WHAT’S NEW IN CLINICAL MEDICINE
GUIDELINES AND BEYOND

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School of Medicine

Conflicts of Interest: None

**Who:** Everyone – “for individual health and public health”

**Other guidelines:** (CD4 count)

- BHIVMA <350 (+ tx risk)
- European <350-500
- WHO <350 + tx risk; Everyone when affordable
GUIDELINES: DHHS & IAS-USA
WHAT TO START

<table>
<thead>
<tr>
<th>Base</th>
<th>3rd drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDF/FTC</td>
<td>EFV</td>
</tr>
<tr>
<td>ABC/3TC**</td>
<td>ATV/r, DRV/r, RAL</td>
</tr>
</tbody>
</table>

*DHHS 2013; IAS – USA 2012

**IAS-USA only (JAMA 2012;308:387)
GUIDELINES: DHHS & IAS-USA: WHEN TO CHANGE ART

Adverse drug reaction
Convenience factor
Virologic failure

- **ACTG:** VL >200 c/mL
- **IAS-USA:** VL >50-200 c/mL
- **DHHS:** VL >200 c/mL
DHHS GUIDELINES: 2013

Who to treat: Everyone (for individual health & public health)

Preferred regimens:
- RIL is “alternative” – if VL <100K (potency)
- Quad is “alternative” – if creatinine cl >70 mL/min (renal issues)

“Acute HIV”: ART should be “offered” (replaces “considered”)

Pregnancy: EFV can be continued

INSTI-regimen: with failure – get genotypic assay for INSTI-resistance

CD4: Every 6-12 months if stable
## CONVENIENCE FACTOR

*EFV/TDF/3TC (Walensky R. Ann Intern Med 2013;158:84)*

<table>
<thead>
<tr>
<th>Drug</th>
<th>Times/d</th>
<th>Pills/d</th>
<th>Food</th>
<th>Cost</th>
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<tr>
<td>EFV</td>
<td>1</td>
<td>1</td>
<td>No</td>
<td>$15K</td>
</tr>
<tr>
<td>EFV*</td>
<td>1</td>
<td>3</td>
<td>No</td>
<td>$9K</td>
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<tr>
<td>DRV/r</td>
<td>1</td>
<td>3</td>
<td>Yes</td>
<td>$15 K</td>
</tr>
<tr>
<td>ATV/r</td>
<td>1</td>
<td>3</td>
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<td>$15K</td>
</tr>
<tr>
<td>RAL</td>
<td>1</td>
<td>3</td>
<td>No</td>
<td>$15K</td>
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</tbody>
</table>
HIV: WHAT’S AHEAD IN 2013 -- 2014

1. Testing
2. The Gardner cascade
3. Economics
4. ART agents
5. HCV
6. Prevention
WHO SHOULD BE TESTED FOR HIV

2006 CDC: Test everyone – ages 13-64 years “because risk based testing has not worked” (plus risk-based annual test)

2007 ACP: Test everyone ages 13-75 years “because VA study revealed many seniors”

2007 USPSTF: Risk-based testing only (Determines payment)

2012 USPSTF: Test everyone ages 15-65 years

2006-12: No new relevant data, 120,000 new US cases of HIV
HIV: WHAT’S AHEAD IN 2013 -- 2014

1. **Test**: 4th generation test
   Early detection? Home VL?

2. **Gardner cascade**: Test, link, retain, treat

3. **Economics**: Patent issue

4. **New ART agents**: DTG, TAF, CVC

5. **HCV**: Cure most in 2-3 years

6. **Prevention**: Slow evolution

7. **HIV care**: Who and Where
1. Testing: Why 30% of persons who test positive for HIV do not know it
WHY 30% OF PERSONS WHO TEST POSITIVE FOR HIV DO NOT KNOW IT

HIV Ab test positive
↓
HIV Ag/Ab positive (4th generation HIV test)
↓
Directly to HIV care

WB

Sensitivity vs. specificity

Early detection (Ag) to:
1) Preserve function
2) Prevent tx
3) There are no false positives
4) Achieve cure
5) Improve LTC
6) Catch up with Europe
Virologic Response to HART Regimen

- Mother stops ART about month 18 – LTFU until month 23
- HIV testing of infant done before restarting ART

Persaud D, et al. 20th CROI; Atlanta, GA; March 3-6, 2013. Abst. 48LB.
### Virologic Studies to Detect Residual HIV in this Very-Early Treated Child

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Sample Type (amount of sample)</th>
<th>Age at Testing</th>
<th>Quantity (per 1 x 10^6 cells)</th>
<th>Number Cells Tested per well/ (No. Replicates positive)</th>
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</thead>
<tbody>
<tr>
<td><strong>Total Proviral DNA</strong></td>
<td></td>
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<tr>
<td>PBMC</td>
<td>24-months</td>
<td>&lt;2.7 [0]</td>
<td>122,000 (0/2)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>26-months</td>
<td>4.2 [0]</td>
<td>113,000 (1/6)</td>
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<tr>
<td>Resting CD4+ T cells</td>
<td>24-months</td>
<td>&lt;3.5 [0]</td>
<td>96,500 (0/3)</td>
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<tr>
<td></td>
<td>26-months</td>
<td>&lt;2.5 [0]</td>
<td>134,000 (0/6)</td>
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<tr>
<td>Enriched for activated CD4+ T cells</td>
<td>24-months</td>
<td>&lt;2.2 [0]</td>
<td>154,000 (0/6)</td>
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<tr>
<td></td>
<td>26-months</td>
<td>&lt;2.6 [0]</td>
<td>130,000 (0/6)</td>
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<td>Monocyte-derived adherent cells</td>
<td>24-months</td>
<td>37.6 [0]</td>
<td>14,300 (1/3)</td>
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<td>26-months</td>
<td>&lt;11.5 [0]</td>
<td>29,000 (0/6)</td>
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<td><strong>Residual Viremia</strong></td>
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<tr>
<td>Plasma</td>
<td>24-months</td>
<td>1- copy/ml</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>26-months</td>
<td>&lt;2- copies/ml</td>
<td>NA</td>
<td></td>
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<tr>
<td>Infectious Virus Recovery</td>
<td>Resting CD4+ T cells</td>
<td>24-months</td>
<td>&lt;1/ 22x10^6 IUMP (No HIV recovered)</td>
<td>NA</td>
</tr>
</tbody>
</table>
Early ART: Reducing the Size of Initial Reservoir? Week 24 Results on ART

Almost all Fiebig I Subjects had Undetectable Integrated HIV DNA in PBMC

Ananworanich J, et al. 20th CROI; Atlanta, GA; March 3-6, 2013. Abst. 47.
### Dynamics of HIV Viremia

*(Fiebig EW. AIDS 2003;17:1871)*

<table>
<thead>
<tr>
<th>Stage</th>
<th>Day</th>
<th>RNA</th>
<th>P24Ag</th>
<th>Ab</th>
<th>WB</th>
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<tr>
<td>I</td>
<td>5</td>
<td>+</td>
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<td>II</td>
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<td>III</td>
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<td>IV</td>
<td>19</td>
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<td>V</td>
<td>88</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>VI</td>
<td>—</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
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</table>
**MAKE IT EASY**

**Sensitivity:** 93%

**Specificity:** 99.8%

**Distribution:** Walmart, CVS, Walgreens, RiteAid, Kroger, etc.

**Sales:** 4,000/wk

**Cost:** $40

**Note:** EW data
- 20-25% test by CDC guidelines
- Charge is $50 – $500/test
CONSUMER AT KIOSK FOR SELF TEST

Do you know HIV status and other STDs?
Do you want to test yourself?
Consumer accuracy: 100%
2. ENGAGEMENT IN HIV CARE
(Gardner EM. CID 2011;52:793)
Does it work?
Answer: Significant benefit in all chronic diseases tested

Is IRB approval needed?
Answer: No, unless trial

Size of award?
Answer: No guidance. Most cost-effective is lottery ticket

Do non-recipients resent status?
Answer: They offer it to all and many reject it.

Are there any studies in HIV patients?
Answer: Only HPTN-65

- Establish care -- $125
- Labs -- $25
- Complete visit -- $100
- VL<400 -- $70 every 3 months
A TEST OF FINANCIAL INCENTIVES TO IMPROVE WARFARIN ADHERENCE
(Volpp KG. BMC Health Sys Res 2008;8:272)

Note: P4P4P has worked in all chronic diseases tested – DM, INR, weight loss, HBP, smoking, etc
3. COST OF CARE

Contemporary costs/yr.  
(*AIDS* 2010;24:2705)

- **HAART** – $12,600 (76%)
- **Meds** – other – $2,100
- **In-patient** – $600
- **Out-patient** – $400 (2.4%)
- **Other** – $900

**Total (Meds)** – $16,600 (88%)

400,000 in care (Gardner) = $5B for ART and $160M for provider  
(Gebo K. *AIDS* 2010;24:2705)
Insurance Coverage of Patients with HIV/AIDS, 2010

- Medicaid: 42%
- Medicare: 12%
- Ryan White/Uninsured: 24%
- Private: 13%
- Unknown: 8%
US Patent Expirations

- AZT/3TC
- AZT/3TC/ABC
- ABC/3TC
- TDF/FTC
- LPV/RTV
- TDF
- ETR
- RPV
- EVG
- GS7340 = 2025

Patent Expirations Timeline:
- 05: AZT, ddC, ddl, d4T, 3TC
- 06: NVP
- 07: EFV
- 08: ABC, DLV
- 09: TDF
- 10: RTV, NFV
- 11: TPV, DRV
- 12: LPV/RTV caps
- 13: ATV
- 14: RTV boosting
- 15: LPV/RTV tabs
- 16: CVC=
- 17: 2023+
- 18: RAL 2022-5
- 19: MVC
- 20: ETR
- 21: RPV
- 22: EVG
- 23: GS7340 = 2025
# COST-EFFECTIVENESS OF GENERIC ART

(Walensky R. Ann Intern Med 2013;158:84)

<table>
<thead>
<tr>
<th>Category</th>
<th>Cost*</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFV/TDF/FTC (Branded ART)</td>
<td>$15,300</td>
</tr>
<tr>
<td>EFV + TDF/FTC (“Generic 2 pill”)</td>
<td>$11,600</td>
</tr>
<tr>
<td>EFV + TDF/3TC (“Generic 3 pill”)</td>
<td>$  9,200</td>
</tr>
</tbody>
</table>

*75% AWP
Comparison

Atripla (EFV/FTC/TDF)

Generic (EFV/3TC/TDF)

Cost:

Atripla: $15,300/year

Generic: $9,200/year

Viral failure: Generic – 6%

Longevity: Generic – reduced 4 months

Estimated savings: $920 million/yr (US)
Change from STR to Multi-tablet Regimen (MTR) After Virologic Suppression

509 patients on STR (TDF/FTC/EFV); 478 (94%) switched to TDF + 3TC + EFV (MTR)

Eligibility
- STR - first cART regimen in 215 (42%)
- On TDF/FTC/EFV ≥ 1 year prior to the change to MTR
- No known compliance problems

Conclusion:
- In a well organized health care setting (free access to ART), switch from TDF/FTC/EFV to a MTR did not change virologic response
- Caveats: Generalizability may be limited by single population, observation time

Engsig F, et al. 20th CROI; Atlanta, GA; March 3-6, 2013. Abst. 579.
4. HIV TREATMENT PRIORITIES

Cost

Next products in the six classes

Long acting agents

• RIL, S/GSK 744 and CMX in development
• Long-acting combinations
• Nanotechnology

Novel delivery: Patches, implants, injections
Exhaustion of drug options by last and cumulative genotype; analysis of 20,323 cases, Western Europe (DeLuca A, et al. JID 2013;1:Epub)
SPRING-1: DOLUTEGRAVIR (DTG) VS. EFV 200 TREATMENT-NAÏVE PATIENTS
Week 96 Efficacy Analysis (<50 c/mL) (Stellbrink JH. 2012 CROI; Abstr. 102LB)

Week 96 Efficacy Analysis (<50 c/mL)

Percent Subjects with HIV-1 RNA <50 c/mL (TLOVR)
- DTG 10mg QD: 88%
- DTG 25mg QD: 79%
- DTG 50mg QD: 78%
- EFV 600mg: 72%

CD4+ change: DTG +338 vs. EFV +301 cells/mm³ (p=NS)
Spring-2: DTG 50 mg qd vs. RAL 400 mg bid
• VL <50 in 88%
• One resistant mutation
• No severe ADR’s

Expedited FDA Review
(Raffi F. Lancet 2013;381:2429)
TFV Plasma and TFV-DP Intracellular Levels
GS-US-292-0102 – Week 24 Analysis
Zolopa A, et al. 20th CROI; Atlanta, GA; March 3-6, 2013. Abst. 99LB.

- **E/C/F/TAF**
  - PBMC TFV-DP exposure was 5.3-fold higher (90% CI: 2.9 to 9.6)
  - Plasma TFV exposure (AUCtau) was 91% lower

<table>
<thead>
<tr>
<th></th>
<th>Plasma TFV PK</th>
<th>TAF/FTC/EVG/c (n=19)</th>
<th>TDF/FTC/EVG/c (n=7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C&lt;sub&gt;trough&lt;/sub&gt; (ng/mL)</td>
<td>11.4 (17.9)</td>
<td>82.8 (26.6)</td>
<td></td>
</tr>
<tr>
<td>AUC&lt;sub&gt;tau&lt;/sub&gt; (ng*hr/mL)</td>
<td>326.2 (14.8)</td>
<td>3795.2 (21.9)</td>
<td></td>
</tr>
</tbody>
</table>

**PBMC TFV-DP AUC<sub>0-24h</sub> at Week 4 or 8**

WK 4 or 8 TFV-DP AUC<sub>0-24h</sub> from QUAD and E/C/F/TAF

Mean with SD

5.3X
Long Acting Parenteral GSK1265744: Macaque Model with SHIV

Results

- Based on very long parenteral (IM or IV) half life – protective effect of 744 will be assessed with q1-3 month dosing

Andrews C, et al. 20th CROI; Atlanta, GA; March 3-6, 2013. Abst. 24LB.
5. HEPATITIS C
HEPATITIS C**

No. infected: 2.7-3.9 million
No. who know it: 40% (NHANES)
- Tested for perceived risk (13%)
- Tested and F/U: 22/170 (13%)

Risk: Birth 1945-65 >75%
- IDU, tx <1992, hemodialysis

CDC: Screen birth cohort and “at risk”

Deaths/yr: 15,106 (2007)

Treatment → SVR (cure): 75% (2014)

Drugs in phase II/III: 37

*MMWR 2012;61 RR4:1

NHANES Hepatology 2012;55:1653
HOW WILL HIV/HCV CHANGE?

HCV Treatment

1991: Interferon
1995: PegINF/rib
2011: PegINF/rib/PI (TPV, BOC) + 57 drugs in development
2012: Pipeline – 37 agents in phase 2 or 3
2013/14: No INF/r, all oral, high cure rates, high cost
Telaprevir + PegIFN + RBV in HIV/HCV Co-infected Patients with Virologic Failure on IFN + RBV: Virologic Response

(Cotte L, et al. 20th CROI; Atlanta, GA; March 3-6, 2013. Abst. 36)
Oral combination GS 7977 + Daclatasvir + ribavirin in patients with HCV GT1 (n=44) (Sulkowski M. EASL, Barcelona, 4/18/12)

See Poordad F. NEJM 2013;368:45; Gane EJ. NEJM 2013;368:34
## ELECTRON Results: Efficacy

### Patients with HCV RNA <LOD* Over Time, n/N (%)

<table>
<thead>
<tr>
<th></th>
<th>SOF + RBV</th>
<th>SOF + LDV + RBV</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Treatment-naïve (n=25) Null responder (n=10)</td>
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</tr>
<tr>
<td><strong>Week 1</strong></td>
<td>8/25 (32)</td>
<td>11/25 (44)</td>
</tr>
<tr>
<td></td>
<td>1/10 (10)</td>
<td>0/9 (0)</td>
</tr>
<tr>
<td><strong>Week 2</strong></td>
<td>17/25 (68)</td>
<td>22/25 (88)</td>
</tr>
<tr>
<td></td>
<td>7/10 (70)</td>
<td>4/9 (44)</td>
</tr>
<tr>
<td><strong>Week 4</strong></td>
<td>25/25 (100)</td>
<td>25/25 (100)</td>
</tr>
<tr>
<td></td>
<td>10/10 (100)</td>
<td>8/9 (89)</td>
</tr>
<tr>
<td><strong>EOT</strong></td>
<td>25/25 (100)</td>
<td>25/25 (100)</td>
</tr>
<tr>
<td></td>
<td>10/10 (100)</td>
<td>9/9 (100)</td>
</tr>
<tr>
<td><strong>SVR4</strong></td>
<td>22/25 (88)</td>
<td>25/25 (100)</td>
</tr>
<tr>
<td></td>
<td>1/10 (10)</td>
<td>9/9 (100)</td>
</tr>
<tr>
<td><strong>SVR12</strong></td>
<td>21/25 (84)</td>
<td>25/25 (100)</td>
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<tr>
<td></td>
<td>1/10 (10)</td>
<td>9/9 (100)</td>
</tr>
</tbody>
</table>

Gane E, et al. 20th CROI; Atlanta, GA; March 3-6, 2013. Abst. 41LB.

*LOD: Lower Limit of Detection
**RELATIONSHIP BETWEEN LIVER DISEASE AND DEATH WITH HIV/HCV CO-INFECTION**  
(Limketkai BN, et al. JAMA 2012;308:370)

**Issue:** Outcome with HIV/HCV  
**Method:** Prospective cohort 638 patients 1993-2011; mean F/U 5.8 years

<table>
<thead>
<tr>
<th>Metavir scoring</th>
<th>PY</th>
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<tr>
<td>F0</td>
<td>1363</td>
<td>1.0</td>
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<td>F1</td>
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<td>F3</td>
<td>194</td>
<td>11.2</td>
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<tr>
<td>F4</td>
<td>388</td>
<td>16.8</td>
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*Liver bx, FibroSure, FibroScan*
Who will do HCV care?
- Gastroenterologists
- HIV/ID Providers
- Primary care

FDA-APPROVED HEPATITIS C VIRUS (HCV) DRUGS
MUTATIONS IN THE HCV PROTEASE GENE ASSOCIATED WITH RESISTANCE TO NONSTRUCTURAL PROTEIN 3 (NS3) PROTEASE INHIBITORS

<table>
<thead>
<tr>
<th></th>
<th>V</th>
<th>T</th>
<th>V</th>
<th>R</th>
<th>A</th>
<th>V</th>
<th>I*V</th>
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<td>Boceprevir</td>
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<td>54</td>
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<td>155</td>
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<td>170</td>
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<td>155</td>
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WILL WE PREVENT HIV

Rate of new cases: 50,000-55,000/yr in US 1990-present

Prevention “bundle”

- Condoms: Variable use
- Circumcision: 60-70% effective US rates: 60% ACA – not covered but recommended AAP
- Needle exchange: IDU rates ↓
- PrEP: 62-91% effective (in trials)
- ART: Multiple trials TDF/FTC or TDF
PrEP Trials: TDF/FTC

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>Population</th>
<th>N</th>
<th>Efficacy</th>
<th>P</th>
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<tbody>
<tr>
<td>PrEx</td>
<td>MSM</td>
<td>2,470</td>
<td>44%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Partners</td>
<td>DC*</td>
<td>4,758</td>
<td>67-75%**</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TDF-2</td>
<td>DC*</td>
<td>1,219</td>
<td>62%</td>
<td>&lt;0.03</td>
</tr>
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</table>

*DC=Discordant Couples  
**TDF – 67%, TDF/FTC – 75%
PrEP TRIALS: CONCLUSION

Trials: TDF2, Partners, IPrEx (FEM – PrEP)
Risk: MSM, discordants, commercial sex
Data: n=6,956 x 13-23 months

Results:
• Prevention efficacy: 62-91%
• ADR: GI 5-10%; ? Long term
• Resistance: 3/3,900
• Adherence: FEM – PrEP
• Cost (AWP): $1,428/mo or $11-14,000/yr

Note: MSM + High risk sex + unprotected sex increases HIV transmission risk 28-fold
**Protocol**: Discordant couples, CD4 350-550: Randomized to ART vs. no ART until CD4 <250

**Results**: N=1,763 (M=890, F-873)

<table>
<thead>
<tr>
<th></th>
<th>ART n=886</th>
<th>No Art n=877</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV transmission*</td>
<td>1**</td>
<td>27</td>
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*Linked cases

**Protection with ART = 96% -- Study continues to determine durability
BREAKTHROUGH OF THE YEAR
HIV Treatment as Prevention
HIV PREVENTION WITH ART

Quinn, et al (NEJM 2000)
No transmission if VL <1500

Swiss Federal Statement 1/8/2008
No sexual tx if VL undetectable

Granich (Lancet, 2009)
WHO: Universal ART for prevention

Cohen M: HPTN 052 2012
Discordant couples: 96-100%

BHIVA: No confirmed HIV tx with NDV (“never”) January, 2013
IMPACT OF COMBINATION PREVENTION ON HIV INCIDENCE
(Cremin I. AIDS 2013;27:447)
7. HEALTHCARE REFORM

HCR IS SOCIALIZED MEDICINE RUN BY CAPITALISTS

- Will HIV remain a specialty
- Will current HIV programs survive
- Will RWCA survive (in part or whole)
HIV: WHAT’S AHEAD IN 2013 – 2014

1. **Testing**: 4th generation test  
   Early detection? Home VL?

2. **Gardner cascade**: TLC: P4P4: & RWCA

3. **Economics**: Generic ART  
   May be out of our control

4. **ART agents**: DTG, TAF, CVC

5. **HCV**: Like ART but cure

6. **Prevention**: Slow and expensive

7. **HCR**: ? Providers, RWCA and HIV centers