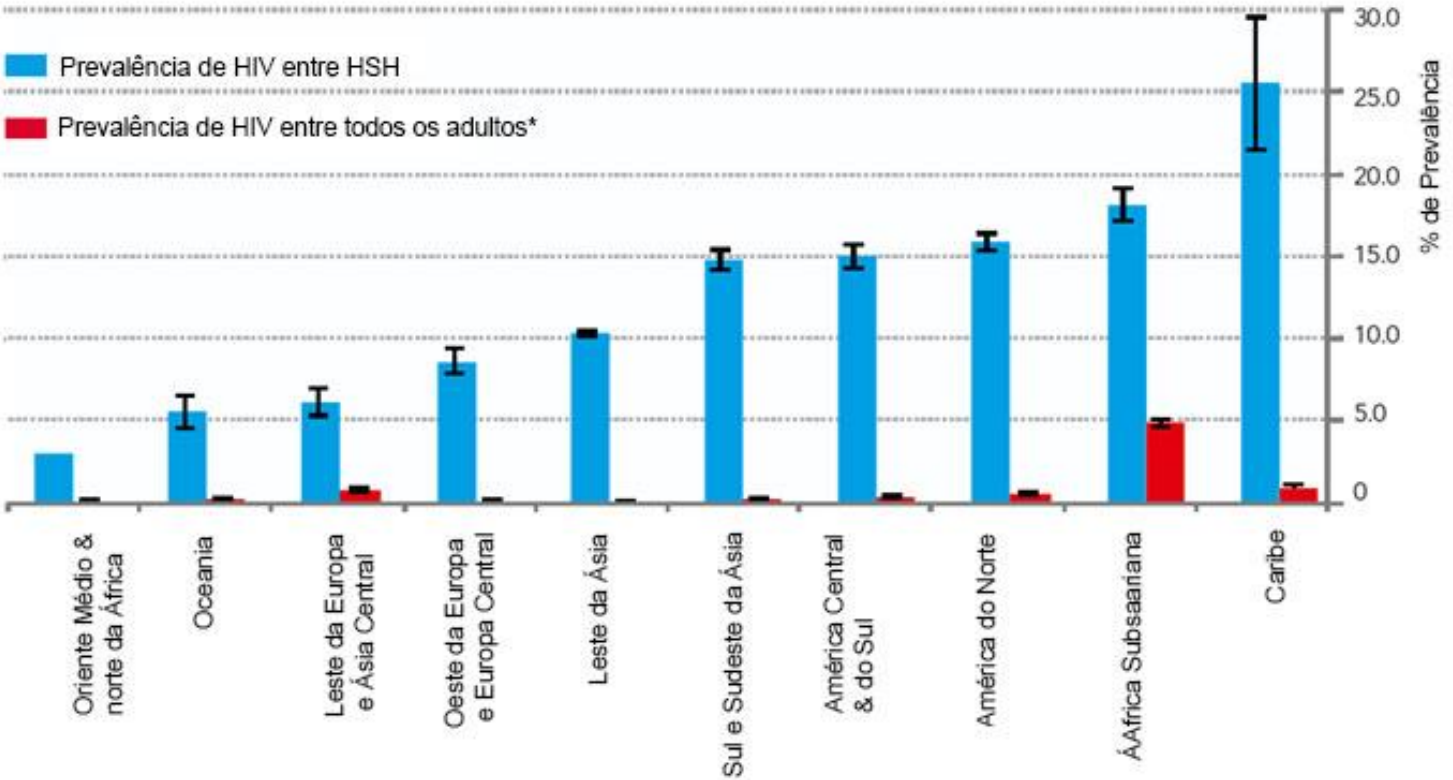
Tratamento como Prevenção entre gays, outros homens que fazem sexo com homens e travestis

Valdiléa G. Veloso
IPEC/Fiocruz
GIV-SP
Setembro 2014

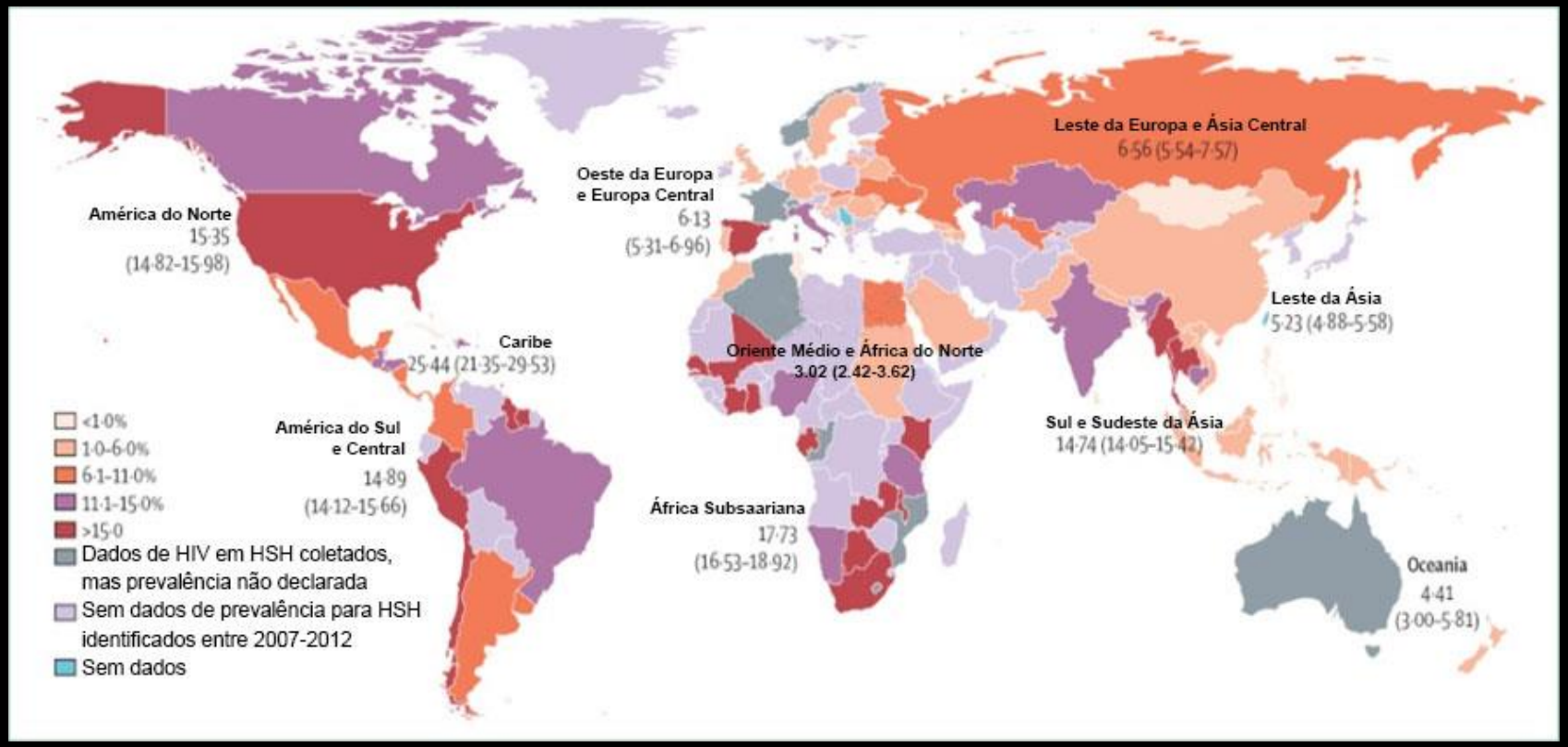
Epidemia global de HIV entre HSH

Pesquisa sobre a prevalência de HIV entre HSH e entre todos os homens em idade reprodutiva por região, atualizada em 2013



Adaptado de Beyrer et al. The Lancet, 2013 [3]. Prevalência de HIV entre adultos, UNAIDS 2012 (dados de 2011) [1]
*Relatório mundial UNAIDS 2012 (dados de 2011)

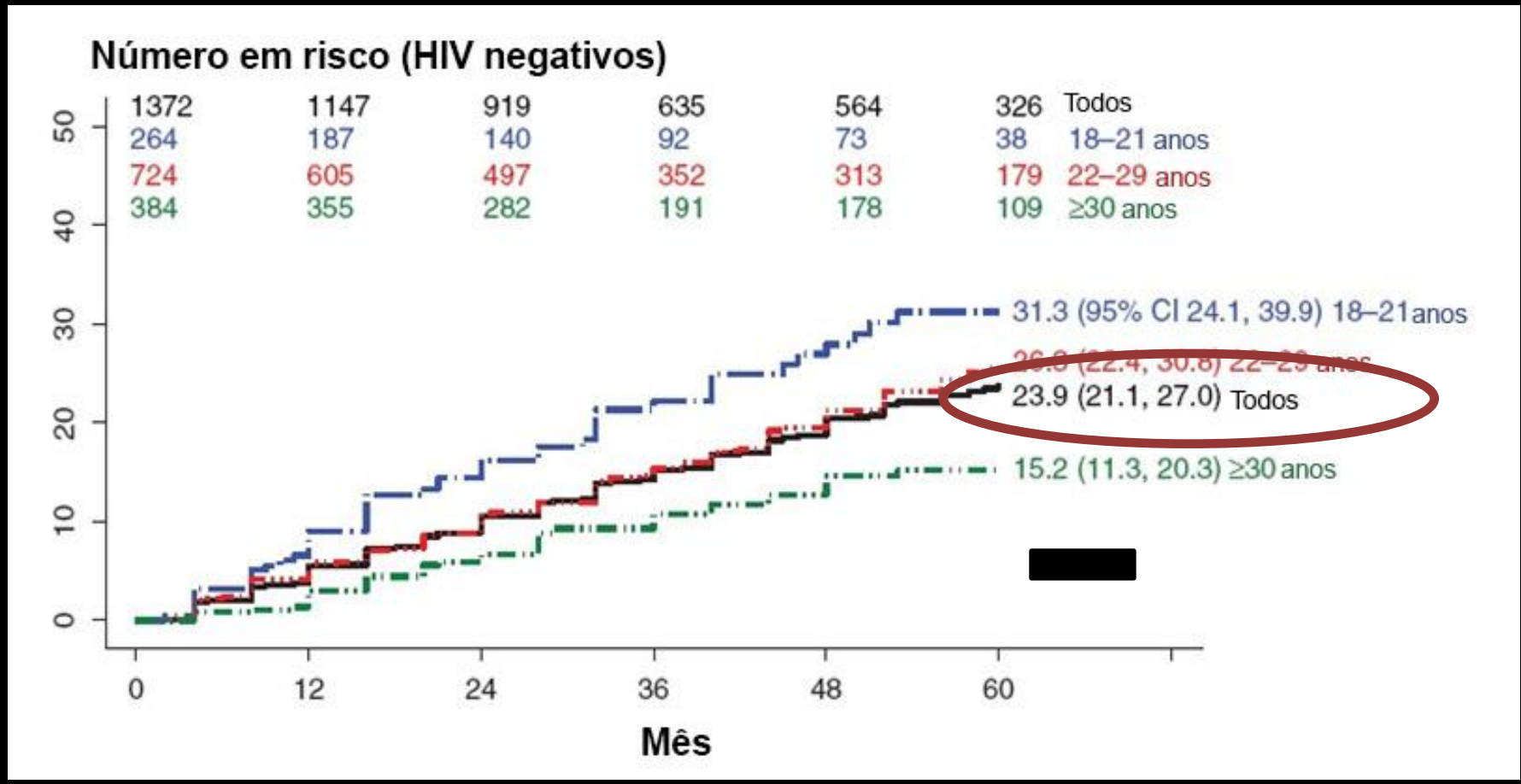
Prevalência Global do HIV Entre HSH 2007-2011



Beyrer et al. The Lancet. 2012

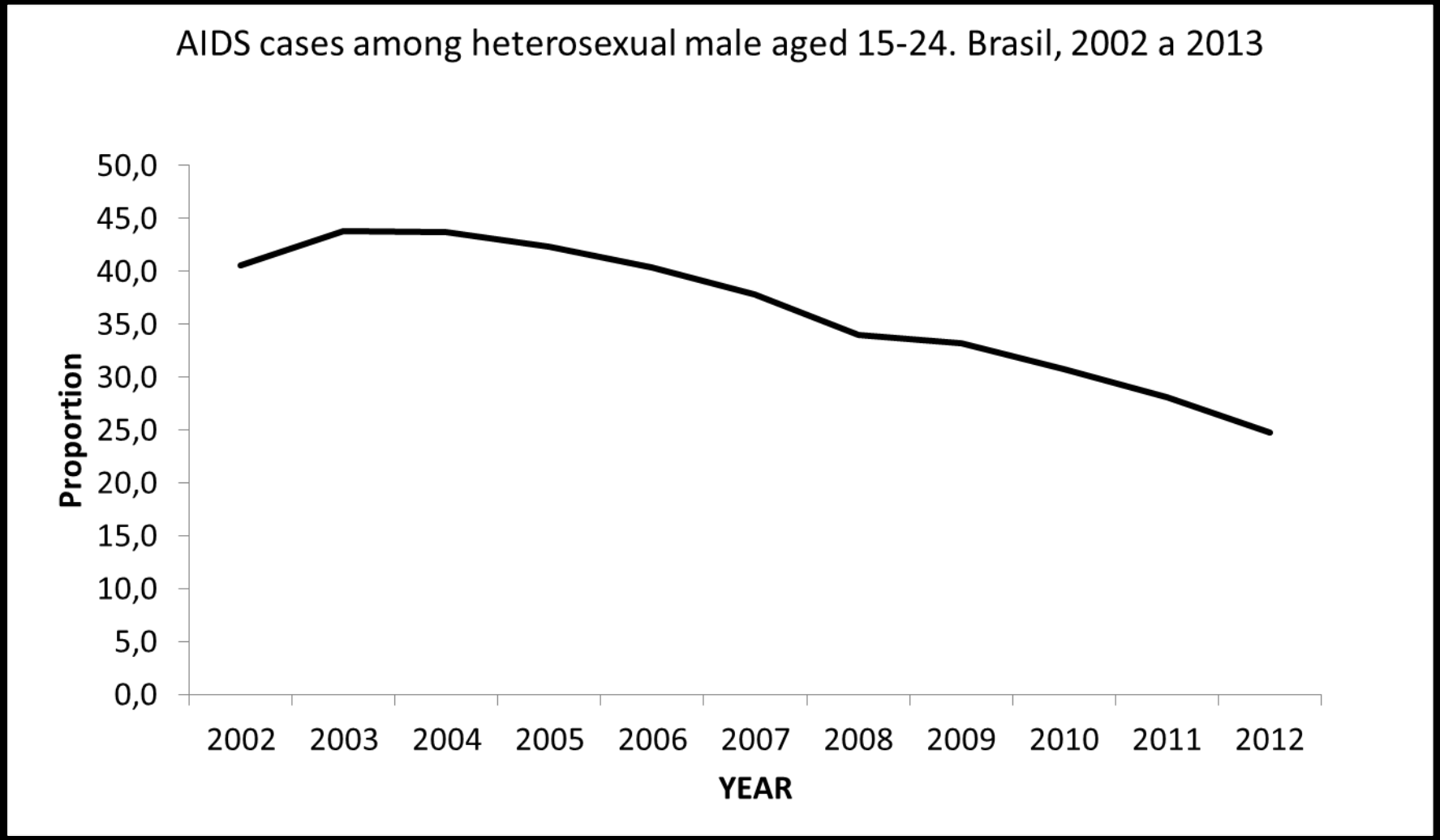
Incidência de HIV em um grupo de HSH Bangkok

Incidência de HIV Kaplan Meier em seis meses acumulados em um grupo de HSH de Bangkok, Tailândia, 2006-2012



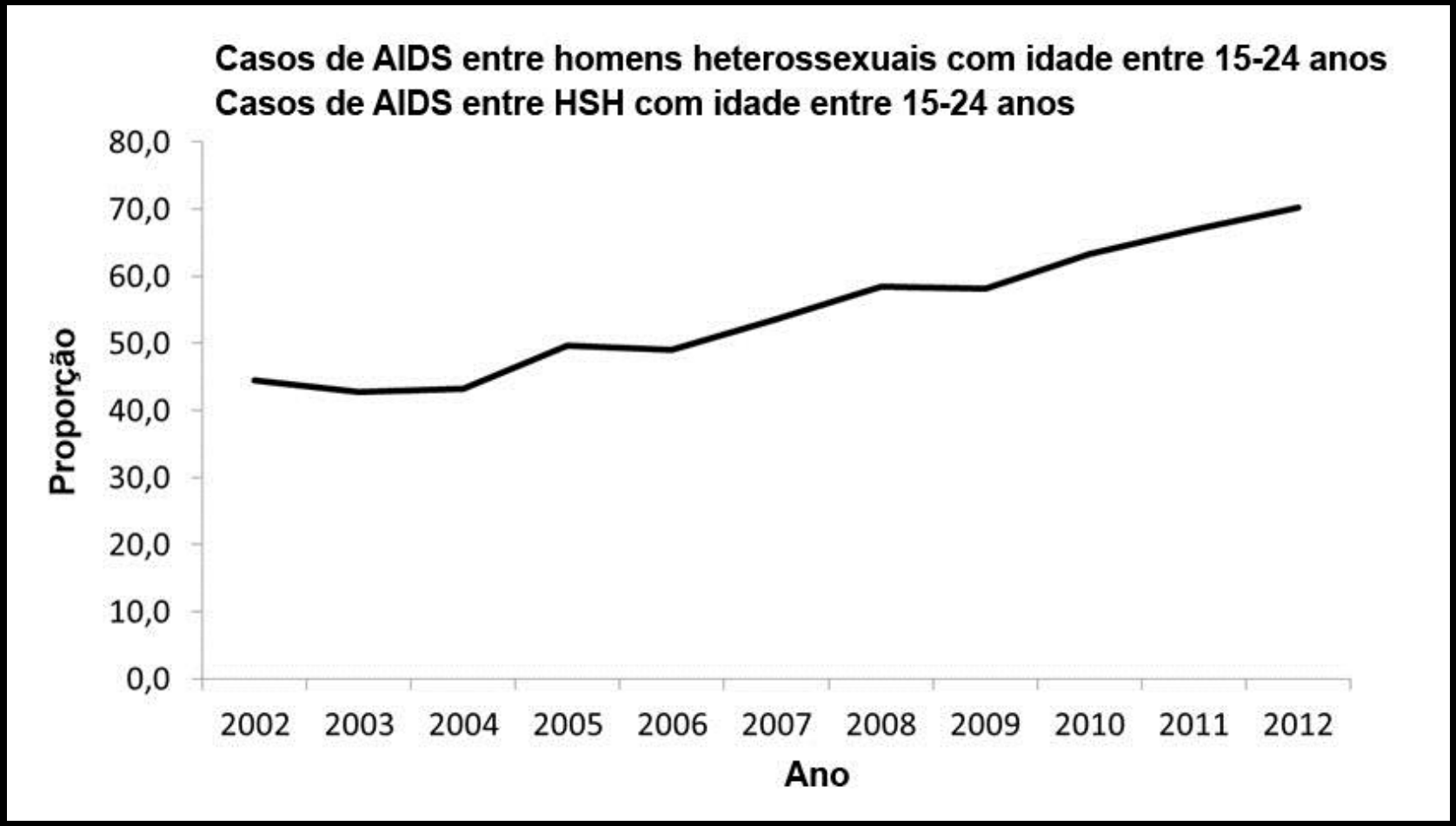
Fonte: van Griensven et al, AIDS. 2013

Casos de AIDS em jovens heterossexuais do sexo masculino - Brasil



MS/SVS/Departamento de DST, Aids e Hepatites Virais. Note:AIDS cases until 30/06/2013

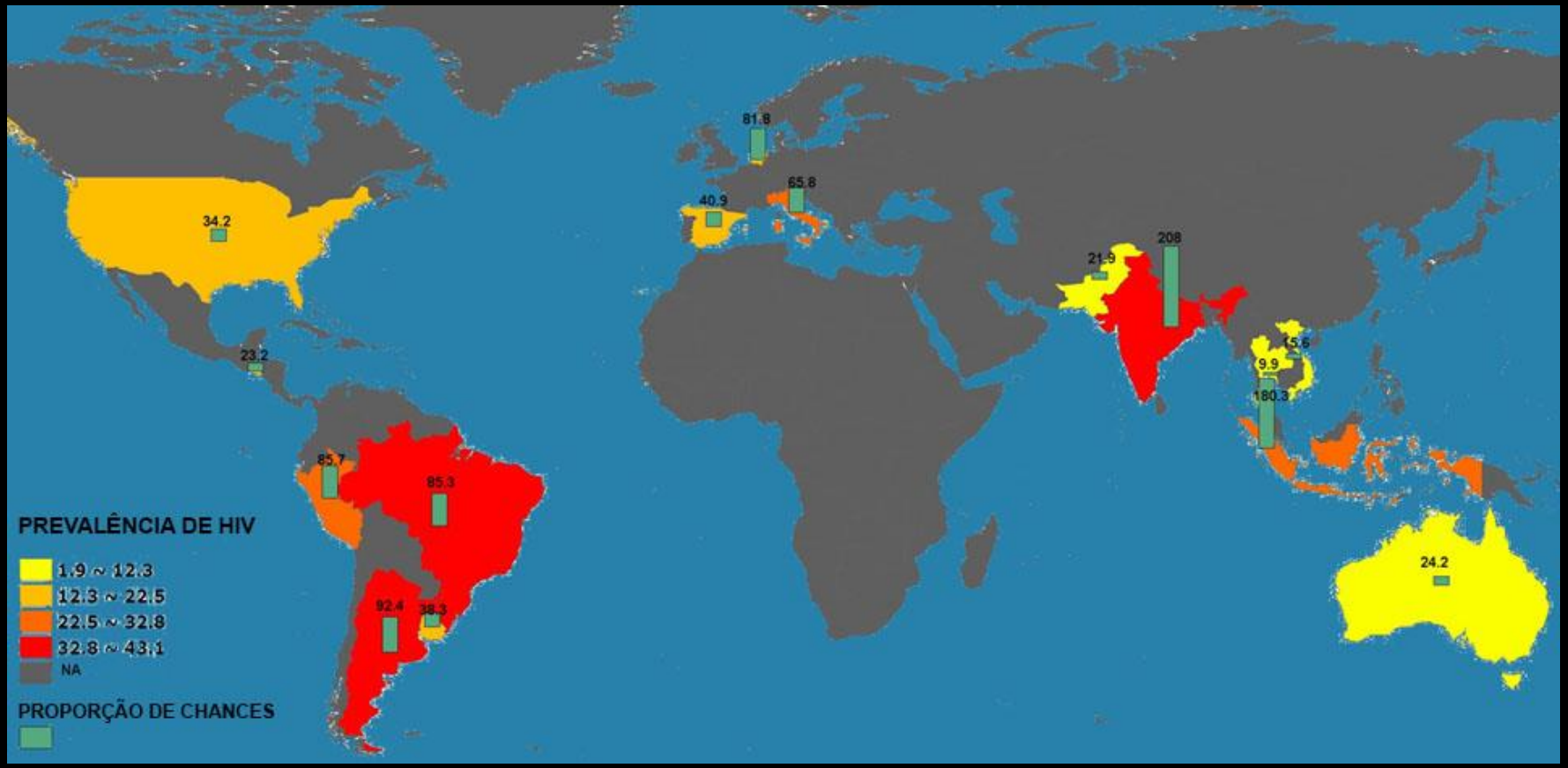
Casos de AIDS em jovens homossexuais masculinos



MS/SVS/Departamento de DST, Aids e Hepatites Virais. Observação: casos de AIDS até 30/06/2013

Mulheres Transexuais

Prevalência de HIV entre TGW e OR em comparação à população geral (entre 15 e 49 anos)



Adaptado de: Baral et al. The Lancet Infectious Disease. 2013

Riscos de Nível Individual

Estimando o risco de transmissão de HIV por ato sexual: uma análise sistemática

Tabela 1. Probabilidade estimada por ato de adquirir HIV de uma fonte infectada, por rota de exposição.

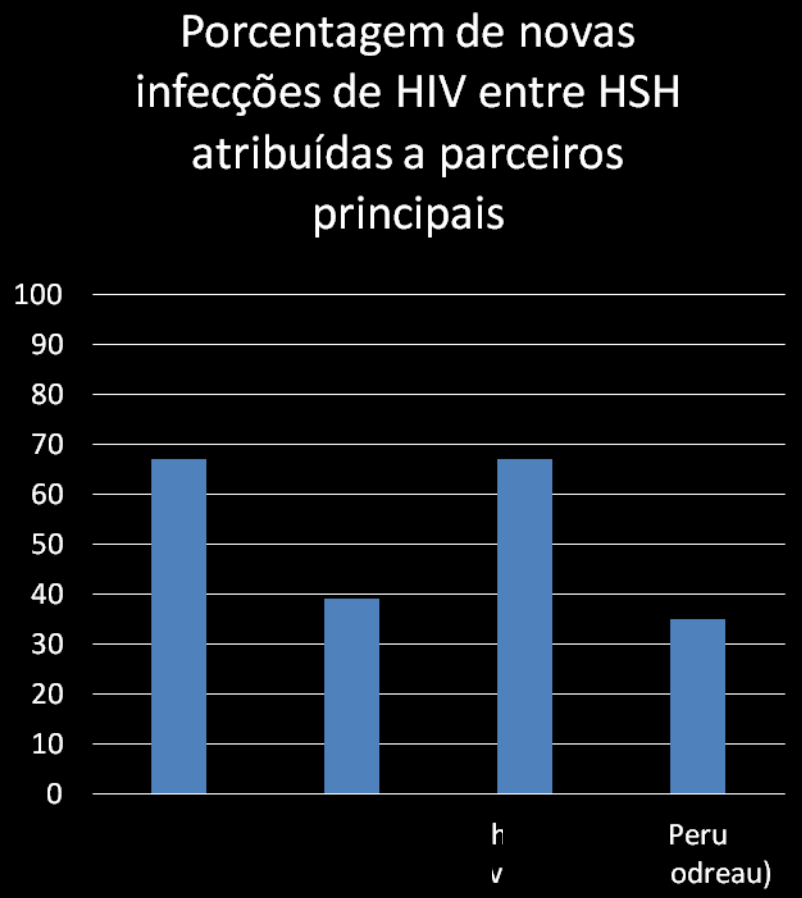
Rota de exposição	Risco por 10 mil exposições a uma fonte infectada	95% de Intervalo de Confiança
Exposição parenteral	9250	(8900–9610)
Transfusão de sangue	63[b]	(41–92)
Uso de drogas injetáveis com compartilhamento de seringa	23	(0–46)
Exposição sexual		
Sexo anal passivo[a]	138[c]	(102–186)
Sexo anal ativo	11[d]	(4–28)
Sexo vaginal-peniano ativo	8[e]	(6–11)
Sexo vaginal-peniano passivo	4[e]	(1–14)
Sexo oral passivo	baixo[f]	(0–4)
Sexo oral ativo	baixo[f]	(0–4)
Transmissão vertical		
Transmissão de mãe para filho	2255[g]	(1700–2890)

Estimativas retiradas de Leynaert et al. Am J Epidemiol 1998; Jin et al. AIDS 2010; Vittinghoff et al. Am J Epidemiol1999; DeGruttola et al. J Clin Epidemiol 1989

Fonte: Patel et al. AIDS.2014

O Papel dos Parceiros Principais na Epidemia de HIV entre HSH

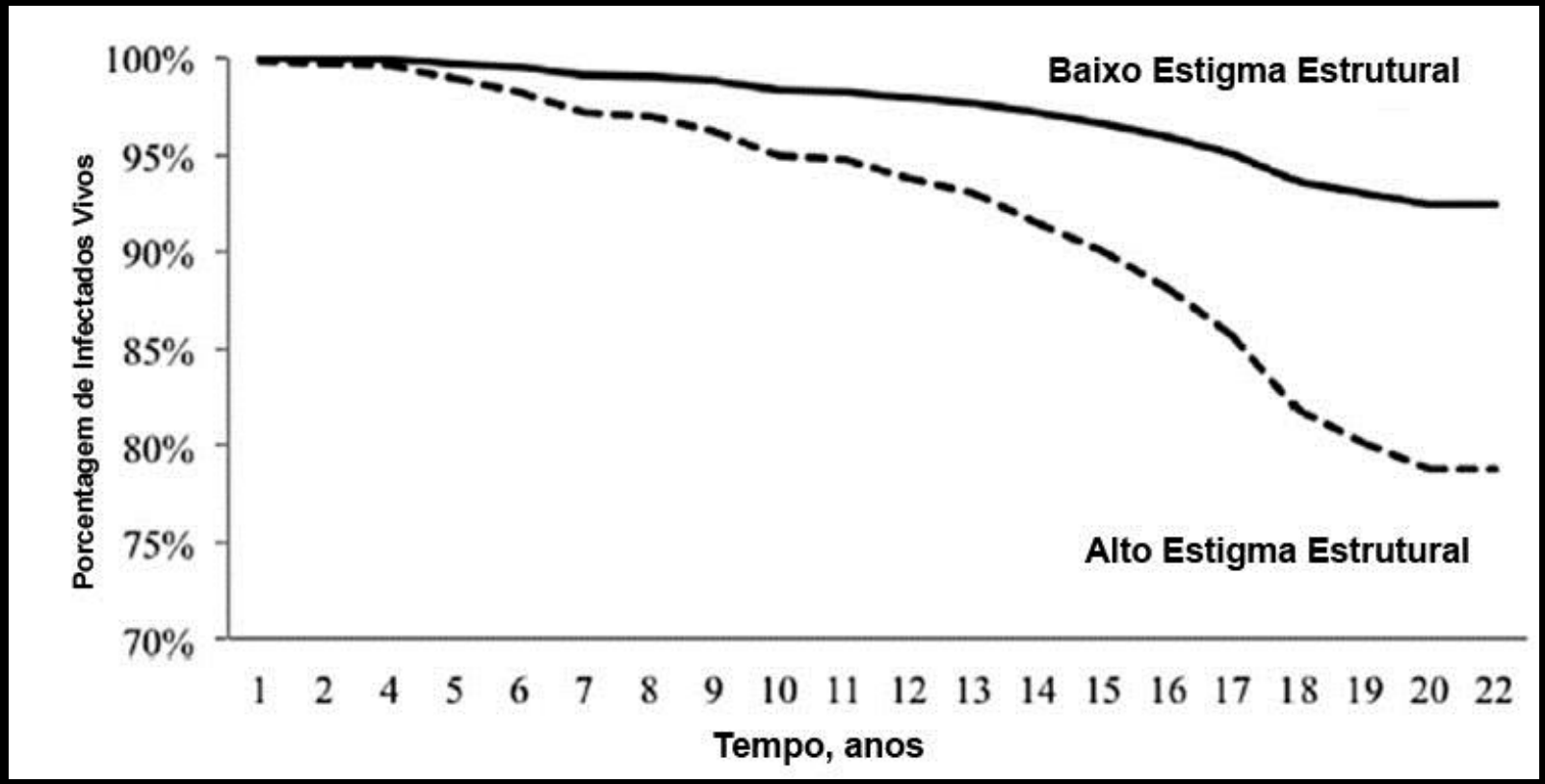
- Grande proporção de novos casos surge de parceiros principais
- Porque, com os parceiros principais, os homens[1]:
  - Mantêm relações com mais frequência
  - São mais propensos a fazer sexo anal
  - São menos propensos a usar camisinha
- Ainda assim:
  - o conhecimento que os homens possuem sobre a condição de seus parceiros não é mais preciso do que o conhecimento que possuem sobre a condição de seus parceiros casuais
  - Homens que são parceiros principais acreditam correr menor risco de infecção por HIV2
  - Homens que são parceiros principais são menos propensos a terem feito o teste de HIV[2] recentemente



Fontes: 1 Sullivan et al,AIDS 2009; 2 ; Goodreau et al, PLoSONE 2012; Davidovich et al, AIDS 2001

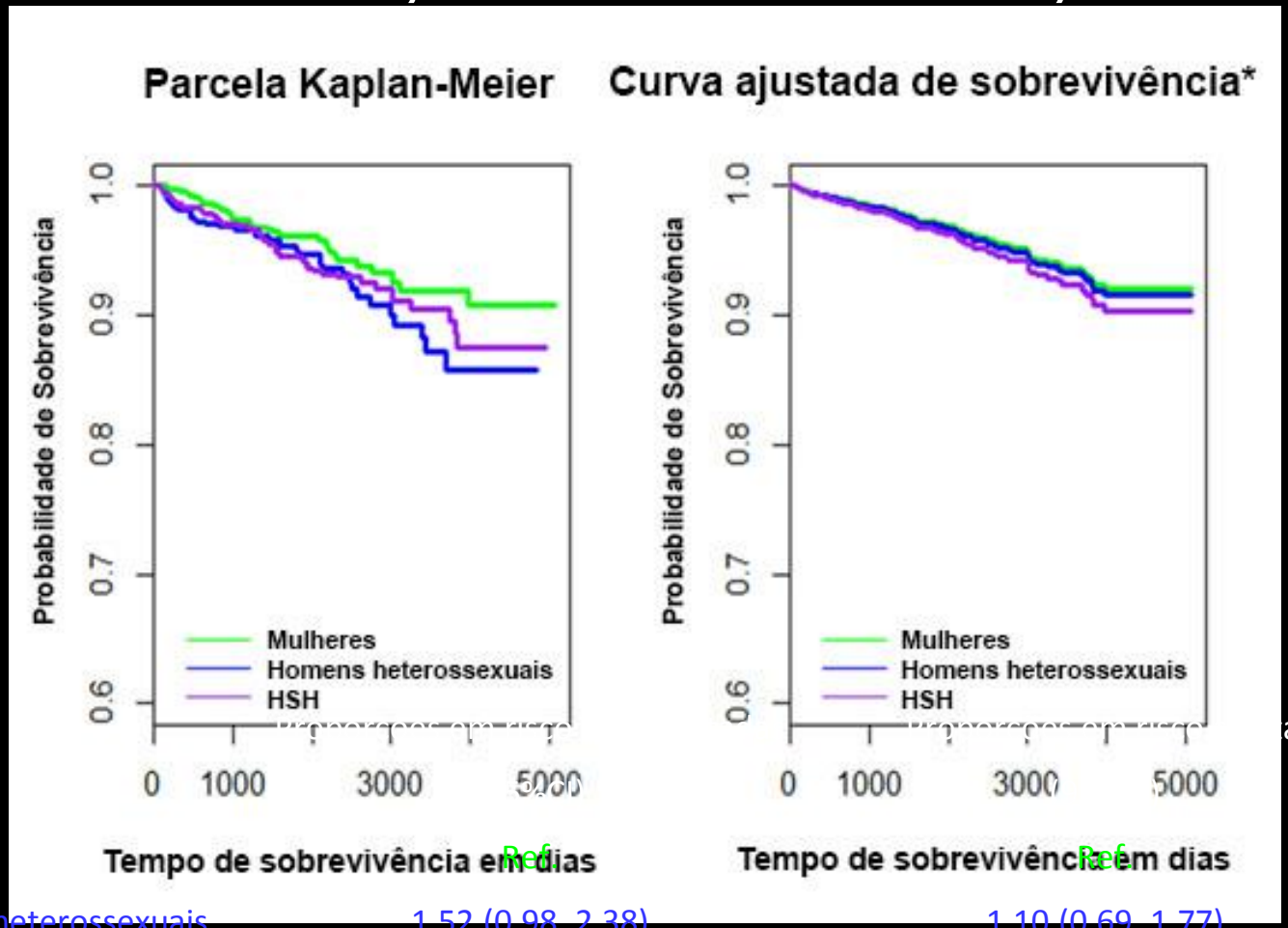
Estigma Estrutural e Mortalidade por todas as causas

Fig. 2. Tempo de sobrevivência por tipo de área residencial, Pesquisa Social Geral/Índice de Mortalidade Nacional, 1988 - 2002



Hatzenbuehler et al. Social Science & Medicine . 2014

Sobrevivência entre indivíduos infectados com HIV em tratamento em Fiocruz, Rio de Janeiro, Brasil



adas*

Mulheres	Ref.	Ref.
Homens heterossexuais	1.52 (0.98, 2.38)	1.10 (0.69, 1.77)
HSH	1.34 (0.88, 2.03)	1.31 (0.82, 2.09)

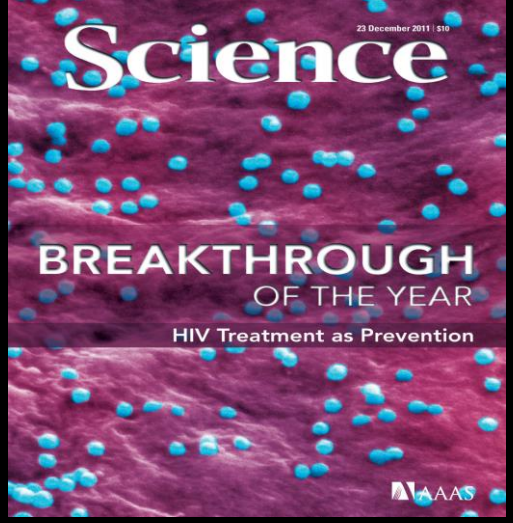
Luz et al under review

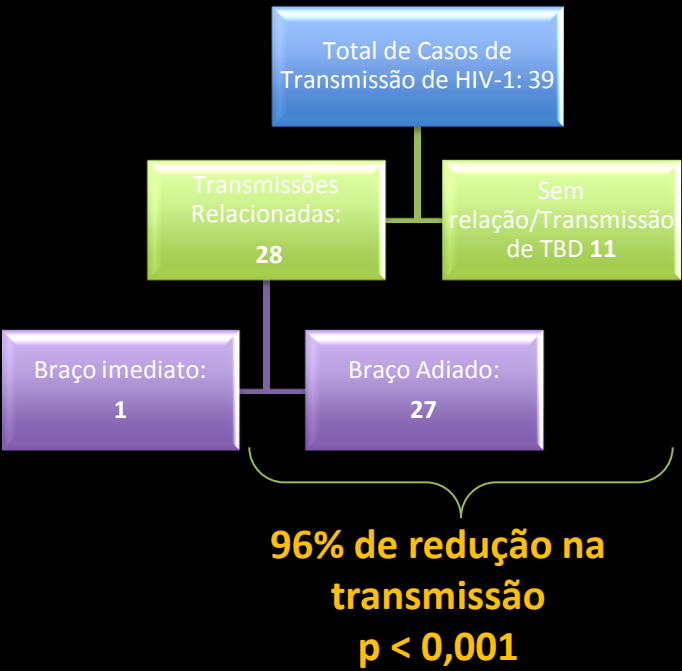
Travestis
Barreiras no Cuidado

- Assédio e violência
- Medo de revelar a identidade transexual
- Falta de ambientes que afirmem seu sexo nos serviços de assistência médica
- Outras prioridades na vida
- Estigma de intersecção
- Falta de profissionais da área médica competentes
- Falta de inclusão em campanhas de conscientização e prevenção da AIDS

- **Baixos níveis de testes de HIV**
  - Canadá 46% Bauer et al 2012
  - Bangkok 50% Nemoto et al 2012
- **Resultados de tratamento: Poucos estudos avaliaram os resultados do cART entre as mulheres transexuais**
  - Menos propensas a receberem tratamento com cART Melendez Melendez et al 2006
  - Pior aderência; mais dificuldades ao integrar o tratamento do HIV em suas vidas Sevelius et al 2010
  - Maior mortalidade relacionada ao HIV Das et al 2010
  - Índices semelhantes de supressão e retenção virológicas no tratamento em ambientes de pesquisa Yehia 2013
- **Acesso e resultados PrEP**
  - Falta de efeito preventivo entre mulheres transexuais no estudo iPrEX Grant et al 2010
  - Poucas mulheres transexuais avaliadas para participação em um Projeto Demo nos EUA Cohen et al CROI 2014

HPTN 052
Tratamento Inicial

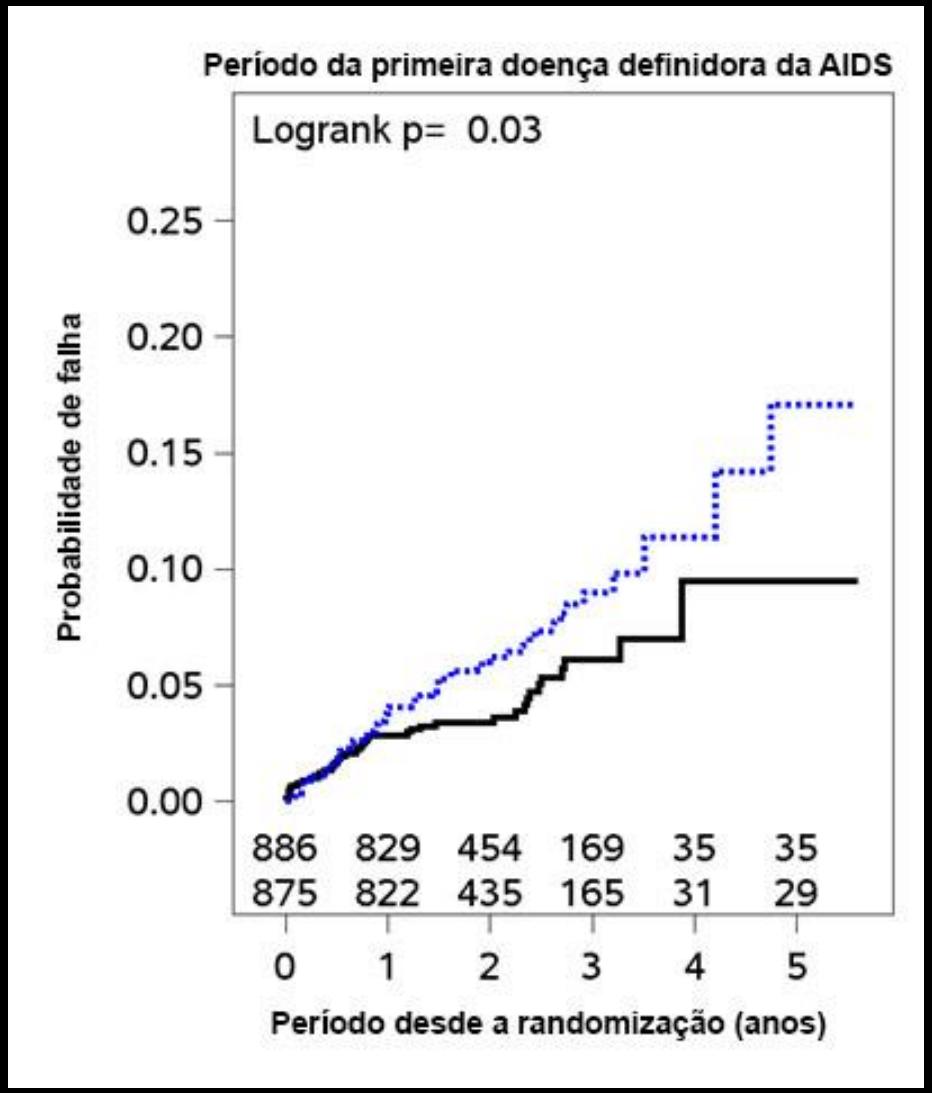




96% de redução na transmissão
p < 0,001

Cohen et al. NEJM 2011

Grinsztejn et al. Lancet ID 2014



Effects of early versus delayed initiation of antiretroviral treatment on clinical outcomes of HIV-1 infection: results from the phase 3 HPTN 052 randomised controlled trial

*Beatriz Grinsztejn, Mina C Hosseinipour, Heather J Ribaudo, Susan Swindells, Joseph Eron, Ying Q Chen, Lei Wang, San-San Ou, Maija Anderson, Marybeth McCauley, Theresa Gamble, Nagalingeshwaran Kumarasamy, James G Hakim, Johnstone Kumwenda, Jose H S Pilotta, Sheela V Godbole, Suwat Chariyalertsak, Marineide Gonçalves de Melo, Kenneth H Mayer, Susan H Eshleman, Estelle Piwowar-Manning, Joseph Makhema, Lisa A Mills, Ravindre Panchia, Ian Sanne, Joel Gallant, Irving Hoffman, Taha E Taha, Karin Nielsen-Saines, David Celentano, Max Essex, Diane Havlir, Myron S Cohen, and the HPTN 052-ACTG Study Team**

Summary

Background Use of antiretroviral treatment for HIV-1 infection has decreased AIDS-related morbidity and mortality and prevents sexual transmission of HIV-1. However, the best time to initiate antiretroviral treatment to reduce progression of HIV-1 infection or non-AIDS clinical events is unknown. We reported previously that early antiretroviral treatment reduced HIV-1 transmission by 96%. We aimed to compare the effects of early and delayed initiation of antiretroviral treatment on clinical outcomes.

Methods The HPTN 052 trial is a randomised controlled trial done at 13 sites in nine countries. We enrolled HIV-1-serodiscordant couples to the study and randomly allocated them to either early or delayed antiretroviral treatment by use of permuted block randomisation, stratified by site. Random assignment was unblinded. The HIV-1-infected member of every couple initiated antiretroviral treatment either on entry into the study (early treatment group) or after a decline in CD4 count or with onset of an AIDS-related illness (delayed treatment group). Primary events were AIDS clinical events (WHO stage 4 HIV-1 disease, tuberculosis, and severe bacterial infections) and the following serious medical conditions unrelated to AIDS: serious cardiovascular or vascular disease, serious liver disease, end-stage renal disease, new-onset diabetes mellitus, and non-AIDS malignant disease. Analysis was by intention-to-treat. This trial is registered with ClinicalTrials.gov, number NCT00074581.

Findings 1763 people with HIV-1 infection and a serodiscordant partner were enrolled in the study; 886 were assigned early antiretroviral treatment and 877 to the delayed treatment group (two individuals were excluded from this group after randomisation). Median CD4 counts at randomisation were 442 (IQR 373–522) cells per µL in patients assigned to the early treatment group and 428 (357–522) cells per µL in those allocated delayed antiretroviral treatment. In the delayed group, antiretroviral treatment was initiated at a median CD4 count of 230 (IQR 197–249) cells per µL. Primary clinical events were reported in 57 individuals assigned to early treatment initiation versus 77 people allocated to delayed antiretroviral treatment (hazard ratio 0·73, 95% CI 0·52–1·03; p=0·074). New-onset AIDS events were recorded in 40 participants assigned to early antiretroviral treatment versus 61 allocated delayed initiation (0·64, 0·43–0·96; p=0·031), tuberculosis developed in 17 versus 34 patients, respectively (0·49, 0·28–0·89, p=0·018), and primary non-AIDS events were rare (12 in the early group *vs* nine with delayed treatment). In total, 498 primary and secondary outcomes occurred in the early treatment group (incidence 24·9 per 100 person-years, 95% CI 22·5–27·5) versus 585 in the delayed treatment group (29·2 per 100 person-years, 26·5–32·1; p=0·025). 26 people died, 11 who were allocated to early antiretroviral treatment and 15 who were assigned to the delayed treatment group.

Interpretation Early initiation of antiretroviral treatment delayed the time to AIDS events and decreased the incidence of primary and secondary outcomes. The clinical benefits recorded, combined with the striking reduction in HIV-1 transmission risk previously reported, provides strong support for earlier initiation of antiretroviral treatment.

Funding US National Institute of Allergy and Infectious Diseases.

Introduction

Combination antiretroviral treatment has reduced morbidity and mortality associated with HIV-1 infection over the past two decades.[1,2] However, the best timing of treatment initiation in people with high CD4 cell counts remains unknown. Findings of observational studies of treatment for HIV-1 infection lend support to early initiation of antiretroviral treatment,[3–6] but data from randomised studies are scarce. In a randomised trial from Haiti,[7] HIV-1 disease progression was delayed and survival extended when antiretroviral treatment was started at CD4 counts of 200–350 cells per µL, compared with initiation at CD4 counts of less than 200 cells per µL.

The HIV Prevention Trials Network (HPTN) 052 study is a worldwide, multicentre, randomised controlled trial designed to compare early versus delayed antiretroviral

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This publication has been corrected. The corrected version first appeared at thelancet.com/infection on March 24, 2014

See Comment page 258

*See appendix (pp 146–50) for a full list of Study Team members

Fred Hutchinson Cancer Research Center, Seattle, WA, USA (M Anderson MN, Y Q Chen PhD, S-S Ou MS, L Wang PhD); Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA (D Celentano ScD, T E Taha MBBS); Research Institute for Health Sciences, Chiang Mai University, Chaing Mai, Thailand (S Chariyalertsak MD); University of North Carolina School of Medicine, Chapel Hill, NC, USA (M S Cohen MD, J Eron MD, I Hoffman PA, M C Hosseinipour MD); Johns Hopkins University School of Medicine, Baltimore, MD, USA (S H Eshleman MD, J Gallant MD, E Piwowar-Manning MT); Harvard School of Public Health, Boston, MA, USA (M Essex DVM, H J Ribaudo PhD); FHI 360, Durham, NC, USA (T Gamble PhD); National AIDS Research Institute (ICMR), Pune, India (S V Godbole MD); Hospital Nossa Senhora da Conceição, Porto Alegre RS, Brazil (M Gonçalves de Melo MD); Instituto de Pesquisa Clinica Evandro Chagas, Fiocruz, Rio de Janeiro, Brazil (B Grinsztejn MD); University of Zimbabwe, Harare, Zimbabwe (J G Hakim MD);

End of the debate about antiretroviral treatment initiation

Published Online March 4, 2014 http://dx.doi.org/10.1016/S1473-3099(13)70329-3

See Articles page 281

Since the mid 1990s we have known that the amount of HIV RNA in plasma affects progression to AIDS or death in untreated individuals.[1] Highly active antiretroviral treatment (HAART) can make plasma HIV RNA undetectable, and use of this treatment leads to striking decreases in morbidity and mortality.[2] However, the best time to initiate HAART has been the subject of prolonged debate.

Although study findings show a clear survival benefit when HAART is initiated before patients' CD4 counts fall below 200 cells per μL, uncertainty surrounds the best time to initiate treatment in asymptomatic patients with higher CD4 cell counts.[3] Clinicians have to balance the risks of delaying antiretroviral treatment against the possible harms associated with premature exposure to HAART, including side-effects, pill burden, cost, and potential for avoidable antiretroviral resistance.[4] Other issues under discussion include expansion of access to HIV treatment versus augmented use of proven and cheaper HIV prevention strategies.[5] These debates are becoming increasingly complicated and risk public health goals conflicting with individual patients' clinical needs.

In *The Lancet Infectious Diseases*, Beatriz Grinsztejn and colleagues report the latest data from the HPTN 052 trial.[6] In this study, HIV-serodiscordant couples were randomly allocated to either early initiation of HAART (ie, at a CD4 count of 350–550 cells per μL) or delayed antiretroviral treatment (ie, starting treatment when their CD4 count fell below 250 cells per μL). Fewer individuals who were assigned to early HAART had primary clinical events (57 individuals *vs* 77 people allocated to delayed treatment; hazard ratio 0·73, 95% CI 0·52–1·03; p=0·074), new-onset AIDS events (40 *vs* 61; 0·64, 0·43–0·96; p=0·031), and tuberculosis (17 *vs* 34; 0·49, 0·28–0·89; p=0·018). These data show a clear benefit to patients of starting HAART early, when the CD4 count is well above 400 cells per μL. The debate about the value of early HAART initiation should now be viewed as settled from both patients' and public health perspectives.

Several challenges remain before we can consider the best approach for rolling out HIV treatment programmes.[7] First, many asymptomatic individuals who are HIV-1-positive are unaware of their HIV status;[8] thus, implementation of universal screening programmes is a priority. Such a strategy benefits not only the health of HIV-positive patients whose status might otherwise be unknown and undetected until late in the course of their infection but also the health of other people to whom they might inadvertently transmit the virus. Early detection also permits early initiation of HAART. Second, immediate linkage to HIV care on initial diagnosis is needed, to prevent loss to follow-up.[9] Third, strategies need to be implemented to ensure high rates of adherence to HAART, to ensure long-term virological suppression and prevention of antiretroviral resistance.[10] Unfortunately, these challenges exist in settings where stigma towards people with and at risk of HIV infection remains very high.[11] As a result, individuals are typically reluctant to be tested for HIV, are frequently lost to follow-up before HAART is initiated, or meet structural barriers that impede access or enable adherence to treatment.[11]

With these challenges at the forefront of the HIV/AIDS agenda, the results of the HPTN 052 trial place humanity at a crossroads, at which a clear understanding exists of the effect of plasma HIV-1 RNA concentrations on disease progression and of the benefits of early HAART initiation for reduction of HIV transmission, which protect patients from important clinical endpoints. Translation of this knowledge into a global public health response remains an urgent challenge.

*Seonaid Nolan, *Evan Wood*
British Columbia Centre for Excellence in HIV/AIDS, St Paul's Hospital, Vancouver, BC, Canada V6Z 1Y6 (SN, EW); and Department of Medicine, Faculty of Medicine, University of British Columbia, Vancouver, BC, Canada (EW)
uhri-ew@cfenet.ubc.ca

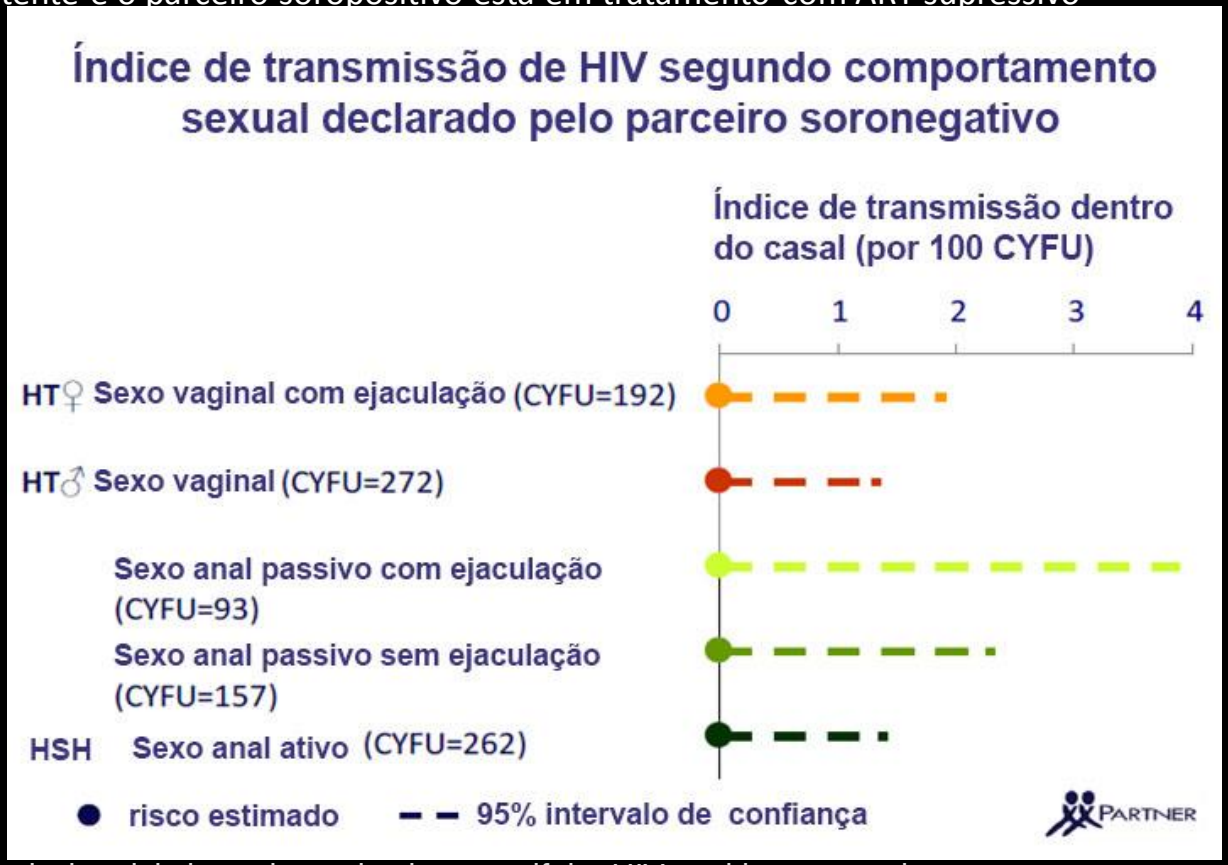
We have received research funding from the Canada Research Chairs programme through a Tier 1 Canada Research Chair in Inner City Medicine (to EW) and from the US National Institute on Drug Abuse (grant number R01-DA021525).

1 Mellors JW, Rinaldo CR J, Gupta P, White RM, Todd JA, Kingsley LA. Prognosis in HIV-1 infection predicted by the quantity of virus in plasma. *Science* 1996; **272**: 1167–70.
2 Hammer SM, Squires KE, Hughes MD, et al, for the AIDS Clinical Trials Group 320 Study Team. A controlled trial of two nucleoside analogues plus indinavir in persons with human immunodeficiency virus infection and CD4 cell counts of 200 per cubic millimeter or less. *N Engl J Med* 1997; **337**: 725–33.
3 Severe P, Juste MAJ, Ambroise A, et al. Early versus standard antiretroviral therapy for HIV-infected adults in Haiti. *N Engl J Med* 2010; **363**: 257–65.

Tratamento como Prevenção

Estudo PARTNER

- estudo observacional em 75 lugares da Europa
- Casais sorodiscordantes para o HIV nos quais o parceiro soropositivo está em tratamento com ART
- risco de transmissão do HIV entre o casal durante os períodos em que a camisinha não é utilizada de forma consistente e o parceiro soropositivo está em tratamento com ART supressivo



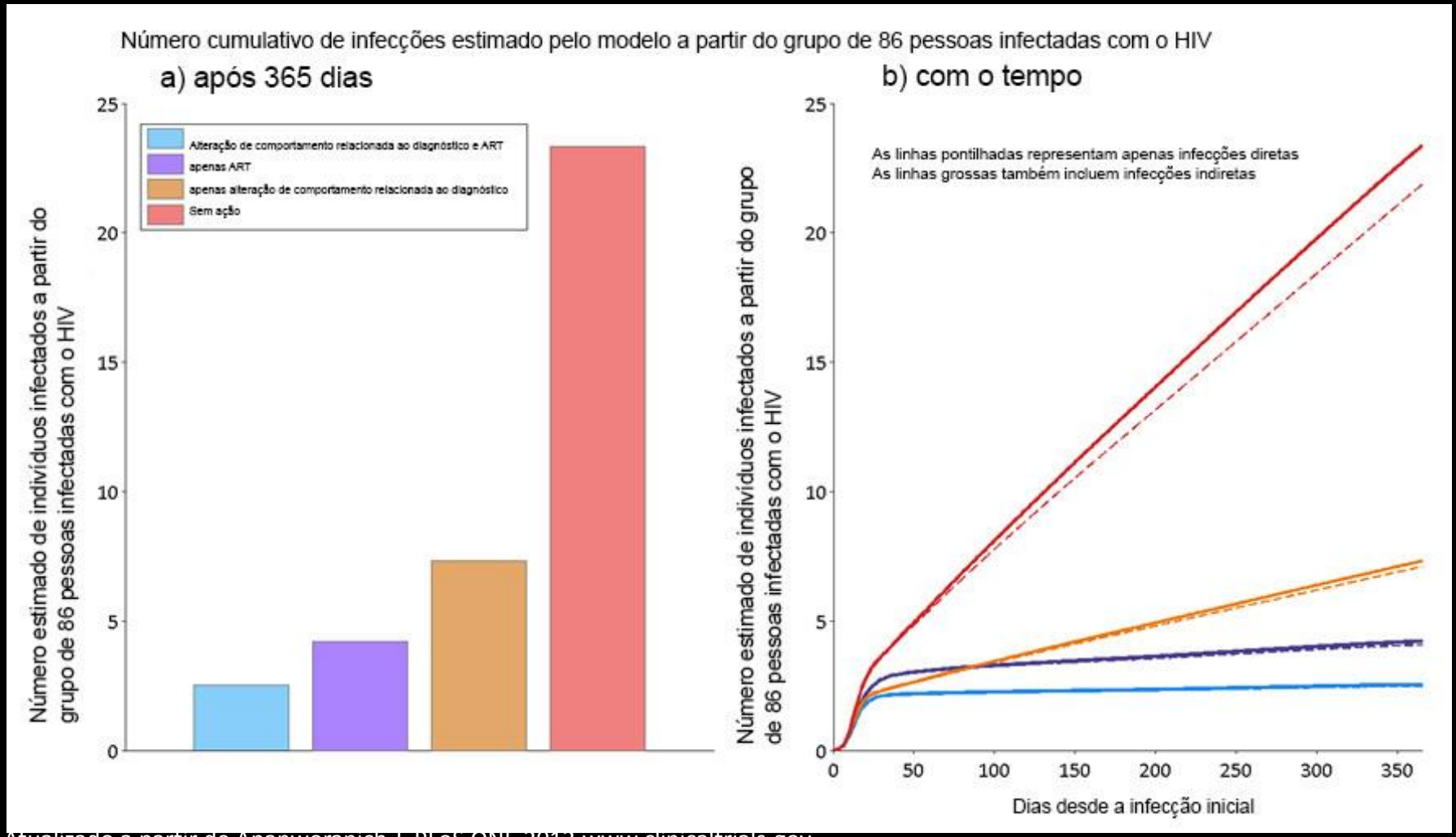
Rodger et al. HIV transmission risk through condomless sex if the HIV positive partner is on suppressive ART: PARTNER study . CROI 2014

Tratamento como Prevenção

Os Opostos se Atraem: Atualmente recrutando candidatos em Sydney, Melbourne, Brisbane, Rio de Janeiro e Bangkok

Criando Demanda para os Testes de HIV

Infecção Aguda
O Grupo de Bangkok



Atualizado a partir de Ananworanich J, PLoS ONE 2012 www.clinicaltrials.gov 00796146

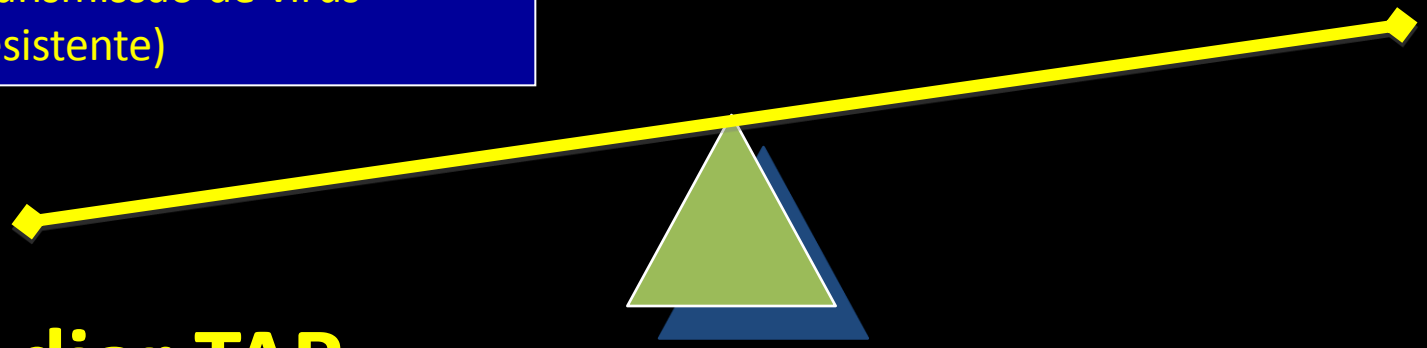
Impulsionadores da Transmissão de HIV entre HSH e Metas para Prevenção

Fator	Intervenções Biomédicas	Intervenções Comportamentais	Facilitadores Estruturais
Alto risco biológico de sexo anal	Preservativos, CCL, PrEP	↑uso de preservativos, aderência à PrEP, ↓ EtOH e uso de drogas	Distribuição de preservatives, CCHC, política para dar suporte à PrEP, tratamento de drogas
Alta carga viral nos parceiros	ART para soropositivos	Elo com o tratamento, a aderência ao ART, retenção no tratamento, teste de HIV	CCHC, cadeias estáveis de suprimento, capacidade de laboratório para monitoramento
Alta incidência de DST	Teste e tratamento	Adesão aos testes	CCHC, treinamento de fornecedores
Falta de consciência sobre a sorocondição de HIV	Teste de HIV	Adesão aos testes, revelação da sorocondição	CCHC, remover barreiras para testes, abordagens de revelação estrutural

Fonte: Patrick Sullivan , et al. The Lancet, 2012

Quando começar o tratamento

- Toxicidade farmacológica
- Preservando opções terapêuticas limitadas
- Risco de resistência (e transmissão de vírus resistente)

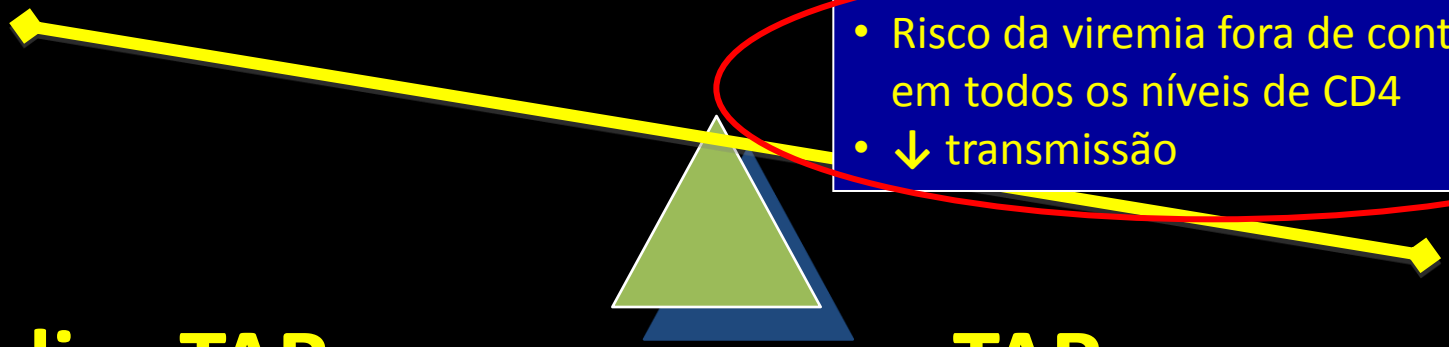


Adiar TAR

Quando começar o tratamento: o equilíbrio agora favorece o TAR precoce

- Toxicidade farmacológica
- Preservando opções terapêuticas limitadas
- Risco de resistência (e transmissão de vírus resistente)

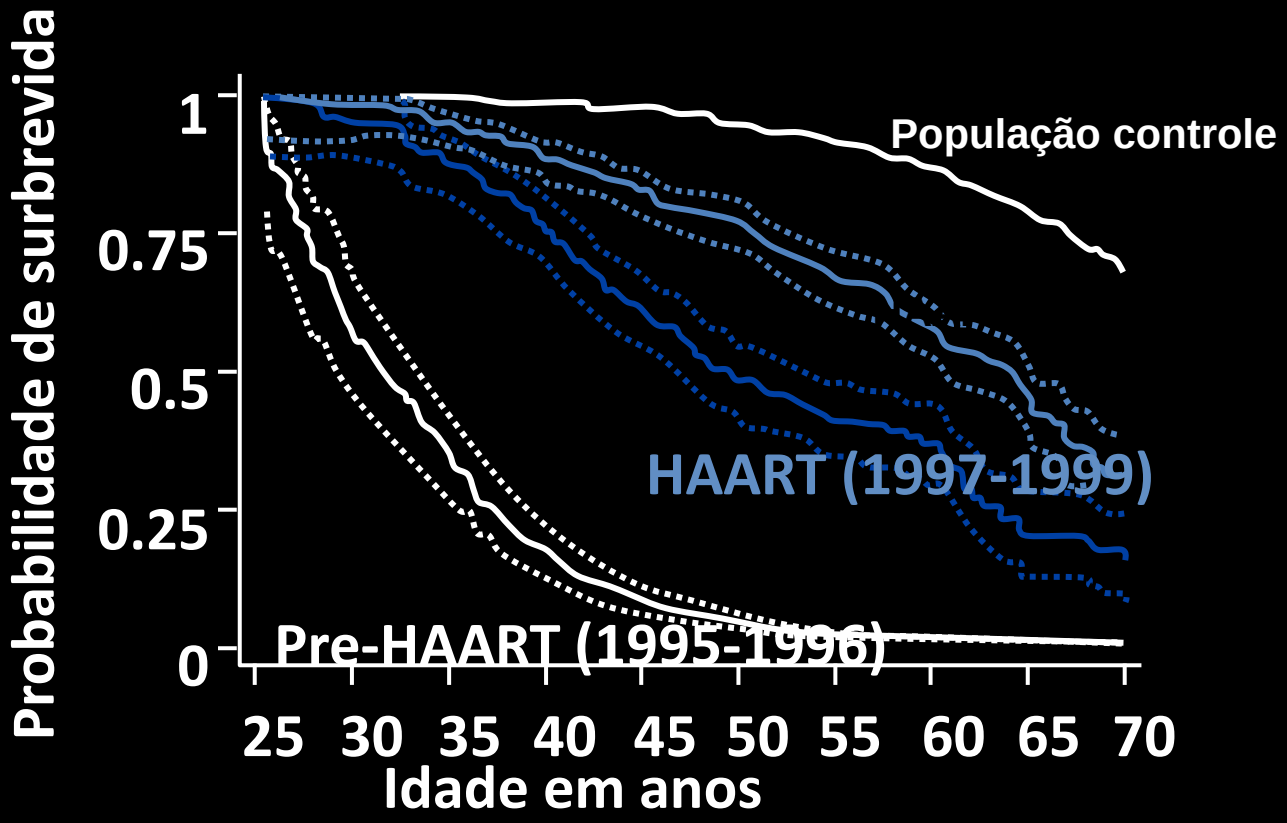
- ↑ potência, durabilidade, simplicidade e segurança dos esquemas atuais
- ↓ do aparecimento de resistência
- ↓ da toxicidade com TAR precoce
- ↑ opções terapêuticas subsequentes
- Risco da viremia fora de controle em todos os níveis de CD4
- ↓ transmissão



Adiar TAR

TAR precoce

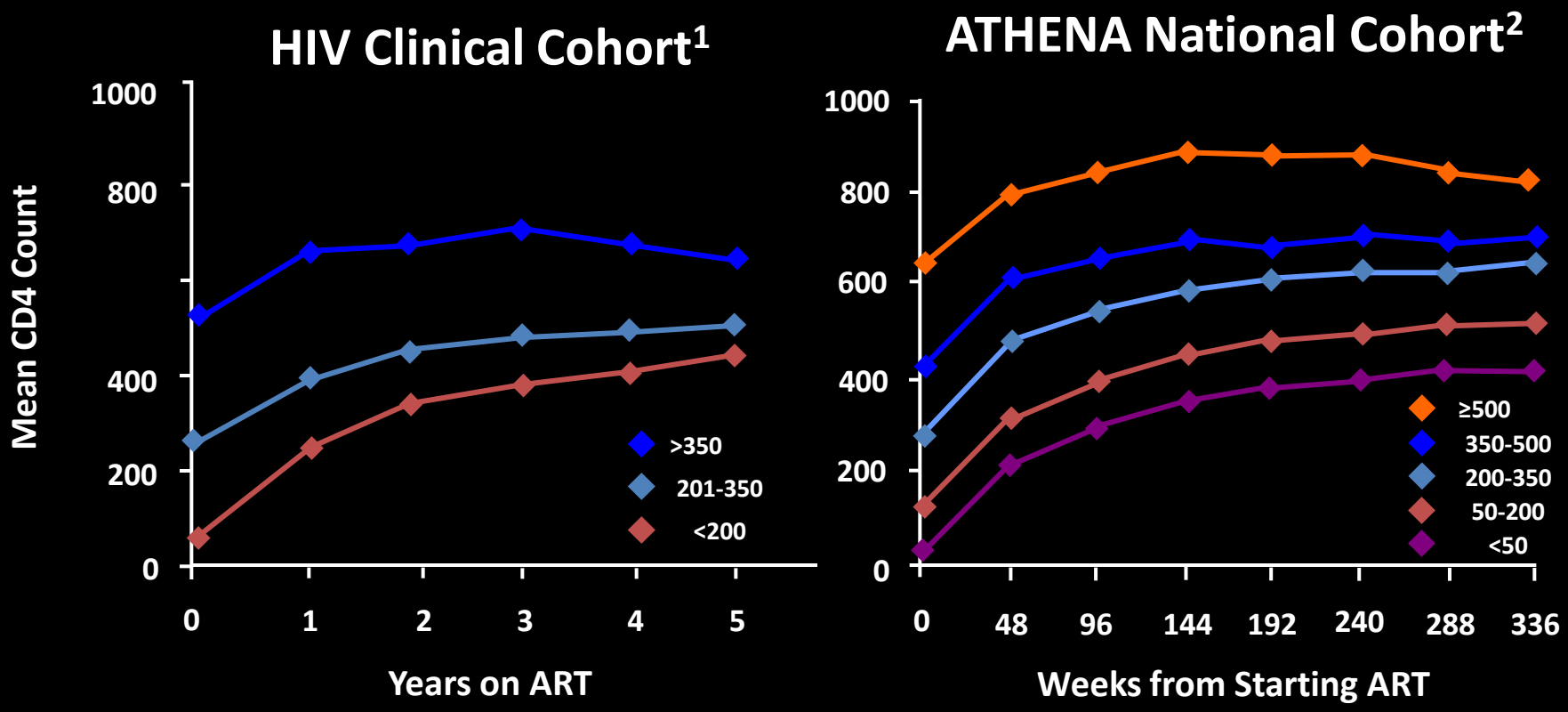
Sobrevida de Pacientes HIV +



Linhas picotadas representam o IC 95%

Lohse *et al. Ann Intern Med*. 2007; 146:87–95.

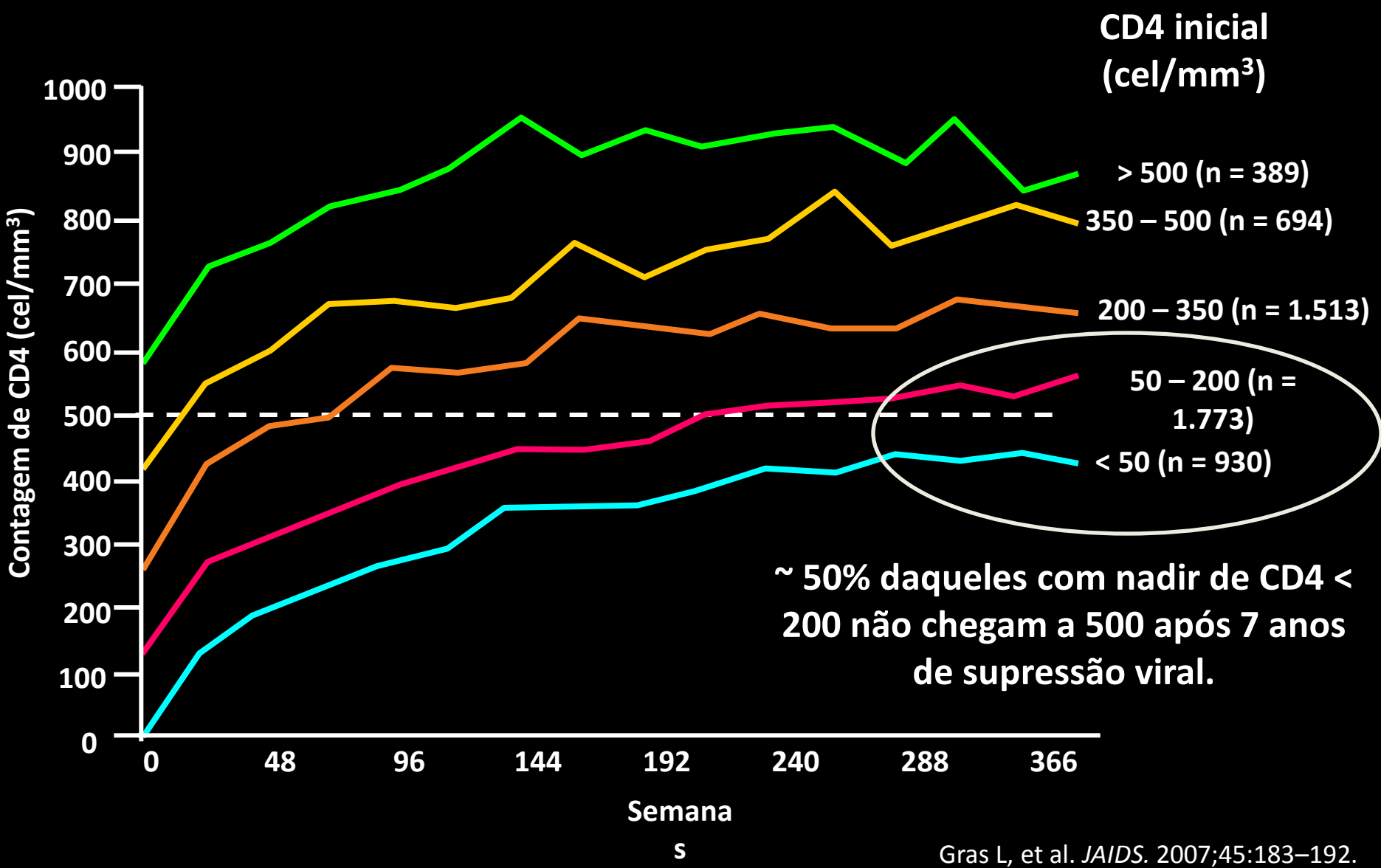
Chance de atingir CD4 normal depende do momento do início do TARV



- A amplitude do aumento da contagem de células CD4 é maior se a TARV for iniciada com baixa contagem de CD4, mas há maior probabilidade de normalização da contagem de CD4 com a terapia mais precoce.

[1]Moore R, et al. *Clin Infect Dis*. 2007;44(3):441-446. [2]Gras L, et al. *J Acquir Immune Defic Syndr*. 2007;45(2):183-192.

O ganho de CD4 abaixo do ideal é frequente nos pacientes que iniciam HAART tardiamente



~ 50% daqueles com nadir de CD4 < 200 não chegam a 500 após 7 anos de supressão viral.

Gras L, et al. *JAIDS.* 2007;45:183–192.

Long-Term CD4+ Cell Count in Response to Combination Antiretroviral Therapy

Paula M. Luz[1]*, Beatriz Grinsztejn[1], Luciane Velasque[1,2], Antonio G. Pacheco[4], Valdilea G. Veloso[1], Richard D. Moore[3], Claudio J. Struchiner[4]

1 Instituto de Pesquisa Clínica Evandro Chagas, Fundação Oswaldo Cruz, Rio de Janeiro, Brasil, **2** Departamento de Matemática e Estatística, Universidade Federal do Estado do Rio de Janeiro, Rio de Janeiro, Brasil, **3** Department of Medicine, Johns Hopkins University, Baltimore, Maryland, United States of America, **4** Programa de Computação Científica, Fundação Oswaldo Cruz, Rio de Janeiro, Brasil

Abstract

Objective: There is a continuous debate on how to adequately evaluate long-term CD4+ cell count in response to combination antiretroviral therapy (ART) among human immunodeficiency virus (HIV)-infected individuals. Our study evaluated the long-term CD4+ cell count response (up to ten years) after initiation of ART and described the differences in the CD4+ cell count response stratified by pretreatment CD4+ cell count, and other socio-demographic, behavioral, and clinical factors.

Methods: The study population included patients starting ART in the clinical cohorts of Rio de Janeiro, Brazil, and Baltimore, United States. Inverse probability of censoring weighting was used to estimate mean annual CD4+ cell counts while adjusting for choice of initial ART regimen, ART discontinuation and losses-to-follow-up.

Results: From 1997 to 2011, 3116 individuals started ART; preferred initial regimen was NNRTI-based (63%). The median follow-up time was 5 years, 10% of the individuals had nine or more years of follow-up. Observed CD4+ cell counts increased throughout the ten years of follow-up. Weighted results, in contrast, increased up to year four and plateaued thereafter with 50% of the population reaching CD4+ cell counts of 449/μL or more. Out of all stratification variables considered, only individuals with pre-treatment CD4+ cell counts ≥350/μL showed increasing CD4+ cell counts over time with 76% surpassing the CD4+ cell count >500/μL threshold at year ten.

Conclusion: The present study corroborates the growing body of knowledge advocating early start of ART by showing that only patients who start ART early fully recover to normal CD4+ cell counts.

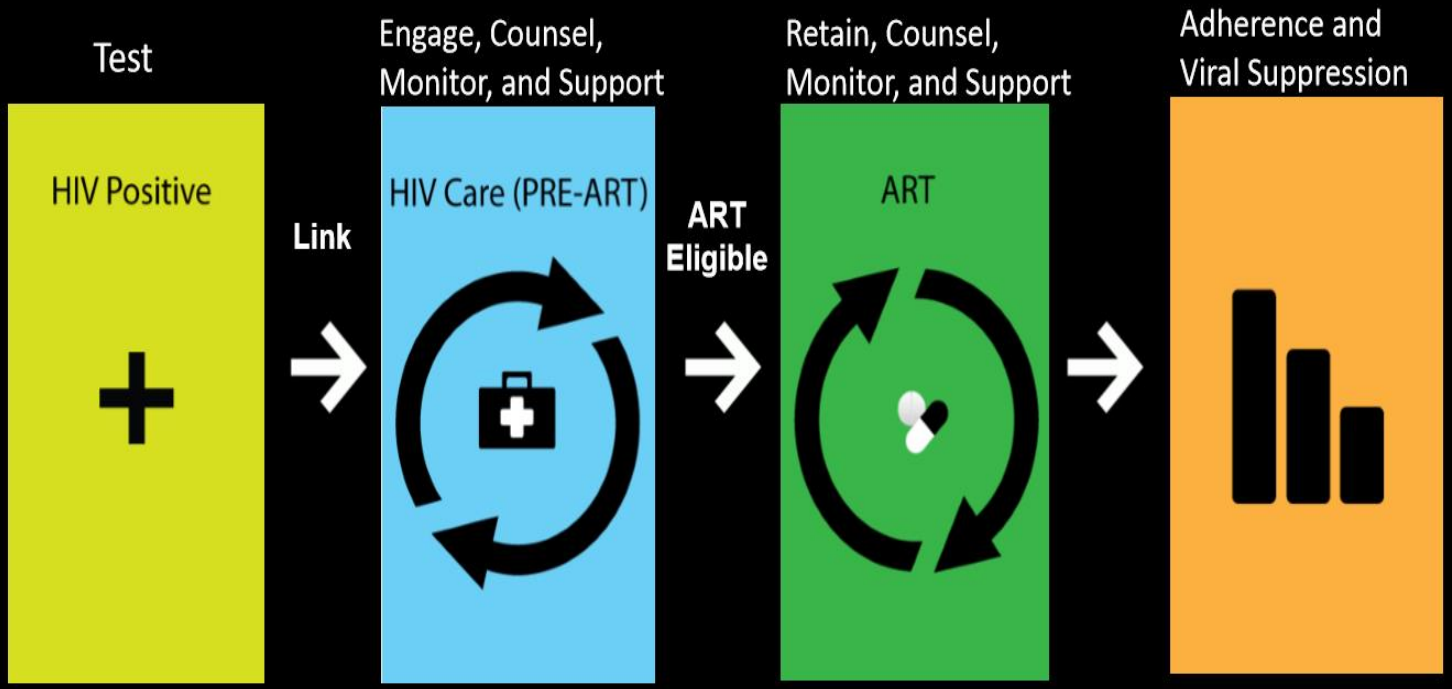
Razões o Tratamento Precoce

- Biologia do vírus – contínua evolução
- Destruição do tecido linfóide
- Inflamação e senescência
- Aumento da incidência das doenças cardiovasculares
- Aumento da incidência de doenças malignas
- Declínio cognitivo

Razões o Tratamento Precoce

- Drogas com melhor perfil de segurança e tolerabilidade
- Esquemas mais cômodos
- Dados de estudos observacionais
- Dados de ensaios clínicos

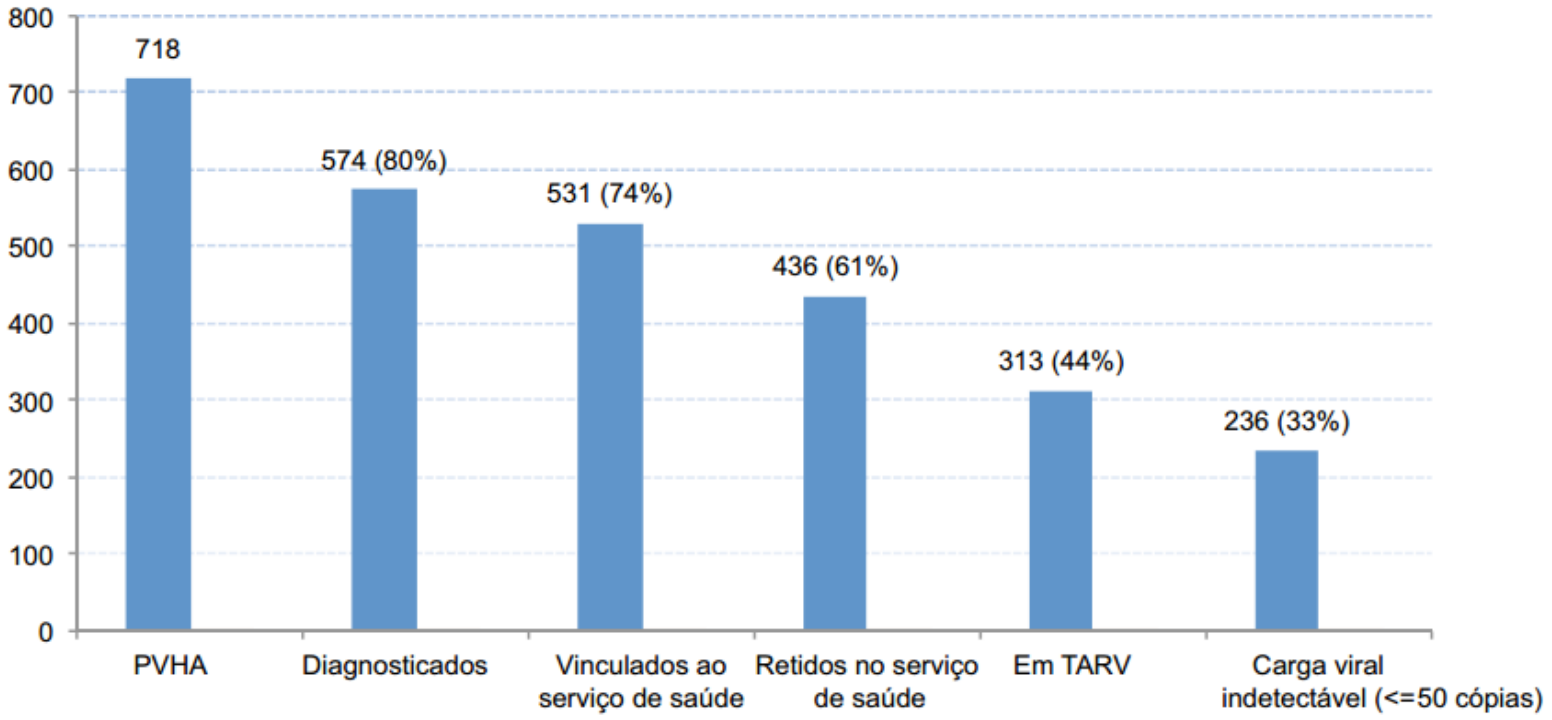
HIV Continuum



McNairy et al, AIDS 2012

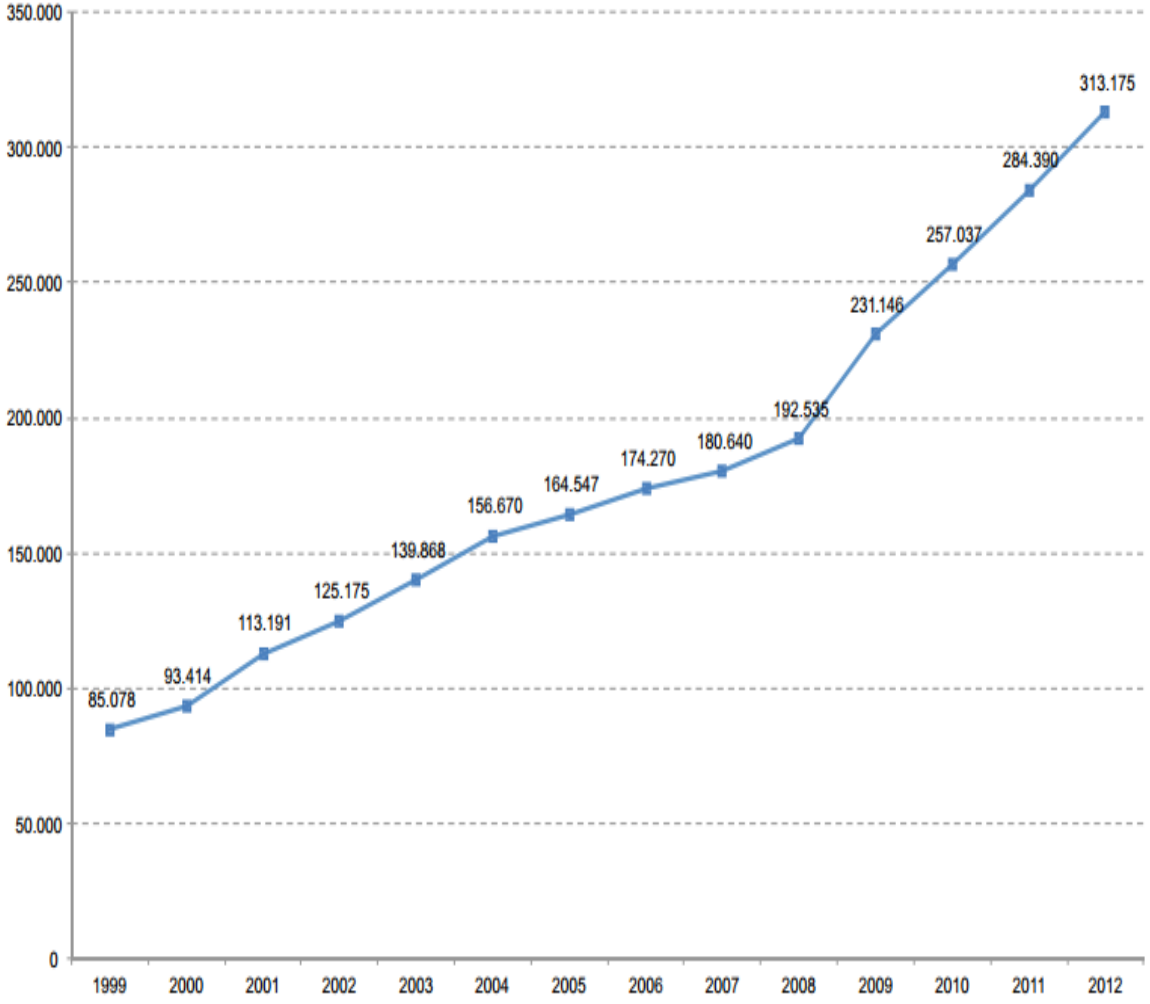
Cascata do Cuidado – Brasil 2012

Figura 2: Etapas do cuidado contínuo de pessoas vivendo com HIV/aids no Brasil em 2012 (em milhares)



Fonte: MS/SVS/Departamento de DST, Aids e Hepatites Virais/Casos registrados no Siscel e no Siclom até 31/12/2012

Figura 4: Número de pacientes em TARV. Brasil, 1999-2012



Fonte: MS/SVS/Departamento de DST, Aids e Hepatites Virais/Casos registrados no Siscel e no Siclom até 31/12/2012

Proporção de pacientes HIV+ virgens de terapia ARV diagnosticados com CD4 abaixo de 200 registrados no SISCEL Brasil, 2006 - 2012.

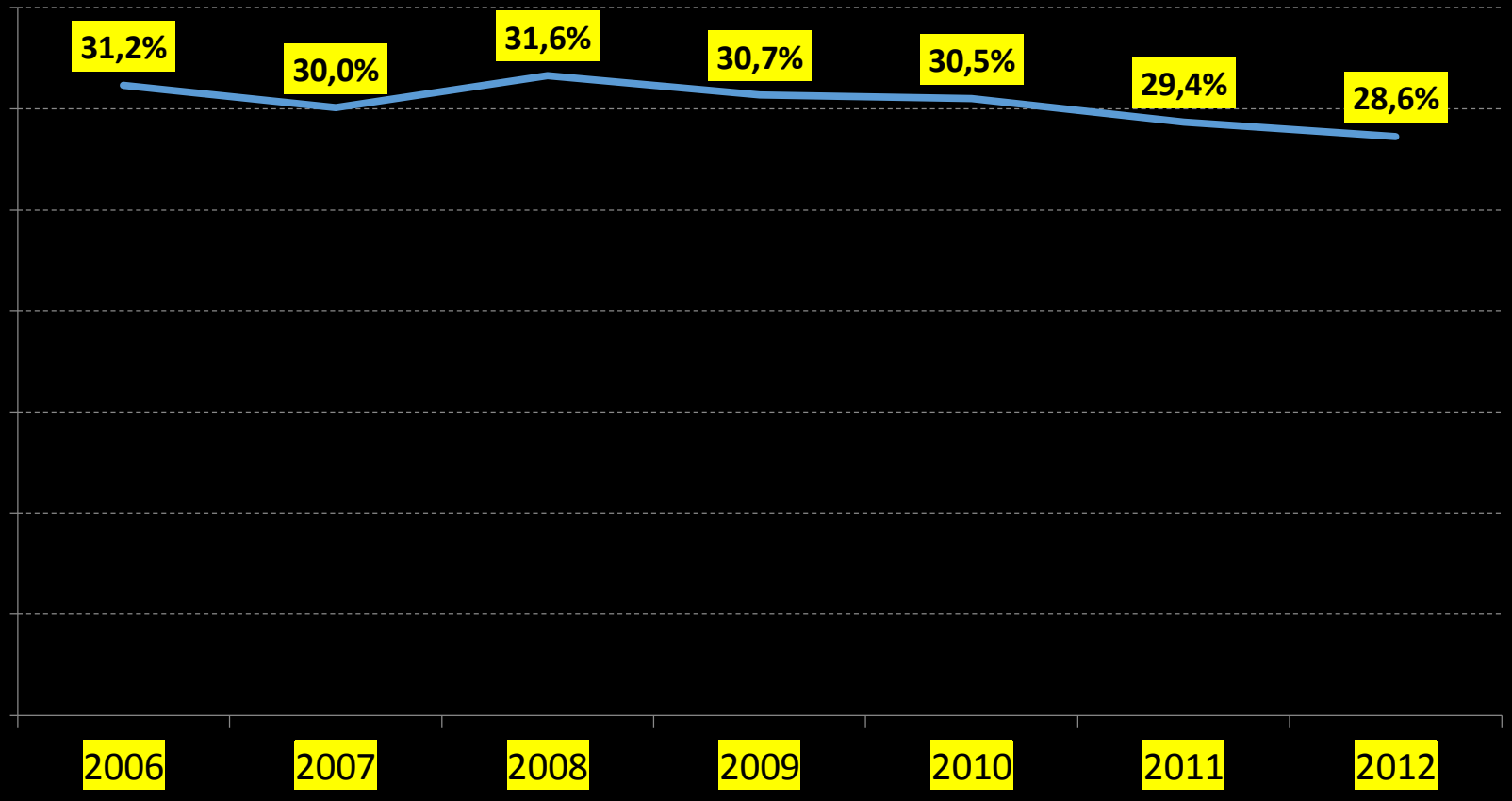
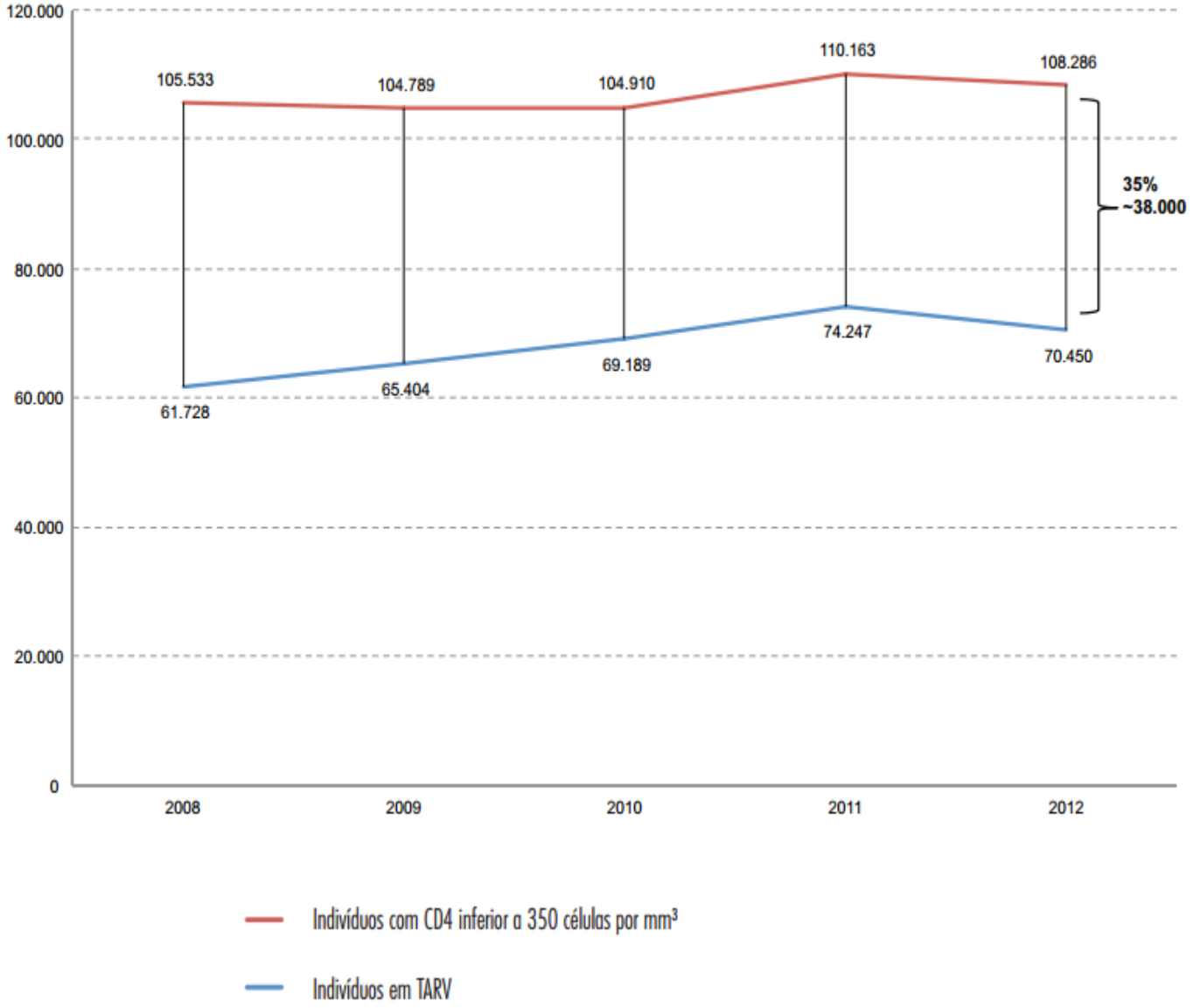
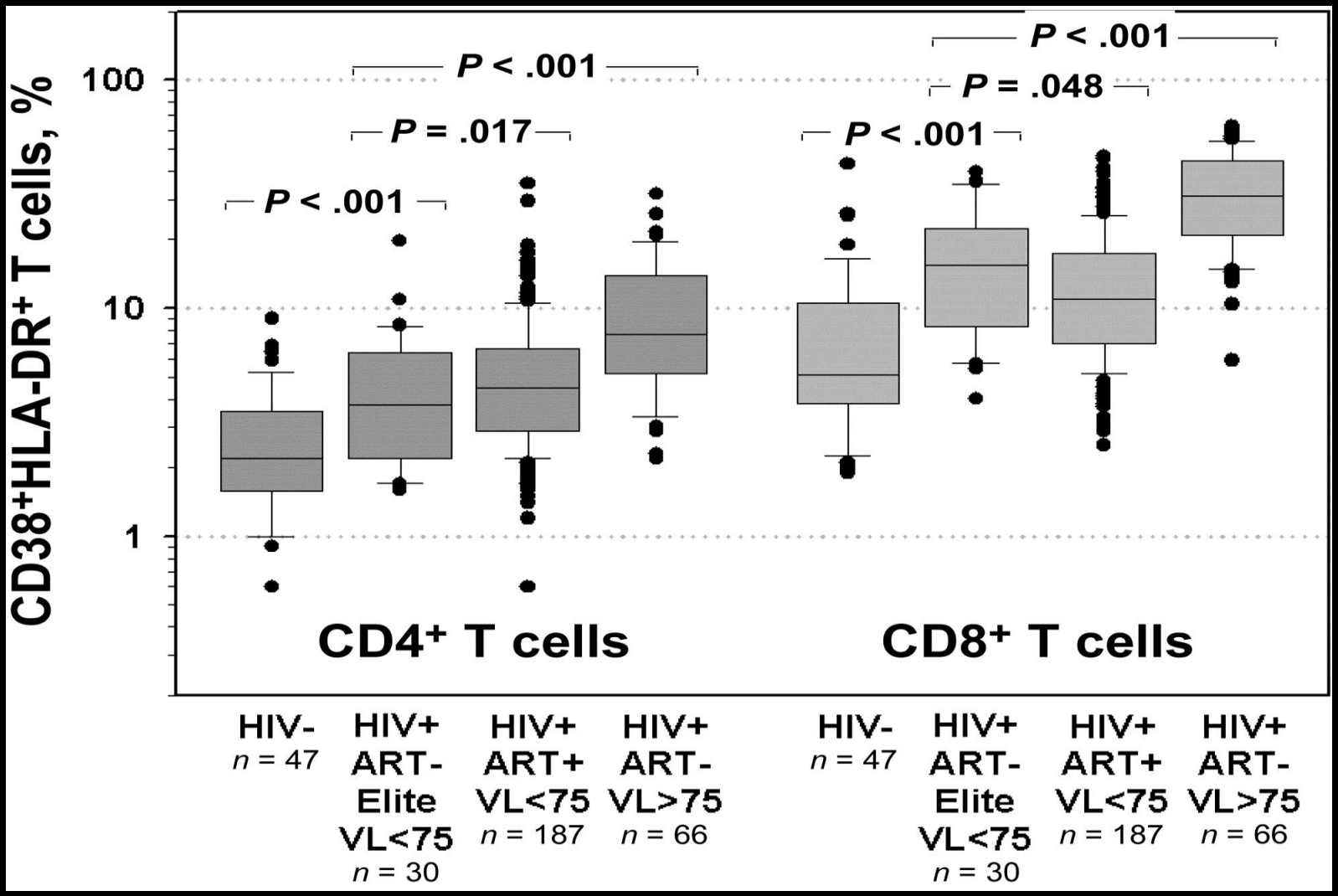


Figura 5: Número de indivíduos com CD4 menor que 350 células por mm³ que estavam em TARV. Brasil, 2008-2012



Fonte: MS/SVS/Departamento de DST, Aids e Hepatites Virais/Casos registrados no Siscel e no Siclom até 31/12/2012

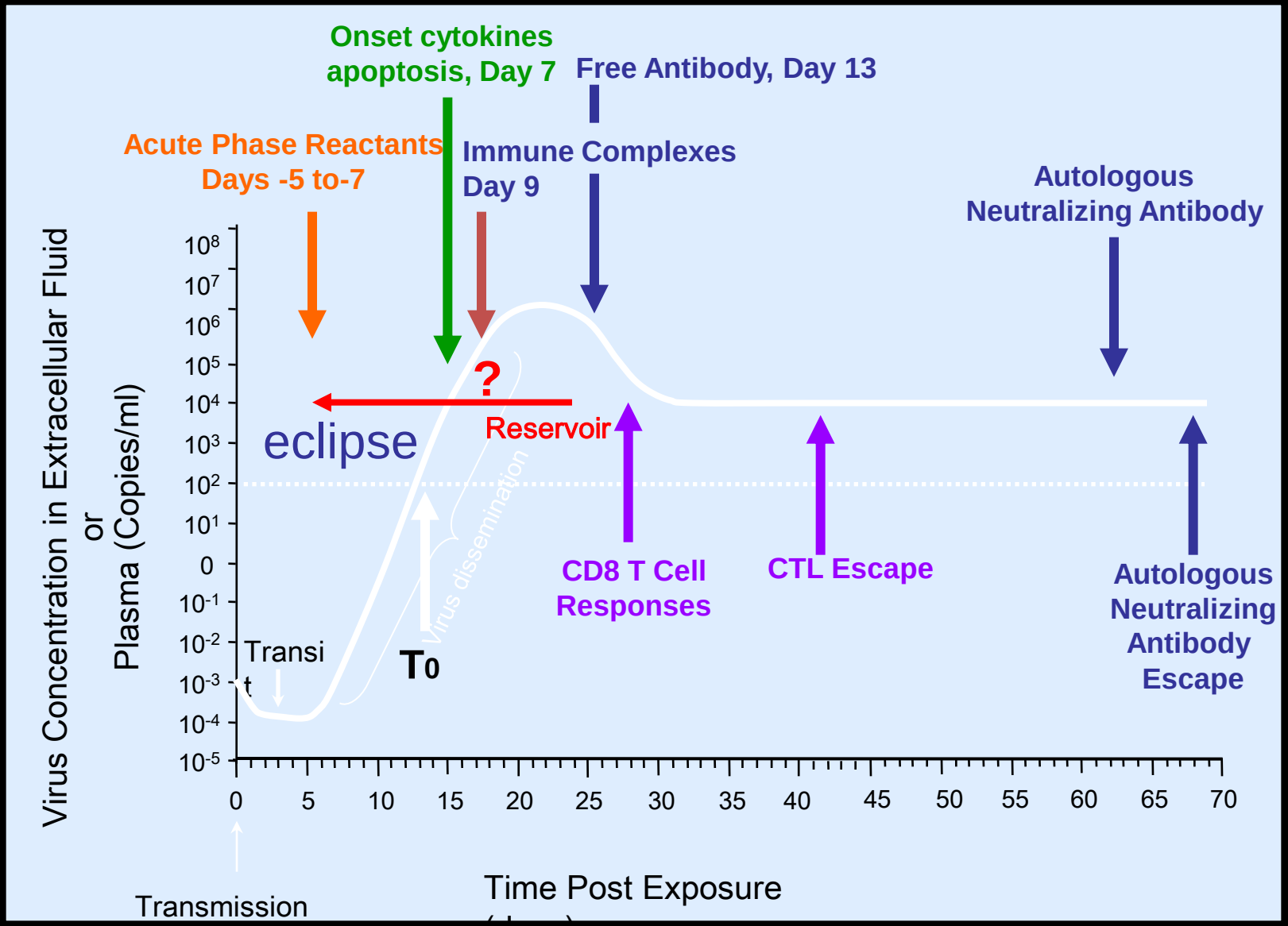
Ativação imunológica persistente durante o TARV



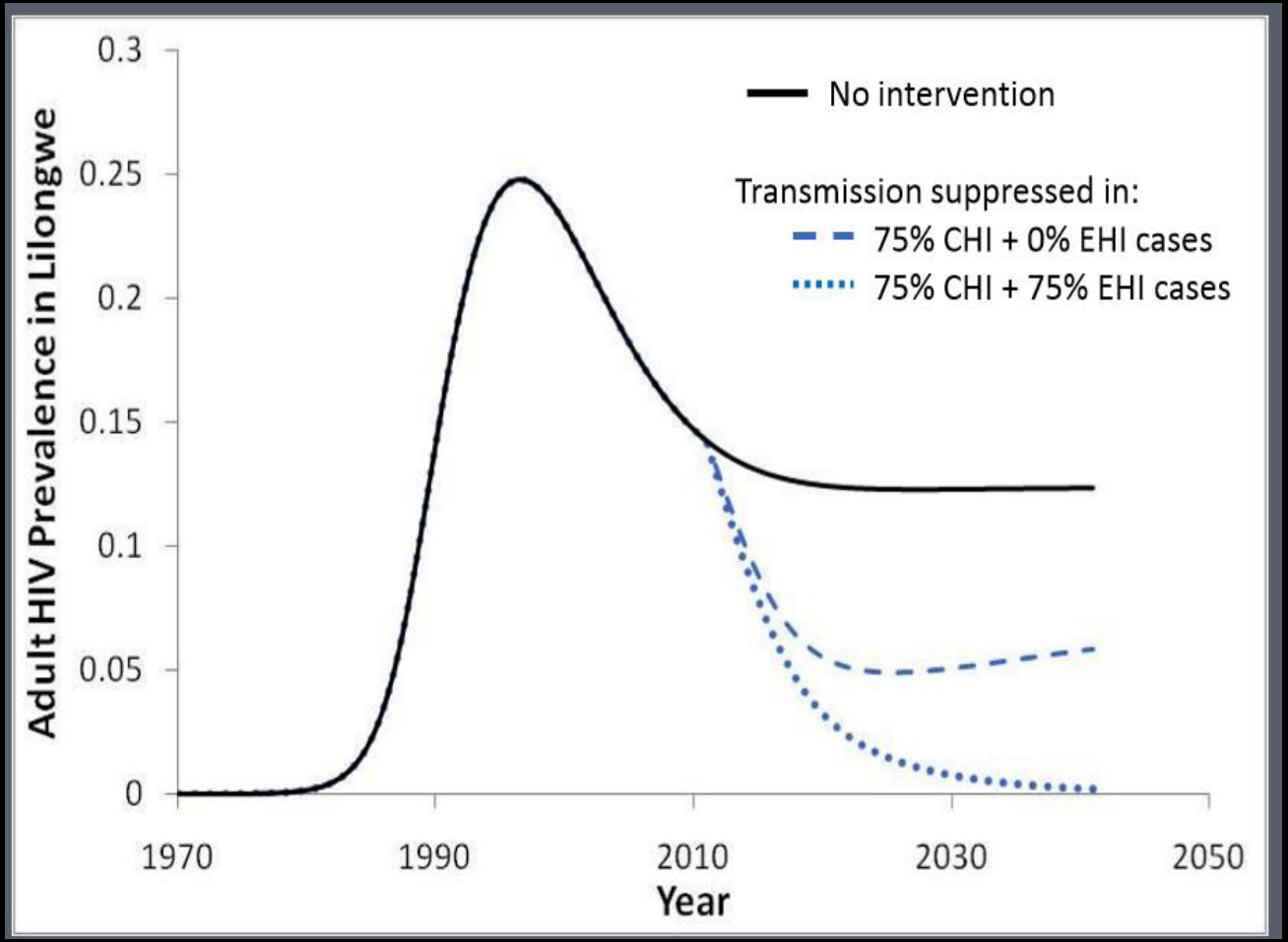
From J INFECT DIS Hunt et al 197(1):126-133.

Acute HIV-1 Infection

Cohen et al, NEJM, 2011



Tratamento da Infecção Aguda



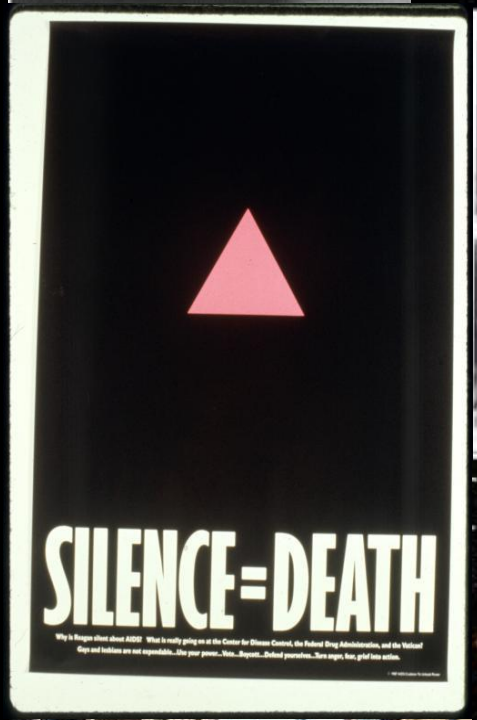
Desafios do TasP na Epidemia em HSH

- Uma maior proporção de infecções em redes de HSH devido a infecções agudas/recentes
- Incidência mais alta de HIV em uma camada mais jovem em vários cenários
  - menos propensos a fazer tratamento
- Diagnóstico tardio do HIV
  - para a maioria dos homens no mundo, o início do tratamento em 2013 ainda estava abaixo dos 300 CD4s
- Compensação de risco?
  - aumento de outras DSTs (EUA, Reino Unido, França, Austrália)
- Dados indisponíveis para a população transexual

Considerações Finais

- Gays, HSH e Travestis continuam correndo alto risco de infecção por HIV em todo o mundo
- A sinergia entre TasP & PrEP
- Homofobia / Transfobia / Criminalização


AIDS: WHERE IS YOUR RAGE? IN THE TRADITION OF STONEWALL
ACT UP! FIGHT BACK! FIGHT AIDS!
QUEERS FIGHTING AIDS!!


SILENCE=DEATH


IV ENCONTRO NACIONAL
DE PESSOAS VIVENDO
DINHEIRO FALTANDO!
AIDS


AIDS 2014


HOW TO
SURVIVE
A PLAGUE


WE DIE - THEY DO NOTHING!
WE DIE - THEY DO NOTHING


"Há uma coisa dentro de mim, contagiosa e mortal, perigosíssima, chamada vida, lateja como desafio".