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Meeting with AHCPR [Agency for Health Care Policy and Research] Press Conference 1/20/94

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DRAFT

Talking Points

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

Press Conference
Clinical Practice Guideline: "Managing Early HIV Infection"
Hubert H. Humphrey Building
Washington, D.C.
January 20, 1994

- Pleased to be here -- to be associated with this important effort to bring knowledge gained from best science, clinical experience, in battle against HIV infection.
  - -- Guideline is more than a message of hope for those who are HIV positive.
  - -- It is highly practical, useful tool for helping maintain health status and quality of life.
  - -- Targeted at primary care physicians who can provide critically important early care for persons recently infected with HIV.
- Too often, individuals discover they are HIV positive only after AIDS is detected, or when opportunistic illnesses appear.
  - -- Evaluating, managing HIV at early stage will help reduce number of persons who are under-diagnosed and under-treated.
  - -- Ineffective care results in unnecessary illnesses.
- Early diagnosis, intervention allow for development of close relationship between HIV-infected individual and health care provider.
  - -- Especially important, because early diagnosis allows providers to counsel persons living with HIV about prevention of HIV transmission to others.
- A close relationship with your provider also has many benefits for patient, people living with HIV:
  - -- Allows immune system to be evaluated regularly.

-- Permits aggressive treatment, at most appropriate moment in course of infection, to avoid or mitigate AIDS-related illnesses, including tuberculosis and pneumonia.

-- Allows people living with HIV to be evaluated for other sexually transmitted diseases (STDs).

-- Also, may allow patients to learn about and participate in clinical trials for new drugs, other HIV therapies.

o Guideline acknowledges fact that people with HIV live everywhere.

-- For example, in both rural and urban areas.

-- Increasingly affects men and women of all races, ethnicities, sexual orientations.

o Let me speak briefly to issue of women with HIV:

-- Centers for Disease Control and Prevention (CDC) estimates 100,000 women in the U.S. are infected with HIV.

-- Women now comprise 4 percent of AIDS cases, but rising rapidly. Nearly half of AIDS cases in women have been reported within last two years.

o Guideline offers special recommendations for women, including need for regular gynecologic exams; discussion of family planning issues, pregnancy and breast feeding.

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o Ultimate goal, of course, is to find a cure for HIV infection.

-- But short of complete cure, there is reason to believe HIV infection may be managed as long-term, chronic condition.

-- Clinical practice guideline on managing early HIV infection is positive step in this direction.

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HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

DRAFT

1-14-94
Embargoed until 1-20
11:15 am

FOR IMMEDIATE RELEASE
11:15 a.m., Thursday,
January 20, 1994

Contact: Public Health Service
(301)594-1364
Bob Isquith ext.173
Bob Griffin ext.169
Peter Garrett ext.152
Paula Zeller ext.148

New guidelines released today by the Public Health Service's Agency for Health Care Policy and Research improve the ability of family doctors, pediatricians and other "front line" primary care practitioners to provide critically important early care for persons recently infected with the human immunodeficiency virus.

"A key recommendation is that some patients who have not yet developed symptoms be given daily preventive doses of a sulfa drug shown to prevent the onset of "Pneumocystis carinii," a principal killer of HIV-infected persons," said HHS Assistant Secretary for Health Philip R. Lee, M.D., who heads the Public Health Service.

Dr. Lee said that using the drug for asymptomatic persons whose CD4 count falls below 200 cells per microliter, could help "perhaps thousands of people, extending their lives and preventing debilitating bouts of illness."

According to Dr. Lee, more than half the people infected with HIV may not know they have the infection, partly because few examining doctors take sexual or drug-use histories that could lead to testing.

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"Many Americans with HIV are not receiving the early counseling and care they need to optimally manage their illness. But this situation should change. And it can change -- if more physicians and people who may have HIV infection are provided the information they need for early, appropriate care."

National AIDS Policy Coordinator, Kristine M. Gebbie, R.N., M.N., said, "This recommendation is just one of many targeted at primary care physicians who are not as current as they should be about HIV." Ms. Gebbie said that too often individuals discover they are HIV positive only after AIDS is detected, or when the opportunistic illnesses that accompany AIDS appear.

"Evaluating and managing HIV at an early stage will help reduce the number of persons who are under-diagnosed and under-treated," said Ms. Gebbie, who added that ineffective care results in unnecessary illnesses and shorter life spans.

According to Dr. Lee, the guideline will mostly benefit primary care practitioners who until now have had limited contact with HIV infected patients or who have not felt confident enough to treat them, as well as people living with HIV and parents or caregivers of HIV-infected children.

The guideline was developed by a private-sector panel of physicians, dentists, nurses, social workers, physician assistants, and a man and a woman living with HIV.

(more)

"We have synthesized important information needed to effectively evaluate and manage selected aspects of early HIV infection, and put it in 'physician-friendly' formats," said Wafaa El-Sadr, M.D., M.P.H., chief of infectious diseases at Harlem Hospital Center in New York, and co-chair of the 19-member expert panel. Dr. El-Sadr said that future guidelines should address other aspects of HIV care.

"With early treatment we have the opportunity to extend life for all those living with HIV, and to assist them in leading productive and healthy lives," said Dr. El-Sadr.

The panel's other co-chair, James M. Oleske, M.D., M.P.H., director of allergy, immunology and infectious diseases in the pediatrics department of the New Jersey Medical School in Newark, said, "It is especially important to treat HIV-infected infants aggressively, since the disease progresses more rapidly in children than in adults." Dr. Oleske said the guideline includes special recommendations for women, adolescents and children, because women and adolescents constitute the fastest growing segments of the estimated 40,000 to 60,000 new cases of HIV infection every year in the United States.

The guideline recommends that the provider try to coordinate all aspects of medical care, as well as obtain needed support and case management services, when available.

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1-14-94

The guideline recommends that:

Disclosure of HIV status

The practitioner should disclose the presence of HIV to a patient or in the case of children, to the parents or caretakers, in person. Counseling should include discussion of the psychosocial and medical effects of the illness, available therapies, and support services.

Patients should also be told about federal, state and local reporting requirements and of potential advantages and disadvantages of voluntary disclosure to family, friends, and others.

Medical Evaluation and Management

Detailed medical history-taking, including sexual and substance use history, is crucial and should emphasize review of HIV test results and previous infections.

Practitioners closely monitor patients' count of CD4 cells beginning with the initial medical evaluation, and every six months thereafter for those with counts above 600 and at least every three months for patients whose counts are between 600 and 200. Monitoring of CD4 count below 200 is dependent on the availability of other interventions.

Preventive therapy for "Pneumocystis carinii" pneumonia (PCP) begin when a patient's CD4 cell count drops below 200 or he or she has an episode of the disease or other specific symptoms.

Pregnant women's CD4 cell count be measured when they begin a prenatal care program or at delivery if they have not had prenatal care.

Patients be screened for "Mycobacterium tuberculosis" and preventive therapy or treatment be started, if warranted. Methods to improve adherence with treatment of tuberculosis should be employed.

All HIV-infected and sexually active adults and adolescents be checked for the presence of syphilis and other sexually transmitted diseases in the initial medical evaluation and regularly thereafter.

(more)

Patients be offered antiretoroviral therapy with zidovidune (ZDV, formerly known as AZT) whose CD4 counts are below 500. Patients should be informed about the potential benefits and risks of early therapy with ZDV, and other options for antiretroviral therapy should be discussed. Pregnant women should be told of possible benefits as well as risks to both themselves and their unborn babies.

Women be given regular pelvic examinations that include Pap smears.

Adolescents be assessed based on their level of sexual and physical maturity, and that drug dosages should be adjusted accordingly.

The provider conduct an oral examination at each visit and recommend that a dentist examine the patient at least two times a year.

The practitioner also conduct an eye examination and recommend the patient see a qualified eye doctor according to a schedule the varies with their age and symptoms.

Contraceptive, family planning, and prenatal counseling be given to all HIV-infected women, with the focus on the patient, and that her psychological state, medical and social support network be assessed.

HIV-infected mothers be informed of the need for contingency planning for future care of their children.

Patients be provided with access to appropriate clinical trials including women, as well as pregnant women and adolescents.

The provider should obtain information regarding available case management programs and provide patients access to them.

Consumer Information

Two accompanying booklets -- for persons living with HIV and for caregivers of HIV-infected children -- urge readers to learn all they can about HIV infection, see their practitioner regularly, and work in partnership with their provider regarding their care.

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The booklets, which are available in English and Spanish, also recommend that women talk with their provider about family planning, pregnancy, breast feeding, and related matters.

The panel also called for women -- including women who are pregnant -- adolescents and children to be included in clinical trials and experimental protocols.

According to AHCPR Administrator J. Jarrett Clinton, M.D., M.P.H., the guideline will be widely disseminated to primary care physicians and other practitioners, and the consumer guides will be made available to HIV screening sites, community and migrant health centers, public health departments, and other settings.

Copies of Early Evaluation and Management of HIV Infection, an accompanying quick reference guide, and the consumer booklets, may be obtained free of charge, through a joint effort with the Centers for Disease Control and Prevention, by calling 1-800/342-2437 (AIDS), 1-800-344-7432 (SIDA) for those who speak Spanish, and 1-800-AIDS-TTY for the deaf. Persons with telephone-equipped facsimile can get the quick reference guide, consumer booklets, and an overview of the guideline by calling AHCPR Instant Fax (301/594-2800) 24 hours a day.

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1/13 c 8:00

The Rockefeller Foundation

Seth Berkley, M.D.
Associate Director
Health Sciences

Steve
try to schedule

December 24, 1993

Dear Ms. Gebbie:

I enjoyed meeting you even if only briefly in Marrakech whilst you were dining with Elizabeth and Meena. I hope you enjoyed the meeting and found its deliberations useful. As we discussed, I am concerned about the development and ultimately the availability of a preventive AIDS vaccine for the developing world. I thought that you might enjoy an informal discussion about this as well as some of the other HIV/AIDS activities underway at the Foundation. I will be in Washington on January 13, 1994 to discuss AIDS in Latin America at a World Bank retreat and thought that if this was convenient, we might meet. Breakfast preferably or an early lunch would be best as I have a 10:00 meeting and will be speaking at 2:30. My secretary will call your office to see if this is convenient. I look forward to meeting with you. In the meantime best wishes for the New Year.

Sincerely yours,

Seth Berkley, M.D.

Ms. Kristine Gebbie
National AIDS Policy Coordinator
Office of National AIDS Policy
Executive Office of the President
Washington, DC 20500

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1133 AVENUE OF THE AMERICAS, NEW YORK, NEW YORK 10036-6755 TEL: (212) 869-8500
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The Rockefeller Foundation

Seth Berkley, M.D.
Associate Director
Health Sciences

January 15, 1994

Dear Ms. Gebbie:

I enjoyed our early morning meeting very much. Thank you for taking time out from your busy schedule to see me. I am enclosing a copy of the World Development Report and the two articles we discussed. I look forward to working with you in the future.

Sincerely yours,

Seth Berkley, M.D.

Ms. Kristine Gebbie
National AIDS Policy Coordinator
Office of National AIDS Policy
Executive Office of the President
750 17th Street, NW
Suite 1060
Washington, DC 20500

enclosures

Reprinted from JAMA ® The Journal of the American Medical Association
December 16, 1992 Volume 268

AIDS in the Global Village

Why US Physicians Should Care About HIV Outside the United States

Data from the World Health Organization suggest that we Americans are in a relatively enviable position. Although the United States has lived through a decade of devastating human immunodeficiency virus (HIV) spread, the current rate of new infections in this country is now diminishing.[1] Not so for persons living in many countries in the developing world where the HIV epidemic progresses unchecked.

Seventy-five percent of the world's 12 million to 13 million HIV-infected persons live, or have lived, in developing countries; this will soon increase to an estimated 90%. The global epidemic has intensified despite a massive prevention effort. In many countries with high infection rates, education campaigns have spread the news about HIV, but this has not led as yet to a decrease in the frequency of high-risk sexual behavior adequate to halt the epidemic. Innovative interventions are desperately needed. It is timely, therefore, that this issue of THE JOURNAL contains an important study from Rwanda by Susan Allen and her colleagues who have shown that confidential HIV testing accompanied by counseling increases safe sexual behavior.[2]

See also p 3338.

American readers of THE JOURNAL might legitimately ask: Why should we be concerned with a heterosexual epidemic of HIV in distant Africa?

A decade ago, the emerging HIV epidemic in the United States taught us how little we understand about the social kinetics of infectious diseases. Initially, we doubted that the new acquired immunodeficiency syndrome (AIDS) could even spread to persons other than homosexual males (the syndrome had almost been named GRID, ie, gay-related immunodeficiency syndrome). This narrowly defined at-risk population provided the heterosexual majority with a false sense of invulnerability to HIV. It quickly became apparent, however, that HIV could indeed spread from male to female and female to male as well as from male to male.

Resultant grim prophecies of massive heterosexual spread in the general American population did not materialize, leading us now to a resumed complacency about the risk of heterosexual spread of HIV. There is, however, ample evidence that the virus does spread heterosexually, given the appropriate milieu. Studies in Africa have demonstrated the ease of heterosexual transmission, with a far greater communicable efficiency than that observed in the United States. The prevalence of HIV in some African cities is now 20% to 30% among sexually active adults.[3] The circumstances facilitating augmented spread in Africa are not entirely understood, but they may represent a combination of biologic and social factors, including coexisting sexually transmitted infections (STIs), absence of circumcision in males, and demographic changes that have facilitated risky sexual behaviors.

This pattern of heterosexual spread is not unique to Africa. Thailand remained indifferent to the specter of HIV spread until 1986.[4] Infections began in intravenous drug users, but were soon seen to spread rapidly in the general population, resulting in a current estimate of 400 000 to 600 000 HIV infections (about 2% of the adult population). The vehicle for this precipitous spread is believed to be Thailand's active commercial sex industry and the high rates of concurrent STIs. Painfully similar scenarios are evident in other developing countries. One of these is India, with a population of 850 million people, which is now in the throes of an explosive and unanticipated heterosexual HIV epidemic.[5]

We do not have to look overseas, however, to find a heterosexual community with a high prevalence of risk factors and sexual behaviors that are unsafe. Many of our impoverished urban communities now exhibit alarming rises in the heterosexual transmission of HIV. In an STI clinic in the Bronx, NY, a study demonstrated an HIV seroprevalence of 3.6% in males and 4.2% in females without customary risk factors other than enhanced heterosexual activity.[6] Factors associated with transmission in this inner-city population were large numbers of sexual partners and STIs acquired under the influence of crack cocaine. A similar spread has been seen in Detroit, Mich,[7] and other inner-city communities. We should not be surprised by these findings; lessons from developing nation populations should have enabled us to predict these selective heterosexual epidemics.

It is not currently possible to judge the magnitude of HIV dissemination in those inner-city subpopulations, although some now predict, again, the beginnings of a major heterosexual epidemic in the United States.

From the Rockefeller Foundation, New York, NY.
Reprint requests to the Rockefeller Foundation, 1133 Avenue of the Americas, New York, NY 10036 (Dr Berkley).

The design of preventive interventions for these high-risk heterosexual groups will be different from those effectively used by members of this society who have greater access to education and health care and are not socially marginalized. The lessons we are learning from the current epidemic in Africa and other resource-poor locations will inevitably have great applicability as we confront our own heterosexual HIV epidemic.

There are other reasons why US physicians should be sensitive to the dimensions and dynamics of the international spread of HIV infection. Global interdependence, modern transportation, and trade have rendered obsolete the distinction between domestic and international health.[8] A recent Institute of Medicine report concerning the threat of novel infectious diseases contends that we are no longer isolated from any community, no matter how geographically remote.[9] Neither political nor even geographic borders provide any effective barrier to the spread of infectious diseases in an age when one can dine in Boston and begin a safari in Africa the next afternoon.

The role of travel as a route of HIV transmission is illustrated in recent data from the United Kingdom.[10] The proportion of HIV infection attributable to heterosexual transmission rose from 4% in 1986 to 23% in 1991. Of those investigated, 83% acquired the infection through sexual intimacy while traveling abroad or with someone from a country with a high risk for heterosexual transmission.[10]

Understanding of HIV epidemics in other countries assumes additional importance since it is likely that much of the future research on effective prevention methods (eg, improved barrier methods, topical virucides, and vaccines) will be undertaken overseas. Furthermore, the genetic variability of HIV requires that any vaccine efforts take into account the worldwide family of viruses, not just those isolated in the United States.[9]

Physicians, as citizens living in a global village, are also reminded of the interdependence of countries.[11] The HIV/AIDS pandemic, with its incalculable social and economic impact, is now devastating many overseas communities. These embattled populations are becoming progressively less productive and are burdened with increasing numbers of children orphaned by AIDS. As a result, development in these countries is adversely affected, and they will require increased economic and medical assistance from the community of developed nations in the near future.

Finally, the AIDS pandemic represents the great new plague of this century. Countries such as Uganda and Thailand have much to teach our political leaders about a policy of openness and leadership in confronting this disease. Due to the void in political leadership in the United States, American physicians have a professional obligation and a moral responsibility to lead the response to this pestilence. HIV is spreading fastest in the developing world and within marginalized communities in the developed world. Consequently, there is a risk that the populace will begin to perceive HIV as an arcane infection limited to the tropics and certain very poor urban areas and thus distance themselves from the problem. It becomes urgent, then, that the American physician maintain an active and intimate role in the global response to this evolving pandemic. As the physician playwright, Anton Chekhov, once noted: "There is no national science just as there is no national multiplication table; what is national is no longer science."

Seth F. Berkley, MD

I am indebted to Stanley M. Aronson, MD, for his moral leadership and critical review of this editorial.

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Printed and Published in the United States of America

Amsterdam Viewpoint

Costly Regional AIDS Conference for the North

Seth Berkley

The International AIDS conference remains a northern enterprise. With over 85% of the participants coming form industrialized countries, it is, in effect, the regional meeting of the North. The costs are high —some $25 million—and the international benefits uncertain, particularly as it diminishes the importance of other regional AIDS meetings. Despite its attempts to invite persons from most countries, it is a meeting where most scientific submissions are of little relevance to the areas with most infected people, those living in Asia and Africa.

The theme of Amsterdam was "a world united against AIDS". The first indications, however, that the world was not united , was the movement of the conference form its intended site in Boston to Amsterdam to protest the United States's immigration policy of restricting entry to those who are HIV infected.

The organizers, sensitive to the issues of human rights and the personal issues associated with the epidemic made every attempt to include all constituencies in the conference. Thus unlike most scientific meetings, activists and politicians were placed side by side with scientists in the program. Consequently, the conference has lost much of its feel as an intense scientific gathering and is becoming a venue for global consciousness raising.

There were many flamboyant exhibition booths advertising the expensive therapies and testing materials for HIV infections. There was also a great deal of protesting but

turn to page 4

Amsterdam: Too Costly

from page 4

Berkley

because the voices of the activists were officially included in the program, protests were less disruptive than in previous conferences. Most protests were directed at the discriminatory practices, at the lack of U.S. government leadership on HIV/AIDS issues, and towards pharmaceutical companies that were accused of overpricing the life-saving drugs. These, however, were western-oriented protests. As in past years, there were no organized protests for the victims in the poorest developing countries, such as sub-Saharan Africa, who are dying of AIDS without the benefit of basic therapy or without pain relieving medications.

The distribution and spread of the world wide pandemic make the absence of protest on behalf of those living in the less developed countries (LDCs) even more disheartening. During the conference WHO announced its latest estimates of HIV infections: as of July 1992, over 13 million persons are infected worldwide.[1] Of these, 70% are living in LDCs and of the one million persons estimated to have been infected over the last six months, 85% of those are living in LDCs.

Perhaps the most sobering session for the international scene was that on measuring and modeling the economic impact of the epidemic. Attended by only about 50 persons of whom only two or three were from developing countries, Daniel Tarantola presented a paper written with Charles Cameron.[2] Using published information on costs and a survey of government expenditures in 37 countries, they calculated worldwide expenditures on HIV/AIDS. They estimated that for 1990 alone, $2.6 - $3.5 billions dollars was spent on HIV/AIDS care worldwide, 10-16% of which was being spent on developing countries where 60-70% of the cases were occurring.

Expenditures in Africa, with over one half of the global burden of infection, were only 1.5 - 2% of the global total for direct care. Estimates of worldwide expenditures for prevention and research were equally distressing: $1.4 billion for prevention with 90% spent in industrialized countries, and $1.7 billion for research with 94% spent in the North. Despite the magnitude of the epidemic 2.8% of the world's expenditure on prevention— only $0.07 per capita.

People from almost every country attended the conference, reflecting an impressive effort by the organizers. However, while I was being confronted with an $885.00 on-site registration fee, I contemplated the costs and implications of a conference of this scale. Over 80% of the participants were from the North. The costs of the conference, not including salaries and lost productivity, were well over $25 million U.S. dollars by my estimate, or more than one-quarter of the World Health Organization's budget for worldwide AIDS activities. Is this a good use of scarce resources?

Most of the scientific presentations at the conference were by Northern investigators focusing on issues that had little relevance for most of the infected persons in the world— those living in Africa and increasingly Asia. Although it is important for scientists from all regions to share experiences, it is particularly important for scientists working in areas with similar transmission patterns and with similar constraints to work together, especially with younger, less experienced colleagues. Unfortunately, these younger relatively unknown LDC scientists rarely receive support to attend the International Conference.

Furthermore, it is vital to convene researchers from the South because they lack the ongoing access to up-to-date libraries, personal journal subscriptions, electronic literature searches, regular visiting professors and guest lecturers enjoyed by researchers from the North. This type of education and networking is best done at the regional conference level where most of the science agenda addresses shared problems. Yet, these conferences are overshadowed by their "big brother", the Amsterdam style International Conference. Regional conferences for the South have been considered second class; for example, expatriate researchers working in Africa usually present their most important work at the International Conference which is considered more prestigious and has major donors in attendance. Expatriate researchers may not even attend the regional conferences. Budgets for these regional conferences are a fraction of those of the International Conference and lower expenses and travel can allow many more researchers to attend. Despite this, it is often difficult to raise funds for the regional meetings and to get researchers and speakers from the North to attend. This is due, in part, to the money spent on the International Conference, as well as the lower prestige of the regional meetings.

Perhaps, this will improve once the regional and the international meetings begin to be held biannually in alternating sequence scheduled to begin in 1995. I, for one, would like to see much more attention and resources focused where the need is greatest—empowering those scientists who are attempting to deal with the majority of the worlds' infections. The prestige and visibility of regional conferences should be strengthened so researchers doing work in those regions consider these conferences as appropriate venues for sharing scientific information.

Despite the laudable motivations of the organizers of the International Conference, we should ask if this gathering is cost effective and in the best interest of the international effort. In a world that is not providing the necessary resources to fight the epidemic, perhaps a better protest to the U.S. policies would have been to cancel this year's conference and redirect the millions of dollars used by international agencies to strengthen the regional conferences. In doing so, the world would, in fact, acknowledge that the areas that bear the largest burden should receive a fairer share of the resources. That equitable treatment would indicate a world truly working to unite against AIDS. ❑

Notes:

1) World Health Organization, Global Programme on AIDS. The current global situation of the HIV/AIDS epidemic. July 1992 (distributed at the VIII International Conference on AIDS, 19-24 July 1992, Amsterdam

2) Cameron C, Tarantola D. The Costs of AIDS in the World, 1990. Abstract WeC1038, VIII International Conference on AIDS, 19-24 July 1992, Amsterdam.

Draft Plan 1/19/94

PROPOSED GAME PLAN
HIV Press Conference
January 20, 1994, 11:15 a.m.

Total estimated time for prepared remarks: 15-20 minutes

[30 sec]	Bill Grigg	Introduction
[3 min]	Philip Lee	Statement
[3 min]	Kristine Gebbie	Statement
[1 min]	Dr. Clinton	Brief Remarks
[3 min]	Dr. El-Sadr	Important guideline recommendations
[3 min]	Dr. Oleske	Important guideline recommendations
[1 min]	Dr. Roy Schwarz AMA	Support of guideline
[1 min]	Dr. William Brown NMA	Support of guideline
[1 min]	Sarah Stanley ANA	Support of guideline
[1 min]	Gordon Nary Physicians Association for AIDS Care	Support of guideline
[1 min]	Cornelius Baker National Association of People with AIDS	Support of guideline
[30 sec]	Dr. Clinton	Guideline availability Introduction of other attendees in audience Open up for Qs and As

STAGING:
Dr. Lee, Ms. Gebbie, Dr. Clinton, Dr. El-Sadr, Dr. Oleske will be seated on dais.

NOTE: **When Q&A session opens up, Dr. Clinton may ask one of the participants not sitting on stage to comment on specific questions. If so, that person may come up to the microphone from the audience.**

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[1 min]	Dr. Clinton	Welcome and Introductions
[1 min]	Dr. El-Sadr	Important guideline recommendations
[1 min]	Dr. Oleske	Important guideline recommendations
[1 min]	Dr. Roy Schwarz AMA	Support of guideline
[1 min]	Dr. William Brown NMA	Support of guideline
[1 min]	Sarah Stanley ANA	Support of guideline
[1 min]	Gordon Nary Physicians Association for AIDS Care	Support of guideline
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HIV GUIDELINE
PRESS CONFERENCE AGENDA
January 20, 1994
Washington, D.C.

Speakers (in order of presentation)

Philip Lee, M.D.
Assistant Secretary for Health, PHS

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

M. Roy Schwarz, M.D.
American Medical Association

William Brown, M.D.
National Medical Association

Sarah Stanley, MS, RN, CNA, CS
American Nurses Association

Gordon Nary
Physicians Association for AIDS Care

Cornelius A. Baker
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

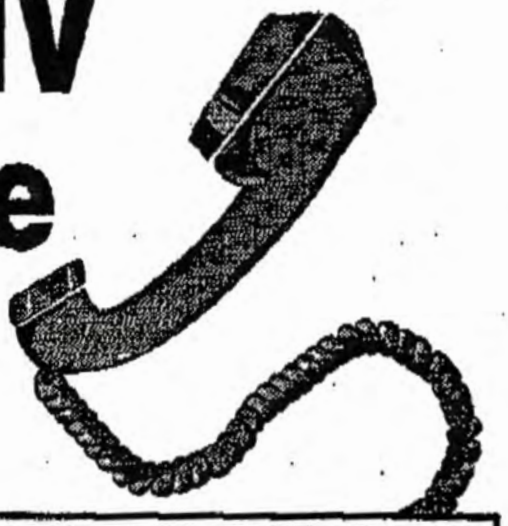
The guideline was developed by a panel of private sector, multi-disciplinary experts who care for people living with HIV. The panel also included a man and a woman who are living with HIV.

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.

KG-
Have you
seen Hope?
Are they in
your parking
lot today?
JL

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

- 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.

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.

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.

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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.

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