



THE UNIVERSITY  
*of* NORTH CAROLINA  
*at* CHAPEL HILL

# HIV and the Law: How Infectious is the Virus?

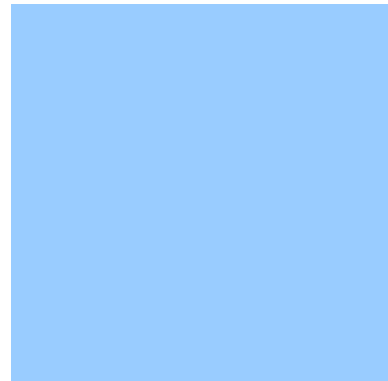


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ASSOCIATION *of*  
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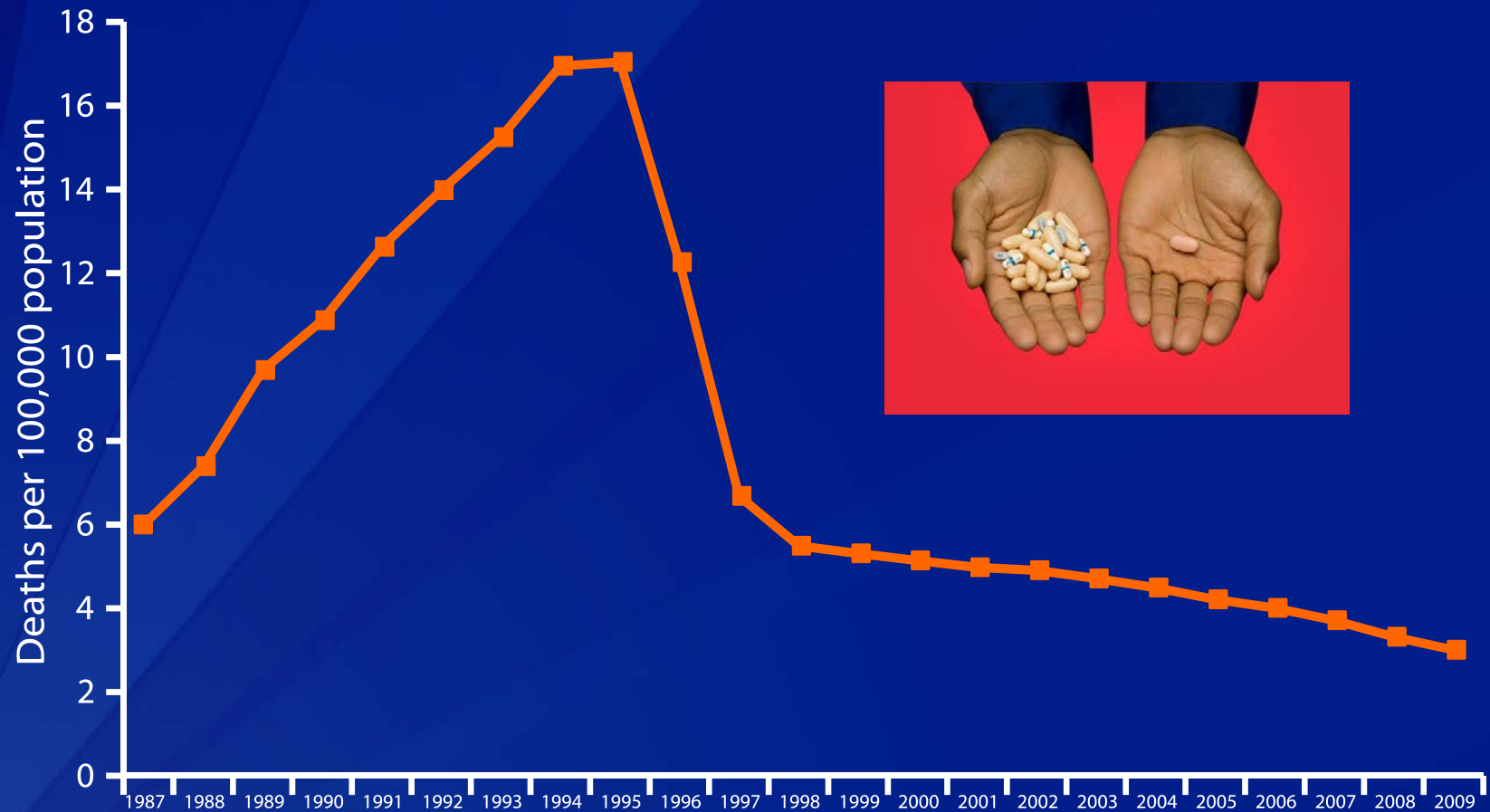


Bureau of Justice Assistance  
U.S. Department of Justice

# Criminal Laws to HIV Exposure

- 32 states and 2 territories have HIV-specific criminal statutes.
  - The majority of these laws are felonies
    - Complete list of statutes at <http://www.hivlawandpolicy.org>
- In jurisdictions without specific HIV statutes individuals have been charged under general criminal laws where HIV exposure has been alleged as an element of the offense (e.g., “dangerous instrument”)

# Trends in Annual Age-Adjusted\* Rate of Death Due to HIV Infection, United States, 1987–2009



Note: For comparison with data for 1999 and later years, data for 1987–1998 were modified to account for ICD-10 rules instead of ICD-9 rules.

\*Standard: age distribution of 2000 US population



# Transmission of HIV-1

## Biological Requirements

### Infectious

*Inoculum (concentration)*

*Phenotypic factors*



### Susceptibility

*Hereditary resistance*

*Innate resistance*

*Acquired (immune)*

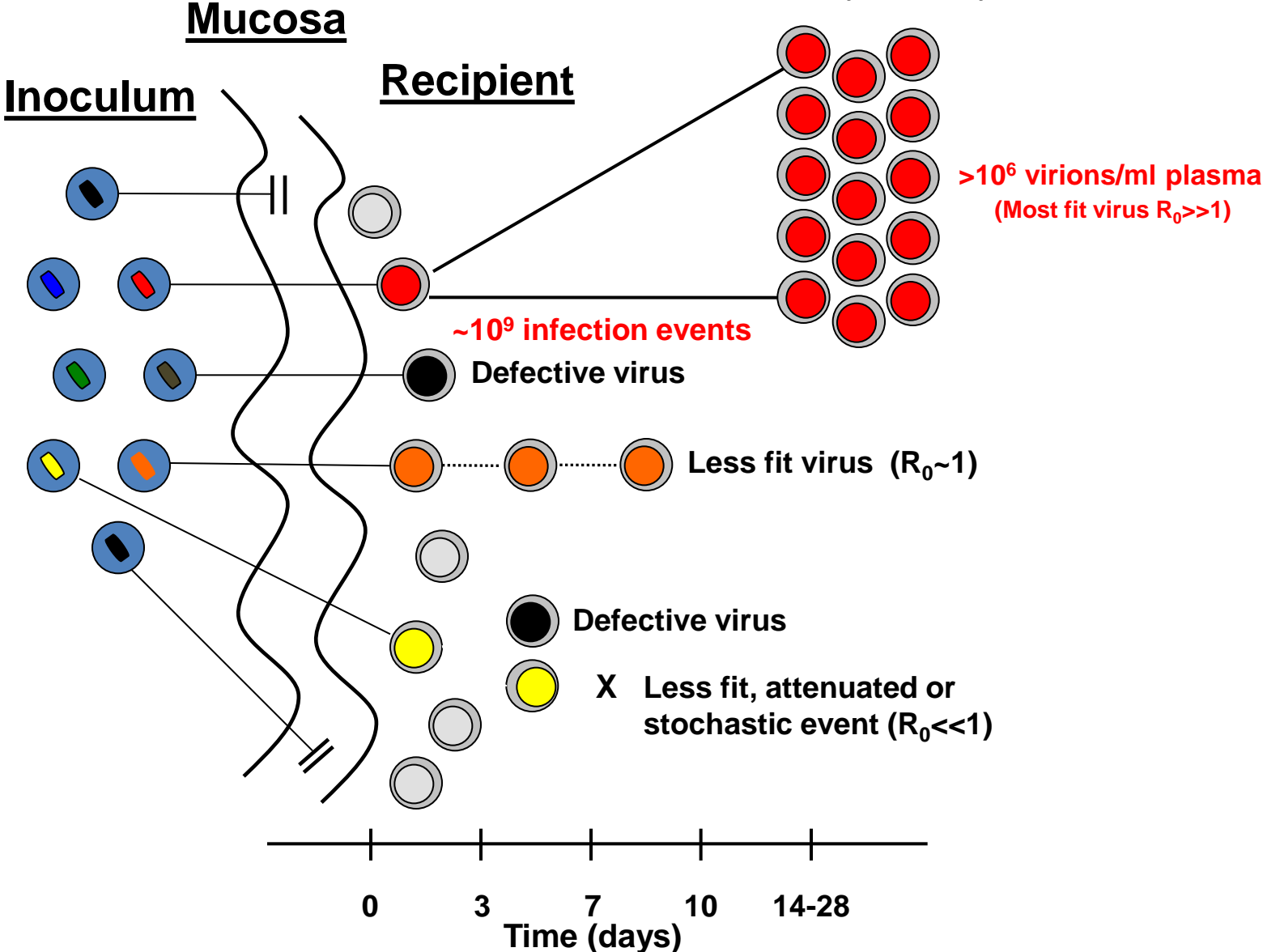
*resistance*

# RULES OF HIV-1 TRANSMISSION

- THERE ARE **THREE** (AND ONLY THREE) ROUTES OF HIV TRANSMISSION
  - BLOOD** and BLOOD PRODUCTS
  - SEXUAL** MUCOSAL CONTACT INCLUDING PENILE-VAGINAL CONTACT, ANAL CONTACT AND POSSIBLY FELLATIO (low to no risk)
  - VERTICAL** TRANSMISSION INCLUDING BREAST FEEDING

# HIV-1 Transmission Model

Cohen et al, NEJM, 2011



# Probability of HIV Transmission?

~1/1000 episodes for couples??

*(Most recently Hughes et. al. JID)*

1/1000 IS AN UNDERESTIMATE??

- “exposed uninfected” partners
- benefits of counseling
- missing amplification factors



# Amplified Transmission of HIV-1

## Infectiousness

Blood Viral Load

Genital Tract Viral Load

*Inflammatory STDs*

Viral clade

**ACUTE INFECTION**

## Susceptibility

Genital ulcers

Inflammatory STDs

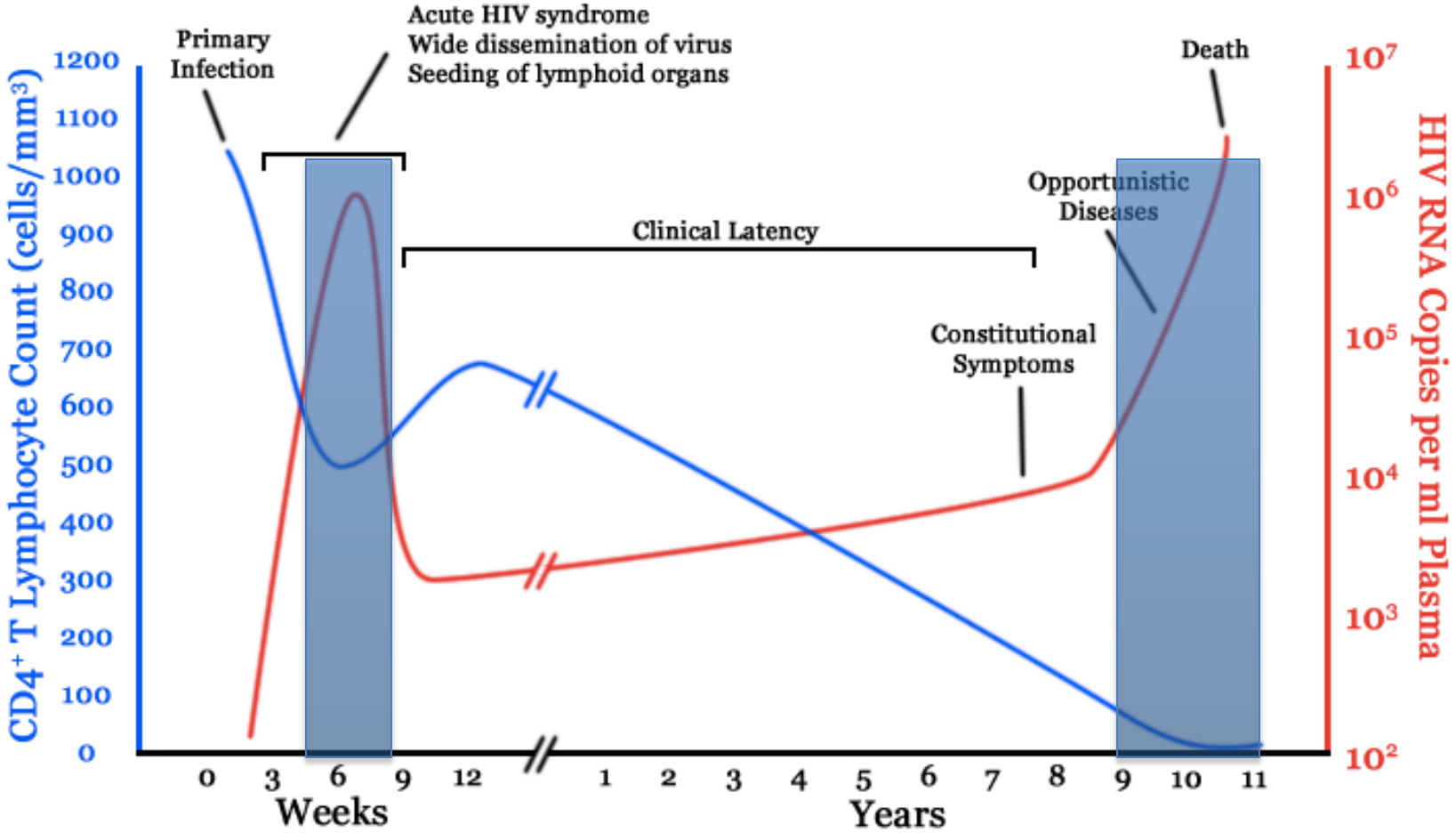
Lack of Circumcision

Cervical ectopy

HLA Haplotype

Cytokine profile

# Timing



# Average risk and individual risk of HIV transmission

Average risk can be assessed reasonably confidently from studies of large numbers of people but cannot be used to confirm individual risk because risk of HIV transmission is influenced by factors such as:

- **type of sexual activity** (vaginal, anal, oral, other)
- **roles during penetrative sex**: insertive vs receptive
- **amount of HIV** in the bodily fluid to which the at-risk person is exposed
- whether or not a **male or female condom** has been used correctly and consistently
- presence or absence of other **sexually transmitted infections** (STIs) in both partners
- whether or not the **penis** of the potentially exposed male partner has been **circumcised**



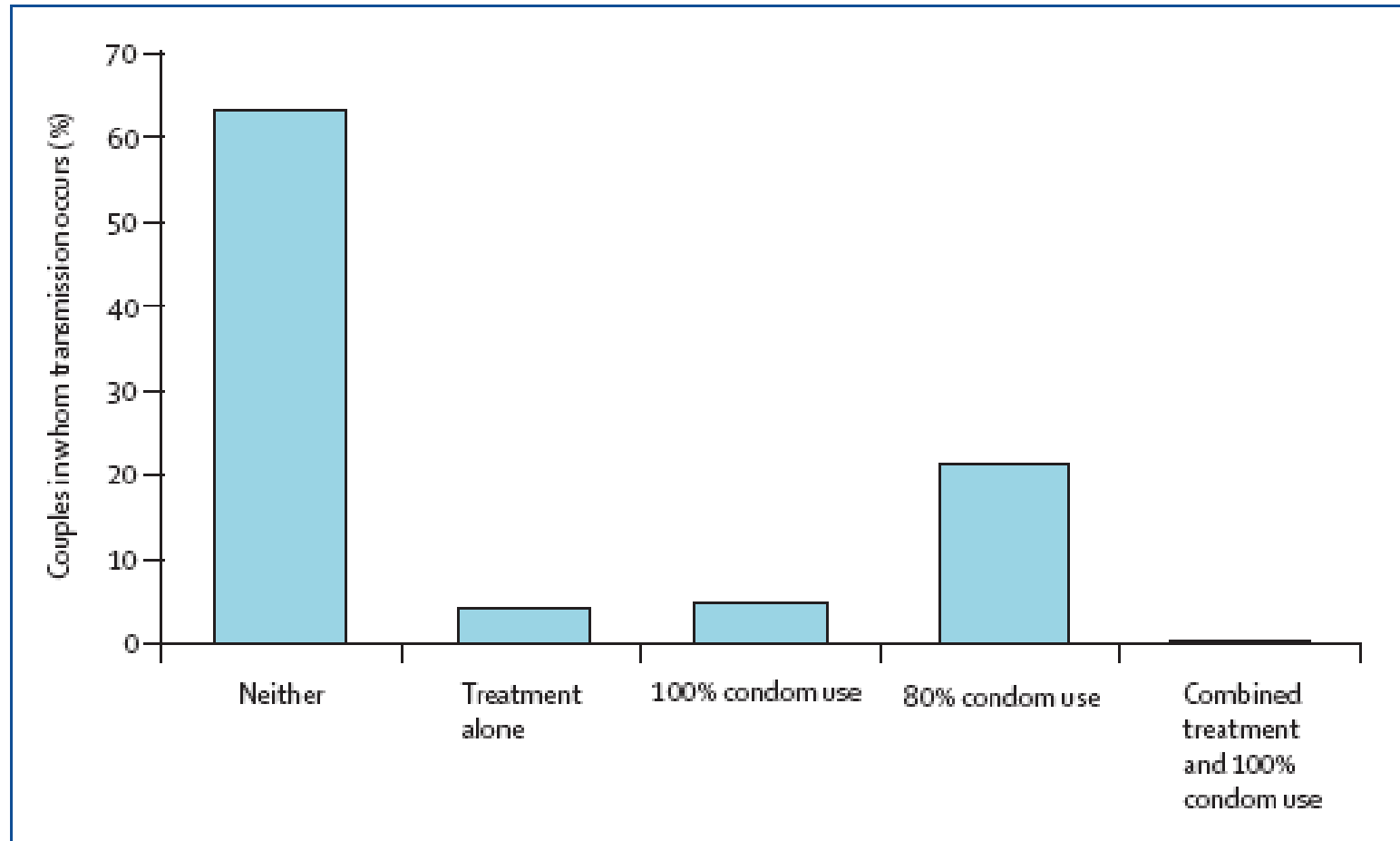
## Risk of HIV transmission per act (in the absence of antiretroviral drugs)

- Receptive **anal sex**: 1.7% [95% CI 0.3-8.9] **1 in 70**
- **Early HIV infection**: 9.2 times [4.5-18.8] asymptomatic phase
- **Late HIV infection**: 7.3 times [4.5-11.9] asymptomatic phase
- Presence or history of **genital ulcers** in either person increases per-act risk **5.3** times [1.4-19.5]
- Estimates for acquisition among **non-circumcised** men at least double circumcised

# HIV transmission risk through anal intercourse

- Per act **unprotected receptive anal intercourse (URAI)**  
**1.4%** [95% confidence interval (CI) 0.2–2.5] per-act  
(no differences heterosexual and MSM) = **1 in 70**  
(systematic review)
- Per act **unprotected insertive anal intercourse (UIAI)**  
**0.066%** [1 in 1666]  
(one study)

# Risk of HIV transmission over 100 sex acts during anal sex between men where one partner is HIV-positive



Garnett GP and Gazzard B. Lancet 372:270-271, 2008

# HIV transmission risk through oral intercourse

- *Cunnilingus* (mouth-vulva/clitoris) and *anilingus* (mouth-anus): theoretical risk
- *Fellatio* (mouth-penis): only type of oral sex that carries more than a theoretical risk of HIV transmission:
  - risk for insertive partner in fellatio virtually nonexistent
  - **risk for receptive partner** (the person who takes the partner's penis into her or his mouth) much lower than the receptive partner in anal or vaginal intercourse
    - estimates range from **zero risk** (based on epidemiological studies amongst heterosexuals) **to a 0.04% (1 in 2,500)** risk of HIV (based on case reports among men who have sex with men)
    - receptive partner's HIV risk thought to be higher if he or she has bleeding gums or other abrasions inside the mouth (but no definitive evidence)

# HIV transmission risk with condom use

- high level of protection when used correctly and consistently
- used consistently, though not necessarily perfectly (i.e. allowing for breakage and slippage) reduces the already statistically low risk of HIV transmission by around 80% compared to not using condoms (Cochrane Review)[\[i\]](#)
- small body of research suggests that level of protection provided by female condoms against HIV is comparable to that of male condoms.[\[ii\]](#)

[\[i\]](#) Weller SC, Davis-Beatty K. Cochrane Database of Systematic Reviews Issue 1, 2002.

[\[ii\]](#) French PP et al. Sexually Transmitted Diseases, 30(5):433-439, 2003



# HIV transmission risk by viral load

- Correlation: amount of virus in blood and risk of heterosexual transmission.
- Infectiousness increases or decreases in relation to viral load level.
  - 2009 systematic review of eleven studies in heterosexual couples found no evidence of HIV transmission if the HIV-positive partner was treated with ART and had a viral load below 400 copies/ml
  - data were also compatible with a maximum of **one transmission per 7900 sex acts if the couple had sex, on average, 100 times a year**, and the probability of transmission remained constant.

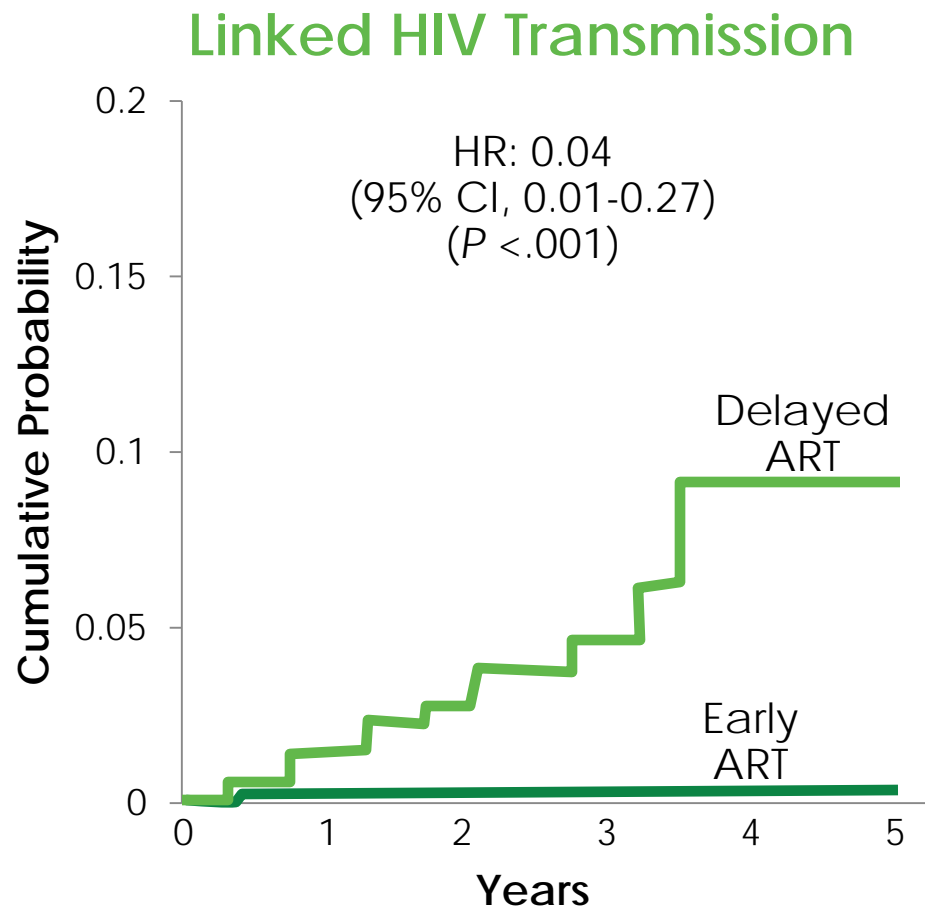
ORIGINAL ARTICLE

# Prevention of HIV-1 Infection with Early Antiretroviral Therapy

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Theresa Gamble, Ph.D., Mina C. Hosseinipour, M.D.,  
Nagalingeswaran Kumarasamy, M.B., B.S., James G. Hakim, M.D.,  
Johnstone Kumwenda, F.R.C.P., Beatriz Grinsztejn, M.D., Jose H.S. Pilotto, M.D.,  
Sheela V. Godbole, M.D., Sanjay Mehendale, M.D., Suwat Chariyalertsak, M.D.,  
Breno R. Santos, M.D., Kenneth H. Mayer, M.D., Irving F. Hoffman, P.A.,  
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Ian Sanne, M.B., B.Ch., Joseph Eron, M.D., Joel Gallant, M.D.,  
Diane Havlir, M.D., Susan Swindells, M.B., B.S., Heather Ribaud, Ph.D.,  
Vanessa Elharrar, M.D., David Burns, M.D., Taha E. Taha, M.B., B.S.,  
Karin Nielsen-Saines, M.D., David Celentano, Sc.D., Max Essex, D.V.M.,  
and Thomas R. Fleming, Ph.D., for the HPTN 052 Study Team\*

# Prevention of HIV-1 Infection With Early ART

- Randomized study of early versus delayed ART in 1763 serodiscordant couples
- Study stopped early by DSMB
- Linked HIV transmission to HIV-negative partner
  - Early ART (n = 1):  
0.1 per 100 PYs
  - Delayed ART (n = 27):  
7 per 100 PYs
- Early ART led to a 96% reduction of sexual transmission of HIV in serodiscordant couples



CI, confidence interval; DSMB, Data and Safety Monitoring Board; HR, hazard ratio; PY, person-year.  
Cohen MS, et al. *N Engl J Med*. 2011;365:493-505.

# Partner Cohort Study: No HIV Transmission Risk Despite “Condomless Sex”

- International Observational Cohort Study of serodiscordant couples
- Analyzed transmission risk from HIV positive on ARVs with undetectable VL from condomless sexual acts—no PEP nor PrEP used in HIV negative
- Analysis of transmissions linked to partner through phylogenetic analysis

	Observed Transmissions	95% CI for 100 CYs
<b>Overall</b>	0	0%-0.4%
<b>Anal sex</b>	0	0%-0.96%
<b>Receptive anal, with or without ejaculation</b>	0	0%-1.97%

- 10-year risk of HIV transmission:
  - 0%-3.9% overall
  - 0%-9.2% for condomless anal sex

ARV, antiretroviral; CY, couple-year; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis. Rodger A, et al. 21st CROI; Boston, MA; March 3-6, 2014. Abstract 153LB.

# Other exposures: Healthcare Worker Post-Exposure Prophylaxis

## DEFINITION OF EXPOSURE

- Percutaneous exposure to contaminated body fluid
- Mucous membrane exposure to contaminated body fluid
- Non-intact skin exposure to contaminated body fluid
- Infectious fluids: **blood, CSF, vaginal secretions, semen, synovial, pleural, peritoneal, pericardial, amniotic**
- Feces, nasal secretions, saliva, sputum, sweat, tears, urine, and vomitus are **not** considered potentially infectious unless they are visibly bloody.
- Over >30 years of the epidemic, only 57 documented transmissions from HIV+ patient to healthcare worker, and not one reported transmission since 1999. (See [http://www.cdc.gov/hiv/pdf/risk\\_occupational\\_factsheet.pdf](http://www.cdc.gov/hiv/pdf/risk_occupational_factsheet.pdf))

# 'Swiss statement' 2008

## Swiss statement:

'Swiss HIV experts generated a great deal of debate following their 2008 consensus statement. This statement proposed that a person's **risk of acquiring HIV is negligible** from an HIV-positive sexual partner who has an **undetectable plasma viral load for at least 6 months** and **no other sexually transmitted infections**. Accompanying materials suggested that such people could **stop using condoms if their sexual partner agrees**.

## UNAIDS/WHO response:

- 'More research is needed to determine the **degree to which the viral load in blood predicts the risk of HIV transmission** and to determine the **association between the viral load in blood and the viral load in semen and vaginal secretions**.....consider other related factors that contribute to HIV transmission including comorbidity with other sexually transmitted diseases.....continue to follow the science of HIV transmission and the **effect of antiretroviral treatment** on the transmission of HIV. UNAIDS and WHO underline the importance of **effective and proven HIV prevention methods for all people irrespective of their HIV status.**'

[i] Bernard EJ. Aidsmap. com, August 5, 2008.

[ii] Vernazza P et al. Bulletin des médecins suisses 89 (5), 2008.

[iii] Swiss AIDS Federation. January 30, 2008.

# RULES OF HIV for LAWYERS – Part 1

- ALL TRANSMISSION OF HIV REQUIRES A DISCORDANT SEXUAL RELATIONSHIP
- MOST SEXUAL ENCOUNTERS ARE CONCORDANT NEGATIVE
- MOST SEXUAL TRANSMISSION OF HIV OCCURS THROUGH UNPROTECTED (I.E., NO CONDOM, NO A.R.T.) ANAL SEX IN NEWLY FORMED RELATIONSHIPS, WHEN THE HIV POSITIVE PARTNER IS NEWLY INFECTED (~4.9 MONTHS OF MAXIMAL CONTAGION RISK) AND LIKELY TO BE UNAWARE HE/SHE IS HIV+
- “LONG-TERM” (>3 MONTHS) RELATIONSHIPS WITH AN HIV POSITIVE PERSON CAN RESULT IN AN HIV TRANSMISSION EVENT, BUT GENERALLY WITH LESS EFFICIENCY THAN OBSERVED THAN WHEN THE INFECTED PARTNER IS AT THE VERY EARLY OR LATE STAGES OF HIV DISEASE (I.E., WHEN TREATMENT HAS BEEN STOPPED OR HAS BECOME INEFFECTIVE)
- EFFICIENCY OF TRANSMISSION IS GREATLY AFFECTED BY INSTANTANEOUS COFACTORS THAT DETERMINE THE INFECTIOUSNESS OF THE INDEX CASE AND THE SUSCEPTIBILITY OF THE NEGATIVE PARTNER AT ONE (SPECIAL) MOMENT IN TIME
- LATEX CONDOMS REDUCE HIV TRANSMISSION SIGNIFICANTLY

# RULES OF HIV FOR LAWYERS – Part 2

- ADHERENCE TO MEDICATION (ART) THAT SUPPRESSES HIV REPLICATION REDUCES HIV TRANSMISSION

## ***IN SHORT:***

- 1) OVERALL, HIV IS NOT TYPICALLY AN EASILY-TRANSMITTED DISEASE
- 2) EFFECTIVE DRUG THERAPY, CONDOM USE REDUCE A SMALL PER-  
ACT RISK TO NEAR ZERO OR ZERO
- 3) CURRENT AVAILABLE HIV TREATMENTS **WORK**: HIV IS A SERIOUS  
CHRONIC DISEASE, BUT FOR MANY IF NOT MOST, REGIMEN OF 1  
PILL/DAY, NEAR-NORMAL LIFE SPAN



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