HIV INITIAL ASSESSMENT AND TREATMENT: WHERE TO BEGIN?
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HIV - WHAT HAS CHANGED?
- Morbidity and Mortality
- Transmission Categories
- Peri-Natal Transmission
- NYS HIV Testing Law
- Testing Algorithm
- Window Period
- HIV Confidentiality Law
- PrEP
- Treatment
- Cure??
For those on therapy - AIDS related illnesses are no longer a threat
Treatment does not fully restore immune health
New inflammation-associated complications have emerged
- Cardio-vascular Disease
- Cancer
- Cumulative toxic effects from older ARVs
Diagnoses of HIV Infection among Adults and Adolescents, by Sex and Race/Ethnicity, 2011—United States and 6 Dependent Areas

Males
N = 39,495
- 2%
- 2%
- <1%
- <1%
- 23%
- 42%
- 30%
- American Indian/Alaska Native
- Asian
- Black/African American
- Multiple races

Females
N = 10,512
- 1%
- 1%
- <1%
- <1%
- 17%
- 63%
- Hispanic/Latino*
- Native Hawaiian/other Pacific Islander
- White

Note: Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been adjusted to account for reporting delays, but not for incomplete reporting.

*Hispanic/Latino can be of any race.

Elimination of Perinatal Transmission

- PACTG 076 Results - 1994
- NYSDOH PCR Study - 1995-97
- NYS 1997 - 99 cases of transmission - 11.5%
- NYS 2012 - 3 cases of transmission - 0.8%
1. Providers legally mandated to offer HIV testing to all persons ages 13 – 64.
2. Prior to asking for consent to perform HIV test, providers must make seven points of information about HIV available to patients
3. Consent for HIV testing can be incorporated into general consent for medical care
4. Consent for the rapid HIV test can be oral (except in Correctional Facilities)
5. NYSDOH has simplified HIV test request forms for laboratories

6. Test providers are legally required to arrange an appointment for follow-up HIV care to all persons who test positive for HIV
7. HIV information may be released to medical providers & health insurers without a written disclosure statement from patient
8. Deceased, comatose, or persons incapable of providing consent who are the source of an occupational exposure may now be HIV tested anonymously
How Soon After Exposure to HIV Can Tests Detect the Virus?

Even among antibody tests, the window period varies

• The so-called “first-generation” & “second-generation” HIV antibody tests detect one type of HIV antibody, 42-60 days after infection

• “Third-generation” tests detect all types of antibodies, making them more sensitive than the first and second-generation tests, about 21-24 days after infection

• “Fourth-generation” tests can simultaneously detect both HIV antibodies and antigens. Tests that look for the p24 antigen can detect it within 14-15 days. Tests can detect plasma HIV RNA (ribonucleic acid) within about 10 days of infection

It is important to know the HIV test(s) your agency or lab uses so you can provide patients with the best advice.

HIV TESTING ALGORITHM

- Use 4th generation antigen/antibody preliminary screening test
- Use of a test to delineate HIV-1 from HIV-2 if results are discordant...
- Use of a Qualitative PCR test to confirm the preliminary screen
ANTIGEN / ANTIBODY TEST

- 4th generation testing is recommended...
- Considered a rapid test (turn around time from test to results is 60 minutes or less)
- 99.8% sensitivity and specificity
- Can detect ag/ab as early as 2 weeks following an exposure.
  - Note: when using a 4th generation test, the window period can be reduced from 90 days to 15 days.

PUBLIC HEALTH LAW AMENDED
(4/1/14)

- Key Provisions of the legislation include:
  - Elimination of the requirement for written consent prior to ordering an HIV-related test in any circumstance outside correctional facilities
  - Oral notification to be provided to the individual being tested, if individual lacks capacity, to the person lawfully authorized to consent for healthcare of the individual
  - The individual must be told each time an HIV test will be done and given the opportunity to decline. All tests must be documented in the patients medical record
PUBLIC HEALTH LAW AMENDED

- Information about HIV testing will be provided via posters, brochures, videos or by providers to the patient with the opportunity to accept or refuse testing
- When used for purposes of patient linkage and retention in care, patient-specific identifying information may be shared between local and state health departments and healthcare providers currently treating the patient
- NYSDOH AIDS Institute is in the process of producing Guidelines for implementation of these amendments

The CDC guidelines recommend PrEP should be considered for HIV-uninfected patients with any of the following indications: (5/2014)

⊙Anyone who is in an ongoing sexual relationship with an HIV-infected partner
⊙A gay or bisexual man who has had sex without a condom or has been diagnosed with a sexually transmitted infection within the past six months, and is not in a mutually monogamous relationship with a partner who recently tested HIV-negative
⊙A heterosexual man or woman who does not always use condoms when having sex with partners known to be at risk for HIV (for example, injecting drug users or bisexual male partners of unknown HIV status), and is not in a mutually-monogamous relationship with a partner who recently tested HIV-negative
⊙Anyone who has, within the past six months, injected illicit drugs and shared equipment or been in a treatment program for injection drug use.
**HIV - WHAT HASN’T CHANGED**
- Stigma
- Fear
- Denial
- Discrimination
- Infection Rates
- STD/HIV Correlation

**HIV/STD LINK**
- Individuals infected with STDs are 2-5 times more likely to acquire HIV if exposed through sexual contact
  - Genital ulcers produce a portal of entry
  - Increase in the concentration of cells in genital secretions that serve as target cells
- If an HIV-infected is also infected with another STD, they are more likely to transmit HIV through sexual contact
  - Higher concentration of HIV in genital secretions
Exposure to HIV at mucosal surface (sex)

Virus collected by dendritic cells, carried to lymph node

HIV replicates in CD4 cells, released into blood

Virus spreads to other organs


It has been estimated that at least 50% and as many as 90% of patients acutely infected with HIV will experience at least some symptoms of the acute retroviral syndrome
### Symptoms in Primary HIV Infection

- Fever - 96%
- Adenopathy - 74%
- Pharyngitis - 70%
- Rash - 70% (5-10 mm maculopapular lesions)
- Myalgias or arthralgias - 54%
- Diarrhea and headache - 32% each
- Hepatosplenomegaly - 14%
- Thrush - 12%
- Nuer - meningencephalitis, neuropathy, etc about 8%

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### HIV+ Post Test Counseling

Counseling or referrals to counseling must be provided on:

- Coping with the emotional consequences of learning test result
- Dealing with discrimination as a result of the disclosure of test result
- Inform the person of available medical treatment and link to services
- Assist with behavior change
- Domestic Violence Screening
- Need to notify sexual/needle sharing partners
NEW PATIENT PROTOCOL

- Vital Signs, Ht & Wt
- Nursing Assessment – medications, surgical history, immunization history, HPI/ROS
- Lab work includes:
  - CBC with Auto Diff
  - CD4/CD Lymph Phenotyping
  - Chlamydia PCR Urine
  - CK - Creatinine Kinase
  - CMP - Comprehensive Metabolic Panel
  - HAV - Hepatitis A IGG
  - HBV - Hepatitis B Core AB, Surface AB & AG
  - HCV - Hepatitis C AB
  - HIV 1 Drug Resistance Genotyping

LABS .... CONTINUED

- HIV PCR - HIV 1 Viral Load
- HLA B 5701
- Lipid Panel
- Liver Panel
- N Gonorrhoeae PCR Urine
- Syphilis - T Pallidum IGG
- TB Gamma Interferon
- Toxoplasma IGG & IGM
- Vitamin D -25 hydroxy level
- UA - Urinalysis and Microscopib

- Additional labs may include:
  - HA1C, HCV Genotype, HCV PCR, TSH
NEW PATIENT PROTOCOL

- Psycho/Social Assessment
  - Mental Health
    - Depression Screening
  - Substance Use Screening
  - Support Systems - Relationships
  - Domestic Violence Screening
  - Housing
  - Transportation
  - Insurance
- Nutrition Evaluation
- Consent Forms/Health Care Proxy
- Referrals

PATIENT EDUCATION

- HIV 101 - Medication Review
  - Discuss HIV disease, living with HIV
  - Assess patient readiness for treatment
  - Brochures - 100 Questions and Answers about HIV and AIDS
- Adherence
- Risk Reduction
- Partner Notification - PNAP
- Disclosure Issues
- Nutrition - Assessment and Counseling
SUPPORT SERVICES

- Support Groups
- Counseling Services
- Case Management
- Drug Treatment
- Pastoral Services
- Acupuncture
- Massage Therapy
- Mental Health Referrals
- Transportation
- Linkage to Community Resources

GUIDELINES FOR THE USE OF ANTIRETROVIRAL AGENTS IN HIV-1-INFECTED ADULTS AND ADOLESCENTS (MAY 2014)

- Antiretroviral therapy (ART) is recommended for all HIV-infected individuals to reduce the risk of disease progression.
  - The strength of and evidence for this recommendation vary by pretreatment CD4 T lymphocyte (CD4) cell count: CD4 count <350 cells/mm³ (AI); CD4 count 350 to 500 cells/mm³ (AII); CD4 count >500 cells/mm³ (BIII).
- ART is also recommended for HIV-infected individuals to prevent transmission of HIV.
  - The strength of and evidence for this recommendation vary by transmission risks: perinatal transmission (AI); heterosexual transmission (AI); other transmission risk groups (AIII).
- Patients starting ART should be willing and able to commit to treatment and understand the benefits and risks of therapy and the importance of adherence (AIII). Patients may choose to postpone therapy, and providers, on a case-by-case basis, may elect to defer therapy on the basis of clinical and/or psychosocial factors.

Rating of Recommendations: A = Strong; B = Moderate; C = Optional
Rating of Evidence: I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational/cohort studies with long-term clinical outcomes; III = Expert opinion
**UPDATED GUIDELINES**

- There's no such thing as a “preferred” first-line regimen
  - 10 different “recommended” regimens, options vary on the nuances of a person’s health
- Three new “recommended” regimens have been added
  - All involve the use of new integrase inhibitors
- Some drugs have been removed from the guidelines
- CD4 testing can be less frequent
  - Patients on HIV meds for 2 or more years and have undetectable viral loads once/year if t-cells over 300, over 500 t-cells, testing is optional
- Testing other T-cell levels is not generally recommended
  - No clinical value in CD8, CD19
- New guidance on HIV treatment “switching”
  - Expert advice on changing regimens

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**HIV LIFE CYCLE: TARGETS OF ANTI-HIV THERAPY**

- **Entry Inhibitors:** Fusion, CD4, CCR5, CXCR4
- **Integrate Inhibitors**
- **Reverse transcriptase inhibitors:**
  - NRTI (nucleosides, nucleotides)
  - NNRTI
- **Protease inhibitors**

Slide Courtesy of Dr. B. Sabundayo, JHU
**ONCE DAILY REGIMEN**

- Atripla - Tenofovir/Efavirenz/Emtricitabine
- Complera - Rilpivirine/Emtricitabine/Tenofovir
- Striibl - Elvitegravir/Cobicistat/Emtricitabine/Tenofovir*
- 572-Trii - Dolutegravir/Abacavir/Lamivudine (to be released soon)

**SIDE EFFECTS OF THE MEDICATIONS**

- Vivid dreams, ‘hang-over effect’ - Atripla
- Increase CPK levels - Integrase Inhibitors
- Dizziness and Drowsiness - Complera
- Serum Creatinine false elevation - Cobicistat and Dolutegravir
- Some Nausea - Cobicistat
- ‘Creeping creatinine’, proteinuria - Tenofovir
- Rash - NNRTI, Prezista
- Gastrointestinal effects - Protease inhibitors
EVIDENCE SUPPORTS COMBINATION ART FOR PREVENTION OF HIV TRANSMISSION

- Transmission only occurs from persons with HIV
- HIV RNA level is single greatest risk factor for HIV transmission
- Combination ART can lower HIV RNA level to undetectable levels
- Observational evidence in heterosexual couples
- Previous modeling work suggests considerable potential
- Knowing one’s HIV status is key to prevention with combination ART
- When to start combination ART is not known

THE END OF AIDS

- Universal Testing
- Linkage to Care
- Access to Medications
- “Treatment as Prevention”
- Eliminate Perinatal Transmission
- Post Exposure Prophylaxis
- PrEP
- Cure!!