Treating HIV in 2018—
Interactive Cases From the Clinic(ians)

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IAS–USA

Learning Objectives

After attending this presentation, learners will be able to select antiretroviral therapy in patients who:

- Are starting initial therapy
- Have persistently low-level viremia
- Have a baseline M184V mutation
- Are pregnant
- Are eligible for PrEP

Question

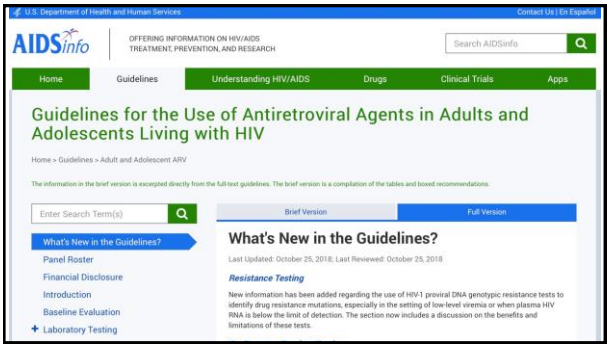
What regimen should I use as initial therapy?

Case 1

- 48 yo Male presents with newly diagnosed HIV infection
- Asymptomatic
- **Initial:** HIV RNA 28,000 c/ml
  CD4 count 650 cells/ul
- Other labs are normal; HLA-B57 positive
- Genotype is Wild-type virus
- No prior medical history. Normal renal function
- Ok to start therapy if you think he should

ARS Question 1: At this point which regimen would you choose?

1. TDF / 3TC / low dose (400mg) EFV (fdc; generic)
2. DTG / 3TC (fdc)
3. ABC/ 3TC / DTG (fdc)
4. TAF/ FTC (fdc) + DTG
5. TAF / FTC/ ELV / cobi (fdc)
6. TAF/ FTC / BIC (fdc)
7. TAF / FTC (fdc) + RAL (once daily)
8. TAF / FTC / RPV (fdc)
9. TAF/ FTC (fdc) + DRV/r (or cobi / fdc)
10. Some other option (e.g., DRV/r + DTG or …)



JAMA | Special Communication

Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults
2018 Recommendations of the International Antiviral Society-USA Panel

Michael S. Saag, MD; Constance A. Benson, MD; Rajesh T. Gandhi, MD; Jennifer F. Hoy, MBBS; Raphael J. Landovitz, MD; Michael J. Mugavero, MD, MHSc; Paul E. Sax, MD; Davey M. Smith, MD; Melanie A. Thompson, MD; Susan P. Buchbinder, MD; Carlos del Rio, MD; Joseph J. Eron Jr, MD; Gerd Fätkenheuer, MD; Huldrych F. Günthard, MD; Jean-Michel Molina, MD; Donna M. Jacobsen, BS; Paul A. Volberding, MD

IMPORTANCE Antiretroviral therapy (ART) is the cornerstone of prevention and management of HIV infection.

Editorial page 1
Author Audio Interview
Related article page 1

Saag MS, Benson CA, Gandhi RT, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults: 2018 recommendations of the International Antiviral Society-USA Panel. *JAMA*. 2018;320(4):1-18.

Recommended Initial Regimens: InSTI Plus 2 nRTIs

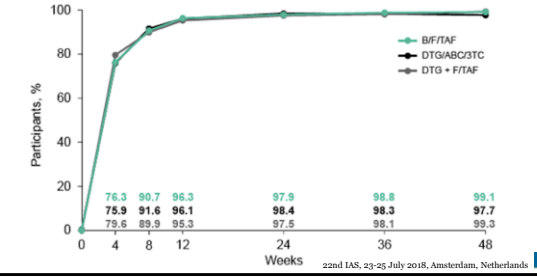
- Bictegravir/TAF/emtricitabine
- Dolutegravir/abacavir/lamivudine
- Dolutegravir plus TAF/emtricitabine
- (Raltegravir plus tenofovir / emtricitabine)*

*HHS Guidelines; AIDSinfo

Saag, Benson, Gandhi, et al, *JAMA*, 2018.

Virologic Response by Visit (FAS)

HIV-1 RNA <50 copies/mL, Missing=Excluded Analysis



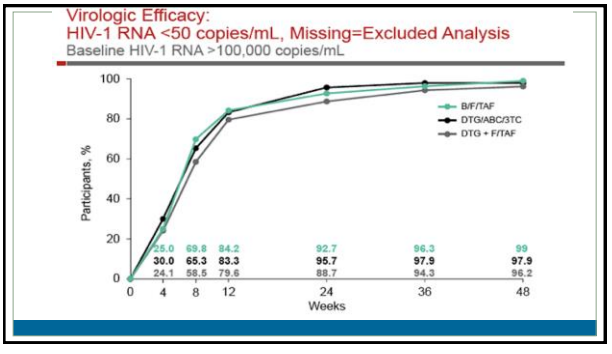
22nd IAS, 23-25 July 2018, Amsterdam, Netherlands

Case 2

- 48 yo Male presents with newly diagnosed HIV infection
- Asymptomatic except for weight loss / fatigue
- **Initial: HIV RNA 760,000 c/ml**
  CD4 count 21 cells/ul
- Other labs are normal; HLA-B57 negative
- Genotype is Wild-type virus
- No prior past medical history. Normal renal function
- Ok to start therapy if you think he should

ARS Question 2: At this point which regimen would you choose?

1. TDF / 3TC / low dose (400mg) EFV (fdc; generic)
2. DTG / 3TC (fdc)
3. ABC/ 3TC / DTG (fdc)
4. TAF/ FTC (fdc) + DTG
5. TAF / FTC/ ELV / cobi (fdc)
6. TAF/ FTC / BIC (fdc)
7. TAF / FTC (fdc) + RAL (once daily)
8. TAF / FTC / RPV (fdc)
9. TAF/ FTC (fdc) + DRV/r (or cobi / fdc)
10. Some other option (e.g., DRV/r + DTG or …)



Recommended Initial Regimens: If an InSTI Is Not Available

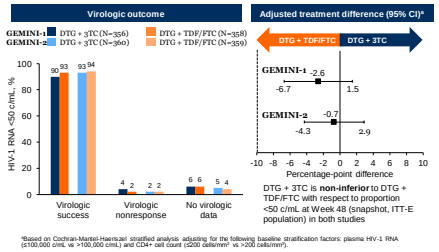
- Darunavir/cobicistat/TAF (or TDF)/emtricitabine*
- Darunavir boosted with ritonavir plus TAF (or TDF)/emtricitabine
- Efavirenz/TDF/emtricitabine
- Elvitegravir/cobicistat/TAF (or TDF)/emtricitabine
- Raltegravir plus TAF (or TDF)/emtricitabine
- Rilpivirine/TAF (or TDF)/emtricitabine (if pretreatment HIV RNA level is <100,000 c/mL and CD4 cell count is >200/µL)
- Fixed-dose Dor/TDF/3TC tablet approved July 2018

HHS Guidelines; Saag, Benson, Gandhi, et al, *JAMA*, 2018.

ARS Question 3: Would you use DTG / 3TC as initial therapy?

1. Yes
2. No
3. Not sure

Snapshot Outcomes at Week 48 for GEMINI-1 and -2

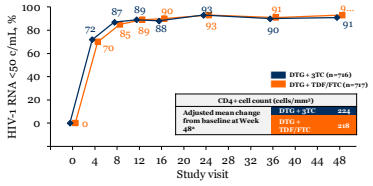


*Based on Cochran-Mantel-Haenszel stratified analysis adjusting for the following baseline stratification factors: plasma HIV-1 RNA (≤100,000 c/mL vs >100,000 c/mL) and CD4+ cell count (≤200 cells/mm³ vs >200 cells/mm³).

Cahn et al. AIDS 2018; Amsterdam, the Netherlands. Slides TUAB0104LB

22nd International AIDS Conference; July 23-27, 2018; Amsterdam, the Netherlands

Snapshot Analysis by Visit: Pooled ITT-E Population

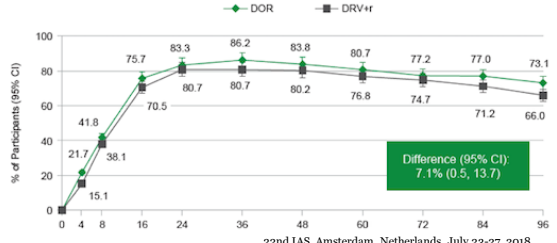


*Calculated from a repeated measures model adjusting for study, treatment, visit (repeated factor), baseline plasma HIV-1 RNA, baseline CD4+ cell count, treatment and visit interaction, and baseline CD4+ cell count and visit interaction.

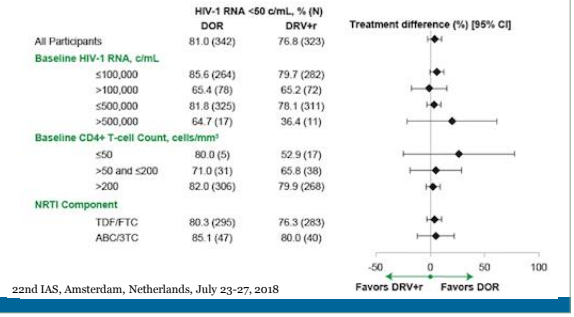
Cahn et al. AIDS 2018; Amsterdam, the Netherlands. Slides TUAB0106LB

22nd International AIDS Conference; July 23-27, 2018; Amsterdam, the Netherlands

Figure 3. Proportion of Participants With HIV-1 RNA <50 c/mL†



22nd IAS, Amsterdam, Netherlands, July 23-27, 2018



22nd IAS, Amsterdam, Netherlands, July 23-27, 2018

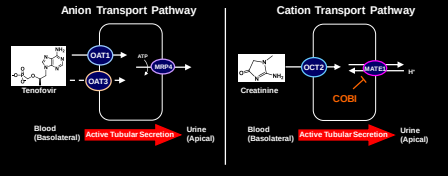
ARS Question 4:

Which ARV drug is most likely to cause a 0.1 mg/dl jump in serum creatinine 1 week after starting Rx?

1. Bictegravir
2. Tenofovir DF
3. Tenofovir AF
4. Atazanavir
5. Emtricitabine

Slide 21 of 41

Tenofovir and COBI Interact with Distinct Renal Transport Pathways

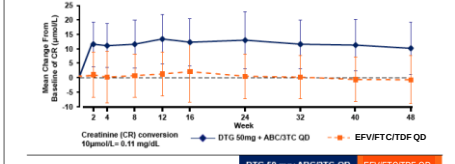


- The active tubular secretion of tenofovir and the effect of COBI on creatinine are mediated by distinct transport pathways in renal proximal tubules

Ray A, et al. Antimicro Agents Chemo 2006;3297-3304
Lepist E, et al. ICAAC 2011; Chicago. #A1-1724

Slide 22 of 41

Renal Safety



	DTG 50 mg+ABC/3TC QD	EFV/FTC/TDF QD
Urine albumin/creatinine Median change (IQR) from baseline (mg/mmol CR) to Week 48	0.00 (-0.30, 0.30)	+0.05 (-0.20, 0.30)

- **Small increase in creatinine due to blockade of Cr secretion[1]**
- **DTG does not affect actual glomerular filtration rate (GFR)[1]**

1. Kotleff, J. et al. Br J Clin Pharmacol. In press: 2012 Aug.
Wolmpiev S, et al. 52nd ICAAC. 9-12 Sept 2012. Abstract H-556b

Question

What is likely the best approach to Long-Acting ARV formulations?

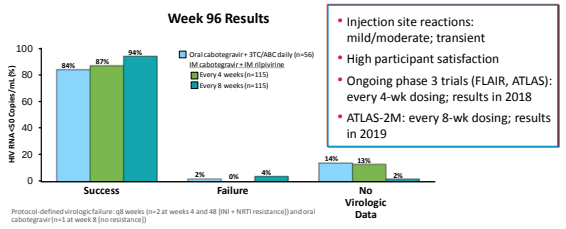
Case 3 (Long-acting "LA" Agents Available)

- 48 yo Male presents with newly diagnosed HIV infection
- Asymptomatic except for weight loss / fatigue
- **Initial: HIV RNA 160,000 c/ml**
  CD4 count 221 cells/ul
- Other labs are normal; HLA-B57 negative
- Genotype is Wild-type virus
- No prior past medical history. Normal renal function
- Ok to start therapy if you think he should

ARS Question 5: Among the LA agents which type would you choose if or when they become available?

1. Long acting Pill Formulation (1 tab every week)
2. Very long acting Pill Formulation (1 tab every 4 - 8 weeks)
3. Long-acting injectable (1 injection every 2 months)
4. Implantable disc (placed in provider's office q 6 months)
5. Would not use Long-Acting formulations
6. No opinion

LATTE-2: Virologic Outcomes With LA Cabotegravir + Rilpivirine as Maintenance Therapy



- Injection site reactions: mild/moderate; transient
- High participant satisfaction
- Ongoing phase 3 trials (FLAIR, ATLAS): every 4-wk dosing; results in 2018
- ATLAS-2M: every 8-wk dosing; results in 2019

Protocol-defined virologic failure: q8 weeks (n=2 at weeks 4 and 48 [INI + NRTI resistance]) and oral cabotegravir (n=1 at week 8 [no resistance])

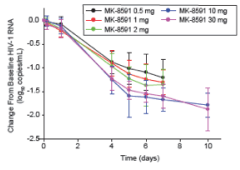
Eron J, et al. *J Int AIDS Soc*. 2017;20(suppl 4):107-108. Abstract MOAX020518.
Margolis DA, et al. *Lancet*. 2017Jul 21. [Epub ahead of print].

Slide 25 of 70

Long-acting NRTI: MK-8591 (EFdA)

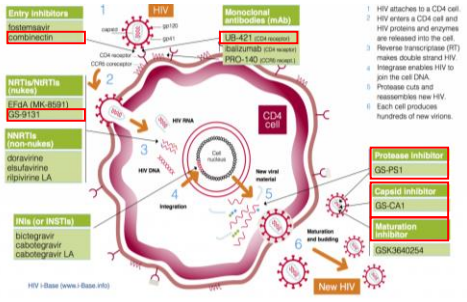
- Nucleoside RT translocation inhibitor (NRTTI)
- Half life of active anabolite: ≈80-130 hr
- Humans: single oral dose as low as 0.5 mg suppressed HIV RNA for >7 day
- Study in healthy volunteers: multiple daily doses as low as 0.25 mg expected to lead to HIV suppression
- Phase 2b trial in people with HIV, in combination with DOR and 3TC, has started (DRIVE2Simplify)
  - Daily dosing

Phase 1b, single-dose, monotherapy study
Study population: ART naïve (N=30)



Grobler CROI 2017 #435
Matthews IAS 2017 #TUPDB02021B
Matthews RP CROI 2018 #26
https://clinicaltrials.gov/ct2/show/NCT03272347

Other investigational drugs in the pipeline:



Question

What regimen should be used as initial therapy when an M184V mutation is present?

Case 3

- 30 yo Female presents with newly diagnosed HIV infection
- Asymptomatic
- **Initial:** HIV RNA 128,000 c/ml
  CD4 count 350 cells/ul
- Other labs are normal; HLA-B57 neg
- Genotype shows **M184V and K103N mutation**
- No prior medical history. No children. Does not plan to become pregnant.
- Ok to start therapy if you think she should

ARS Question 6: At this point which regimen would you choose?

1. TDF / 3TC / low dose (400mg) EFV (fdc; generic)
2. DTG / 3TC (fdc)
3. ABC/ 3TC / DTG (fdc)
4. TAF/ FTC (fdc) + DTG
5. TAF / FTC/ ELV / cobi (fdc)
6. TAF/ FTC / BIC (fdc)
7. TAF / FTC (fdc) + RAL (once daily)
8. TAF / FTC / RPV (fdc)
9. TAF/ FTC (fdc) + DRV/r (or cobi / fdc)
10. Some other option (e.g., DRV/r + DTG or …)

Question

Seems like we are now starting ARV therapy for about everyone, what about starting therapy immediately at time of diagnosis?

Case 4

- 30 yo Male was diagnosed with HIV infection 4 hours ago in the ER
- Asymptomatic
- **Initial:** HIV RNA 17,000 c/ml (HIV DNA positive)
  CD4 count 470 cells/ul
- Other labs are normal; HLA-B57 neg
- Genotype determined from DNA is wild-type
- No prior medical history.
- Ok to start therapy if you think he should

ARS Question 7: When would you choose to start therapy?

1. Right now in the ER
2. Within 1 - 2 days (outpt Clinic)
3. In the next 2 weeks (outpt Clinic)
4. Within 2 – 4 weeks
5. Some other option

Same Day ART– A Randomized Trial

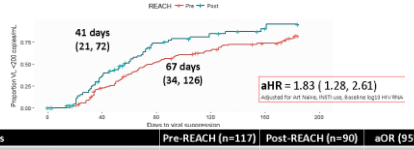
- Home based testing in rural Lesotho
- Newly HIV +, no other chronic conditions requiring care, randomized to usual care vs. same day ART
  - Usual Care: labs, 2 clinic visits → ART
  - Same Day: no labs, 30 days TDF/3TC/EFV
- End Points – 3 month care linkage and % HIV RNA <200 c/mL at 12 months

274 patients	Usual Care	Same Day
% 3 months linked	43	69
% 12 months suppressed	34	50

Labhardt #94

Expedited ART– Experience in Atlanta

- Grady reduced barriers, with goal to begin ART within 72hrs
- Pre-intervention days to ART = 22, Post-intervention days to ART= 4.



Outcomes	Pre-REACH (n=117)	Post-REACH (n=90)	aOR (95% CI)
Attended 1st scheduled appointment[†]	85 (73)	73 (81)	1.63 (0.82, 3.22)
Achieved viral suppression[¥]	87 (74)	61 (68)	0.77 (0.39, 1.52)

[†]Adjusted for age, race, sex and being ART Naïve
[¥]Adjusted for age, race, baseline HIV RNA & INSTI use

Colasanti #1109

ARS Question 8:

Do InSTIs cause IRIS?

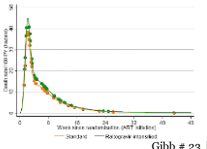
1. Yes
2. No
3. Not sure

Do INSTIs Cause IRIS?

- ART naïve adults/children in Africa, CD4 <100
- Randomized to ART vs. ART + 12 weeks RAL
- IRIS judged by blinded committee based on clinical description and timing with regard to ART

	ART + RAL	ART
Number Subjects	902	933
Mean Baseline CD4	38	36
% Baseline VL > 100k	77	74
Δ VL @ wk 4	- 3.4 L	- 2.7 L
% Mortality @ wk 24	10.9	10.2
# Fatal IRIS	**36**	**31**
# All IRIS	**89**	**86**

Incidence of fatal IRIS-compatible events



Gibb # 23

Question

Should I change a regimen when low level detectable virus is present?

Case 5

- 55 yo male referred to you for evaluation
- Diagnosed 18 years ago with HIV infection
- **Initial:** HIV RNA 936,000c/ml
  CD4 count 70 cells/ul
- **Current:** HIV RNA 85 c/ml (prior value 62 c/ml)
  CD4 count 525 cells/ul
- Started on NEL/D4T/3TC; subsequently treated with
  - LOP-r / TDF/FTC,
  - EFV/ FTC/ TDF (fdc).
  - Now **DTG / DRV/c / 3TC**
- No historical resistance tests are available

ARS Question 9: Should you change ARV therapy now?

1. Yes
2. No
3. Not sure

Question

What regimen should I use as initial therapy in a pregnant patient?

Case 6

- 30 yo woman presents with newly diagnosed HIV infection
- Asymptomatic, 2.5 months pregnant
- **Initial:** HIV RNA 28,000 c/ml
  CD4 count 650 cells/ul
- Other labs are normal; HLA-B57 neg
- Genotype is Wild-type virus
- No prior medical history. First pregnancy
- Ok to start therapy if you think she should

ARS Question 10: At this point which regimen would you choose?

1. TDF / FTC / EFV (fdc)
2. ABC/ 3TC / DTG (fdc)
3. TAF / FTC/ ELV / cobi (fdc)
4. TDF / FTC / RPV (fdc)
5. TAF/ 3TC (fdc) / DTG (fdc)
6. TDF/ FTC (fdc) / DRV/r (or cobi / fdc)
7. TAF/ FTC / ATV/r (or cobi / fdc)
8. TDF / FTC / ATV/r (or cobi / fdc)
9. Some other option

TAF PK - Fetus

- Intracellular concentration of Tenofovir-DP is 4-5 times higher for TAF compared to TDF
- Does this expose the fetus to a higher risk of birth abnormalities?
- Does this lower the risk of vertical transmission?

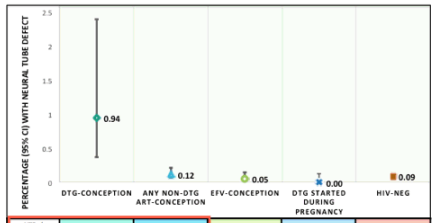
Andrew Hill, 2016 WHO meeting

Dolutegravir in pregnancy: Background

- No fetal toxicity or teratogenicity in animal studies described in manufacturer's submission for regulatory approval[1]
- High placental transfer of DTG relative to other ARVs in an ex vivo study[2]
- "*Unexpected placental transfer of DTG with fetal accumulation and then slow neonatal clearance*"[3]
- ***18 May 2018: Report of Neural tube defects in 4/426 (0.9%) babies born to women taking DTG in Botswana…compared to 14/11,173 (0.1%) non-DTG[4]***

DOI: 10.1056/NEJMc1807653 ; 24 July 2018

NTD Prevalence Difference by Exposure

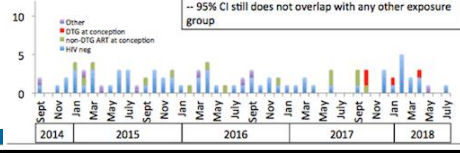


NTDs/ Exposures	4/426	14/11,300	3/5,787	0/2,812	61/66,057
% with NTD (95% CI)	0.94% (0.37%, 2.4%)	0.12% (0.07%, 0.21%)	0.05% (0.02%, 0.15%)	0.00% (0.00%, 0.13%)	0.09% (0.07%, 0.12%)
Prevalence Difference (95% CI)	ref	-0.82% (-0.24%, -2.3%)	-0.89% (-0.31%, -2.3%)	-0.94% (-0.35%, -2.4%)	-0.85% (-0.27%, -2.3%)

Update since 1 May 2018

- From 1 May-15 July, there were **2 more NTDs;** 1 in an infant exposed to **DTG *started during pregnancy*** (8 weeks GA) and 1 birth to an **HIV-uninfected** woman
  - NTDs in DTG started in pregnancy: 1/3104 (0.03%, 95% CI 0.01%, 0.18%)

Updated prevalence of DTG exposure at conception is 4/596 (0.67%, 95% CI 0.26%, 1.7%)
-- 95% CI still does not overlap with any other exposure group



ARS Question 11: What prophylaxis should be used in a newly diagnosed patient with CD4 < 50 cells/ µL?

1. TMP / SMX
2. TMP / SMX + azithromycin
3. TMP / SMX + fluconazole
4. TMP / SMX + fluconazole + azithromycin
5. Fluconazole + azitromycin

Interface of ART and OIs: OI Prophylaxis

- *Mycobacterium avium* complex (MAC)
  - Primary MAC prophylaxis not recommended if effective ART is initiated immediately
- *Pneumocystis jiroveci* pneumonia
  - Primary prophylaxis is still recommended for those who meet CD4+ cell count criteria

Saag, Benson, Gandhi, et al, *JAMA*, 2018.

Question

Should I stop abacavir in older patients?

Case 7

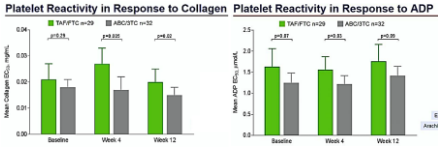
- 62 yo male started on ARV Rx years ago (resistance history: wild type virus) **returns to you for care after 4 years** (Rx'd elsewhere)
- Has been through several regimens; now on ABC/ 3TC / DTG (fdc)
- **Now:** HIV RNA < 20 c/ml (persistently)
  CD4 560 cells/ul
  Cholesterol 180 mg/dl (HDL 52 / LDL 100)
  Creat 1.3 / eCrCl = 80 cc/min
- Smoker
- PMHx negative (No cardiac history)
- On atorvastatin and daily low-dose ASA

ARS Question 12: Besides asking him to quit smoking, what would you do?

1. Continue his current ARV Rx
2. Change his ABC/3TC to TAF / FTC containing Rx
3. Change his ABC/3TC to DRV/rit (continue DTG)
4. Some other option

ABC → TAF – Effect on Platelets

- 61pts on ABC/3TC containing regimen randomized to continue or to switch to TAF/FTC. Platelet aggregation measured by platelet reactivity



- Switch to TAF/FTC resulted in less reactivity of platelets by collagen assay
- Does this explain possible CV risk associated with ABC? In the Framingham study ADP response was much more predictive for CVD than collagen response

(MK Puurunen, JAHA 2018)

Mallon #677LB

Trial funded by Gilead Sciences, Inc

Question

Should I switch from EFV / FTC / TDF (fdc) in a patient who has been on it for the last 10 years?

Case 8

- 55 yo Female referred to you for evaluation
- Diagnosed 14 years ago with HIV infection
- **Initial:** HIV RNA 36,000c/ml
  CD4 count 150 cells/ul
- **Current:** HIV RNA <20 c/ml
  CD4 count 525 cells/ul
- Started on EFV + FTC/ TDF (fdc) in Jan 2004
- Changed to STR in 2006. Only regimen.
- Reports **no symptoms** currently. Creatinine 0.8 (eGFR > 60 cc/min)
- Generally feels well

ARS Question 13: At this point you would:

1. Continue her current ARV Rx
2. Change her ARV Rx to generic low-dose (FDC) EFV (400mg) / 3TC / TDF
3. Change her ARV Rx to 2 nucs and RPV
4. Change her ARV Rx to 2 nucs and a boosted PI
5. Change her ARV Rx to 2 nucs and an InSTI (integrase inhibitor)
6. Something else

Question

Should I give PrEP to a sero-negative partner of a successfully treated HIV patient?

Case 9

- 45 yo Male makes an appointment to request PrEP
- His partner is HIV positive and has been on successful ARV Rx for 17 years (consistently <50 c/ml)
- Generally feels well
- No significant PMHx
- No medications
- Denies any partners outside of his relationship with his partner

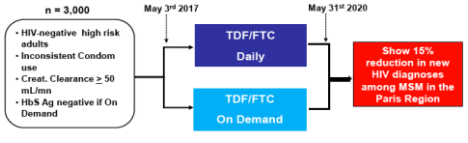
ARS Question 14: At this point you would:

1. Prescribe TDF / FTC (fdc) daily
2. Prescribe 2:1:1 (TDF/ FTC) PrEP
   - 2 doses 12 hours prior to anticipated sexual activity
   - Then one dose daily for 2 days
3. Not prescribe PrEP
4. Not sure what to do

Study Design

Prévenir ANRS
http://prevenir.anrs.fr/

Open-Label Prospective Cohort Study in the Paris Region



- **Participants opted for either Daily or On Demand PrEP and could switch regimens**
- Follow-up every 3 months with 4th Gen ELISA HIV test and plasma creatinine
- STI screening at physicians' discretion (Guidelines recommend every 3 months in MSM)
- Condoms, gels, risk reduction and adherence counseling, Q on sexual behavior

22nd IAS, Amsterdam, Netherlands, July 23-27, 2018

Baseline Characteristics

Characteristics (Median, IQR) or (n, %)	Daily n = 724 (45.4%)	On Demand n= 870 (54.6%)	P-value
Age (years)	36 (30-44)	36 (30-44)	0.10
MSM	708 (98)	865 (99.4)	
Heterosexual men or women	7 (0.1)	5 (0.6)	<.01
Transgender	8 (1.1)	0 (0)	
No regular sex partner	380 (53)	437 (51)	0.41
History of PrEP use	408 (56.5)	515 (59.2)	0.28
Use of Chemsex*	128 (17.7)	124 (14.3)	0.06
No. condomless sex acts in prior 4 weeks	3 (1-8)	2 (0-4)	<.001
No. sexual partners in prior 3 months	15 (7-25)	10 (5-15)	<.001

* at last sexual intercourse : cocaine, GHB, MDMA, mephedrone...

HIV Incidence (mITT Analysis)

Treatment	Follow-Up Pts-years	HIV Incidence per 100 Pts-years (95% CI)
TDF/FTC (Daily)	443	0 (0-0.8)
TDF/FTC (On Demand)	506	0 (0-0.7)

Mean Follow-up in this Open-Label Cohort: 7 months (SD: 4)

Incidence of study discontinuation:
3.3/100 PY including 1.5/100 PY who discontinued PrEP

85 HIV-infections averted*

* assuming an incidence of 9.17/100 PY as observed in the ANRS Ipergay study in Paris

Question

How should I counsel a patient with undetectable HIV RNA re sexual transmission risk?

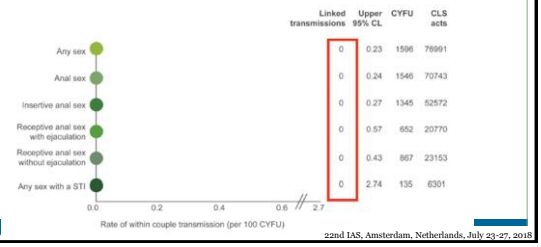
Case 10

- 48 yo Male presents with newly diagnosed HIV infection
- Asymptomatic except for weight loss / fatigue
- **Initial: HIV RNA 160,000 c/ml**
  CD4 count 221 cells/ul
- Other labs are normal; Started on ARV Rx
- Returns for a 3 month follow up visit
- **HIV RNA < 20 c/ml; CD4 390 cells/ul**

ARS Qiestopm 15: Assuming he remains undetectable, you tell him that his risk of transmitting HIV to a seroneg partner via sex is:

1. Zero risk (under these circumstances)
2. Virtually zero risk (no one knows for sure)
3. Very low risk
4. Possible
5. It depends on which ARV regimen he's on
6. C'mon Saag, I don't like this question!

Rate of HIV transmission according to sexual behaviour reported by the negative partner



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Upper 95% CI around estimated rate of zero HIV transmissions: PARTNER 1 compared to PARTNER 1&2

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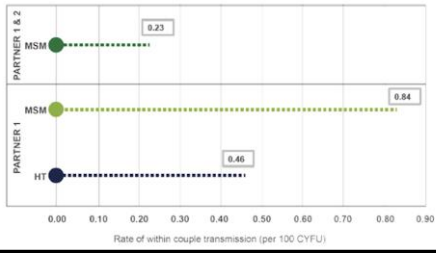
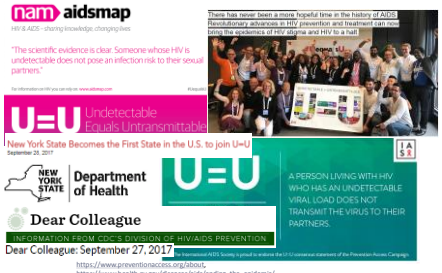


U=U: Undetectable=Untransmittable



Conclusion

- Undetectable = Untransmissable (U = U)
- Debate about how soon to initiate ARV Rx after diagnosis of HIV
- Presence of M184V does not effect initial Rx much (except for use of ABC at higher viral load)
- DTG ***may be*** OK in pregnant women; TAF pending more data. Stay tuned!
- Do not need to change ARV therapy if persistent low level viremia
- 2:1:1 PrEP is an emerging approach for prevention in select populations

Question-and-Answer