


# 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

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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

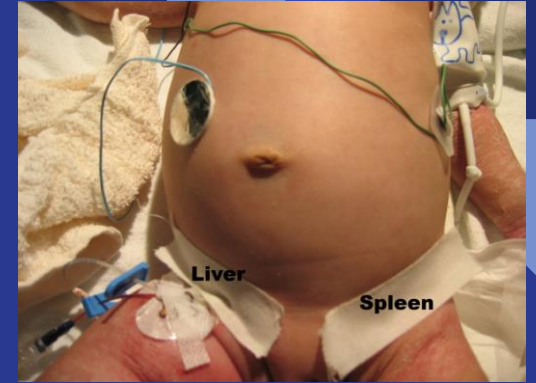
**Syphilis outbreak declared in Alberta amid ‘rapid increase’ in cases**



**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:

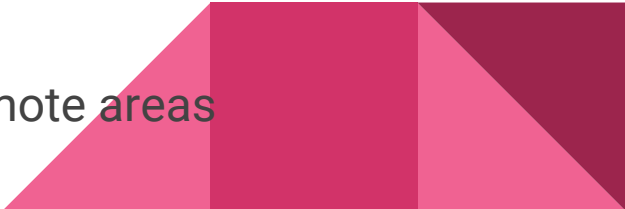
- Indigenous persons (~40%)
- Females (~50%)
- IDU ~20%
- Same sex males ~20%
- One or more risk factor ~33%

## 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
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# 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

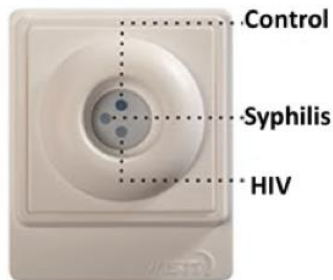
- To evaluate the field performance of two dual HIV/Syphilis POCT (from fingerprick whole blood specimens) when compared to standard testing for HIV and syphilis (from serum-based specimens).
- To evaluate the utility of POCT and the impact on management of cases for syphilis among high-risk and hard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



# Test kits

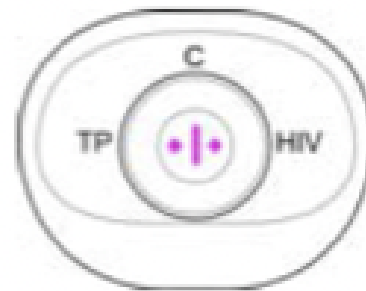
**OUR SECONDARY OBJECTIVE:** to evaluate the performance of dual HIV-syphilis tests through use of an ITA; data will be collected so that companies can submit to meet HC requirements for consideration of licensure, if shown to be effective.

- **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 dils, 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 dils 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**