Management and Prevention of HIV Infection: Case Discussion

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DISCLOSURES
Grant support:  Gilead, Merck, ViiV
Consultant:  Bristol Myers Squibb, Gilead, Janssen, Merck, Teva, ViiV

Case 1

• 34 year old man presents to clinic after having a routine HIV Ab screening test that was positive in a local testing site. He also had a CD4 count sent and was told it was 570 cells/ul
• The patient was immediately referred to you and is upset but understands that there are good treatments available and he has insurance to cover costs of care, but is nonetheless not completely sure he wants to start treatment
• He has no past medical history, is asymptomatic, has had 5 different partners of unknown HIV status during the past year, 2 in the last month with inconsistent use of condoms for several years

Case 1

Which of the following is closest to what you would recommend to this patient with regards to starting ART?

A. Strongly encourage to start
B. Recommend he start
C. Support him in his wishes to defer
D. Other
START Study Outcomes: Composite Primary Endpoint and its Components

- Immediate ART superior to deferred ART
  - Serious and non-serious AIDS events
- 68% of the primary endpoints with CD4 > 500 cells/mm³
- Similar reductions in events across all subgroups
- No increase in AEs associated with immediate ART


When to Start ARVs

<table>
<thead>
<tr>
<th>AIDS or HIV-Related Symptoms</th>
<th>CD4 Count (cells/mm³)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;200</td>
</tr>
<tr>
<td>United States (2016)</td>
<td></td>
</tr>
<tr>
<td>IAS-USA (2016)</td>
<td></td>
</tr>
<tr>
<td>British HIV Association (2016)</td>
<td>Yes</td>
</tr>
<tr>
<td>European AIDS Clinical Society (2016)</td>
<td>Yes</td>
</tr>
<tr>
<td>WHO (2016)</td>
<td></td>
</tr>
</tbody>
</table>


AIDS or HIV-Related Symptoms

- <200
- 200-350
- 350-500
- >500

United States (2016) Yes Yes Yes Yes
IAS-USA (2016) Yes Yes Yes Yes
British HIV Association (2016) Yes Yes Yes Yes
European AIDS Clinical Society (2016) Yes Yes Yes Yes
WHO (2016) Yes Yes Yes Yes

Case 1

If you and patient decide that starting is the right thing to do, what would you recommend next?

A. Send routine laboratory studies, HIV genotype and schedule for f/u appointment when results return
B. Send routine laboratory studies without a HIV genotype and start ARVs immediately
C. Send routine laboratory studies with a HIV genotype and start ARVs immediately
D. Something else

Case 1: 34 yo asymptomatic man, CD4=570 cells/uL
State-transition Markov process model to assess mortality risk associated with ART delays
Patient level data from 3 South African cohorts
Estimated increase in mortality from 11 to 14.7% (relative increase of 34%) with a 10-week delay in ART
Relative risk similar across CD4 counts but differ for absolute risks

Hoffmann CJ, et al. JAIDS 2013; 63:105-111

• RCT in South Africa clinics (n=377)
• SOC had 3-5 additional clinic visits over 2-4 wks prior to ARVs
• Primary outcome was VL < 400 c/mL within 10 months
  • 64 vs. 51%; RR 1.26 (1.05, 1.50)
• Secondary outcome was initiation ART within 90 days
  • 97 vs. 72%; HR 1.36 (95% CI 1.24, 1.49)

New SFGH patients, RAPID era: 2013-2014

<table>
<thead>
<tr>
<th>Indicator</th>
<th>RAPID Cohort (n=39)</th>
<th>Universal ART (n=47)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sociodemographics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age: mean(range)</td>
<td>32 (21-47)</td>
<td>35 (19-68)</td>
<td>NS</td>
</tr>
<tr>
<td>Male: n (%)</td>
<td>39 (100%)</td>
<td>43 (92%)</td>
<td>NS</td>
</tr>
<tr>
<td>Non-white ethnicity</td>
<td>23 (59%)</td>
<td>34 (71%)</td>
<td>NS</td>
</tr>
<tr>
<td>Homeless</td>
<td>11 (28%)</td>
<td>13 (25%)</td>
<td>NS</td>
</tr>
<tr>
<td>Uninsured</td>
<td>39 (100%)</td>
<td>47 (100%)</td>
<td>NS</td>
</tr>
<tr>
<td>Staging</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute (Ab-&lt;6m)</td>
<td>21/30 (70%)</td>
<td>8/31 (26%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Log10VL</td>
<td>4.9 (2.8-6.6)</td>
<td>4.5 (1.6-6.1)</td>
<td>NS</td>
</tr>
<tr>
<td>CD4 mean (range)</td>
<td>474 (3-1391)</td>
<td>417 (11-1104)</td>
<td>NS</td>
</tr>
</tbody>
</table>
Uptake of same-day ART

RAPID era 2013-2014: transmitted resistance and drug regimens

<table>
<thead>
<tr>
<th>Indicator</th>
<th>RAPID (n=39)</th>
<th>Universal ART (n=47)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype obtained</td>
<td>32/39 (82.1%)</td>
<td>43/47 (91.5%)</td>
<td>0.21</td>
</tr>
<tr>
<td>Any^</td>
<td>8/32 (25.0%)</td>
<td>18/43 (41.9%)</td>
<td>0.13</td>
</tr>
<tr>
<td>Major NNRTI-R^</td>
<td>7/32 (21.9%)</td>
<td>11/43 (25.6%)</td>
<td>0.71</td>
</tr>
<tr>
<td>Major PI-R</td>
<td>1/32 (3.1%)</td>
<td>2/43 (4.7%)</td>
<td>0.99</td>
</tr>
<tr>
<td>Major NRTI-R</td>
<td>0 (0%)</td>
<td>1/43 (2.3%)</td>
<td>0.99</td>
</tr>
<tr>
<td>ART initiated^6</td>
<td>39/39 (100%)</td>
<td>38/47 (80.9%)</td>
<td>0.003</td>
</tr>
<tr>
<td>INSTI use^6</td>
<td>35/39 (89.7%)</td>
<td>32/38 (84.2%)</td>
<td>0.47</td>
</tr>
</tbody>
</table>

RAPID Antiretroviral Regimens

- TDF/FTC + DTG 26 (67%)
- EVG/CObI/FTC/TDF 7 (18%)
- TDF/FTC + DRV + RTV 4 (10%)
- TDF/FTC + RAL 1 (2%)
- ABC/3TC/DTG 1 (2%)

- TDF/FTC + DTG 26 (67%)
- EVG/CObI/FTC/TDF 7 (18%)
- TDF/FTC + DRV + RTV 4 (10%)
- TDF/FTC + RAL 1 (2%)
- ABC/3TC/DTG 1 (2%)
**Case 1**

You encourage him to start on the same day and he agrees. He states that he has no specific concerns regarding adherence, side effects or dosing schedule. Which of the following would you recommend?

A. Two NRTIs + boosted PI  
B. Two NRTIs + RAL  
C. TDF/FTC/EFV  
D. TDF (or TAF)/FTC/RPV  
E. TDF (or TAF)/FTC/COBI/EVG  
F. TDF (or TAF)/FTC + DTG  
G. ABC/3TC/DTG  
H. Something else

34 yo asymptomatic man  
CD4 = 570 cells/ul  
All laboratory studies are pending

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**Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents**

**Most treat before HIV drug resistance results available**

**World NRTI-based regimen**

**Recommended ART Regimens**
- DRV/r plus TAF/FTC or TDF/FTC
- DTG plus TAF/FTC or TDF/FTC

**Transmitted mutations conferring NRTI resistance are more likely than mutations with PI or INSTI resistance**

Resistance to DRV/r and DTG emerges slowly; transmitted resistance to DRV is rare and has not been reported to DTG.
Case 1
You decide to defer therapy pending labs and he now returns: VL 23,000 copies/mL; HBsAb+, HCV Ab-, HLA-B5701 neg, chemistries WNL. Genotype is WT. He is ready to start ARVs and has no specific concerns regarding adherence, side effects or dosing schedule. Which of the following would you recommend?
A. Two NRTIs + boosted PI
B. Two NRTIs + RAL
C. TDF/FTC/EFV
D. TDF (or TAF)/FTC/RPV
E. TDF (or TAF)/FTC/COBI/EVG
F. TDF (or TAF)/FTC + DTG
G. ABC/3TC/DTG
H. Other

Case 1
If you chose a tenofovir-based regimen, which would you use?
A. TAF
B. TDF

Tenofor Alafenamide (TAF)
90% Lower TFV Levels in Plasma Minimizes Renal and Bone Effects While Maintaining High Potency for Suppressing HIV
Same patient that you sent off awaiting labs only in this case CD4=145 cells/μL, VL=180,000 c/mL and he missed several clinic appointments after initial visit. He admits to using alcohol and experiencing mild depression. He has met with psychologist a few times and is relatively stable and drinking “some what less.” Which of the following would you recommend?

A. Two NRTIs + boosted PI
B. Two NRTIs + RAL
C. TDF (or TAF)/FTC/COBI/EVG
D. TDF (or TAF)/FTC + DTG
E. ABC/3TC/DTG
F. Other
Low Virologic Failure and Treatment-Emergent Resistance With Boosted PIs

<table>
<thead>
<tr>
<th>Trial Name</th>
<th>F/u, Wks</th>
<th>Treatment Arm</th>
<th>Virologic Failure, n (%)</th>
<th>Treatment-Emergent Primary Mutations, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CASTLE[1]</td>
<td>96</td>
<td>ATV/RTV + TDF/FTC (n = 440)</td>
<td>28 (6)</td>
<td>1 (RTI), 7 (NRTI)</td>
</tr>
<tr>
<td>ACTG 5202[1]</td>
<td>96</td>
<td>ATV/RTV (n = 313)</td>
<td>120 (34)</td>
<td>68 (NRTI), 36 (NRTI)</td>
</tr>
<tr>
<td>Study 102[3]</td>
<td>144</td>
<td>ATV/RTV + TDF/FTC (n = 315)</td>
<td>120 (34)</td>
<td>68 (NRTI), 36 (NRTI)</td>
</tr>
<tr>
<td>ARTENS-1[4]</td>
<td>96</td>
<td>DRV/R + TDF/FTC (n = 345)</td>
<td>98 (26)</td>
<td>2 (NRTI)</td>
</tr>
<tr>
<td>FLAMINGO[5]</td>
<td>96</td>
<td>DRV/R + TDF/FTC (n = 345)</td>
<td>98 (26)</td>
<td>2 (NRTI)</td>
</tr>
<tr>
<td>ACTG 5203[5]</td>
<td>96</td>
<td>ATV/RTV + TDF/FTC (n = 443)</td>
<td>29 (7)</td>
<td>2 (NRTI), 1 (RTI)</td>
</tr>
</tbody>
</table>


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Dolutegravir + NRTIs in Treatment-Naive Patients

HIV-1 RNA < 50 c/mL by Snapshot Analysis: 95% CI for Treatment Difference

**SINGLE[1]**

- ATV/RTV + TDF/FTC (n = 411)
- 29 (7)
- 1 (RTI), 4 (NRTI)

**FLAMINGO[1]**

- DRV/R + TDF/FTC (n = 414)
- 39 (9)
- 1 (RTI), 4 (NRTI)

**SPRING-2[1]**

- ATV/RTV + TDF/FTC (n = 413)
- 23 (5)
- 1 (RTI), 4 (NRTI)

**ARIA[2]**

- ATV/RTV + TDF/FTC (n = 352)
- 16 (4)
- 1 (RTI), 4 (NRTI)

No resistance selected for in any DTG-containing regimen

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Low Virologic Failure and Lack of Treatment-Emergent Resistance With DTG

<table>
<thead>
<tr>
<th>Trial Name</th>
<th>F/u, Wks</th>
<th>Treatment Arm</th>
<th>Virologic Failure, n (%)</th>
<th>Treatment-Emergent Primary Mutations, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPRING-2[1]</td>
<td>96</td>
<td>ATV/RTV + TDF/FTC (n = 413)</td>
<td>29 (7)</td>
<td>1 (RTI), 4 (NRTI)</td>
</tr>
<tr>
<td>SINGLE[1]</td>
<td>144</td>
<td>ATV/RTV + TDF/FTC (n = 414)</td>
<td>39 (9)</td>
<td>1 (RTI), 4 (NRTI)</td>
</tr>
<tr>
<td>FLAMINGO[1]</td>
<td>96</td>
<td>ATV/RTV + TDF/FTC (n = 414)</td>
<td>23 (5)</td>
<td>1 (RTI), 4 (NRTI)</td>
</tr>
<tr>
<td>Study 102[3]</td>
<td>144</td>
<td>DRV/R + TDF/FTC (n = 348)</td>
<td>186 (50)</td>
<td>9 (NRTI), 10 (NRTI)</td>
</tr>
<tr>
<td>Study 103[3]</td>
<td>144</td>
<td>DRV/R + TDF/FTC (n = 348)</td>
<td>186 (50)</td>
<td>9 (NRTI), 10 (NRTI)</td>
</tr>
</tbody>
</table>

Case 2

- 49 year old man with stable DM who had been HIV-negative presents to you for advice regarding how to best avoid HIV infection in his new relationship with an HIV-infected man
- He states that his partner has been on ARVs for nearly two years with good viral suppression
- Although they mostly use condoms he had heard that they may not be necessary if his partner is suppressed on ARVs
- He would rather not use condoms but wants to know what his risks would be without

Case 2
Which of the below would be closest to what you would tell him with regards to his risks of acquiring HIV from his current partner if they choose to not use condoms?

A. You would be at some risk and should ideally use condoms
B. The risk would be very low but can’t tell you that it is completely safe
C. Your risk under these circumstances is essentially zero
HPTN 052: Final Results of HIV Prevention in Stable Heterosexual Couples

- Linked HIV transmission to HIV-negative partner (n=46)
  - Overall 93% reduction in risk of transmission with early therapy
- Linked partner infections diagnosed after index partner started ART (n=18)
  - Recently initiated ART (n=4)
  - Virologic failure (n=4)
- No HIV transmission among people who were suppressed
  - Timing of the linked transmission events supports the model that HIV transmission is very unlikely in the setting of viral suppression

*Phylogenetic methods compared HIV pol sequences from index partner pairs and controls. Linkage probability was further assessed by comparing the genetic distances between pol sequences (Bayesian analysis).


Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressing Antiretroviral Therapy

Condomless Sex With Viologically Suppressed HIV-Infected Individuals
How Safe Is It?

- Contribution to HPTN 052
  - Condomless sex
  - MSM
- Limitations
  - Power, especially for highest risk MSM
  - Cohort of serodiscordant couples
  - Median duration of condomless sex at entry ~2 years
  - Median duration on suppressive ARVs at entry >7 years
  - Adherence rates >90%
  - Counseled to use condoms
- Additional lessons
  - High rate of STIs
  - Transmissions from non-regular partners

JAMA 2016; 316:149-150
Case 2

He and his partner decide, based upon the information you provided him that they would not use condoms as long as the infected partner’s viral load is undetectable. Then your patient asks you if you would recommend he use PrEP. Which of below would be closest to what you would recommend?

A. With an HIV-infected partner it would be appropriate for you to be on PrEP
B. Your risk with your current partner on ARVs is too low to justify PrEP
C. I would totally leave it up to you
D. Something else

Case 2

He decides that he wants to use PrEP. He is 4th generation HIV-negative, HBsAb+, has CrCl- 70 mL/min. Which would be closest to what you would recommend:

A. TDF/FTC once daily
B. TDF/FTC around sex
C. TDF/FTC four times per week
D. TDF once daily
E. Strongly encourage him not to take PrEP since risk is low and renal function impaired
F. Something else

Table of Recommendations

<table>
<thead>
<tr>
<th>Condition</th>
<th>CDC</th>
<th>WHO</th>
<th>IAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSM or heterosexual Men and Women</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• HIV (+) sex partner*</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>• Inconsistent condom use, or recent STI, or high number of sexual partners</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>• IDU</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Commercial sex work</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• In high-prevalence area or network (for MSM and women only)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• PEP use (the last 3 years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• TDF 300 mg (IDU only)</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Regimen suggested

<table>
<thead>
<tr>
<th>Drug</th>
<th>CDC</th>
<th>WHO</th>
<th>IAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDF 300 mg + FTC 200 mg</td>
<td>Once Daily</td>
<td>Once Daily</td>
<td>Once Daily</td>
</tr>
</tbody>
</table>

Revised 07/16/14

*For any regular sex partner should consider if they are on ARVs with undetectable VL

Case 2

- Your patient starts TDF/FTC once daily
- He returns several times over the next 12 months with STIs and ultimately admits that he has sex with multiple men without condoms outside of his current relationship
- You counsel him to use condoms and he continues to return with frequent STIs but to be repeatedly HIV-negative
- He is noted during the past year to have a progressive decline in CrCl to approximately 50 mL/min

Case 2

The patient is having continued high risk sex despite counseling and has progressive decline in renal function. Which of the below is closest to what you would recommend?

A. Continue daily TDF/FTC with close monitoring or renal function
B. Tell him it is no longer safe for him to take TDF/FTC so he needs to be more consistent with condom use and PrEP is no longer an option
C. Switch to four days per week TDF/FTC
D. Switch to TAF/FTC
E. Switch to non-tenofovir-based PrEP
F. Something else

iPrex Open Label Extension: HIV Incidence and Drug Concentrations

Phase 2 study of safety and tolerability of maraviroc-containing regimens to prevent HIV infection in MSM (HPTN 069/ACTG A5305)

- 5 incident infections (4 MVC alone, 1 MVC + TDF); no sig difference by regimen.
- 2 with undetectable drug levels at every visit, 2 low levels at seroconversion visit and 1 variable concentrations

Gulick RM, et al. JID 2016

Case 3

56 year old man with long history of HIV, DM, and CAD. He has been followed off ARV for several years and now finally agrees to start.
- No symptoms and negative exam with bp- 125/75
- CD4 335 cells/μL; VL 120,000 copies/mL
- HLA-B5701-negative
- HgbA1C 7.1% on metformin 1000 mg bid
- HBVsAb+, HCV Ab-
- UA with 2+ protein, CrCl 47 mL/min
- HIV genotype is WT

Which of the following would you recommend?

A. TAF/FTC/EVG/COBI
B. TAF/FTC + RAL
C. TAF/FTC + boosted PI
D. TAF/FTC + DTG
E. ABC/3TC/DTG
F. ABC/3TC + boosted PI
G. ABC and TAF-sparing regimen
H. Something else

56 yo man with chronic HIV, DM, CAD
- CD4 335 cells/μL; VL- 120,000 copies/mL
- HLA-B5701-negative
- CrCl= 47 mL/min, UA 2+ proteinuria
- HgbA1C- 7.1% on metformin 1000 mg bid
- HCV-neg; HBsAb+
- Genotype: WT
Case 3

Which of the following would you recommend if the same patient started out with relatively normal renal function but experienced a decline while on a stable suppressive regimen of TDF/FTC + RAL?

A. Monitor without change
B. TAF/FTC-based regimen
C. ABC/3TC-based regimen
D. ABC and TAF-sparing regimen
E. Something else

Case 3

• 56 yo man with chronic HIV, DM, CAD
• VL suppressed on TDF/FTC + RAL
• HLA-B5701-negative
• eGFR < 60 mL/min, UA 2+ proteinuria
• Baseline Genotype- WT

Abacavir and Cardiovascular Events

<table>
<thead>
<tr>
<th>Study/Design</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>D:A:D[1]</td>
<td>Cohort collaboration (prospective)</td>
</tr>
<tr>
<td>Danish HIV Cohort[2]</td>
<td>Cohort (linked with registries)</td>
</tr>
<tr>
<td>Montreal study[3]</td>
<td>Nested case-control study</td>
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<tr>
<td>SMART[4]</td>
<td>Post hoc subgroup analysis of RCT (use of ABC not randomized)</td>
</tr>
<tr>
<td>Swiss HIV Cohort[6]</td>
<td>Cohort (retrospective)</td>
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<tr>
<td>FHCRCARDS[7]</td>
<td>Equivocal nested case-control study</td>
</tr>
<tr>
<td>NA-ACCORD[8]</td>
<td>Equivocal cohort retrospective</td>
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<tr>
<td>VA-Clinical Case Registry[9]</td>
<td>- Post hoc meta-analysis of RCTs</td>
</tr>
<tr>
<td>Brothers et al analysis[10]</td>
<td>- Post hoc meta-analysis of RCTs</td>
</tr>
<tr>
<td>FDA meta-analysis[12]</td>
<td>- Post hoc meta-analysis of RCTs</td>
</tr>
</tbody>
</table>

GS-112: Switching to a TAF-Based Regimen in Pts With Renal Impairment

Multicenter, open-label phase III trial

Virologically suppressed, HIV-positive pts with mild-moderate renal impairment (stable eGFR [30-69 mL/min]) (N = 242)

<table>
<thead>
<tr>
<th>PI</th>
<th>NNRTI</th>
<th>INSTI</th>
<th>CCR5 Antag.</th>
<th>TDF</th>
<th>ABC</th>
<th>Other NRTI</th>
<th>No NRTI</th>
</tr>
</thead>
<tbody>
<tr>
<td>ART use, %</td>
<td>44</td>
<td>42</td>
<td>24</td>
<td>3</td>
<td>65</td>
<td>22</td>
<td>7</td>
</tr>
</tbody>
</table>

GS-112: Key Results

Change in eGFR from Baseline to Wk 48

<table>
<thead>
<tr>
<th></th>
<th>TDF</th>
<th>Non-TDF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Change from Baseline (mL/min)</td>
<td>-2.2</td>
<td>-2.7</td>
</tr>
</tbody>
</table>

*P < 0.05

Actual GFR by iohexol Clearance from Baseline to Wk 24

<table>
<thead>
<tr>
<th></th>
<th>TDF</th>
<th>Non-TDF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean iohexol clearance (mL/min)</td>
<td>83 63 50 43 49</td>
<td>63 62 50 45 40</td>
</tr>
</tbody>
</table>


Case 3

If you were going to go with ABC and TAF-sparing regimen, which of the following would you recommend?

A. Boosted PI alone
B. Boosted PI + 3TC
C. Boosted PI + INSTI
D. Boosted PI + NNRTI
E. DTG alone
F. DTG + 3TC
G. DTG + RPV
H. Something else

- 56 yo man with chronic HIV, DM, CAD
- CD4 335 cells/uL; VL- 120,000 c/mL
- HLA-B5701-negative
- CrCl= 47 mL/min, UA 2+ proteinuria
- HgbA1C- 7.1% on metformin 1000 mg bid
- HCV-neg; HBsAb+
- Genotype: WT

NEAT: RAL + DRV/RTV vs. TDF/FTC + DRV/RTV in Naive Pts at 96 Wks

- Randomized, open-label phase III study of DRV/RTV + RAL vs DRV/RTV + TDF/FTC in ART-naive pts

<table>
<thead>
<tr>
<th>Primary Endpoint at Wk 96: Adjusted Difference Estimate (95% CI)</th>
<th>RAL - TDF/FTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bl HIV RNA &lt; 100,000</td>
<td>17.4</td>
</tr>
<tr>
<td>≥ 100,000</td>
<td>7</td>
</tr>
<tr>
<td>CD4 cell count &lt; 250</td>
<td>27</td>
</tr>
<tr>
<td>≥ 250</td>
<td>15.6</td>
</tr>
</tbody>
</table>

Simplification to RTV-Sparing and/or NRTI-Sparing or NRTI-Limiting Regimens (partial list)

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Switch Regimen</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASSURE[1]</td>
<td>296</td>
<td>ATV + ABC/3TC</td>
<td>Similar efficacy as continued standard ART; decline in urine β2-microglobulin/creatinine ratio</td>
</tr>
<tr>
<td>OLE[2]</td>
<td>250</td>
<td>LPV/RTV + 3TC</td>
<td>Similar efficacy as continued standard ART or FTC</td>
</tr>
<tr>
<td>NA[3]</td>
<td>48</td>
<td>DRV/RTV + 3TC</td>
<td>Small study; encouraging efficacy</td>
</tr>
<tr>
<td>ATLAS-M[4]</td>
<td>266</td>
<td>ATV/RTV + 3TC</td>
<td>Improved efficacy vs ATV/RTV + 2 NRTIs</td>
</tr>
<tr>
<td>SALT[5]</td>
<td>286</td>
<td>ATV/RTV + 3TC</td>
<td>Similar efficacy as continued standard ART</td>
</tr>
<tr>
<td>KITE[6]</td>
<td>60</td>
<td>LPV/RTV + RAL</td>
<td>Small study; encouraging efficacy</td>
</tr>
</tbody>
</table>

Thank You!!