



Modernization of North Carolina's HIV control measures

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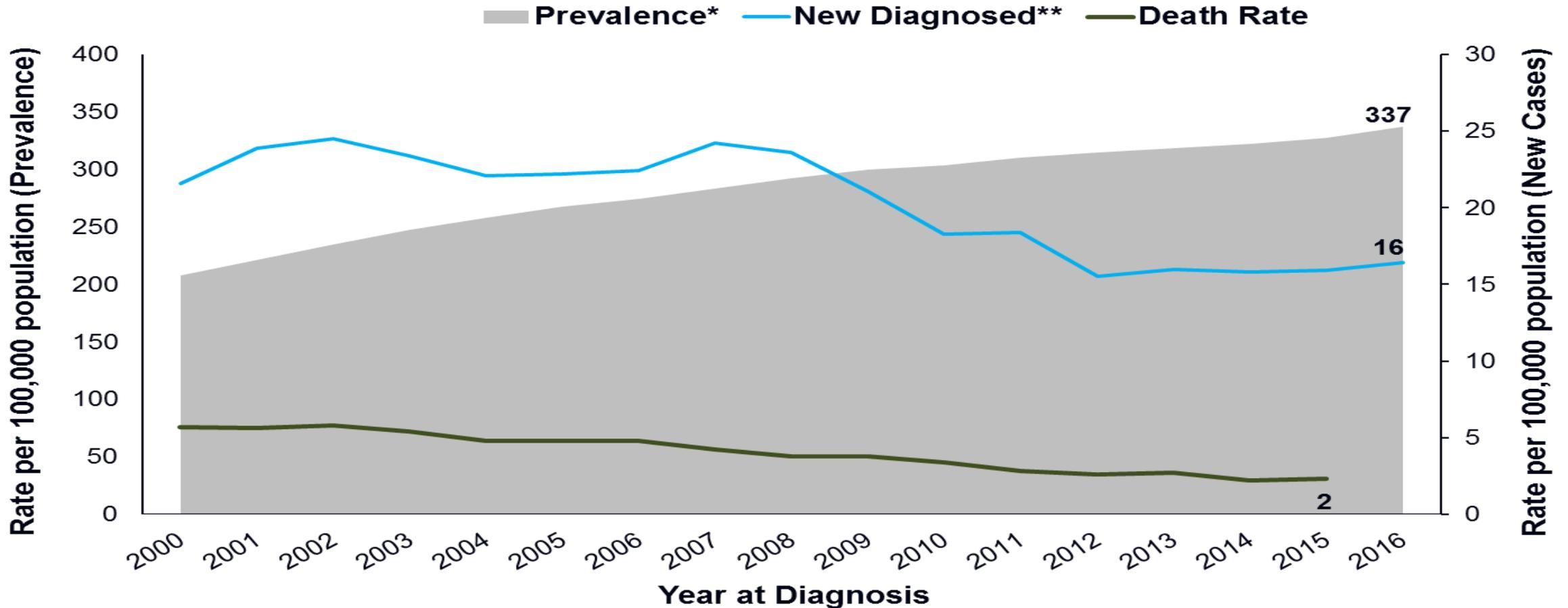
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Webinar Agenda

- Brief update on NC's HIV epidemic
- Summary of scientific evidence behind HIV control measure changes
- How can the modernized HIV control measures assist LHDs in everyday responsibilities
- How CDB can assist LHD efforts to assure all HIV positive clients achieve HIV viral suppression



North Carolina HIV Infection Rates by Year of Diagnosis, 2000-2016



*Based on most recent address in eHARS as of December 31 of the given year.

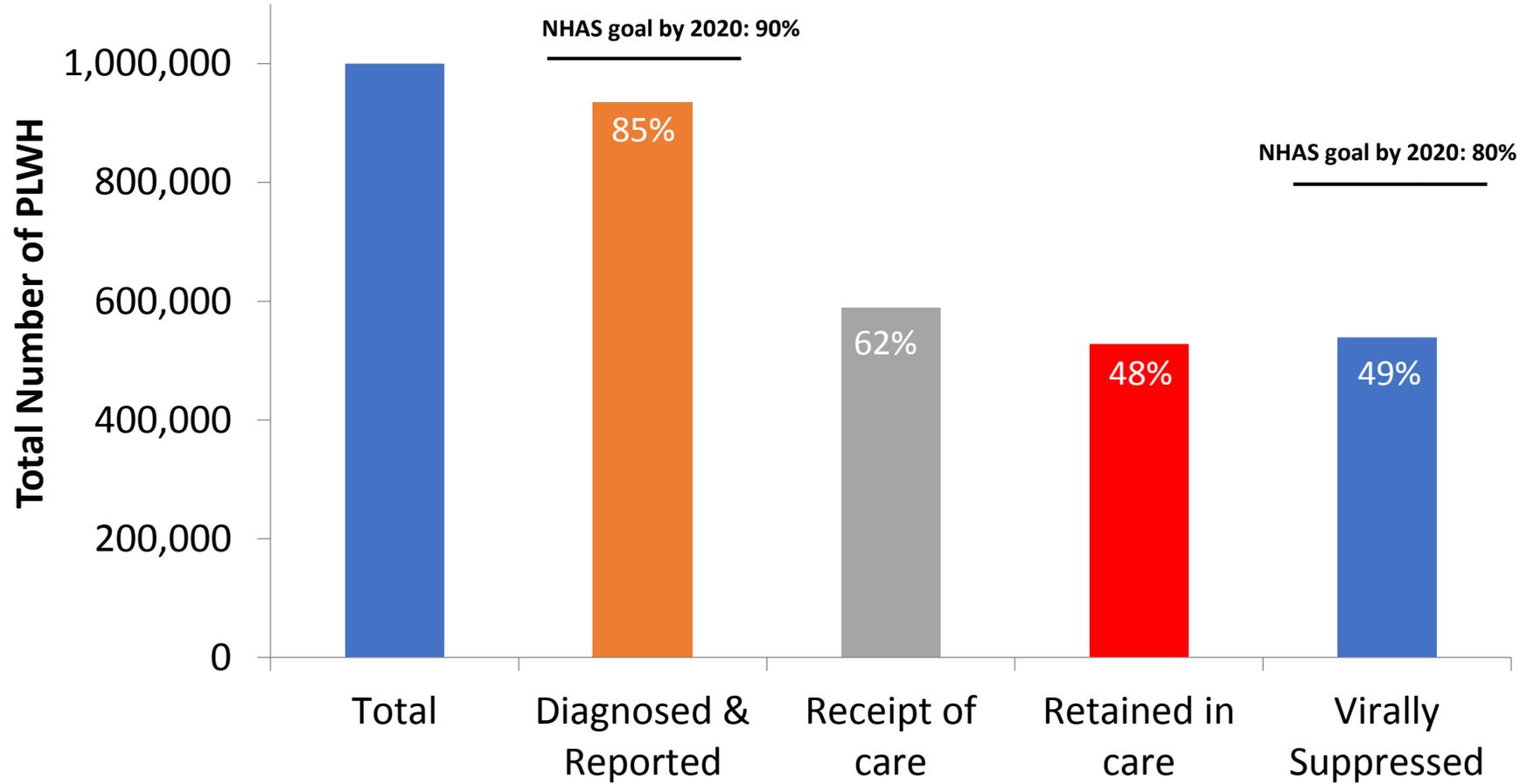
**New cases are only among adults and adolescents (13 years and older).

Data Source: enhanced HIV/AIDS Reporting System (eHARS) (data as of June 27, 2017) and North Carolina Vital Statistics, Volume 2: Leading Causes of Death 2000-2015.

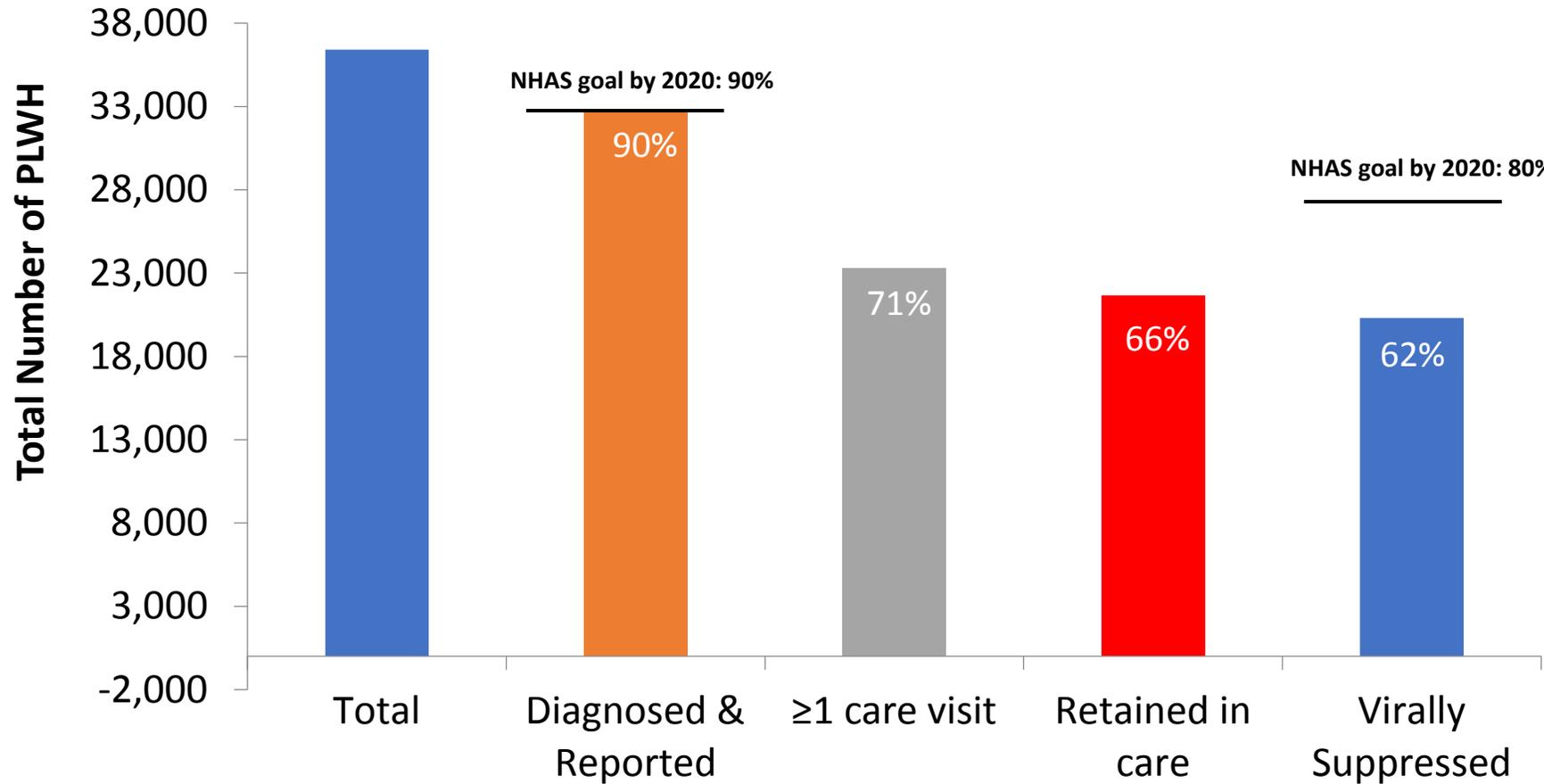


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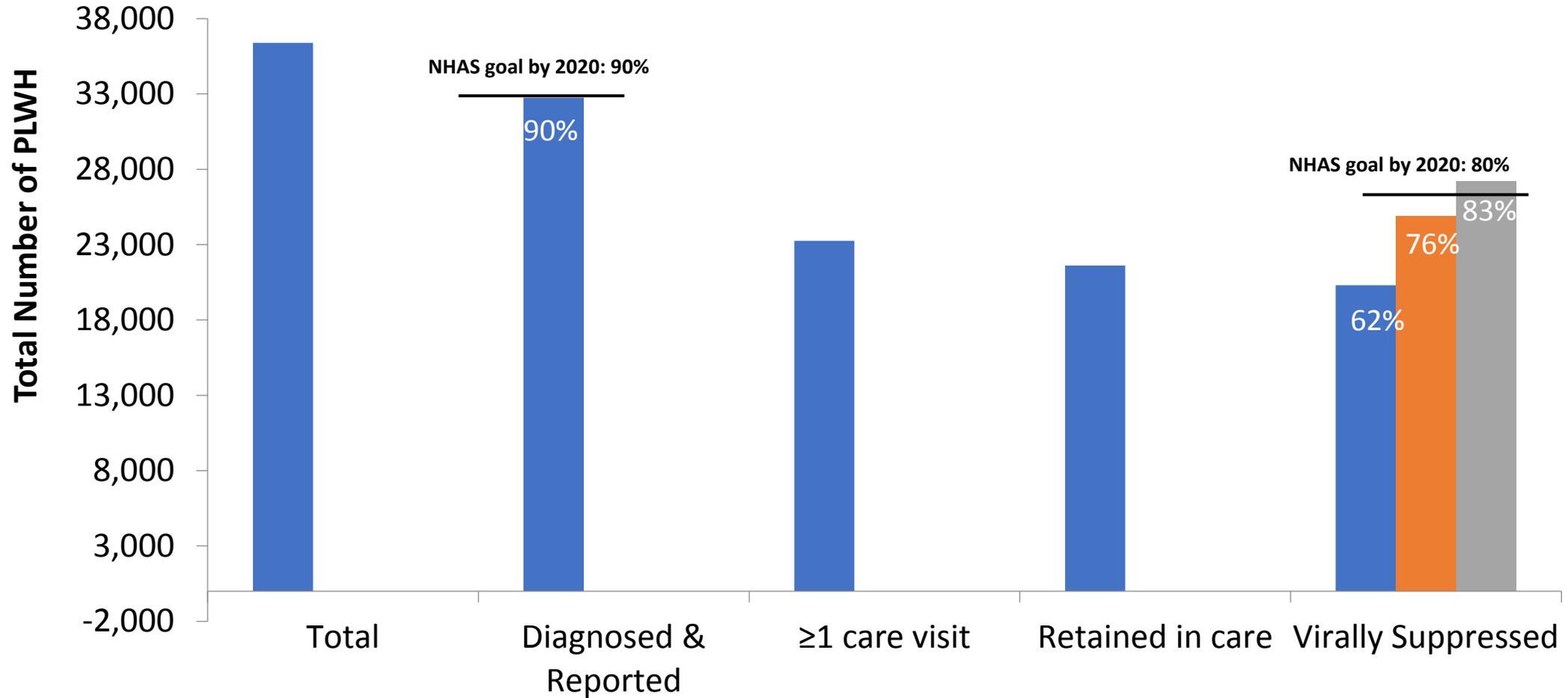
HIV Continuum of Care in the US, 2014



HIV Continuum of Care in North Carolina, 2016



HIV Continuum of Care in North Carolina, 2016



Why change North Carolina's HIV control measure rule?

- The first HIV control measures were implemented in 1988
- There have been significant advances in HIV treatment and prevention efforts over the last 30 years
- Goals of modernizing the control measure rule:
 - Ensure they reflect current science regarding HIV treatment and transmission
 - Give clear guidance on how to distinguish infectious from noninfectious (sexually) clients
 - Provide local health directors with tools to assist out of care clients access the resources necessary to engage in care
 - Encourages persons living with HIV to engage in HIV care and get virally suppressed.



EVIDENCE: Undetectable=Untransmittable

- HPTN 052 Study
- PARTNER Study
- Opposites Attract Study



HPTN 052 study

Does antiretroviral therapy (ART) prevent the sexual transmission of HIV-1 infection in sero-discordant couples

- Phase III randomized, controlled trial
- Enrolled participants at 13 sites in 9 countries
- 97% of couples were heterosexual
- Partners followed for 8509 person-years

93% Reduction in HIV-1 transmission



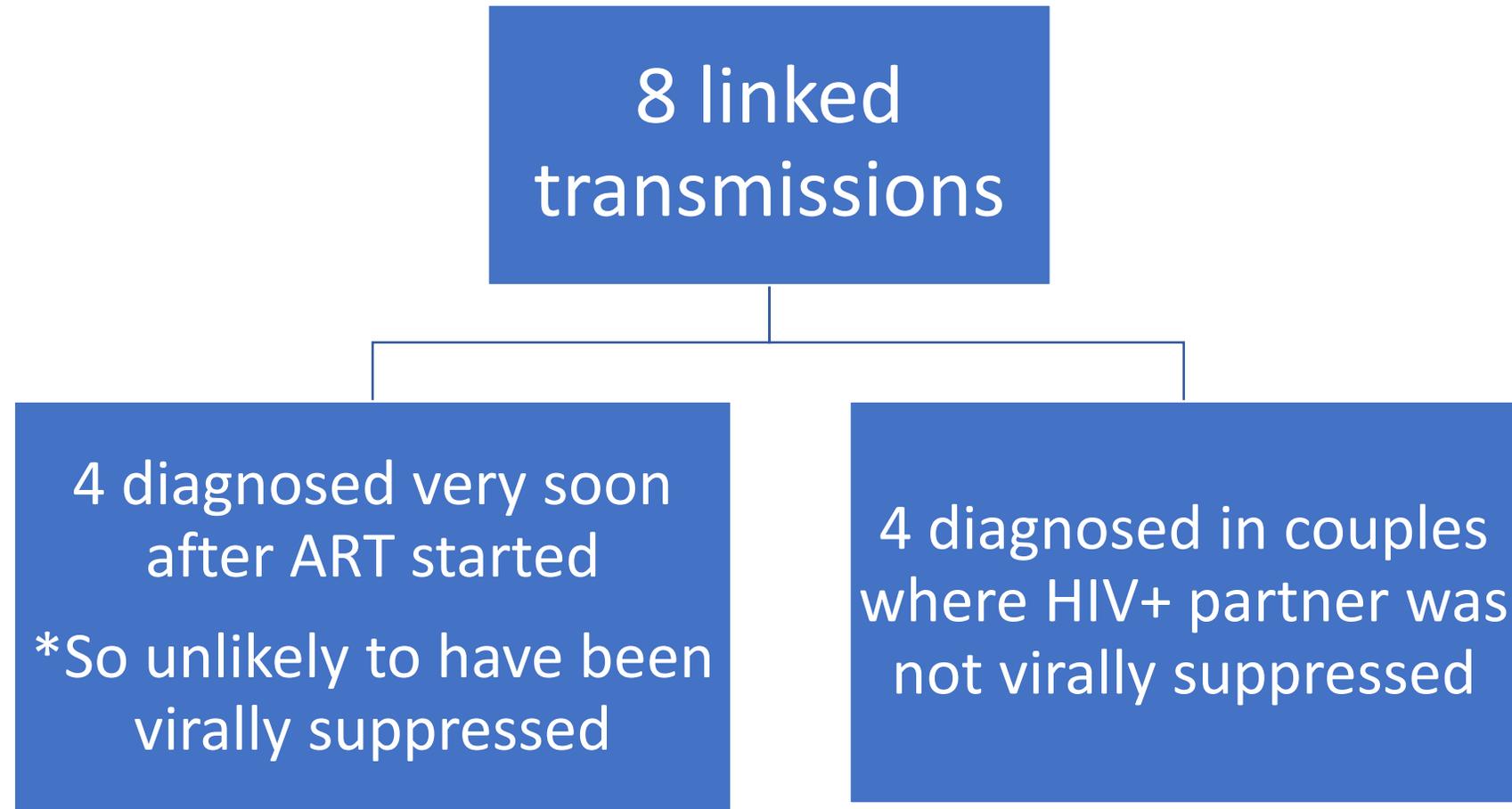
HPTN 052: Delving into the details

93% reduction in transmission risk \neq No risk



HPTN 052: Delving into the details

93% reduction in transmission risk ≠ No risk



HPTN 052: Conclusion

There were NO linked HIV transmissions among couples where the HIV positive partner was stably virally suppressed.

Game changer → HIV-1 treatment was now proven to prevent HIV transmission.

Worldwide mandate to get all persons living with HIV into care and on ART.



HPTN 052: Limitations

- Study was designed to look at efficacy of starting ART on HIV-1 transmission, not the association between viral suppression and HIV-1 transmission.
- Standard prevention messages were given to all study participants and condoms were encouraged and made available, so could reduction in transmission be due to differential condom use in treatment arm?
- The majority of the couples were heterosexual, so would the reduction in transmission risk be similar for male-to-male partnerships?



Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act*

Type of Exposure	Risk per 10,000 Exposures
Parenteral	
Blood Transfusion	9,250
Needle-Sharing During Injection Drug Use	63
Percutaneous (Needle-Stick)	23
Sexual	
Receptive Anal Intercourse	138
Insertive Anal Intercourse	11
Receptive Penile-Vaginal Intercourse	8
Insertive Penile-Vaginal Intercourse	4
Receptive Oral Intercourse	Low
Insertive Oral Intercourse	Low
Other^	
Biting, Spitting, Throwing body fluids, Sharing sex toys	Negligible



PARTNER Study

Estimate the risk of HIV-1 transmission among HIV sero-discordant couples who do not use condoms routinely.

- Prospective cohort study at 75 sites in 14 countries
- Enrolled both heterosexual and male-male couples
- All couples reported routine condomless sex
- HIV negative partner could not be on Pre-Exposure Prophylaxis
- HIV positive partner had to be on ART

Specifics of analysis group:

- 894 couple years of follow up
- 44,450 condomless sexual acts of any type
- 21,030 condomless anal sex acts
- HIV-positive partner had to have HIV RNA < 200 copies/mL



PARTNER Study

There were NO linked HIV transmission among couples where the HIV positive partner was stably virally suppressed.

Despite a high prevalence of STIs (mainly syphilis and gonorrhea) among heterosexuals (5%) and male-male (16%) couples.

Strong evidence that viral suppression prevents the sexual transmission of HIV for heterosexuals and MSMs.



PARTNER Study: Limitations

- The enrollment restrictions based on reported condom, PrEP and HIV ART use loses some of the “real world” applicability of the study results.



Opposites Attract Study

What is the risk of HIV-1 transmission from anal sex in male-male sero-discordant couples when the positive partner is on ART.

- Prospective longitudinal cohort study with sites in 3 countries
- Report having anal sex at least 1x/month with sero-discordant partner
- Commit to at least bi-annual clinical assessments

Specifics:

- ~600 couple years of follow up
- Almost 17,000 condomless anal sex acts; more than 70% when the HIV positive partner was virally suppressed AND the HIV negative partner was not on PrEP



U=U: Summary of Evidence

Three large international studies with over a decade of observations of thousands of HIV sero-discordant couples who engaged in more than 70,000 condomless penile-vaginal or anal sex acts found

NO linked HIV transmission events among sero-discordant couples where the HIV positive partner was taking ART and stably virally suppressed.



The BIGGEST change underlining the modernization of the HIV control measures is the recognition of when there is a risk for sexual transmission



Defining PLWH who are not at risk for sexually transmitting the virus

To fall into this group, the PLWH must meet ALL of the below criteria.

- **In HIV care, meaning they are being routinely seen by a clinician who manages their HIV disease**
- **Adherent to their HIV clinician's treatment plan, which includes:**
 - Taking HIV antiretroviral therapy as their clinician directs
 - Attend all scheduled medical appointments or rescheduling in advance when issues arise and an appointment cannot be kept
 - Adhering to all clinician ordered HIV laboratory testing aimed at routine monitoring of HIV RNA level
- **Virally suppressed for at least 6 months (HIV RNA levels below 200 copies per milliliter) at the time of sexual intercourse**



This change does not affect the Public Health message!

Since public health law is intended to prevent the transmission of disease, PLWH who are not at risk for sexually transmitting HIV are no longer required to use condoms or notify future sexual partners

Public Health still advises and encourages all sexually active individuals including PLWH to:

- **Have an open and honest discussions with all sexual partners regarding their sexual history and risk**
- **Use condoms to prevent the transmission of other STIs**

****The burden to prove the PLWH meets all the criteria to be non-infectious is on the client, not public health.****



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Other Changes to the HIV control measures

For PLWH who remain infectious:

- 1) They must notify all future sexual partners of their status AND
- 2) Use a condom with all sexual encounters unless
 - the sexual intercourse partner is also HIV positive
 - the sexual intercourse partner is taking PrEP as directed by a provider
 - the sexual intercourse occurred in the context of a sexual assault in which the PLWH was the victim



Other Changes to the HIV control measures

Organ Donation

- Permissible when done as part of a clinical research study meeting the regulations described in the federal HOPE ACT (HIV positive organ donation to HIV positive recipients)

Notification of exposed partners (two options)

- Client can do themselves, OR
- Can give names to DIS who will perform confidential notification

Determination of significant transmission risk

- Incorporated the official CDC's risk estimates by reference into update.

Isolation Orders

- Addition of important referral resources to strengthen effectiveness of the isolation orders



How can the modernized HIV control measures assist LHDs in everyday responsibilities

- Incentivize PLWH to get in and remain engaged in care
- Allows Public Health to focus time and resources on PLWH who need our assistance getting into care
- Provides LHDs with tools to maximize success of intervention efforts
- Provides clear guidance on how to handle common community issues (i.e. bites in schools)



How CDB can assist LHD efforts to assure all HIV positive clients achieve HIV viral suppression

DCMV investigation initiated

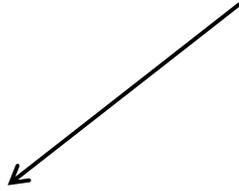
Client is non-infectious

Client is infectious

- NCEDSS /NC ECHO documentation of viral suppression status and timeframe
- Verification by HIV provider of patient's care & adherence status
- Client provides proof of in care/viral suppression status



DCMV investigation initiated

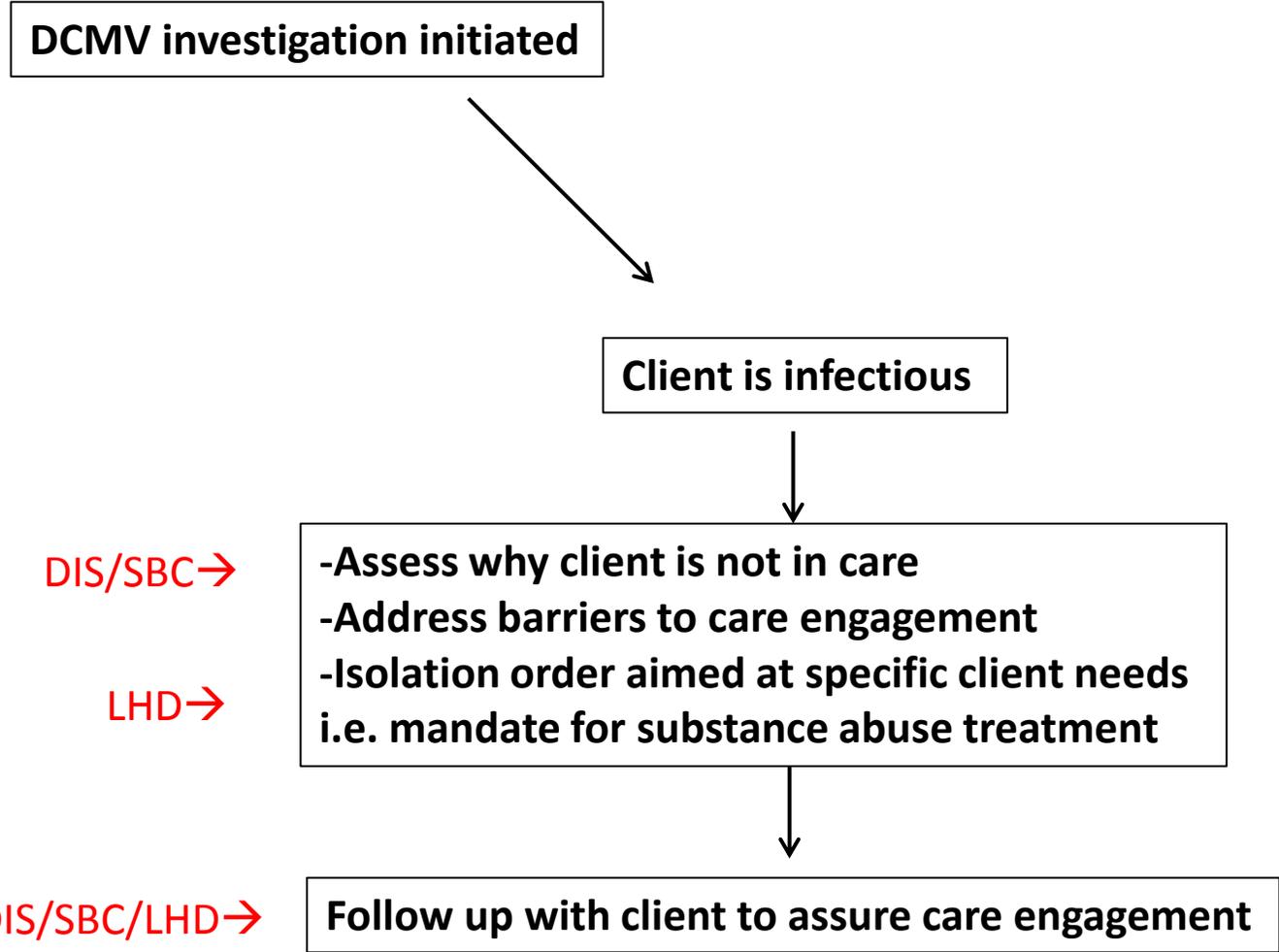


Client is non-infectious



Standard public health messaging on STI risk reduction





UNDETECTABLE = UNTRANSMITTABLE



HPTN 052, PARTNER and Opposites Attracts Studies changed the way we view HIV treatment and prevention

Next Steps?

- Promote HIV treatment as prevention
- Focus resources on linking newly diagnosed PLWH to care
- Address barriers to PLWH remaining in care
- PrEP referrals for high-risk HIV negative individuals



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Questions?

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