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For a Free copy of the HIV Guideline call:

National AIDS Hotline
1-800-342-AIDS

Spanish service call:

1-800-344-7432

1-800-344-SIDA

Deaf access call:

1-800-AIDS-TTY

or write:

HIV Guideline
CDC National AIDS Clearinghouse
P.O. Box 6003
Rockville, MD 20849-6003

Case Management

- Coordinate medical care and support services for the patient or refer to a formal case management system. Develop contacts with case management programs in the community.
- Recognize that in the early stages of HIV, required services will emphasize assistance with housing, job, and financial issues. In the later stages, the focus of assistance will shift to medical issues.
- Ensure that patients are referred to case management programs that are administered and staffed by knowledgeable, resourceful, and empathetic individuals.

Important Things to Remember About Early HIV Infection

For the Practitioner:

- ❑ Early detection and treatment of HIV infection and preventive therapies are effective in delaying the onset of life-threatening symptoms.
- ❑ The first counseling and evaluation session is a crucial one because it not only determines the stage of HIV infection and the aspects of the patient's condition that need care, but because it lays the foundation for the future relationship with the patient. An open and constructive relationship facilitates greater patient involvement in care and can help prevent the spread of the disease.
- ❑ It is important to keep abreast of clinical trials open in the community. Advising patients, including pregnant women, of such trials will facilitate access of all patients to new treatment opportunities.
- ❑ There are many dimensions to the care of persons with early HIV infection in addition to the medical aspects. These include providing mental health and crisis management counseling and assisting with social support services, such as housing, insurance, and jobs. Become more knowledgeable in these areas, or develop referrals so that your patients are given comprehensive and coordinated care.
- ❑ Find out more about early HIV management. Read *Clinical Practice Guideline Number 7: Evaluation and Management of Early HIV Infection* and use its companion *Quick Reference Guide for Clinicians*. Seek out sources of information on aspects of early HIV care not covered in the guideline. Give your patients *Understanding HIV* or *HIV and Your Child* so that they can be more informed about HIV and its treatments.

For the Consumer:

- ❑ It is important to find out if you have HIV infection and to begin care early. Early care can delay the onset of life-threatening illnesses associated with HIV infection.
- ❑ Talk frankly with your primary care provider about the pros and cons of telling people your HIV status. Also discuss your concerns about HIV infection, treatment and preventive therapies, and the effects of HIV infection on your life and family and friends.
- ❑ Find out about the many HIV information and support services available to you and your family and use them. Work with your care provider to develop a coordinated and comprehensive treatment plan.
- ❑ Order the free consumer booklet *Understanding HIV or HIV and Your Child*, which provides information on HIV infection and its treatments and lists sources for further information and help.
- ❑ The U.S. Government's Agency for Health Care Policy and Research, which prepared the consumer booklets, also has a *Clinical Practice Guideline* and a *Quick Reference Guide for Clinicians* on evaluating and managing early HIV infection. You can order these free publications for your primary care provider.

- Enhance the quality and extend duration of life by improving skills to diagnose and treat selected important complications of early HIV infection.
- Encourage the participation of patients and their families in the development and implementation of care plans.
- Increase the access of all patients to opportunities to obtain new treatments and participate in investigational trials.
- Establish the degree to which present treatment, counseling, and diagnosis practices are science-based.
- Identify areas for future HIV guidelines.

Recommendations

Recommendations as summarized below were issued for selected aspects of early HIV care:

Disclosure Counseling

- When disclosing HIV status to a patient, include a face-to-face discussion of the psychosocial and medical effects of HIV, available therapies and social services, State reporting requirements, and potential advantages and disadvantages of voluntary disclosure to family, friends, and associates.
- Strongly urge patients to disclose their HIV status to significant others, particularly sex and needle-sharing partners, to prevent further transmission of HIV.
- During counseling, assess the patient's need for coordinated care and mental health treatment.

Evaluation and Care of Adults and Adolescents

- Conduct a thorough medical, sexual, and substance use history and a physical examination of the patient, with particular attention to HIV-related symptoms. Providers caring for adolescents should be aware of issues specific to this age group, including assessment of physical and sexual maturity, psychosocial aspects of adolescence, and impediments to accessing care.

  At the initial examination:

- Assess immune status by determining the number of CD4 cells. Measure the number of CD4 cells every 6 months when the count is over 600 cells/μl and at least every 3 months when the count is between 200 and 600 cells/μl. Discuss and offer antiretroviral therapy. Recommend *Pneumocystis carinii* pneumonia therapy.
- Screen patients for *Mycobacterium tuberculosis* infection and cutaneous anergy. Discuss and recommend preventive therapy if necessary. Adherence to treatment can be improved by developing strong relationships with patients and by using directly observed therapy or case management.
- Evaluate patients for syphilis infection by taking a careful history and performing a non-treponemal test. Perform a treponemal test and an evaluation of cerebrospinal fluid if necessary. Begin penicillin treatment if infected.
- Conduct an oral examination at each visit and recommend twice yearly visits to the dentist.
- Conduct an eye examination, including a funduscopy. Repeat at each visit. Refer the patient to an eye specialist when there are any unusual signs or symptoms.
- For pregnant women, measure CD4 cells at entry into prenatal care or at delivery if there has been no prenatal care. Recommend PCP therapy and discuss and offer antiretroviral therapy as for non-pregnant adults. Evaluate for syphilis infection at entry into prenatal care, during the third trimester, at delivery, or at exposure to or presentation with a sexually transmitted disease. Complete penicillin treatment at least 4 weeks before delivery to prevent congenital syphilis.
- Conduct regular gynecological examinations in HIV-infected women, with particular attention to Pap smears.
- Conduct objective, nonjudgmental pregnancy counseling and include discussion of the risks of perinatal transmission, the effects of pregnancy and childbirth on HIV progression, and the long-term effects of pregnancy decisions on the family. Advise the patient against breast-feeding.

Evaluation and Care of Infants and Children

Because HIV infection frequently progresses more rapidly in infants and children than in adults and because the disease characteristics are different, early diagnosis and aggressive management are vital.

- Evaluate CD4 cell count and percentage at regular intervals, beginning at 1 month of age. Begin PCP prophylaxis after an episode of PCP or if the CD4 cell count or percentage falls below age-adjusted normal values. Begin antiretroviral therapy if there is symptomatic HIV infection or if CD4 count or percentage falls below age-adjusted values.
- Conduct a neurological assessment at each visit. Perform a baseline CAT scan or MRI at time of diagnosis, and conduct age-related developmental assessments every 3 months to age 2 and every 6 months thereafter. After excluding other diagnoses, treat infants and children with HIV-related central nervous system disease with antiretroviral therapy.

DRAFT

Guideline Development

The Agency for Health Care Policy and Research convened a private-sector, interdisciplinary panel of physicians, nurses, allied health professionals, and others active in the HIV and AIDS fields who worked together to develop the guideline. One of the panel's first tasks was to select the topics that would be covered by the guideline. Once the topics were chosen, the panel and selected outside consultants reviewed thousands of scientific and clinical studies. After this review, the panel considered health policy issues, such as the effect of the guideline on health care resources, medical ethics issues, concerns of patients and practitioners, medicolegal issues, and insurance concerns. During this phase of guideline development, the panel held two public hearings to solicit oral and written testimony from groups and individuals not on the panel but concerned about the issue.

The results of the literature review and public hearings were used to develop a draft guideline. The draft guideline was then submitted to a carefully chosen group of experts for peer review of scientific content and to clinicians and other health care professionals representative of the users for whom the guideline was being developed. This latter group evaluated the guideline for validity, credibility, and usefulness in their own practice settings. Comments from reviewers were used in finalizing the guideline. HIV-infected individuals and parents of infected children provided input for the consumer guides.

Early HIV Guideline Presentation

The Guideline is presented in several forms. The *Guideline Report* presents supporting technical information and a comprehensive bibliography. The *Clinical Practice Guideline*, intended for the practitioner, contains a discussion of the topics, the panel's recommendations with supporting evidence and references, and a series of algorithms and tables. The *Quick Reference Guide for Clinicians*, also intended for the practitioner, is a brief summary of and companion volume to the *Clinical Practice Guideline*. It provides highlights of the guideline and presents the tables and algorithms. Two *Consumer Guides* -- *Understanding HIV* and *HIV and Your Child* -- published in English and Spanish, provide information to help patients work in partnership with their health care providers. The *Clinical Practice Guideline*, the *Quick Reference Guide*, and the *Consumer Guides* are available free of charge. Write to AHCPR HIV Guideline, CDC National AIDS Clearinghouse, P.O. Box 6003, Rockville, MD 20849, or call (800) 342-AIDS.

U.S. Department of Health and Human Services
Public Health Service
Agency for Health Care Policy and Research

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AHCPR Agency for Health Care Policy and Research

Guideline Overview

Evaluation and Management of Early HIV Infection

January 1994 No. 7

As the epidemic of HIV/AIDS in the United States enters a second decade, persons with HIV infection are living longer and have an improved quality of life. In the face of sometimes overwhelming barriers, the efforts of many in the public and private sectors, working as individuals or in groups, have had an effect on this most challenging public health crisis.

Yet, the realities of the epidemic must be confronted. Every year, there are 40,000 to 60,000 new cases of HIV in the United States. In 1992, the HIV-related costs for our Nation just for medical care and time lost from work were more than $10 billion. This figure does not include the enormous physical, emotional, and psychological injury to individuals and families coping with an illness that often is considered to be self-inflicted and deserved. Our society must address an epidemic that is spreading to diverse areas and unsuspecting populations.

This guideline was developed with a sense of hope and an urgent need to continue to respond intensively. Clinicians, scientists, administrators, advocates, politicians, activists, those infected, and affected families must persist in their work to enhance and expand advances in treatment and care, while forging a more effective public health response to this epidemic. The importance of prevention and its linkage to early diagnosis and care, has put into focus the need for the primary care provider to coordinate and manage many aspects of early HIV infection. The guideline recognizes this crucial role and provides specific recommendations on the evaluation and management of selected aspects of early HIV care.

Addressing the Problem

The Agency for Health Care Policy and Research, a Federal Government agency within the U.S. Public Health Service, convened a panel of private-sector experts and consumers to develop a clinical practice guideline on HIV infection. The panel chose to focus on the evaluation and management of early HIV infection. This topic was considered important for a number of reasons:

- More people with HIV infection are living without major symptoms.
- Medical intervention in early HIV infection has more potential to prevent complications and delay disease progression.
- Counseling and education provided during the early stages of HIV infection have the potential to prevent the spread of HIV.
- Assuring early diagnosis and enrollment into case management programs facilitates patient and family involvement in treatment and care programs.
- Access to and availability of required medical and psychosocial services can be anticipated and successfully managed when HIV is diagnosed before illness or disabilities develop.

The panel developed several major objectives in shaping the guideline:

- Educate health professionals and consumers regarding the importance of early diagnosis, counseling, and coordinated care in limiting the consequences of HIV infection.

HIV Guideline Panel: Wafaa El-Sadr, M.D., M.P.H. (Co-Chair), Harlem Hospital Center, New York, New York; James Oleske, M.D., M.P.H., (Co-Chair), New Jersey Medical School; Bruce Agins, M.D., New York State Department of Health; Kay Bauman, M.D., M.P.H., Wahiawa General Hospital, Wahiawa, Hawaii; Carol Brosgart, M.D., Alta Bates Medical Center, Berkeley, California; Gina Brown, M.D., Columbia Presbyterian Medical Center, Jaime Geaga, PA-C, M.P.H., Filipino Task Force on AIDS, San Francisco, California; Deborah Greenspan, B.D.S., DSc., ScD., University of California, San Francisco; Karen Hein, M.D., Albert Einstein College of Medicine, Bronx, New York; William Holzemer, R.N., Ph.D., University of California, San Francisco; Rudolph E. Jackson, M.D., Morehouse School of Medicine, Atlanta, Georgia; Michael Lindsay, M.D., M.P.H., Grady Memorial Hospital, Atlanta, Georgia; Harvey Makadon, M.D., Harvard Medical School, Boston, Massachusetts; Martha Moon, M.S., R.N., San Francisco, California; Claire Rappoport, M.S., San Francisco General Hospital; Gwendolyn Scott, M.D., University of Miami; Walter Shervington, M.D., Office of Human Services, Baton Rouge, Louisiana; Lawrence Shulman, M.S.W., Sociomedical Resource Associates, Westport, Connecticut; Constance Wofsy, M.D., M.A., San Francisco General Hospital

Agency for Health Care Policy and Research (AHCPR)

Evaluation and Management of Early HIV Infection

PRESS CONFERENCE AGENDA
January 20, 1994, 11:15 a.m.
Hubert H. Humphrey Building, Washington, DC

Speakers (in order of presentation)

Philip Lee, M.D.
Assistant Secretary for Health

Kristine Gebbie, R.N., M.N., F.A.A.N.
National AIDS Policy Coordinator

J. Jarrett Clinton, M.D.
Administrator, AHCPR

Wafaa El-Sadr, M.D., M.P.H.
James M. Oleske, M.D., M.P.H.
Co-chairs of HIV Guideline Panel

Representative Name
Title, American Medical Association

Representative Name
Title, National Medical Association

Representative Name
Title, American Nurses Association

Representative Name
Title, Physicians Association for AIDS Care

Representative Name
Title, National Association of People With AIDS

QUESTION AND ANSWER SESSION

KEY POINTS ABOUT HIV GUIDELINE

BACKGROUND

1. Early Diagnosis and Care Are Essential

Proper management of early HIV infection and its complications may enable the person living with HIV to remain symptom-free longer and to play an important role in future management.

Early diagnosis and intervention allow for the development of a close relationship between the HIV-infected individual and the provider. Additionally, early diagnosis of HIV allows the provider to counsel the person living with HIV about ways to avoid transmission to others.

2. People with HIV Live Everywhere

HIV infection occurs in both urban and rural populations. HIV infection increasingly affects men and women of all races, ethnicities, and sexual orientations, as well as infants, children, and adolescents.

3. Primary Care Can Make a Difference

Primary care provides the first opportunity for HIV-infected individuals to receive early medical and psychosocial interventions.

FOR PROVIDERS

4. Tool for All Practitioners, Especially Primary Care

This guideline is an information tool for health care practitioners, especially primary care providers, to evaluate and manage selected aspects of early HIV infection. The guideline presents information in manageable units and helps practitioners be more effective and efficient in their care of people living with HIV.

5. Providers Should Coordinate Care

The practitioner responsible for an HIV-infected person's care should make every effort to coordinate all aspects of this care and facilitate access to support services and case management.

6. The Guideline Addresses Selected Topics of Early Management of HIV Infection

The selected topics addressed in the guideline include:

- detailed medical history-taking including sexual and substance use history and examination of HIV test results
- disclosure of HIV status and necessary counseling
- assessment of immune function by measuring CD4 cells
- preventive therapy for Pneumocystis carinii pneumonia (PCP)
- discussion of initiation of antiretroviral therapy
- evaluation and management of infection with Mycobacterium tuberculosis (M.Tb.)
- diagnosis and treatment of syphilis
- oral, eye, and gynecologic assessment
- reproductive counseling
- access to clinical trials

7. The Guideline Includes Special Recommendations for Women, Adolescents, and Children

HIV infection is increasing most rapidly among women, adolescents, and children. Primary care providers should give special attention to:

- women: regular pelvic examinations, including Pap smears, and reproductive counseling
- adolescents: assessment based on level of sexual maturity, and prescribed drug dosages adjusted accordingly; evaluation of sexually active adolescents for sexually transmitted diseases (STDs)
- infants and children: early diagnosis and treatment for infants, with special attention to neurological assessment, because the disease progresses more rapidly in small children than in adults
- providers should help HIV infected persons, especially infants, children, adolescents, and women (including pregnant women), access clinical trials and experimental protocols; call 1-800-TRIALS-A for information about ongoing trials

FOR PEOPLE LIVING WITH EARLY HIV AND THEIR CAREGIVERS

8. Learn About HIV

Learn all you can about HIV infection and its manifestations: work in partnership with your primary care provider to stay as healthy as possible.

9. Develop Patient/Provider Partnership for Regular Care

- People living with HIV should have their immune system checked regularly.
- People living with HIV are susceptible to a type of pneumonia called Pneumocystis carinii pneumonia, or PCP.
- People living with HIV should begin taking medications to prevent the development of this pneumonia when their immune system becomes weaker, as measured by their CD4 count dropping below 200.
- Discuss with your provider the need to monitor for infection with tuberculosis and syphilis.
- Talk to your primary care provider about other treatments you may need and the availability of clinical trials.

10. Women Should Request Additional Services

Women should have regular pelvic exams, including Pap smears, and should discuss questions about family planning, pregnancy, and breast feeding with their primary care providers. Women should also inquire about the availability of clinical trials.

11. Keep Others Safe

People living with HIV should speak with their health care provider about ways to avoid transmission of HIV to others.

GENERAL POINTS

12. Guideline Was Developed by Health Care Providers and Consumers

The guideline was developed by a panel of private sector, multi-disciplinary experts who care for people living with HIV. The panel also included a man and a woman who are living with HIV.

13. Guideline is Based on Science and Expert Opinion

The guideline covers selected topics of early HIV care, and is based upon the best science available. When literature and evidence were lacking, consensus among panel members was used. The panel reviewed over 30,000 sources in the professional literature, consulted with a wide variety of outside experts, and had the document reviewed by intended users and people living with HIV in many health care settings. The panel hopes that this guideline will identify areas for future research and guidelines.