HIV Update
2017 Annual FOMA Convention
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Disclosures - none
Who should be routinely screened for HIV according to CDC guidelines?

1. All individuals regardless of risk
2. All individuals as long as written consent & post test counseling is done
3. Only those who request
4. High risk individuals (mandatory) & voluntary screening for everyone else
5. MSM: AA males > 15yo
Which test is recommended for initial HIV testing?

1. Western Blot
2. 2\textsuperscript{nd} Generation HIV antibody test
3. 4\textsuperscript{th} Generation HIV antibody/antigen test
4. HIV 1 nucleic acid test
Which of the following individual is an appropriate candidate for PrEP?

1. Hiv neg male who has unprotected sex with multiple male sex partners in past yr.

2. Hiv neg female in a monogamous relation who has recently treated for HSV2 and uses cocaine

3. Hiv (+) male who admits to sex with multiple partners

4. Hiv neg female who admits to unprotected sex with one male of uncertain HIV status.
Question nonsexual transmission

If seeing IVDU with cellulitis on forearm what can one consider?

1. offer patient information on opioid substitution tx
2. offer patient Truvada information regarding PrEP?
3. Treat cellulitis
4. shared injection equipment (needles or works)
5. Known Hiv + injecting partner
6. All of the above
456.033 HIV

- Modes of transmission
- Infection control

  behavioral-reducing condomless sex, dec # of partners, dec IVDU frequency, dec sex trade

  biomedical- Tx as prevention, PrEP, PEP, Tx STD

  structural- universal precautions to safe blood supply, clean syringe programs, funding HIV test

- Clinical management
- Prevention
Routes of Transmission

- Homosexual and heterosexual intercourse (anal, vaginal, oral)
- Injection drug use
- Vertical transmission (pregnancy, delivery, breast feeding)
- Contaminated blood products/ transfusion
- Occupational transmission involving health-care workers exposed to HIV-infected specimens
Blood Transfusion 9250
Needle-Sharing IVDU 63
Percutaneous (Needle-Stick) 23
Receptive Anal Intercourse 138
Insertive Anal Intercourse 11
Receptive Penile-Vaginal Intercourse 8
Insertive Penile-Vaginal Intercourse 4
Receptive Oral Intercourse Low
Insertive Oral Intercourse Low
Other^ negligible
Biting, throwing of body fluids, Sharing sex toys, spitting
### Risk of HIV transmission via vaginal intercourse, per sexual act

**HIGH INCOME COUNTRIES**

| Risk to female having sex with HIV-positive male | 0.08% (1/1250) |
| Risk to male having sex with HIV-positive female | 0.04% (1/2500) |

**LOW INCOME COUNTRIES**

| Risk to female having sex HIV-positive male | 0.30% (1 in 333) |
| Risk to male having sex with HIV positive female | 0.38% (1 in 263) |

Summarised from Boily MC et al. *Heterosexual risk of HIV-1 infection per sexual act: systematic review and meta-analysis of observational studies. Lancet Infect Dis 9: 118-29, 2009*
## Risk of HIV transmission via anal intercourse, per sexual act

- **Per-act probability**

- **Insertive partner's risk (circumcised)** 0.11% (1 in 909)

- **Insertive partner's risk (uncircumcised)** 0.62% (1 in 161)

- **Receptive partner's risk (without ejaculation)** 0.65% (1 in 154)

- **Receptive partner's risk (with ejaculation)** 1.43% (1 in 70)

Universal HIV screening

- In all health-care settings, screening for HIV infection should be performed routinely for all patients aged 13--64 years. Health-care providers should initiate screening unless prevalence of undiagnosed HIV infection in their patients has been documented to be <0.1%. In the absence of existing data for HIV prevalence, health-care providers should initiate voluntary HIV screening until they establish that the diagnostic yield is <1 per 1,000 patients screened, at which point such screening is no longer warranted.

- All patients initiating treatment for TB should be screened routinely for HIV infection (108).

- All patients seeking treatment for STDs, including all patients attending STD clinics, should be screened routinely for HIV during each visit for a new complaint, regardless of whether the patient is known or suspected to have specific behavior risks for HIV infection.
Universal “opt-out” screening

- All pregnant women in the United States should be screened for HIV infection

- If HIV testing is declined then one needs to document in the medical record patient denial

- A second HIV test during the third trimester for women in settings with elevated HIV incidence (>17 cases per 100,000 person-years) is cost-effective and might result in substantial reductions in mother-to-child HIV transmission
Repeat HIV screening annually

- Persons likely to be at high risk include: injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and MSM or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test.

- Health-care providers should encourage patients and their prospective sex partners to be tested before initiating a new sexual relationship.

- Repeat screening of persons not likely to be at high risk for HIV should be performed on the basis of clinical judgment. Unless recent HIV test results are immediately available, any person whose blood or body fluid is the source of an occupational exposure for a health-care provider should be informed of the incident and tested for HIV infection at the time the exposure occurs.
Barriers to testing

- **Systemic**
  - Washington survey only 5% routinely offer
  - 57% perceived their pt populations low risk
  - Legislative continued use of “opt IN” policies vs. “OPT out”

Patient based barriers
- lack of awareness
- improved tx options
- personal risk
- availability of low cost/free tests
Strategies to overcome barriers

• Systemic approach expand opt out testing (no separate consent form requirements)- universal opt out hiv screening is associated with higher test rates

• Educate practitioners on current testing

• Increase public funding

• Increase health care access

• Expand rural outreach
Strategies to overcome barriers

- Patient education
- Risk discordant couples
- Behavior risk factor
- Testing privacy
- Message effective tolerable treatments
- Low income assistance programs
Benefits of universal screening

• Earlier dx HIV
• Reduces stigma associated with testing that requires assessment risks & behaviors
• Improves survival
• Cost effective QOL not just tx OI
• Earlier linkage to care
• Decrease transmission reduce community viral load
• Reduce risk hiv thru mother to child transmission
EVIDENCE OF UNIVERSAL TESTING BENEFITS

• PRENATAL AND PERINATAL HIV TESTING HAS BEEN HUGH SUCCESS

• 1988-1993 USA 1000-2000 CHILDREN ANNUALLY BECAME INFECTED WITH HIV FROM MOTHER TO CHILD

• SINCE 2006 MOTHER TO CHILD ROUTE HAS DECREASED
Perinatal HIV Transmission

- In utero: 25-40% of cases
- Intrapartum: 60-75% of cases
- Breastfeeding: 14-29% increase
  - Without ART transmission rate is 16-25%
  - With AZT, transmission was 11% in 1995
  - Today, risk is <2% with ART, routine testing, elective c-section as appropriate formula feeding
Perinatally Acquired HIV Infected Cases, Born in Florida, by Year of Birth, 1979-2014, N=1,220

Note: These data represent a **95% decline** in HIV-perinatally infected births from 1993 (N=109) to 2014 (N=6). These data include ALL perinatally acquired HIV Infection cases BORN in Florida. 2014 data are provisional. One of the babies born in 2014 have developed AIDS. Data as of 06/30/2015.
FS 381.004 HIV required by state law

1. Persons convicted of prostitution or of procuring another to commit prostitution
2. Pregnant females
3. Test by medical examiners autopsy
4. Occupational exposure
5. Inmates before release from prison
6. Court ordered as in sexual battery cases
FS 381.004

- No written consent
- Inform the patient that you recommend the testing as per CDC guidelines – frame it as part of their yearly screening labs
- Inform if HIV (+) report DOH
- Encourage voluntary disclosure to all current & past partners and HCW
Any person who, knowing him/herself HIV (+) & is aware of the risk of transmission through sexual intercourse, to have intercourse without informing his/her partner of his/her HIV status and receiving consent.

Any person who, knowing him/herself to be HIV positive and knowing that HIV may be transmitted through donating blood, plasma, organs, skin or other human tissue, donates blood, plasma, organs, skin or other human tissue is guilty of a felony of the 3rd degree.
Federal & State Laws

- As of 2009 all states now have confidential name based HIV infection reporting
- Florida partner notification service is available name of HIV + is not disclosed
history

- HIV discovered in 1981
- Family Retroviridae
- Genus Lentivirus
Origin and spread of HIV

- AIDS outbreak becomes pandemic
  - Initially seen in Europe, United States
  - Spread to Asia and the Americas

- HIV found in human blood sample from 1959

- Clinical syndrome defined by CDC in 1982

- Epidemiology suggests transmission via blood, semen, vaginal secretions, and breast milk
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HIV testing

- 4th generation HIV antibody/P24 antigen test
- HIV antibodies test for both HIV1 & HIV2
- HIV1 RNA viral load turns positive 5 days prior to 4th generation test suspect AHI
- HIV RNA VL is more sensitive than P24 Ag
- HIV VL turns (+) 10-15 days after HIV is acquired.
The AIDS pandemic:
Adults and children living with HIV/AIDS, 2013

- 4.3 M new HIV infections in 2013
- 2.9 M deaths due to HIV/AIDS in 2013
- 39.5 M living with HIV/AIDS; 50% females

Origin and spread of HIV

- HIV variants emerge
  - HIV-1
    - Isolated in 1983
    - Origin chimpanzee
    - Most prevalent strain worldwide
  - HIV-2
    - Isolated in 1985
    - Origin in the sooty mangabey
    - Dominant in West Africa
Clinical features of acute HIV infection - AHI

<table>
<thead>
<tr>
<th>Feature</th>
<th>frequency</th>
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<tbody>
<tr>
<td>Fever</td>
<td>70-80%</td>
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<tr>
<td>Fatigue</td>
<td>66-70%</td>
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<tr>
<td>Rash</td>
<td>50%</td>
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<tr>
<td>Myalgia</td>
<td>50%</td>
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<td>Sore throat</td>
<td>40-80%</td>
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<tr>
<td>Headache</td>
<td>45%</td>
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<tr>
<td>Lymphadenopathy</td>
<td>40%</td>
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<td>GI symptoms (n/v, diarrhea)</td>
<td>30%</td>
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STD

- HSV 2
- Syphilis
- Chlamydia
- Gonorrhea
- Trichomonas
- Hepatitis B and Hepatitis C

Remember infection with STD can invoke a more virulent form HIV and increase the transmission of HIV.
Impact of STDs on HIV Infection

- Early detection and treatment of Sexually Transmitted Diseases (STDs) has a major impact on sexual transmission of HIV.

- Much of heterosexually transmitted HIV infections can be prevented by reducing other underlying STDs.

- STDs increase HIV infectivity and susceptibility.
Healing Chancres, Darkfield negative
Why screen

- 1.2 million US HIV infected
- 1 in 8 of those infected are unaware of their status
- Early id of hiv generally leads to reduced transmission because dx is associated with decrease in risky behavior
- ART is more effective when initiated earlier before the development of advanced immunosuppression
The Epidemic in Florida

Population in 2014: 19.6 million →
(3rd in the nation)
Newly diagnosed** HIV infections in 2014: 5,897
(1st in the nation in 2013, up 17% from 2013 in FL)
Newly diagnosed** AIDS cases in 2014: 2,349
(1st in the nation in 2013, down 21% from 2013 in FL)
Cumulative pediatric AIDS cases diagnosed** through 2014: 1,548
(2nd in the nation in 2013)

Persons diagnosed and living***
with HIV disease through 2014: 110,000 →
(3rd in the nation in 2013)

HIV prevalence estimate through 2014: 126,100
(accounts for 12.8% national estimated unaware of their status)

HIV Incidence Estimates in 2013: 4,120
(There was a 18% decrease from 2007-2013)

HIV-related deaths in 2014: 878
(Down 6% from 2013)

* Other = Asian/Pacific Islanders; American Indians/Alaskan Natives; multi-racial.
** Data by year of diagnosis for 2014, data as of 06/30/2015
*** Living (prevalence) data as of 06/30/2015
Highest # 2013 New AIDS

1. FLORIDA  3225
2. CALIFORNIA  2725
3. TEXAS  2707
4. NEW YORK  2319
5. GEORGIA  1648

Note: Over the past ten years, HIV infection cases decreased among blacks by 25% and among whites by 2%. In contrast, there was a 16% increase in HIV infection cases among Hispanics during this same period.

*Other includes American Indian/Alaska Native, Asian/Pacific Islander, and multi-racial.

Note: Over the past ten years, black men represented the highest proportion (> 35%) of male HIV infection cases by race/ethnicity. From 2005 to 2014, the percentage of male HIV cases increased by 5 percentage points among Hispanics and 1 percentage point among whites. In contrast, the HIV cases decreased by 6 percentage points among blacks over the same time period.

*Other includes American Indian/Alaska Native, Asian/Pacific Islander, and multi-racial.
Total HIV and AIDS Cases Diagnosed in 2013 and Population, by Race/Ethnicity, United States*

Note: In 2013, blacks are over-represented among the HIV and AIDS cases, accounting for 46% of HIV cases and 50% of AIDS cases, but only 12% of the population. Similarly, Hispanics represent 17% of the population and account for 21% of the HIV cases and 20% of the AIDS cases. All displayed data are estimates. Estimated numbers resulted from statistical adjustment that accounted for reporting delays, but not for incomplete reporting.

*Source: U.S. data, CDC HIV surveillance report, Vol. 25, Tables 1a & 2a, 2014 data not available,
**HIV infection data are estimated reports from all 50 states with confidential name-based HIV infection reporting.
***Other includes Asian/Pacific Islanders, Native Alaskans/American Indians and multi-racial individuals.
Note: In this snapshot of 2014, HIV cases by race/ethnicity among males is more evenly split compared to HIV cases among females where blacks are over-represented, accounting for 62% of adult cases among women. *Other includes Asian/Pacific Islanders, Native Alaskans/American Indians and multi-racial individuals.
Top Florida Counties

- MIAMI DADE
- BROWARD
- ORANGE
- HILLSBOROUGH
- PALM BEACH
HIV Infection Case Rates* by County of Residence,** Reported in 2014, Florida

Statewide Data:
N= 6,147
State Rate = 31.4
Rate per 100,000 population

*Population data were provided by Florida CHARTS as of 7/9/2015.
**County totals exclude Department of Corrections cases (N=128).
Numbers on counties are cases reported.
Adult AIDS Cases, by Sex and Race/Ethnicity, Reported in 2014, Florida

Males
N=1,881

- 44%
- 31%
- 23%
- 2%

Females
N=804

- 69%
- 16%
- 13%
- 2%

Note: In this snapshot of 2014, blacks are over-represented among the AIDS cases, accounting for 44% of adult cases among men and 69% of the adult cases among women.
*Other includes Asian/Pacific Islanders, Native Alaskans/American Indians and mixed races
Adult HIV Infection Cases by Mode of Exposure, Reported in the United States* and Florida

U.S. (2013)  
N=47,165

25% 65%

3% <1% 7%

U.S. data, CDC HIV surveillance report, Vol. 25, Table 1a. (from all 50 states) 2014 data not available.

Florida (2014)  
N=6,132

30% 62%

2% 5%<1%

MSM  IDU  MSM/IDU  Heterosexual  Other

Note: NIRs redistributed. Similar to the AIDS data, the estimated proportion of reported MSM cases for the US is larger than that of Florida (65% vs. 62% respectively). Also, the proportion of IDU cases are higher in the U.S. (7% vs. 5%) and heterosexual cases are smaller (25% vs. 30%) when compared to HIV Infection cases reported in Florida.

*Source: US data, CDC HIV surveillance report, Vol. 25, Table 1a. (from all 50 states) 2014 data not available.
Underlying Factors Affecting HIV/AIDS Disparities

- Amount of HIV already in the community
- Late diagnosis of HIV or AIDS*
- Access to/acceptance of care*
- Stigma, denial*
- Discrimination, homophobia*
- HIV/AIDS complacency*
- Poverty and unemployment

*Factors that HIV/AIDS initiatives can impact.
CONDOMS

• DESPITE AWARENESS COMPaigns 50% GAY MEN DO NOT USE & REPORTED CONDOM USAGE IS HIGHER THAN ACTUAL USE

• Females anal sex 11% reported use of condoms

• 60% TEENAGERS USE CONDOM

• PROBLEM IS ANAL SEX UNDERSTUDIED
condoms

• Blame, ignorance, apathy or irresponsibility?

• Bias - do not like the feelings of condoms, lack of spontaneity, unpleasant taste, loss of erection, seen as sign of sexual promiscuity, or as a declaration of distrust or infidelity

• Believe that they will not acquire HIV - sense immortality

• Negotiate sex

• Feeling of vulnerability fear of being identified as high risk or as a part of stigmatized population
condoms

- Condom fatigue
- Strategies to reinforce condom use
- Check out their HIV status and check the status of their partner as their sense of responsibility
- PROPER USAGE CAN DECREASE DX 70%
- CONSISTENT USAGE OF LATEX CONDEMS CONTINUE TO BE ADVOCATED FOR PRIMARY PREVENTION
Prevention

- Vaccines
- Microbicides
- Treatment of sexually transmitted infections (STIs)
- Post-exposure prophylaxis (PEP)
- Treatment as prevention (TasP)
- PrEP
Occupational PEP

- Hiv status source should be determined
- Should be started as soon as possible after occupation exposure <72 hours
- Test HIV may be concluded 4 months post exposure if 4th generation testing is used
- Three drug therapy for 28 days
PrEP-prevention

- 1 in 4 MSM
- 1 in 5 IVDU
- 1 in 200 Heterosexuals should be counseled about PrEP
- Truvada (emtricitabine/tenofovir) approved 2012 for Pre exposure prophylaxis
PrEP

- PrEP can reduce risk of sexually acquired HIV 90%
- 70% reductive HIV in IVDU
- There is full prevention potential PrEP
- Truvada 200/300 must be taken daily if CrCl > 60ml/min
- Renal dose adjustment
- Patients seen every 3 months for follow up and including HIV testing and Rx refills
- Risk reduction counseling, adr, sti
PrEP

- Sero discordant heterosexual couples at time of conception/pregnancy
- Test for hepatitis BsAg & HepBsAB, renal status
- Prior authorization form Florida Medicaid
PrEP inject drugs (off label)

- 8% risk of acquiring risk to HIV via IVDU
- Included transfusion of infected blood, sharing equipment during IVDU and percutaneous needle sticks
- Strategies include needle & syringe programs – federal & state funding is low
- Opioid substitution therapy- buprenorphine based regimens/methadone
- Drug resistance data on Truvada – limited to those who had unrecognized acute HIV infection
Role of Male Circumcision

• African study of 3274 men/1674 underwent circumcision

• Study stopped early after interim analysis 60% reduction in HIV transmission heterosexually acquired in the circumcised group

• Three randomized controlled trials have shown that male circumcision provided by well-trained health professionals in properly equipped settings is safe. WHO/UNAIDS recommendations emphasize that male circumcision should be considered an efficacious intervention for HIV prevention in countries and regions with heterosexual epidemics, high HIV and low male circumcision prevalence.

• Penile foreskin contains large numbers of HIV-target cells
Study: Brothers Y Hermanos

- **Brothers y Hermanos Study** 2,235 Black and Latino MSMs in New York, Philadelphia and Los Angeles
  
  May 2005 to April 2006 “Is your penis circumcised or cut? 
  Black participants were more than twice as likely to be circumcised as the Latinos: 74% versus 33%
  Circumcised Black MSMs were: older, higher level of education, higher income and identify as gay than were uncircumcised Black MSMs.
  Fewer differences between circumcised and uncircumcised Latino MSMs.
  Summary: Circumcision conferred neither risk nor protection among Black men or Latino men who have sex with men

*Journal of Acquired Immune Deficiency Syndromes, December 15, 2007*
circumcision

- Male circumcision provides only partial protection, and therefore should be only one element of a comprehensive HIV prevention package which includes: the provision of HIV testing and counseling services; treatment for sexually transmitted infections; the promotion of safer sex practices; the provision of male and female condoms and promotion of their correct and consistent use.
prevention

• Treatment is Prevention
WHO now recommends a “treat-all” approach as soon as possible HIV diagnosis, regardless of the WHO clinical stage, CD4 cell count, or patient’s age.

This approach is supported by clinical trials that confirm that early use of ART keeps patients with HIV alive and healthier and reduces HIV transmission.

WHO has also broadened its recommendation for the use of oral pre-exposure prophylaxis (PrEP), containing tenofovir, to include additional groups at substantial risk.

Previously, PrEP was recommended only for men who have sex with men (MSM).

The guideline now supports the use of PrEP in all people who are at substantial risk of acquiring HIV; populations identified include some MSM groups, certain transgender untreated HIV infection. Individual risk varies greatly in these populations and depends on individual behavior. The revised guidelines will be published in 2016.
ART
Easier, less toxic, and more potent therapy
DECREASED TRANSMISSION, INCREASED POTENCY, DURABILITY, SIMPLICITY, SAFETY OF CURRENT TX

TOXICITY, PRESERVATION OF TX OPTIONS, RISK OF RESISTANCE
Potential Benefits of Early Therapy

- Untreated HIV is associated with development of AIDS and non-AIDS-defining conditions.
- Earlier ART may prevent HIV-related end-organ damage; deferred ART may not reliably repair damage acquired earlier.
- Increasing evidence of direct HIV effects on various end organs and indirect effects via HIV-associated inflammation.

End-organ damage occurs at all stages of infection.
Potential Benefits of Early Therapy (2)

- Potential decrease in risk of many complications, including:
  - HIV-associated nephropathy
  - Liver disease progression from hepatitis B or C
  - Cardiovascular disease
  - Malignancies (AIDS defining and non-AIDS defining)
  - Neurocognitive decline
  - Blunted immunological response owing to ART initiation at older age
  - Persistent T-cell activation and inflammation
hiv is an inflammatory process

Increased comorbidities

- Low CD4+ T-cell nadir
- Coinfections (hepatitis, CMV, EBV, and HPV)
- Persistent inflammation
- Cumulative cART exposure
- Lifestyle (smoking, etc)
- Aging

HIV-Associated Non-AIDS Conditions

- Majority of the risk from “standard” risk factors (eg, genetics, environment, diet)
  - Increasing age and substance use (including alcohol and tobacco) add to risk
    - Substantially higher rates of smoking, alcohol, drug use in HIV-infected patients
- HIV and ART (or both) may add to risk
  - May/may not be associated with CD4+ cell count, CD4+ count nadir, or HIV-1 RNA
  - Role of chronic viral infection
  - Role of chronic inflammation
- Appropriate treatment selection and/or dose reduction is warranted for ART agents or other medications that are primarily eliminated by the kidneys.

- Referral to a nephrologist is recommended for patients with:
  - Proteinuria (grade 1+ by dipstick analysis)
  - Reduced renal function (GFR < 60 mL/min/1.73 m²)
  - Need for treatment of CKD/transplantation
Multiple Factors May Contribute to Diabetes in HIV

- Lipoatrophy/visceral fat accumulation
- Genetic factors
- PIs/NRTIs
- Liver disease (HCV, steatosis)
- HIV?
- Low testosterone?
- Obesity
- Meds/opiates
- Cytokines
- Age
- Free fatty acids

Insulin resistance
β-cell dysfunction
Hypogonadism: Testing, Treatment, Goals

- **Laboratory testing**: use free testosterone with a morning measurement; should be confirmed with repeat testing

- **Treatment effects**: testosterone therapy has some short-term benefits on muscle, bone, mood in HIV-infected persons
  - Effects on frailty, CV disease, mortality, body composition, glucose metabolism unclear

- **Goal**: midnormal range for free testosterone

- **Safety**: Long-term safety unclear
  - Monitoring essential: Hct, edema, BPH symptoms, PSA, prostate exam, lipids

Osteoporosis in HIV-Positive Patients

- Osteoporosis and fractures are common in HIV-positive patients and will increase with aging.

- Risk factors include:
  - HIV: chronic infection, ART (TDF, certain PIs, any ART initiation)
  - Traditional: smoking, alcohol, HCV, low T, low weight

- Screening: dual-energy x-ray absorptiometry should be considered in all HIV-positive postmenopausal women and in men aged older than 50 yrs.

Best Practices for HIV-Positive Patients and Cardiovascular Risk

- HIV-infected patients should be managed with aggressive primary prevention
  - Control BP, lipids, smoking cessation
- Recognition of wider array of cardiac conditions
  - Heart failure, arrhythmias
- Drug–drug interactions (statins, PIs)
Common ARV drug- drug Interactions

- Simvastin & lovastatin contraindicated with PI’s
- Use the lowest possible dose of statins:
  Pitavastatin, atorvastatin, rosuvastatin, pravastatin
- Drug levels are different with each PI
- PDE5 inhibitors:
  Use lowest dose every 48-72 hours- dosed differently for each one
Initiation of therapy

- Readiness to start – pharmacist appointment is integrated
- The extra visit screens for the truly motivated patient
- One on one personal attention by pharmacist
- Schedule is open and they can call directly to the pharmacist for any issues possibly related to medication effect concern
- One month follow-up lab monitoring
Improving Adherence

- Support and reinforcement
- Simplified dosing strategies
- Reminders, alarms, timers, blisterpak, pillboxes
- Ongoing patient education
- Trust in primary care provider
DHHS Guidelines 2013: When to Start

- ART recommended for all HIV-infected patients in US
- Strength of recommendation varies depending on CD4+ count
  - CD4+ < 350 (AI); CD4+ 350-500 (AII); CD4+ > 500 (BIII)
- Certain groups highlighted as priorities for therapy
  - History of AIDS-defining illness
  - Pregnancy
  - HIV-associated nephropathy
  - HBV coinfection (AII); HCV coinfection
  - At risk of transmitting HIV to sexual partners
  - Acute HIV infection

DHHS Guidelines for Antiretroviral Therapy in Adults and Adolescents. February 2013.
Current ARV Medications

### NRTI
- Abacavir (ABC)
- Didanosine (ddI)
- Emtricitabine (FTC)
- Lamivudine (3TC)
- Stavudine (d4T)
- Tenofovir (TDF & TAF)
- Zidovudine (AZT, ZDV)

### NNRTI
- Delavirdine (DLV)
- Efavirenz (EFV)
- Etravirine (ETR)
- Nevirapine (NVP)
- Rilpivirine (RPV)

### PI
- Atazanavir (ATV)
- Darunavir (DRV)
- Fosamprenavir (FPV)
- Indinavir (IDV)
- Lopinavir (LPV)
- Nelfinavir (NFV)
- Saquinavir (SQV)
- Tipranavir (TPV)

### Fusion Inhibitor
- Enfuvirtide (ENF, T-20)

### CCR5 Antagonist
- Maraviroc (MVC)

### Pharmacokinetic (PK) booster
- Ritonavir (RTV)
- Cobicistat (COBI)

### Integrase Inhibitor (INSTI)
- Dolutegravir (DTG)
- Elvitegravir (EVG)
- Raltegravir (RA)
Complete regimes once daily

- 6 regimes complete
- Atripla
- Complera
- Odefsey
- Stribild
- Genvoya
- Triumeq
Rating Scheme for Recommendations

- **Strength of recommendation:**
  - A: Strong
  - B: Moderate
  - C: Optional

- **Quality of evidence:**
  - I: ≥1 randomized controlled trials
  - II: ≥1 well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes
  - III: Expert opinion
Recommendations for Initiating ART: Considerations

- “Patients starting ART should be willing and able to commit to treatment and should understand the benefits and risks of therapy and the importance of adherence.”
- Patients may choose to postpone ART
- Providers may elect to defer ART, based on an individual patient’s clinical or psychosocial factors, but ART should be started as soon as it is feasible to do so
CD4 <200
Candidiasis of bronchi, trachea, esophagus, or lungs
Invasive cervical cancer
Coccidioidomycosis
Cryptococcosis
Cryptosporidiosis, chronic intestinal (greater than 1 month's duration)
Cytomegalovirus disease (particularly CMV retinitis)
Encephalopathy, HIV-related
Herpes simplex: chronic ulcer(s) (greater than 1 month's duration); or bronchitis, pneumonitis, or esophagitis
Histoplasmosis
Isosporiasis, chronic intestinal (greater than 1 month's duration)
Kaposi's sarcoma
Lymphoma, multiple forms
Mycobacterium avium complex
Tuberculosis
Pneumocystis carinii pneumonia
Pneumonia, recurrent
Progressive multifocal leukoencephalopathy
Salmonella septicemia, recurrent
Toxoplasmosis of brain
Wasting syndrome due to HIV
Initial Regimens: Recommended

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<tr>
<th>INSTI based</th>
<th>PI based</th>
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<tr>
<td>• DTG/ABC/3TC; <strong>only</strong> if HLA-B*5701 negative (AI)</td>
<td>• DRV/r (QD) + TDF/FTC (AI) or TAF/FTC (AII)</td>
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<tr>
<td>• DTG (QD) + TDF/FTC (AI) or TAF/FTC (AII)</td>
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<td>• EVG/COBI/TDF/FTC; <strong>only</strong> if pre-ART CrCl &gt;70 mL/min (AI) or EVG/c/TAF/FTC (AI)</td>
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<td>• RAL + TDF/FTC (AI) or TAF/FTC</td>
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Note:
3TC can be used in place of FTC and vice versa; TDF: caution if renal insufficiency
Baseline labs

- HIV antibody testing (if prior documentation is not available or if HIV RNA is below the assay’s limit of detection) (AI);
- CD4 T-cell count (CD4 count) (AI);
- Plasma HIV RNA (viral load) (AI);
- Complete blood count, chemistry profile, transaminase levels, blood urea nitrogen (BUN), and creatinine, urinalysis, and serologies for hepatitis A, B, and C viruses (AIII);
- Fasting blood glucose and serum lipids (AIII); and
- Genotypic resistance testing at entry into care, regardless of whether ART will be initiated immediately (AII). For patients who have HIV RNA levels <500 to 1,000 copies/mL, viral amplification for resistance testing may not always be successful (BII).
- Tropism and HLA- B5701
Baseline

- Pap smear
- Pregnancy test lactating female
- RPR and std testing
- QuanitiFeron gold
Persons for Whom HCV Testing Is Recommended

**Adults born from 1945 through 1965 should be tested once (without prior ascertainment of HCV risk factors)**

HCV testing is recommended for those who:
- Currently injecting drugs
- Ever injected drugs, including those who injected once or a few times many years ago
HEPATITIS C SCREENING

Have certain medical conditions, including persons:
- who received clotting factor concentrates produced before 1987
- who were ever on long-term hemodialysis
- with persistently abnormal alanine aminotransferase levels (ALT)
- who have HIV infection

Were prior recipients of transfusions or organ transplants, including persons who:
- were notified that they received blood from a donor who later tested positive for HCV infection
- received a transfusion of blood, blood components, or an organ transplant before July 1992
- Children born to HCV positive women

HCV, HIV, and Hepatitis B testing based on a recognized exposure is recommended for:
Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures
The FDA is changing its recommendation that men who have sex with men (MSM) be indefinitely deferred – a policy that has been in place for approximately 30 years – to 12 months since the last sexual contact with another man.

- These updated recommendations better align the deferral period for MSM with the deferral period for other men and women at increased risk for HIV infection – such as those who had a recent blood transfusion or those who have been accidentally exposed to the blood of another individual.

- Reflects the most current scientific evidence and continue to ensure the safety of the U.S. blood supply
456.061 practitioner disclosure of confidential information: immunity from civil or criminal liability

1. Shall not be civilly or criminally liable for disclosure of confidential information to a sexual partner or a needle sharing partner under the following circumstances

A. if your pt test + & pt discloses their needle sharing partner or sexual partner

B. The doctor recommends the pt notify the sexual partner or needle sharing partner of their positive status & the pt refuses & the doctor informs the pt of his or her intent to inform the partner

C. in good faith advises the partner shall be done in accordance with protocols developed by the DOH
(2) The practitioner shall not be civilly or criminally liable for failure to disclose information relating to a positive HIV test result to a sexual partner or needle sharing partner.
Florida state statue 381.004
HIV test

• A general release without such prior written authorization is not sufficient to release HIV test results.

• “This information has been disclosed to you from records whose confidentiality is protected by state law. State law prohibits you from making any further disclosure of such information without the specific written consent of the person to whom such information pertains, or as otherwise permitted by state law. A general authorization for the release of medical or other information is NOT sufficient for this purpose.”
Informed consent is no longer required in health care settings in Florida prior to testing for HIV.

Patients must be notified either orally or in writing that they will be tested for HIV unless they decline (opt-out of) testing.

Notification must include information that a positive HIV test result, along with identifying information will be reported to the county health department and of the availability and location of sites at which anonymous testing is performed.

If the patient opts out, it must be noted in their medical record.

A patient need not be notified that their blood is being tested for HIV in the event of a significant exposure for health care personnel.

A patient need not be notified that their blood is being tested for HIV in the event of a significant exposure for non-health care personnel during a medical emergency.
384.25 reporting

(1) Each person who makes a diagnosis of or treats a person with a sexually transmissible disease and each laboratory that performs a test that concludes with a positive result for a sexually transmissible disease or a result indicative of human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS) shall report such facts as may be required by the department by rule, within a time period as specified by rule of the department, but in no case to exceed 2 weeks.
The Bottom Line…

“Drugs don’t work if people don’t take them.”

- C. Everett Koop, Former US Surgeon General
Success = Adherence

- Adherence is a key determinant of clinical outcome in patients receiving HAART.

- Adherence is a complex process influenced by patient-related variables, provider-related variables, and regimen-related variables.

- The number of prescribed daily doses is inversely related to adherence.

- Patients tend to prefer regimens with fewer daily doses, low pill burden, no food restrictions.

- The expansion in HIV treatment options means that some patients can now start therapy using a once a day regimen with a low pill burden.
Who should be routinely screened for HIV according to CDC guidelines?

1. All individuals regardless of risk
2. All individual as long as written consent & post test counseling is done
3. Only those who request
4. High risk individuals (mandatory) & voluntary screening for everyone else
5. MSM: AA males > 15yo
Which test is recommended for initial HIV testing?

1. Western Blot
2. 2\textsuperscript{nd} Generation HIV antibody test
3. 4\textsuperscript{th} Generative HIV antibody/antigen test
4. HIV 1 nucleic acid test
Which of the following individual is an appropriate candidate for PrEP?

1. Hiv neg Male who has unprotected sex with multiple male sex partners in past yr.

2. Hiv neg female in a monogamous relationship who has recently treated for HSV2 and uses cocaine

3. Hiv (+) male who admits to sex with multiple partners

4. Hiv neg female who admits to unprotected sex with one male of uncertain HIV status.
Practice recommendations

- **Screen** all pregnant women and individuals ages 13-64 yo (15-65USPSTF) for HIV infection- problem hiv test not covered on Medicare

- **Prescribe tenofovir/disoproxil emtricitabine (Truvada)** for pre-exposure prophylaxis for patients at high risk of acquiring HIV

- **Harm reduction**-Offer needle and syringe exchange programs & when appropriate opioid substitution therapy to individual who inject drugs
Websites to Access the Guidelines

- http://www.aidsetc.org
- WWW.CDC.GOV/HIV/RISK/PREP/INDEX.HTML
- http://www.truvada.com/truvada-patient-assistance
Harm reduction training & resources

- http://www.ihra.net/north-america-harm-reduction-programmes
- http://www.samhsa.gov/medication-assisted-treatment
- http://pcssmat.org/
- Acknowledge my colleague Archie McLean DO