

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

# **OVERVIEW OF THE RESEARCH PROGRAM**

Tinatin (Tatia) Kuchuloria, MD, PhD, MSc  
CDC Foundation

# Why is Research Important for HCV Elimination?

- ❑ World's first HCV elimination program
- ❑ Monitor progress
- ❑ Document lessons learned
  - What worked well?
  - What presented challenges?
- ❑ Document elimination: were the elimination goals actually achieved?

# Documenting HCV Elimination



Research broadly defined to include surveillance, monitoring and evaluation, and research

# Need for Coordination of Research, Early 2016

- ❑ Ensure access to quality data for stakeholders
- ❑ Avoid duplication of efforts as resources are limited
- ❑ Transparency
- ❑ Ensure that lessons learned, information, and findings are disseminated

## Questions – Early 2016

### □ Examples

- Impact of HCV treatment on morbidity and mortality?
- Is HCV incidence increasing or decreasing?
- Effectiveness of screening and linkage to care strategies?
- Importance of community transmission in the HCV epidemic?
- Effectiveness of treatment strategies targeting high risk populations on transmission and prevalence?
- Effectiveness of primary care providers to deliver care and treatment for HCV (vs. specialists)
- Can monitoring of patients on treatment be simplified?
- Effectiveness (and Cost-Effectiveness) of HCV Core-Ag (vs. Anti-HCV + PCR)?

# Benefits of Scientific Committee Vision – Early 2016

- ❑ **Maintain clean and up-to-date databases**
  - Treatment database (STOP-C, Elimination-C)
  - 2015 Serosurvey
  - Screening database (proposed)
  - Others
- ❑ **Review and approve study proposals**
- ❑ **Support of approved proposals**
  - Study implementation and data collection
  - Data analysis
  - Manuscript writing

# Establishment of the Scientific Committee

## ❑ Established in August, 2016

- Research agenda development
- Transparency
- Coordination
- Communication

## ❑ Members

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

# Scientific Committee

- ❑ Co-chaired by NCDC and CDC
- ❑ Members
  - Ministry of IDPs from the Occupied Territories, Labor, Health, and Social Affairs
  - National Center for Disease Control and Public Health of Georgia
  - Infectious Diseases, AIDS and Clinical Immunology Research Center
  - Clinic Hepa
  - Clinic Neolab
  - Clinic Mrcheveli
  - US CDC
- ❑ Non-members may be invited ad hoc

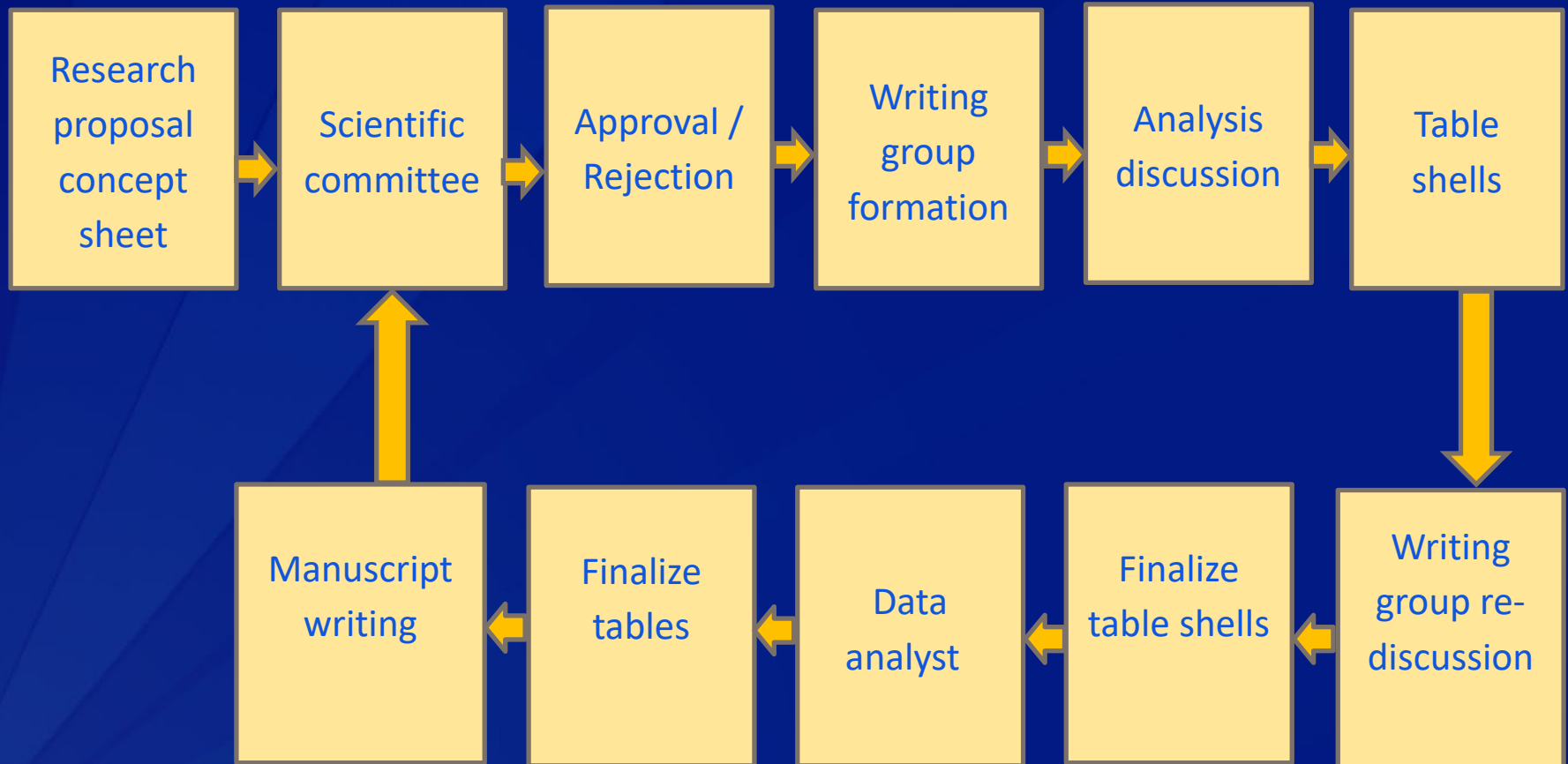




# Roles of the Scientific Committee

- ❑ **Review, approve, and support study proposals**
  - IRB review and approvals
  - Assist in securing funding
  - Study implementation
  - Data analysis
  - Manuscript writing

**FLOW DIAGRAM of protocol for submitting a research proposal (for STOP-C/Serosurvey/Special studies)**



**U.S. Centers for Disease Control and Prevention, Division of Viral Hepatitis  
/ Government of Georgia**

**Concept Proposal Sheet (EXAMPLE)**

**1. Type of Proposal:**

- |  |   |
|--|---|
| <input type="checkbox"/> Treatment data proposal       | <input checked="" type="checkbox"/> Serosurvey proposal   |
| <input type="checkbox"/> Laboratory proposal           | <input type="checkbox"/> Special Studies proposal / Other |
| <input type="checkbox"/> Revision to existing proposal |   |

**2. Title of project:**

Characteristics and Risk Factors for HCV Infection of PWID in Georgia, 2015

**3. Data to be used:**

- |                                       |  |  |
|---------------------------------------|--|--|
| <input type="checkbox"/> STOP-C       | <input type="checkbox"/> C Elimination | <input checked="" type="checkbox"/> Serosurvey |
| <input type="checkbox"/> Surveillance | <input type="checkbox"/> Other         |  |

**Specify subset (if applicable):**

Data were restricted to PWID aged 18 and older.

**4. Date of proposal (and revision date, if applicable):**

November 20, 2016 (original)

**5. Anticipated product:**

Manuscript/Abstract

**6. Target Journal:**

The American journal of drug and alcohol abuse

**7. Proposing author:**

Principle investigator (PI)

**8. Proposed writing group:**

-PI, Subject Matter Expert, Other contributors (may include members from the scientific committee)

-Must include at least one author from NCDC and CDC (responsible parties of the serosurvey)

**9. Supervisor/s:**

PI

**10. Rationale for project:**

# Roles of the Scientific Committee (Cont.)

- ❑ **Coordination with**
  - Ministry of Health
  - Clinical Committee
  - International organizations
- ❑ **Guest speakers**

# Progress

## (August 2016 – November 2018)

- ❑ **Number of proposals:**
  - Reviewed - 52
  - Approved - 44
  
- ❑ **International conferences/Publications:**
  - Abstracts - 53
  - Manuscripts - 17

# TAG Day 1

## □ Science day agenda:

- Immediate and long-term clinical outcomes
- Evaluation of diagnostics and treatment delivery models both at specialized and non-specialized HCV care settings
- Novel Approaches to Laboratory Diagnostics
- Improving Access to Care and Treatment
- Surveillance
- Economic evaluation

# Acknowledgements

- Ministry of IDPs from the occupied territories, Labor, Health, 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
- Partners: FIND, Abbott, MDM, University of Bristol, Boston University, Emory University, Johns Hopkins University, WHO, and others

# Conclusions

- ❑ Robust research agenda is critical to achieve elimination
- ❑ Lessons learned from the Georgia HCV Elimination can guide other elimination efforts globally
- ❑ Coordination of efforts (among partners and stake-holders) improves efficiency and quality