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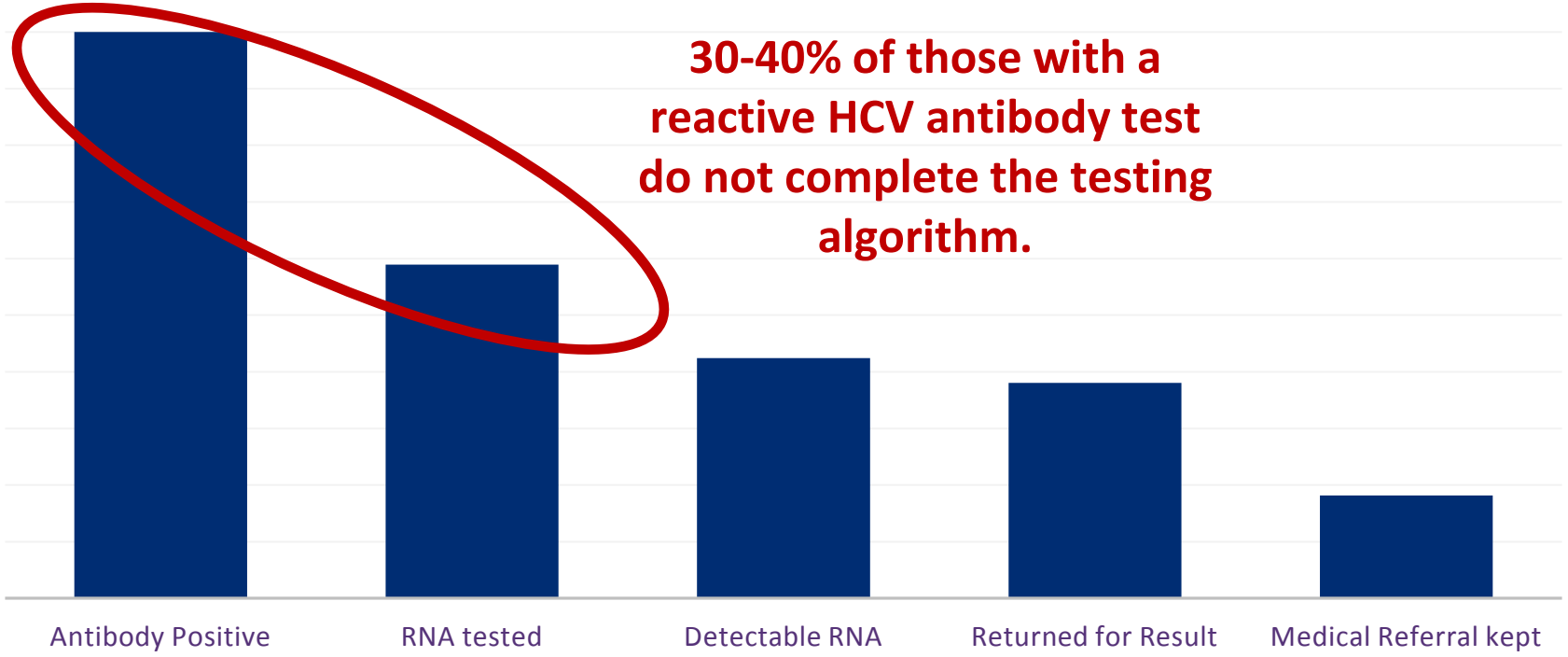
Pilot Study: Feasibility of HCV RNA Diagnostic Testing via Dried Blood Spot in Non-Clinical Settings in New York State

Bureau of Hepatitis Health Care, AIDS Institute

The Challenge



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Challenges to Traditional HCV RNA Testing

- Requires venipuncture blood sample
  - Clinical setting with staff trained in phlebotomy
  - Invasive procedure
  - Requires additional time with the client
  - May be difficult to access veins on PWID
  - Potential trigger for PWID
- Requires specific preparation, handling and storage of samples
- Specimen shipping restrictions, including:
  - Geographic limitations
  - Temperature control
  - Limited transit time
  - Special packaging required

Dried Blood Spot (DBS) Sampling

Blood from a finger stick is placed on a filter paper card that is allowed to air dry for at least 4 hours.

Advantages of Dried Blood Spot Sampling

- Used extensively for other diagnostic testing and disease surveillance
- Less invasive procedure
- Requires minimal blood volume (4 spots of 30-100µl each)
- Limited training necessary
- Longer window of time for transport (15 days vs 3-7 days)
- Sample stability

Pilot Study Opportunity

- Wadsworth Center, Bloodborne Viruses Laboratory (BVL) developed and validated HCV RNA test using DBS samples
- Collaboration between Wadsworth and the BHHC on a six month IRB-approved pilot using DBS
- Aim to collect 300 test specimens across six Programs enrolled in the NYS Rapid Testing Program:
  - 3 Community Based Organizations (CBO)
  - 2 Syringe Exchange Programs (SEP)
  - 1 Hospital-Based Clinic

Pilot Objectives

- Evaluate the feasibility of dried blood spot specimen collection for HCV RNA testing in conjunction with HCV rapid antibody testing in nonclinical settings
- Assess quality of dried blood spot specimens submitted from non-clinical settings to ensure they meet specimen acceptance criteria for HCV RNA testing.
- Evaluate staff experience and client experience with dried blood spot collection process

Community Partners in NYC Participating in the DBS Pilot

- Community Health Action of Staten Island (CHASI)
- Mount Sinai Internal Medicine
- VOCAL NY

COMMUNITY HEALTH ACTION OF STATEN ISLAND
A MEMBER OF BRIGHTPOINT HEALTH

Mount Sinai

REACH

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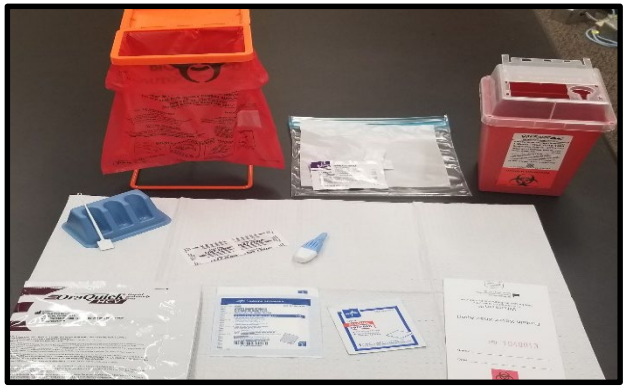
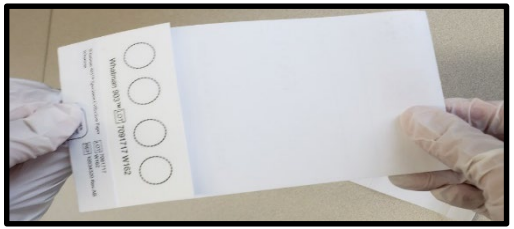
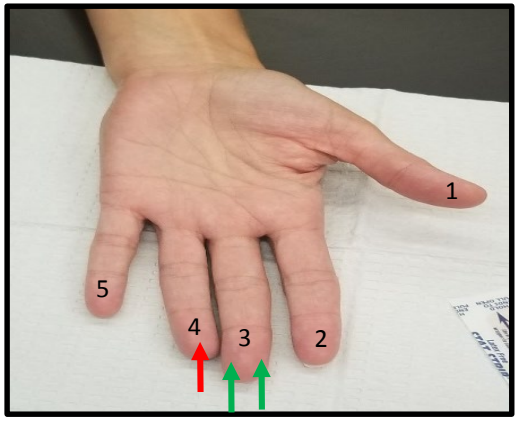
Pilot Implementation

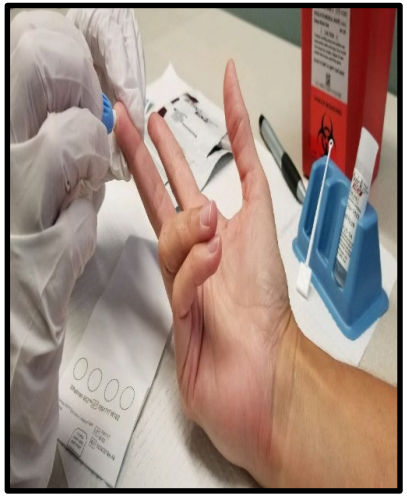
- NYSDOH AIDS Institute provided:
  - DBS collection and shipping supplies
  - Training for staff
  - Analysis of staff and client surveys
- Wadsworth Center BVL provided:
  - HCV RNA testing
  - Specimen tracking and reporting through Clinical Laboratory Information Management System (CLIMS)

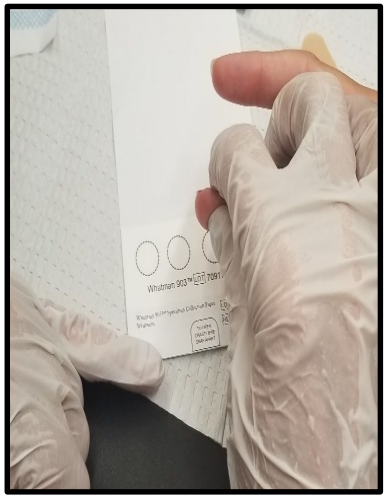


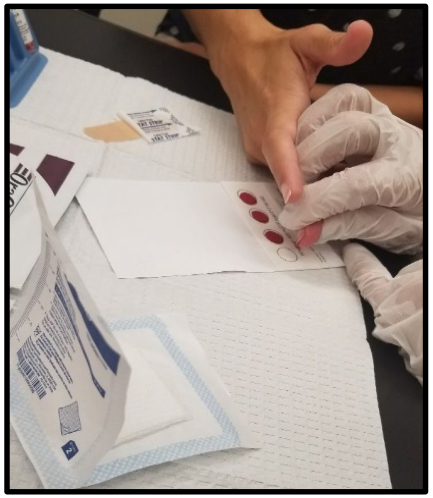


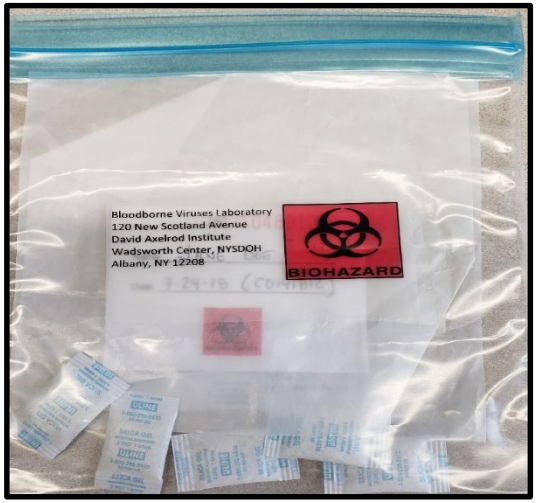
DBS Training











Interim Pilot Outcomes

- 284 samples submitted as of August 31, 2019
  - 13 of 154 samples, quality precluded analysis
  - 16 of 154 samples, yielded indeterminate result
  - 255 of 154 samples, provided diagnostic outcomes
- Programs report DBS being well-received by clients and testing staff

Challenges and Lessons Learned

- Frequent staff turnover
  - Need for repeat training and enhanced supervision
- Poor sample quality
  - Reinforce messages about smears, layering of blood, alcohol residue
- Logistical considerations
  - Consider higher volume of testing and the implication on transportation from the field as well as the need for space to allow samples to dry appropriately

Challenges and Lessons Learned

- Insufficient sample due to incomplete cards/circles
  - Revised pilot guidance to promote completion of 4 circles
  - Developed a size guide tool to help staff assess adequacy of sample size
  - Recommended use of high-flow lancets to ensure adequate sample size and reduce client discomfort.
- Difficult specimen collection during winter weather in outreach sites
  - Used hand warmers to increase circulation
  - Used hand sanitizer to encourage participants to massage hands and increase blood flow

Challenges and Lessons Learned

- Time management when incorporating DBS into testing
  - Programs highlighted the importance of understanding client's time constraints.
  - To reduce time, some programs collected the DBS card first, then the OraQuick® HCV Rapid Antibody test to ensure adequate sample collection on a single fingerstick.
  - Some programs opted to give clients the option of conducting the antibody test and DBS simultaneously or sequentially.

Limitations

- DBS for HCV RNA testing is not commercially available.
- Wadsworth Center used a CLEP approved laboratory-developed test for qualitative detection of HCV RNA. For DBS, the limit of detection is higher than plasma samples.
- DBS processing adds steps to the current laboratory process. At this time, Wadsworth has limited capacity to process a high volume of DBS specimens.
- Venipuncture RNA testing remains the gold standard for care. DBS should enhance, not replace venipuncture testing.

Conclusion

- Additional tool with potential to increase client acceptance of HCV diagnostic testing, particularly for those who are:
  - Reluctant to accept an off-site referral
  - Tested in non-clinical outreach settings without access to phlebotomy
  - Difficult to draw blood on
- DBS offers simplified specimen packaging and shipping
- Potential application for future use for research projects and public health outbreak investigations.

Acknowledgements

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Questions for NYS HCV RTP Staff

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