Primary Care of People with HIV

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Disclosures:
Advisory Board: EMD Serono, Theratechnologies; Consultant: Theratechnologies, EMD Serono; Grant Recipient/Research Support to MGH from: Gilead Sciences, Merck & Co., ViiV Healthcare
Learning Objectives

- Formulate an evaluation strategy for a newly diagnosed person with HIV

- Identify measures that can be taken by the care team to keep a person with HIV healthy
Case

- 45 yo M, originally from Haiti, with worsening odynophagia. EGD: esophageal ulcers
- HIV Ag/Ab and confirmatory test positive. CD4 count 75. HIV RNA 250,000 copies/mL

- He asks you 3 questions:
  - “Do I have AIDS?”
  - “How should I be treated”?
  - “What do I need to do to stay healthy?”
Approach to the HIV+ Patient: 4 Steps

Step 1: History, Examination and Lab Tests

Step 2: Opportunistic infection prophylaxis (if indicated)

Step 3: Antiretroviral therapy: when to start and what to start

Step 4: Preventive Care: how to keep people healthy
Step 1: History

- Risk behaviors; approx. date of infection
- Symptoms
- Exposures: tuberculosis, endemic fungi, sexually transmitted infection (STIs)
- Psychiatric history
- Family history: cancer; myocardial infarction
- Tobacco, alcohol, illicit drug use; sexual history
- Medications, including alternative meds
- Disclosure
Physical Exam

Prurigo nodularis

Kaposi Sarcoma

Aphthous ulcers

Oral candidiasis

If CD4 count <50 or visual symptoms, refer to ophthalmology

Images courtesy of Drs. Anisa Mosam, Richard Johnson and Medscape
Question:

Which test should you order in ALL newly diagnosed people with HIV?

A. CMV IgG
B. HIV tropism
C. HIV genotype (reverse transcriptase/protease)
D. HIV genotype (reverse transcriptase/protease/integrase)
E. HIV phenotype
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Please enter the URL below.

https://api.cvent.com/polling/v1/api/polls/sp-apvy06

Note: Many popular websites allow secure access. Please click on the preview button to ensure the web page is accessible.
Lab Evaluation: Routine Tests

- Chemistries, BUN/Cr, liver function tests
- CBC/diff
- Fasting lipids and glucose
- G6PD: blacks; males from Mediterranean, India, Southeast Asia
- Urinalysis (U/A)

DHHS guidelines for use of antiretroviral agents in HIV-1-infected adults and adolescents. Feb 12, 2013.
http://AIDSinfo.nih.gov
Aberg J et al, CID, 2013
Labs: Screening for Infection

- Serologic testing for infections that can reactivate:
  - Cytomegalovirus IgG (only if at low risk so that counseling can be provided if test is negative)
  - Toxoplasma IgG

- Hepatitis serologies (A, B, C)

- Tuberculin skin test (TST) or interferon-gamma release assay (IGRA)
  - TST >5 mm is positive in HIV+ patients
  - If negative and patient’s CD4 count is <200, repeat TST or IGRA after immune reconstitution

Aberg J et al, CID, 2013
For sexually active individuals:

- Screen for syphilis, gonorrhea (GC) and chlamydia (CT) at first evaluation
- Screen at least annually (more frequently if exposures)
- For MSM:
  - Urethral (urine NAAT) screen for GC/CT if insertive intercourse
  - Screen for rectal and pharyngeal STI if receptive intercourse
- If multiple or anonymous partners, more frequent screening, e.g. every 3-6 months

https://www.cdc.gov/std/prevention/screeningreccs.htm
HCV Testing

- HCV antibody (Ab) at care initiation and then annually for high-risk MSM, people who inject drugs
  - Increasing sexual transmission of HCV in HIV+ MSM
  - At Fenway Health in Boston, HCV incidence 1.6/100 person-yrs
- If HCV Ab negative but suspicion high (elevated LFTs, recent exposure), check HCV RNA
  - Window period until seroconversion may be up to 12 wks

Lab Evaluation: HIV-specific Tests

- **CD4 count**: best predictor of risk of OI or cancer\(^1\)
  - CD4 count < 200: toxoplasma, PCP, PML, Cryptosporidiosis, oral and esophageal candidiasis, Kaposi sarcoma, NHL
  - CD4 count <50: risk of MAC, CMV, primary CNS lymphoma

- **HIV RNA** (“viral load”)

- **HIV resistance testing**

- **HLA-B5701**: if considering abacavir\(^2\)
  - Positive: 8% of US whites. \(~2\% of US African-Americans and Hispanics\(^1\)
  - If B5701+, do not prescribe abacavir (50% chance of hypersensitivity reaction)

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\(^1\)Moore, Ann Intern Med 124:633.  \(^2\)E Phillips, CID, 2006
## HIV Drug Resistance Testing

<table>
<thead>
<tr>
<th>Patient</th>
<th>Resistance Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newly Diagnosed or Treatment Naive</td>
<td>Genotype (RT and PR) (Integrase genotype only if suspicion based on history)</td>
</tr>
<tr>
<td>Virologic Failure to 1\textsuperscript{st} or 2\textsuperscript{nd} Lines of Therapy</td>
<td>Genotype (Integrase geno. if failing INSTI)</td>
</tr>
<tr>
<td>Suspected Complex Resistance</td>
<td>Phenotype and Genotype</td>
</tr>
<tr>
<td>Considering CCR5 antagonist</td>
<td>DNA tropism</td>
</tr>
</tbody>
</table>

### Interpretation of genotypes:
- [www.iasusa.org/content/hiv-drug-resistance-mutations](http://www.iasusa.org/content/hiv-drug-resistance-mutations)
Transmitted Drug Resistance Mutations

• CDC study of ART-naive people
  – Overall: 18%
  – NRTI: 5.7%
  – NNRTI: 11.5%
  – PI: 3.9%

• US National HIV Surveillance System
  – Overall INSTI resistance: 0.4%
  – Transmitted INSTI resistance: 2/4631 (0.04%)
    • N155H; E92Q: high level resistance to EVG, RAL; low level resistance to DTG

• Compared 96-week clinical outcomes and cost-effectiveness of integrase resistance testing in newly diagnosed patients

• **Conclusion**: Integrase resistance testing projected to result in worse outcomes and was not cost effective

Koullias et al, CID, 2017
Step 1: History, Examination and Lab Tests

Step 2: Opportunistic infection (OI) prophylaxis (if indicated)*

Step 3: Antiretroviral therapy

Step 4: Monitoring

*Covered in more depth in a later talk
Case (Continued)

- 45 yo M with odynophagia and esophageal ulcers
- HIV Ag/Ab and confirmatory test positive. CD4 count 75. HIV RNA 250,000 copies/mL
- PMH: GERD, allergic rhinitis, hyperlipidemia, smoking
- Medications: omeprazole, fluticasone
- Estimated GFR 48
- HIV Genotype: no resistance mutations
- HLA-B5701 positive

→ CD4 count < 200 – “You have AIDS”
Question:
CD4 count: 75, HIV RNA 250,000. OI Prophylaxis?
A. None
B. Trimethoprim/sulfamethoxazole
C. Azithromycin
D. Trim/sulfa + azithromycin
E. Ganciclovir
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https://api.cvent.com/polling/v1/api/polls/sp-edec0k

Note: Many popular websites allow secure access. Please click on the preview button to ensure the web page is accessible.
• Pneumocystis pneumonia (PCP) prophylaxis (trim/sulfa DS daily) if:
  − CD4 count <200 (CD4 percentage <14)
  − History of thrush

• *Mycobacterium avium* complex prophylaxis (azithromycin 1200 mg weekly) if CD4 count <50
  − NB: some experts forego MAC prophylaxis; prioritize ART
Approach to the HIV+ Patient: 4 Steps

- **Step 1**: History, Examination and Lab Tests
- **Step 2**: Opportunistic infection prophylaxis
- **Step 3**: Antiretroviral therapy: when to start and what to start*
- **Step 4**: Preventive Care

*Covered in a later talk
HIV Therapy Recommended Regardless of CD4: START

- HIV-infected adults with CD4 >500
- Randomized to immediate or deferred ART
- TB, KS, lymphoma — most common AIDS-related events — all less frequent in immediate-ART group
- Cancer rates (combining AIDS/non-AIDS) lower in immediate-ART group

Accelerated Initiation of ART: San Francisco

• **RAPID**: City-wide effort to link all new HIV diagnoses to care in ≤5 days: linkage navigators; trained clinicians; average initial visit time 2.5 hr

• ART: tenofovir/FTC + INSTI or boosted DRV

• 2013 to 2016: time from HIV diagnosis to ART initiation decreased from 35 to 6 d

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### Median Time to Care, ART, and Virologic Suppression

<table>
<thead>
<tr>
<th>Metric</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>%Δ 2013-16</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Care within 1 year (%)</td>
<td>372 (93)</td>
<td>318 (97)</td>
<td>282 (96)</td>
<td>258 (97)</td>
<td></td>
</tr>
<tr>
<td>Diagnosis to care (days)</td>
<td>8</td>
<td>7</td>
<td>7</td>
<td>5</td>
<td>-38%</td>
</tr>
<tr>
<td>1st Care Visit to ART (days)</td>
<td>27</td>
<td>17</td>
<td>6</td>
<td>1</td>
<td>-96%</td>
</tr>
<tr>
<td>ART to VL&lt;200c/mL (days)</td>
<td>70</td>
<td>53</td>
<td>50</td>
<td>38</td>
<td>-46%</td>
</tr>
<tr>
<td>Diagnosis to VL&lt;200 c/mL (days)</td>
<td>134</td>
<td>92</td>
<td>77</td>
<td>61</td>
<td>-54%</td>
</tr>
</tbody>
</table>

Bacon O et al, CROI 2018, abstract 93
“What do I need to do to stay healthy?”
Challenges in Preventive Care
“What do I need to do to stay healthy?”

**Approach to HIV+ Patient: 4 Steps**

**Step 1:** History, Examination and Lab Tests

**Step 2:** OI prophylaxis (if indicated)

**Step 3:** Antiretroviral therapy

**Step 4: Preventive care**

- Screening for cervical and anal cancer
- Smoking cessation
- Cardiovascular disease prevention
- Osteopenia/osteoporosis
- Vaccines
Screening for Cervical and Anal Cancer

- Cervical and anal cancer (CA) incidence much higher in HIV+ patients than in the general population

Robbins H et al, AIDS, 2014
Cervical Cancer Screening in Women with HIV

• < 30 years
  – Cervical pap at time of HIV diagnosis
  – If normal, repeat every 12 months
  – If 3 consecutive paps are normal, then every 3 yrs
  – Co-testing (pap and HPV) not recommended
  – Refer for colposcopy if ASCUS on pap and reflex HPV test positive or if pap result is LSIL or worse

Cervical Cancer Screening in Women with HIV

• >= 30 years
  – Pap alone or pap with HPV co-testing
  Pap alone:
  – At time of HIV diagnosis; then annually
  – If 3 consecutive paps normal, then every 3 yr
  Pap with HPV co-testing:
  – If pap and HPV negative, screen every 3 yr
  – If pap normal and HPV positive, repeat testing in 1 yr; if HPV type 16 or 18 positive, refer for colposcopy
  – If ASCUS and HPV positive, refer for colposcopy
  – For LSIL or worse, refer for colposcopy

Anal cytology

- Recommended by HIVMA/IDSA for:
  - Men who have sex with men
  - Women with history of receptive anal intercourse or abnormal cervical pap
  - All patients with genital warts

- If abnormal → high-resolution anoscopy

- Randomized study (ANCHOR): does treatment of anal high-grade squamous intraepithelial lesion (vs. active surveillance) in HIV+ men and women prevent anal cancer?

Aberg J et al, CID, 2013
Screening for Other Cancers in People with HIV

- Follow general population guidelines
- Given high rates of smoking in people with HIV, particular attention to lung cancer screening

Summary of Recommendation and Evidence

<table>
<thead>
<tr>
<th>Population</th>
<th>Recommendation</th>
<th>Grade (What's This?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults Aged 55-80, with a History of Smoking</td>
<td>The USPSTF recommends annual screening for lung cancer with low-dose computed tomography (LDCT) in adults aged 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.</td>
<td>B</td>
</tr>
</tbody>
</table>
About 1 in 4 ART-adherent HIV+ male smokers will die of lung cancer

Assumes complete adherence to ART and no loss to follow-up

Reddy et al., JAMA Intern Med 2017
Smoking Cessation for People with HIV

- Behavioral and/or pharmacologic approaches
  - Combination better than either alone

- Pharmacotherapy: nicotine replacement, bupropion, varenicline
  - Alone or in combination
  - No dose adjustments with ART

Adapted from slide from Roger Bedimo, MD

http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2826
Increased Frequency of “non-AIDS-related” Complications

- Cardiovascular disease (CVD)[1-4]
- Metabolic syndrome and diabetes
- Cancer (non-AIDS)
- Bone fractures/osteopenia [5,6]
- Liver failure[7]
- Renal Disease
- Peripheral neuropathy
- Cognitive decline [8]
- Premature aging/frailty[9]


Slide courtesy of J. Eron, M.D.
Chronic Inflammation in HIV Patients: “Inflammaging”

Deeks, Gandhi, Chae, Lewandrowski, NEJM, 2012
Acute MI rates in 3851 HIV-infected and 1,044,589 HIV-uninfected patients from 1996-2004 (11.1 vs 7.0 events/1000 years)


Risk of MI higher in HIV+ adults than age-matched uninfected adults
CVD Prevention: Lipid Management

• 2013 AHA guidelines for general population
  – LDL-C >190, DM, ≥7.5% risk of atherosclerotic CV disease → statins
  – No lipid targets
• How to apply to HIV+ pts is uncertain → refer to REPRIEVE if ASCVD <10%

Stone NJ et al, Circulation, 2013
CVD Prevention: Lipid Management

- Beware of drug interactions between statins and PIs or cobicistat

<table>
<thead>
<tr>
<th>Statin</th>
<th>Level with PI</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pravastatin</td>
<td>--</td>
<td>Safe (caution when pravastatin given with DRV)</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>↑</td>
<td>Use with caution/low dose</td>
</tr>
<tr>
<td></td>
<td></td>
<td>≤ 20 mg/d atorva with DRV¹</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>↑↑↑</td>
<td></td>
</tr>
<tr>
<td>Lovastatin</td>
<td>↑↑↑↑</td>
<td>Contraindicated</td>
</tr>
<tr>
<td>Rosuvastatin</td>
<td>↑</td>
<td></td>
</tr>
<tr>
<td>Pitavastatin</td>
<td>--</td>
<td></td>
</tr>
</tbody>
</table>

¹http://www.fda.gov/Drugs/DrugSafety/ucm293877.htm#sa
CVD Prevention: General Population Guidelines

• Hypertension management

• Diabetes screening and management

• Abdominal aortic aneurysm: ultrasound (one time) in men ages 65-75 who ever smoked

• Aspirin prophylaxis (to prevent CVD and colon cancer)
Osteopenia/Osteoporosis

- HIV and specific antiretrovirals (like TDF) are risk factors for premature bone loss

- Experts recommend bone densitometry in HIV+ post-menopausal women and men over age 50
Question: Vaccines

- 45 yo HIV+ M. CD4 count 75. HIV RNA 250,000 copies/mL
- HAV IgM negative/IgG positive; anti-HBs positive
- He receives the influenza vaccine

Once he is on suppressive ART, which of the following additional vaccines should he receive?

A. Zoster vaccine
B. HPV vaccine
C. Meningococcal B vaccine
D. Pneumococcal vaccine
E. All of the above
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Note: Many popular websites allow secure access. Please click on the preview button to ensure the web page is accessible.
# Recommended Vaccines in People with HIV

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Age group (years)</th>
<th>CD4 cell count (cells/μL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13 to 18</td>
<td>19 to 26</td>
</tr>
<tr>
<td>Influenza*</td>
<td>1 dose annually</td>
<td></td>
</tr>
<tr>
<td>Tetanus, diphtheria, acellular pertussis (Tdap)/tetanus, diphtheria (Td)*</td>
<td>1 dose Tdap, then Td booster every 10 years</td>
<td></td>
</tr>
<tr>
<td>Measles, mumps, rubella (MMR)Δ</td>
<td>2 doses if CD4 cell count ≥200</td>
<td></td>
</tr>
<tr>
<td>Varicella (VAR) †</td>
<td>2 doses if CD4 cell count ≥200</td>
<td></td>
</tr>
<tr>
<td>Herpes zoster (HZV)§</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human papillomavirus (HPV)¶</td>
<td>3 doses</td>
<td></td>
</tr>
<tr>
<td>Pneumococcal conjugate (PCV13)¶</td>
<td>1 dose</td>
<td></td>
</tr>
<tr>
<td>Pneumococcal polysaccharide (PPSV23)¶</td>
<td>2 doses</td>
<td></td>
</tr>
<tr>
<td>Hepatitis A (HepA)†</td>
<td>2 or 3 doses depending on vaccine</td>
<td></td>
</tr>
<tr>
<td>Hepatitis B (HepB)¶</td>
<td>3 doses</td>
<td></td>
</tr>
<tr>
<td>Meningococcal (MenACWY)¶¶</td>
<td>2 doses, then booster every 5 years</td>
<td></td>
</tr>
<tr>
<td>Meningococcal B (MenB)¶¶</td>
<td>2 or 3 doses depending on vaccine</td>
<td></td>
</tr>
<tr>
<td>Haemophilus influenzae type b (Hib)ΔΔ</td>
<td>1 or 3 doses depending on indication</td>
<td></td>
</tr>
</tbody>
</table>

- Recommended for adults and adolescents with HIV infection
- Recommended for adults and adolescents with HIV infection and other indications
- Contraindicated
- No recommendation

Adapted from the Advisory Committee on Immunization Practices (ACIP) recommended immunization schedules for adults and adolescents. These immunization schedules are available at [https://www.cdc.gov/vaccines/schedules/hcp/index.html](https://www.cdc.gov/vaccines/schedules/hcp/index.html). Detailed information on these and other vaccines can be found at [https://www.cdc.gov/vaccines/hcp/acip-recs/index.html](https://www.cdc.gov/vaccines/hcp/acip-recs/index.html).
HBV vaccination

- All HIV+ patients should be screened for HBV infection (HBsAg, anti-HBs, +/- anti-HBc)
- If non-immune → HBV vaccine at 0, 1, 6 mo.
- If vaccine series interrupted, does not need to be restarted\(^1\). Give 2\(^{nd}\) & 3\(^{rd}\) doses at least 8 wk apart
- Check anti-HBs after completing primary series
  - If anti-HBs <10 → second series of HBV vaccinations
  - Consider revaccinating with a double dose

\(^1\)http://www.cdc.gov/hepatitis/HBV/HBVfaq.htm.
HBV Response: DD vs. SD Vaccine

In retrospective study, double-dose (DD) vaccine associated with higher response rate than standard-dose (SD) vaccine.

Isolated anti-HBc

• HIV+ pts with isolated anti-HBc are at risk for acquiring HBV\(^1\)

• Most HIV+ pts with isolated anti-HBc do not have an anamnestic anti-HBs response after HBV immunization\(^2,3\), suggesting they may benefit from vaccination

• Check HBV DNA to rule out occult HBV (rare)
  – If negative, vaccination should be considered\(^4\)

HPV Vaccine

• Recommended for females and males with HIV ages 9 through 26 years
  - 9-valent vaccine, 3 doses, at 0, 1-2 and 6 months
  - ~4% of HPV associated cancers in males, 14% in females related to 5 additional HPV types present in 9-valent vaccine
  - For those who have completed vaccination with bi-or quadrivalent vaccine, providers may “consider” additional vaccination with 9-valent vaccine

Pneumococcal Vaccine

- Invasive pneumococcal disease in HIV+ patients: 173/100,000 (more than 20x higher than for adults without high-risk conditions)

<table>
<thead>
<tr>
<th>History</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Previous Pneumococcal Vaccination</td>
<td>• PCV-13 followed by PPSV-23 at least 8 wks later</td>
</tr>
<tr>
<td></td>
<td>• Five yr later, revaccinate with PPSV-23</td>
</tr>
<tr>
<td>Previously Received PPSV23</td>
<td>• PCV-13 ≥1 yr after last PPSV23</td>
</tr>
<tr>
<td></td>
<td>• Five yr later, revaccinate with PPSV-23</td>
</tr>
</tbody>
</table>

ACIP. Recommended Adult Immunization Schedule: US 2017
Meningococcal Vaccine

- Risk of invasive meningococcal disease 5-13 times greater in HIV than in general population (risk greatest if CD4 low, VL high)
- Outbreaks among MSM in US and Europe

<table>
<thead>
<tr>
<th>History</th>
<th>Recommendation (age &gt; 2y)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Previous Meningococcal Vaccination</td>
<td>• Two doses of meningococcal conjugate vaccine: MenACWY-CRM (Menveo) or MenACWY-D (Menactra), at least 2 mo. apart</td>
</tr>
<tr>
<td></td>
<td>• Booster doses every 5 yrs</td>
</tr>
<tr>
<td></td>
<td>• If indicated, also give serogroup B vaccine (Truemba or Bexsero) – eg, in outbreak or if functional or anatomic asplenia</td>
</tr>
</tbody>
</table>

ACIP. Recommended Adult Immunization Schedule: US 2017
Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines

• Recombinant zoster vaccine (RZV): subunit vaccine containing recombinant glycoprotein E plus a novel adjuvant (AS01B)
  – >90% efficacious at preventing zoster in age groups from 50 to >70

• Recommended for:
  – Immunocompetent adults aged ≥50 years, irrespective of prior receipt of zoster vaccine live (ZVL) or previous zoster
  – RZV preferred over ZVL

• Two doses, 2-6 months apart

• Local and systemic reactions severe enough to prevent normal activities: >10%

• Data on immunocompromised hosts forthcoming
  – Recommended if low dose immunosuppression (<20 mg/d prednisone)
Step 1: Staging: History, Examination, Labs

- 45 yo M with HIV and esophageal ulcers
- GERD, allergic rhinitis, hyperlipidemia, smoking
- Meds: omeprazole, fluticasone (interact with several commonly used regimens)
- CD4 cell count 75, HIV RNA 250,000
- Estimated GFR 48
- HIV genotype: no resistance mutations
- HLA-B5701 positive
- HAV IgM negative/IgG positive; anti-HBs positive
- IGRA for TB: negative
Approach to HIV+ Patient:
4 Steps

**Step 2: OI Prophylaxis:** CD4 count 75: PCP Px indicated

**Step 3: ART – individualizing therapy**
- On fluticasone: interacts with PI and cobicistat-containing Rx
- HLA-B5701+: abacavir contraindicated
- Estimated GFR 48: avoid TDF; TAF OK

**Step 4: Preventive health**
- Smoker. Hyperlipidemia. ASCVD risk score: >7.5%
- Immune to HAV, HBV
Case – Bringing it all back home

• Trim/sulfa initiated for PCP prophylaxis
• Started dolutegravir + FTC/TAF → Odynophagia resolved
• Cardiovascular disease prevention:
  – Lifestyle changes
  – Consider statin (or referral to REPRIEVE)
  – Smoking cessation counseling
• Vaccinations (after he’s on suppressive ART):
  – PCV-13 followed by PPSV-23 (>8 wk later)
  – Meningococcal conjugate vaccine
• Repeat IGRA for TB once CD4 count >200
Thank you for your attention!