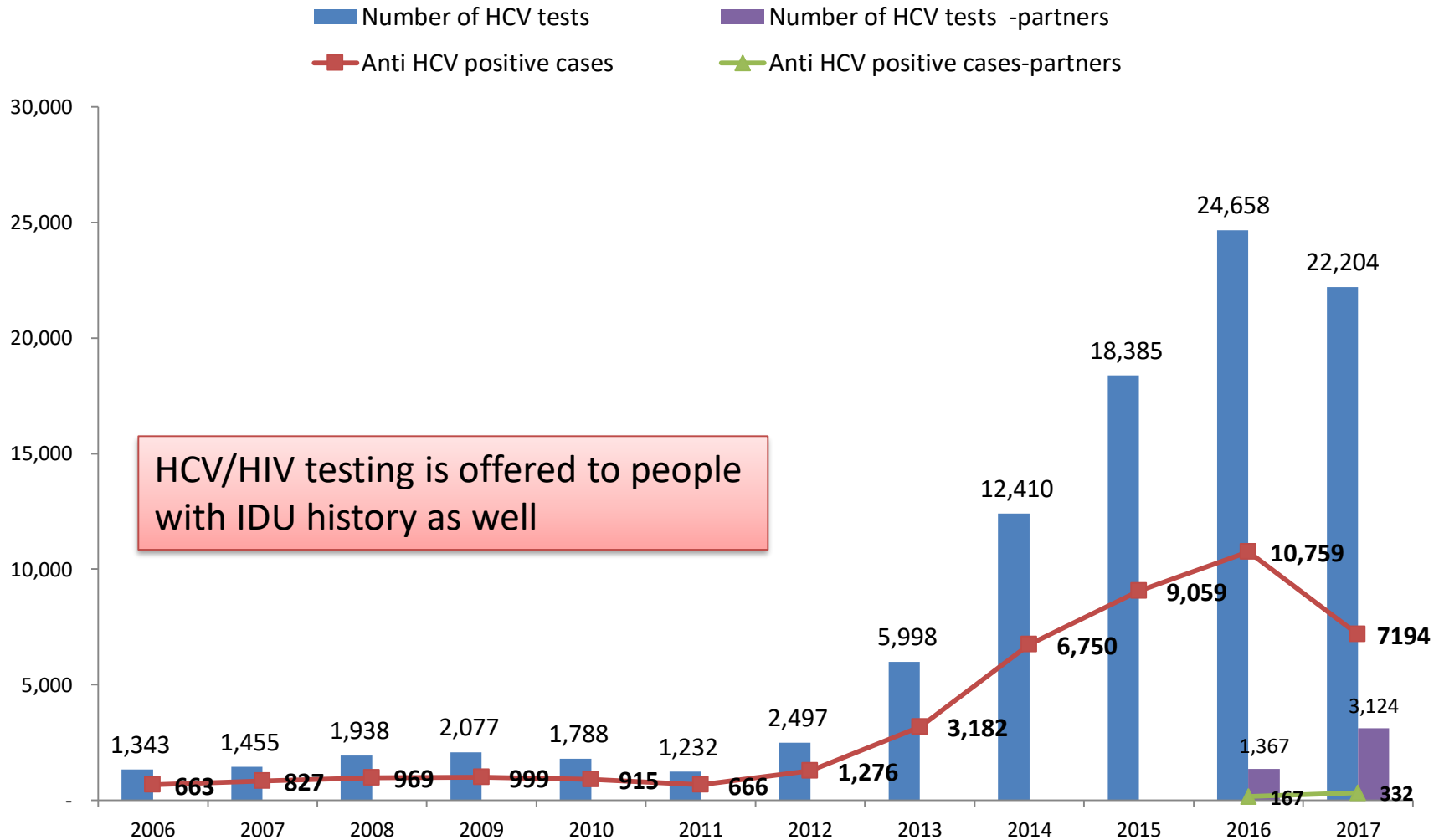


Needle and Syringe Program's Geography in Georgia



BSS study results	Year	Number of PWID
1	2010	40,000
2	2012	45,000
3	2014	49,700
4	2017	52,500

Number of HCV testing sessions among PWIDs by years



Harm Reduction program data, 2017

City	Harm Reduction Site	HCV Screening	HCV positive cases	No RNA diagnose	RNA tested and involved in treatment
Tbilisi	New Vector	1402	516	322	60%
	New Way	2284	661	425	65%
	Hepa+	2393	672	135	35%
	Aceso	2132	576	282	51%
Kutaisi	New Way	2683	1193	955	20%
Zugdidi	Qsenoni	1795	708	212	90%
Batumi	Imedi	1414	467	210	35%
Telavi	Step to Future	1015	240	141	38%
Gori	Step to Future	1645	499	272	55%
Poti	Ordu	751	277	168	43%
Ozurgeti	Fenix	1063	242	20	90%
Samtredia	New Way	883	245	200	47%
Rustavi	New Vector	1935	513	178	50%

To address the barriers within HCV Elimination program

- **In 2016** GHRN conducted qualitative study to assess First Phase of HCV Elimination program
- **In 2018** GHRN together with partners plans to carry out quantitative study

Title of project:

Study of barriers to enrollment into HCV elimination program among PWID

Part of NCDC Study of barriers among general population

Objective of the proposed research is to identify barriers of enrollment into HCV elimination program among HCV antibody positive people

Duration:

9 months (April-December, 2017)

Collaborators and responsibilities

Organization	Responsibilities	
Health Research Union	The project lead (PI) - plans and supervises all project activities, participates in developing research design/protocol, data analysis, development of recommendations and preparation of research papers	
Georgian Harm Reduction Network	Ensures Interviewers' selection and trainings; Conducts on-site monitoring visits at 13 harm reduction sites; ensures high quality of quantitative data	
Medecins du Monde, France	Support in development of study design, data analysis and manuscript preparation	Funders
US CDC		
NCDC		

Methods

- The data that are entered into the elimination program databases will allow tracking each individual from screening to the sustained viral response (SVR) test.
- The stratified sample of PWID having positive HCV antibody test between April-September, 2017 and not linked to care will be selected.
- Individuals **who are lost to follow-up** are defined as those not having HCV RNA or Core antigen test in the treatment database at 90th day from being screened HCV positive.
- A **“linked to care”** individual is defined as: HCV+ screening and having RNA/Core antigen test in the treatment database.

Methods

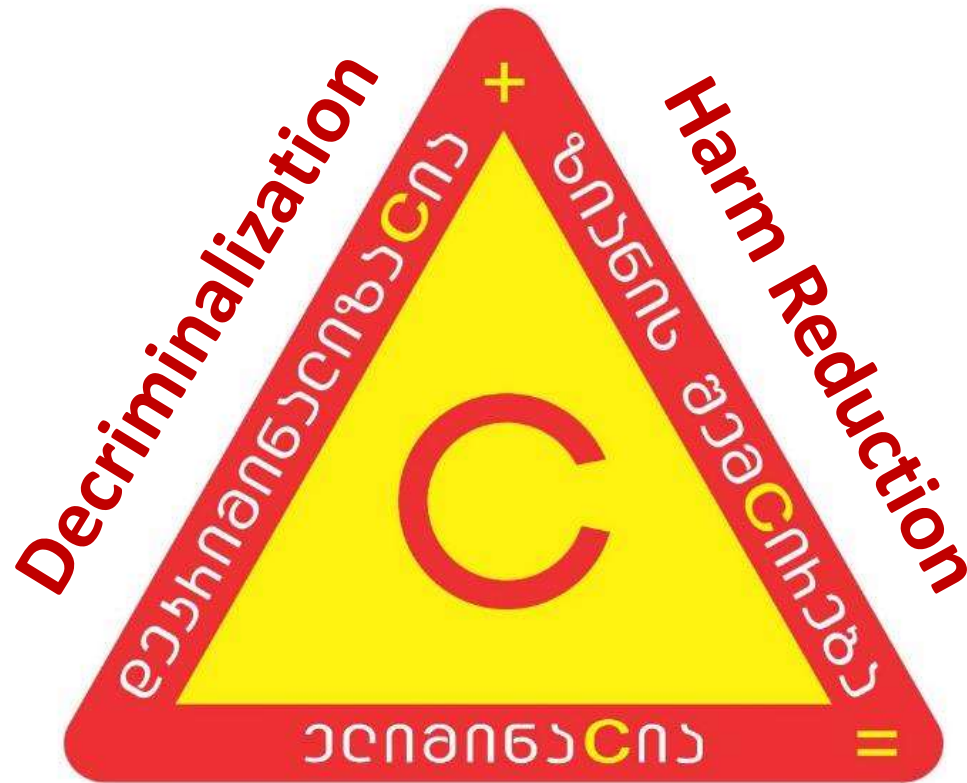
- Proportional to size sample of lost to follow up as well as linked to care PWID from each HR site will be selected.
- Overall **sample size will be 500 PWID.**
- The telephone interviews will be used.
- Interviewers will be recruited from HR center staff (HIV voluntary counseling and testing counselors) and trained prior to the start of the study.

Methods

- Five attempts to reach each study participant will be made, as done by NCDC barriers' study interviewers.
- Failure to reach the respondent as well as refusal rate will be calculated.
- The questionnaire will be piloted and adapted accordingly.
- The questionnaire will be similar to the one used by NCDC, with few additional questions specific to PWID

Expected outcomes

- We expect the study results will generate important data to understand barriers of linkage to HCV care among PWID.
- This will make possible to plan effective interventions to improve the enrollment into HCV elimination program ensuring better coverage of most important and hard to reach population as PWID **to achieve HCV elimination goal.**



C Elimination

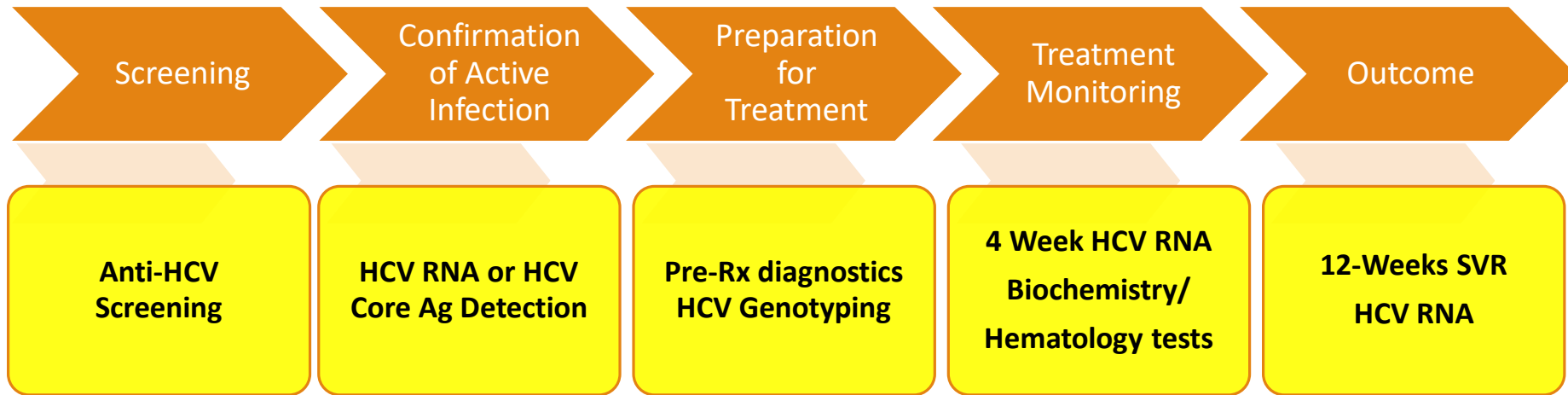
Thank you!

Progress Made in Assuring Quality HCV Diagnostics in Georgia

BETH SKAGGS, PHD

CDC SOUTH CAUCASUS OFFICE

Access to Accurate and Timely Laboratory Diagnostics is the Backbone of the HCV Elimination Program



- In 2015-2016 ~600,000 HCV related tests were performed in Georgia
- US reports ~1-3% error rate among all clinical laboratory tests
- A 2% error rate of HCV screening in Georgia would result in **12,000** incorrect HCV tests over this 2 year period
- Quality Management System is intended to detect errors, prevent them in the future and reduce cost

Where We Were.....

**Challenges Presented in April 2016*

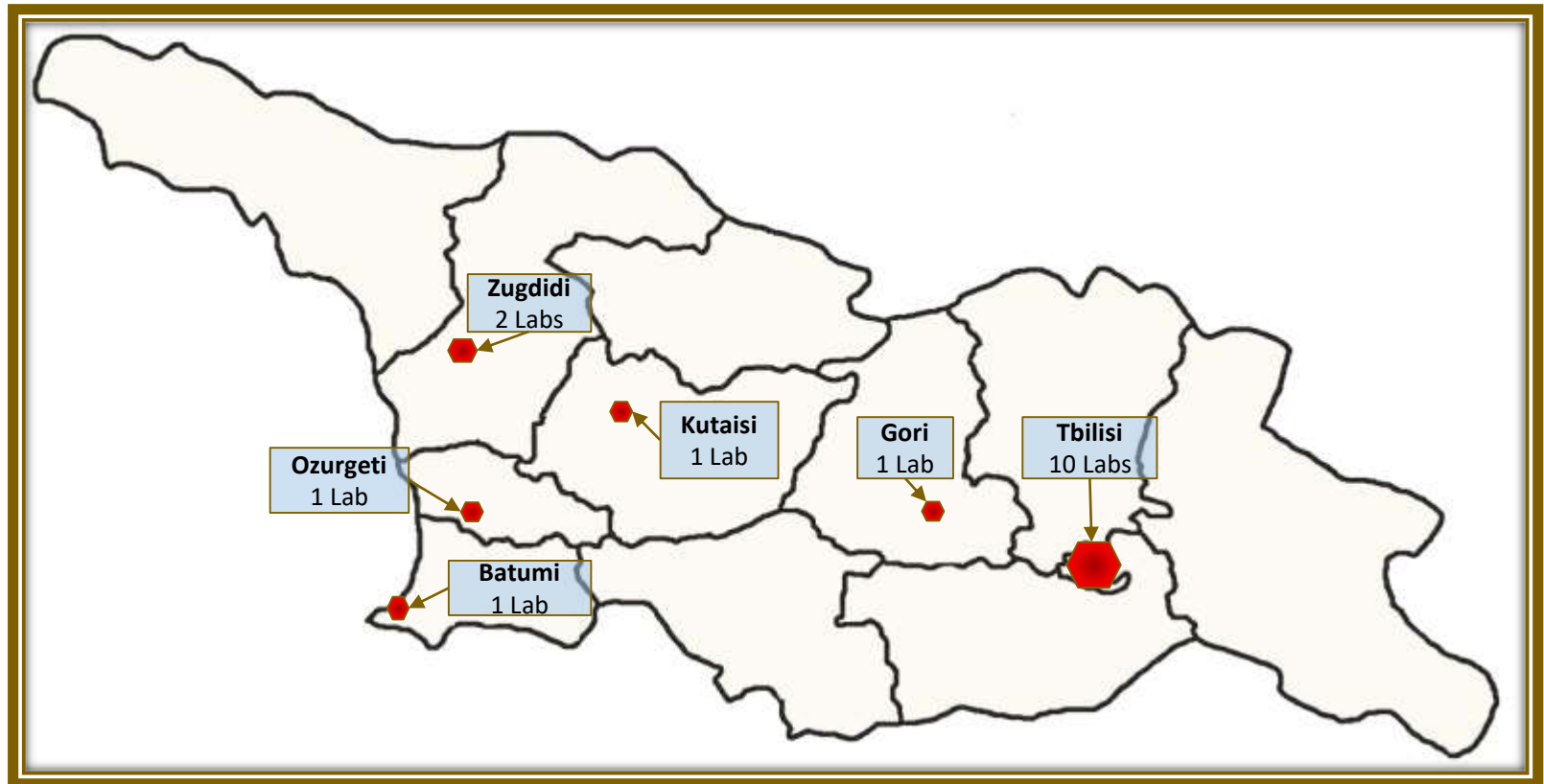
- Appropriate laboratory services in regions yet to be established
 - Services in Tbilisi are adequate
- No unified external quality control system exists
 - Quality control limited to internal control procedures
- Test-kits used by laboratories vary based on availability from the suppliers; most of test-kits have not been validated
- Unified standard procedures not identified for participating labs
- No national certification systems for clinical laboratories exists
- No systematic training of lab personnel in biosafety standard
- Screening HIV antibodies not part of program

Current Situation...March 2018

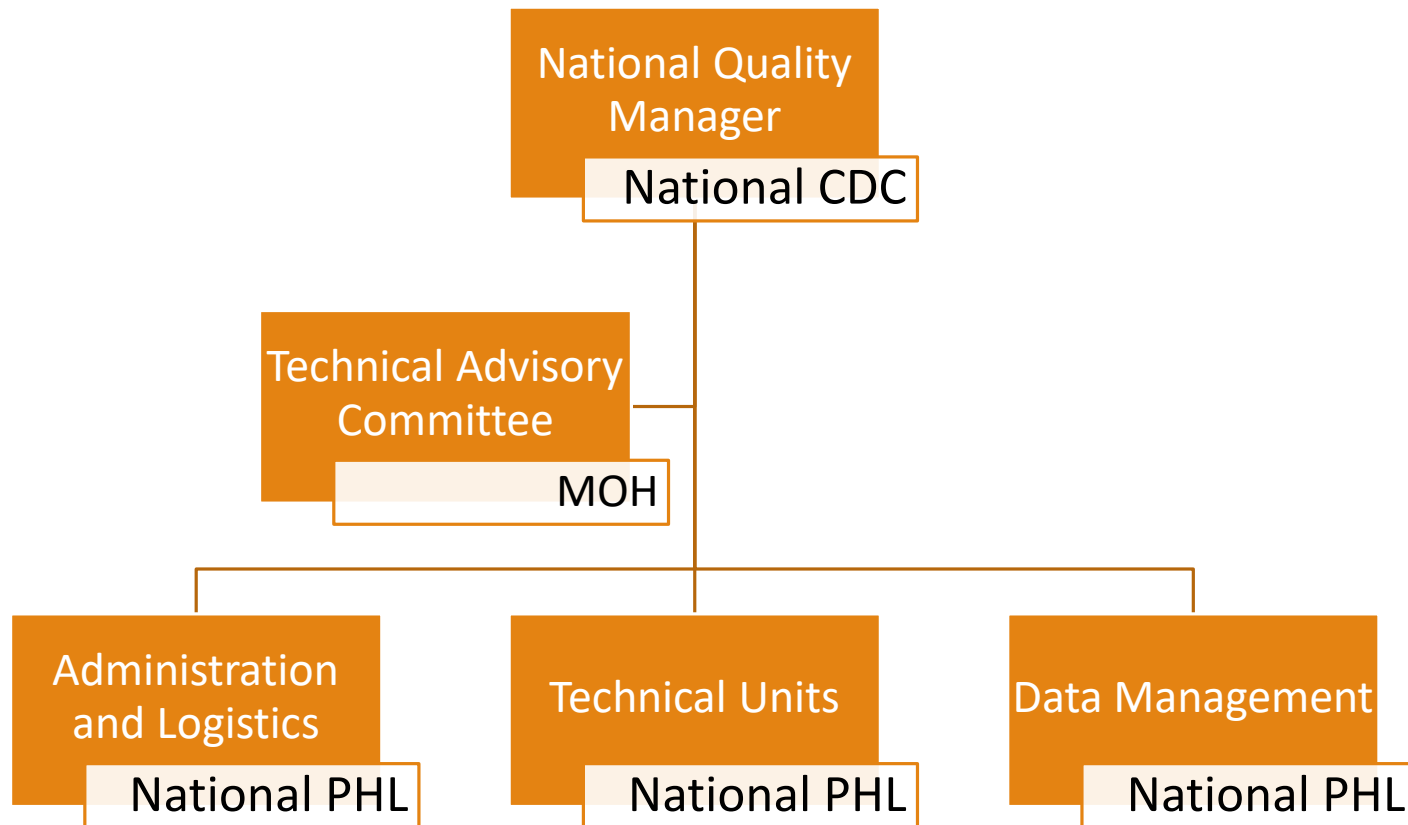
- Regulatory Basis for Laboratory Quality Assurance
 - Elimination Plan Strategy 4: Improve HCV Laboratory Diagnostic
 - Identification of National Reference Laboratory (NRL)
 - Creation of a National External Quality Assurance Program for PHL, Clinical and Blood Bank Laboratories
 - MoH decree “On provision of Lab Quality Assurance for the Hepatitis C elimination program”
 - Minimum requirements and mandatory tests for lab providers participating in hepatitis C elimination program
 - Development of SOPs and implementation in the participating labs
 - National EQA Program Structure
- Laboratory Regulation effective January 2017

Expanded Access to HCV Laboratory Diagnostics

16 HCV PCR Laboratories (14 HCV Genotype); 1 HCV Core Ag Laboratory



Establishment of a National EQA Program



Role of NRL in Establishment of National External Quality Assurance Program

- Demonstrate acceptable performance in International EQA Programs
 - HCV VL and genotyping
 - Serology for HBV, HCV, and HIV
 - HCV Core Antigen
- Maintain and expand ISO 15189 accreditation
- Develop Georgian proficiency testing (PT) Panels
 - Agreement with Blood banks
 - Characterization, prep and store of >600 PT aliquots
 - Monthly stability testing of PT aliquots
 - Routine monitoring and documentation of internal quality control



Role of NRL in Establishment of National External Quality Assurance Program

■ Develop EQA Program Documents (dual language)

- Panel Instructions for participants
- PT Survey forms
- Panel Receipt Confirmation forms
- Individual and Summary Reports
- Feed Back
 - Data analysis and recommendations
 - Site visits



■ Continue to enroll laboratories

■ Provide Result Reports to participating labs and follow up support as requested

■ Retain confidentiality and secure storage of EQA Program Data

Hepatitis C Viral Load & Genotyping External Quality Assessment Program

GENATCVL 2017
 PANEL RECEIPT CONFIRMATION FORM

Your lab code:

RECEIVED:
 organization/
 laboratory:
 address:
 Phone/FAX No:
 email:

Please complete form, scan and send back immediately by e-mail to:

Current Partner: Yasser Elmehrik, Head of quality division
 National Center for Disease Control & Public Health (NCDC)
 Quality Control Unit of Legal Center for Public Health Research
 9 M. Azzam Street, 688 Tbilisi, Georgia. yasser.elmehrik@ncdc.ge

Phone No.: (+995) 599 884 081
 email: yasser.elmehrik@ncdc.ge

GENATCVL 2017
 Panel 1 (June 2017) — Individual Report

Participating Laboratory Name and Address:

AVERSI
 Rt. JTE, Vacha-Pshavla St., 0303, Tbilisi
nasa.dzveladze@aversi.ge

Thank you for participating in the Hepatitis C Viral Load & Genotyping External Quality Assessment Program. Listed below are the expected results for the program:

Your lab code:	001
Date proficiency panel received: (dd/mm/yyyy)	11/06/2017
Date results reported: (dd/mm/yyyy)	11/06/2017
Turn-around time (business days)	2

Hepatitis C Viral Load Results

No	Specimen and Lab number	Intended result VL range (Log10)*	Your result Detected VL (Log10)	Evaluation	Remarks
1	GENATCVL 01 107.300.19006	Positive 4.67-6.65	Positive 6.51	Acceptable	V
2	GENATCVL 02 107.300.19006	Negative 3.80-5.80	Negative 6.80	Excellent	
3	GENATCVL 03 107.300.19006	Positive 4.49-6.47	Positive 5.96	Good	IR
4	GENATCVL 04 107.300.19006	Positive 4.89-6.55	Positive 6.15	Good	IR
5	GENATCVL 05 107.300.19006	Positive 5.86-6.68	Positive 6.28	Good	IR

* Suggested acceptable viral load range

Georgian National PT Panel for Viral Load and Genotyping

- Locally representative source
- Each panels includes 5 specimens
- Coding of PT specimens is unique for each laboratory to avoid consultation of obtained results between labs prior to submission
- Distributed 3 times per year
- Data from the participating laboratories analyzed for feedback
 - Individual Laboratory and Summary Reports



National EQA Program Results 2017

Expansion of Laboratories has Created a Diversity of Reagents, Kits and Equipment

	Viral Load (16 labs)	Genotyping (14 labs)
RNA Isolation Kits	9	10
PCR Assay Kits	6	7
PCR Equipment	9	8

**Currently no data on types of Qualitative HCV kits in use*



Small tubes, significant tests.

We offer the most advanced and sensitive
IVD-CE marked Real-Time PCR diagnostic
tests in these tubes.

biosphore



Methods for PT Results Analysis

- All viral load results are quantitative and reported in $\log_{10}$
- For each PT specimen, **Mean and Standard Deviation (SD)** of quantitative VL results are calculated from all laboratories, including Reference Laboratory
 - +/- 1 SD - Excellent
 - +/- 2 SD – Good
 - +/- 3 SD - Acceptable
- Two laboratories do not perform Genotyping
- In December 2017 PT Round, 2 laboratories did not participate citing insufficient funding/reagents to do so

EQA Program Results 2017



Table 1: QUANTITATIVE VIRAL LOAD

PT Round	# of Labs Reporting	Total # of VL Results	Percent within 1 SD - Excellent	Percent between 1-2 SD - Good	Percent between 2-3 SD - Acceptable
July 2017	13/13	65	80%	14%	6%
Sept 2017	15/15	75	75%	19%	6%
Dec 2017*	13/15	65	75%	21%	3%

Table 2: GENOTYPE

PT Round	# of Labs reporting	Percent with correct result	Notes
July 2017	11/13	100%	2 labs do not perform test
Sept 2017	13/15	100%	2 labs do not perform test
Dec 2017*	11/15	100%	2 labs do not perform test

*Two enrolled laboratories did not participate in Dec PT round citing excess costs to do so

Specimen 01 – HCV Viral load (comparative)

Obtained results (log₁₀) (July)

Lab	Ref	001	002	003	004	005	006	007	008	009	010	011	012	013	*	*
SD	-1 SD	+1SD	+3SD	+1SD	+1SD	+1SD	+2SD	+1SD	-2SD	+1SD	-2SD	+1SD	-2SD	+1SD		
log ₁₀	5.34	5.69	6.31	5.70	5.72	5.79	6.00	5.88	5.30	5.67	5.06	5.58	5.29	5.48		
Result	Excel	Excel	Accept	Excel	Excel	Excel	Good	Excel	Good	Excel	Good	Excel	Good	Excel		

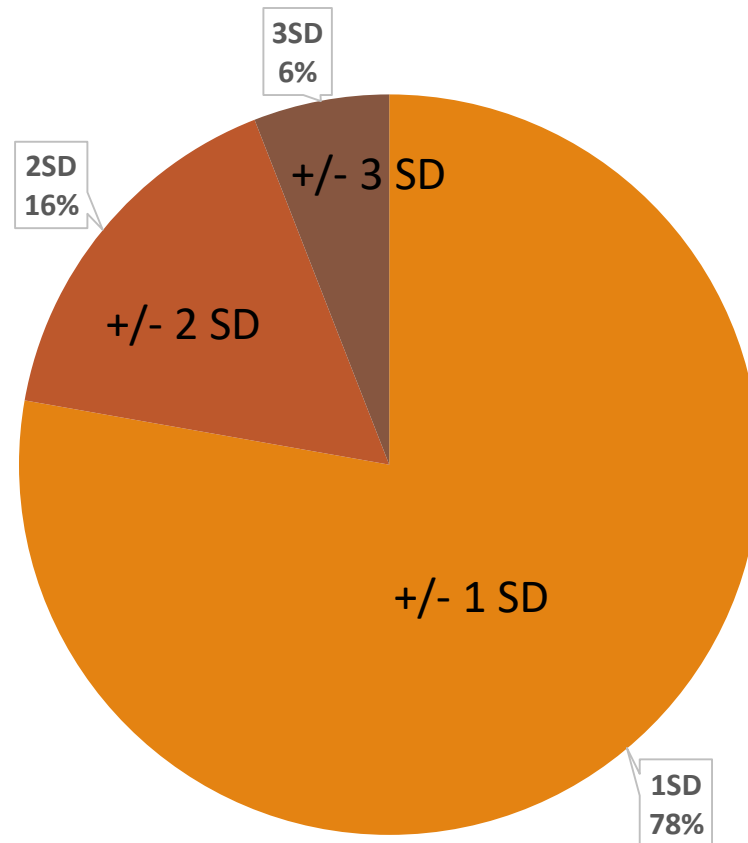
Obtained results (log₁₀) (Sept)

Lab	Ref	001	002	003	004	005	006	007	008	009	010	011	012	013	014	015
SD	-1SD	-1SD	+1SD	+1SD	-1SD	+1SD	+1SD	+1SD	+2SD	+1SD	-2SD	+2SD	-2SD	+1SD	-1SD	+1SD
log ₁₀	5.27	5.47	5.84	5.74	5.22	5.76	5.74	5.76	5.87	5.69	4.80	6.07	5.03	5.62	5.43	5.65
Result	Excel	Excel	Excel	Excel	Excel	Excel	Excel	Excel	Good	Excel	Good	Good	Good	Excel	Excel	Excel

Obtained results (log₁₀) (Dec)

Lab	Ref	001	002	003	004	005	006	007	008	009	010	011	012	013	014	015
SD	-1SD	-1SD	+1SD		-1SD	-1SD	+1SD	+1SD	+1SD	+2SD	-2SD		-3SD	-1SD	-1SD	+2SD
log ₁₀	5.35	5.42	5.85		5.56	5.52	5.57	5.99	5.78	6.16	5.06		4.71	5.46	5.46	6.30
Result	Excel	Excel	Excel	N/A	Excel	Excel	Excel	Excel	Excel	Good	Good	N/A	Accept	Excel	Excel	Good

Cumulative 2017 EQA Program Results- Quantitative HCV Viral Load



Qualitative Interpretation of HCV Viral Load Results - 2017

PT Round	HCV RNA Qualitative interpretation	HCV Genotyping
	# of Labs reporting Percent correct results	# of Labs reporting Percent correct results
July 2017	13 100%	11 100%
Sept 2017	15 100%	13 100%
Dec 2017	13 100%	11 100%

- No false negative results
- No false positive results
- No errors with Genotype

Conclusions and Recommendations

- Significant diversity of the reagents and equipment
 - FDA-approved automated tests most accurate
- Some labs modify test methods without validation
 - All labs should follow the manufacturers recommended protocols, conduct and document test validations
- Some laboratories have switched to qualitative PCR for confirmatory testing
 - EQA Panels need to be modified to better control for qualitative PCR testing and interpretation
- HCV Rapid Testing are not quality assured
 - Centralize procurement of all HCV rapid tests and include verification of tests in NRL before confirming purchase
- Standardized package of SOPs for quality management and biosafety are not available

Where We Were.....

**Challenges Presented in April 2016*

- Appropriate laboratory services in regions yet to be established ✓
- No unified external quality control system exists ✓
- No national certification systems for clinical laboratories exists ✓
- Screening for HIV antibodies not part of program ✓
- Test-kits used by laboratories vary based on availability from the suppliers; most of test-kits have not been validated ✗
- Unified standard procedures not identified for participating labs ✗
- No systematic training of lab personnel in biosafety standard ✗

Next Steps

- Expand pool of PT specimens to include additional genotypes; and new tests: qualitative PCR and GenExpert
- Establish HCV serology EQA panels and program for blood banks
- Standardize specimen rejection criteria for referred specimens to quickly identify and correct problems in specimen collection and transport systems
- Include hematology and biochemistry EQA results in National EQA database for all labs in elimination program
- Conduct laboratory assessments, including review of test validation documentation
 - Document progress in labs assessed in 2015
 - Establish baseline data for new labs since 2015

Remaining Gaps

- Quality Assurance System for HCV Rapid Tests
 - Funding for centralized procurement and supply chain management
- Package of standardized SOPs
 - use and documentation of IQC
 - test validation
 - Root Cause Analysis and Corrective and Preventative Action
 - management of infectious waste
- Standardized training in QMS and biosafety
 - To support compliance with laboratory certification standards

Acknowledgements

Dr Jan Drobeniuc, Division of Viral Hepatitis, CDC

Dr Radu Cojocaru, Asst Prof, School of Public Health, Moldova

Dr George Kamkamidze, Director, NeoLab

Dr Maia Alkhazashvili, Manager, Lugar Center, NCDC

Dr Roena Sukhiashvili, Mol Dept, Lugar Center, NCDC

Dr Gvantsa Chanturia, Head of Mol Dept, Lugar Center, NCDC

Dr Nazibrola Chitadze, Head of Serology Dept, Lugar Center, NCDC

Nino Berishvili, HepC EQA Program, Lugar Center

Laboratory service providers of the HCV Elimination Program



Decentralization of HCV Care: Simplified Diagnostics and Treatment Monitoring

Karla Thornton, MD, MPH
Professor, Infectious Diseases
University of New Mexico
Associate Director, Project ECHO
09 March 2018



Overview

- Importance of decentralization of care to achieve elimination goals and address the TAG recommendations
- Real world examples of decentralization and simplified algorithms
 - New Mexico, United States
 - Punjab, India

Why Decentralization?

TAG Recommendations to Meet Elimination Goals

- Rapid increase in number of providers in primary care trained to test and treat HCV
- HCV Treatment sites should include all hospitals, prisons, harm reduction programs, medication assisted treatment centers and TB and HIV treatment sites
- Referral relationships should be formalized and strengthened between the current major HCV treatment sites and non-tertiary care providers integrating HCV testing and treatment services in clinical settings
- The major HCV treatment sites can provide mentors and educators for newly trained providers
- ECHO provides a platform to strengthen educational, training and referral relationships

Decentralization and Simplified Treatment Algorithms

- There is not one accepted, tested way to implement decentralization
- There is not one accepted, simplified treatment algorithm
- Some key principles
 - Expands access to care
 - Better serve individual needs (treat closer to home or in acceptable setting) – integrated service delivery, differentiated care
 - Minimize expensive diagnostics (e.g., use pangenotypic if available to avoid genotyping)
 - Minimize labs without sacrificing safety

Georgia: Projects Underway

- Simplified diagnostics and treatment monitoring of HCV infected patients in rural primary care facilities in the country of Georgia
 - Tengiz Tsertsvadze, IDACIRC
- Simplification of pretreatment diagnostic evaluation and on-treatment monitoring procedures within HCV Elimination Project
 - Jaba Zarqua, Mrcheveli

Real World Examples

- New Mexico, United States
- Punjab, India



Moving Knowledge Instead of Patients

New Mexico

- Low population density, large geographic area
 - 315194 km²
 - 2.086 million people
- Most areas have few health care providers and no specialists



Hepatitis C in New Mexico (2004)



- More than 35,000 reported HCV cases
- Less than 5% had been treated
- Only one academic health center treated HCV
- Highest rate of cirrhosis deaths in the nation

Goals of Project ECHO

- Develop capacity to safely and effectively treat HCV in all areas of New Mexico and to monitor outcomes
- Develop a model to treat complex diseases in rural locations and developing countries

Methods

- Use technology to leverage scarce healthcare resources (specialty knowledge and expertise)
- Share “best practices” - reduce variation in care
- Case based learning (learning by doing)
- Centralized database to monitor outcomes

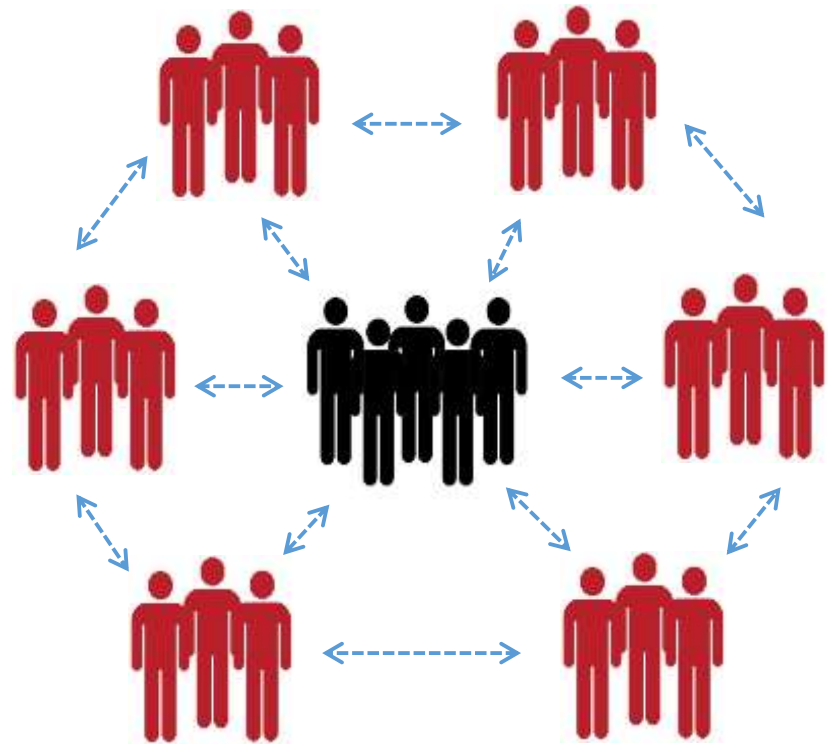
Steps

- Train physicians, nurses, pharmacists and their teams in HCV care
- Conduct teleECHO clinics – “Knowledge Network”
- Initiate case-based guided practice – “Learning loops”
- Collect data and monitor outcomes centrally



Learning Loops

- ✓ Interactive Learning Environment
- ✓ Co-management of Cases
- ✓ Learning by doing
- ✓ Learning from didactics
- ✓ Learning from each other
- ✓ Collaborative Problem Solving

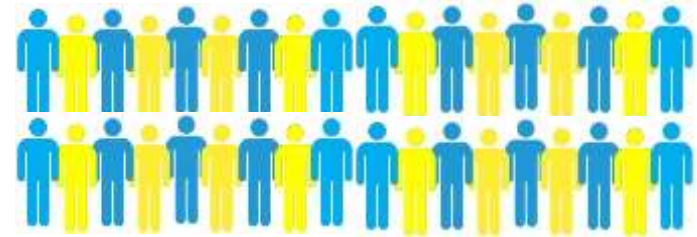


ECHO vs. Telemedicine

ECHO Supports
Community Based
Primary Care Teams

Patients reached with specialty
knowledge & expertise

ECHO



Traditional
Telemedicine



Specialist Manages Patient Remotely





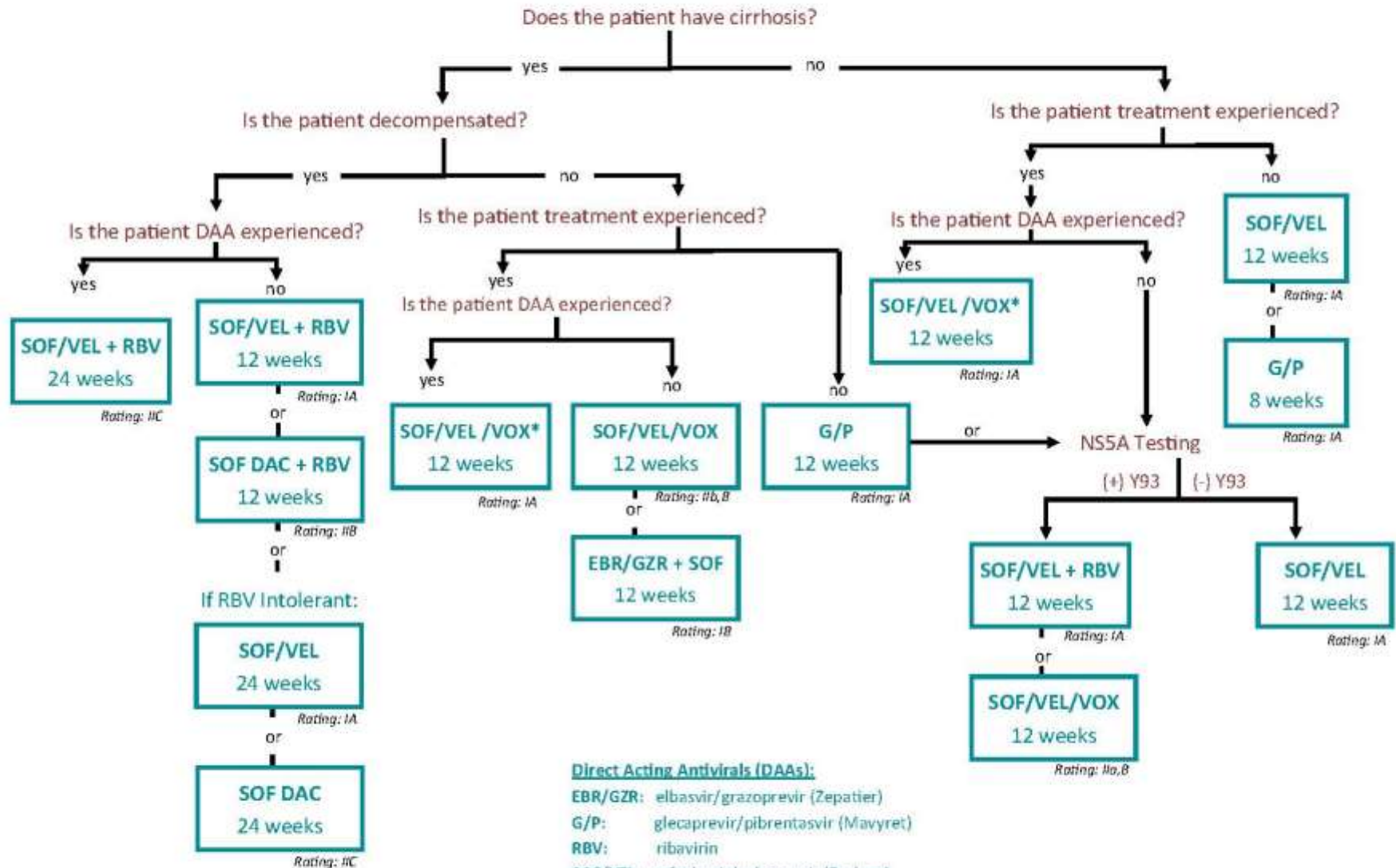
● Project ECHO Spoke Participant



Project ECHO Hub



Genotype 3 Patients



*Rating for Level of Recommendation

Direct Acting Antivirals (DAAs):

EBR/GZR: elbasvir/grazoprevir (Zepatier)

G/P: glecaprevir/pibrentasvir (Mavyret)

RBV: ribavirin

SOF/VEL: sofosbuvir/velpatasvir (Epclusa)

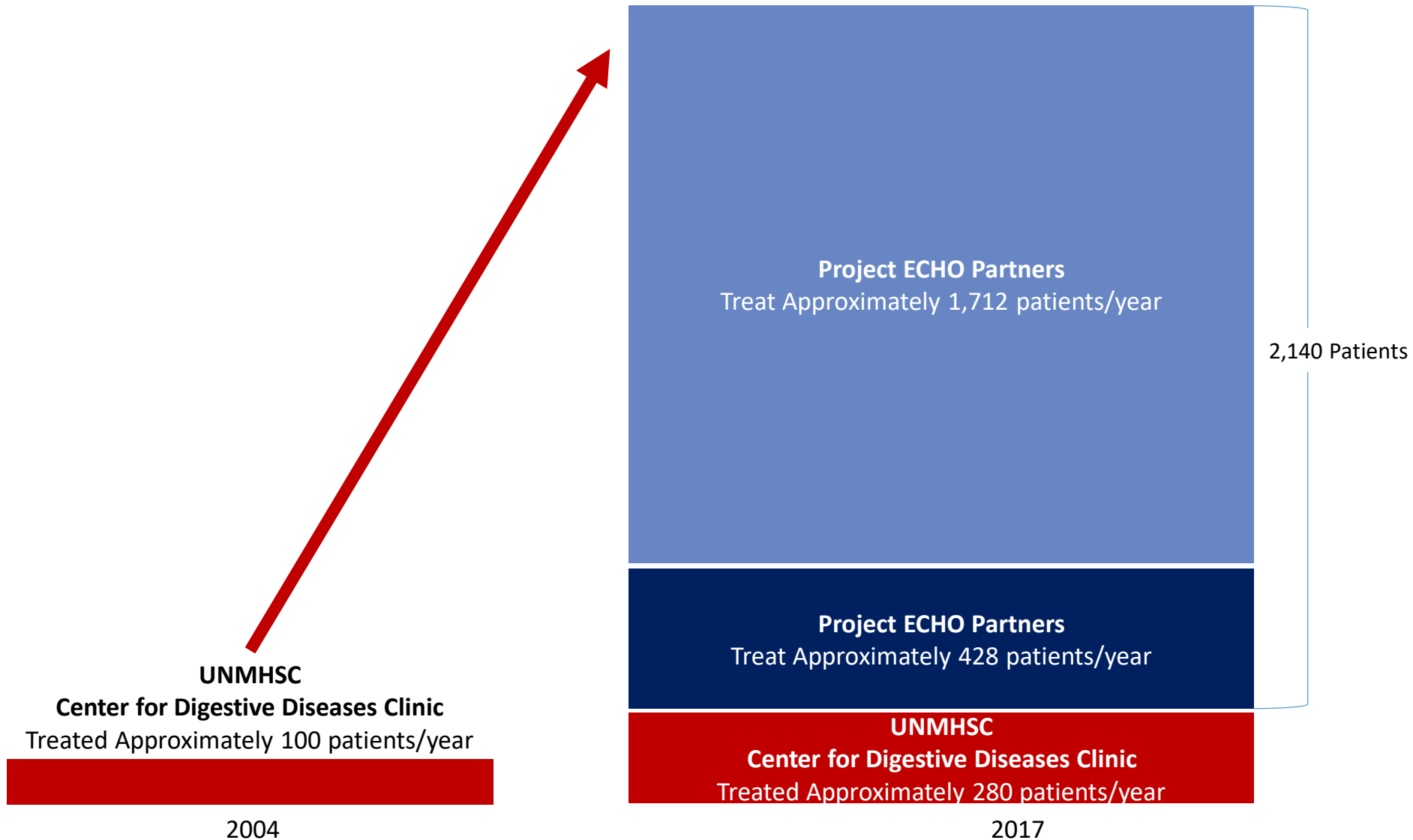
SOF/VEL/VOX: sofosbuvir/velpatasvir/voxilaprevir (Vosevi)**SOF DAC:**

sofosbuvir and daclatasvir

*IF NS5A-experienced, add weight based RBV

						for 12 weeks	
				Hepatitis C Minimum Visit/ Labs Flow Sheet			
Week of Treatment	Screening	Wk 0 Start of Tx	Wk 2	Wk 4	Wk 8	Wk 12 End of Tx	Wk 24
Dates	N/A	01/01/18	01/15/18	01/29/18	02/26/18	03/26/18	06/18/18
Visit		x	x	x	x	x	x
HCV RNA	x						x
CBC w/ Diff	x			x	x	x	x
Chem 7	x			x	x	x	x
LFTs/HFP	x			x	x	x	x
HBsAg HBs Ab HBc Ab*	x						
Key Points to Remember: 1) Week 0 Visit is the day of the first dose of medication. 2) Lab draws are done the end of the treatment week. 3) HBc Ab should be total or IgG.							
Patient Name:		Date of Birth:			Patient ID:		Genotype:
REV: 11/20/17 SLS							

Hepatitis C Treatment in New Mexico



Tackling the Hepatitis C Disease Burden in Punjab

- June 2016 - Government of Punjab launched a public health program under the Mukh Mantri Punjab Hepatitis-C Relief Fund (MMPHCRF) that offers free HCV treatment to all residents of Punjab
- The goal is to eliminate HCV from Punjab in 10 years
- Treatment offered through a decentralized network of 22 District Hospitals and 3 Government Medical College
- 250 clinicians have been identified for training on diagnosis and treatment of chronic HCV

Burden of Hepatitis C in Punjab



- Prevalence – 3.29%
- Anti-HCV positive - ~920,000
- Viremic ~600,000

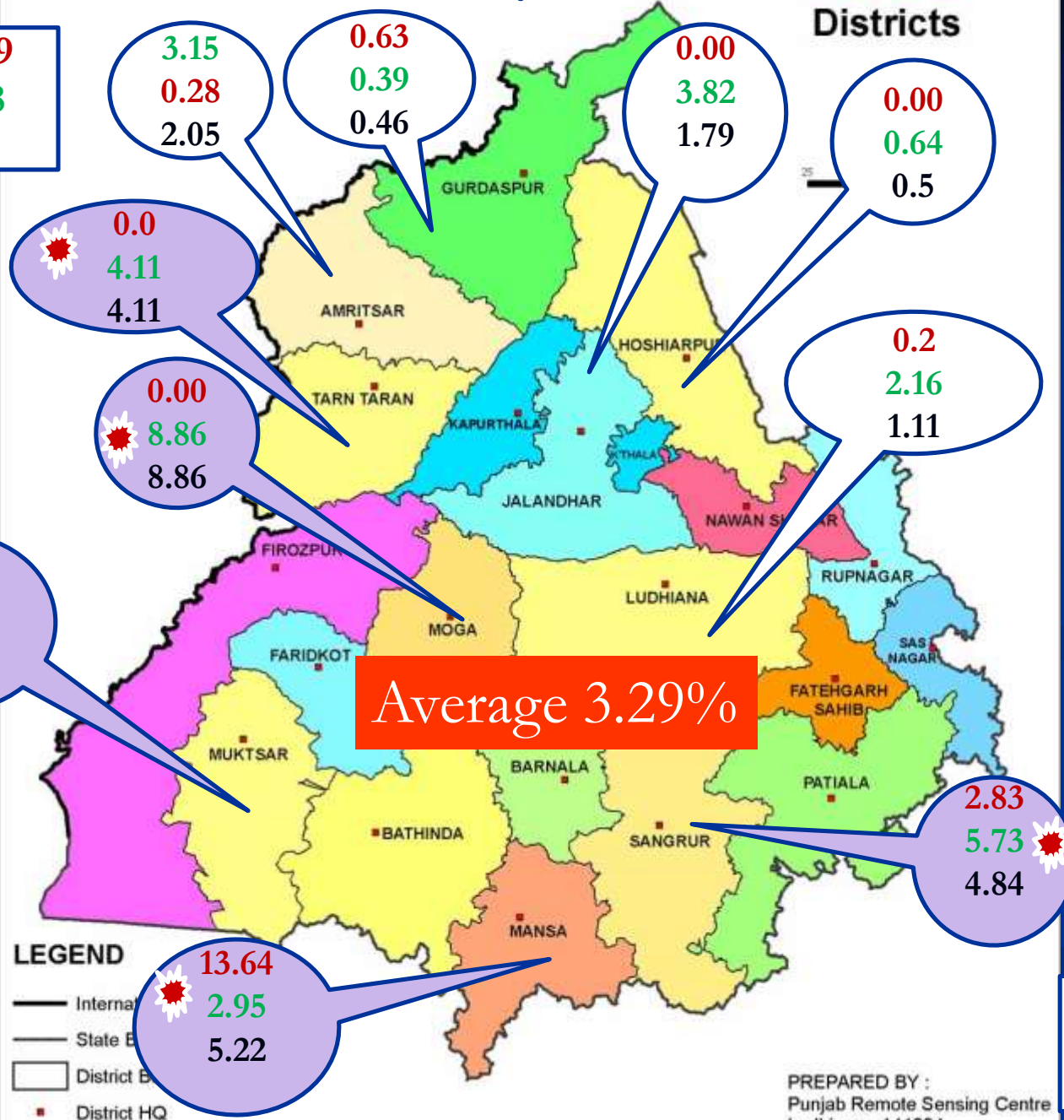
■ Demography	
■ Districts	22
■ District Hospitals	22
■ Sub Divisional Hospitals	41
■ CHCs	150
■ Govt Medical Colleges	03

HCV Prevalence in Surveyed Districts

PUNJAB
Districts

Urban%- 3.09
Rural%- 3.38
Total%-3.29

22 districts

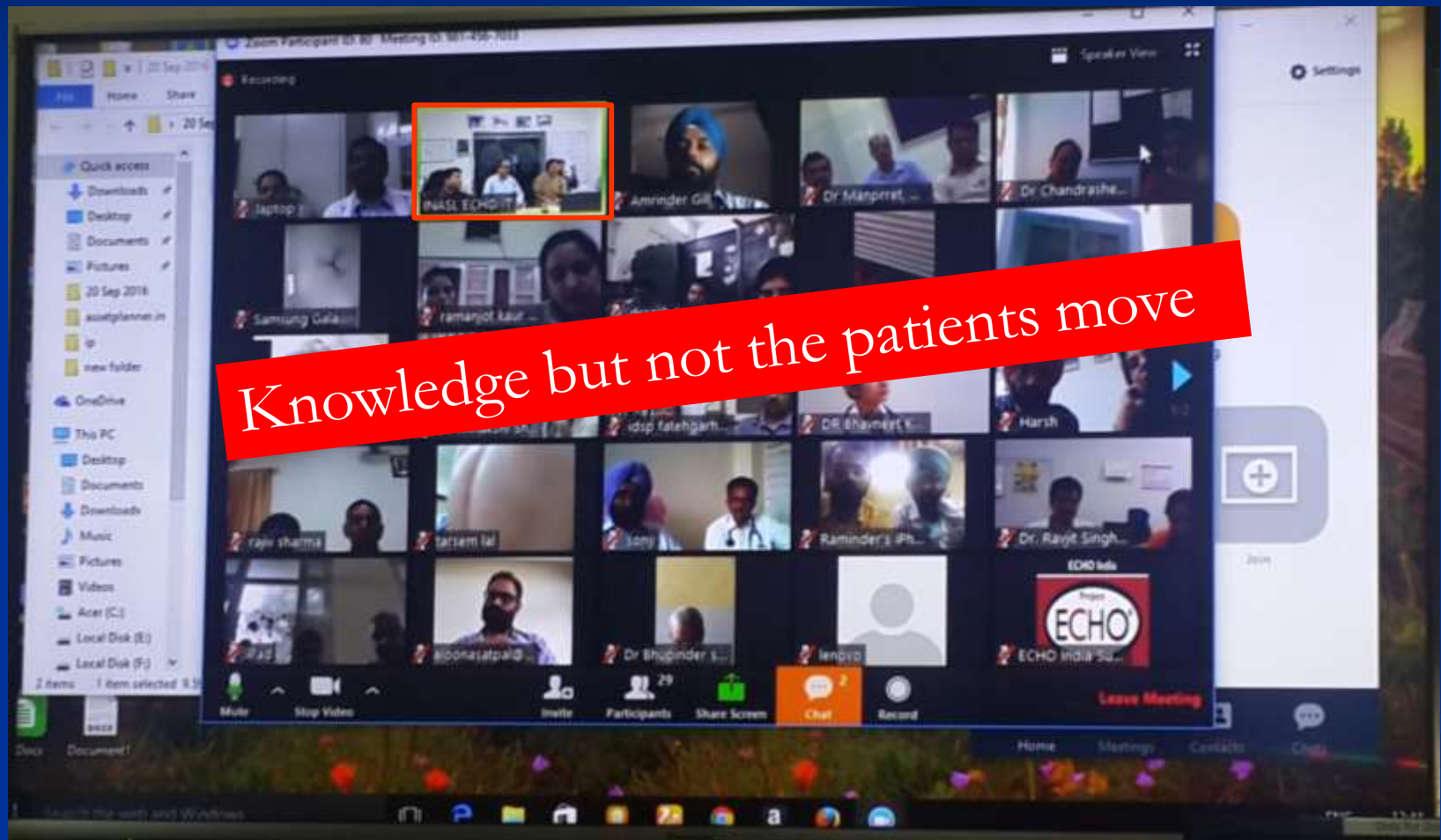


PREPARED BY :
Punjab Remote Sensing Centre
Ludhiana - 141004

Capacity Building of HCW

- **Hep C Workshop** – 4 hour course
 - 80 Clinicians trained from 25 centers (3 GMCs + 22 District Hospitals)
- **ECHO**
 - Hub: PGIMER, Chandigarh
 - Spokes (25 centers)
 - Syllabus
 - Case discussions
 - Didactic lectures
- **What's App Group**

ECHO Session-Spokes



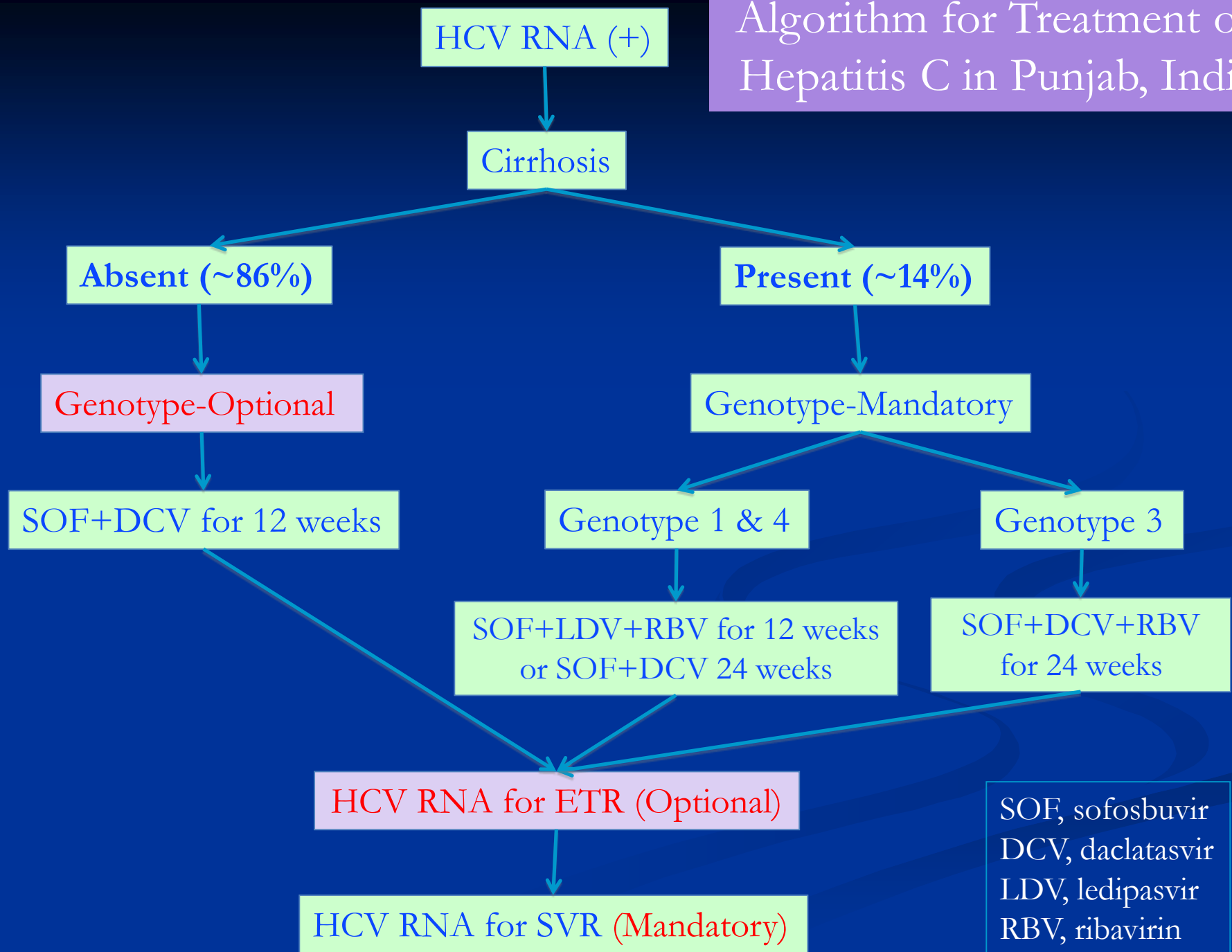
Assessment Prior to Treatment (HCV RNA +)

- Detailed history and physical examination
- Baseline tests
 - CBC, LFT, RFT (Renal Function Tests)
- Viral co-infections
 - HBsAg, HIV
- Ultrasound of the abdomen
- Women of childbearing age
 - Urine pregnancy test
- Evaluation for diagnosis of cirrhosis

Evaluation of Cirrhosis

- **Fibroscan** — Cirrhosis (METAVIR F4): ≥ 12.5 kPa
- If Fibroscan not available:
 - Platelets $< 75,000/\text{cmm}$
 - APRI ≥ 2.0
 - FIB-4 > 3.25

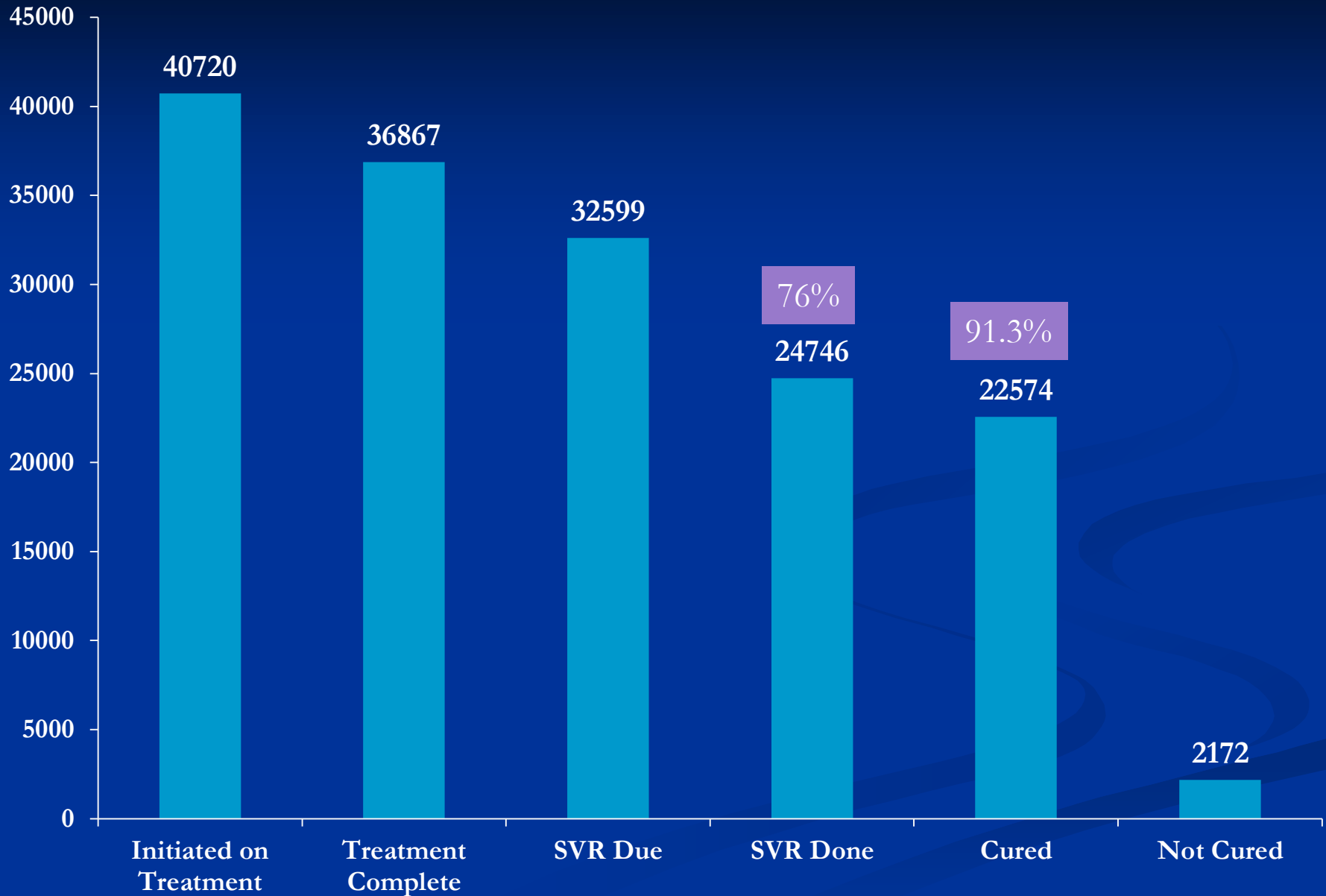
Algorithm for Treatment of Hepatitis C in Punjab, India



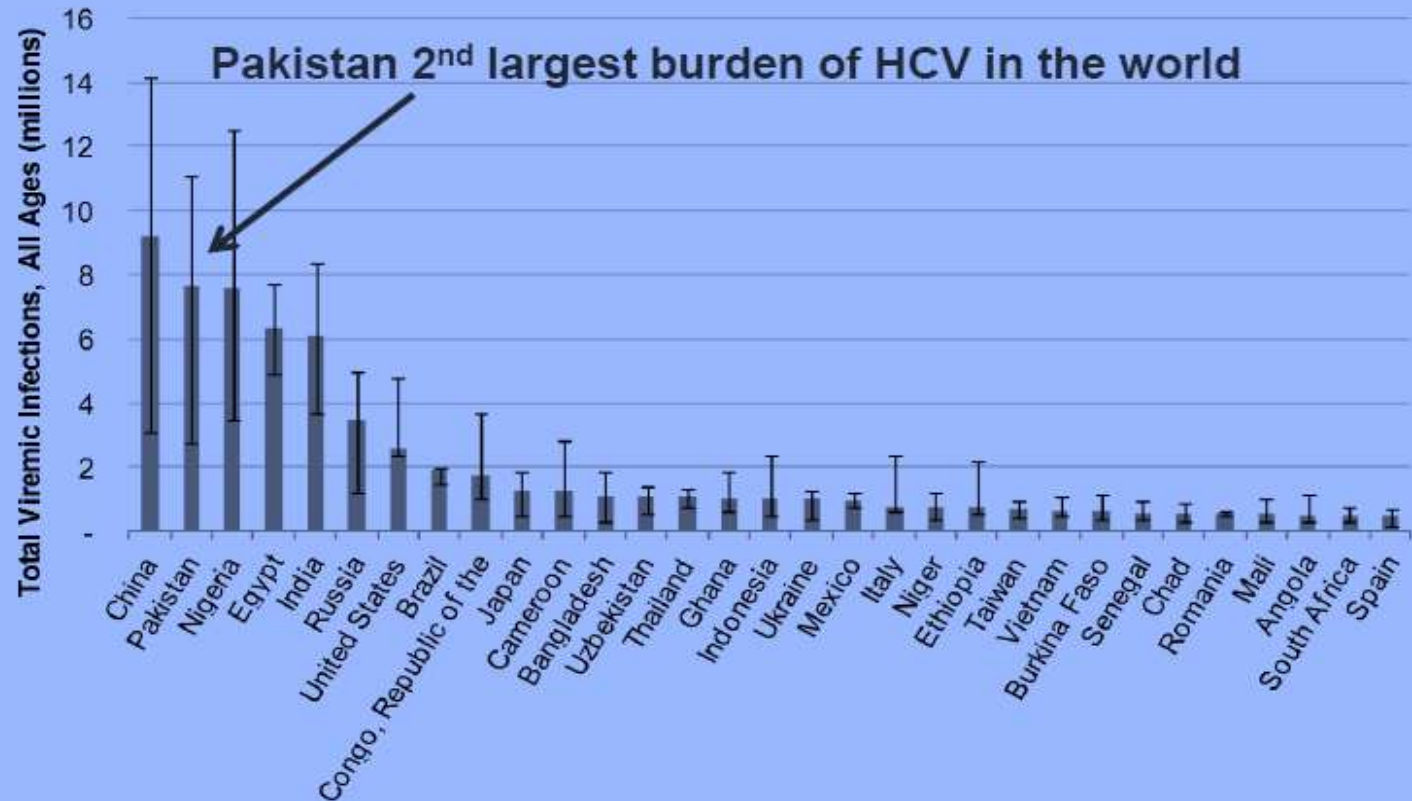
Follow up and Tracking of patients

- Treatment Cards for patients availing MMPHCRF
- Master Data with UID for each case: Aadhar based
- Follow up of case: Every 4 weeks in order to counsel the patient and to check the patient
- Centralized case record
- SVR (Sustained Viral Response) records: 12 weeks after treatment completion

Cascade Report (June 2016 - Jan 2018)



Pakistan



Gower E, Estes CC, Hindman S, Razavi-Shearer K, Razavi H. Global epidemiology and genotype distribution of the hepatitis C virus. J Hepatology 2014.

Replication of the ECHO Model in Georgia

Project ECHO and the Georgia HCV Elimination Program

- ECHO Immersion
 - January 2016
Albuquerque, NM
- First TeleECHO Clinic
 - February 2016



Georgia HCV Elimination Program



Summary

- Pioneering work
- Need for ongoing evaluation and quality improvement
- Decentralization – need for intense coordination
- Need ongoing education/mentorship of providers
 - Dissemination of new information
 - Complexity of cases
 - Referral pathways

Slide Acknowledgements

- Rhada Diman, MD

Scientific Committee Progress

Tinatin Kuchuloria, MD, PhD, MSc

CDC Foundation

Establishment of the Scientific Committee

- ❑ Established in August, 2016
 - Research agenda development
 - Transparency
 - Coordination
 - Communication
- ❑ The need for such a committee was to
 - Avoid overlapping efforts
 - Assist stakeholders in data analysis
 - Assist in dissemination of research findings
 - Obtain resources for conducting priority activities



Scientific Committee

- Co-chaired by NCDC and CDC representatives

- Members

- MoLHSA
- NCDC
- IDACIRDC
- Clinic Hepa
- Clinic Neolab
- Clinic Mrcheveli
- US CDC

Members and Non-members

❑ Members

- Clinicians, researchers, policy-makers
- Local and international stake-holders

❑ Non-members (e.g.: NGOs, Universities, other partners) may be invited ad hoc

- University of Bristol
- FIND
- Boston University Medical Center
- LIFER
- ECHO
- MDM
- EASL Foundation

Roles of the Scientific Committee

- ❑ Review, approve, and support study proposals
 - IRB review and approvals
 - Assist in securing funding
 - Study implementation
 - Data analysis
 - Manuscript writing
- ❑ Coordination with
 - MoLHSA
 - Clinical Committee
 - International organizations
- ❑ Journal club

Scientific Committee Progress (August 2016 – February 2018)

- ❑ Number of proposals reviewed/approved:
 - 40 reviewed
 - 32 approved
- ❑ Types of proposals approved
 - Clinical outcomes (treatment/SVR, long-term survival, other)
 - Linkage and access to care
 - Innovative diagnostics
 - Simplified regimens and treatment expansion
 - HCV incidence studies
 - Molecular epidemiology
 - Establishing a specimen repository
 - Modeling

Scientific Committee Progress – Funding

Proposal Type	Funded	Funding required	N/A	Total
Epi studies	5	4	2	11
Database Analysis	1	0	9	10
Diagnostic studies and sample archive	4	0	0	4
Healthcare Evaluation	5	0	0	5
Modeling & Economic Evaluation	1	1	0	2
Total	16	5	11	32

Presentations and Publications

❑ Oral and Poster presentations

- EASL, 2017 – 9 poster presentations & Georgia session
- AASLD, 2017 – 5 poster presentations
- WHS, 2017 – 7 poster presentations & Georgia session
- EASL, 2018 – 6 poster/1 oral presentations & Georgia side-meeting

❑ Manuscripts

- Already published - 4
- In press - 2
- Finalized and submitted to the peer reviewed journal - 1
- Drafted - 1

Screening & Linkage to Care

A Key Challenge....

Improving Access to Care and Treatment

- Recently approved proposals to improve access to care and treatment:
 - Assess effectiveness of screening and linkage
 - Assess barriers
 - Decentralization of services into primary care and harm reduction settings

Documenting HCV Elimination



The Role of Research in Public Health Programs

- ❑ “The research-policy arena is assumed to be a retail store in which researchers are busy filling shelves of a shop front with a comprehensive set of all possible relevant studies that a decision-maker might some day drop by to purchase.¹”
- ❑ Co-production of research knowledge increases
 - Relevance
 - Comprehensibility
 - Likelihood of use of a piece of research

¹ Lomas J. Connecting research and policy. *Can J Policy Res.* 2000;1:140–144

Do you sometimes feel like this?



“My policy-maker doesn’t understand me!”

Conclusions

- ❑ Coordination of efforts improves efficiency
- ❑ Robust research agenda is critical to support elimination program goals
- ❑ Lessons learned from the Georgia HCV Elimination will guide other elimination efforts globally

Acknowledgements

- Ministry of Health, Labor and Social Affairs of Georgia
- National Center for Disease Control and Public Health of Georgia
- Infectious Diseases, AIDS and Clinical Immunology Research Center, Georgia
- Clinic Neolab, Georgia
- Clinic Mrcheveli, Georgia
- Centers for Disease Control and Prevention, USA
- CDC Foundation, USA
- Non-member organizations: ECHO, University of Bristol, FIND, others

Thank you

❑ “If it can’t be done in Georgia, it can’t be done.”

- *Francisco Averhoff*



“Hepatitis C Cured Patient Association”



Founders:

Mr. Temur Radiani, Doctor of Biology, Author of the idea;

Mr. Irakli Koridze, an economist;

Mr. Ezekiel Intskirveli-Chkheidze, Head of Kvemo Kartli Forestry Service;

Mr. Beso Kupreishvili, Founder and Director Of Finger Theater.



Introduction



Mission

Promoting successful implementation of HCV elimination program in Georgia, Raising awareness on viral hepatitis and reduction of stigma and discrimination related to hepatitis in society.



Goals (I)

1. Uniting the Patients Cured from HCV and forming a supportive advocacy group;
2. Raising awareness on HCV elimination program in the population;
3. Reducing stigma and discrimination related to hepatitis in medical institutions and societies;
4. Attracting population to increase awareness on the problem of hepatitis C;

Goals (II)

5. Cooperation with governmental, non-governmental organizations and funds to support the communication activities within HCV elimination program;
6. Increasing popularity and availability of the successful programs and disseminating information on new initiatives; cooperation with the EU professional institutions;
7. Sharing the Information and Experience on HCV Elimination in Georgia
Participating in international meetings and conferences organized by international advocacy organizations;
8. Expansion of Association by increasing the involvement of cured patients.

Advocacy

A right to be heard is our
opportunity to speak out.

Many people, one voice.



Suggestion's

- Changes in Legislation/Mandatory screening
- Strengthening Infection Control in Health Care and Non-Medical Facilities



WORLD HEPATITIS DAY



**JULY
28TH**

Baby boomers
[**1945**
to
1965]
more likely to
have **HCV** than
other adults

More than
75%
of adults with **HCV**
in US are baby
boomers

325
million people
with chronic
hepatitis
infections
worldwide
in 2015

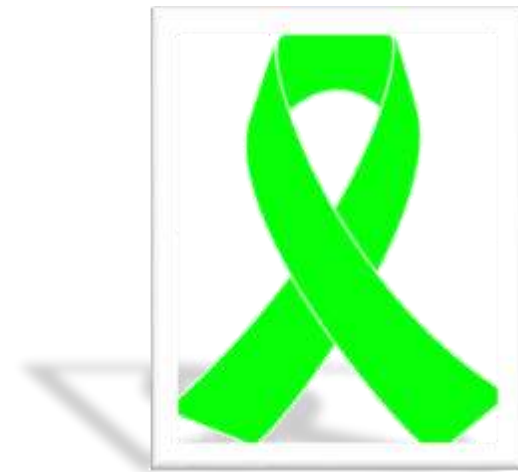
HBV & HCV
cause
80%
of liver cancer
cases in
the world

Currently,
90%
of people with
HBV and
80%
with **HCV**
are unaware
of their
status

Every
30
to
45
seconds
a person dies
from
HBV

Injecting drug
users account for
at least
60%
of **HCV**
transmission
in the US

Hepatitis B Virus = HBV
Hepatitis C Virus = HCV



Memorial Day ???



"In my struggle for my life, I've learned that whatever happens to you, you should never give up, you should keep fighting, and eventually with a little luck and a lot of help from kind people, the virus will be defeated! I am sure that a few more years will pass and we will all be celebrating the full elimination of hepatitis C in my country,".

Temur Radiani, cured of HCV, Georgia

Thank you for attention!

Questions?

5th HEPATITIS C

Technical Advisory Group

TAG Meeting

February 9, 2018

blood Safety

Eteri Kipiani

National Center for Disease Control and Public Health



Outline

- Status of blood safety program in blood banks
- Progress
- Challenges
- Next steps

Current Status

Distribution of Blood Banks in Georgia, 2018

22 blood establishments hold state license in blood production service, 15 blood banks out of them participate in the State Safe Blood Program (2 additional banks have been involved since 2018)



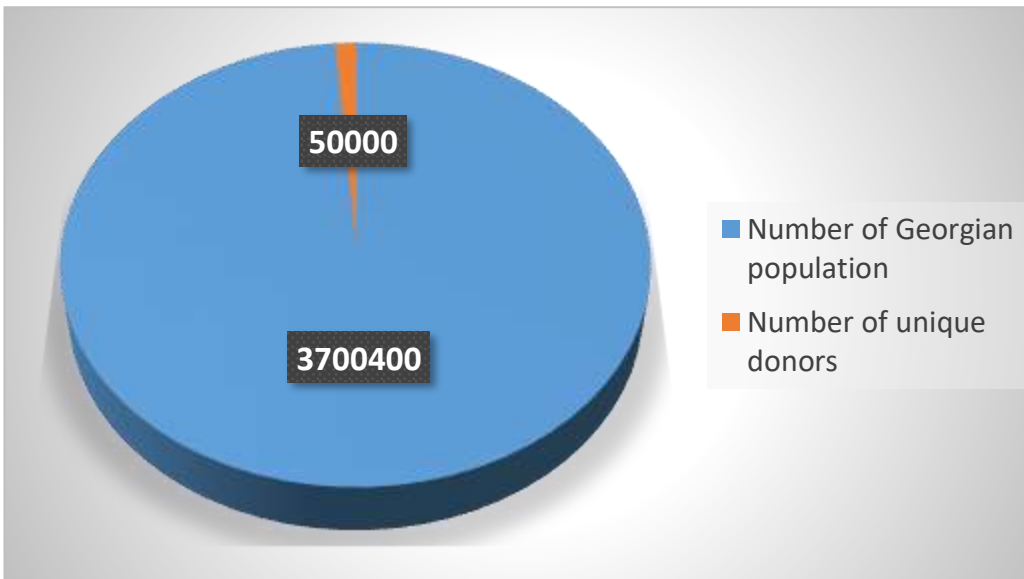
Current Status

Country Requirement, 2017

1%

Blood donation by 1% of the population can meet a nation's most basic requirements for blood

Percentage of Georgian population donating blood



In 2016, a total of 53000 blood transfusions were performed by hospitals

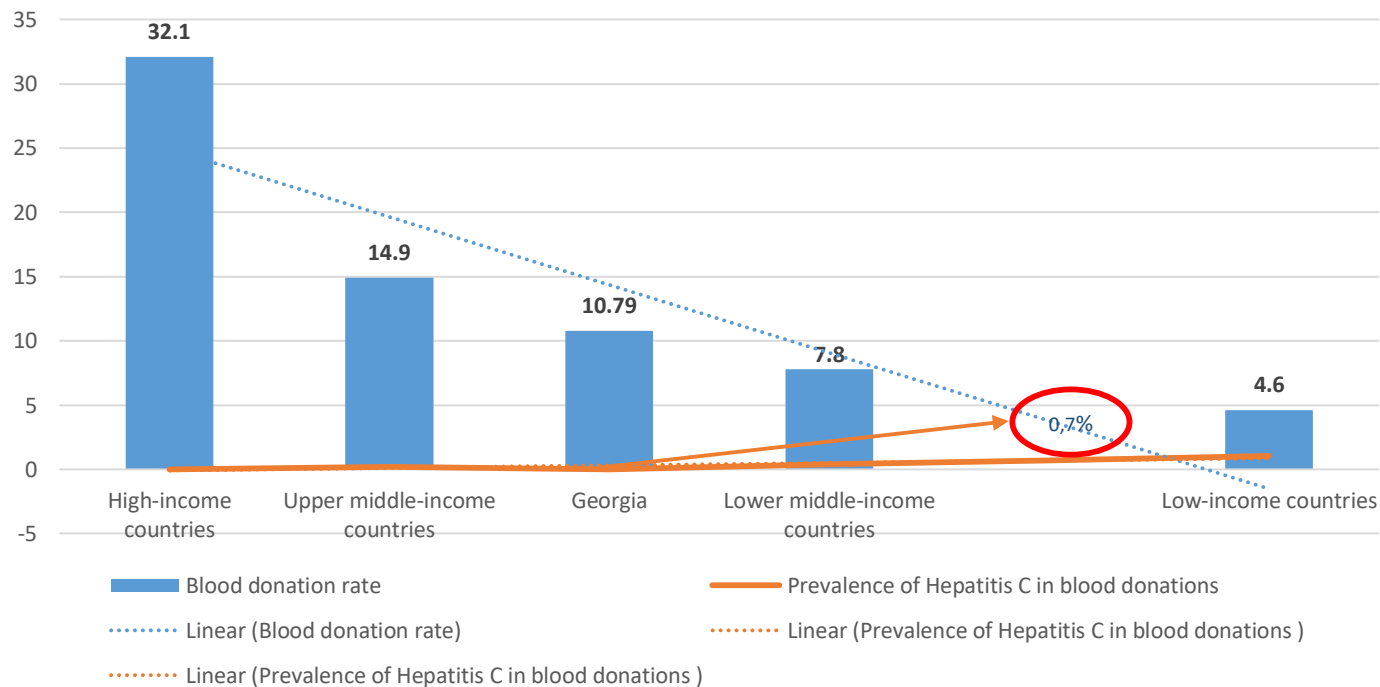
In the same year, 1,4% of Georgian population donated blood and more than 80000 donations were collected by blood banks

Current Status

Country Profile

- Blood donation rate is higher in high-income countries, while prevalence of Hepatitis C shows inversely proportional trend
- Georgia is between upper and lower middle income countries in blood donation rate and between lower middle-income and low-income countries in the prevalence of Hepatitis C

Blood Donation Rate and HCV Prevalence by Country Income



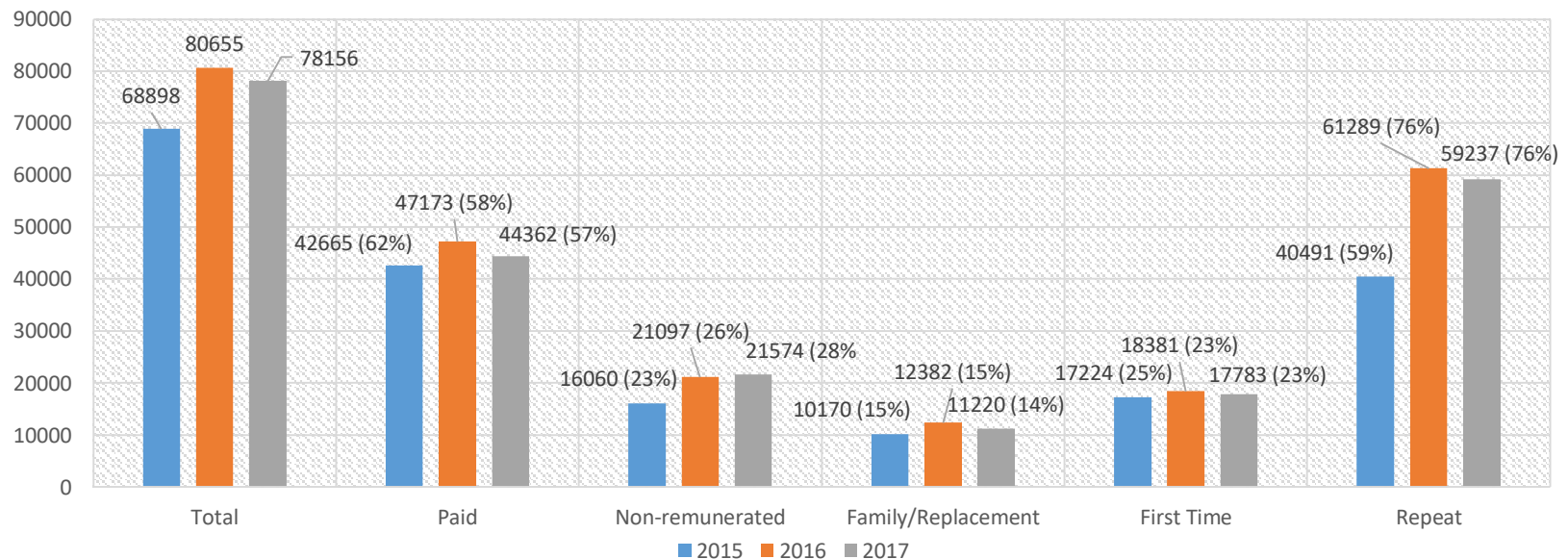
Statistical Data, 2015-2017

Voluntary vs. Paid vs. Family/Replacement

Based on analysis of statistical data from 2015-2017:

- Paid donations prevail on the number of non-remunerated and family/replacement donations
- Repeat donors constitute the majority of donations
- Total number of donations has increased by 12% during last three years with slight increase (up to 5%) in the number of non-remunerated donations

Number and Percentage of donations by donor status, 2015-2017



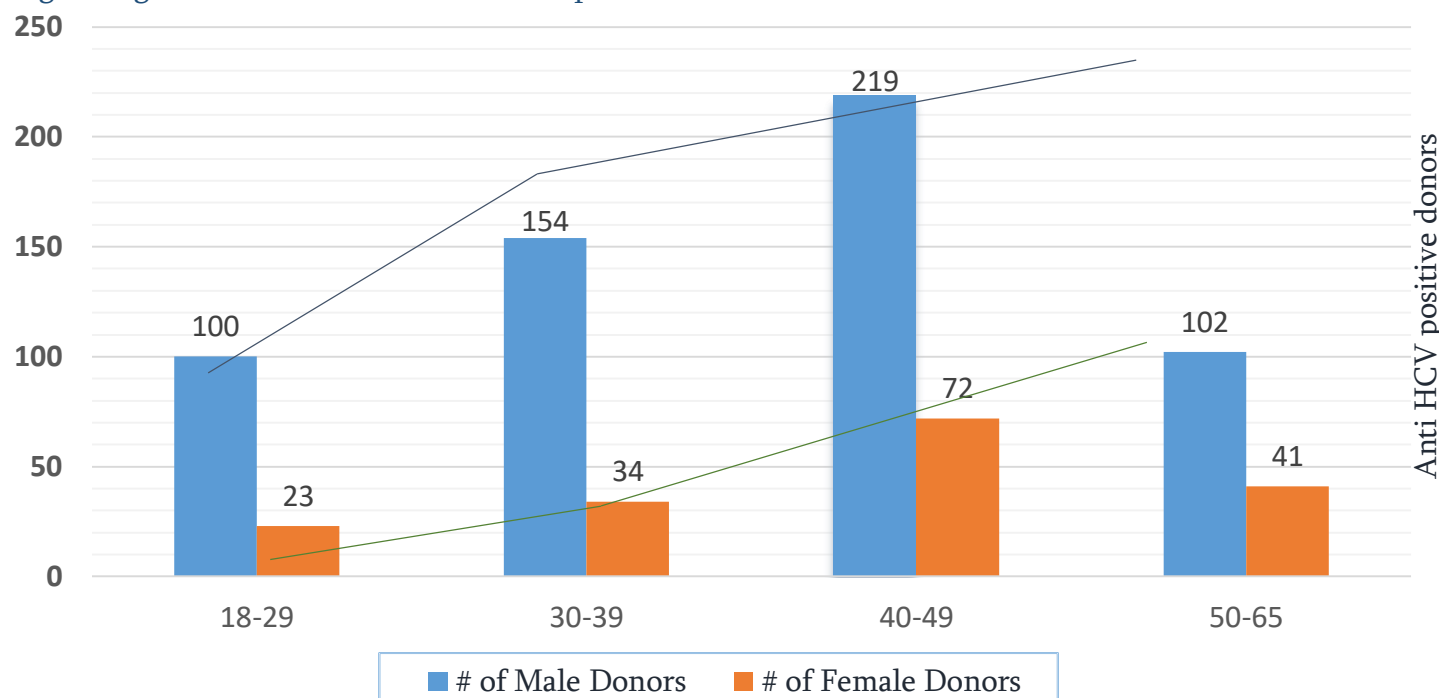
Current Status

Age and Gender Distribution, 2017

More than 100 000 donations have been made at all blood banks (including those not participating in the program):

- Male donors constitute majority (58%) of the total donors
- Highest prevalence was observed among males in age group of 40-49 and 30-39

Age and gender distribution in anti-HCV positive blood donors, 2017

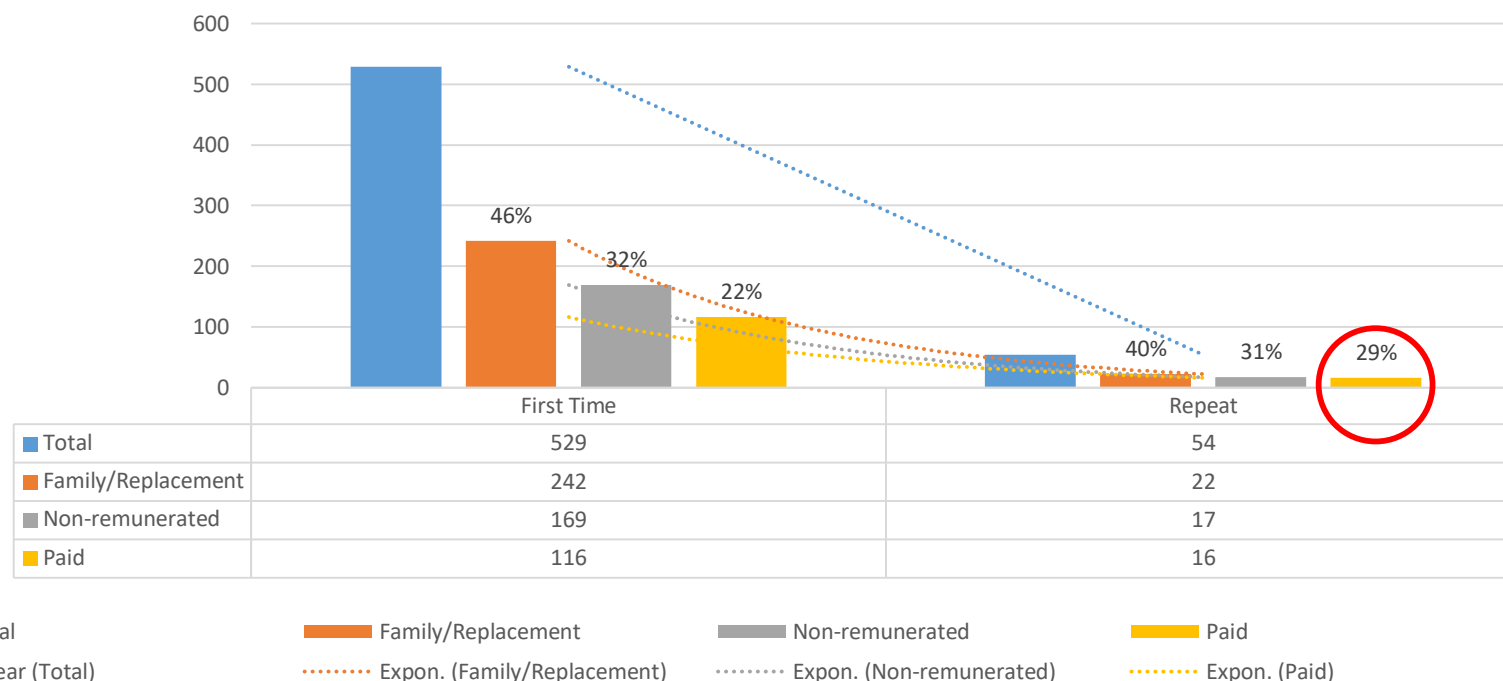


Current Status

First-time vs. repeat donors among anti HCV positive donations

In 2017, a total of 78 156 donations have been performed by blood banks participating in the program, including 583 anti HCV positive donations with the highest rate in first-time family/replacement and first-time voluntary unpaid donors and the lowest in paid and voluntary unpaid repeat donors

Anti HCV Prevalence in Repeat and First-time Donor Population by Donor Status, 2017

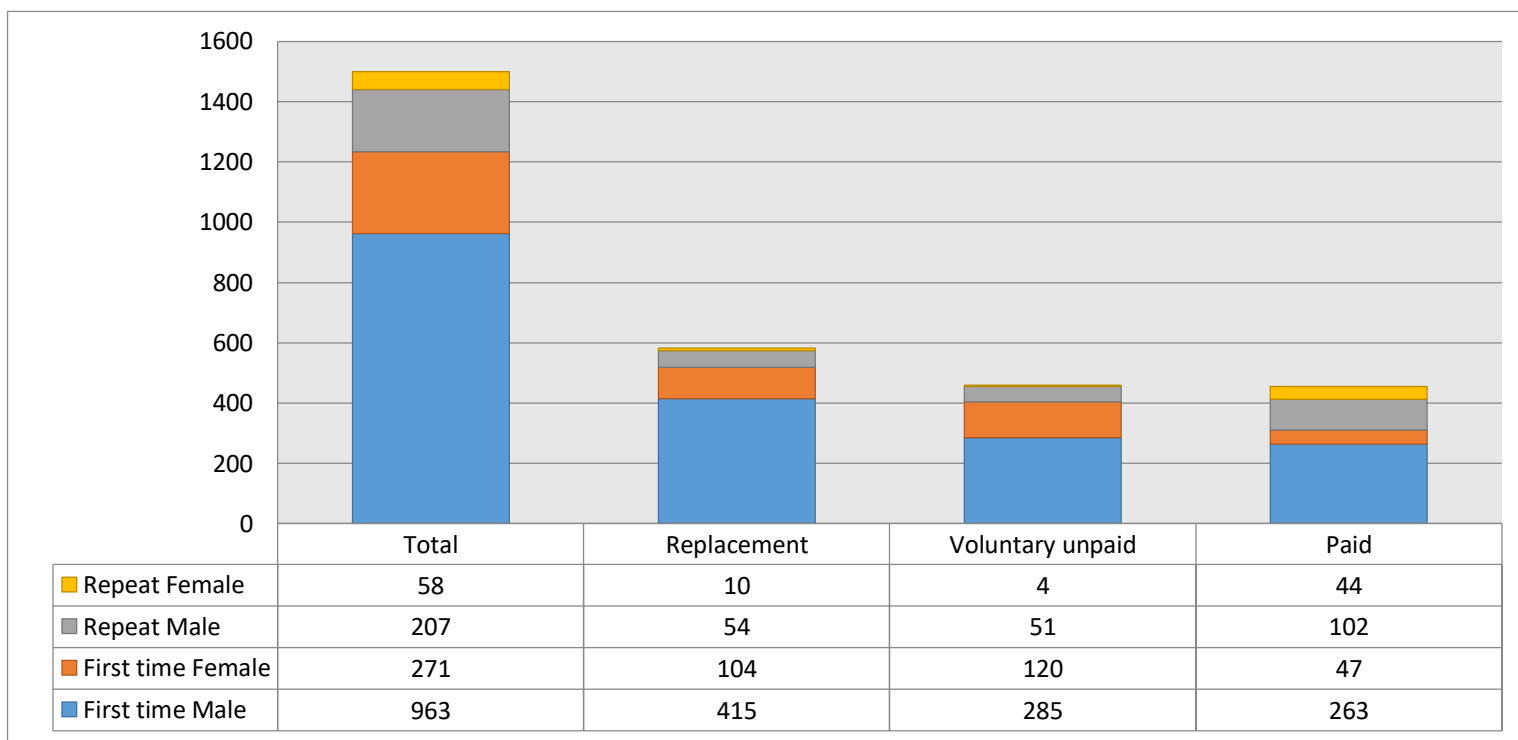


Curt Status

Anti HCV prevalence by gender and donor status, 2015-2016

According to the statistical data analysis of 2015-2017, first time replacement and voluntary unpaid male donors prevail on the number of repeat

Anti HCV Prevalence in Repeat and First-time Donor Population by Gender and Donor Status, 2015-2017

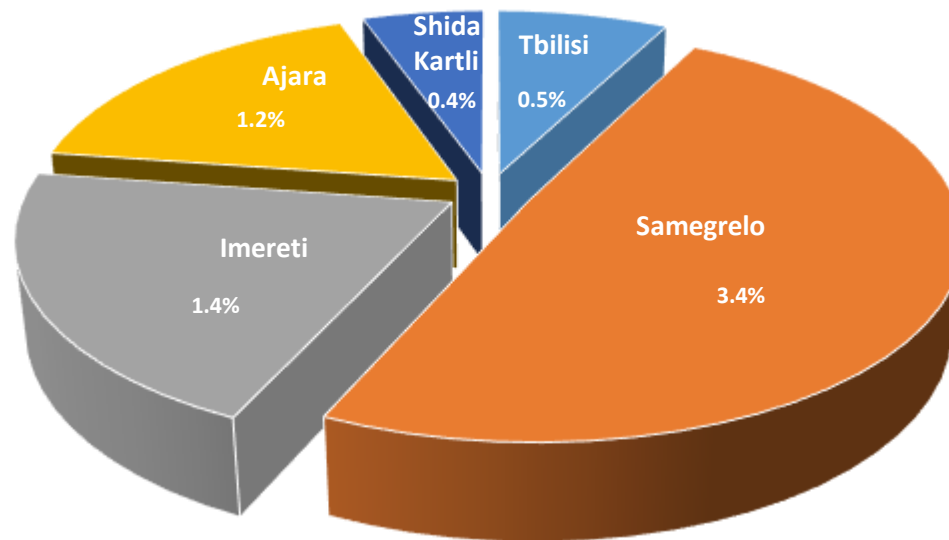


Current Status

Distribution of Anti HCV Positive Donations in the Regional Context

In 2017, highest rate of antibody positive donations were registered by blood bank located in Samegrelo region showing direct correlation with national burden of HCV spread in Georgia

Regional Distribution of anti HCV positive donations



■ Tbilisi ■ Zugdidi, Samegrelo Region ■ Kutaisi, Imereti Region ■ Batumi, Ajara ■ Gori, Shida Kartli Region

Progress

Amendments to State Safe Blood Program

External Quality Control System

- Blood banks that do not participate in the program were given the opportunity to participate in the external quality control system
- An additional professional testing mechanism has been added through the Lugar Center
- Two additional specialists will be assigned to draw out SOPs and provide monitoring and inspection of blood banks

Confirmatory Testing

- Blood banks must ensure:
- Transportation of Hepatitis C screening-positive samples to the Center for confirmatory testing using Cor-Ag method
 - Transportation of HIV screening-positive blood samples to AIDS Center for confirmatory testing
 - Mandatory notification of screening positive blood donors about their status
 - Removal of blood and blood components from previous donations of screening positive donors

Financing

- All participating blood banks will receive 17 GEL for each donation
- Quarterly, the blood banks will receive additional 2 GEL for each donation if proportion of voluntary donations has increased by 10% compared to the previous year, or if the proportion of voluntary donations within the total donations is 50%
- In addition, the blood banks will receive additional 3 GEL for each donation quarterly, if the proportion of voluntary donations within the total donations is 50%, and within these voluntary donations, 30% are regular voluntary donations



Progress

Amendments to Licensing Requirements

The Safe Blood Working Group prepared the first draft of changes to licensing requirement.

Current Requirements	Amendments
Infrastructure and facilities for personal hygiene, cleaning and disinfection of the premises	Donor selection: All donors undergo a screening process to assess their suitability. Questionnaire must be designed to elicit information relevant to health and lifestyle of donor. On completion it is signed by the donor. List of conditions are in the standards and may be useful to include in the questionnaire. Hemoglobin concentration must be determined each time the donor attends to donate blood or blood components.
Safe medical waste segregation, collection, storage, disposal, recycling and/or destruction according to the rules established by legislation	Donation: - Minimum 12 square meters for donor chair and additionally, at least 6 square meters for extra chair - Scale for donation.
To ensure the proper regime of disinfection and sterilization and the relevant accounting according to the rules prescribed by legislation	Equipment: scale for donor, scale for blood components, tonometer, donor chair, refrigerated centrifuge, plasma extractor, domestic refrigerator, refrigerator for red cells (+2 +6, if produced), plasma freezer (-80 -16), Platelet incubator and shaker (+20 +24, if produced)

Progress

Amendments to Licensing Requirements

Current Requirements	Amendments
Blood and blood components storage facilities and equipment according to the legislation	Infrastructure: registration and medical examination room with adequate furniture and facilities for registration and selection of donors, blood collection room, room for laboratory for blood group serology, room for laboratory for TTI testing (shall be air-conditioned), sterilization and washing room, refreshment room, waiting room, store and records room.
Uninterrupted water and electricity supply	Testing-typing: minimum ELISA for TTI testing and minimum Test Tube Method for blood group typing
Maintenance of medical and statistical documentation according to the legislation	Blood component preparation: refrigerated centrifuge, equipment for apheresis (for plasma centers)
Respective specialty certificates/qualifications of medical personnel as required by the legislation	Blood storage: storage areas must provide for appropriately secure and segregated storage of different types of blood and blood components including quarantine and released materials. Storage areas should be maintained within appropriate temperature limits. Frozen, refrigerated or heated storage conditions should have a temperature recording and alarm. Quarantined status areas should be marked clearly.
	Participation in the State External Quality Control System

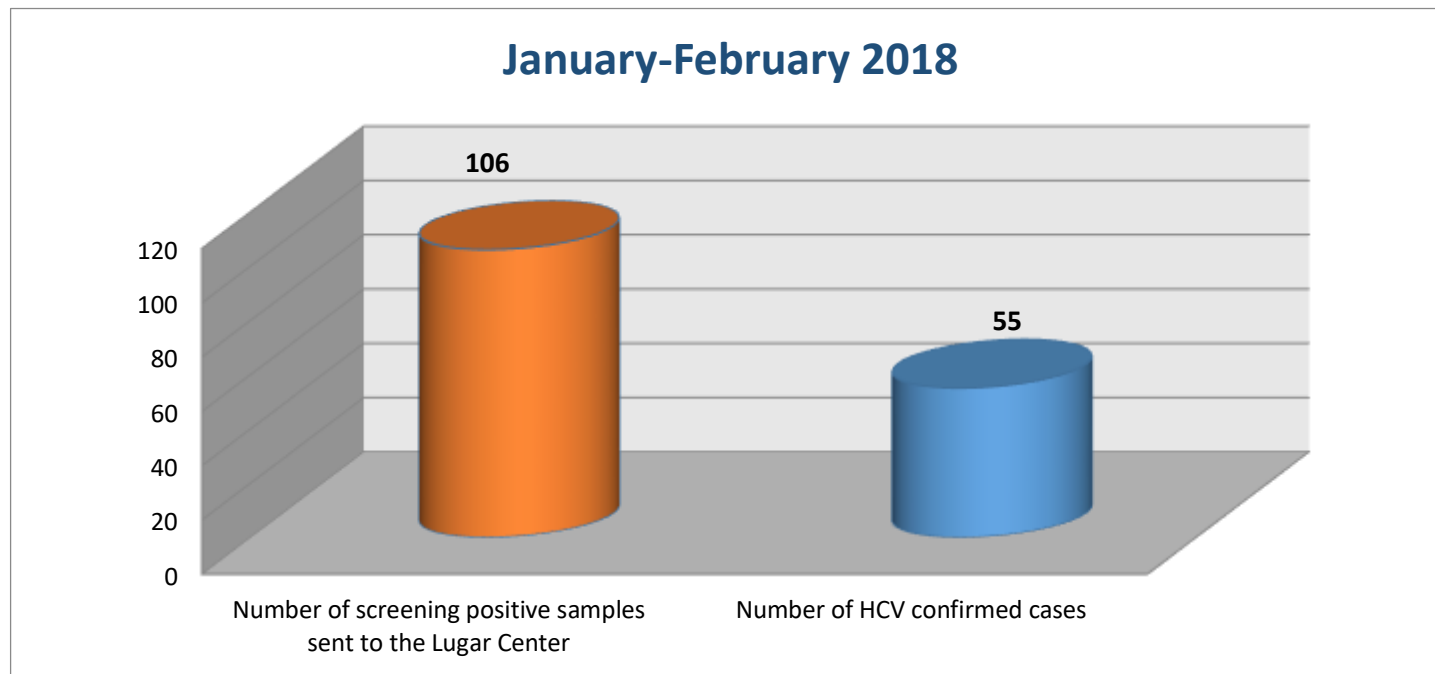
Progress Activities

- All licensed blood banks and majority of hospitals performing blood transfusion are involved in the Donors' Unified Electronic Database enabling vein-to vein traceability of TTI infections
- Development of the national guidelines for blood donor TTI testing is in the process, including algorithms of blood donor screening as well as confirmatory testing, donor re-entry algorithms, product disposition, donor notification and management
- One laboratory specialist was contracted for providing external quality control and selection process for recruitment of transfusion medicine specialist is in progress
- Negotiation with Global Fund on procurement (donation) of two NAT equipment has been started

Progress

Linkage to Diagnostic Services

- Confirmatory testing of HCV screening positive cases was introduced within the Hepatitis C Management Program that eliminated financial barrier to in depth diagnostic services
- Since 2018, blood banks transfer hepatitis C screening-positive samples to the Center for Cor-Ag confirmatory testing
- During January-February 2018, a total of 14608 donations were screened, 106 screening positive samples were sent to the Lugar Center, 55 confirmed results have been found



Progress KAP Survey

Main Barriers

Social problems, unclear procedures from donor registration to blood realization, donation stress

Lack or depreciation of important information, patients bear expensed for blood taken from voluntary donors

Remote location of blood banks, absence of advertisements and motivational stories in movies, TV series

Lack of actuality of the issue, believe that blood should not be sold at any cost, willingness popular faces deliver messages, rumors and myths

Mistrust to blood banks, lack of stimulation of unpaid voluntary repeat donations

Voluntary
Unpaid Repeat
Donation

Progress

Communication Campaign

Activities



- Supporting events related to the World blood Donor Day were held within the week
- 4 blood drive days were held in corporative organizations (blood was taken from 230 persons)
- Popularization materials with campaign logotype and slogan were prepared and distributed among general and donor population
- A seminar for media representatives was held at NCDC
- Short motivational text messages were sent to 29,367 potential, eligible donors

Multimedia Campaign



- Live television broadcasting of voluntary blood donation was organized to raise public awareness
- 10 television broadcasts were dedicated to the popularization of voluntary repeat donations
- 24 infographics were prepared and posted on Facebook page I am a Blood Donor
- Number of creative and awareness raising posts were prepared and posted on Facebook page
- 13 educational and informational articles were prepared and published in print and social media

Progress

EU Technical Assistance Tools



In December 2017, NCDC submitted Strategic TAIEX and Twinning Projects to European Commission aiming at approximation of national blood safety regulations to EU directives.

DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

COMMISSION DIRECTIVE 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components

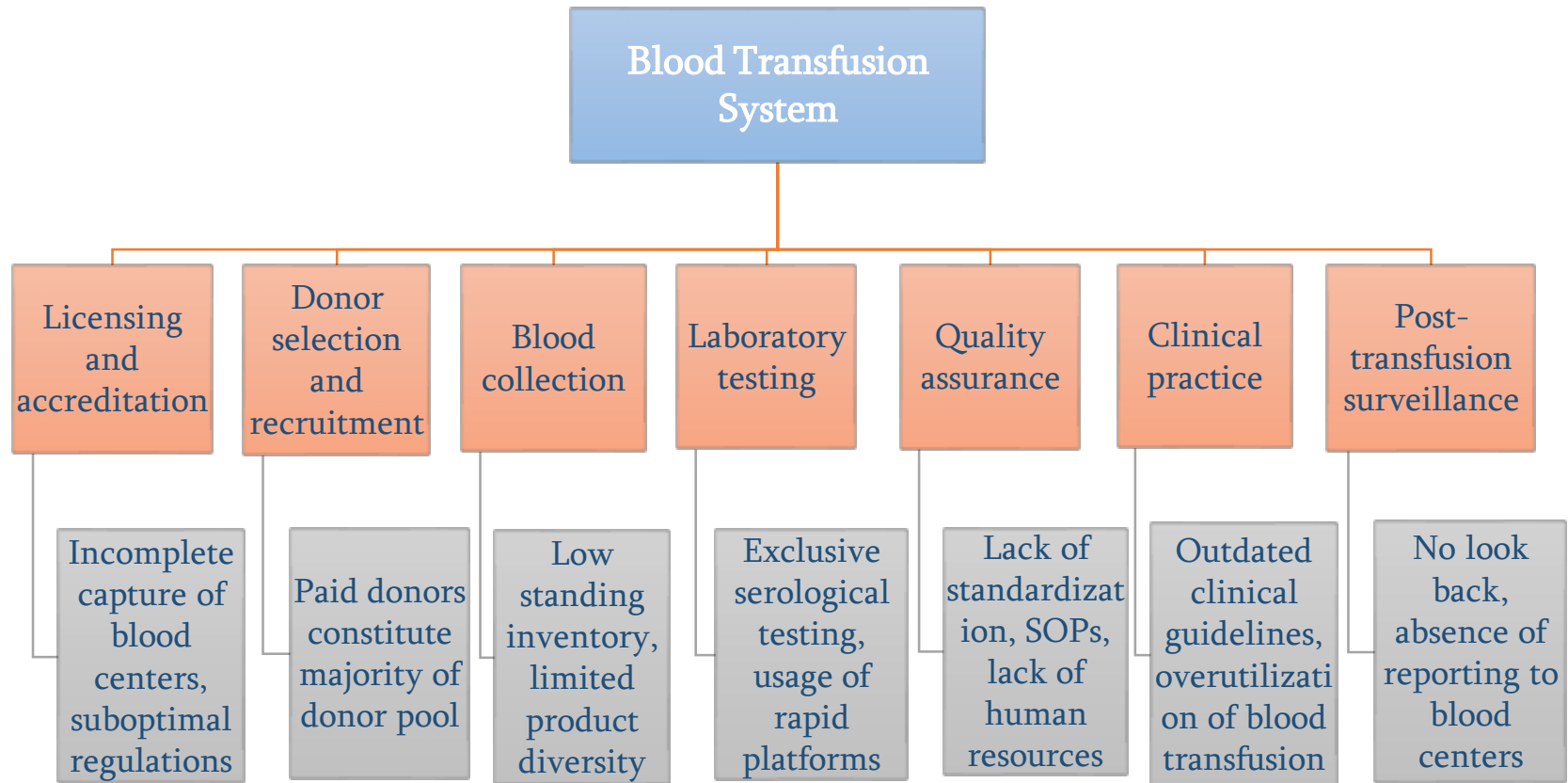
COMMISSION DIRECTIVE 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events

COMMISSION DIRECTIVE 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments

- ★ TAIEX project was approved
- ★ Twinning project was included into the priorities short list



Challenges



Next Steps

Still need to be done

Finalize national guidelines for TTI testing

Finalize building of external quality control system and involve all blood banks

Finalize amendments to licensing requirements and submit for endorsement

Prepare for expert mission within TAIEX tool

Implement necessary activities to introduce NAT piloting in 2019 (including NAT apparatus and trainings)

Increase voluntary unpaid repeat donations

Conduct active communication campaign to raise population awareness on voluntary regular blood donations

Thank you for your attention!

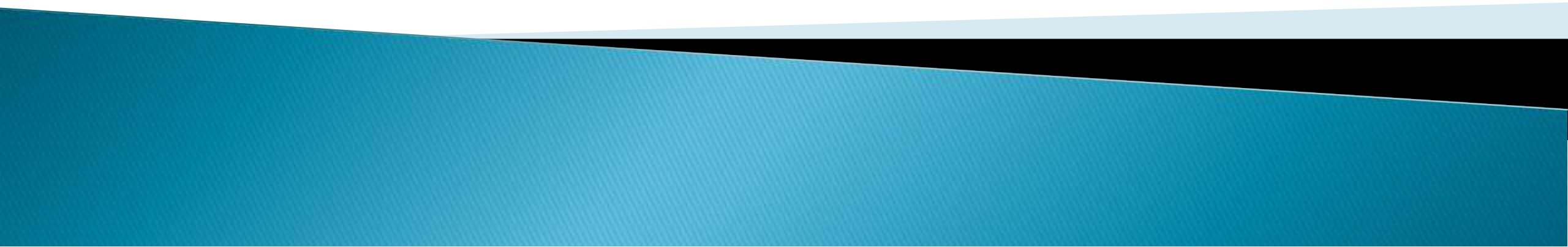
Stay connected with us
E-mail: e.kipiani@ncdc.ge
Web site: donori.ncdc.ge



HCV treatment decentralization

Harm Reduction group

Maia Butsashvili



Background

- PWID are a major source of the burden of HCV in the country as documented by the national HCV sero-survey conducted in 2015
 - Recent modeling indicates that priority treatment of PWID is needed to reach the elimination goals
- 

Problems related with HCV infected PWID medical care

- ▶ Double-stigma in society
 - ▶ Possible discrimination in medical institutions
 - ▶ Unwillingness of medical infrastructure to meet the demands of this patient group
 - ▶ Solution – user friendly, non-judgmental and unbiased medical setting
- 

Integrating HCV care with HR services

Integrated services

- Can mitigate stigma
- Encourage HCV treatment access by creating non-judgmental environment at the familiar institution (HR center)
- Based on trusting relationships and supports

The effectiveness of this strategy can be assessed to determine if this model can be expanded nationally.



Milestones of HCV treatment integration initiative with HR services

April, 2016

- ▶ Meeting on integration of HCV treatment with harm reduction services – during EASL meeting, Barcelona

June, 2016

- ▶ Meeting of ECHO and CDC team with civil society representatives and NCDC at HRU/NEOLAB office to discuss HCV treatment integration with HR services
- ▶ TAG recommendations

December 2017

- ▶ First meeting on HCV treatment decentralization
- 

Working group

Decentralization Effort

Objective: Decentralization of HCV treatment and care services.

Oversight & Coordination Group

Objective: Coordination and management of the decentralization effort. Final decisions made by this group and approval sought from appropriate institutions

Primary Health
Care/Hospital
Group

Harm Reduction
Group

Objective: Development of a practical model of care to be implemented at designated health care sites. Presentation of plan to oversight group.

Challenges to Address

- ▶ Simplified Diagnostics and Treatment guidelines/algorithms
 - ▶ Ensure Laboratory and Diagnostics integration
 - ▶ Develop and Disseminate SOPs
 - ▶ Develop Curriculum for Harm Reduction Centers
 - ▶ Initial and Continued (CME) Training for Harm Reduction staff
- 

Challenges to Address (cont.)

- ▶ Use of ECHO platform to facilitate training when applicable
 - ▶ Develop necessary information systems/modules to support decentralization projects into the national Elim-C database
 - ▶ Develop reasonable minimum criteria required for facilities to provide services to HCV patients
 - ▶ Incorporate lessons, findings from harm reduction center related pilot projects into practical model/action plan.
- 

Roles and Responsibilities:

- ▶ Meet as a group as recommended by the Oversight committee and the workgroup Chair
 - ▶ Adhere to timeline of task completion outlined by the oversight committee and workgroup chair
 - ▶ Develop an action plan for decentralization at Harm Reduction Centers that addresses the challenges below
 - ▶ Adhere to expectations of meetings, communication, documents/products set by the oversight workgroup (meeting minutes, action plans, white papers, proposals, etc.)
- 

Concerns related to integrating HCV treatment with HR services

- ▶ Unwillingness of HR center personnel
 - ▶ Low trust among patients and preference to be treated at specialized clinics
 - ▶ Quality of treatment and poorer outcome
- 

Study to evaluate barriers of integrated care

Funded by CDC/TEPHINET

- ▶ KAP survey of OST/NSP personnel on HCV care integration to evaluate readiness of health personnel to provide HCV care at OST/NSP sites.
 - ▶ Qualitative evaluation of HCV treatment integration to understand barriers and challenges of HCV integrated care
 - ▶ Patient satisfaction survey
 - ▶ Chart review form for patients enrolled in integrated care services
- 

Patient satisfaction survey

Preliminary results

Question	Answer	%
Is the location of medical facility convenient for you?	Yes	93.3
How satisfactory are the conditions (building, waiting space, sanitary conditions) at the medical facility?	Good	97.9
Are you satisfied with the attitude towards you from your doctor?	Yes	98
Are you satisfied with the attitude towards you from the nurses?	Yes	98

Patient satisfaction survey

Preliminary results

Have you received comprehensive information about hepatitis C treatment and side effects?	Yes	98%
Do you think that your confidentiality is protected during HCV treatment?	Yes	96.2%
Do you think that it's convenient to receive HCV treatment and methadone substitution therapy at the same clinic?	Yes	98%
In general, how would you assess HCV treatment services at this facility?	Very Good	93.5%
Will you recommend your family member/relative/friend (if interested) to be enrolled in National HCV Elimination Program?	Yes	100%

Provider attitude to HCV treatment integrated services (IS)

Preliminary data (N=51)

Question	Answer	%
Do you believe HCV treatment should be integrated with HR services	Yes	98
Do you believe your institution has enough administrative resources for IS?	Yes	82.8
Do you believe your institution has appropriate infrastructure for IS?	Yes	68.8
Willing to have IS at their institution	Yes	98

Diagnostics

Necessary diagnostic tests

➤ Screening

- *(HCV antibody test)*

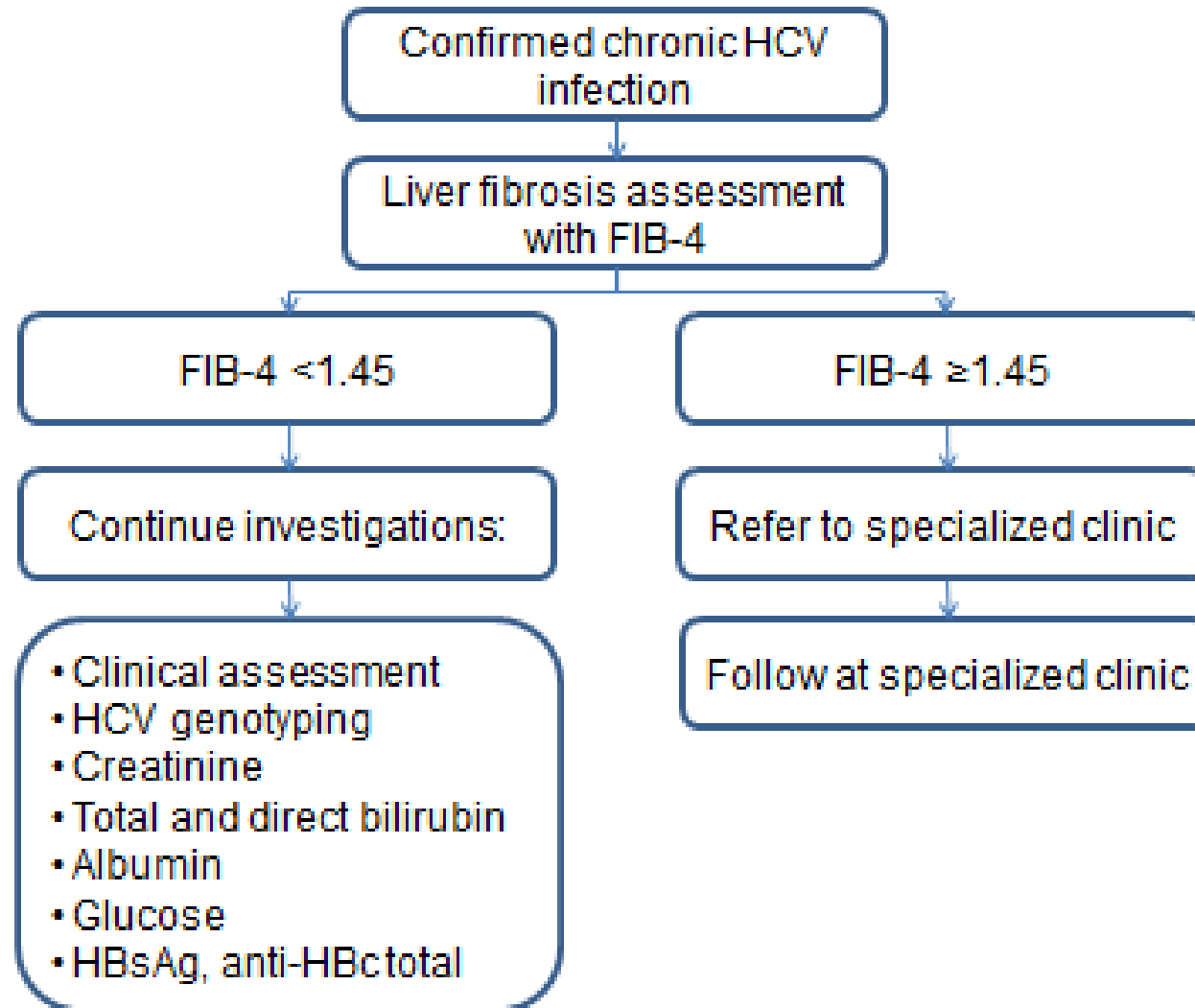
➤ Confirmatory testing

- *Core Antigen, RNA PCR (Quantitative, Qualitative), GeneExpert*
- *Centralized location of confirmatory testing (Lugar Center)*

➤ Pre-treatment diagnostics

- Simplify requirements
- Minimize cost

Simplified Algorithm of pre-treatment diagnostics



Simplified Treatment Monitoring Algorithm

Simplified treatment monitoring procedures				
Measurements	Treatment Duration (weeks)			After treatment completion (weeks)
	4	8	12	12 or 24
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*

- **Develop reasonable minimum criteria required for facilities to provide services to HCV patients**
- **Incorporate lessons, findings from pilot projects into model**