



# Enhanced Syphilis Screening among HIV-Positive Men: Evaluation of a Clinic-Based Intervention (ESSAHM)

## 1. BACKGROUND

Syphilis re-emergence among urban men who have sex with men (MSM) in Canada has serious implications for those co-infected with HIV. In our research in Ontario, lifetime syphilis prevalence was 23.4% (95%CI 21.7,25.2) as of 2009, and incidence was 4.0 per 100 person-years (PY) (95%CI 3.0, 5.2), over 300 times greater than the rate of 0.01 per 100PY reported for the general male population.

Routine and frequent syphilis screening has the potential to ensure timely detection and treatment, minimize disease burden, and help control the ongoing spread of syphilis and HIV. Preliminary mathematical models developed by members of

our team suggest that frequent (every three months) syphilis screening could have a significant impact on reducing syphilis transmission among the most high-risk MSM.

With men in HIV care, we have a practical and

inexpensive opportunity to intervene because patients undergo routine blood tests for HIV viral load every 3-6 months. Based on findings from the UK, Australia and local syphilis epidemiology, a clinic-based intervention could be beneficial; however, a randomized, controlled, pragmatic, multi-center trial is needed to firmly establish the effectiveness of this approach.

## 2. OBJECTIVES

To enhance syphilis screening among HIV-positive men by conducting a clinic-based intervention that incorporates syphilis testing into routine HIV bloodwork. Trial objectives are to determine to what degree the intervention:

1. Increases screening coverage (proportion of men who undergo syphilis testing at least annually)
2. Increases screening frequency (shortens the interval between syphilis tests)
3. Reaches men at highest risk
4. Results in more detected cases of untreated syphilis.

## 3. DESIGN

The trial is designed as a pragmatic, stepped wedge cluster-randomized controlled trial that gradually introduces the intervention across four HIV clinics in Toronto and Ottawa including St. Michael's Hospital, Sunnybrook Hospital, Toronto General Hospital and The Ottawa Hospital.

After an initial trial run-in and 6-month control period which started in February 2015, clinics will be randomized to one of 4 roll-out schedules (Figure 1). Each clinic will have at least one 6-month control period and one 6-month intervention period across 30 months of data collection. The intervention is to do syphilis serology whenever a male patient has an order for HIV viral load, which generally occurs every 3-6 months. The control condition is the maintenance of current practices. Test results will be obtained from the Public Health Ontario Laboratories (PHOL) and will be supplemented by a standardized clinical worksheet and medical chart review for those testing positive. Detailed clinical, psychosocial and behavioural data will be available for those who are also participants of the OHTN Cohort Study.

Process evaluation plans include audit and feedback of compliance to identify potential barriers. Health economic components include evaluation of the impact and cost-effectiveness of the intervention. A Trial Steering Committee was formulated to provide overall trial supervision, ensure that it is being conducted in accordance with the principles of good clinical practice, and advise on possible protocol amendments. There are three community representatives on the committee who will help guide the conduct of the trial, ensuring community relevance and assist with interpretation and framing of conclusions based on final results.

## 4. SIGNIFICANCE

This trial will be the first of its kind in Canada or internationally to evaluate a clinic-based intervention to enhance syphilis screening among persons with HIV. If the intervention is effective, our program science approach involving researchers and knowledge users will facilitate scale-up in the study sites and at other HIV clinics. The trial will also inform ongoing efforts to determine which combination of interventions is most cost-effective and achieves the greatest impact.

The results of this trial may also influence decision-making by other Canadian and industrialized world centres experiencing syphilis outbreaks among MSM. At a national level, we will engage with the Public Health Agency of Canada, which establishes national STI testing and treatment guidelines. Internationally, findings will add to the small but growing body of evidence on the feasibility and effectiveness of clinic-based interventions to improve syphilis screening among HIV-positive men.

FIGURE 1. STEPPED WEDGE DESIGN

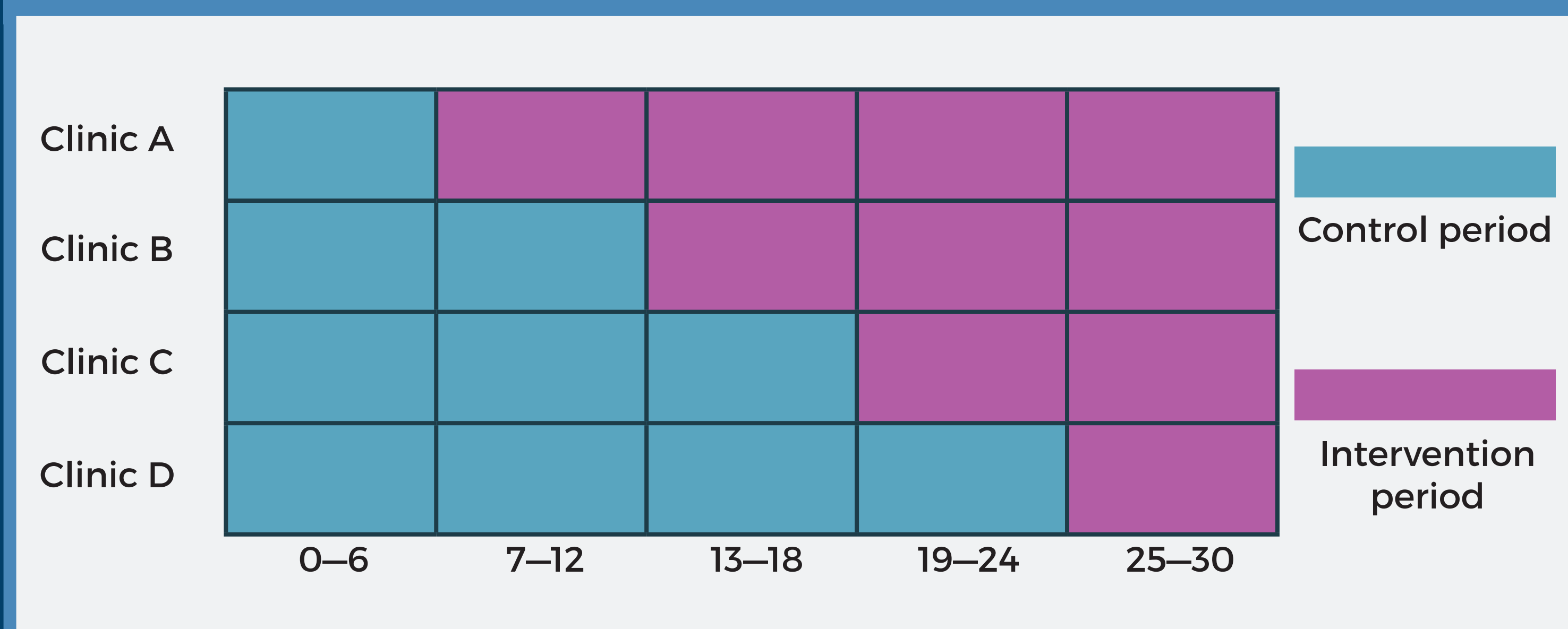
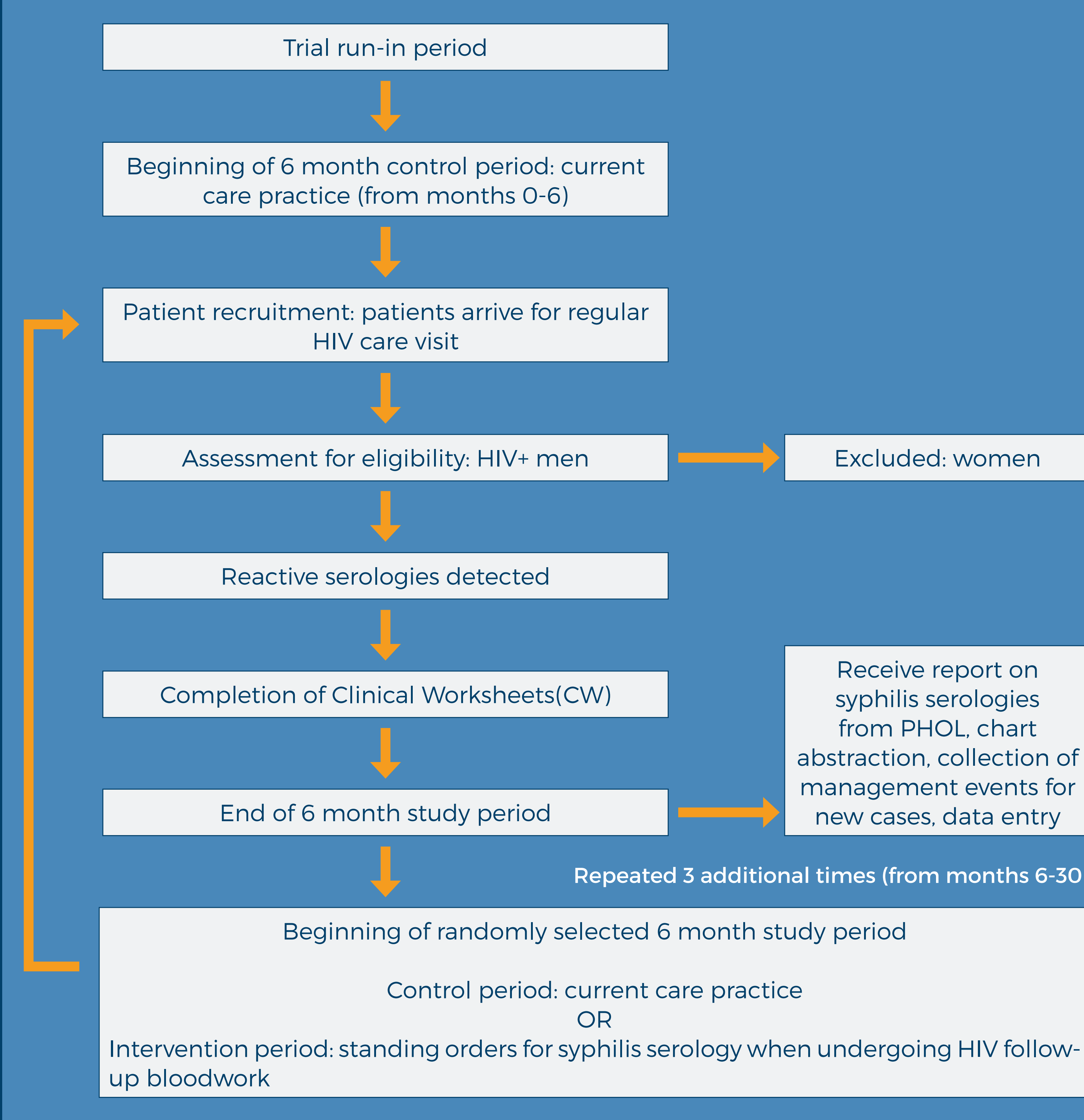


FIGURE 2. PATIENT DATA COLLECTION TIMELINE & PROCEDURES



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8. Ontario Ministry of Health and Long-Term Care
9. AIDS Committee of Toronto
10. Gay Men's Sexual Health Alliance
11. Poz Prevention Working Group
12. Ottawa Hospital Research Institute

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### CONFLICT OF INTEREST DISCLOSURE

I have no conflicts of interest.

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