Cost-Effectiveness of PrEP

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Disclosures

- Member of the HPTN 069 NEXT-PrEP (Novel Exploration of Therapeutics for PrEP) clinical trial team
- No financial disclosures

Agenda

- Cost-effectiveness overview
- PrEP cost-effectiveness model considerations
- Cost-effectiveness of PrEP in United States and South Africa: current findings
- Issues and future research needs

Cost-effective ≠ Cost saving

Cost-effectiveness is about value for money

- Cost-effectiveness analysis is about comparative assessment of worth
- Very, very few health interventions are cost-saving
- Cost-effectiveness is evaluated from the societal perspective
- Cost-effectiveness analysis does not directly address the cost impact on specific budgets

Only one of many measures of the appropriateness of health interventions

- Clinical duty
- Ethical duty
- Equity / justice
- Patient preference
- Economic efficiency

Choosing a cost-effectiveness threshold

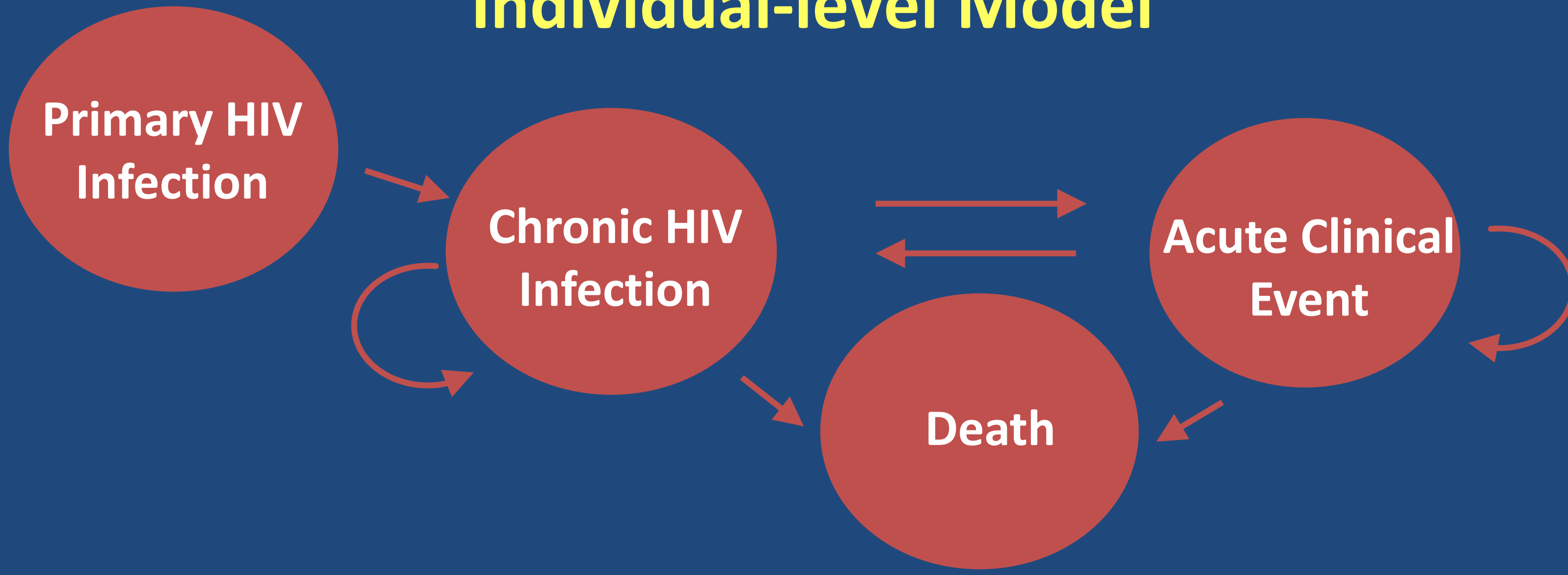
- $100,000/QALY now frequently used in the US
- 1-3x GDP/capita frequently used in middle and low-income countries
  - $8,100/DALY-$24,300/DALY for South Africa
  - Although benchmark is $/DALY, also has been applied to $/LY

Discounting: valuing appropriately over time

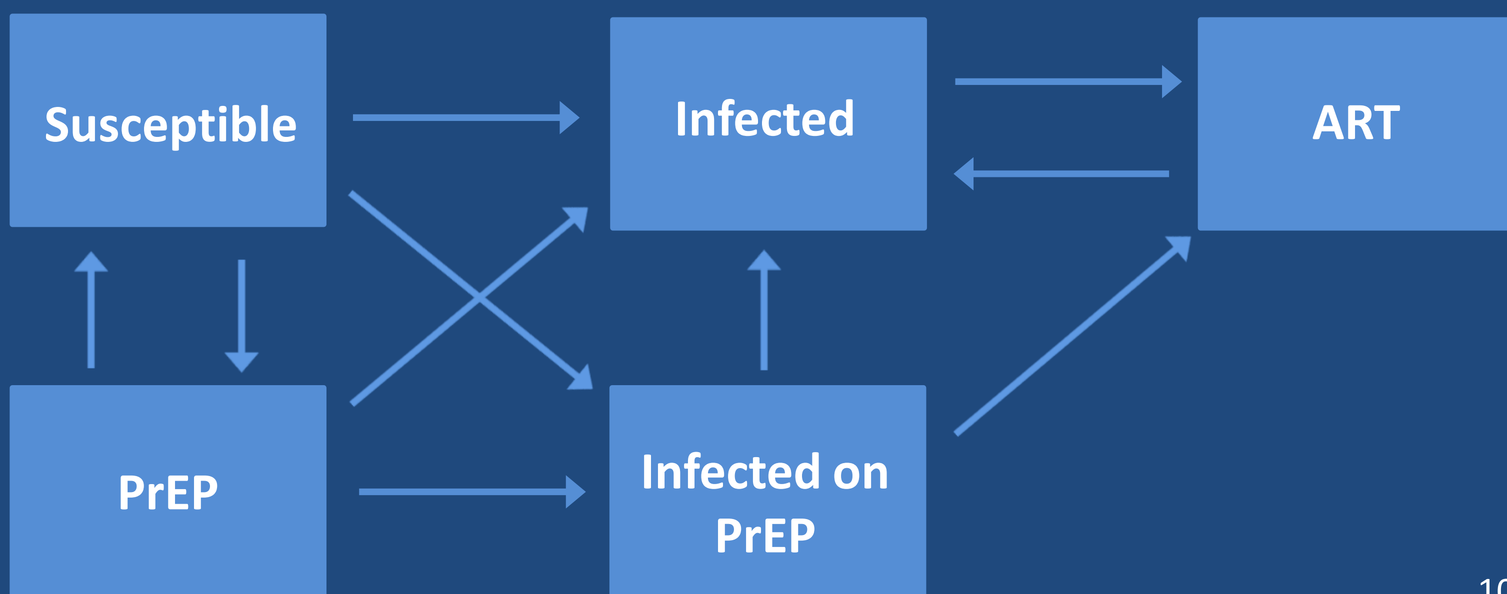
- We prefer receiving benefits (money, health) now versus later
- Discounting reduces future streams of costs and effects to a common **present value**
- Spending on prevention now may not bear fruit for many years
- Treatments that save lives now can result in additional costs in the future
- Impact depends on when costs and benefits occur and the time horizon of the study

All models are wrong, some models are useful

Individual-level Model



Transmission Model



Individual-level model inputs

- Target population demographics
- HIV incidence (varies by age/risk group)
- Effectiveness of PrEP (efficacy, adherence)
- Disinhibition (reduces effectiveness of PrEP)
- Duration of PrEP (e.g. lifetime, 20-30 years)
- Risk of resistance
- HIV testing frequency with and without PrEP
- ART initiation with and without PrEP

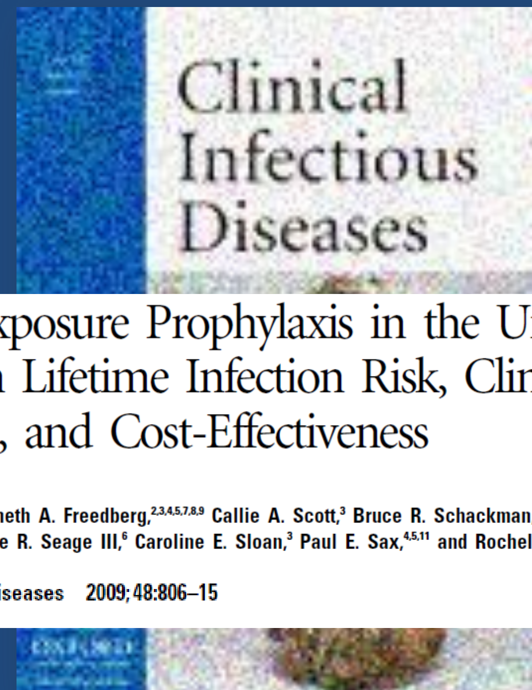
Transmission model inputs

- Initial HIV prevalence
- Initial ART coverage and changes over time
- Initial coverage of other prevention programs (condom use) and changes over time
- Timing of PrEP roll-out into the population

Modeling the impact of HIV chemoprophylaxis strategies among men who have sex with men in the United States: HIV infections prevented and cost-effectiveness

Kamal Desai[a], Stephanie L. Sansom[b], Marta L. Ackers[b], Scott R. Stewart[c], H. Irene Hall[b], Dale J. Hu[b], Rachel Sanders[d], Carol R. Scotton[b], Sada Soorapanth[b], Marie-Claude Boily[a], Geoffrey P. Garnett[a] and Peter D. McElroy[b]

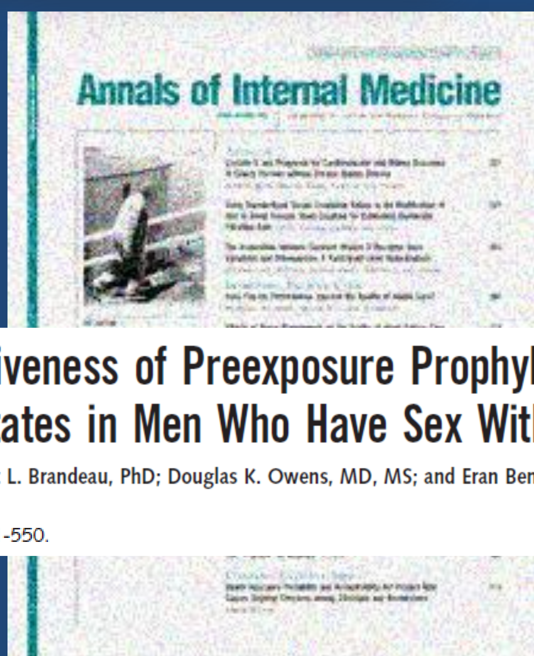
AIDS 2008, **22**:1829–1839



HIV Preexposure Prophylaxis in the United States: Impact on Lifetime Infection Risk, Clinical Outcomes, and Cost-Effectiveness

A. David Paltiel,[1] Kenneth A. Freedberg,[2,3,4,5,7,8,9] Callie A. Scott,[3] Bruce R. Schackman,[12] Elena Losina,[8,9,10] Bingxia Wang,[3] George R. Seage III,[6] Caroline E. Sloan,[3] Paul E. Sax,[4,5,11] and Rochelle P. Walensky[2,3,4,5,11]

Clinical Infectious Diseases 2009; 48:806–15



The Cost-Effectiveness of Preexposure Prophylaxis for HIV Prevention in the United States in Men Who Have Sex With Men

Jessie L. Juusola, MS; Margaret L. Brandeau, PhD; Douglas K. Owens, MD, MS; and Eran Bendavid, MD, MS

Ann Intern Med. 2012;156:541-550.

Study model characteristics

	Desai (2008)	Paltiel (2009)	Juusola (2012)
Type	**Transmission**	**Individual-level**	**Transmission**
Time horizon	**5 years**	**lifetime**	**20 years**
PrEP	tenofovir/ emtricitabine	tenofovir/ emtricitabine	tenofovir/ emtricitabine
No PrEP	unclear	Annual HIV testing and ART initiation at CD4 <350	67% annual testing and ART initiation at CD4<350 or CD4<500
Base case HIV incidence	0.75%-1.85% (varies by age)	1.6%	0.8%, 2.3% high risk

Study model inputs for PrEP

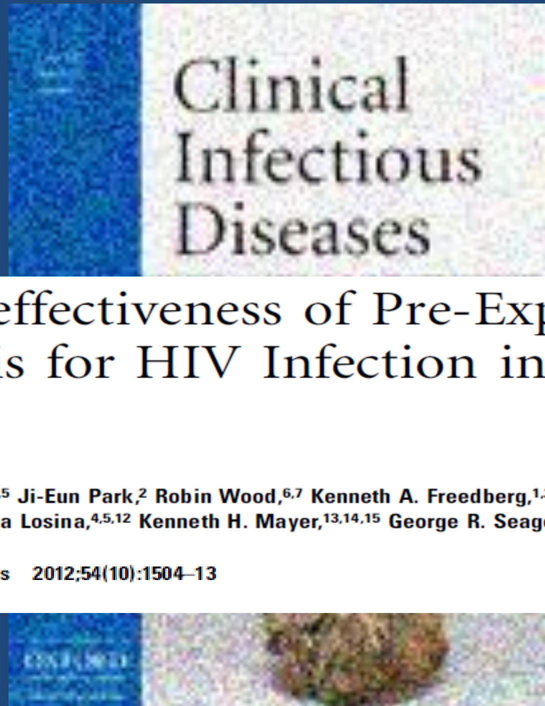
	Desai (2008)	Paltiel (2009)	Juusola (2012)
Effectiveness	50%	50%	44%
Monthly medication cost	$943	$724	$776
Full use of meds?	Yes	Yes	Yes
Monitoring	quarterly	lab quarterly, MD semi-annually	every 2-3 months
Labs	“medical monitoring”	HIV, CBC, metabolic, chemistry, lipids	HIV, STI, creatinine, urea nitrogen
Resistance evaluated?	No	Yes	Yes

Cost-effectiveness of PrEP in US MSM: study findings

- Cost-effectiveness ratio is more attractive when PrEP is targeted to high-risk MSM:
  - <$100,000/QALY with high incidence (2-3%) vs. >$200,000/QALY with lower incidence (0.8%)
  - Mixed results for intermediate incidence (1-2%)
  - Ways to target: younger age, 5+ annual partners, not being tested for HIV annually
- Cost-effectiveness improves dramatically when effectiveness improves or cost of PrEP is lower
- Results less sensitive to resistance, toxicity

Cost of PrEP in US MSM

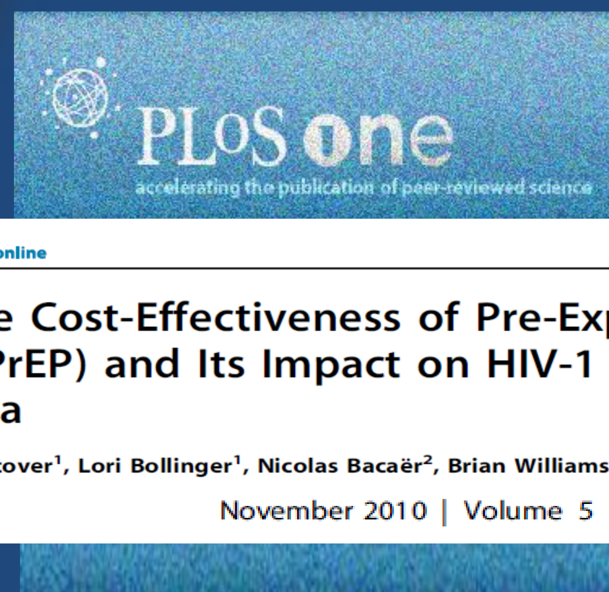
- High-risk MSM, average annual cost for a 20-year program (based on Juusola, 2012)
  - 100% coverage: $4,250 million cost, $500 million health care savings, $3,750 million net cost
  - 20% coverage: $850 million cost, $150 million health care savings, $700 million net cost



The Cost-effectiveness of Pre-Exposure Prophylaxis for HIV Infection in South African Women

Rochelle P. Walensky,[1,2,3,5] Ji-Eun Park,[2] Robin Wood,[6,7] Kenneth A. Freedberg,[1,2,5,8,11] Callie A. Scott,[2] Linda-Gail Bekker,[6,7] Elena Losina,[4,5,12] Kenneth H. Mayer,[13,14,15] George R. Seage III,[9,10] and A. David Paltiel[16]

Clinical Infectious Diseases 2012;54(10):1504–13



OPEN ACCESS Freely available online PLoS one

Evaluating the Cost-Effectiveness of Pre-Exposure Prophylaxis (PrEP) and Its Impact on HIV-1 Transmission in South Africa

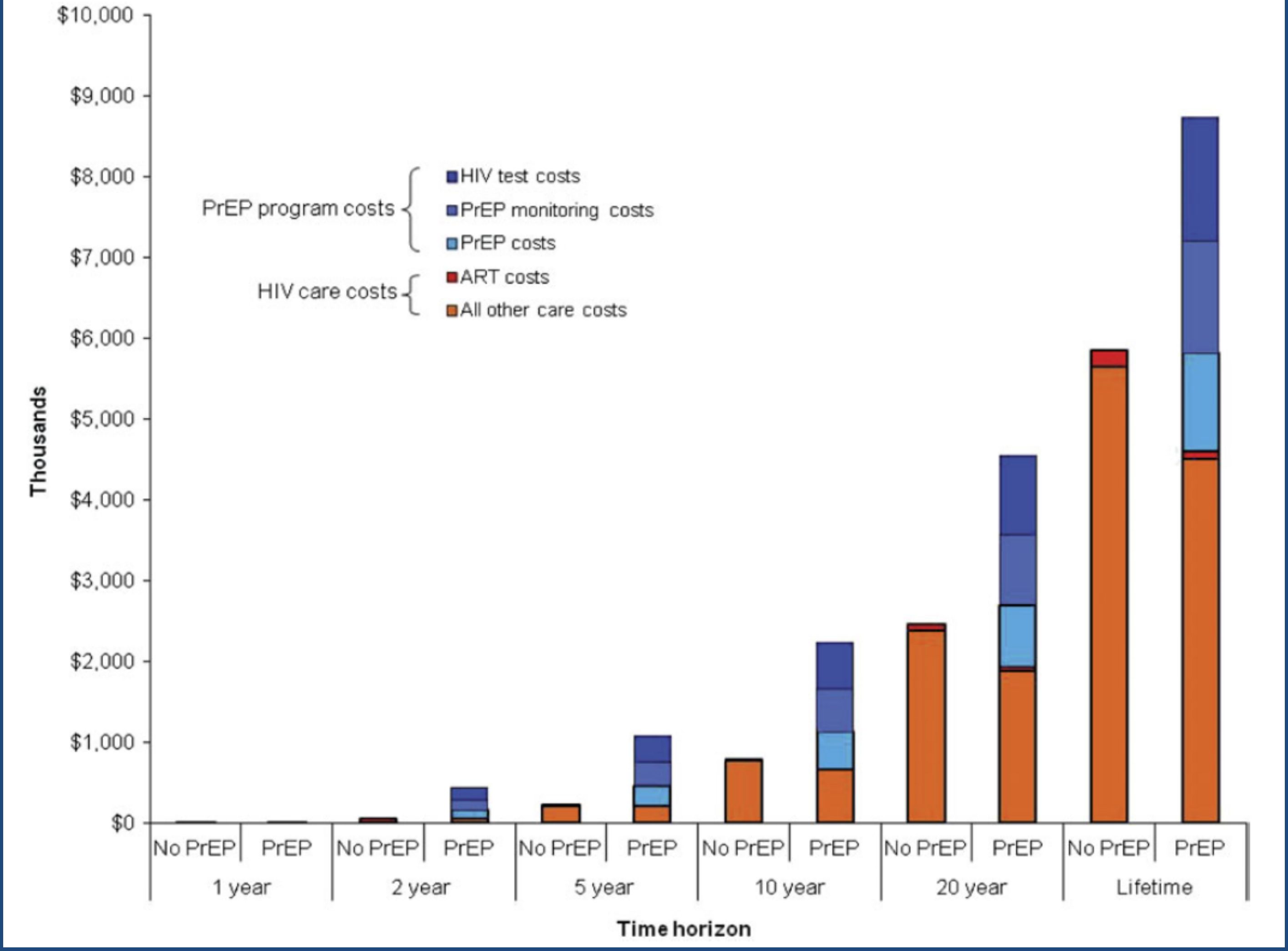
Carel Pretorius[1]*, John Stover[1], Lori Bollinger[1], Nicolas Bacaër[2], Brian Williams[3]

November 2010 | Volume 5 | Issue 11 | e13646

Cost-effectiveness of PrEP in young South African women

- Walensky (2012) modeled individual-level impact of 39% efficacy vaginal gel based on CAPRISA results, annual PrEP cost $188, lifetime perspective
- Cost-effectiveness is <1 x South Africa GDP at 2.2% annual incidence age 25 and younger
- May be cost saving if targeted to higher risk women <u>and</u> higher efficacy or lower cost
- Results less sensitive to resistance, toxicity

Cumulative cost in young South African women (US$ per 1,000 women enrolled)



Impact of ART expansion in South Africa on cost-effectiveness of PrEP in young women

- Pretorius (2010) extended a previous model of transmission impact of expanded ART coverage in South Africa to examine PrEP
- Results point to interaction between PrEP and ART coverage
  - At current ART coverage, synergies occur with PrEP
  - PrEP becomes less cost-effective with expanded ART coverage, but impact occurs only when coverage is 3x level in 2010
  - PrEP retains impact longer when targeted to higher risk women

Issues identified across studies

- Implementation impact on efficacy and cost
  - Adherence: medication adherence and wastage, monitoring adherence, duration of PrEP
  - Coverage of target group vs. those at low risk
- Interaction between PrEP and TasP
  - Individual-level: testing and entry into care
  - Transmission: impact of TasP on probability of transmission without PrEP

Priorities for future studies

- Evaluating new PrEP modalities, integrating cost-effectiveness studies into clinical trials
- Evaluating “real world” implementation
  - Uptake in high risk groups
  - Adherence and duration on PrEP
  - Access barriers and insurance coverage
  - Budget impact
- Modeling cost-effectiveness of combination interventions, including PrEP and TasP

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