Practice Guidelines for the Primary Medical Care of Persons Living with HIV/AIDS

Ryan White Treatment Modernization Act Part A, San Diego County

In conjunction with Public Health Services guidelines and accepted community practices, the Standards of Care Committee recommends the following standards of care guidelines for patients enrolled in the Ryan White Program Primary Care Program for San Diego County. Assessments of the process of care will be based on the following recommended guidelines.

Source Documents

1) Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents: Panel on Clinical Practices for the Treatment of HIV Infection, October 10, 2006

2) Guidelines for the Prevention of Opportunistic Infections in Persons Infected with Human Immunodeficiency Virus: U.S. Public Health Services and Infectious Diseases Society of America, June 14, 2002

3) Prevention and Treatment of Tuberculosis among Patients Infected with Human Immunodeficiency Virus: Centers for Disease Control and Prevention, MMWR 1998 47/RR-20 October 1998

4) Acquired Rifamycin Resistance in Persons with Advanced HIV Disease Being Treated for Active Tuberculosis with Intermittent Rifamycin-Based Regimens: Centers for Disease Control and Prevention, MMWR 51(10), 214 – 215, March 2002

5) Guidance for STD Clinical Preventive Services for Persons Infected with HIV, Sexually Transmitted Diseases: 2006; 55/RR-11, August 4, 2006

6) Healthcare Provider's Role in Syphilis Control: Gail Bolan, M.D., Medical Board of California ACTION REPORT, p. 20, February 2003

7) Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States: Public Health Services Task Force, October 12, 2006

8) A Guide to the Clinical Care of Women: Edited by Jean R. Anderson, M.D. 2005 Edition produced and distributed by HRSA. Available online: http://hab.hrsa.gov/publications/womencare05/

A. Antiretroviral therapy and opportunistic infection prophylaxis (primary and secondary) are recommended in accordance with the most recent US Public Health Service guidelines. Guidelines may have been updated since the versions listed above – current versions are available at http://www.aidsinfo.nih.gov/guidelines/

B. Guidelines for staging and baseline evaluation, recommended to be completed within the first two visits

1) Complete history, to include at least the following:
   a) General background
      - o Ethnicity
      - o Sex
      - o Family history
      - o Social history
      - o Travel history
      - o Pet contacts within last 12 months

   b) Current/lifetime sexual and drug use history – using standardized risk assessment instrument to include items such as the following:
      - o Sexually transmitted diseases history (including herpes) lifetime and for last 5 years
      - o Assess whether in a monogamous relationship
      - o Gender of sex partners
      - o Number of partners in last 3 months
      - o Partners HIV status
      - o Injecting drug use, lifetime and last 5 years
      - o Exposure sites—rectal, urethral, oral
      - o Use of drugs with sexual activity
      - o San Diego County Sexual Risk Assessment
      - o Use of condoms

   c) HIV care history
      - o HIV status, including recent/historical CD4+ T cell count/viral load
      - o Prior and current antiretroviral regimen
      - o Resistance test results (if available)
      - o Current prophylaxis
      - o Prior HIV-related complications
      - o CDC HIV stage

   d) General medical history
      - o Immunizations
      - o Hepatitis history
      - o Tuberculosis risk
      - o Reproductive history (females) including parity, LMP, Method of Birth Control
      - o Current allergies
      - o Other current medications
      - o Significant childhood illnesses
      - o Other medical history
      - o Mental Health histories, past/current problems, symptoms of depression, psych meds

2) Review of symptoms and overall physical exam, including height, weight, temperature, blood pressure, pulse, respirations, general appearance, skin, HEENT, opthalmoscopy, chest, cardiac, abdomen, rectum (and anoscopy if anorectal symptoms), pelvic (women), breasts, genitalia, extremities, lymph nodes, mental status, nervous system and reflexes

3) Lab tests, including but not limited to:
   - Complete blood count with differential and platelet count
   - Chemistry panel including liver test and renal function
   - Glucose, cholesterol and triglyceride screening
   - T-cell subsets (quarterly)
   - HIV plasma RNA (quarterly)

- CMV IgG
- Syphilis serology (annually; see Section I.1 Periodicity of Selected Baseline History, Physical and Lab Tests)
- Gonorrhea (urine or urethral/endocervical amplification swab or culture) (annually; see Section I.1
    - Periodicity of Selected Baseline History, Physical and Lab Tests)
    - Also rectal/pharyngeal culture if indicated by exposure or symptom history
- Chlamydia (urine or urethral/endocervical amplification swab) (annually)
- HSV-2 serology (recommended)
- Leukocyte esterase (LE) urine dipstick (men)
- Toxoplasma IgG
- Hepatitis A serology
- Hepatitis B surface antigen and core antibody, surface antibody at physician's discretion
- Hepatitis C antibody
- PPD (annually, unless already known to be infected with TB or documented anergy)
- Chest X-ray (PA and lateral) if history of TB exposure or pulmonary symptoms (as indicated)
- Pap smear (women) (every 6 – 12 months)
- Examination of vaginal fluid (microscopic wet mount or other methods) to identify trichomoniasis or bacterial vaginosis (every 6 – 12 months)
- Anal pap test (optional)

Evidence of any of above tests within the past 6 months is acceptable unless risk factors indicate value of a current test (i.e. STD testing)

4) Appropriate referrals, including but not limited to:
- Treatment adherence counseling
- Ryan White CARE Act dental program (recommended annually)
- Ophthalmologist if CD4 < 50 (recommended)
- Case management (if eligible)
- Medical nutrition therapy
- Clinical trials
- Mental health
- Substance abuse

C. Guidelines for use of plasma HIV RNA measurements

1) Patients may have 8 standard or ultrasensitive assays per year at provider's discretion. Provider must show justification for more than 8 per year.
(Roche PCR standard measures 400 - 750,000 copies/mL; Beyer assay 75 - 500,000 copies/mL; ultrasensitive measures 50 - 75,000 copies/mL)
2) General indications for testing
    a) Baseline evaluation for prognosis
    b) Among patients not on antiretroviral therapy, every 3 – 4 months
    c) Among patients starting antiretroviral therapy or changing an antiretroviral regimen, 2 – 8 weeks after regimen initiation or change
    d) Among patients on an established antiretroviral regimen, every 3 – 4 months to detect maximal treatment effect and to assess for maintenance of response
3) Other indications
    a) Discordant CD4+ T cell and viral load responses
    b) Required addition or removal of medications that may impact antiretroviral bioavailability (e.g., rifabutin, anticonvulsants in protease inhibitor-treated patients)
    c) Confirmation of rising HIV RNA level if a treatment change will be based on the value

It is recommended that all plasma RNA results be verified with a repeat determination before starting or making changes in therapy UNLESS there is other substantiating clinical or laboratory evidence supporting a therapy change.

D) Guidelines for hyperlipidemia

1) Fasting lipid panel (HDL/LDL/total cholesterol/triglycerides) if non-fasting total cholesterol or triglycerides are abnormal at initial visit
2) It is recommended that fasting lipid panel be ordered/repeated within 6 weeks to 3 months of initiating protease inhibitor or NNRTI therapy, and at least once per year thereafter

E) Guidelines for Immunization

1) Offered as soon as possible after initial evaluation at recommended doses
2) Viral loads should not be measured within three weeks of an immunization.
3) Pneumovax, influenza, tetanus, Hepatitis B (if not immune) and Hepatitis A (if not immune)
4) Influenza vaccine: recommended yearly with trivalent inactivated vaccine (live attenuated vaccine is contraindicated in HIV positive persons).
5) Hepatitis Vaccine:
   a) Hepatitis B: recommended in persons with negative serology. Double dosing is now recommended in increase seroconversion (40ug) rates. For those patients who do not seroconvert after the first series, a second series is recommended. If these persons do not seroconvert, they are unlikely to respond to a third series.
   b) Hepatitis A: Seroconversion rates are likely related to CD4 counts. The vaccine may be given in persons who are sero-negative however if there is no response and the CD4 counts are less than 500, persons can receive a repeat of series when CD4 counts are higher.
6) Pneumococcal: Recommended for all patients with a one-time repeat after 5 years.
7) Tetanus Vaccines: Recommended every 10 years. Recommend next booster contain pertussis booster (Tdap).
8) Live Vaccines (Live attenuated influenza vaccine, Varicella or Zoster vaccine, Vaccinia (small pox), Yellow Fever, Live Oral Polio, Measles*, Typhoid) are contraindicated in persons with severe immunosuppression based on the persons age (per ACIP): CD4<750 for those younger than 12 months, <500 for ages 1-5, and <200 for those >6 years old.

   *Consider MMR in patients who are not severely immunosuppressed per above criteria and no history of OI or CD4<200 given recent outbreaks of measles.

9) Booster doses as recommended by CDC guidelines.

F) Additional guidelines for Care of Women

1) Guidelines for Cervical Neoplasia (modified Algorithm 6 of AHCPR 94-0573)
   a) Pap smear at baseline and again at six months if normal; normal Pap smears repeated in 12 months (6 months if patient has a history of human papilloma virus (HPV) or with previous Pap smears showing squamous intraepithelial lesion SILs)
   b) Women with abnormal Pap smears or a history of an untreated abnormal Pap smear referred for coloposcopy with minimum follow-up every 6 months
2) Annual mammograms initiated no later than age 40

G) Guidelines for HIV Resistance Testing

1) A baseline genotype is recommended for antiretroviral naïve patients
   a) Refer patients suspected of acquiring HIV in the last 12 months to the UCSD First Choice Program
2) Resistance testing for patients experiencing treatment failure
   a) Viral load must be greater than the sensitivity threshold of the assay in use
   b) On a stable antiretroviral regimen for at least 1 month prior to resistance testing
   c) Potentially able to tolerate at least 2 antiretroviral medications patient is not currently taking

d) Test selection guidelines

- Always consider a genotype as the first option
- For patients *without* a boosted protease inhibitor (PI) in the current treatment regimen experiencing a first treatment failure – order a genotype
- For patients *with* a boosted PI in the current treatment regimen experiencing a first treatment failure – provider discretion; consider a genotype as first option
- For all patients experiencing a second treatment failure or beyond – provider discretion; consider a genotype as first option

e) Patients are limited to one genotype and one phenotype, or one GT, annually

3) The following patients are not eligible for resistance testing:

a) Patients with current non-adherence (e.g. failure to keep appointments or failure to obtain medication refills where this is known)

b) Active alcohol or drug abuse that would, in the opinion of the physician, compromise active follow up or adherence to treatment regimen

c) Life expectancy less than 6 months, or comfort care status

H) Guidelines for Therapeutic Drug Monitoring

No guidelines other than PHS

I) Guidelines for periodicity of selected baseline history, physical and lab tests

1) STDs: Repeat annually (gonorrhea, chlamydia, LE test [men]) or more frequently if behaviors indicate. Alternately, annual testing could be deferred based on sexual behavior.
   - o Every 2 – 3 months for patients with very high-risk behavior (e.g. multiple anonymous partners; meeting partners in a bath house, sex club or via the internet; commercial sex workers)
2) Syphilis screening every 3-4 months (in conjunction with CD4 or viral load test)
3) Risk assessment: Sexual and drug use behavior assessment repeated every 3 to 6 months
4) For women, LMP, Method of Birth Control
5) Other exposures: Travel and pet exposure history annually

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Incorporated references updated as necessary

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