



# NEWARK EMA HIV HEALTH SERVICES PLANNING COUNCIL

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## HIV PRIMARY MEDICAL CARE STANDARDS OF CARE

ALL POPULATIONS, INCLUDING ADOLESCENTS/YOUNG ADULTS AND OLDER ADULTS

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The following standards are specifically for the care of HIV disease and are put forward as a means to evaluate the quality of HIV-specific care in the Newark EMA. As these standards are not exhaustive, they should not be used as a guideline. For a complete description of the medical management of HIV infection, please see the most recent edition of "Medical Management of HIV Infection", John G. Bartlett, M.D., Johns Hopkins University, Department of Infectious Diseases (<http://www.hopkins-aids.edu>). Additional information can also be found on the following web sites: [www.hivatis.org](http://www.hivatis.org) and [www.cdc.gov](http://www.cdc.gov).

### STANDARD OF CARE 1.0

In the provision of primary medical care for persons living with HIV/AIDS in the Newark EMA, the primary care physician shall be ultimately responsible for ensuring that the client understands all information exchanged in the clinical setting, including their rights and responsibilities. Acknowledgement of the patients understanding must be documented in the progress notes.

The following must be taken into account for each patient accessing services:

- 1.1 IN ALL COMMUNICATION WITH CLIENTS (WRITTEN AND VERBAL), THE PHYSICIAN SHALL TAKE INTO ACCOUNT INDIVIDUAL CLIENT FACTORS INCLUDING, BUT NOT LIMITED TO:**
  - a. culture
  - b. gender and sexual orientation
  - c. language
  - d. age
  - e. environment
  - f. education
  - g. religion/spirituality
  - h. other aspects of social history
- 1.2 TAKING INTO ACCOUNT THE ABOVE MENTIONED FACTORS, THE PROVIDER OF HIV PRIMARY MEDICAL CARE SERVICES SHALL ENCOURAGE THAT COMPETENT AND RESPECTFUL COMMUNICATION OCCURS AT ALL LEVELS OF CLIENT CONTACT.**

## STANDARD OF CARE 2.0

Care for persons with HIV disease should reflect competence and experience in both primary care and therapeutics known to be effective in the management of persons with HIV infection. HIV providers must either make available the full continuum of primary care as well as HIV care to their patients with HIV or establish a collaborative relationship with the patient's primary care physician.

The following components of care should be demonstrated in the clinical record:

### 2.1 A BASELINE MEDICAL EVALUATION (WHICH MAY TAKE UP TO THREE VISITS) WHICH CONTAINS A MEDICAL AND SOCIAL HISTORY/PHYSICAL AND ADDITIONAL DOCUMENTATION:

- a. History of HIV positive status, including route of transmission, where first diagnosed and previous HIV negative tests.
- b. Confirmation of HIV infection by laboratory means.
- c. History of Tbc testing, exposure and/or prophylaxis.
- d. PPD test results for those without a history of a positive test or a PPD result within the prior year. Recorded attempts to contact clients who not return for PPD reading.
- e. Past Medical History; especially stressing pertinent illnesses associated with HIV including opportunistic infections and STDs.
- f. *WOMEN*: Detailed reproductive history including date of last menstrual period (LMP), history of menses, contraception, pregnancy and childbirths, Papanicolaou test (PAP smear) results, and hysterectomy. Women of childbearing age should be advised of the benefits of antiviral therapy during pregnancy, according to expert guidelines.
- g. *OLDER ADULTS*: discuss relevant health maintenance screening for co-morbidities commonly experienced by older adults including colonoscopy screening for colon cancer, etc.
- h. Psychosocial evaluation to document impediments to treatment compliance and adherence and determine need for specific mental health interventions.
  - Evaluation of family structure and support
  - Evaluation of peer group structure and supports
  - Evaluation of school and/or work performance
- i. Baseline clinical data
  - CBC with differential and platelets
  - Chemistry panel (including liver function and lipid profile)
  - CD4
  - Viral load
  - STD screen (syphilis serology, gonorrhea and chlamydia)
  - Pap smear for women and women, as appropriate.
  - Toxoplasma IgG (for those with CD4 less than 200)
  - Hepatitis A, B and C screening
  - Vital signs
  - Baseline body weight and height
  - Present medications and antiviral drug history
  - Drug resistance testing
  - HLAQ-B\*5701
- j. Assessment/history of mental health and substance abuse disorders (including legal and illegal drugs as well as alcohol and tobacco), and appropriate referrals made if needed.
- k. Clients should have the risks and benefits of antiviral therapy discussed and be offered medications using the most recent treatment recommendations, local standards and individualized evaluation of retro-viral therapeutics as guidelines.
- l. Clients should have the risks and benefits of prophylaxis for opportunistic infections discussed and be offered medications using the most recent treatment recommendations, especially for PCP and Mycobacterium tuberculosis, and local standards as guidelines.
- m. The status of immunizations (Pneumovax, Hepatitis A<sup>1</sup>, Hepatitis B, Influenza, etc)
- n. Update immunizations as appropriate.
- o. Obtain sexual history/exposure including questions regarding past and present sexual practices.

- p. Obtain initial nutrition history/assessment
- q. Obtain family history
- r. Oral Health Care practices

## 2.2 FOLLOW-UP VISITS WHICH RECORD AND ADDRESS

- a. Basic wellness check
  - Age appropriate vital signs
  - WOMEN: LMP
- b. Detailed adherence education and counseling tailored to the client's educational level and lifestyle. Document:
  - Assessment for readiness to initiate treatment
  - Risks, benefits and complexities of treatment
  - Compliance success and non-compliance problems
  - Side effects
  - of drugs
- c. WOMEN: Support for the female patient in the prevention of or in achieving pregnancy.
- d. Ongoing assessment of antiviral therapy, patient history of adverse clinical events with anti-retroviral therapy (i.e. history of neuropathy, alcoholism, pancreatitis, methadone treatment, etc.); and an awareness of drug interactions with over-the-counter, prescription and illegal drugs as well as herbal therapies.
- e. Monitor CD4 and HIV viral load every 3-4 months to evaluate effectiveness of HIV therapy and immunologic functions. For patients that are adherent to therapy and have sustained viral load for more than 2-3 years, the frequency of CD4 and viral load monitoring may be extended to every 6 months.
- f. Monitor labs to evaluate adverse effects of antiretrovirals as appropriate: for example cbc to monitor for anemia in patients who take bone marrow suppressive agents, monitor lipid panel for patients taking lipid increasing agents, monitor chemistry for patients taking nephrotoxic agents.
- g. Assess/monitor for new onset co-morbidities such as hypertension, diabetes mellitus, copd etc.
- h. HIV drug resistance testing such as genotyping or phenotyping resistance assays should be used when clinician suspects treatment failure and is considering a change in antiretroviral treatment.
- i. Co-receptor tropism assays if clinician is considering use of antiretrovirals belonging to the CCR5 class.
- j. Sexual, substance abuse (including needle exchange sharing) risk behaviors for HIV transmission, HIV prevention information as appropriate.
- k. Assessment and treatment to include oral-dental disorders, ophthalmologic disorders as appropriate.
- l. Prophylaxis against opportunistic infections (OI) and immunizations should be offered to each client at the appropriate levels determined by the CDC or local standards of care. Patients for whom OI prophylaxis is indicated should have documentation of current therapies.
- m. WOMEN: All HIV infected women should have a referral for a Papanicolaou test (PAP smear) within the previous 12 months. Normal smears should be followed with second smear six months later. If both results are negative, subsequent PAP smears should be performed annually. Smears showing severe inflammation or reactive changes should be re-evaluated promptly. Diagnosis of squamous intraepithelial lesion (SIL) or atypical squamous cells of undetermined significance should be followed with colposcopic examination of the lower genital tract.
- n. Offer age appropriate preventive care and screening for non-HIV related conditions, or provide referral to a primary care physician for this purpose.
- o. Annual PPD test, with results recorded. Recorded attempts to follow-up clients who do not return for PPD reading. For all positive PPD tests (5mm in duration): prophylaxis with recommended agents or documentation that appropriate prophylaxis regimens have been completed/
- p. Annually screen for syphilis. Screen women annually for gonorrhea and Chlamydia.
- q. Consider discussing medical aspects of advanced directives, including pain management, nutritional support and other aspects of palliative care.
- r. All reportable illnesses must be reported to the local health department and include documentation in the chart.
- s. Annual developmentally specific and appropriate mental health assessment including:
  - Social history
  - List illnesses experienced/experiencing
  - Assessment for dementia and other neuro-psychiatric HIV related disorders
  - Depression suicide risks

<sup>1</sup>This recommendation is specific to men who have sex with men, injecting and non-injecting drug users, those with Hepatitis C infection and others at risk (e.g. day care center employees and persons traveling to developing countries)

### **STANDARD OF CARE 3.0**

In addition to demonstrating competency in the provision of HIV disease specific continuous, coordinated and comprehensive care, HIV clinical service programs must show evidence that their performance follows norms for ambulatory care.

Clinical programs must demonstrate policies and performance regarding:

#### **3.1 LICENSING, KNOWLEDGE, SKILLS AND EXPERIENCE**

Quality assurance to encourage that the requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are met or exceeded in reference to:

- a. Organizational/professional licensing
- b. Professional supervision of staff
- c. Staff training, continuing education
- d. Mechanism to encourage patients rights and confidentiality and access to care

#### **3.2 ACCESS, CARE AND PROVIDER CONTINUITY**

- a. Are efforts made to assure that the waiting time for scheduled appointments is less than 30 minutes?
- b. Is the waiting time for:
  - Initial appointment less than 2 weeks?
  - Routine appointments less than 4 weeks?
  - Urgent appointments less than 24 hours?
- c. Are there procedures in place to follow-up on missed appointments?
  - Is there clear assignment of responsibility for contacting the client?
- d. Do patients have prompt access on a 24 hour basis to a clinical staff member who is on-call to respond to emergent health problems?
- e. Is there a mechanism for urgent care evaluation and/or triage?
- f. Is there a mechanism for inpatient care (or referral) and return to ambulatory care?
- g. Is there a mechanism for the provision of emergency medical care?
- h. Does the provider have a mechanism to outreach to clients who are no longer in contact with the health care system?
- i. Continuity of care: Is patient assigned to a primary provider within the facility?
- j. Are there care services which include (or arranged by referral):
  - Laboratory
  - Radiological studies/imaging
  - Pharmacy
  - Developmentally specific mental health services
  - Gastroenterology/Hepatology
  - Hematology
  - Neurology
  - Psychiatry
  - Ophthalmology
  - Dermatology
  - Outpatient surgery
  - Obstetrics and gynecology
  - Pediatrics, adolescent medicine and pediatric sub-specialties
  - Pulmonary
  - Oncology
  - Dentistry
  - Case Management
  - Physical therapy
  - Nutritional counseling
  - Substance Abuse treatment

- Developmentally specific and appropriate behavioral health counseling
  - Antiretroviral counseling/therapy for pregnant women
  - Information for persons with inherited coagulopathies and referral to the local federally funded hemophilia treatment center
  - Pain management/palliative care
- k. Continuity: Assure establishment of a mechanism for communication between collaborating care providers, both primary care and specialists
  - l. Are case conferences (which include off-site and on-site providers, e.g. case management, mental health, substance abuse, permanency planning as well as primary care providers) conducted at entry into care and every six months thereafter?
  - m. If not, is there any other process that encourages continuity with referring providers?
  - n. Is education provided to the family, caregiver and/or significant other?
  - o. Is there access to clinical investigations?

## HIV PRIMARY MEDICAL CARE STANDARDS OF CARE *ADDITIONAL SPECIAL CONSIDERATIONS FOR: PEDIATRIC PATIENTS*

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For a complete description of the medical management of HIV exposed infants and HIV infected children, please see the most recent guidelines. This document references the "Guidelines for the use of Antiretroviral Agents in Pediatric HIV Infection" (Guidelines) at url <http://aidsinfo.nih.gov>

### **STANDARD OF CARE 1.0**

"Management of HIV infection in infants and children is rapidly evolving and becoming increasingly complex; therefore, wherever possible, management of HIV infection in children should be directed by a specialist in the treatment of pediatric HIV infection. If this is not possible such experts should be consulted regularly"

Care for HIV exposed and/or infected infants and children should reflect competence and experience in perinatal HIV prophylaxis, primary care and therapeutics known to be effective in the management of persons with HIV infection.

The following components of care should be demonstrated in the clinical record:

#### **1.1 A BASELINE MEDICAL EVALUATION FOR EXPOSED INFANTS AND CHILDREN**

Early identification of HIV infected women is crucial to prevent HIV exposure to children. The following guidelines should be followed:

- a. HIV infected women should receive appropriate antiretroviral therapy and prophylaxis against opportunistic infections.
- b. Provision of antiretroviral chemoprophylaxis with ZDV during pregnancy, labor and to newborns
- c. Counseling of infected women about the risks for HIV transmission through breast milk.
- d. After childbirth, the following guidelines should be followed to monitor the child's sero-conversion status
- e. Initial testing of exposed infant is recommended by age 48 hours.
- f. Initiation of prophylaxis against *Pneumocystis carinii* pneumonia (PCP) in all HIV exposed infants beginning at age 4 to 6 weeks in accordance with PHS guidelines.
- g. Exposed infants with initially negative virologic tests should be retested at age 1 to 2 months.

- h. Exposed children with repeatedly negative virologic tests should be retested at age 3 to 6 months
- i. Serology after 12 months is recommended.
- j. Testing should be repeated between 15 to 18 months to confirm the negative diagnosis.

## **1.2 A BASELINE MEDICAL EVALUATION FOR INFECTED INFANTS AND CHILDREN**

- a. Repeated virologic tests should be done preferably using HIV DNA PCR method to confirm diagnosis.
- b. CD4+ T cell values should be obtained as soon as possible after diagnosis and every 3 months thereafter.
- c. HIV RNA copy number should be assessed as soon as possible after diagnosis and every 3 to 4 months thereafter.
- d. Resistance testing is recommended prior to initiation of therapy.
- e. Adherence assessment should begin before therapy is initiated and be incorporated into every clinic visit.
- f. Education to families about adherence before initiation of therapy
- g. Appropriate antiretroviral therapy with at least three drugs is recommended for initial treatment.
- h. Regimens should be simplified to the extent possible with respect to number of pills, volume of liquid or frequency of therapy.
- i. In the setting of persistent viremia, testing for antiretroviral resistant virus should be considered.
- j. Intensive follow-up with patient after start of therapy to assess adherence, drug tolerance and virologic response.

## **1.3 MONITORING OF PEDIATRIC HIV INFECTION**

- a. When caring for HIV infected infants and children, CD4 T cell values should be obtained as soon as possible after a child has a positive virologic test for HIV and every 3 months thereafter.
- b. Complete physical examination.
- c. Age related developmental history or examination.
- d. Body weight, height and head circumference (for children 36 months of age or younger), and vital signs.
- e. Neurological examination.
- f. Laboratory data which includes:
  - CBC with platelets
  - Comprehensive Metabolic panel
  - T&B cell enumeration
  - Viral load (quantitative HIV RNA PCR assays)
  - Chest X-ray
  - PPD test results for those without a history of a positive PPD test (not Tine) or a PPD result within the past year.
- g. PCP prophylaxis (throughout the first year of life) unless anemia develops then risk-benefit needs to be substituted. An infant, who has 2 negative PCR HIV assays one after 4 months of age, can have PCP prophylaxis stopped.
- h. Education on unexplained fever or respiratory system(s) as reasons to call the doctor.
- i. Oral Hygiene practices.

## **1.4 FOLLOW-UP VISITS WHICH RECORD AND ADDRESS**

- a. Visit frequency minimum every 3 months.
- b. Body weight, height and vital signs.
- c. Developmental history or examination.
- d. Nutrition and growth (plot growth parameters and assess growth velocities)
- e. Oral examination
- f. Neurological examination.
- g. Assess pubertal development (precocious, delayed) and assign Tanner staging.
- h. Repeat assessments of CD4 and HIV viral load measurements. (Repeat T&B cells and viral loads at least every 3 months).
- i. Assess for indications for PCP, MAC and all prophylactic strategies as per Guidelines.
- j. Implementation of rational combination antiviral therapy as outlined in Pediatric HIV Guidelines.
- k. If the CD4 count is 50 or below or at the discretion of the pediatric medical care provider, the patient should have an ophthalmic examination by a trained retinal specialist every 6 months or as recommended by the specialist.

- l. Comply with approved vaccination schedules for HIV positive infants and children at the following url ([http://aidsinfo.nih.gov/guidelines/op\\_infections/O1\\_112801.html](http://aidsinfo.nih.gov/guidelines/op_infections/O1_112801.html)) Table 10 – Recommended immunization Schedule for Human Immunodeficiency Virus-infected Children.
- m. Establishment of a mechanism to inform children of their HIV status and to involve them in their care.
- n. Guidance to help parents/guardians/care givers including relatives and foster parents anticipate changes and problems with growth, development and education. Advice to parents/guardians/care givers including relatives and foster parents on disclosing their child’s HIV status to the school.
- o. Assess health and social conditions that may affect compliance with medical appointments: homelessness, mental illness, substance abuse; or consideration for case management.
- p. Establish a plan for developmentally appropriate discussions on primary HIV prevention.
- q. Consider discussing medical aspects of advanced directives, including pain management, nutritional support and other aspects of palliative care.

## **STANDARD OF CARE 2.0**

In addition to demonstrating competency in the provision of HIV disease specific care, HIV clinical service programs must show evidence that their performance follows norms for ambulatory care.

Clinical programs must demonstrate policies and performance regarding:

### **2.1 LICENSING, KNOWLEDGE, SKILLS AND EXPERIENCE**

Please see 2.1 above (all populations) except that training and/or experience must be specifically with the medical care of children with HIV.

### **2.2 ACCESS, CARE AND PROVIDER CONTINUITY**

Please see 2.2 above (all populations). All services and referrals must be age appropriate and meet the physical, emotional and understand the social needs of patients between the ages of 0 and 18.