4th HEPATITIS C TECHNICAL ADVISORY GROUP

TAG Meeting

ESTABLISHMENT OF THE SYSTEM FOR ARCHIVING SAMPLES COLLECTED WITHIN THE HEPATITIS C ELIMINATION PROGRAM

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Background

- Establishment of the system for archiving samples collected within the Hepatitis C Elimination Program (CDC Foundation 01.07.2017-30.06.2018)

- Aim – Bank samples collected from the hepatitis C elimination program for use in future studies

Background

- Establishment of the system for archiving samples will serve to create library of the samples that will allow to perform future studies:
  - Study of HCV antiviral resistance levels;
  - Transmission of anti-viral resistant strains among active PWID;
  - Viral RNA sequencing for re-infected individuals will discriminate between treatment failure and reinfection;
  - Virological testing for HCV, HBV, and HIV in the cohort of seronegative blood donors to estimate the rate of false negative and window period positive donations that have been transfused;
  - Studies evaluating or validating simplified diagnostic platforms and other potential investigations.

Activities

- Communication with MOH:

Both HCV treatment contract and confirmatory testing informed consent documents includes verbiage on sample archive

- Communication with Blood Banks:

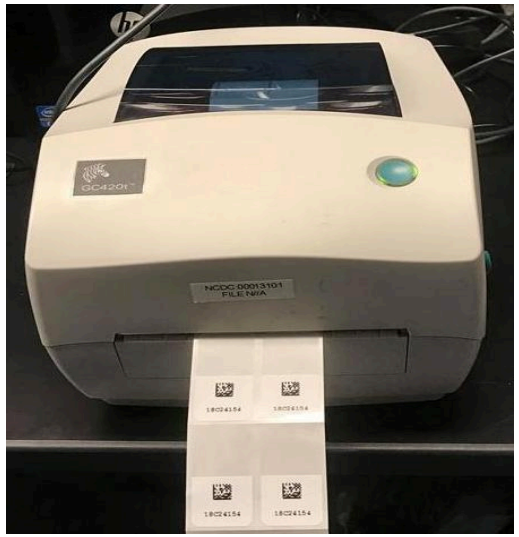
Rejected blood samples should be re-defined so that they are not assigned to the bio-waste category.

Methods

- Two 1.5 ml of each plasma/serum in cryogenic screw-cap vials are collected from the following activities:
  - Each clinical site were requested to prepare an aliquot of plasma/serum sample collected from each HCV positive patient.
  - HCV baseline confirmation using HCVcore Ag
  - Blood bank samples are collected including seronegative samples for HCV, HBV and HIV. Blood banks is requested to send plasma bags of rejected blood.
  - Samples are collected from the Harm Reduction Centers;
  - Aliquots of samples were collected as part of the projects „Establishing Georgian PWID cohort study to estimate incidence of HCV infection“, funded by the CDC Foundation
  - Up to 6,000 serum samples collected from 2015 National Survey.

Methods

- All collected samples are aliquoted and labeled with a unique barcode identification number.
- Aliquots from ZDLs and treatment providing centers are batched and shipped to the Lugar Center using transportation system established through the NCDC/Lugar Center laboratory network on a weekly basis.
- Received samples are scanned and registered with demographic, risk factor and other collected data in PACS (Pathogens Asset Control System) and stored at - 80^0C.



Sample Inventory

- PACS Input data for stored samples:
  - ✓ Source of the samples (blood banks, serosurvey, others).
  - ✓ HCV, HBV, or HIV status
  - ✓ Sample volume
  - ✓ Epi data: gender, sex, age
  - ✓ Risk factor data if known

Archived Samples

- 6,018 serum samples collected from 2015 National Survey (7.7% HCV Ab positive or 5.4% HCV RNA positive)
- HCV confirmation using HCVcore Ag (Screening positives, FIND (drug users), Treatment Clinics)) - 11,761 samples (71% HCVcoreAg and HCV RNA positive)
- Cepheid protocol 115B HCV VL performance evolution (237 samples - 75% HCV RNA positive)
- Rejected blood donors samples from two blood banks (Jo Ann and Kvantaliani) (83 samples – 57% HCV Ab positive)
- Establishing Georgian PWID cohort study to estimate incidence of HCV infection (1768 samples – 42% HCV Ab positive)
- FIND Xpert Finger stick HCV VL assay evolution/Protocol Nr 8151-01-2/1 (310 plasma samples - 48% HCV RNA positive)

Outcome

- Multicenter laboratory evaluation study of Rapid Diagnostic Tests (RDTs) detecting antibodies against hepatitis C virus using archived, frozen plasma samples (FIND Protocol N: 8162-2/1)
  - to identify tests with performance meeting or having the potential to meet WHO quality standards (Evaluation of sensitivity and specificity of anti-HCV RDTs of 10 different manufacturers, measured against the composite reference standard composed of two Enzyme Immunoassays (EIAs) and a Line Immunoassay (LIA).

- Evolution of sensitivity and specificity of two different manufacturers rapid test kits, purchased by the government for Hepatitis C screening sites

Sustainability of the project

- - 86 ^{0}C ultra-low freezers and consumables were purchased by the NCDC

- Dedicated staff are assigned for sample handling/storage and data entry to PACS

Summary

- More than 14,000 samples are archived
- PACS system are used for maintenance of bio-bank
- Additional freezers and consumables are purchased
- Archived samples are successfully used in scientific projects

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Thank you for
your attention!