

Dual syphilis and HIV point of care testing to improve access to testing among inner city, remote, rural and hard to reach populations in Alberta

Ameeta Singh, BMBS(UK), MSc, FRCPC
February 4, 2020

STBBI testing and Linkages to Care: Reaching the Undiagnosed
Ottawa, ON



I would like to acknowledge that we are meeting today on the unceded traditional territory of the Algonquin people

Acknowledgments/Partners

CIHR REACH (Sponsor)

- Dr. Sean Rourke

FNIHB

- Dr. Tom Wong
- Dr. Wadieh Yacoub
- Christina Smith

2 First Nations Communities in Alberta

Alberta ProVLab

- Dr. Kevin Fonseca

bioLytical

- Rick Galli

MedMira

- Hermes Chan

Alberta Health Services

- Dr. David Strong
- Dr. Petra Smyczek
- Jennifer Gratrix
- Penny Parker

Royal Alexandra Hospital

- Dr. Kathryn Dong
- Dr. Rebeccah Rosenblum

Edmonton Remand Centre

- Dr. Rabia Ahmed
- Dan Woods
- Candace Kercher

The context... in July 2019

Syphilis has skyrocketed across Alberta – except in Calgary – and officials are trying to figure out why

CANADA

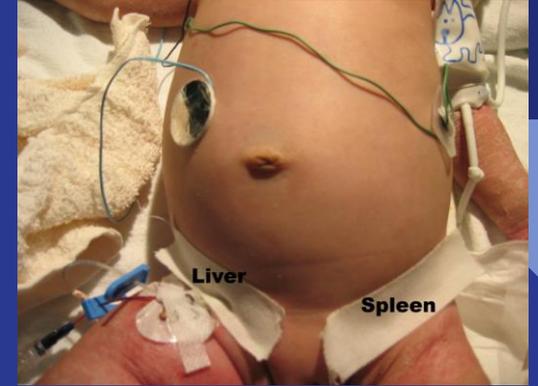
Syphilis outbreak declared in Alberta amid ‘rapid increase’ in cases



Worst since 1948: Edmonton the epicentre of syphilis outbreak declared in Alberta

Question asked of us?

Could POCT syphilis help with our response to this outbreak?



Who is affected by infectious syphilis in Alberta?

Disproportionately affected:

- Indigenous persons (~40%)
- Females (~50%)
- IDU ~20%
- Same sex males ~20%
- One or more risk factor ~33%

Congenital cases

- 2017-2019: 63 cases, 13 stillbirths
- 73% mothers aged 20-34

> 2000 infectious syphilis cases in Alberta
60% of cases in Edmonton

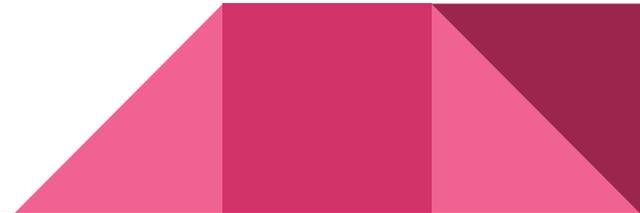
Strengths in Alberta for management of STIs

- Centralized STI Services and database with regional support by RNs
 - Rapid reporting of new syphilis positives to STI Services; coordination of case management, follow up, partner notification by STI services
 - 3 STI Clinics
 - STI Medical Consultants (Edmonton/Calgary)
 - Test and treat by RNs
 - Average time to all test results 5-10 days; longer in remote areas
- 

Our primary objective..

To respond to the outbreak in Alberta

- Expedite testing so that treatment can be provided at the point of care
 - Estimated loss to follow up or significant delays to treatment in 20-30% of all new positives (esp. ED/inner city hospital/remand centre)



Research Objectives

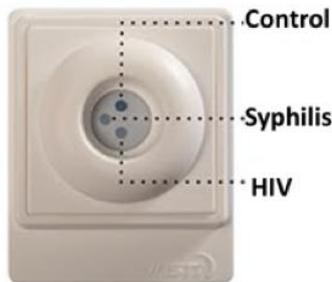
- To evaluate the field performance of two dual HIV/Syphilis POCT (from fingerprick whole blood specimens) when compared to standard testing for HIV and syphilis (from serum-based specimens).
- To evaluate the utility of POCT and the impact on management of cases for syphilis among high-risk and hard to reach populations.



Test kits

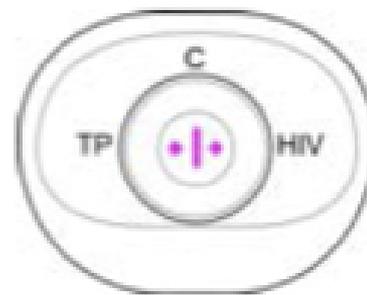
OUR SECONDARY OBJECTIVE: to evaluate the performance of dual HIV-syphilis tests through use of an ITA; data will be collected so that companies can submit to meet HC requirements for consideration of licensure, if shown to be effective.

- **INSTI Multiplex HIV-1/2 Syphilis AB test**



**HIV(+)
Syphilis (+)**

- **Multiplo Rapid TP/HIV test**



MedMira Inc, Halifax, NS

bioLytical Laboratories Inc, Richmond, BC

Selection of test kits

Strengths

- Both Canadian companies
- 5 minutes or less to rest results
- HIV performance good for both kits; bioLytical only Health Canada approved HIV POCT
- Field staff in Alberta familiar with bioLytical kit

Weaknesses

- Treponemal test only
- Limited field data (1 field study each, small sample size) for syphilis using finger prick whole blood:
 - bioLytical: sensitivity for TP antibodies 56.8% (95% CI 44.7-68.2) but when RPR \geq 1:8 dilutions, sensitivity increased to 100% (78.2-100%); specificity 100% (98.1-100%)
 - MedMira: sensitivity 73.5-94.6%; specificity 92.8-99.5%
 - >70% Alberta cases in preceding year had RPR \geq 1:8 dilutions at diagnosis

Participants/Sites

Participants:

1,500 individuals [Indigenous communities experiencing a resurgence of syphilis, gay, bisexual, and other men who have sex with men (gbMSM), sex workers, street-involved people, persons who use injection drugs (PWID)] \geq 16 years.

- **Persons living with HIV (PLWH) as well as persons who are known to be previously syphilis positive are also eligible to participate.**

Sites

- **Edmonton STI Clinic Outreach Team sites** (subsidized housing, shelters, alternate educational facilities, addiction services, other community-based organizations and clinical settings)
- **Two First Nations communities** in Alberta
- **Edmonton Remand Centre**
- **Royal Alexandra Hospital Emergency Department** by ARCH team

Current status

A few approvals in place:

- **Alberta Health Services Laboratory Services Provincial POCT Committee**
- **Two First Nations communities (Band Councils)**

Pending approvals/submission

- **CIHR (SMH) contract**
- **University of Alberta Research Ethics Board (REB) – under review**
 - Many concerns – consent issues (we now have 3 different consent forms), test administrators (usual staff vs research staff), incentives (unable to offer in remand)
- **Once REB approval obtained, will need Operational Approval from all AHS sites**
- **Approval of Investigational Testing Applications by Health Canada**

Next steps



- Await approvals
- Tentative date set for training day (study procedures, confidentiality, how to perform the test, quality assurance) of March 30, 2020
- Will we be able to start April 1, 2020?????



"We want to tell people that, just like ice hockey or fencing, you don't have sex naked. You should wear a condom,"
Roger Staub, head of the Swiss Health Office's AIDS prevention