What PAs Need to Know About HIV Prevention and Preexposure Prophylaxis (PrEP)

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Disclosure

- Jonathan Baker & Kerin Berger have no relevant financial, professional or personal relationships to disclose.
- We will discuss off-label use of medications and procedures:
 - Emtricitabine and tenofovir for Hepatitis B Virus treatment • Intermittent emtricitabine/tenofovir dosing for HIV pre-exposure prophylaxis

 - *Off label medications

and procedures will be identified on the slides

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Objectives

- At the end of this session, participants should be able to:
- Identify risk factors for HIV among patients
- Become familiar with HIV prevention methods, including PrEP, PEP, and treatment as prevention
- Reference current guidelines for the use of ARVs as prevention • Discuss how HIV prevention can be tailored as part of patient-
- centered care

You're a PA in Internal Medicine...

A 54 year old black female patient presents for her annual exam

- PMHx: hypothyroid, post-menopausal
- Medications: levothyroxine, multivitamin
- NKDA, no significant family Hx, no surgical Hx
- Social Hx: Divorced from her husband 3 months prior

What STI Testing is Appropriate for this Pt?

On sexual history the patient reports 2 male partners in the last 3 months. She does not use condoms because she is post-menopausal. She engages in oral-penile intercourse, oral-vaginal intercourse, penilevaginal intercourse. She denies anal intercourse or anolingus.

- HIV, urine gc/Ct, oral gc/Ct, syphilis
- She declines HIV testing stating that she is not at risk...
- What patient education is appropriate?















Lab Results

Lab Results:		
• HIV Ag/Ab	NR	S
 Genital gc 	NR	G
 Oral gc 		C

Syphilis NR Genital Ct NR Dral Ct NR

Now what patient education is appropriate for this patient?

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CDC Recommendations for PrEP

Heterosexual with opposite gender sexual partner in last 6 months • Infrequent condom use with 1+ partners with HIV risk factors OR

• sexual relationship with HIV

624,000 individuals in the US meet this criteria

Smith

Preexposure Prophylaxis (PrEP)

HIV-negative people at high risk of acquiring HIV employing antiretroviral medication to reduce risk of becoming infected with HIV as part of comprehensive HIV prevention services

Daily oral tenofovir/emtricitabine is the only FDA approved PrEP

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Pr	EP Randomized	Controlled Clini	cal Tr	ials
Study	Location	Population	Drug	Prevention
iPrEX	International & Domestic	2,499 MSM	F/TDF	44%
Partners PrEP	Africa (Kenya, Uganda)	4,758 heterosexual Serodiscordant couples	TDF F/TDF	62% 73%
TDF2	Botswana	1,219 heterosexuals (🕬 😵)	F/TDF	63%
Bangkok Tenofovir	Bangkok	2413 IVDU (ഔ&೪)	TDF	48.9%
iPergay	France & Canada	414 MSM (2-1-1 dosing)	F/TDF	86%
Discover	International & Domestic		F/TAF	TAF noninferior*
FEM-PrEP	Africa	1,951 heterosexual women	F/TDF	Unable to
VOICE	Africa	5.029 heterosexual women	F/TDF	Evaluate

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PrEP Real World Efficacy

Estimated >450,000 individuals on PrEP with ~6 cases of failure

• No HIV diagnoses among 657 individuals in the Kaiser system

- No HIV diagnoses among 972 individuals in the Northern CA Kaiser
- PROUD Study- 544 patients randomized to delayed or immediate PrEP
 3 infections in "immediate" arm
- 20 infections in "deferral" arm (12 month deferral)
- No HIV diagnoses among 3700 MSM New South Whales (ongoing)
 - 35% statewide reduction in HIV diagnosis among MSM

olk 2015, Chan 2016, Marcus 2016, McCormack 2016, Grulich 2018



You're a PA in Primary Care...

A 25 year old Latino, male patient presents to establish care

• No PMHx, medications, drug allergies, family Hx, surgical Hx

• Social Hx: Admits social etoh, denies drug use

• Sexual Hx: He asks "this is confidential right? Will my parents find out my answers?" He reports only ever having 1 partner and always using condoms.

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You're a PA in Primary Care...

You assure your visibly nervous pt of confidentiality & standard Qs

• Your culturally sensitive sexual history identifies:

- *M*, *AMAB* (assigned male at birth), *He Pronouns*, who reports having only male sexual partners x 4 years. No primary partner. Engages in anal intercourse, oral-penile sex. Denies oral-anal sex. He sometimes meets his partners on a social app on his phone.
- No longer visibly nervous, he admits to 4 partners in the last 6 months & intermittent condom use



...However...

38,700 is still too many!

HIV infections among MSM remain about 26,000/year 35% increase among MSM 25-34 yo 20% increase among latinx MSM 50% of new HIV infections occur in southern states which represent 37% of the US populations

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You're a PA in Primary Care...

You've never prescribed PrEP, but you recently learned about it You feel ready to write (electronically submit) your first Rx **The patient asks: Is it safe?**



You're a PA in Primary Care...

Phew! Good thing you watched this presentation!

The patient asks:

- What are the side effects?
- Will my insurance cover it?
- When will I need to come back?

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Side Effects

Diarrhea (2%)		
	Vomiting	↓Bone mineral density
Dizziness (2%)	Abdominal pain	Kidney failure
Gas	Decreased appetite	Lactic acidosis
Nausea	Weight loss	Liver disease
Headache	Malaise	Muscle weakness
Rash	Muscle pain/cramp	Pancreatic disease
Skin discoloration	Dysphagia	
	Shallow breathing	
	Sleepiness	



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Baseline Labs

- HIV Ag/Ab
- RPR
- Hep A total ab (MSM)
- Hep B surface ab/ag
- Hep C ab
- GC/CT (genital, pharyngeal, rectal)
- Creatinine
- Urine HCG

Q3 Month Follow Up Labs

• HIV Ag/Ab

- Creatinine
- STI Screening depending on patient's risk (q3-6months):
- RPR, three site GC/CT

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C 2018

You're a PA in Primary Care...

Lab Results:		• CMP:	
• HIV Ag/Ab	NR	 Glucose 	121
• Syphilis	NR	 Sodium 	142
· ·		 Potassium 	4.3
 Genital gc/Ct 	NR	 Chloride 	108
 Oral gc/Ct 	NR	 Urea Nitrogen 	20
• Rectal gc/Ct	NR	 Creatinine 	1.15
0,		• AST	26
 HBsAb/HBsAg 	Reactive/NR	• ALT	22
• HAV Ab, HCV Ab	NR	Alk Phos	88
[HCG test in FCBP]			

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3 month Lab Resu	lts:	• CMP:	
• HIV Ag/Ab	NR	 Glucose 	121
• Syphilis	NR	 Sodium 	142
		 Potassium 	4.3
 Genital gc/Ct 	NR	 Chloride 	108
 Oral gc/Ct 	Gc+/Ct-	 Urea Nitrogen 	20
 Rectal gc/Ct 	NR	 Creatinine 	1.15
• HBsAb/HBsAg	Reactive/NR	• AST	26
		• ALT	22
 HAV Ab, HCV Ab 	NR	 Alk Phos 	88

Will PrEP Increase Risky Behaviors?

Risk homeostasis\risk compensation posits an individual will maintain an average level of risk they find acceptable.

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"Sexual health is a state of physical, mental and social well-being in relation to sexuality."

-World Health Organization

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Hepatitis C Transmission Among PrEP Users

- Sexual transmission of HCV among MSM living with HIV is well documented; few cases among HIV-negative MSM
- 2 cases of sexual HCV acquisitions among 485 MSM in Kaiser San Francisco

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You're a PA in Primary Care...

6 months later your patient returns:Does my body get resistant to it if I take it every day?

PrEP and HIV Viral Resistance

Inadequate ARV therapy is known to result in resistance; individuals who become infected with HIV should discontinue PrEP immediately to prevent development of resistance

t 2010, Baeten 2012, Thigpen 2011, Van Damme 2012

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You're a PA in Primary Care...

6 month Lab Resu	lts:	• CMP:	
• HIV Ag/Ab	NR	 Glucose 	121
• Syphilis	NR	Sodium	142
• Genital gc/Ct	NR	Potassium	4.3
0,		ChlorideUrea Nitrogen	108 20
• Oral gc/Ct	NR	Creatinine	1.40 [0.60-1.35]
 Rectal gc/Ct 	NR	• AST	52 [10-40]
 HBsAb/HBsAg 	Reactive/NR	• ALT	22
• HAV Ab, HCV Ab	NR	 Alk Phos 	88

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You're a PA in Emergency Medicine...

- A 30 year old MSM presents citing exposure to HIV 6 hours prior
- Sexual Hx: He engaged in condomless oral and insertive anal intercourse with a partner of unknown HIV status
- Medications: tenofovir/emtricitabine, citalopram
- No drug allergies, family Hx, surgical Hx
- Social Hx: Admits social etoh, denies drug use

Post Exposure Prophylaxis (PEP)

- Expert consultation is recommended in all cases, but do not delay PEP initiation
- Begin PEP within 72 hours of exposure; preferably within 2 hours
 Baseline Labs: HIV, CBC, CMP
- Repeat HIV Ab at 6 wks, 2 mos, 6 mos
- Occupational PEP HCW exposure to HIV+ or unknown status source
- Non-occupational (nPEP) Sexual or IVDU exposure

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You're a PA in Emergency Medicine...

The patient is already on F/TDF PrEP, does he need PEP?

- Additional ARVs for PEP are not recommended when a patient is already on PrEP
- PEP has limited evidence
- What if the patient wasn't on PrEP?

PEP to PrEP Transition

What is the indication for a patient utilizing PEP to initiate PrEP?

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You're a PA in Gynecology...

- A 45 yo female presents for annual pap and exam • Medications: OCP
- No drug allergies, family Hx, surgical Hx
- Sexual Hx: Monogamous with a male partner for 3 years Engages in oral, receptive vaginal, and receptive anal intercourse Partner is living with HIV
- Social Hx: Admits social etoh, denies drug use

She read about an HIV-prevention drug... Can she start it?

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Patient Awareness of PrEP

• Disparities by race

- Non-Hispanic black MSM significantly less likely to be aware of PrEP compared to Non-Hispanic white MSM
- Education level
 - College educated MSM were significantly more aware of PrEP than MSM with education levels up to the $8^{\rm th}$ grade
- Having an HIV test or a +STI test did not increase awareness of PrEP

• Increased awareness if patients were out to their PCP

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Disclaimer

- Generics and brand names used
- TDF (Truvada) and TAF (Descovy) generics very similar

You're a PA in Family Medicine

A 17-year-old nonbinary (they/them) patient presents for a school physical with their caregiver (grandmother)

- PMHx: none
- Medications: none
- NKDA, no significant family Hx
- Social Hx: senior in high school, on lacrosse team, alcohol: 5-7 beers per setting at parties, tried cocaine for first time this past summer, marijuana weekly, lives with grandmother

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You're a PA in Family Medicine

When you get to sexual practices, grandmother leaves the room:

- Non-binary, AMAB, reports oral sex, anal receptive, anal insertive sex, insertive vaginal sex
- Using condoms for vaginal sex only
- Meets anal sex partners on Grindr and other apps
- No prior HIV testing or STI testing
- No history of HPV vaccine

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You're a PA in Family Medicine

PE:

- W: 75 kg, H: 72 inches
- No significant findings

Labs:

- HIV antibody test negative in office (phew)
- 3 site STI testing collected in office

Assessment:

- Recommend HPV vaccine
 (TAF/E)
- Discuss PrEP options. Patient interested in Descovy (TAF/FTC).

Descovy (TAF/FTC)

• FDA approved for PrEP October 2019

• Indications:

- Adolescents and adults \geq 35kg, high risk for HIV-1 transmission • *EXCLUDES: individuals having receptive vaginal sex
- Dose: TAF 25mg/ FTC 200mg daily
 - \cdot TAF is prodrug of TDF
 - Plasma exposure to TAF, intracellularly converted to TDF at higher
 - levels

Lower drug levels

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Descovy (TAF/FTC)

• Labs:

- Initial: r/o HIV infection, Hep B surface antigen, baseline
- SrCr/CrCl, STI testing, urine glucose, urine protein
- · CrCl > 30 mL/min (Crockcroft Gault Calculation)
- Follow up
- Every 3 months
- Blackbox warning
- Acute HBV exacerbation

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TAF vs TDF: DISCOVER Trial

- Double blind, randomize HIV seronegative
- Median age: 34
- Majority white
- Criteria:

- Criteria:
 2 condomless unique sexual partners in previous 12 weeks OR
 Diagnoses of GC, CT, syphilis within 24 weeks
 Cisgender MSM and TGW
 *Does not include cisgender/endo women or transmen or any vaginal
- Subjects were seen in follow-up visits at Weeks 4, 12, and every 12 weeks thereafter; 50% followed up at 96 weeks

DISCOVER TRIAL for TAF vs TDF

- "TAF noninferior to TDF"
- No changes in sexual behaviors
- Safety Concerns
- Renal
- Bone Mineral Density
- · Lipid levels

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DISCOVER TRIAL TAF VS TDF: Short Term AEs

	Either Arm in the DISCOVER Trial of HIV-1 Uninfected Participants			
	DESCOVY (N=2,694)	TRUVADA (N=2,693)		
Diarrhea	5%	6%		
Nausea	4%	5%		
Headache	2%	2%		
Fatigue	2%	3%		
Abdominal pain ^a	2%	3%		

HIV-1 U	tory Assessments of Rena ninfected Participants Rec DA in the DISCOVER Trial	
	DESCOVY (N=2,694)	TRUVADA (N=2,693)
Serum Creatinine (mg/dL) ^a Change at Week 48	-0.01 (0.107)	0.01 (0.111)
eGFR _{CG} (mL/min) ^b Change at Week 48	1.8 (-7.2, 11.1)	-2.3 (-10.8, 7.2
Percentage of Participants who Developed UPCR >200 mg/g ^c At Week 48	0.7%	1.5%
eGFR _{CG} =estimated Glomerular Filtrati a. Mean (SD). b. Median (Q1, Q3). c. Based on N who had normal UPC	ion Rate by Cockcroft-Gault; UPCR=u CR (≤ 200 mg/g) at baseline.	rine protein/creatinine rat

DISCOVER)	p and Spine BMD at Weeks 48 an	
	F/TAF	F/TDF
	Hip BMD ¹	
Baseline	N=190	N=185
Mean (SD) (g/ cm ²)	1.029 (0.154)	1.02 (0.132)
Week 48	N~158	N-158
Mean (SD) % Change from Baseline	+0.183 (2.384)	-0.988 (2.435)
Week 96	N=100	N=105
Mean (SD) % Change from Baseline	+0.424 (2.612)	-1.202 (2.897)
	pine BMD ²	
Baseline	N-190	N=188
Mean (SD) (g/cm ²)	1.131 (0.161)	1.131 (0.138)
Week 48	N=159	N=160
Mean (SD) % Change from Baseline	+0.496 (2.988)	-1.123 (2.945)
Week 96	N-100	N=112
Mean (SD) % Change from Baseline	+0.877 (3.143)	-1.248 (3.918)

DISCOVER TRIAL TAF VS TDF: Lipid

- •TDF greater decreases in fasting lipids
- •TDF higher incidence of fasting lipids
- •No association with cardiovascular risk
- •Two-fold increase in lipid lowering therapy

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Unclear

- "TAF is noninferior to TDF"
- Pre-existing renal function, BMD, hyperlipidemia
- •Age?*
- Length of time on TDF?*
- •New to PrEP?*

Off label nsideratior

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You're a PA in Sexual Health (LA)

- A 45 year old white man presents for PrEP follow up
- PMHx: Rectal CT, negative repeat testing on multiple occasions
- Medications: Truvada (TDF/FTC) for 5 years
- NKDA, no significant family Hx
- Social Hx: Denies alcohol and drug use, non-smoker, stable housing, occupation: sex worker, travels for work monthly
- Does not want to take PrEP everyday because knows his sexual schedule due to occupation.

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You're a PA in Sexual Health

- Sexual practices include:
 - M, AMAB (assigned male at birth) reports oral sex, anal receptive, and anal insertive sex
 - Clients: 3 regular clients, engages 3 times monthly; 0% condom
 - use

 Non-clients: 100% condom use

You're a PA in Sexual Health

- Patient concerned about long term use of Truvada (TDF/FTC). Does not want to switch to Descovy (TAF/FTC). Very adamant about scheduled sexual encounters. Does not want to continue daily PrEP.
- What recommendations are appropriate for this patient?

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"On Demand" or 2-1-1 Dosing

- Tenofovir/emtricibine is NOT approved or recommended for intermittent use
- Relies on anticipation of sex
- Less drug = less potential for side effects and adverse events
- Glidden et al suggest:
 - "[Intermittent dosing] is clearly preferable to no PrEP at all"

What's Next: PrEP Pipeline

- Dapivirine ring (27% effective women in Sub-Saharan Africa)
- Injectable cabotegravir every 8 weeks (HPTN-083)
- Implantable PrEP (\$140 million grant)
- Topical tenofovir for MSM (Rectal Microbicides)

n 2016, HPTN, Bill & Melinda Gates Foundation, MTN 2016

None of these are approved or recommended for PrEP

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You're a PA in Gastroenterology...

A 45 year old female patient presents for a second opinion

- Diagnosed with Crohns vs. UC with OSH
- BRBPR, tenesmus, mucous discharge, no significant abd Sx
- PMHx: PE (10 years prior)
- Medications: ASA 81 mg, Mesalamine suppository
- NKDA, no surgical Hx
- Family Hx: Denies family Hx of IBD
- Social Hx: single, etoh social, denies drug use, travels frequently for work,

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You're a PA in Gastroenterology...

- Your culturally sensitive sexual history identifies:
 F, AFAB, She pronouns, reports male sexual partner. No primary partner. Consistently uses condoms with RVI, but not for RAI, oral sex. 4 partners in the last 6 months.
- Rectal gc+, treated with ceftriaxone/azithromycin and symptoms fully resolve

• What patient education is appropriate?



AI and HIV Risk

from an Infected Source,	by Exposure Act
Type of Sexual Exposure	Risk per 10,000 Exposures
Receptive anal intercourse	138
Receptive penile-vaginal intercourse	8
Insertive anal intercourse	11
Insertive penile-vaginal intercourse	4
Oral intercourse	low

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1.2 Million Americans Meet Eligibility for PrEP

MSM with male sexual partner in last 6 months Al without condoms in past 6 mos **OR** STI in prior 6 mos **OR** sexual relationship with HIV+ partner 492,200

Heterosexual with opposite gender sexual partner in last 6 months Infrequent condom use with 1+ partners with HIV risk factors OR sexual relationship with HIV 624,000

IV drug users who injected non-Rx drugs in last 6 months Any equipment sharing OR in treatment program in last 6 months OR risk of sexual acquisition 115,000

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Take Home Points

- HIV prevention IS the responsibility of health care providers, especially in primary care
- Biomedical HIV prevention options vary and meet the needs of a diverse patient population
- Tenofovir/emtricitibine as daily pre-exposure prophylaxis for HIV is highly effective, safe, and easy to manage in a primary care setting

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"No more excuses,

We have the tools to end the epidemic: It is up to us to do it."

> -Anthony S. Fauci Director of the NIAID at NIH

* ©	Resources	
Finding a PrEP Provider	www.preplocator.org www.greaterthan.org/get-prep/	
Uninsured/underinsured/ Copay Assistance	www.panfoundation.org www.copays.org www.health.ny.gov/ (PrEP-AP) Manufacturer rebate programs	
FREE CME: Preventing HIV Inf The Role of Pre-Exposure Prop http://www.medscape.org/vi		

Question 1

Order the below interventions from most effective to least effective intervention for reducing risk of HIV transmission

- 1. Condoms, PrEP, UVL, Counselling
- 2. PrEP, Condoms, UVL, Counselling
- 3. Counselling, Condoms, PrEP, UVL
- 4. UVL, PrEP, Condoms, Counselling

CONDOMS: Consistent condom use UVL: Viral Suppression of partners with HIV PREP: Tenofovir/emtricitabine pre-exposure prophylaxis (PrEP) COUNSELLING: Safe Sex Counselling by their PCP

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Question 2

Your patient presents for 3 month follow up for tenofovir/emtricitabine PrEP and reports increased number of sexual partners and decreased condom use. All of the following are appropriate, except:

- 1. Encourage your patient to undergo asymptomatic STI screening every 3-6 mos and sooner if needed
- 2. Discontinue tenofovir/emtricitabine PrEP
- 3. Discuss tenofovir/emtricitabine PrEP adherence
- 4. Draw bloodwork for HIV and Creatine

Question 3

A patient on tenofovir/emtricitabine PrEP presents to the ED within 72 hours of potential HIV exposure, what is the most appropriate practice?

- 1. Discontinue tenofovir/emtricitabine PrEP and test at 6 wks, 3 mos, and 6 mos
- 2. Continue patient on tenofovir/emtricitabine, and add raltegravir for 28 days as PEP
- 3. Reassure the patient that their risk of HIV acquisition is minimal and they should continue daily tenofovir/emtricitabine PrEP
- 4. Check a viral load (HIV RNA) for earliest detection of HIV

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Prevente Maddeo 32 1 (2017) 55-63 Stelle, kasse J, et al. Pattert recommendations for HP information is Marka, have Michael et al. "Contention previous programs and the Marka and Michael et al. "Contention previous programs and the marka - credit free that have been been been been been been been be	memouse Prophysika, ICO, Mark 2010, Baktera (30 Sattik V presention a memory New Graph Committed Markon 37 L2 (2013) 2123-2132. data in the United States, 2013 2011; "Source provide Process and Sattik 2013 (2013) 17 memory Process and a straight of the Process and Proce
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