Preliminary evaluation of Dried Blood Spots to test for hepatitis C virus (HCV) antibodies among people who inject drugs, sex workers and men who have sex with men in Cape Town.

LUCINDA GAELEJWE\(^1,2\), Jack Manamela\(^2\) Angella Musisi\(^2\) Lillian Makhatini\(^2\) Susan Malfeld\(^2\) Andrew Scheibe\(^3\), Katherine Young\(^3\), Anna Versfeld\(^3\), Lorraine Moses\(^3\), Andrea Schneider\(^3\), Peggy Modikoe\(^3\) Rudolph Basson\(^3\), Mfezi Mcingana\(^3\), Joezette Mackay\(^3\), Angelina Satira\(^3\), Nelson Medeiros\(^4\), Dawie Nel\(^4\), Kalvanya Padayachee\(^4\), Kevin Rebe\(^5,6\) Penelope Daki\(^5\), Mark Sonderup\(^7\), Wendy Spearman\(^7\), Harry Hausler\(^3\), Adrian Puren\(^1,2\), Nishi Prabdial-Sing\(^1,2\)

1.University of Witwatersrand, Johannesburg, School of Pathology, 2.National Health Laboratory Services-National Institute of Communicable Diseases, Johannesburg, South Africa, 3.TB/HIV Care Association, Cape Town, South Africa, 4. OUT LGBT Well-being, Pretoria, South Africa, 5.Anova Health Institute, South Africa, 6.Division of HIV and Infectious Diseases, Department of Medicine, University of Cape Town, South Africa, 7.Division of Hepatology, Department of Medicine, University of Cape Town, Cape Town, South Africa
Global HCV prevalence

• It is estimated that approximately 185 million people are infected with hepatitis C virus (HCV) (WHO, 2002).

• Estimated 71 million people have chronic hepatitis C infection (WHO, 2017).

• Current global estimates of 23.7 new HCV infections per 100 000 people (WHO, 2017).

• Approximately 399 000 people die each year from hepatitis C (WHO 2017).
HCV prevalence in Africa

- Africa has the highest anti-HCV prevalence (2.9%) (Petruzziello et al., 2016).
- Egypt has the highest HCV prevalence of 17.5% (Lavanchy., 2011).
- South Africa has an estimated 1.7% HCV prevalence (Lavanchy., 2011).
- Despite the high reports of HCV prevalence in Africa, HCV still remains under-diagnosed/no data especially among high-risk-groups (SWs, MSM and PWUDS/IDs).
Rationale and advantages of using Dried Blood Spots (DBS)

- Need to access hard-to-reach populations to provide diagnostics services, provide treatment and monitoring and surveillance.

DBS
- Ease of blood collection (finger prick)
- Easy to handle
- Easy store
- Transported from distant clinics to centralized laboratory without refrigeration
- Retain specimen integrity
- Cost-effective especially in low-resource settings
Aim & Objectives

Aim
• To assess the accuracy of HCV antibody testing using DBS as an alternative matrix.

Objectives
• Measure accuracy of HCV testing using DBS. Determine the Sensitivity/Specificity.
  Determine the predictive values (PPV/NPV).
Study Approvals


Methods

Sample collection

• Participants recruited from sites in Cape Town.
• Whole blood was drawn for DBS preparation and serology testing.
• 50µl of blood from an EDTA tube spotted onto filter paper (DBS) (Whatman 903) testing.
• Whole blood and DBS pairs sent to NICD for testing.
Methods

Data collection

• The information on the request form was captured on HCV database using Epi info version 3.2.4.

• All testing results were recorded on the Epi Info version 3.2.4. software and Excel spread sheets using Microsoft windows 7.
Laboratory testing
Processing DBS on ARCHITECT i* System

One spot (50 μl) of whole blood on the Whatman 903 card

Shaking for 1 hour at room temperature

400 μl of Elution Buffer was added

The DBS elute was transferred into new tube

Anti-HCV test

Transfer into sample cups

Centrifuge
Statistical analysis for accuracy

• Sensitivity - the proportion of true-positives which actually test positive.

• Specificity - the proportion of true-negatives which actually test negative.

• Positive Predictive Value - is the proportion of people with a positive test result that actually have the diseases.

• Negative Predictive Values - is the proportion of people with a negative test result that actually do not have the diseases.
Results

- Samples were recruited from August 2016 - 31 July 2017.

High risk groups (SWs), (MSM) and (PWUDs/IDs) samples of paired plasma and DBS from Cape Town sites

- Plasma
  - Positive: n=103
  - Negative: n=69

- DBS
  - Positive: n=101
  - Negative: n=71
Results

Sensitivity and specificity

- Sensitivity 96.04%  95% CI  90.17% to 98.91%
- Specificity 95.77%  95% CI  88.14% to 99.12%

Positive Predictive Value (PPV) and Negative Predictive Value (NPV)

- PPV = 97.00%  95% CI  91.44% to 98.99%
- NPV = 94.44%  95% CI  86.66% to 97.80%
Limitations

- The S/CO values in RLUs of the DBS was not established.
- Our study was based on venepuncture and not finger prink.
- No optimization on the volumes of DBS required for testing.
What do the results mean?

- DBS are sensitive and specific (>95%).
- DBS have a high accuracy in determining a true positive and a true negative in a population of individuals that are positive with HCV and negative for HCV.
What do these results mean for South Africa?

- We can use DBS as a new sample matrix for anti-HCV antibody detection in individuals in the high-risk-groups (SWs, MSM and PWUDS/IDs).
- Better surveillance on HCV positive individuals.
- Better HCV diagnosis, monitoring, prevalence in South Africa.
Acknowledgments

Centre of Vaccines and Immunology and staff
Centre of HIV Serology and staff

Collaborating Partners
• TB/HIV Care Association (THCA)
• The Division of Hepatology, Department of Medicine, University of Cape Town, Faculty of Health Sciences, University of Cape Town
• OUT LGBT Wellbeing
• Anova Health Institute
• National Institutes for Communicable Diseases (NICD)

Participants in the study

Funding
• Study Sponsor: Bristol Myers Squibb Foundation (BMSF)
• NRF
References


