Miami-Dade County Ryan White Program

Minimum Primary Medical Care Standards for Chart Review

Medical Care Subcommittee
Miami-Dade HIV/AIDS Partnership

Statement of Intent: *All local Ryan White Program-funded practitioners are required by contract to adhere, at a minimum, to the Public Health Service (PHS) Guidelines.*

Requirements

1. **Requirements for Practitioners** (Physicians, Nurse Practitioners, and Physician Assistants):

   - Practitioner must be a Physician (MD or DO), Nurse Practitioner, or Physician Assistant with current and valid license to practice medicine within the State of Florida
   - Practitioners must have a minimum experience treating 20 HIV+ clients over the past two years
   - Practitioners are strongly encouraged to complete at least 30 hours of HIV-related Continuing Medical Education (CME) Category 1 credits within a period of two years. When a new practitioner is working with a contracted practitioner, new practitioner is encouraged to comply within one year.
   - New practioners should be linked to existing Ryan White Program providers, AETC or through an AAHIVM specialist to support the new provider.
   - New providers will receive a chart review within 6 months.
   - Treat and monitor patients in adherence with current DHHS Guidelines and other standards of care, to include, but not limited to:
     a. DHHS Clinical Guidelines
        http://www.aidsinfo.nih.gov/Guidelines/
     b. US Preventive Taskforce
        http://www.uspreventiveservicestaskforce.org/BrowseRec/Index
     c. American Cancer Society Guidelines for the Early Detection of Cancer
        http://www.cancer.org/docroot/PED/content/PED_2_3X_ACS_Cancer_Detection_Guidelines_36.asp
     d. European AIDS Clinical Society (EACS) guidelines on the prevention and management of metabolic diseases in HIV
        http://www.eacsociety.org/guidelines/eacs-guidelines/eacs-guidelines.html
     e. ACC/AHA Guideline on the Treatment of Blood Cholesterol
        http://circ.ahajournals.org/content/129/25_suppl_2/S1
     f. CDC Recommended Adult Immunization Schedule
        http://www.cdc.gov/vaccines/schedules/hcp/adult.htlm
     g. Incorporating Recommendations for HIV Prevention with Adults and Adolescents with HIV in the US
        http://stacks.cdc.gov/view/cdc/26062

h. Although not paid for by the Ryan White Program, below are PrEP, nPEP and PEP guidelines:
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm
https://aidsinfo.nih.gov/contentfiles/healthcareoccupexpogl.pdf
http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf

- Follow an action plan to address any areas for improvement that are identified during quality assurance reviews.

Minimum Standards of Which Practitioners Will Be Measured

Assessments and Referrals

2. **Initial** - At initial visit:
    a. Comprehensive initial history
    b. Mental health and substance abuse assessment
    c. Physical examination, including review of systems
    d. Vital signs, including weight, BMI, height (no shoes)
    e. Gynecological exam per guidance for females
    f. Wellness exam for females
    g. Rectal examination and stool guaiac testing
    h. Sexual transmitted infection assessment as appropriate including at a minimum GC, Chlamydia at anatomical sites of potential exposure, RPR, and for females trichomoniasis NAAT of vaginal secretions.
    i. Age appropriate cancer screening
    j. Adherence to medications
    k. Risk reduction
    l. Safer sex practices-discussions may include PrEp, PEP, nPep and should include condom usage
    m. Pregnancy Planning:
        1) Preconception counseling for men and women
        2) Contraceptive counseling for men and women including assessment and type of birth control method

3. **Interim Monitoring and Problem-Oriented visits** - At every visit:
    a. Vital signs, including weight/BMI
    b. Physical examination related to specific problem, as appropriate
    c. Interval changes in vital signs addressed, especially trend in weight over time
    d. Adherence to medications
    e. Risk reduction
    f. Safer sex practices-discussions may include PrEp, PEP, nPep and should include condom usage

4. **Annual** - At each annual visit:
    a. Update comprehensive initial history, as appropriate
    b. Physical examination, including review of systems
    c. Vital signs, including weight, BMI, height (no shoes)
    d. Interval changes in vital signs addressed, especially trend in weight/BMI over time
    e. Mental health and substance abuse assessment

f. Gynecological exam per guidance for females
g. Wellness exam for females
h. Rectal examination and stool guaiac testing
i. Sexual transmitted infection assessment
j. Age appropriate cancer screening
k. Adherence to medications
l. Risk reduction
m. Safer sex practices-discussions may include PrEp, PEP, nPep and should include condom usage
n. Preconception counseling for men and women

Assess and document health education on:

o. Nutritional assessment/care
p. Oral health care
q. Mental Health assessment (particularly clinical depression)/care
r. Exercise
s. Drugs/Alcohol/Tobacco (including smokeless) assessment/care
t. Domestic violence
u. Birth control
v. Advance Directives (completion or review)

5. **Additional Charting/Documentation at least annually:**
   a. Problem list complete and up-to-date
   b. Medications list complete with start and stop dates, dosages
   c. Allergies list complete and up-to-date
   d. Immunization list complete and up-to-date

Assessments to be included at Incremental Visits

HIV Specific

6. **CD4 T-cell count** [i,ii] - Entry into care, follow-up before ART every 3-6 months, ART initiation or switch, treatment failure, or if clinically indicated. For patients documented as adherent after two (2) years on ART with consistently suppressed viral load with CD4 counts of 300-500 cells/mm^3 test every 12 months, for those who have CD4 counts > 500 cells/mm^3, per PCP discretion, CD4 monitoring is optional. In accordance with the HRSA HAB performance measures, the local program defines consistently suppressed viral load as <200 copies/ml.

7. **HIV RNA** [i,ii] - Entry into care, follow-up before ART every 3-6 months, ART initiation or switch, 2-8 weeks post-ART initiation, treatment failure, or if clinically indicated. For patients documented as adherent with suppressed HIV Viral Load and stable clinical and immunologic status for > 2-3 years, can extend interval monitoring to every 6 months.

8. **ARV therapy is recommended and discussed** [i,ii] - Risks and benefits are discussed and if treatment initiated, follow-up with adherence. If declined, refusal is documented in record.

9. **Treatment of opportunistic infections and prophylaxis for opportunistic infections** [i,ii] - Specifically, but not limited to, Mycobacterium avium complex (MAC), Pneumocystis Jiroveci Pneumonia (PCP), and Toxoplasmosis (Toxo) prophylaxis per DHHS Guidelines[i].

10. **Resistance testing** [i,ii] - Entry into care, ART initiation or switch, treatment failure, or if clinically indicated. For treatment-naïve patients, if resistance testing was performed at entry into care, repeat testing is optional post-ART initiation; for patients with viral suppression who are switching therapy for toxicity or convenience, resistance testing will not be possible and therefore is not necessary. Genotype testing conducted at entry into care, prior to start of antiretroviral (ARV) therapy and when failing therapy (HIV viral load ≥ 1,000).

11. **HLA-B*5701** [i,ii] - If considering start of abacavir and document in record carrying data forward to most current volume *(Currently not paid for by the Ryan White Program due to payer of last resort restrictions; must access test through ViiV Healthcare's HLA Aware Program).*

12. **Tropism testing** [i,ii] - If considering use of CCR5 antagonist (HIV viral load must be ≥ 1000) or if clinically indicated. If performed, record carried forward to most current volume *(Currently not paid for by Ryan White Program due to payer of last resort restrictions; must access tropism test through ViiV Healthcare's Tropism Access Program).*

STI Screenings

13. **Anal HPV Screening** [ii] - Men who have sex with men (MSM), women with a history of receptive anal intercourse or abnormal cervical Pap test, and all HIV-infected persons with genital warts should have anal Pap tests.

14. **Bacterial STIs (Syphilis**, **N. gonorrhoeae** (GC), **C. trachomatis** (Chlamydia) [i,ii]) and **parasitic STIs (Trichomoniasis)**- Screening should be performed at least annually for all sexually active patients, more frequently might be appropriate depending on individual risk behaviors, the local epidemiology of STDs, and whether incident STDs are detected by screening or by the presence of symptoms. Women or men who have sex with men (MSM) who engage in receptive anal intercourse - screen for rectal gonorrhea and Chlamydia. Women or MSMs who engage in receptive oral intercourse - screen for pharyngeal gonorrhea (Chlamydia not recommended). For MSMs with multiple or anonymous partners, or have sex during illicit drug use, or use methamphetamine, or have sex partners with these risk factors, screening is recommended at 3-6 month intervals.[iii] Assume that all adult patients are sexually active unless noted in history or progress note that patient denies being sexually active. Testing at anatomic site of exposure, is the preferred approach including self collection.

General Health including Labs

15. **ALT, AST, T. bili, D. bili** [i,ii] - Entry into care, follow-up before ART every 6-12 months, ART initiation or switch, 2-8 weeks post-ART initiation, or if clinically indicated.

16. **Basic chemistry** [i,ii] - Entry into care, follow-up before ART every 6-12 months, ART initiation or switch, 2-8 weeks post-ART initiation, or if clinically indicated. Serum Na, K, HCO3, Cl, BUN, creatinine, glucose (preferably fasting). It is suggested to monitor phosphorus while on tenofovir; determination of renal function should include estimation of creatinine clearance using Cockroft & Gault equation[iv] or estimation of glomerular filtration rate based on MDRD equation.

17. **CBC w/ differential** [i,ii] - Entry into care, follow-up before ART every 3-6 months, ART initiation or switch, 2-8 weeks post-ART initiation if a zidovudine-containing regimen, or if clinically indicated.

18. **Fasting Glucose** (12 hours fasting) **OR Hemoglobin A1c** [i,ii] - Entry into care, follow-up before ART annually if normal, ART initiation or switch, every 3-6 months if abnormal or borderline at last measurement, every 6 months if normal at last measurement, or if clinically indicated.

19. **Fasting Lipid Profile** [i,ii] (12 hours fasting) - Entry into care, follow-up before ART annually if normal, ART initiation or switch, consider 2-8 weeks post-ART initiation, every 6 months if abnormal or borderline at last measurement, every 12 months if normal at last measurement, or if clinically indicated.

20. **Urinalysis** [i,ii] - Entry into care, at time of ART initiation or change, every 6 months in patients with HIV-associated nephropathy and in patients on a tenofovir-containing regimen, or if clinically indicated[vi].

21. **TB Testing** [vi] - QuantiFERON TB Gold, T-Spot, or Tuberculin Skin Test (TST), placed by the Mantoux method, should be performed as close to diagnosis of HIV infection and annually thereafter. If tested when CD4 < 200, repeat after CD4 increases to above 200. Annual TB test is recommended if patient is deemed high risk (repeated or ongoing exposure to known active TB, after incarceration, after living in congregate setting, active drug user or other risk factor for TB). If TB test is positive or has had active Tuberculosis documented with adequate treatment, annual chest X-ray should be performed. If chest X-ray cannot be afforded, cough screen questionnaire may be used as suggested by David Ashkin, MD.

22. **Bone Densitometry** [iv] - Follow algorithm (Page 8 of this document). Age 40-50 calculate FRAX to determine earlier screening and use "secondary causes" check box when using FRAX calculator. FRAX calculator**:** http://www.shef.ac.uk/FRAX/. All greater than or equal to 50 men and postmenopausal women need DEXA.

23. **Colon and Rectal Cancer Screening** [v] - Colorectal cancer screening recommended for individuals between 50-75 years of age. For those with several first-degree relatives who had prostate cancer at an early age, this discussion should take place at age 40. Local preference is Immunochemical Fecal Occult Blood Test (iFOBT) once a year; iFOBT + flexible sigmoidoscopy OR double-contract barium enema every 5 years or colonoscopy every 10 years (if no findings).

24. H**epatitis A Screening** [vii] - Unless Hepatitis C infected, may consider administering immunization when CD4 cell count greater than 200 cells/$mm^{3.}$ At initial screening, Hepatitis A total antibody (HAVAb) or IgG (not IgM).

25. **Hepatitis B Screening** [i] - At initial screening, Hepatitis B core antibody (HBcAb) total or IgG (not IgM), Hepatitis B surface antibody (HBsAb), and Hepatitis B surface antigen (HBsAg). If HBsAg is positive, evaluate Hepatitis B Viral Load by DNA PCR, and obtain Hep Be Ag and Ab.

26. **Hepatitis C Screening** [i] - At initial screening, Hepatitis C antibody (HCVAb) with reflex to HCV PCR. If HCVAb with reflex to HCV PCR is positive evaluate Hepatitis C (HCV) Viral Load, genotype, and include treatment plan in record; If negative and active Injection Drug User or other HCV risk factor, repeat HCVAb with reflex to HCV PCR at least annually but no more than quarterly; If there is an unexplained chronic LFT elevation, Hepatitis C viral load should be evaluated (even if HCVAb with reflex to HCV PCR is negative).

27. **Gynecological Exam** [ii, viii,xiv] (females), In women and adolescents with HIV, initiation of cervical cancer screening with cytology alone should begin within one year of onset of sexual activity, or if already sexually active, within the first year after HIV diagnosis but no later than 21 years of age. Cervical cancer screenings in women who are infected with HIV should continue throughout a woman's lifetime (ie, not stopping at age 65 years). In women infected with HIV who are younger than 30 years, if the initial cytology screening result is normal, the next cytology screening should be in 12 months. If the results of three consecutive annual cervical cytology screenings are normal, follow-up cervical cytology screen should be every 3 years. Co-testing (cervical cytology and human papillomavirus [HPV] screening) is not recommended for HIV-infected women younger than 30 years. Women infected with HIV who are 30 years and older can be screened with cytology alone or co-testing. After women screened with cytology alone have had three consecutive annual test results that are normal, follow-up screening can be every 3 years. Women infected with HIV who have one negative co-test results (normal cytology and HPV negative) can have their next cervical cancer screening in 3 years. In women with HIV infection, co-testing results that are cytology negative but HPV positive are managed as in the general population. Women with HIV who have cervical cytology results of low-grade squamous intraepithelial lesions or worse should be referred for colposcopy. For women with HIV infection who are 21 years or older and have atypical squamous cells of undetermined significance (ASC-US) test results, if reflex HPV testing results are positive, referral to colposcopy is recommended. If HPV testing is not available, repeat cervical cytology in 6-12 months is recommended, and for any result of ASC-US or worse on repeat cytology, referral to colposcopy is recommended. Repeat cytology in 6-12 months, but not HPV testing, is recommended for HIV-infected women younger than 21 years with ASC-US test results. Although not explicitly stated in the Panel guidelines, women with HIV infection who have ASC-US, HPV-negative results (whether from reflex HPV testing or co-testing) can return to regular screening.

28. **Mammogram** [ix] **(**females) - Starting at age 40, screening recommended annually.

29. **Pregnancy test** [i,ii] (females) - If starting an efavirenz-containing regimen or if clinically indicated.

30. **Annual wellness visit** (females)-should include pelvic exam, breast exam, STD testing, birth control and preconception counseling, as applicable.

31. **Prostate-specific antigen (PSA) Screening** [x] (males) - PSA testing is an individualized decision to be made by clinician and patient based on current guidelines.

Immunizations

32. **Hepatitis A vaccination** [i,ii] - Offer vaccination if not immune. Assess for response 30 days after vaccination by performing Hep A antibody IgG or Hep A Total antibody. Document in record carrying data forward to most current volume.

33. **Hepatitis B vaccination** [i,ii] - Offer vaccination if not immune. Double dose is considered. Assess for response 30 days after vaccination by performing Hepatitis B surface antibody quantitative (Hep B SAb Quant). Document in record carrying data forward to most current volume.

34. **Human Papillomavirus (HPV) Vaccine** [xii] - Routine HPV vaccination at age 11 or 12 years. The vaccination services can be started beginning at age 9 years. Vaccination is also recommended for females aged 13 through 26 years and for males aged 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series. Males aged 22 through 26 years may be vaccinated. ACIP recommends vaccination of men who have sex with men and immunocompromised persons through age 26 years if not vaccinated previously *(Currently not paid for by Ryan White Program).*

35. **Influenza vaccination** [i,ii] - Offer TIV annually and document in record.

36. **Meningococcal vaccination** [xiii]**-** All HIV-infected persons aged ≥2 months should routinely receive meningococcal conjugate vaccine; children aged <2 years should be vaccinated using a multidose schedule. Persons aged ≥2 years with HIV who have not been previously vaccinated should receive a 2-dose primary series of meningococcal conjugated vaccine. Persons with HIV who have been previously vaccinated with meningococcal conjugated vaccine should receive a booster dose at the earliest opportunity (at least 8 weeks after the previous does) and then continue to receive boosters at the appropriate intervals. If the most recent dose was received before age 7 years, a booster dose should be administered 3 years later. If the most recent dose was received at age ≥7 years, a booster should be administered 5 years later and every 5 years thereafter throughout lifetime. See vaccination guidelines**.**

37. **Pneumococcal polysaccharide (PPSV 23) and Pneumococcal conjugated (PCV13) vaccination** [i,ii,xi] **-** Should receive a dose of PCV13 (Prevnar 13), followed by a dose of PPV23 (Pneumovax) at least 8 weeks later. If previously vaccinated with PPV23, give PCV13 at least 1 year after PPV23. Administer to patients with CD4 cell count ≥200/ul. A second PPSV23 dose is recommended 5 years after the first PPSV23 and then again at age 65. At age 65, adults who have not received PCV13 nor PPSV23, should be given PCV13 followed by one PPSV23 6-12 months later. If at age 65 or older, PPSV23 has been given, administer PCV13 at least one year after the PPSV23 received at or after age 65.

38. **Tetanus, diphtheria, pertussis (Td/Tdap)** [xi] - Substitute 1-time dose of Tdap, for adults age 19-64 who have not received a dose of Tdap previously, for Td booster; then boost with Td every 10 yrs. Document in record carrying data forward to most current volume

39. **Varicella** [xi] - Test for immunity and vaccinate per guidelines.

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[i] Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Accessed on November 11, 2015.

[ii] Primary Care Guidelines for Management of Persons Infected with HIV: 2013 Update by the HIV Medicine Association of the Infectious Disease Society of America. (Clin Infec Dis January 2014, vol. 58) Accessed August 21, 2015.

[iii] *Counseling for Patients with HIV Infection and Referral to Support Services*, page 18, *Sexually Transmitted Diseases Treatment Guidelines, 2006,* http://www.cdc.gov/MMWR/PREVIEW/MMWRHTML/rr5511a1.htm. Accessed July 21, 2009

[iv] Recommendations for Evaluation and Management of Bone Disease in HIV. Clinical Infectious Disease 2015:60; 1242-1251.

[v] Adult Prevention and Treatment of Opportunistic Infections Guidelines Working Group. Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents. March 24, 2009. MMWR 2009; 58 (early release) pp 1-198. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e324a1.htm. Accessed July 21, 2009.

[vi] For patients with renal disease, consult "Guidelines for the Management of Chronic Kidney Disease in HIV-Infected Patients: Recommendations of the HIV Medicine Association of the Infectious Diseases Society of America" (Clin Infect Dis 2005; 40: 1559-85).

[vii] Routine pelvic examination and cervical cytology screening. ACOG Committee Opinion No. 431. American College of Obstetricians and Gynecologists. Obstet Gynecol 2009;113:1190–3.

[viii] https://aidsinfo.nih.gov/contentfiles/lvguidelines/AA_Tables.pdf Accessed August 21, 2015.

[ix] http://www.cancer.org/docroot/PED/content/PED_2_3X_ACS_Cancer_Detection_Guidelines_36.asp. Accessed July 21, 2009.

[x] http://www.aidsetc.org/pdf/workgroups/pcare/pcwg-heptools.pdf. Accessed July 21, 2009.

[xi] http://www.cdc.gov/vaccines/schedules/hcp/adult.htlm. Accessed February 24, 2016.

[xii] Human Papillomavirus Vaccination: Recommendations of the Advisory Committee on Immunization Practices (ACIP), March 27, 2015 MMWR 2015: 64 pp 300-304. Available at: http://www.cdc.gov/mmwr/pdf/wk/mm6411.pdf#page=12. Accessed February 22, 2016.

[xiii] Recommendations for Use of Meningococcal Conjugate Vaccines in HIV-Infected Persons-Advisory Committee on Immunization Practices, 2016, November 4, 2016 MMWR 2016: 65 pp 1189-1194. Available at: https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6543.pdf. Accessed February 13, 2017.

[xiv] Gynecologic Care for Women and Adolescents with Human Immunodeficiency Virus. (The American College of Obstetricians and Gynecologists, vol. 128, no. 4, October 2016)

Note: Inclusion of the BONE DENSITOMETRY ALGORITHM (Extract from pg 1244 CID 2015:30 (15 April)) is not included at this time as it is pending approval of usage, due to copyright restrictions.