



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
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**Subj: Hepatitis Technical Advisory Group (TAG) Recommendations for Achieving the
2020 Goals Toward Eliminating Hepatitis C Infection in the Country of Georgia**

Dear Dr. Sergeenko:

On November 3-4, 2015, the Georgian Ministry of Labour, Health, and Social Affairs (MOLHSA), along with experts from the U.S. Centers for Disease Control and Prevention's (CDC's) Division of Viral Hepatitis (DVH), the World Health Organization (WHO), and other international partners, convened Georgia's first external Hepatitis Technical Advisory Group (TAG) meeting. A total of 11 experts in the field of viral hepatitis prevention and control served as TAG members. The 2-day meeting began with presentations from Georgian MOH representatives, who provided TAG members with information about the problem of viral hepatitis in that country, covering such topics as the burden of hepatitis C virus (HCV) in Georgia, existing care delivery systems and linkage to care and treatment, models of HCV elimination and proposed elimination targets (by 2020), surveillance, preventing transmission, and existing mechanisms for resource mobilization.

Following these presentations, breakout groups comprised of TAG members and representatives from the Georgia MOLHSA met to discuss aspects of the draft elimination plan in the context of proposed goals for HCV elimination in the country of Georgia. Taken together, the presentations and work-group discussions informed TAG recommendations.

The TAG applauds the Georgian government for recognizing the nation's burden of HCV disease and committing to improving hepatitis C prevention, care, and treatment. TAG recognizes the ambitious targets for HCV elimination outlined in the country's HCV Elimination Plan. In keeping with goals mentioned in the WHO Global Hepatitis Strategy, Georgia's Plan sets forth the following targets, to be reached by 2020: 90% of HCV infected persons have been tested for their infection, 95% of people with chronic infection have received treatment, and 95% of persons who receive treatment are cured of their HCV. Meeting these targets by 2020 will result in approximately 80% of HCV-infected adults cured of their HCV infection, representing approximately 120,000 people treated and 113,000 cured of HCV. Since the baseline prevalence of HCV is approximately 5% in the adult population, a 90% reduction in prevalence equates to a 0.5% prevalence. Reaching these goals would also reduce mortality by at least 65%.

The TAG recognizes that work is already underway in Georgia: analysis of the first national HCV serologic survey is ongoing, and the first phase of the elimination program also is underway, resulting in over 5,000 HCV-infected persons starting treatment since early May 2016. Further, the TAG commends Phase 2 planning efforts that aim to provide Georgians with comprehensive HCV prevention services. To assist the country of Georgia in meeting the country's HCV elimination goals, the TAG provides the following guidance for development of the 2020 HCV elimination plan.

Advocacy, Awareness and Education, and Partnerships for Resource Mobilization

- Conduct public awareness campaigns regarding the HCV Elimination Program, with the goal of reducing HCV transmission and increasing acceptance of HCV testing and entry into care and treatment. The campaign can address 1) the importance of infection control and the role of both patients and providers in creating public demand for safe infection-control practice and 2) the need to reduce stigma associated with HCV infection and injection-drug use and to employ harm reduction and other interventions that reduce the risk of HCV transmission.
- Educate the community regarding where HCV testing and treatment is offered, particularly targeting those populations recommended to receive HCV testing. The Georgia government can conduct campaigns designed specifically to increase HCV testing, such as observance of World Hepatitis Day and designation of National HCV Testing Day(s).
- When these other priorities are addressed, health promotion campaigns can also target the general population to encourage consumers to demand newly opened, sterile equipment for all percutaneous procedures in settings other than health-care facilities (e.g., tattoo, piercing, and acupuncture establishments).
- Ensure that all health promotion and awareness campaigns are informed by evidence on the societal factors that drive stigma.

Prevention of Transmission

Harm Reduction

- Increase provision and quality of harm-reduction services. These services should be largely covered by Needle and Syringe Programs (NSP) and opiate substitution treatment (OST) programs, with the goal of achieving 80% NSP coverage and potentially providing services to 20,000 OST patients by 2020.
- Revise existing OST programs to assure effectiveness (e.g., include the option to obtain take-away doses and eliminate co-payments); additionally, include paraphernalia in the sterile kits for NSPs.
- Provide free universal testing for HIV and HCV at OST and NSP sites; as sites become established, hepatitis B testing can be added as a preventive service.
- Train physicians and other health-care providers how to best manage HCV testing, care, and treatment for persons who inject drugs (PWID) and include education regarding

provision of OST. Explicitly state in the Plan the need to combat discrimination in the course of care for PWID by providing physicians and other health-care providers with appropriate sensitivity training for this population.

- Create Centers of Excellence to bring together OST and HCV care and treatment. Starting with these centers, develop specific, community-based approaches (e.g., directly observed therapy, peer support, and reminder messages) for PWID to strengthen linkages to care and adherence to HCV treatment and prevention. The TAG encourages development of demonstration projects, preferably beginning within the next 12 months; however such projects should not hamper or delay any general strategies aimed at increasing PWID access to treatment.
- Plan to implement a decentralized model of HCV treatment provided in OST and NSP sites and other settings that manage large numbers of PWID.
- Create strong collaborations with law enforcement, government, non-governmental organizations, and the public to facilitate implementation of the plan. Prepare to transition from a law-enforcement based approach to one that is health-based to decriminalize injection-drug use. This type of policy is needed to achieve all goals and objectives of Georgia's elimination program and to sustain program success after the elimination goals are achieved.
- Implement methods to monitor program effectiveness for the PWID population, such as employing a cross-sectional, national survey among PWID.

Blood Safety

- Continue to implement WHO recommended procedures to improve blood safety.
- Continue to implement procedures to decrease the number and proportion of blood donors paid for their donation or recruited by family members. Voluntary blood donation could be promoted through collaborative initiatives with private partners (e.g., designating and promoting blood donation days with the help of a mobile blood donation unit) and creating positive media regarding blood donation. Also, prioritize recruitment of repeat donors who were HCV seronegative and with no risk for HCV identified on their prior donation. Repeat donors are at lower risk of HCV after they have once tested negative.
- Develop nationwide, universal standard operating procedures and guidelines for the handling of blood products.
- Seek partnerships with industry to obtain high quality, affordable HCV tests with the goal of universal nucleic acid testing (NAT) of all donated blood. One option is to test donated blood using an HCV antigen assay in addition to enzyme immunoassays (EIA).
- Consider conducting HCV RNA testing on aliquots from accepted donors received during the past year and stored at the Lugar Center. Such testing would provide information about the numbers of false-negative donors (e.g., persons who donated blood during the window period). Results from such a study would help to further determine the utility of additional NAT testing.

- Consider testing donor blood for liver enzymes (ALT) to detect window period and EIA false-negatives; availability of these test results could improve knowledge about HCV seroconverters in Georgia.
- Incorporate transfusion medicine curricula as part of medical education and training programs to decrease the unnecessary use of donated blood and blood products.

Infection Control and Prevention in Health-Care and Non-Health-Care Settings

- Promote development of infection prevention and control (IPC) programs, to be first implemented in hospitals and larger outpatient facilities, followed by smaller clinics and medical offices.
- Update policies to include patient and health-care worker (HCW) safety (e.g. needle-stick injury programs, post-exposure prophylaxis, and HBV vaccination for HCWs). This may include revising national IPC guidelines based on WHO IPC guidelines and expanding IPC committees.
- Review results from past IPC assessments and conduct new IPC assessments within health-care facilities to improve understanding of the breaks in IPC leading to transmission (e.g. multi-dose vials versus reuse of needles/syringes).
- Educate HCWs regarding prevention of HCV transmission, including conducting pre-service training for medical and nursing students and developing/revising IPC curricula based on National IPC Guidelines.
- Establish an accreditation body to enforce safe injection practices.
- Require all major hospitals to establish infection-control committees with personnel empowered to do surveillance and recommend interventions to prevent infection transmission between patients, staff, and visitors to the hospital.
- Determine institutional incentives for compliance with IPC.
- Develop guidelines and standard operating procedures for sterilization and disinfection.
- Integrate judicious use of injections into National Essential Medicine Policy.
- Review available policies addressing waste management and revise/develop policies, as needed (e.g., implement the “polluter pays” principle).
- Draft legislation to prevent HCV transmission via regulation of tattoo and piercing parlors.
- Implement activities to reduce frequency and inappropriate use of injection or blood products that pose unnecessary risks for patients.

HCV Screening, Care, and Treatment

Screening

- Guided by the national serologic survey, recommend HCV target populations of sufficient size to successfully diagnose the number of HCV infected persons necessary to meet elimination goals. For example, target populations with an estimated HCV prevalence greater than the national average on the national serosurvey. Select target

populations on the basis of demographics, geographic locations, risks of transmission, and other characteristics associated with increased prevalence of HCV infection.

- Continue to adopt HCV testing for pregnant women.
- Employ a rapid scale-up of HCV testing for target populations. This activity promotes identification of persons in need of immediate care and treatment, preventing mortality while helping to destigmatize the disease and build and sustain public support for the program.
- Implement strategies and new validated technologies to simplify the testing process for current HCV infection (e.g., point-of-care tests in safe-injection programs and laboratory-based reflex virologic testing of anti-HCV-positive specimens collected in clinical centers).
- Seek partnerships to increase affordability, quality, and access to testing, particularly with corporations providing diagnostic tests to decrease the per-test cost of HCV antibody, virologic, and genotype testing.
- Integrate routine (i.e., standing orders for opt-out testing) HCV testing with other laboratory testing ordered for persons receiving care in inpatient and outpatient settings.
- As a first step, establish routine HCV treatment services for both patients and HCWs within HCV Centers of Excellence.
- As testing programs are established, help clinicians avoid unnecessary repeat testing by developing a web-accessible HCV testing database linked to HCV treatment data.
- In collaboration with the national public health laboratory, develop a process to evaluate and verify the quality of laboratories conducting HCV testing.

Care and Treatment

- Expand access to HCV treatment by increasing the number of gastroenterology and infectious disease specialists capable of providing HCV therapies in 2016, followed by expanding the number of primary-care physicians trained to provide HCV treatment services (beginning in 2017). Other clinical settings (e.g., TB clinics) should be considered as well for training, as patients with HCV co-infection are also being seen in these facilities. Project ECHO (Extension for Community Healthcare Outcomes) can help these providers deliver quality HCV care and treatment.
- HCV testing and treatment activities should continue to prioritize identification of persons with evidence of HCV-related liver disease with immediate linkage to curative therapy.
- Develop strategies targeting populations with ongoing risk for HCV transmission (particularly PWID) to optimize adherence and completion of HCV therapy.
- Use interferon-free regimens (i.e., all oral, direct-acting antivirals) in the vast majority of patients and earmark cost savings associated with use of less expensive treatment to pay for expanded testing initiatives.
- Simplify treatment guidelines to streamline patient management and minimize blood draws and unnecessary viral load tests, reducing costs incurred by patients and increasing the number of persons receiving treatment. The current directly-observed therapy (DOT)-

like/video-taped delivery mechanism is a barrier to decentralization, patient confidentiality, and access in general.

- Provide gender-sensitive prevention and treatment services that allow equal access for women and men.
- Update national HCV treatment guidelines as new medications become available.
- Conduct cost analyses to determine a clear balance between the investment in treatment and in prevention.

Surveillance

- Ensure that the surveillance system yields data to detect new or recent HCV infections (including outbreaks) and the data to monitor performance of prevention, testing, and treatment programs.
- Collect data from all viral hepatitis testing laboratories and treatment sites serving the general population, and conduct sentinel surveillance on key populations targeted for prevention, testing, and treatment interventions (e.g. PWID and persons living in correctional facilities).
- Focus surveillance on outcomes and the HCV care cascade.
- Simplify the amount of data being collected to ensure high quality, complete data collection. If developing a full surveillance system is cost and time prohibitive, consider creating sentinel regions and/or clinics where the impact of the program can be thoroughly and accurately measured and monitored.

Laboratory

- Improve laboratory quality assurance to accommodate expansion of HCV testing. Quality assurance (QA) is particularly important when various testing methods are employed.
- Promptly develop laboratory QA certification and a national lab certification system, and establish standard operating procedures.
- Examine laboratory data to determine the proportion of hepatocellular carcinoma and deaths attributable to HBV and HCV.
- Monitor the HCV care cascade using lab data, to include European Association for the Study of the Liver (EASL) criteria for late presentation.
- Identify and implement diagnostics and surveillance for active HCV infection to assess program outcomes.

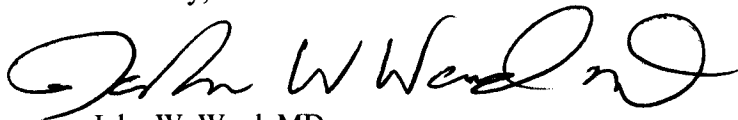
Measuring Impact of Georgia's HCV Elimination Plan

- Establish a monitoring and evaluation system to include key indicators for all elements of the Elimination Program (surveillance, prevention, and care and treatment); provide TAG with this information annually.

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- Create additional models to determine the impact of the 2020 elimination targets.
- Conduct a repeat national seroprevalence study in 2021 to re-measure HCV prevalence and assess the impact of scaled-up testing and treatment efforts as informed by the HCV Elimination Plan and its associated targets (i.e., by 2020, testing 90% of persons and treating 95% of all persons found to be infected).
- Establish yearly service coverage targets for all key interventions (e.g., testing, treatment, harm reduction, and injection safety).

Sincerely,

A handwritten signature in black ink, appearing to read "John W. Ward, MD". The signature is fluid and cursive, with a large initial "J" and "W".

John W. Ward, MD
Director, Division of Viral Hepatitis
Centers for Disease Control and Prevention