



**ANNUAL HIV CONFERENCE**  
 of the Florida/Caribbean AIDS Education and Training Center  
 May 13-14, 2011  
 Orlando, FL  
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## Highlights from CROI

**18th Conference on Retroviruses and Opportunistic Infections**  
 Boston, MA February 28 to March 3, 2011

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This slide set has been peer-reviewed to ensure that there are no conflicts of interest represented in the presentation.

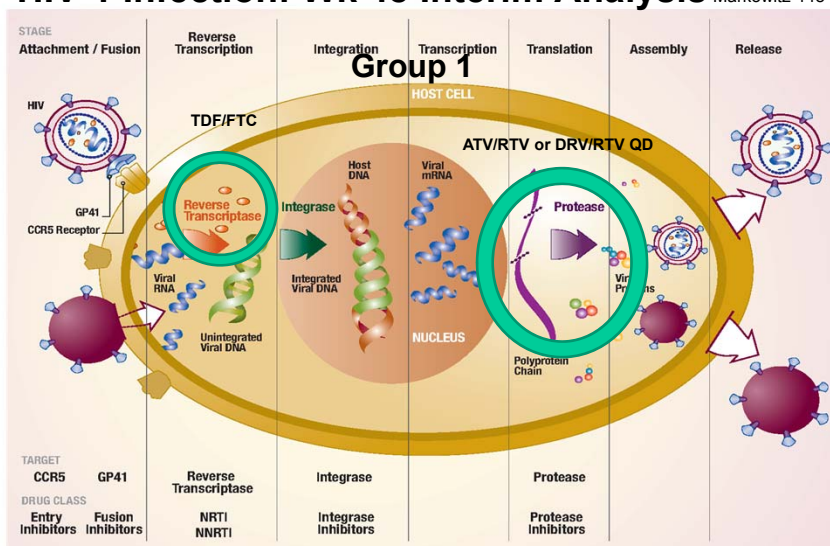


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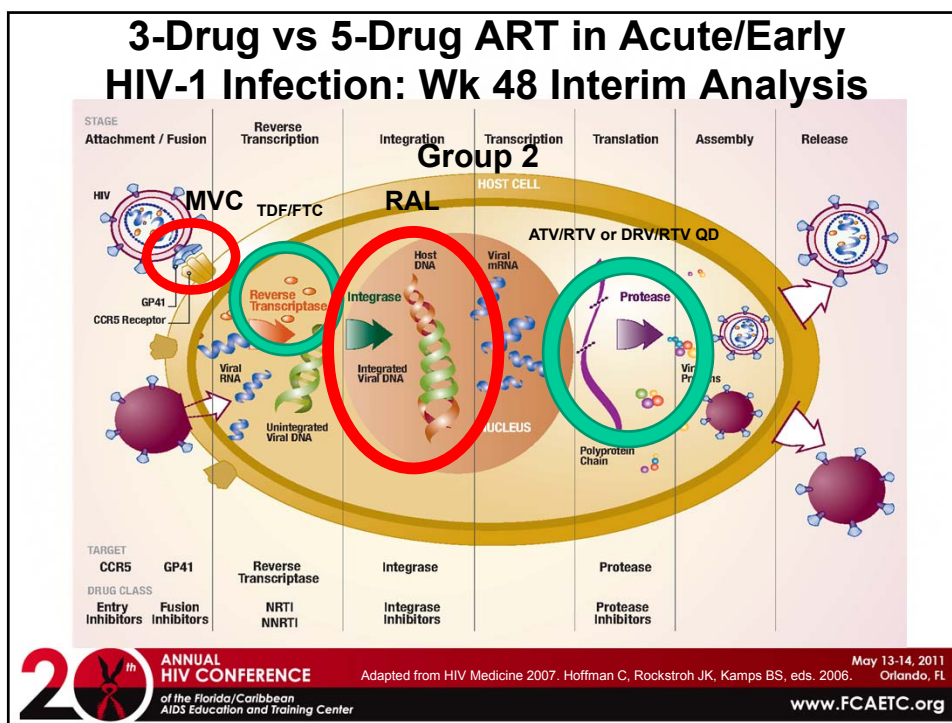
# TREATMENT-NAÏVE PATIENTS


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## 3-Drug vs 5-Drug ART in Acute/Early HIV-1 Infection: Wk 48 Interim Analysis Markowitz 148




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 Adapted from HIV Medicine 2007. Hoffman C, Rockstroh JK, Kamps BS, eds. 2006.  
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### 3-Drug vs 5-Drug ART in Acute/Early HIV-1 Infection: Wk 48 Interim Analysis

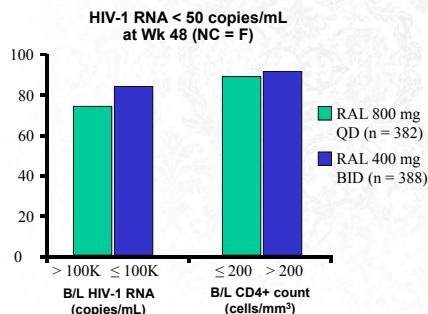
#### 5-drug regimen showed no improvement vs 3-drug regimen at 1 yr regarding

- Plasma viremia by standard or single-copy assays
- Proviral DNA or cell-associated HIV-1 RNA
- Levels of naive, total CD4+ cells or markers of immune activation

## QDMRK: QD vs BID Raltegravir in Treatment-Naive Patients

- **RAL QD inferior to RAL BID at Wk 48 (each with TDF/FTC)**

- 83.2% vs 88.9% < 50 c/mL
- $\Delta$  QD-BID: -5.7 (95% CI: -10.7 - -0.83);  
P value for noninferiority = .044



- **The once a day arm shows:**

- Lower RAL trough levels
- More patients failing at <400 copies/ml
  - $\geq 2$  RAL mutations
- More FTC mutations
- More integrase mutations

"What the study showed is that the current way we give raltegravir, twice a day, is very effective and well tolerated. The experimental way we tried, the once-daily regimen, while quite active, did not quite measure up to giving the drug twice a day," Joseph Eron, MD



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Eron J, et al. CROI 2011. Abstract 150LB

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## QDMRK: QD vs BID Raltegravir in Treatment-Naive Patients

- What about patients who achieved suppression to < 50 c/mL at w 24? Do they continue <50 copies or fail the regiment at 48 wks?
  - Numbers **favored BID** raltegravir treatment.
    - 4.7% QD rebounded to > 50 c/mL
    - 2.7% BID rebounded to > 50 c/mL
- Data does not address if twice daily raltegravir or another first line TDF/FTC containing regimen were switched to once daily raltegravir after a patient had been suppressed to < 50 c/mL for a long period of time. More research is needed.



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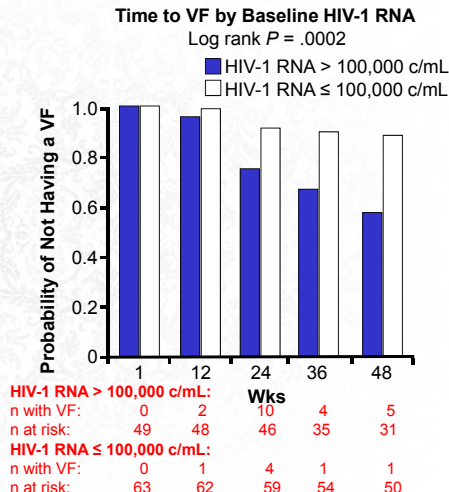
Eron J, et al. CROI 2011. Abstract 150LB

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## ACTG A5262: DRV/RTV + RAL Without NRTIs in Treatment-Naive Patients

- **Single-arm study (N = 112)**
  - RAL 400 mg BID + DRV/RTV 800/100 mg QD
- **Virologic failure: 16% at Wk 24; 26% at Wk 48**
- **VF associated with baseline VL > 100,000 c/mL**
  - HR 3.76 (95% CI: 1.52-9.31; P = .004)
- **5/25 VFs with genotypes had integrase mutations; all had baseline VL > 100,000 c/mL**
- **THM: Not a good option base on high failure rate**

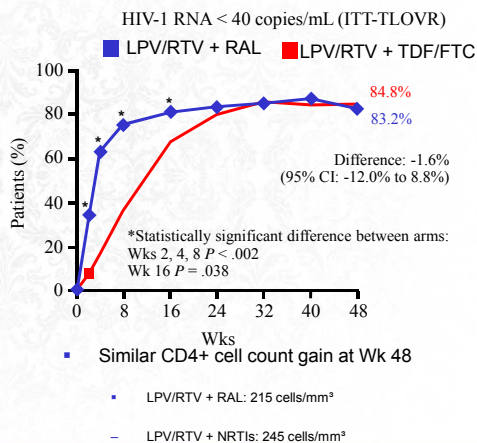


Taiwo B, et al. CROI 2011. Abstract 551.

**20th ANNUAL HIV CONFERENCE** Slide from CCO  
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## AIDS 2010-PROGRESS: LPV/RTV + RAL vs LPV/RTV + NRTIs in Treatment-Naive Patients

- Randomized, open-label, multicenter phase III trial in treatment-naive patients with HIV-1 RNA > 1000 copies/mL
  - LPV/RTV 400 mg BID + RAL 400 mg BID (n = 101) vs
  - LPV/RTV 400 mg BID + TDF/FTC 300/200 mg QD (n = 105)
- **Relatively low mean baseline HIV-1 RNA**
  - 4.25 log<sub>10</sub> copies/mL



**20th ANNUAL HIV CONFERENCE**  
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 Reynes J, et al. AIDS 2010. Abstract MOAB0101.  
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## Slide 10

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**IMR2** is this from 2011 or 2010 conference? it is up to you if you want to keep it  
but the title is 2011 CROI  
Jay: I use as sample of previous data of no Nuc regiment and the reason why we need more data.  
Ivan Melendez-Rivera, 5/4/2011

# INTENSIFICATION



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## MVC Intensification Studies

- **MVC or placebo added for 24 wks in 45 patients with VL < 48 c/mL for > 1 yr on stable HAART but CD4+ gain < 100 cells/mm<sup>3</sup> and CD4+ count < 350 cells/mm<sup>3</sup> during previous yr<sup>[1]</sup>**
  - No difference in absolute CD4+ cell count
  - MVC led to 2-fold increase in CD4+ and CD8+ T-cell activation in GALT
- **ACTG 5256: MVC added for 24 wks in 34 patients with VL < 50 c/mL for ≥ 48 wks on stable HAART but CD4+ count < 250 cells/mm<sup>3</sup>**
  - Previous analysis showed MVC intensification not associated with clinically significant CD4+ gain<sup>[2]</sup>
  - Decrease in CD4+ and CD8+ activation with MVC, partially reversed after withdrawal<sup>[3]</sup>
- **MARAVIBOOST: 30 treatment-naive patients treated for 24 wks with TDF/FTC + RAL ± MVC<sup>[4]</sup>**
  - Faster CD4+ gain with MVC intensification, no difference in virologic response



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1. Hunt P, et al. CROI 2011. Abstract 153LB. 2. Wilkin TJ, et al. CROI 2010. Abstract 285. May 13-14, 2011  
3. Wilkin TJ, et al. CROI 2011. Abstract 574. 4. Massanella M, et al. CROI 2011. Abstract 547. Orlando, FL

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## RAL Intensification Studies

- **CD4 Level**
  - Increase in patients suppressed on HAART with poor CD4 recovery (Massanella et #545)
- **Immune Activation**
  - Decrease as measured by several CD8 and CD4 activation markers. (Massanella et al s #281).
    - Partially reversed when raltegravir was stopped
  - No significant change in immune activation (Gandih #51)



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## NEW FRIENDS ON THE ROAD



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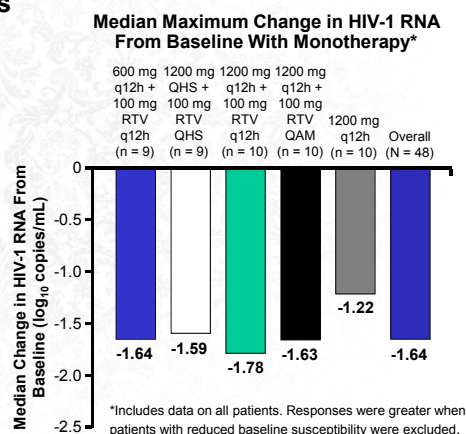
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## Rilpivirine

- **Similarities between raltegravir QD data and the ECHO and THRIVE data. (Rimsky L et al. ICAAC 2010 H1810)**
  - More virologic failures with rilpivirine in VL $\geq$ 100,000 copies/ml
  - More resistance to FTC and the NNRTI class.
- **Significantly fewer AE on rilpivirine pts (Mills CROI 2011 #420)**
  - Discontinuation (1.6% vs. 2.9%; rilpivirine vs. efavirenz respectively).
  - AE's predominantly occurred early and there was little difference between the two treatment groups after the first 12 weeks.
  - AE more common in patients with a history of neurologic or psychiatric illness.
- **Better lipid profile (Arribas #819)**
  - Framingham score was the same in both groups
- **Not significant  $\Delta$  in 25 (OH) Vit D levels (Wohl #79LB)**

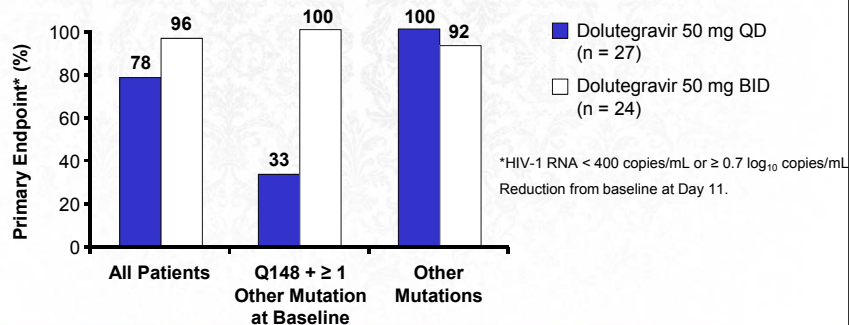
## BMS-663068: Oral HIV Attachment Inhibitor


- **First of novel class that inhibits CD4 binding**
- **PK suggest QD or BID dosing without boosting**
- **Most common grade 1/2 AEs**
  - Headache, rash, micturition urgency, nasopharyngitis
- **↓ Baseline susceptibility in some pts due to envelope polymorphisms; screened by baseline IC<sub>50</sub>**



## VIKING: Dolutegravir “Functional Monotherapy” in Pts With RAL Resistance

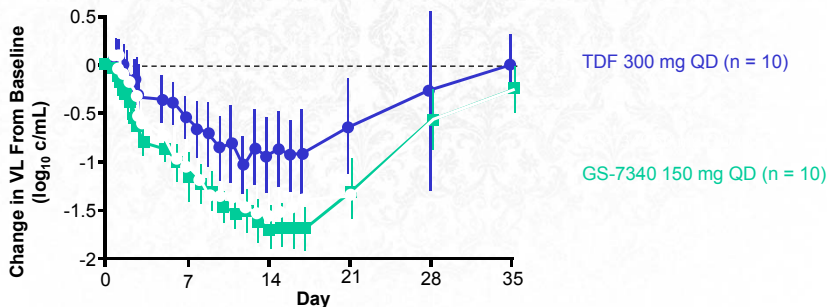
- BID dosing of dolutegravir (S/GSK1349572) more effective through Day 11 in patients with Q148 mutation
  - Q148 most common RAL mutation, confers greatest resistance





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 Eron J, et al. CROI 2011. Abstract 151LB. May 13-14, 2011 Orlando, FL  
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## GS-7340: 14-Day Monotherapy With TDF Prodrug in HIV-Infected Patients

- Lower TDF plasma concentrations, higher intracellular concentrations obtained with GS-7340 vs TDF
  - Hypothesized that this may result in greater efficacy, reduced toxicity
- 14-day mean VL reduction significantly greater with GS-7340 vs TDF




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 Markowitz M, et al. CROI 2011. Abstract 152LB. Graphic from cco.com  
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## New Markers

- **Cystatin C :alternative to GFR [#839]<sup>IMR3</sup>**
  - Elevated cystatin C ( $\geq 1$ mg/L) were associated with abnormal lipid levels and higher levels of the inflammatory markers IL-6 and CRP
- **sCD163<sup>(soluble)</sup>: novel marker of macrophage activation (Burdo, abstract 813)**
  - found to be elevated in HIV+ at the presence of non-calcified plaque
  - may have a role in identifying patients at high risk for CVD that needs further confirmation
- **Neurofilament H in the cerebrospinal fluid (CSF)** <sup>(Nath #407)</sup>
  - a biomarker for impending cognitive decline and point the way to early initiation of neuroprotective treatments



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HIV DISEASE AND

## TREATMENT COMPLICATIONS



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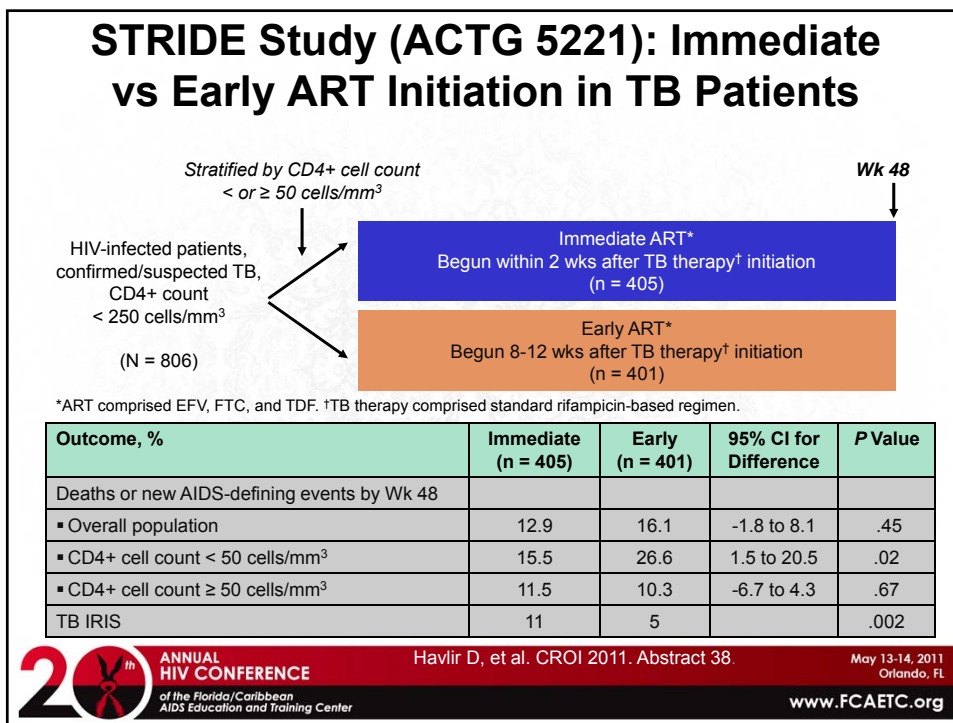
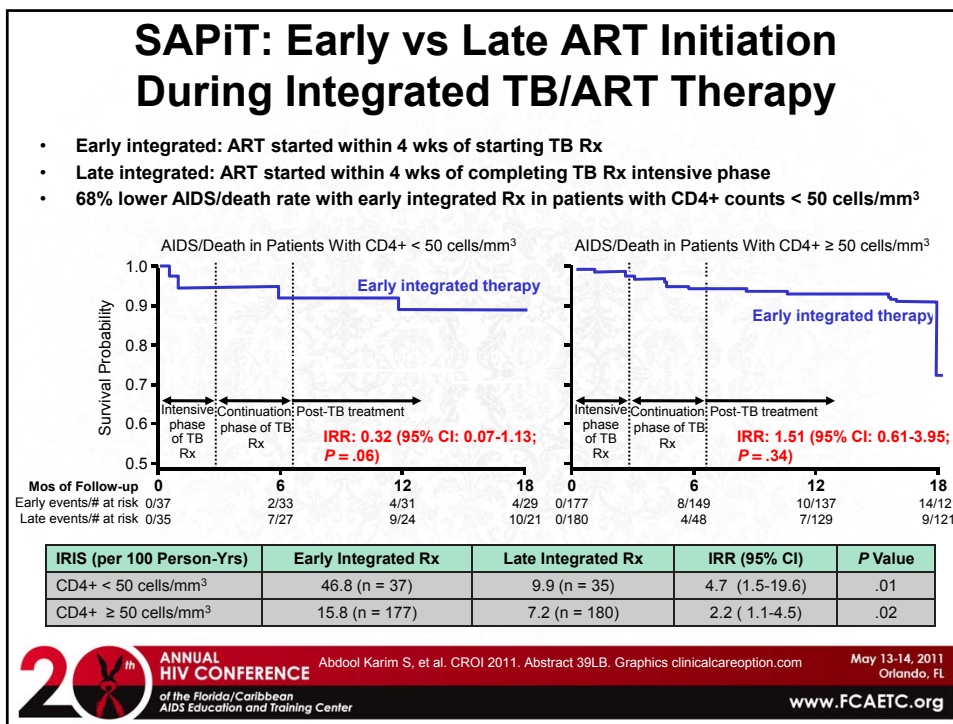
Slide 19

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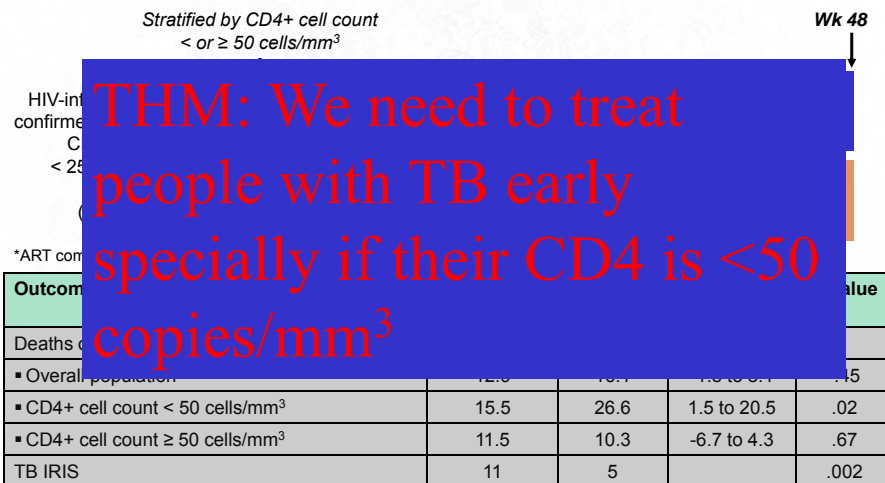
**IMR3** THE LIMITATION OF THIS STUDY WAS THAT IT IS FROM STORED SAMPLES FROM SMART STUDY AND IT NEEDS TO BE REPEATED

Ok. I will point out that at the presentation

Ivan Melendez-Rivera, 5/4/2011

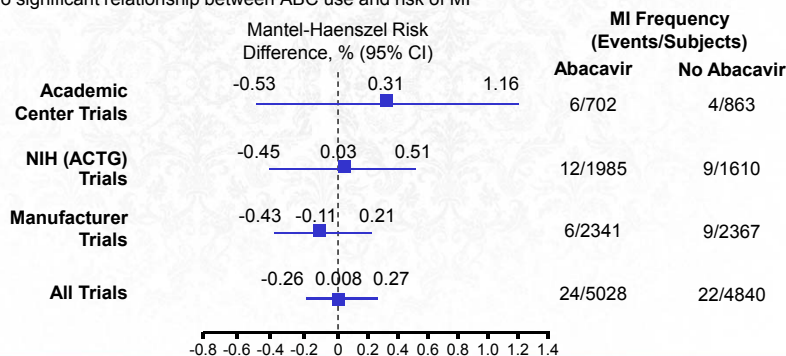


## STRIDE Study (ACTG 5221): Immediate vs Early ART Initiation in TB Patients



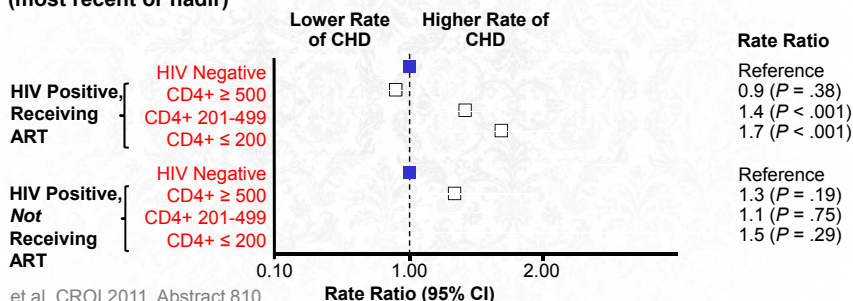
## Heart and HIV FDA Meta-analysis of Risk of Myocardial Infarction in Abacavir Trials

- Conflicting evidence from previous datasets regarding possible association of ABC use with increase in MI risk
- Current analysis: 26 controlled trials in which ABC use was randomized; source data obtained for analysis
  - No significant relationship between ABC use and risk of MI



## CD4+ Cell Count and CHD Risk in HIV-Infected Patients

- Cohort study of HIV+ and HIV- Kaiser Permanente members
- Overall, increased risk of CHD ( $P < .001$ ), MI ( $P < .001$ ) in HIV+ vs HIV- patients
- No increased risk of CHD in treated HIV+ patients with CD4+  $\geq 500$  cells/mm<sup>3</sup> (most recent or nadir)



Klein D, et al. CROI 2011. Abstract 810.

\*Adjusted for age, race, sex, tobacco use, alcohol/drug abuse, obesity, diabetes, and use of lipid-lowering and antihypertensive therapy. The following factors were time varying in the analysis: ART, CD4+ count, age, diabetes, lipid-lowering therapy, antihypertensive therapy, remaining factors were fixed variables.



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## Lipodystrophy and HIV

### FRAM: Limb Muscle Mass, Central Adiposity, and 5-yr Mortality in HIV+ Pts

- Multivariate regression analysis of 922 HIV+ pts, grouped in 3 groups
- 5 years mortality risk associated with:
  - Low limb muscle mass
  - High central adiposity
  - Even after accounting for inflammation, renal disease and other known factors related to mortality
- Peripheral lipoatrophy not associated with mortality
- Substantial proportion of this mortality risks may unrecognized due to the on BMI to assess wasting, which misses the combination of low muscle and higher VAT
- THM: Measure waist circumference and mid arm circumference to HIV-infected patients



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Scherzer R, et al. CROI 2011. Abstract 76.

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## Bone and HIV

- **HCV coinfection increases fractures** <sup>1</sup>
- **Initial bone loss is an immune reconstitution phenomenon associated with the rapid reconstitution of the T cells**<sup>2</sup>
  - $\uparrow$  CD4 =  $\uparrow$  RANKL =  $\uparrow$  osteoclastic activity =  $\uparrow$  resorption rate of the bone.
  - $\uparrow$  osteoblast activity to stabilize the situation
- **In HIV-infected young males treated with ART, there may be a failure to achieve peak bone mass**<sup>3</sup>
  - Tenofovir
    - $\uparrow$ PTH,  $\downarrow$ Vit. D3 & Calcium



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1. Volk, #914 ; Yin # 830; 2. Ofookun t # 78; 3. Labarga #824

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## Vitamin D and HIV

- **TMC278 (rilpivirine) does not change vitamin D levels when compared to those receiving efavirenz. (Whol #79)**
  - 6 nmol/L, vs 3 ng/ml difference
  - Longer follow up required
- **Vitamin D replacement**
  - Risk of developing diabetes was reduced (30,000 units per month) (Guaraldi #827)
  - 12-wks high-dose vitamin D<sub>3</sub> is safe and significantly reduces both vitamin D insufficiency and serum parathyroid hormone (PTH) levels in youth treated with tenofovir. (Havens #80)
  - Does not improve endothelial function (by FMD) (Longenecker #829)



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## The Kidney and HIV

- **Baseline Renal Function as predictor of Mortality and Renal disease progression (836)**
  - GFR 30-59 mL/min/1.73m<sup>2</sup> had a **1 to 2-fold increase** in risk of all-cause mortality
  - GFR < 30 mL/min/1.73m<sup>2</sup> was associated with a **3 to 4-fold increase** in risk of all-cause mortality.
    - Risk factor for progression to stage 4-5 CKD
- **Clinical characteristics associated with the risk of GFR decline included:**
  - Black race, older age, hepatitis co-infection, diabetes, and hypertension.



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## Chronic Inflammation and HIV

- **Inflammation & CVD**
  - Desvarieux et al. (abstract 803) Duration of HIV infection but not duration of ART was independently associated with cIMT thickness
  - Hunt et al. (abstract 814) Higher levels of CCR-5 expression on T-cells significantly correlated with lower Flow mediated Dilatation FMD
- **Role of innate immunity**
  - Abnormal function of antigen-presenting cells (APCs) was identified as a potential contributor to chronic inflammation (Nagy, abstract 316)
- **ART interruption/ inflammation**
  - **SMART study** : ART discontinuation was strongly associated with elevations of IL-6, TNF alpha, IL-10 and CXCL-10 (aka IP-10) all of which are products of macrophage activation (Cozzi-Lepri, abstract 301).



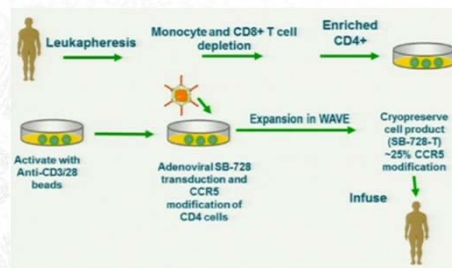
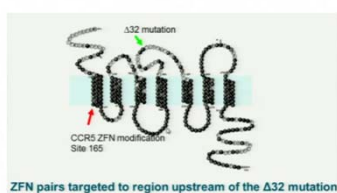
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## Chronic Inflammation and HIV

- **HIV/endothelial function-effects of coagulation/inflammation.** Diehl et al. (abstract 802)
  - HIV may be associated with a pro-thrombotic state that contributes the excess CVD risk.
    - Elevated levels of d-dimer can be attributed to immune activation.
      - D-dimer is a breakdown product of fibrin. Elevated levels are usually interpreted to mean a state of increased coagulation is present.
  - **Premature aging extends to endothelial function and may reduce the ability to lyse clots, predisposing HIV-infected persons to completed vascular thromboses.**
  - **Untreated HIV is associated with an inflammatory, procoagulant state with reduced levels of factors synthesized in the liver.** (Baker, abstract 811)
  - **HIV+ has elevated levels of anti-thrombin III (in the ART groups) and lower endogenous thrombin potential (all HIV groups) compared to HIV-negatives suggest reduced clotting ability.** (Hsue, abstract 797)
- **Immune activation/incomplete immune recovery**
  - Causes: microbial translocation, coinfections, residual viremia,
- **ARV Treatment:**
  - Early HAART, (Vivek Jain #517)
  - Maraviroc, (Wilkins #574; Hunt #153lb)
  - Hydroxychloroquine (Piconi #382)



## IS THERE A CURE?

## Gene Therapy to Generate CCR5-Deficient Autologous CD4+ Cells

- **SB-728-T: Zinc finger nuclease-mediated disruption of CCR5 on CD4+ cells**
  - Autologous cells infused at varying concentrations in 9 patients on HAART
  - Engraftment and in vivo expansion demonstrated by 2.9-fold median increase in ZFN-modified cells by Day 14
- **No serious AEs in a median of 192 days (85-366)**
- **After single infusion**
  - CD4+ counts increased; sustained in 5/6 patients
  - CD4:CD8 ratio normalized in 3/5 patients
- **No data presented about how functional these cells are.**



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Lalezari J, et al. CROI 2011. Abstract 46.

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## PrEParing for PrEP



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## iPrEx: PrEP in HIV-Negative, At-Risk MSM and Transgender Women

- **N = 2499 subjects randomized to oral TDF/FTC or placebo**
  - 44% reduction in HIV acquisition through 136 wks previously reported<sup>[1]</sup>
    - Update: 42% risk reduction through 144 wks<sup>[2]</sup>
- **AEs of PrEP mild, time limited<sup>[2]</sup>**
  - Headache (4%), nausea (2%), weight loss (2%)
- **Small but significant decrease in BMD<sup>[3]</sup>**
- **All infections were associated with undetectable (91%) or low (9%) drug concentrations<sup>[4]</sup>**
  - 92% reduction in the risk of HIV-infection when the presence of detectable drug was considered
- **No evidence of resistance in seroconverters<sup>[2]</sup>**



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1. Grant RM, et al. N Engl J Med. 2010;363:2587-2599.
2. Grant R, et al. CROI 2011, Abstract 92.
3. Mulligan K, et al. CROI 2011, Abstract 94LB.
4. Anderson P, et al. CROI 2011, Abstract 96LB.

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## Current CDC Guidance on PrEP

### CDC Interim Guidance on HIV Pre-Exposure Prophylaxis for Men Who Have Sex with Men



Below is CDC interim guidance for health-care providers electing to provide pre-exposure prophylaxis (PrEP) for the prevention of HIV infection in adult men who have sex with men and who are at high risk for sexual acquisition of HIV.

#### Before initiating PrEP

##### Determine eligibility

- ▶ Document negative HIV antibody test(s) immediately before starting PrEP medication.
- ▶ Test for acute HIV infection if patient has symptoms consistent with acute HIV infection.
- ▶ Confirm that patient is at substantial, ongoing, high risk for acquiring HIV infection.
- ▶ Confirm that calculated creatinine clearance is  $\geq 60$  mL per minute (via Cockcroft-Gault formula).

##### Other recommended actions

- ▶ Screen for hepatitis B infection; vaccinate against hepatitis B if susceptible, or treat if active infection exists, regardless of decision about prescribing PrEP.
- ▶ Screen and treat as needed for STIs.

##### Beginning PrEP medication regimen

- ▶ Prescribe 1 tablet of Truvada\* (TDF [300 mg] plus FTC [200 mg]) daily.
- ▶ In general, prescribe no more than a 90-day supply, renewable only after HIV testing confirms that patient remains HIV-uninfected.
- ▶ If active hepatitis B infection is diagnosed, consider using TDF/FTC for both treatment of active hepatitis B infection and HIV prevention.
- ▶ Provide risk-reduction and PrEP medication adherence counseling and condoms.

#### Follow-up while PrEP medication is being taken

- ▶ Every 2–3 months, perform an HIV antibody test; document negative result.
- ▶ Evaluate and support PrEP medication adherence at each follow-up visit, more often if inconsistent adherence is identified.
- ▶ Every 2–3 months, assess risk behaviors and provide risk-reduction counseling and condoms. Assess STI symptoms and, if present, test and treat for STI as needed.
- ▶ Every 6 months, test for STI even if patient is asymptomatic, and treat as needed.
- ▶ 3 months after initiation, then yearly while on PrEP medication, check blood urea nitrogen and serum creatinine.

#### On discontinuing PrEP (at patient request, for safety concerns, or if HIV infection is acquired)

- ▶ Perform HIV test(s) to confirm whether HIV infection has occurred.
- ▶ If HIV positive, order and document results of resistance testing and establish linkage to HIV care.
- ▶ If HIV negative, establish linkage to risk-reduction support services as indicated.
- ▶ If active hepatitis B is diagnosed at initiation of PrEP, consider appropriate medication for continued treatment of hepatitis B.

Abbreviations: STI = sexually transmitted infection; TDF = tenofovir disoproxil fumarate; FTC = emtricitabine.

\* These recommendations do not reflect current Food and Drug Administration-approved labeling for TDF/FTC.

Source: "Interim Guidance: Pre-exposure prophylaxis for the prevention of HIV infection in men who have sex with men," CDC, *Morbidity and Mortality Weekly Report*, January 28, 2011.



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<http://www.cdc.gov/nchstp/newsroom/PrEPMSMGuidanceGraphic.html>

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## Medication as Prevention Methods

- Raltegravir vaginal gel<sup>1</sup>: 3hrs post exposure provide significant protection to macaques from SHIV infection
- Tenofovir
  - Vaginal formulation of 1% gel accepted on females<sup>3</sup>
    - MSM<sup>2</sup> was neither entirely safe nor fully acceptable.
  - Single use, oral or rectally might not be effective at preventing HIV infection due to anal sex<sup>2</sup>
- Dapivirine (TMC 120) vaginal microbicide ring<sup>4</sup>
- Monoclonal antibodies C2F5, C4E10, and C2G12<sup>5</sup>

1. Dobard et al OA#30; 2. Antron #34LB; 3. Hendrix #35LB; 4. IPMSS #1001; 5. Morris #990



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## Protection: TWD (The Wise Decision)



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## Take Home Message

- In Acute HIV infection treatment, 5 drugs is not better than 3 related to VL suppression and immune recovery (keep simple!)
- "Nuc-sparing" regimens should be used cautiously, if at all.
- Intensification of antiretroviral therapy does not appear to change plasma HIV RNA levels measured by single copy assays.
- Measure waist circumference and mid arm circumference to HIV-infected patients allow early detection of wasting and can decrease mortality if manage on time.
- Replacement of Vitamin D3 is effective
- ART-initiation is associated with a 2-6% decrease in BMD over the first 48-96 weeks of therapy regardless of the regimen started
- Studies of the pathogenesis and treatment of chronic inflammation represent a critical unmet medical need
- Needs for strategies to achieve high levels of adherence if we want PrEP to work.



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