

HIV TESTING

AFRICA

(HIV TRANSMISSION)

LEVEL 1 - 3 OF 3 STORIES

The Associated Press

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HEADLINE: Advocacy groups blasts U.S.-funded AIDS research overseas

BYLINE: By LAURAN NEERGAARD, Associated Press Writer

DATELINE: WASHINGTON

BODY:

The United States is paying for experiments in poor countries that could allow 1,000 babies to die of AIDS unnecessarily by withholding a protective drug from HIV-infected pregnant women, the patient advocacy group Public Citizen charged Tuesday.

The government says the studies are ethical because they are the only way to find new HIV protections that poor countries can afford. Pregnant women in developing countries today do not get the AZT therapy that American AIDS patients use to protect their unborn children.

But in a letter signed by prominent bioethicists and Dr. Wilbert Jordan, head of the Black Los Angeles AIDS Consortium, Public Citizen compared the U.S.-funded foreign research to the infamous "Tuskegee experiment" in Alabama in which the government withheld syphilis treatment from poor black patients.

Also, federal law says U.S. doctors cannot do experiments abroad that would not be tolerated here, the letter added in requesting a federal investigation.

"We are confident that you would not wish the reputation of your department to be stained with the blood of foreign infants," said the letter to Health and Human Services Secretary Donna Shalala.

Shalala did not immediately respond, but the National Institutes of Health and Centers for Disease Control and Prevention vigorously defended the studies.

"In the absence of identifying some regimen that is affordable, hundreds of thousands of kids are going to die," said the CDC's Dr. Phillip Nieburg.

Studies in 1994 studies on American women indicated that taking the drug AZT during pregnancy and labor - and giving it to infants for six weeks after birth - cuts by two-thirds babies' chances of catching HIV from mothers.



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The Associated Press, April 22, 1997

But that treatment costs about \$ 800 per person, too expensive for developing countries, so doctors are studying potential alternatives such as shorter courses of AZT or giving malnourished pregnant women vitamin A.

But nine of these U.S.-funded studies in Africa, Thailand and the Dominican Republic compare the possible new therapies with dummy pills, instead of giving the comparison women the U.S.-style AZT treatment.

The government insists a placebo comparison is the only way to prove potential new therapies are better than no treatment.

But Public Citizen's Dr. Peter Lurie accuses the researchers of a double standard by "conducting abroad experiments we would not condone here."

He estimated that 416 babies unnecessarily caught HIV in two just-completed foreign studies that gave their mothers placebos. An additional 600 babies are at risk in the continuing experiments, he said.

But ethics rules "also say you don't study a treatment that can't be used in the country where the study is being undertaken," countered NIH's Dr. Jack Killen, who noted each country agreed to these studies. "They look at it as a chance to deal effectively with the thousands of infants a day who are not in a study," by identifying affordable treatments.

The United Nations, South Africa and Europe are funding similar placebo-controlled studies in developing countries.

"We're doing this for their benefit," said Dr. Joseph Saba, head of the United Nation's AIDS study.

"We are informing the women that they have a ... risk of not getting any treatment," added Saba, who said the World Health Organization in 1995 declared placebo-controlled studies the best way to quickly find AZT alternatives.

But Jordan, who ships his California patients' leftover AZT to Africa, argues that researchers knowingly pass up a chance to save some infants in the studies.

"We are doing something overseas that we wouldn't be doing here," he said. "We've just continued to infect everyone."

Lurie noted that yet another study in Thailand, funded by Harvard University and the NIH, did compare "short-course" AZT to U.S.-style longer AZT therapy, proving experiments without dummy pills are feasible.

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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUL 15 1997

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009-1001

Dear Dr. Wolfe:

On April 22 you wrote to me regarding clinical trials of medical interventions designed to discover methods to reduce maternal-infant transmission of human immunodeficiency virus (HIV) in developing countries. During the process of the development of my response, you wrote to President Clinton on this same matter and provided him with some additional information. I note in both letters your conclusion that the experimental designs for some of these studies are unethical because they do not meet the standard of health care that would be required were they to be conducted in the United States. This letter and its enclosure are in response to both your letter to me and your letter to the President.

Your letters raise issues about how best to seek safe and effective methods to prevent HIV infection in newborns in developing countries whose health care systems lack the substantial level of services and resources available to citizens of industrialized countries. All parties are in agreement that, before initiating any intervention seeking to identify such methods, it is essential to ensure that the intervention being studied is ethically and scientifically acceptable to the developing countries, offers sufficient promise to justify the involvement of human subjects, and is realistically adoptable if the intervention is shown to be sufficiently safe and effective. I have reviewed your letters with Dr. Harold Varmus, Director, National Institutes of Health (NIH), and Dr. David Satcher, Director, Centers for Disease Control and Prevention (CDC). In addition, Dr. Harold Shapiro, Chair of the National Bioethics Advisory Commission, has received copies of your letters.

At my request, Drs. Varmus and Satcher conducted a rigorous assessment of the previous reviews of the needs, resources, and health care capabilities of the developing countries involved. They also reviewed the process of scientific development and ethical assessment leading up to and guiding the current conduct

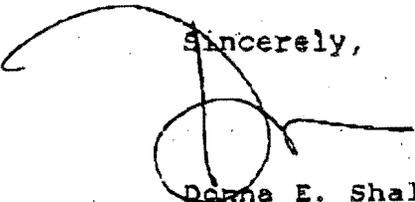
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of these clinical trials. These two distinguished scientists and public health leaders have concluded that researchers in the host countries and the United States are carrying out scientifically meritorious and ethically sound experimental designs, providing effective protection of human research subjects, and faithfully adhering to approved research protocols that are consistent with the recommendations of the World Health Organization and approved by all of the countries involved. I enclose a copy of their report. Please note that the two CDC-supported protocols referenced in the report had significant procedural shortcomings that have been addressed.

I endorse the assessment of Drs. Varmus and Satcher and therefore have concluded that the pertinent NIH- and CDC-sponsored clinical trials should continue. Three facts weighed heavily in my judgment. First, there is the demonstrated, urgent need for feasible interventions for preventing maternal-infant transmission of HIV in developing countries. Second, in industrialized as well as in developing countries, historical controls and national or local health statistics do not provide an adequate baseline against which to compare the outcomes of new HIV interventions. Third, the ACTG 076 zidovudine (AZT) regimen is presently not feasible as the standard of care in many developing countries because it is too logistically complex and resource-intensive and, therefore, inappropriate for use as a comparison arm of an HIV trial at this time.

Clinical trials in developing countries present a variety of extraordinarily difficult choices. I recognize that not every one of us would make the same decisions in every instance; yet, lack of unanimity on issues as complex as these is neither infrequent nor necessarily reflective of errors in decision-making. With respect to the clinical trials designed to reduce HIV infections in newborns in developing countries, I am satisfied that the choices are being addressed through a sound synthesis of knowledge, compassion, and prudence. As this Department proceeds to sponsor these and other clinical trials in developing countries, I assure you that we and our collaborators in those countries will remain committed to the simultaneous achievement of improved medical care, meritorious science, and assiduous protection of human research subjects.

Sincerely,



Donna E. Shalala

Enclosure

**THE CONDUCT OF CLINICAL TRIALS
OF MATERNAL-INFANT TRANSMISSION OF HIV
SUPPORTED BY THE UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
IN DEVELOPING COUNTRIES**

**A SUMMARY OF THE NEEDS OF DEVELOPING COUNTRIES,
THE SCIENTIFIC APPLICATIONS, AND THE ETHICAL CONSIDERATIONS
ASSESSED BY THE NATIONAL INSTITUTES OF HEALTH AND
THE CENTERS FOR DISEASE CONTROL AND PREVENTION
1994-1997**



JULY 1997

THE CONDUCT OF CLINICAL TRIALS OF
MATERNAL-INFANT TRANSMISSION OF HIV
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For the past three years the United States Department of Health and Human Services (HHS), through its National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC), has been engaged in the development and conduct of clinical trials designed to identify feasible interventions for preventing maternal-infant transmission of HIV in developing countries. The Director, NIH, the Director, CDC, and other senior scientists and administrators within the NIH and CDC, at the request of the Secretary, HHS, conducted a thorough assessment of the previous reviews of the needs, resources, and health care capacities of these developing countries and the process of scientific development and ethical evaluation leading up to and guiding the current conduct of these clinical trials. As an added measure, comments of a number of experts in biomedical ethics and the biosciences outside of NIH and CDC were also sought and considered. Based on this assessment, NIH and CDC have determined that, although these are complex matters, the studies have the potential to be of enormous value to the developing countries and are scientifically well-founded and ethically acceptable.

The NIH/CDC assessment addressed three major questions related to these clinical trials. What is the need for these studies? Are the studies adequately designed to examine options for treatment that will meet that need? Is the involvement of human subjects in these studies consistent with the internationally accepted principles of autonomy, justice, and beneficence as implemented by the United States Federal Policy for the Protection of Human Subjects, including the equitable selection of subjects, obtaining of voluntary informed consent, and employing the input, review, and authorization of the appropriate ethical and other bodies in the U.S. and in the developing countries where the research is being conducted?

THE NEED

One regimen of antiretroviral therapy has been shown to reduce substantially the likelihood of maternal-infant transmission of HIV. The identification of this successful regimen was the result of the National Institutes of Health's AIDS Clinical Trials Group protocol 076 (ACTG 076 or 076) in 1994. In spite of this knowledge, approximately 1,000 HIV-infected infants are born each day, the vast majority of them in developing countries. This occurs, in part, because the regimen proven to be effective is simply not feasible as a standard of prevention in much of the developing world.

There are two reasons for this lack of feasibility. First, to follow the regimen that has proven efficacy requires that the women be reached early in prenatal care; be tested for and counseled concerning their HIV status; comply with a lengthy oral treatment regimen; receive intravenous administration of the antiretroviral zidovudine (ZDV or AZT) during labor and delivery; and refrain from breast-feeding. Additionally, the newborns must receive 6 weeks of oral AZT therapy. During and after the time the mother and infant are treated with AZT, both must be carefully monitored for adverse effects of exposure to this drug. In the developing world countries that are the sites of these studies, these requirements could seldom be achieved, even under the infrequent circumstance when women present early enough for the screening and care requirements of the 076 therapeutic regimen to be implemented. Second, the wholesale drug costs for the AZT in the 076 regimen are estimated to be in excess of \$800, an amount far greater than these developing countries could afford as standard care. For example, in the developing country of Malawi, the cost of AZT alone for the 076 regimen for one HIV-infected pregnant woman and her child is more than 600 times the annual health care budget allocation for one person. Less complex and expensive alternatives are urgently needed to address the staggering impact of maternal-infant transmission of HIV in developing countries.

In June 1994, after the results of ACTG 076 were released, the World Health Organization (WHO) convened a group of researchers and public health practitioners from around the world in Geneva. This international panel called for the use of the 076 regimen in the industrialized world, where it is feasible, but immediately called for the exploration of alternative regimens that could be used in the developing world, stating that logistical issues and cost would preclude the widespread application of the 076 regimen. The WHO panel called for international coordination of research efforts to develop simpler, less costly drug regimens. This coordination continues in the form of meetings two to three times per year of the UNAIDS Informal Working Group on Prevention of Mother to Child Transmission of HIV. As a result, there is a global research agenda addressing the need to devise efficacious regimens that can be safely and widely implemented in the developing world.

THE STUDY DESIGNS

The NIH- and CDC-supported studies of maternal-infant transmission of HIV in developing countries are designed to meet the critical need just described. The panel convened by WHO in Geneva stated in Recommendation 6 of its *Recommendations from the Meeting on Prevention of Mother-to-Infant Transmission of HIV by Use of Antiretrovirals, Geneva 23-25 June 1994* (attached as an appendix to this report):

Since the ZDV regimen studied in ACTG 076 is not applicable in those parts of the world where most MTI [mother-to-infant] transmission of HIV occurs, placebo-controlled trials offer the best option for obtaining rapid and scientifically valid results.

The WHO panel went on to explain in its commentary on the recommendation:

Most of MTI transmission of HIV occurs in the developing world, where the ZDV regimen used in ACTG 076 is not applicable because of its cost and operational requirements. In those parts of the world, the choice of a placebo for the control group of a randomized trial would be appropriate as there is currently no effective alternative for HIV-infected pregnant women.

For each individual study there has been careful consideration of the specific needs of and treatment feasibility within the country in which it would be implemented. NIH, CDC, collaborating U.S. institutions, and the host countries will continue to monitor each study and any changes in the countries that may have an impact on study design. It is an unfortunate fact that the current standard of perinatal care for the HIV-infected pregnant women in the sites of the studies does not include any HIV prophylactic intervention at all. Nor does the standard of care for these HIV-infected women include the combination therapies recommended and used for some HIV-infected women in the U.S. However, the inclusion of this regrettable, but real, performance-site standard in the form of placebo controls provides the direct comparison of standard and new intervention that is needed to form the basis for rational policy decisions and will result in the most rapid, accurate, and reliable answer to the question of the value of the intervention being studied compared to the local standard of care.

The NIH- and CDC-supported studies are designed in a manner consistent with the still-pertinent recommendations of the WHO panel and have been developed in on-site collaboration with the health ministries, physicians, and researchers of the host countries. There is strong support for the design of the NIH- and CDC-supported studies, including the placebo arms, within the countries where the clinical trials are being carried out, in part because the studies are assessing regimens that might realistically be employed to decrease mother-to-infant transmission, taking into account the health care resources and operational capabilities of these countries.

HUMAN RESEARCH SUBJECT PROTECTIONS

The acceptability of the involvement of human subjects in the studies under discussion has been scrupulously reviewed beginning with the first proposal for ACTG 076 which was a placebo-controlled study conducted in the U.S. and France. After the complex 076 treatment regimen was proven successful, the WHO conference in Geneva quickly issued clear guidelines for research taking into account the extremely wide range of health care capabilities that characterize the broad spectrum of countries described by the term developing countries. As mentioned earlier, these matters have been debated in formal discussions, forums, and required reviews in the U.S., in international settings, and in the countries where the clinical trials are or will be

carried out.¹ Even so, CDC determined that Assurances for performance site countries required by HHS regulations at Title 45, Part 46, Section 103 had not been obtained prior to enrolling subjects. CDC acted immediately to notify OPRR and to address these administrative procedures. The Assurances for the CDC-Thailand and CDC-Cote d'Ivoire studies were conditionally approved by OPRR on July 7, 1997 and July 14, 1997 respectively. CDC amended its human subjects protection administrative procedures to be in full compliance with 45 CFR 46.103.

Arguments against the NIH- and CDC-supported studies appear to rest on the proposition that it is unethical to conduct a clinical trial unless it offers all participants a chance to receive an effective intervention if such is available anywhere in the world, even if it is not available at the site of the clinical trial. Ideally, this would be so for all clinical trials for all therapies. But the reality is that often it is not possible. The very purpose of the NIH- and CDC-supported studies of maternal-infant transmission of HIV in developing countries is to identify interventions other than those of 076 and we agree with the WHO Geneva panel's Recommendation 2 that:

It should be emphasized that the results of ACTG 076 are only directly applicable to a specific population. Moreover, the ZDV regimen employed in the ACTG 076 study has a number of features (cost, logistical issues, among others) which limit its general applicability. Therefore, no global recommendations regarding use of ZDV to prevent MTI transmission of HIV can be made.

The use of historical controls was considered and found to be unacceptable because existing epidemiological data for the host countries are inadequate for this purpose. We agree with the commentary on Recommendation 5 of the WHO Geneva panel that:

(r)andomized controlled trials offer the best evaluation of new treatment regimens. The use of historical controls is strongly discouraged, due to the wide changes with time in the study population (differences in the distribution of disease stages), the circulating viral strains, the diagnostic tools used for the ascertainment of the HIV infection status of infants (antibodies in earlier cohorts compared to direct viral markers in more recent cohorts), and the treatment practices (increased use of zidovudine

¹ A useful exploration of these events is contained in an article written by Jon Cohen and published in Science, Vol. 269, pp. 624-626, 4 August 1995.

in HIV-infected pregnant women with AIDS-related symptoms and/or CD4+ lymphocyte counts).

The WHO guidelines clearly indicate that the in-country health care capabilities of each country in which maternal-infant HIV transmission research is to be conducted must be used to define the type of research which is ethical and therefore permissible in that country. If a country will be able to afford only very minimal increments in the resources directed toward improved perinatal care for HIV-infected pregnant women and their children, then trials like those focused on vitamin A and other micronutrients are ethical, permissible, and desirable.

In other countries, such as Thailand, the situation is far more complex. Thailand is a country that may be able to afford a simplified AZT/076-like regimen. However, Thai researchers, physicians, and public health officials are understandably interested in seeing a number of issues addressed before any AZT is placed in general use in HIV-infected pregnant women in their country: (1) Is a much simplified 076-like regimen (e.g., initiation of prenatal treatment at 36 weeks of pregnancy, oral instead of intravenous AZT during labor and delivery, elimination of AZT given to the infant) effective in reducing transmission? (2) What adverse outcomes related to AZT use will be seen in Thai populations? Will adverse effects not seen in the U.S. and Europe occur in Thailand? (3) Is AZT administered orally to Thai women safe and well-tolerated? Do Thai women metabolize AZT such that the dose used is the right one to use in all Thai HIV-infected pregnant women? and, (4) How does the type of HIV seen in Thailand (which has demonstrable differences from the type seen in the U.S.) respond to AZT?

Seeking answers to these questions are two studies, one supported by CDC and one supported by NIH. The CDC-Thai study will determine how well tolerated and how effective a very simple AZT regimen is in a population of women who are infected with a subtype of HIV predominantly different from that observed in the U.S. and who also have co-factors for transmission that may differ from those seen in American populations. Because it is a two-arm, placebo-controlled clinical trial, the CDC-Thai study will provide rapid answers to many of the important questions noted above. It also will enable the Ministry of Health and physicians in Thailand to make better-informed decisions about the use of a much-simplified AZT regimen for general use in HIV-infected pregnant women.

Complementing the CDC-Thai study is an NIH-Thai study to determine how much additional benefit, as compared to how much additional cost and adverse effect, is occasioned by small increments in treatment complexity. The NIH-Thai study has four arms, each a modest increment *over* the treatment arm in the CDC-Thai study. However, even the most complex arm of the NIH-Thai study is *not* identical to the treatment arm of 076. The NIH-Thai study will benefit from the baseline that is established by the CDC-Thai study.

Since the NIH-Thai study provides some level of AZT to all participants, the data from the CDC-Thai study would be particularly important for interpretation of results if the outcomes were the same for each of the four arms. Taken together, these two studies will provide a broad range of

information about the likely value of AZT as a strategy to interrupt maternal-infant transmission of HIV.

In an analysis of the spectrum of studies supported by the NIH and CDC in Africa and Asia, it is clear that we have adhered to international guidelines, including the recent WHO guidelines which address specifically the ethical conduct of research in the post-076 era. The primary consideration in decisions about the appropriate conduct of research has been this: Once the research is completed at a given site, will the population which the study participants represent be able to profit from what is learned from that research?

The International Ethical Guidelines for Biomedical Research Involving Human Subjects that were prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO are:

...intended to indicate how the ethical principles embodied in the Declaration [of Helsinki] could be effectively applied in developing countries.

To evaluate interventions that they could not implement realistically would be exploitive of those in the participant country since there would be no likelihood of meeting requirement 15 of the *Guidelines* that obliges:

...any product developed [through] such research will be made reasonably available to the inhabitants of the host community or country at the completion of successful testing...

Therefore, we have determined that the more compelling ethical argument is against using a regimen that if found to be superior in the study could not possibly be used in the prevention of maternal-infant transmission of HIV in the host country. Turning once again to Malawi for example, health officials there refused to permit the conduct of a study involving a full course regimen of AZT (such as that used in ACTG 076) because they believed it would be unethical to undertake such a study in Malawi given that its very limited resources and poor health infrastructure make the introduction of AZT as standard treatment for HIV-infected pregnant women unfeasible. Instead, the health officials wanted research on alternative treatment approaches that might reduce maternal-infant transmission of HIV. The justification and ethical foundation for the NIH- and CDC-supported studies incorporate the reality that the clinical trials are examining other alternatives that could actually be used for the majority of HIV-infected pregnant women and mothers in the countries in which the clinical trials are being carried out. The process of ethical review of these trials has been rigorous. It has included community and scientific participation and the application of the U.S. rules for the protection of human research subjects in reviews by the relevant institutional review boards (IRBs) in the U.S. and in the countries where the clinical trials are carried out. Support from local governments has been obtained and each active study has been and will continue to be reviewed by an independent Data

and Safety Monitoring Board. These studies are in compliance with broadly accepted principles of ethics of international research, in which the need to take into account the reality of available and feasible health care is a consideration of substantial importance.

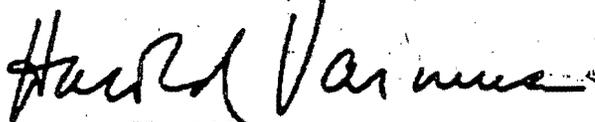
In summary, these studies all address an urgent need in the countries in which they are being conducted. They have been developed with extensive in-country input and participation, and they are consistent with widely accepted principles and guidelines of bioethics. Our perspective and our decision to support these trials rest heavily on local support and approval. In this regard, we point to the words of Edward K. Mbidde, Chair, AIDS Research Committee, Uganda Cancer Institute, in a letter, dated May 8, 1997, to the Director, NIH:

These are Ugandan studies conducted by Ugandan investigators on Ugandans. [Elsewhere in the letter he discusses Ugandan ethical review.] Due to lack of resources we have been sponsored by organizations like yours [NIH]. We are grateful that you have been able to do so.

There is a mix up of issues here which needs to be clarified. It is not NIH conducting the studies in Uganda but Ugandans conducting their study on their people for the good of their people.

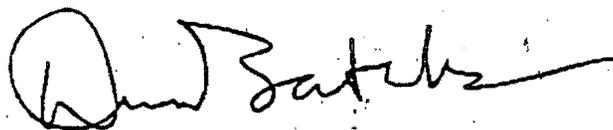
The issues surrounding these studies are, indeed, complex and subject to some disagreement. However, final judgments about their appropriateness must be heavily weighted in favor of decisions made at the local level, as long as those decisions are consistent with international standards and those of the U.S. We know of no other way to realistically and rapidly address the gravity of mother-to-infant transmission of HIV in the developing world and the current lack of a proven, feasible intervention against it, than to continue the studies on which our two agencies have embarked.

DATED: JUL 15 1997



Harold Varmus

Director, National Institutes of Health



David Satcher

Director, Centers for Disease Control and Prevention

Appendix attached

RECOMMENDATIONS FROM THE MEETING ON MOTHER-TO-INFANT
TRANSMISSION OF HIV BY USE OF ANTIRETROVIRALS,
GENEVA 23-25 JUNE 1994

The number of children infected with HIV is increasing with the ever-expanding AIDS pandemic. To date, it is estimated that more than 1 million children have been infected with HIV, most of them through mother-to-infant (MTI) transmission. During the period 1990-2000, the World Health Organization (WHO) projects that as many as 5-10 million children will be HIV-infected at birth or through breast-feeding, the majority of them in sub-Saharan Africa. In this context, the recent documentation of a clear reduction of the risk for MTI transmission of HIV by use of zidovudine (ZDV) in pregnancy constitutes a major breakthrough, opening new areas for research and intervention in this field.

An interim analysis of a phase III randomized, placebo-controlled trial (ACTG 076), conducted in the United States and France, to evaluate the efficacy, safety and tolerance of zidovudine (ZDV) for the prevention of MTI transmission of HIV has demonstrated a clear reduction of the risk for MTI transmission for the group who received ZDV. The study was conducted by the Pediatric AIDS Clinical Trials Group (ACTG) of the National Institute of Allergy and Infectious Diseases (NIAID) in collaboration with the National Institute of Child Health and Human Development (NICHD) in the United States, and by the Institut National de la Santé et de la Recherche Médicale (INSERM) and the Agence Nationale de la Recherche sur le SIDA (ANRS) in France.

Eligible participants were HIV-infected pregnant women who had received no antiretroviral treatment during the current pregnancy, had no clinical indications for maternal antepartum ZDV therapy, and had baseline CD4+ lymphocyte counts greater than 200 cells/mm³. The ZDV regimen consisted of antepartum ZDV (100 mg orally 5 times daily) initiated between 14 and 34 weeks gestation and continued throughout the remainder of pregnancy, followed by intrapartum intravenous ZDV (loading dose 2 mg/kg starting in labour, followed by continuous infusion of 1 mg/kg/hour until delivery), followed by oral administration of ZDV (syrup 2 mg/kg every 6 hours for 6 weeks beginning 8 to 12 hours after birth) to the infant. The primary study endpoint, HIV infection of the infant, was defined by one positive HIV culture obtained from peripheral blood. Specimens for viral culture were obtained from the infants at birth, 12, 24 and 78 weeks postpartum.

At the time of the interim analysis, 477 women had been enrolled. The median age was 25 years (range 15 to 43), the median CD4+ lymphocyte count was 550 cells/mm³ (range 200 to 1,818), and the median gestational age at entry was 26 weeks. Maternal demographics revealed a predominantly minority population: only 19% were white non-Hispanic. The baseline characteristics of the women were balanced between the two randomized groups. There were 364 infants with sufficient data to be included in the interim efficacy analysis, 180 in the ZDV group, 184 in the placebo group. As of this analysis, 13 infants in the ZDV group and 40 in the placebo group were HIV-infected (i.e. had at least one positive HIV culture). Based on a Kaplan-Meier estimate at 18 months, the transmission rate in the placebo group was 25.5% whereas the rate in the ZDV group was 8.3%. This corresponded to a 67.5% relative reduction in transmission risk. This risk reduction was highly statistically significant (two-sided $p=0.000056$).

Reported maternal and infant side effects were balanced between the two randomized

groups with the one exception that hemoglobin levels were lower for infants in the ZDV group. The mean decrease in hemoglobin was less than 1 gram/dl, did not require transfusion, and resolved within 12 weeks after completion of ZDV therapy. The study currently provides no information regarding any late effects of ZDV in infants, including those who do not become infected with HIV.

The publication of these results prompted WHO to convene an international meeting on the prevention of MTI transmission of HIV by use of antiretrovirals, attended by over 50 scientists and representatives from research funding agencies, drug regulatory agencies, and pharmaceutical companies, which took place in Geneva from June 23-25, 1994. The objectives of the meeting were to review the preliminary data on the efficacy of ZDV in preventing MTI transmission of HIV, to define the current public health implications of the ACTG 076 results, to review potential alternative antiretroviral drug regimens, more adapted to circumstances in developing countries, and to propose coordination of the research efforts of the various agencies and institutions who plan intervention studies in this area. The recommendations made by the group that convened in Geneva were as follows:

1. ~~ACTG 076~~ has demonstrated that MTI transmission of HIV can be reduced by use of ZDV. Therefore, the concept of reducing MTI transmission of HIV by use of antiretrovirals has been shown to be valid.

2. It should be emphasized that the results of ACTG 076 are only directly applicable to a specific population. Moreover, the ZDV regimen employed in the ACTG 076 study has a number of features (cost, logistical issues, among others) which limit its general applicability. Therefore, no global recommendations regarding use of ZDV to prevent MTI transmission of HIV can be made.

The study population in ACTG 076 consisted of asymptomatic HIV-infected pregnant women with CD4+ lymphocyte counts higher than 200 cells/mm³, living in the United States and France, most of them from minority populations (only 19 percent were white non-Hispanic). They did not breast feed their children, with one exception. Although it is anticipated that the ZDV regimen used in ACTG 076 would also reduce MTI transmission when given to HIV-infected pregnant women with AIDS-related symptoms and/or low CD4+ lymphocyte counts (< 200 cells/mm³), the magnitude of this effect in this population with a presumably higher viral load is unknown. It should also be noted that the MTI transmission rate in the ACTG 076 placebo group (25%) is higher than the transmission rates usually found in European populations (15-20%). This may be the result of chance, or may indicate differences in the study populations which may impair the generalization of the results.

In ACTG 076, pregnant women were available to start ZDV treatment between 14 and 34 weeks of gestational age. Such a ZDV regimen, starting early in pregnancy, is not suitable for women who would not present at health facilities before delivery.

This regimen is also costly (US\$ 1,000 to 1,500 per treatment), and requires intravenous administration during delivery. Both features make the ACTG 076 ZDV regimen difficult to apply in many developing country situations.

Nevertheless, it is clear that where availability, cost and logistic factors are not limiting factors, ZDV should be offered to HIV-infected pregnant women for the purpose of preventing MTI transmission of HIV.

3. At present, there is no information regarding potential long-term ZDV toxicity to infected and uninfected infants. Neither do we know the implications of (repeated) ZDV treatment during pregnancy for the efficacy of later ZDV treatments of the mothers. Attempts should be made to undertake long-term follow-up of mothers who received prolonged antiretroviral treatment during pregnancy and of their infants, to ascertain whether there are long-term adverse effects.

In vitro and animal experiments have revealed potential genotoxic and carcinogenic effects of ZDV and other available nucleoside analogue reverse transcriptase inhibitors. ZDV induced chromosomal abnormalities in cultured lymphocytes at 3 µg/ml, and was mutagenic in mouse lymphoma cells at 1,000 µg/ml. Moreover, vaginal squamous cell neoplasms were described in mice and rats who had received ZDV doses equivalent to 3 and 24 times the ordinary human exposure. Long-term follow-up of infants who were exposed in utero is thus required.

Follow-up of mothers is advised to determine the implications of (repeated) ZDV treatment during pregnancy on the likelihood of emergence of ZDV-resistant viral strains.

4. Since there is currently no safety or efficacy information available for other antiretrovirals used in pregnancy, their use in attempting to prevent MTI transmission of HIV should be limited to clinical trials.
5. To increase the applicability of antiretrovirals in the reduction of MTI transmission of HIV, it is essential to explore simpler and less costly drug regimens in the full spectrum of HIV-infected pregnant women. Such regimens, including interventions restricted to the intrapartum period, should be urgently studied in randomized controlled trials. Separate studies on safety and pharmacokinetics may have to be done in populations from which no such data are available.

As it is currently estimated that over 50% of MTI transmission occurs around delivery, the most cost-effective intervention using antiretroviral drugs would be an intrapartum treatment. This treatment would also have the advantage of being suitable for women who do not present at health facilities before delivery, and would therefore be better adapted to many "real life" situations, both in the industrialized world and in developing countries. Ideally, this treatment should be cheap, easy to administer, given in one or a few doses, safe, and effective. Nevirapine (NVP), a non-nucleoside reverse transcriptase inhibitor, and related compounds, have a rapid and dramatic impact on viral load, and may thus be suitable candidates for this type of interventions. Studies are still needed on safety and tolerance in pregnant women before efficacy trials can be initiated.

Randomized controlled trials offer the best evaluation of new treatment regimens. The use of historical controls is strongly discouraged, due to the wide

changes with time in the study population (differences in the distribution of disease stages), the circulating viral strains, the diagnostic tools used for the ascertainment of the HIV infection status of infants (antibodies in earlier cohorts compared to direct viral markers in more recent cohorts), and the treatment practices (increased use of zidovudine in HIV-infected pregnant women with AIDS-related symptoms and/or low CD4+ lymphocyte counts).

In populations where no data on the safety and the pharmacokinetic properties of antiretroviral drugs exist, such studies may need to be done. There are known variations in drug metabolism and tolerance across ethnic groups. In addition, concurrent other diseases may decrease tolerance.

6. *Since the ZDV regimen studied in ACTG 076 is not applicable in those parts of the world where most MTI transmission of HIV occurs, placebo-controlled trials offer the best option for obtaining rapid and scientifically valid results.*

Most of MTI transmission of HIV occurs in the developing world, where the ZDV regimen used in ACTG 076 is not applicable because of its cost and operational requirements. In those parts of the world, the choice of a placebo for the control group of a randomized trial would be appropriate as there is currently no effective alternative for HIV-infected pregnant women. In addition, the difference between the MTI transmission rates of HIV between two treatment groups is likely to be maximized when a placebo is used for the control group, thereby decreasing the sample size required to document statistically significant differences between the two groups. Placebo-controlled trials would therefore guarantee the most expeditious identification of appropriate interventions.

7. Detailed information regarding the timing and mechanisms of transmission should continue to be sought so that optimal interventions can be developed. Other approaches to prevent MTI transmission of HIV such as vaginal disinfection, caesarean section, and active and passive immunization, should also be studied.

Although there is increasing evidence for late transmission of HIV during pregnancy, it would be important for the further development of interventions, and particularly intrapartum interventions, to know the exact timing of transmission around delivery.

Vaginal disinfection, if shown to be effective, would have several advantages with regard to its applicability. It is a cheap and probably safe intervention, which may be done in all women at delivery regardless of their HIV infection status (no need for HIV testing), and which may have beneficial effects in the prevention of other infectious diseases transmitted to infants during delivery. However, because the anticipated absolute decrease in MTI transmission rate of HIV due to vaginal disinfection would presumably be low (less than 5%), the sample size required to document statistically significant differences with a non-intervention group would be larger than 2,000 evaluable mother-infant pairs.

The analysis of data from the European Collaborative Study indicates a possible halving of MTI transmission rate of HIV by use of caesarean section. However, these results should be interpreted with caution: there was a large heterogeneity of MTI transmission rates of HIV across centers with similar caesarean section rates, and data from other large prospective studies do not always confirm

these results. Randomized trials using caesarean section as an intervention would be necessary before any recommendations are made. These trials would require large sample sizes (more than 2,000 evaluable mother-infant pairs if ZDV regimens are provided to participants), and would require careful procedures to randomize pregnant women to a mode of delivery. In addition, interventions based on the use of caesarean section to decrease MTI transmission rate of HIV may raise several difficulties, such as possible post-operative complications in HIV-infected women, the exposure of the medical personnel to HIV, and the cost of the intervention.

8. A particular issue in many affected populations is the need to breast feed. Where breast-feeding is recommended irrespective of HIV status, studies must be designed to accommodate this policy.

In places where breast-feeding is widespread and recommended, clinical trials should enrol breast-feeding women. Antiretroviral drug regimens, when given during pregnancy and at delivery, may prevent HIV infections which would be later transmitted to the infant through breast-feeding. The overall efficacy of the antiretroviral treatment on MTI transmission of HIV can therefore be ascertained only after termination of breast-feeding.

Also, there is a need for trials evaluating the efficacy of antiretroviral therapy given in the early postpartum period to the mother and/or to the child, as there are indications that this period is associated with the highest rate of transmission of HIV through breast milk.

9. Any study conducted should be part of a research strategy which may reasonably be expected to lead to interventions which will be affordable, feasible and sustainable in the same setting.
10. The study of interventions and, if shown to be effective, their implementation, will require HIV testing to be offered to pregnant women attending for antenatal care. This testing must be voluntary, accompanied by pre- and post-test counselling, and confidentiality must be assured.
11. Since the primary endpoint of studies to prevent MTI transmission of HIV is the infection status of the infant(s), studies should be designed with follow-up sufficiently long for accurate ascertainment of this endpoint. In particular, if breast-feeding is practised, the follow-up may need to extend past discontinuation of breast-feeding because of the possibility of late transmission.
12. Every large intervention study should be monitored by an independent Data and Safety Monitoring Board.
13. To ensure that the most relevant scientific questions are addressed, and to achieve complementarity, there is a need for world wide coordination of research activities. WHO should assume this coordinating role, as it is in a unique position to do so.

The rapid spread of the HIV pandemic urges scientists to develop effective preventive tools. Several research questions still need to be answered to identify the

most appropriate antiretroviral drug regimens for the prevention of MTI transmission of HIV. Most of these research questions will be addressed in the form of efficacy trials evaluating various antiretroviral drug regimens adapted to specific study populations. World wide coordination is necessary to guarantee that all pivotal research questions are addressed, and to avoid unnecessary duplication of activities. It is recommended that WHO assumes this coordinating role.

* * *

During the meeting, several protocols for placebo-controlled trials evaluating the efficacy of antiretrovirals for the prevention of MTI transmission of HIV were reviewed (see Table 1 in annex). As discussed earlier, the most promising interventions are the two protocols using oral nevirapine started at the beginning of labour.

Table 1 Experimental treatments suggested for placebo-controlled clinical trials, depending on the timing of the intervention and the breast-feeding practices of the study population, with an estimation of the sample size required.

	Artificial feeding	Breast-feeding
Interventions starting during the antenatal period	ZDV PO 4 weeks prenatally Increased ZDV PO during delivery ZDV PO 1 week to the infant (optional) Sample size: 219 * 2	ZDV PO 4 weeks prenatally Increased ZDV PO during delivery ZDV PO 1 week postnatally to the mother and to the infant Sample size ¹ : 288 to 603 * 2
Interventions starting at delivery	NVP PO during delivery NVP PO 1 week to the infant (optional) Sample size: 468 * 2	NVP PO during delivery NVP PO 1 week postnatally to the mother and to the infant Sample size ¹ : 458 to 1,200 * 2

ZDV= zidovudine NVP= nevirapine
PO= per os

¹The smaller sample size is based on the assumption that antiretroviral treatment decreases the transmission of HIV through breast-feeding by 30%. The larger sample size is based on the assumption that antiretroviral treatment has no effect on the transmission of HIV through breast-feeding.

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DEPARTMENT OF HEALTH & HUMAN SERVICES



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Assistant Secretary for Public Affairs

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Date: 9/19/97 Total number of pages sent: 2

Comments: NOTE:

This has already been faxed to
Josh Silberman in the WH Press office

File AIDS Testing in Africa (S)

AZT TRIALS

Background: The New England Journal of Medicine published an editorial and an article today about clinical trials in developing nations. The National Institute of Health and the Centers for Disease Control and Prevention are sponsoring several clinical trials in a number of developing nations, aimed at preventing mother-to-infant transmission of the HIV virus in those nations. Most of the studies involve a placebo control. The editorial compares this with the infamous Tuskegee study, in which treatment was knowingly withheld from African-American men who had syphilis.

(Contact: Campbell Gardett at HHS: 202-690-6343 or Laurie Boeder at HHS: 202-690-7850)

- These studies – which are funded by NIH and CDC – are scientifically well-founded, ethical and essential to conduct. NIH and the CDC, as well as public health authorities throughout the world and in the countries hosting this research, believe these studies offer the only scientifically valid and ethically acceptable means of developing and evaluating a feasible, effective therapy for these countries.
- Since the outset, the studies have been evaluated and reviewed by the ethical committees of not only the U.S. and European institutions involved but, in every case, by an ethical committee from the countries in which these studies are carried out.
- The use of placebo control was ultimately chosen by the countries themselves and by the international medical research community because it is the only approach that can be expected to produce a sufficiently clear response, in a reasonable time period, to the questions that must be answered: is the intervention safe and effective, and is it feasible in the developing world?
- Worldwide it is estimated that more than 1 million children have been infected with HIV through mother-to-infant transmission. WHO projects that during this decade alone, 5-10 million children will become infected with HIV through perinatal transmission, the vast majority of them in the developing world. NIH and CDC are committed to helping the developing nations find feasible interventions for preventing mother-to-child transmission of HIV. To do so, we must be committed to research that can be relied upon to produce usable results.
- We have conducted an extensive review of the process of scientific development and ethical assessment applicable to these trials. The women in the study are fully informed of the nature of the studies. Because of poor economic conditions and low standards of public health care in the participating countries, the women in the studies infected with HIV are not able to afford the considerably more expensive protease inhibitors now available in the United States, and would otherwise have not received treatment. It must not be forgotten why the studies are taking place - to find a simpler, less costly treatment that can be made available in these developing countries.

PROGRESS in PREVENTION

*Research and Support
for Community Action*

Mother-to-Child HIV Transmission Decreases in the U.S. But Challenges Remain For Perinatal Prevention

As the lead federal agency for preventing HIV, CDC has several key responsibilities: surveillance of the American epidemic; biomedical and behavioral prevention research; support of prevention programs and provision of technical assistance; evaluation of what works; strategic communications; and HIV/AIDS prevention technical assistance to states and communities. Recent reductions in mother-to-child, or perinatal, HIV transmission reflect the effectiveness of this multi-level prevention strategy. Challenges remain -- chief among them the need to ensure pregnant women have prenatal care early in pregnancy and can sustain care throughout pregnancy and beyond.

Increasing Impact on Women

Through December 1994, CDC received reports of 58,428 cumulative cases of AIDS among adult and adolescent women (13 years of age and older) in the U.S. Women account for more and more AIDS cases--they were only 7% of all AIDS cases in 1985, but jumped to 19% in 1995. AIDS is now the third leading cause of death among women 25-44. And AIDS is actually increasing faster in women than it is in men. In 1994 alone, 14,081 women were reported with AIDS. Women of childbearing age account for the vast majority of those cases: 84% were reported in women 15-44 years old. In 1993, an estimated 7,000 HIV-positive women gave birth in the U.S., or about 1 in every 625 births. Not every baby born to an infected mother is also infected. In fact, without preventive treatment, the mother-to-child transmission rate was 15-30%, or about 1,000-2,000 infants in 1993.

In 1994, clinical trials in the U.S., Canada, and France conducted by America's National Institutes of Health and France's National Institute of Health and Medical Research (INSERM) showed that some HIV-infected women could reduce the risk of transmitting the virus to their babies by as much as two-thirds by taking zidovudine (ZDV or AZT) during pregnancy, labor and delivery, and by giving their babies AZT for the first 6 weeks after birth. In 1994, CDC issued guidelines for using AZT during pregnancy and, in 1995, published guidelines for routinely counseling all pregnant women about HIV and offering them an HIV test.

What's Working To Prevent Mother-to-Child Transmission

The guidelines for routine counseling and voluntary testing, coupled with AZT treatment if the mother is HIV infected, are showing positive effects on the American perinatal transmission rate.

preventing 656 infant HIV infections and a savings of \$105.6 million in medical care costs, and a net cost-savings of \$38.1 million. These results strongly support routine counseling, voluntary testing, and AZT use.

It is possible that these savings could be increased, if research shows a shorter course of ZDV during pregnancy is just as effective. Several clinical trials of short-course ZDV during pregnancy are underway in sub-Saharan Africa. In developing countries, the extensive ZDV course used in the U.S. is not feasible. If it can be demonstrated that a short course works, it will be a promising advance for addressing the terrible toll perinatal transmission takes internationally. A model presented by a CDC researcher indicates that a national perinatal HIV prevention program in most sub-Saharan African countries would reduce transmission and provide significant societal savings, after the substantial initial investment in public health infrastructure and drugs.

PERINATAL PRESENTATIONS IN VANCOUVER

Oral

Cost Effectiveness of Short-Course Zidovudine to Prevent Perinatal Human Immunodeficiency Virus Type-1 Infection in a Sub-Saharan African Developing Country Setting, Gordon Mansergh.

Declining Mother-to-child HIV Transmission Following Perinatal Zidovudine Recommendations, United States, R. J. Simonds.

Perinatal HIV Transmission Risk and the Effect of Pregnancy or Infant Zidovudine Use in a Multicenter Study, 1994-1995, Richard W. Steketee.

Poster

Breastfeeding Among HIV-Infected Women, Los Angeles and Massachusetts, 1988-1993, Jeanne Bertolli.

Early Diagnosis of Perinatal HIV Infection Comparing DNA-Polymerase Chain Reaction and Plasma Viral RNA Amplification, Teresa M. Brown.

Preventing Perinatal HIV Infection: Costs And Effects Of A Recommended Intervention In The U.S., Paul. G. Farnham.

Detection of Phylogenetically Linked HIV Strains Among a Population of Epidemiologically Unrelated Women, Marcia L. Kalish.

Perinatal Zidovudine Use after Perinatal ZDV Recommendations in the United States, Sherry L. Orloff.

Lack Of Timely Prenatal Care Among Women Infected With HIV: Implications For Prevention Of Perinatal HIV Transmission In The United States, Anna Shakarishvili.

CORE CENTER
GORE TO CHICAGO.

VICE PRESIDENT GORE KICKS OFF MAJOR IN CHICAGO

August 31, 1998

Today, the Vice President joined Cook County Commissioner John Stroeger to kick off the opening of the Core Center.

Background on HIV/AIDS. There are currently between 650,000 and 900,000 Americans living with HIV/AIDS, and between 40,000 and 60,000 Americans are diagnosed with HIV each year. The number of Americans diagnosed with HIV/AIDS fell 6 percent between 1995 and 1996, and the number who died from AIDS fell by 23 percent. The number of perinatal transmissions fell by 43 percent between 1992 and 1996.

Kicked Off Opening of Chicago's Historic Core Center A model partnership between the Federal government and The Department of Health and Human Services increased the funding a historic public-private funding partnership to provide prevention, education, and treatment. Specialized outpatient center.

Announced Release of DeSario Case. Ruling to Ensure Access to care Nearly 90 percent of people with AIDS depend on Medicaid and

HIGHLIGHTED THE ADMINISTRATION'S UNPRECEDENTED RECORD IN INCREASING ACCESS TO HIV/AIDS. The Vice President also highlighted the Clinton Administration's continuing commitment to improve treatment, prevention and research for people with HIV/AIDS. Since President Clinton and Vice President Gore took office, the Administration has made an unprecedented increase in funding for HIV/AIDS, including:

Increasing Ryan White CARE grants by nearly 200 percent. Ryan White provides treatment for HIV/AIDS. Since 1993, funding for Ryan White has increased by over 200 percent. The Administration's FY 1999 budget requested \$1.3 billion for Ryan White -- an \$154 million increase from last year.

Increasing the AIDS Drug Assistance Programs (ADAP) by 450 percent. ADAP helps pay for costly, critical drug therapies for people with HIV/AIDS. This year, the Administration has requested \$385.5 million for ADAP, a 35 percent increase over FY1998.

Increased Housing Opportunities for People With AIDS (HOPWA) program by 100 percent. The Department of Housing and Urban Development has increased funding for people with HIV and AIDS by nearly 100 percent. (Need info re program.)

Increased Prevention at the Center for Disease Controls (CDC).

Fighting to Pass a Strong, Enforceable Patients' Bill of Rights. A strong, enforceable patients' bill of rights would help assure Americans with HIV/AIDS high quality health care by providing critical protections, such as direct access to the specialists they need, continuity-of-care

protections to prevent abrupt changes in care, and an independent appeals process that assures that critical care protections are made by informed medical professionals not HMOs.

Proposed Historic Initiative To Eliminate Racial Disparities in Health. While minorities account for only about 25 percent of the US population, they account for more than 50 percent of the cases with HIV and AIDS. The Clinton Administration has proposed a historic race and health initiative with the ambitious goal of reducing health disparities for in six critical areas including HIV/AIDS. This initiative includes \$250 million for demonstration grants to find effective local community efforts to combat HIV/AIDS and \$150 to fund effective programs that



HIV/AIDS BUREAU
OFFICE OF COMMUNICATIONS
301 443-6652
FAX: 301 443-0791

FACSIMILE TRANSMITTAL SHEET

TO: <i>Aron K.</i>	FROM: <i>D Bailey</i>
COMPANY:	DATE:
FAX NUMBER:	TOTAL NO. OF PAGES INCLUDING COVER:
PHONE NUMBER:	SENDER'S REFERENCE NUMBER:
RE:	YOUR REFERENCE NUMBER:

URGENT FOR REVIEW PLEASE COMMENT PLEASE REPLY PLEASE RECYCLE

NOTES/COMMENTS:

Some additional information. ~~Health grants~~
Did not receive grant awards in Chicago area
for titles III & IV. am getting that info &
will provide.

#1: Background on The CORE Foundation, recipient of almost \$10 million in construction grant supporting development of the Cook County/Rush Health Center. This Center's purpose is to become a focal point for community-wide efforts to address HIV/AIDS and other related communicable diseases, including prevention, care, and research.

The project brings together the largest public and private hospitals in Illinois -- Cook County Hospital and rush-Presbyterian-St. Luke's Medical Center. The CORE Foundation is a nonprofit entity that is composed of two members - Cook County and Rush.

The grant of \$9.824 million was awarded under Section 1610((b), specified in language of the appropriations bill PL 104-134, and specified in the President's budget as submitted to Congress. The CORE Foundation was notified in June 96 of the funding. The construction is a \$19.9 million project.

Secretary Shalala participated in the ground breaking of the facility in Spring 1997.

The project is nearing completion. A grand opening ceremony will be held September 17, 1998, and the facility will open to admit its first patients on October 19.

The target population to be served includes all patients seeking HIV/AIDS or related care at Cook County Hospital, plus those who will be referred or transferred from Rush. In 1995, these facilities treated approximately 2500 patients living with HIV.

The services provided will have three areas of focus: education and prevention, linked to community care; specialized outpatient care and an array of support service for community based health care providers and individuals; clinical research through access to experimental treatment and participation in clinical trials.

#2: State Regional Meeting to be held in Chicago September 23-25:

The HIV/AIDS Bureau will hold the first in a series of State regional meetings in Chicago on September 23-25. The purpose of the meeting is to bring together State agencies (medicaid, HIV/AIDS, maternal-child health, and primary care) to discuss critical issues related to the inclusion of special needs populations in Medicaid managed care programs. The first meeting in Chicago includes representatives from 11 States, including Illinois.

EVA Siler
404-639-8008
NEET

INFO ON BREAKDOWN OF
FUNDING FOR AIDS PREVENTION PROGRAMS
MEMORANDUM

CDC

TO: SARAH AND HOW MUCH FUNDING HAS
FROM: ARON INCREASED SINCE 1993
DATE: 8/14/98
RE: AIDS

AIDS prevention programs

- # AND % OVERALL DECLINES IN AIDS HIV DIAGNOSIS SINCE 1993

Recent Trends in Pediatric AIDS Cases

Perinatal HIV transmissions, which accounts for 91% of pediatric HIV infections, peaked during the early 1990s before preventive treatments were available. Since the implementation of AZT treatments for prenatal care and infancy, dramatic reductions in perinatal transmissions have occurred:

No big increases in Anding

1994 and 95

when speedily this was the case

How many cases were there before/now

- Between 1992 and 1996 perinatally acquired AIDS cases declined 43% in the U.S. In 1997, this trend continued with a 30% decline. (CDC).
- Perinatal HIV transmission rates have declined from 21% to 6-11% (CDC).
- Perinatal prevention prevents 656 HIV infections annually providing a net savings of \$38.1 million. (CDC)

estimated 1,000-2,000

Recent Trends in Female AIDS Cases

1997: 432

Unlike the decline seen in perinatal transmission as well as the infection rate in males, the rate of infection for females has increased in recent years:

Between 95 and 96, AIDS mortality decreased by 72%

had increased 16% on average between 1987 and 1994 before leveling off in 1995

- Between 1995 and 1996, there was a 3% increase in initial HIV diagnoses among women while HIV diagnoses declined 3% among men. (CDC)
- For this reason, the proportion of all AIDS cases reported among adult and adolescent women nearly tripled from 7% in 1985 to 22% in 1997. (CDC)
- The trends for young women are alarming. Young women comprise 44% of the cases reported for 13-24 year-olds (seen as an indicator of overall trends in infection) (CDC)

We have reported overall declines when we have

The increasing rates in the female population are driven by the minority population:

- African-American and Hispanic women represent less than 25% of all U.S. women, yet they account for 76% of AIDS cases reported to date among women in the country. (CDC).
- In 1996, new AIDS cases increased by 12% among African American heterosexual women and 5% among Hispanic women. (NIH)

Issues to be Addressed

- One of the best methods of preventing perinatal transmission is to prevent infection in the mother.
- Young and minority women are disproportionately affected by STDs that make them at least 2-5 times more vulnerable to HIV infection. Improved STD treatment will be a critical strategy for slowing heterosexual spread of HIV (currently 38% of

Handwritten signature/initials

cases among women).

- The multi-drug combinations needed to treat an infected person are not affordable or accessible to many who need them. It is also necessary to begin to develop drugs for drug-resistant strains of the virus.
- Many do not qualify for Medicare, under disability, until they are diagnosed with AIDS even though early intervention can control HIV. However, 90% of children with HIV receive benefits through Medicaid due to lack of income.
- Many managed care providers don't provide adequate privacy to adolescents seeking treatment since medical bills are often sent to parents.

Other Questions

- What programs have been implemented to deal with pediatric and female HIV/AIDS cases?
- What must occur for perinatal transmission to decrease further?
- Is prevention of perinatal transmission the only effective method to decrease pediatric AIDS cases?
- What programs have been successful and targeting minority female populations?
- Have drug resistant strains of HIV emerged?
- How soon will topical microbicides that can kill HIV be available?
- How close is NIH to developing an AIDS vaccine?

FAX

JT
Jasculca/Terman
and Associates

DATE ▶ Friday, August 28, 1998

Jasculca/Terman and Associates
730 N. Franklin St., Ste. #510
Chicago, IL 60610

Telephone/(312)337-7400
Facsimile/(312)337-8189

Any problems with this transmission
please call (312)337-7400

FROM ▶ Anne-Marie St. Germaine

TO ▶ Aron Ketchel, VP

COMPANY ▶

FAX NUMBER ▶ 202 456-5557,,497

TOTAL PAGES ▶ 2
(including cover)

NOTES ▶

▶ This message is intended only for the use of the individual to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If this message was sent to you in error, kindly notify us immediately by telephone (collect). Thank you.

The CORE Center

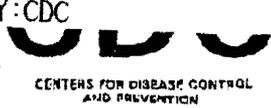
Community Action Committee

HEALTH, HIV OR SOCIAL SERVICE-RELATED AFFILIATIONS
IN CHICAGOLAND METROPOLITAN AREA

ADODI Chicago
Advisory Council - Association of Asian
Pacific Community Health Organizations
AIDS Foundation of Chicago
AIDS Legal Council of Chicago
AIDS Pastoral Care Network
AIDS Policy Center
American Red Cross
American Society of Clinical Pathologists
A Real Read Performance Ensemble
Asian Health Coalition of Illinois
Asian Human Services
Aware Talk Radio
Better Existence With HIV
BLACKlines Magazine
BRASS
Brothers United in Support/Test Positive
Aware Network
CALOR
Central Intake Target Access Point
Chicago Advocacy Network
Chicago Black Lesbians and Gays
Chicago Area HIV Services Planning
Council
Chicago Dept. of Public Health's Strategic
Planning Committee - HIV Policy &
Programs
Chicago Health Outreach
Chicago HIV Prevention Planning Group
Chicago Organizing Committee for the
Latino Lesbian and Gay Organization's
Conference - October 1998
Chicago Prevention Research Project
Chicago Women's AIDS Project
Chicago Lawyer's Committee for Civil
Rights Under Law, Inc.,
The Child Care Association
Children's Place
City of Chicago Advisory Council on Gay
and Lesbian Issues
City of Chicago's Domestic Violence
Advisory Coordinating Council
Coach House
Community Standards Review Panel for
CDC/CDPH
The CORE Center - Volunteers/Peer
Educator Program
The Crossroads Fund
Department of Children & Family Services

El Rincon
Entry House
Family & Children's AIDS Network
Glaxo/Wellcome Community Advisory
Board
HIV Positive Action Coalition
Horizons Community Services
Howard Brown Health Center - *GAY FOCUSED*
Human Resource Development Institute, Inc.
Illinois Assistive Technology Project
IDPH - HIV Prevention Planning Group
Illinois HIV/AIDS Latino Providers
Illinois Methadone Coalition
Immigrant/Refugee Health Task Force
Interventions
Logan Square Gay, Lesbian, Bisexual,
Transgendered Neighbors
Midwest AIDS Trading & Education
Center
National Association of Social Workers
National Lesbian & Gay Journalists
National Minority AIDS Council
National Women's AIDS Council
1998 AIDS Watch
1998 CAEAR Coalition
Northside Domestic Violence Consortium
People of Color Coalition
Piser Chapels
Provident Hospital - Infectious Disease
Committee
Queer Nation Chicago
School Street Movement- Sex Police
Sister's of Sobriety
Society of Professional Journalists Assoc.
South Side Caucus
South Side Help Center
Southside HIV/AIDS Resource Providers
Stop AIDS Chicago
Test Positive Aware Network
UIC College of Medicine/Dept. Family
Practice
United Way Family Life Priority Grants
Committee
Vision House
Westtown/Humboldt Park HIV Providers
Coalition
Women's Justice Fund
Woodlawn Health Center

2



FACSIMILE TRANSMISSION

National Center for HIV, STD, and TB Prevention

Corporate Square

Atlanta, Georgia

TO:

FROM:

Eva Margolies Seiler

Name

Aaron Ketchel

Name

Address

Office of the Director
NCHSTP

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SUBJECT: VP Gore visit to Chicago

MESSAGE:

Per discussion - here is information on

two possible sites

TESTIMONY OF
C. MICHAEL SAVAGE
CHIEF EXECUTIVE OFFICER
SINAI FAMILY HEALTH CENTERS
BEFORE
THE HOUSE COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEE ON LABOR, HEALTH & HUMAN SERVICES AND
EDUCATION

2358 RAYBURN HOB

Thank you, Mr. Chairman, for providing Sinai Family with the opportunity to present testimony before your Subcommittee this year.

I serve as Chief Executive Officer of Sinai Family Health Centers, the largest network of community health centers in the Chicago area. Our mission is to provide high quality, cost effective, comprehensive primary and preventive health care. We are governed by a community-based Board of Directors, most of whom are patients or community members.

Born out of Mount Sinai Hospital in the 1980s, Sinai Family was awarded Federally Qualified Health Center status in 1991 and became an independent community-based health center network. We have 23 sites - 18 community health centers, 2 school-based clinics, and 3 special clinics located inside social service agencies - and we have about 170,000 visits annually by approximately 60,000 unduplicated patients.

1990 U.S. Census figures show that Chicago has seven out of the ten poorest communities in the country. Sinai Family has facilities in five of these communities, serving the indigent, unemployed, or working poor regardless of their ability to pay. Beyond providing treatment for illness or episodic conditions, we also emphasize complete continuity via ongoing health care, health education, and health management for families and individuals throughout their lives - from the prenatal to geriatric stages.

Sinai Family's vision for the healthy future of our patients is focused on a plan to develop a system of *urban community health care*. In order to maintain and expand this commitment, we continually reassess and respond to the rapidly changing urban health care environment. We provide quality and cost effective health care to all our patients, and it is for this mission that we ask for your Subcommittee's crucial support.

Mr. Chairman, over 41 million Americans are uninsured today - the highest figure since Medicare and Medicaid were enacted. Community health centers fill a critical void by

providing care to over 10 million persons not presently served by other providers, and for those who could not otherwise afford primary health care.

In Cook County, Medicaid enrollment has decreased by 60,000 in the last two years. This drop in enrollment is due largely to an improved economy and changes in welfare and immigration laws. Unfortunately, it is very likely that the vast majority of these individuals, even if they are employed, are now uninsured. Sinai Family continues to serve these often uninsured patients.

With the increased enrollment of Medicaid patients in managed care, Sinai Family and community health centers throughout the country are receiving decreased reimbursement for serving Medicaid patients. Even though Sinai Family has reengineered its services delivery system and instituted other changes to reduce encounter costs by 22 percent, we are being squeezed financially by reduced levels of reimbursement and increased numbers of uninsured persons.

For these reasons, Sinai Family is pleased that the National Association of Community Health Centers (NACHC) is working with Congress and the Administration to secure an increase in Fiscal Year 1999 for America's community health centers in the hopes of making comprehensive primary health care available to an additional 350,000 uninsured persons nationwide. Sinai Family strongly supports NACHC's request for an additional \$100 million in funding for HRSA's Consolidated Health Center Program.

A top priority for Sinai Family is addressing the needs of infants and their mothers. Accordingly, Sinai Family was pleased to be given the opportunity, along with three other community health centers, to reduce infant mortality and low birth rates on Chicago's Westside through a Healthy Start grant which was awarded last fall. 19 out of every 1,000 babies born on Chicago's Westside die in their first year of life. Through this Bureau of Maternal & Child Health (BMCH) Healthy Start grant, Sinai Family will reduce this shockingly high infant mortality rate, and low birth weight rates, by 20 percent through the implementation of studied

and proven community health care practices. Sinai Family asks that the Committee continue to fund the Healthy Start program to expand and enhance pre and postnatal care.

Sinai Family has also developed innovative programming to address some of the specific health care problems faced by those elderly living in Chicago's poorest neighborhoods. In addition to a general increase in health care problems as they get older, seniors often find that poverty and crime act as barriers to seeking and receiving adequate health care. Consequently, many seniors are forced to allow illnesses and disease to go untreated until the problems develop into severe health threats.

Sinai Family's *Senior Outreach Program* is aimed at addressing the problems faced by the inner-city elderly. The program provides medical screenings and access to health care for senior residents of public housing. In the last four months, the *Senior Outreach Program* has identified and linked to primary health care services 400 seniors with serious health problems. Sinai Family asks that the Subcommittee encourage the Administration on Aging to evaluate the degree to which outreach programs assist vulnerable senior populations meet their preventive and primary health care needs.

Finally, Sinai Family urges the Subcommittee to encourage the Center for Disease Control & Prevention (CDC) to continue to work with community based organizations to control the spread of infectious diseases. There is now strong evidence that the presence of other STDs increases the likelihood of both transmitting and acquiring HIV and conversely that increased STD treatment can slow the spread of HIV.

Sinai Family also shares this Subcommittee's concern about the disproportionately high prevalence of cancer among disadvantaged and minority populations. Despite overall lower rates of breast and cervical cancer among African American women, the late diagnosis of these two treatable diseases is resulting in higher mortality rates. Sinai believes that as the CDC moves to deal with rising rates of cancer among minority

women, funding should be made available for early screening and treatment programs specifically designed to address the needs of this particular population.

Mr. Chairman, Sinai Family thanks you for the opportunity to present testimony to your Subcommittee this year.

TESTIMONY OF
ANTHONY COLE
VICE PRESIDENT
HAYMARKET CENTER
BEFORE
THE HOUSE COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEE ON THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN
SERVICES, EDUCATION AND RELATED AGENCIES

2358 RAYBURN HOB

Thank you, Chairman Porter, for providing Haymarket Center with the opportunity to present testimony to your Subcommittee again this year.

My name is Anthony Cole and I am Vice President of Haymarket. We are a comprehensive substance abuse treatment center on the Near West Side of Chicago. We were founded in 1975 by Monsignor Ignatius McDermott. Over the past twenty-three years, we have developed several unique programs to address the needs of high-risk females and the non-violent drug offender. Haymarket currently offers comprehensive and integrated treatment services to an average of 13,000 clients annually. We are the largest drug abuse treatment center in the City of Chicago and the third largest in the State of Illinois.

I present this testimony this year to provide a status report on Haymarket's ongoing efforts to be innovative and effective in our programming.

We at Haymarket believe that the treatment community needs to be encouraged to further develop and to refine what is called a "continuum of care." This "continuum" is the integration of drug abuse prevention, drug abuse treatment, health services including HIV/AIDS, day care, parent training, vocational education, job placement and screening for domestic violence and gambling addiction. This integration of services enables the treatment community to help more addicts become productive members of society more quickly.

Haymarket has been given the opportunity to evaluate our integration of services theory through a CSAT demonstration grant which was awarded in Fiscal Year 1995. Through this CSAT Residential

Women & Children (RWC) Grant we are providing residential treatment to more than twenty chemically dependent women and their children. We are also conducting a rigorous evaluation of our long term treatment model and its effectiveness in reducing recidivism rates among chemically dependent women, and the severity and types of impairment experienced by their drug-exposed children.

We ask that the Committee encourage CSAT to continue to fund Knowledge Development & Applications (KDA) projects which expand and enhance treatment for high risk and hard-to-place populations. In order to meet the challenge of limited federal resources, the treatment community needs to equip ourselves with a better understanding of which treatments are most effective with which subgroups of abusers and addicts. We need to recognize the variations among these groups, and that program models developed to treat a white, male population are not directly transferable to other groups like pregnant and postpartum women. These clients bring with them a whole other set of clients - their children. Few treatment facilities approach women as mothers as well as individuals, or deal with matters related to the well-being of their children.

Haymarket understands that the federal government has limited prevention and treatment resources. However, we believe that these limited resources need to be targeted towards high-risk populations such as pregnant and postpartum women and their children. Especially when one considers that the greatest cost savings are associated with treating this population. In addition to the savings connected to treating the mother, there are significant savings to be realized by delivering drug-free infants. The expense of intensive hospital care for each drug-exposed newborn ranges from \$20,000 to \$40,000. The average total cost of care from birth to age 18 for each drug-exposed child is \$750,000 according

to the General Accounting Office

I also recognize that this Subcommittee receives no credit or benefit from savings to the Medicaid program resulting from increased appropriations for treatment. This is unfortunate -- just look at the numbers: at least one in every five Medicaid dollars spent on hospital care is as a result of substance abuse -- at a cost of \$8 billion a year. An untreated addict can cost society an estimated \$43,200 annually, compared with an average \$16,000 for a year of residential care. Haymarket remains concerned that, as the trend of shifting public health care to managed care continues, little attention is being paid to how to effectively transfer managed care practices to publicly funded residential treatment settings, which are the last safety net for many.

Haymarket believes that there is a direct correlation between the comprehensive nature of treatment and reductions in recidivism rates. Accordingly, we have incorporated a preventative health services clinic into our treatment programs. Through the establishment of an on-site clinic, in partnership with a Federally Qualified Health Center in Chicago, we have been able to address the variety of medical and health related problems which impede our clients' treatment progress. We urge the Committee to encourage the CDC and HRSA to continue to work with community-based organizations to control the spread of infectious disease, the reduction of chronic disease, and the reduction of risk factors through preventive and primary health care.

Finally, Haymarket is looking to expand the vocational education and job placement services we offer our clients. Once they have completed treatment, and have begun to address other medical and health related problems, the one impediment they face is a lack of employment opportunities. Haymarket is

looking to collaborate with the Job Corps Center, which is scheduled to open in Chicago this year, in developing an outpatient demonstration project. We ask that the Committee encourage the Department of Labor to consider working with community-based organizations in this and other innovative ways. The Department has been charged with developing welfare-to-work curriculum programs but if welfare-to-work efforts are to succeed the current treatment system's capacity will need to be increased. For example, the Illinois Department of Health & Human Services estimates that forty percent of the State's TANF population has a substance abuse problem and is in need of treatment services.

In closing, Haymarket requests that you help the treatment community create a "continuum of care" for individuals with drug abuse problems so that those individuals can address their problems more quickly and completely.

Office of HIV/AIDS Housing



Office of Community Planning and Development
 U. S. Department of Housing and Development
 451 Seventh Street SW, Room 7154
 Washington, DC 20410-7000

Cover

From: David Vos, Director
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Date: August 19, 1998

Number of pages, including cover:

Material sent to: Aron Ketchel, Office of the Vice President 456-5560; 5557 fax

Comments: Here is the information requested on the HOPWA program and grants in the Chicago area. I believe the area HUD office will have more information on how the City is using its formula funds, that I can pass along in the near future.

Illinois (outside of the Chicago and St. Louis EMSAs)	John R. Lumpkin, MD Director Illinois Department of Public Health 525 W. Jefferson Street Springfield, IL 62761-0001	Ms. Terry Dobbs Direct Services Administrator AIDS Activity Section Illinois Dept. of Public Health 525 W. Jefferson Street Springfield, IL 62761 217-524-5983
Chicago IL PMSA	Thom Dombkowski Program Director, Division of HIV/AIDS Public Policy and Programs Chicago Department of Public Health Room 2-148, DePaul Center 333 South State Street Chicago, IL 60604-3972 312-747-9641	Larry Wolf Division of HIV/AIDS Public Policy and Programs Chicago Department of Public Health Room 2-148, DePaul Center 333 South State Street Chicago, IL 60604-2972 312-747-8815

HOPWA Projects in Chicago

The following community profiles describe how the City of Chicago and the State of Illinois (two of the 32 States and 59 cities that are eligible for HOPWA formula funds) have used federal and other resources to address the housing needs of low-income Americans with HIV/AIDS in their areas. These community profiles are summaries of activities that are part of the area's consolidated plan for the use of formula allocations made available by HUD's Housing Opportunities for Persons with AIDS (HOPWA) program. Communities may use the annual allocation over a three year operating period.

Since 1992, HUD has distributed a total of \$1,145,135,000 by formula allocations in eight fiscal years. In most cases, the earlier allocations have been fully used in provided needed housing assistance to persons with HIV/AIDS and their families who have pressing housing needs. The most recent grants are generally in a development stage that involves community consultations, the development and refinement of plans, and the selection of providers, often by local request-for-proposal processes. Following development, programs initiate operations, select trained staff, identify clients, and coordinate services with other area providers. Property development activities, such as site selection, predevelopment plans, construction and rehabilitation efforts, code inspections, and licensure actions may also be involved in specific projects. Grantees and their sponsors also monitor the assistance provided to clients, may adapt activities to improve the responsiveness of services and consult clients, undertake evaluations and report on the accomplishments of their activities.

Over time, the number of communities that qualified for formula allocations has increased from the original award of 38 formula grants in 1992 to the current FY98 allocation of 88 formula grants. Under the statute, a community is eligible if it is a metropolitan area of over 500,000 population or a State that has at least 1,500 cumulative cases of AIDS as of March 31 of the year prior to the appropriation. HUD uses AIDS surveillance information from CDC in determining formula eligibility and in making allocations under the formula criteria. Ninety percent of the annual HOPWA appropriation is distributed by formula, e.g. \$183.6 million of the \$204 million appropriated for FY98. Ten percent is used by HUD to select Special Projects of National Significance, and projects in non-formula areas under a national competition.

▼ Chicago, IL

FY 1992 \$ 919,000
FY 1993 \$ 2,292,000
FY 1994 \$ 3,122,000
FY 1995 \$ 3,288,000
FY 1996 \$ 3,394,000
FY 1997 \$ 3,805,000
FY 1998 \$ 3,900,000

The HOPWA formula grant, first funded in 1992, serves persons living with HIV/AIDS and their families in the nine counties in the Chicago metropolitan area.

The HOPWA formula program, administered by the City of Chicago's Department of Health, funds a program with five main areas of activity: (1) rent subsidies/financial assistance, which includes emergency housing placements and an average of six months rental assistance; (2) assistance for persons with HIV/AIDS residing in community residences, with residency averaging 138 days; (3) supportive services to maintain a continued level of independence; (4) costs for advocacy and technical assistance; and (5) expanding of housing resources through acquisition, renovation, construction and the leasing of sites.

These five levels of activity within this region is an attempt on the part of the city to streamline allocations and contracts in order to provide the necessary services to clients in the most expedient manner. Priority consideration is given to those person living with HIV/AIDS who are homeless or in imminent danger of becoming homeless.

▼ State of Illinois

FY 1996 \$ 391,000

FY 1997 \$ 467,000

FY 1998 \$ 489,000

The State of Illinois was not eligible for a HOPWA formula allocation until 1996. The State grant, administered by the Illinois Department of Public Health, serves all of Illinois outside of the Chicago and St. Louis Metropolitan Statistical Areas.

In March, 1996, the Illinois Department of Public Health learned that it would be administering the HOPWA formula funds for the State. By May, 1996 the Department had submitted a draft proposal for HOPWA funding for comment to the Ryan White Title II Advisory Council members, AIDS service organizations, local AIDS Task Forces, statewide housing-related organizations and other interested parties. In June 1996, a final program plan and request for proposal was issued.

Based on the input of the various organizations and citizens involved in the plan, the Department chose to utilize the HOPWA funds by linking into the established HIV care consortia system. The system divides the 102 Illinois counties into eleven regions with an identified lead agency that coordinates a continuum of care for persons and their families affected by HIV/AIDS. The following services are provided by the local HIV care consortia members: case management, rent assistance, emergency housing assistance, utility assistance, primary medical care, lab services, dental care, nutritional services, mental health counseling, legal services, substance abuse counseling and transportation.

In 1995, the following two grants were selected in a national competition in this area as Special Projects of National Significance:

▼ In Joliet, Illinois, a grant for \$465,991 was made to Cornerstone Services, Inc., a non-profit, comprehensive social service agency that provides housing, mental health, employment, developmental, educational, and recreational services to persons with

disabilities. Cornerstone developed a program in collaboration with AIDS Ministry of Illinois, a non-profit, non-denominational social service agency that provides housing, support groups, advocacy, referrals, and counseling for people living with AIDS. Over the three-year operating period, this project is providing independent living options with supportive services for eight persons with AIDS and mental illness in suburban Will County, Illinois. Services will include intense case management and advocacy, counseling and mental health services, substance abuse treatment, daily living skills training, employment services, crisis intervention, and socialization and support groups. The project provides rental assistance for housing that allows people living with AIDS to avoid isolation from the larger community.

▼ **Travelers and Immigrants Aid of Chicago's First Step Program** received a grant for \$1,030,000 to provide assistance to address substance abuse recovery, housing stability, and HIV-related health issues of homeless and low-income people living with AIDS by establishing an innovative housing recovery program. The project draws participants from the Uptown and Lakeview areas of Chicago where the City's Department of Health indicated that there had been 972 and 1,302 cumulative cases of AIDS respectively. HOPWA funds have been used to establish a 15 unit substance-abuse housing recovery program for homeless people living with AIDS that includes case management, a day health program, emergency transitional housing, psychiatric and clinical mental health services, community health nursing, housing resource development and rental assistance, and primary health care. Over the three-year operating period, the grantee expects to serve between 45 and 60 people living with AIDS. Additionally, the grant funds a comparative assessment of different service models employed while working with homeless people living with AIDS who also have substance abuse problems. Through the examination of four models of housing and service delivery based on variables of housing delivery, the abstinence/recovery continuum, and the HIV health status of participants, the grantee is developing predictors of success for various approaches. This information is intended to be used on a national scale for enhancing the delivery of services for people living with AIDS.

Housing Opportunities for Persons With AIDS (HOPWA)
Annual Progress Report
January 1, 1996 - December 31, 1996

Part 1 Summary

Exhibit A - Overview of Accomplishments

The City of Chicago Department of Public Health was the recipient of \$3,394,000[✓] in Formula HOPWA funding for the 1996 fiscal year. An RFP was issued on March 18th for Community Residence Operating Support, Food Services, Home Health Care, Housing Advocacy, and Legal Services/Entitlement Advocacy. Eligible applications were read, scored, evaluated and discussed by members of an independent review panel comprised of PWAHIV/PWAs, other member of affected populations, business persons, and staff and volunteers of community-based and AIDS-service organizations.

The panel ranked all proposals in order of funding preference within each category, as well as made funding recommendations for each proposal. For this funding year, the City approved the allocation of funds to 23 agencies. Some agencies were funded in more than one service area.

Our main objective for this funding cycle of the HIV/AIDS Housing Initiative was to target programs and projects that provided services to low-income persons with HIV-disease or AIDS in Chicago and the surrounding 15 communities comprising the Eligible Metropolitan Area (EMA). [Note: Low income individuals are defined as any individual or family whose income does not exceed 80 percent of the median income for the area, as determined by HUD, with adjustments for smaller and larger families]. Priority consideration was given to homeless PWHIV/AIDS or those who were in imminent danger of becoming homeless.

In FY 94/95 CDPH awarded the AIDS Foundation of Chicago (AFC) and AIDS Housing of Washington a contract to develop a five year comprehensive housing plan for the EMA. The top recommendation for the Housing Plan was the development and implementation of a centralized information and referral system. This has been completed in FY 96.

Our five program objectives were:

- * Maintain a centralized information and referral system that would provide accurate and up-to-date information about HIV/AIDS housing services in the Chicago EMA. The program will be accessible by telephone for a minimum of forty (40) hours each week to consumers and potential consumers of HIV/AIDS Housing services, service providers and members of the public.

- * Provide a minimum of three thousand five hundred (3,500) months of rental assistance to no fewer than three hundred twenty-five (325) HIV/AIDS disabled, low income residents of the Chicago EMA.
- * Provide housing in a community-based residence for an average length of stay of 138 days each for 58 persons;
- * Provide short-term SRO housing for an average of 90 days each for 46 persons;
- * Provide supportive services such as food, home health, and legal/entitlement advocacy services for up to 500 persons.

During the third year of the HOPWA program we have successfully met, and in most cases exceeded, our projected goals for the number of persons to be served.

- * Four community based organizations were identified in the area of Resource Expansion. Chicago House & Social Service Agency, Samaritan Housing/ United Methodist, Children's Place Association, and TIA/Century Place Development/Sutherland Hotel. An additional \$500,000 for Resource Expansion has yet to be allocated. The HOPWA allocations in this service area will provide the following:

Chicago House & Social Service Agency- This project will focus on housing for single men. The agency is in the process of identifying an appropriate sight at present.

The Children's Place Association- will be able to house 3 families with up to 5 members each. The building will also have a day care center which will be able to accommodate 55-60 children. The agency is awaiting its environmental impact approval from the State of Illinois and HUD.

Samaritan Housing/United Methodist- will be able to provide 15 units of housing for homeless individuals infected with HIV/AIDS on the south side.

TIA/Century Place Development/Sutherland Hotel- will use their award to provide 25 apartments as well as an innovative day care program in a south side site. Additional funding for the project will be provided by other funding sources such as Shelter Plus Care.

- * Ten community residences were funded to provide a total of 37,202 days of care. As a result of HOPWA funding we were able to increase the number of beds in the communities of color by 34. Three newly funded providers, (AIDS Care on the city's north side, Interfaith/Vision House on the south side and Omni Incorporated Initiative on the west side) allowed for the increase in the number of clients served as well as the expansion of subsidized housing and supportive services in areas that had heretofore had limited access to these services. Furthermore, it has fostered networking and awareness among service providers in this area.
- * Eight community-based agencies were awarded monies to provide supportive services ranging from home health and food services to legal assistance/entitlement advocacy. This program has been particularly successful due to the collaboration and coordination among all of the HOPWA funded agencies. Inter-agency referrals have created an extremely effective means of service delivery.

A newly funded agency, HIVCO began the provision of home delivered meals and/or groceries to PWHIV/AIDS in the suburban EMA. AIDS Legal Council of Chicago has been able to set up an office at Cook County Hospital (the largest provider medical care to low-income PWHIV/AIDS in the EMA) where clients can access legal services.

- * Four agencies were funded to provide Housing Advocacy to PWHIV/AIDS. The services ranged from connecting clients with landlords with available rentals to providing legal representation for individuals with housing related issues. HOPWA funded advocates also work closely with state and local governments to ensure that Section 8 legislation includes consideration for PWHIV/AIDS.

Healthcare Alternative Systems was newly funded this year to provide housing advocacy to the growing number of Hispanic clients needing this service on Chicago's west side.

Exhibit B - Program Improvements

Barriers

Due to a late start in implementing the centralized housing and referral system, the disbursement of rent subsidies is the most significant challenge facing the Chicago EMA. The HOPWA rental assistance program began assisting clients upon execution of the contract to the AIDS Foundation of Chicago. AFC has implemented a system of equitable distribution of subsidy slots by using epidemiological data of living AIDS cases in the EMA. The funding allows for approximately 6.5 slots per 100 living AIDS cases. The incidence of cases was then divided by community area, and a corresponding number of slots were assigned to each of five partner agencies.

Eligibility requirements which were initially determined in conjunction with the Housing Plan, included having an AIDS-related disability. This ruled out individuals with only an HIV diagnosis. An important component was the ability to develop a plan whereby the client would eventually be able to pay for housing with other resources. The positive aspect of centralized program administration has allowed for coordinating the use of HOPWA funds with Title I short term rental assistance. System integration however, has taken some time.

Solutions

Focus groups were convened during the winter to address some of the inherent problems of eligibility criteria and systems integration. The following changes will be implemented:

- (1) Three tiers of client eligibility will be set forth (Level 1 = disabled by HIV; Level 2 = HIV+ and otherwise disabled; and Level 3 = HIV+, not disabled) to enable all clients demonstrating financial need to obtain assistance if funding allows.
- (2) Case managers will assess clients to establish priority level.
- (3) AFC will closely monitor funding utilization, and may restrict access to level 1 or to Level 1 and Level 2 clients at any time in order to assure that funding will be available throughout the contract year for Level 1 clients.

While clearly acknowledging the advantages and strengths of the new program the focus groups consistently raised two concerns (1) lack of consumer-level publicity and (2) inconsistency among case managers in assessing client need and assisting clients in applying for the program.

To resolve these issues, efforts will be made to actively involve housing advocates at the CBO partner agencies in providing training and technical assistance to case managers on an ongoing basis. To further publicize the program, consumer-oriented marketing materials are being developed to be distributed throughout the EMA.

Housing Opportunities for Persons With AIDS

Community Collaborations to Provide Housing and Related Services for Persons Living with HIV or AIDS

Office of Community Planning and Development
U.S. Department of Housing and Urban Development

Program: The Housing Opportunities for Persons with AIDS (HOPWA) program provides housing assistance and supportive services for low-income persons with HIV/AIDS and their families. Grants are provided: (1) by formula allocations to States and metropolitan areas with the largest number of cases and incidence of AIDS; and (2) by competitive selection of projects proposed by State and local governments and nonprofit organizations. Grantees are encouraged to develop community-wide comprehensive strategies and to form partnerships with area nonprofit organizations to provide housing assistance and supportive services for eligible persons.

Consolidated Planning: All HOPWA formula grants are available as part of the area's Consolidated Plan, which also includes the Community Development Block Grant, HOME Investment Partnerships program and Emergency Shelter Grants. Plans are developed through a public process that assesses area needs, creates a multiple-year strategy and proposes an action plan for use of Federal funds and other community resources in a coordinated and comprehensive manner. Ninety (90) percent of the appropriation is allocated by formula to eligible communities.

Formula Awards: In FY 1998, a total of \$183.6 million is allocated by formula to the qualifying cities for 59 eligible metropolitan statistical areas (EMSAs) and to 29 eligible States for areas outside of EMSAs. Eligible formula areas have at least 1,500 cumulative cases of AIDS, as of March 31, and metropolitan areas have a population of at least 500,000. One-quarter of the formula is awarded for metropolitan areas that have a higher than average per capita incidence of AIDS. HUD uses statistics from the Centers for Disease Control and Prevention in allocating funds.

Competitive Grants: Ten percent of funds are awarded by competition. HUD published the SuperNOFA for Targeted Housing and Homeless Assistance programs in the Federal Register on April 30, 1998 (63 FR 24009) and made available \$20.15 million for the 1998 HOPWA competition. Applications are due to HUD by July 10, 1998 and the application package may be obtained from the SuperNOFA Information Center at 1-800-HUD-8929 or 1-800-483-2209 TTY. In FY97, \$19.6 million was made available and HUD selected 20 new projects, including:

(1) eight grants for **Special Projects of National Significance (SPNS)** which, due to their innovative nature or their potential for replication, are likely to serve as effective models in addressing the needs of eligible persons, including one project that will provide **National HOPWA Technical Assistance**;

(2) seven grants under the **HIV Multiple Diagnoses Initiative (MDI)** which were also SPNS grants that target assistance to homeless persons living with HIV/AIDS who also have chronic alcohol and/or other drug abuse issues and/or serious mental illness. Seven FY96 MDI grantees received additional evaluation funds. MDI projects participate in an evaluation of project accomplishments that HUD is coordinating with HHS. Applications for SPNS and MDI grants can be submitted by States, units of general local government and nonprofit organizations;

(3) five grants in non-formula areas for **Projects which are part of Long-term Comprehensive Strategies** for providing housing and services for eligible persons; applications for this category can be submitted by States and local governments in areas that did not qualify for formula allocations.

Program uses: HOPWA funds have helped many communities establish strategic AIDS housing plans, better coordinate local and private efforts, fill gaps in local systems of care, and create new housing resources. HOPWA funds may be used for a wide-array of housing, social services and program planning and development costs. Eligible activities include, but are not limited to, the acquisition, rehabilitation or new construction of housing units, costs for the operation and maintenance of facilities and community residences, rental assistance and short-term payments to prevent homelessness.

HOPWA may also be used to fund services, such as health care and mental health services, drug and alcohol abuse treatment and counseling, intensive care when required, nutritional services, case management, assistance with daily living, housing information and placement assistance and other services. The eligible activities are subject to certain standards and limitations.

In December 1996, the President's National AIDS Strategy recognized that "maintaining consistent funding for the housing component of the services safety net will continue to be a national priority. Without stable housing a person living with HIV has diminished access to care and services and a diminished opportunity to live a productive life."

Performance Measures. Grantees report on accomplishments under two HOPWA performance measures (the number of short-term/transitional units created; the number of permanent housing units created during their operating year). Grantees may also evaluate their program based on local goals and objectives.

Goals: The program is authorized by statute "to provide States and localities with the resources and incentives to devise long-term comprehensive strategies for meeting the housing needs of persons with acquired immunodeficiency syndrome and families of such persons." Additionally, the

National AIDS Strategy established national goals to end the epidemic of HIV and AIDS and to ensure that all people living with HIV have access to services, from health care to housing and supportive services, that are affordable, of high quality, and responsive to their needs.

Safe, decent and affordable housing is more than a goal. It is a common daily need of each of us as well as a vital component of our common response to HIV.

Secretary Andrew Cuomo

Authorization: The program is authorized by the AIDS Housing Opportunity Act (42 U.S.C. 12901) as amended by the Housing and Community Development Act of 1992 (Pub. L. 102-550, approved October 28, 1992). Funds were appropriated in FY 1992 and for subsequent years. The Department's appropriation for Fiscal Year 1998 provides \$204 million for HOPWA.

Regulations: The program is governed by the HOPWA Final Rule, 24 CFR Part 574, as amended, and the Consolidated Submissions for Community Planning and Development Programs, Final Rule, 24 CFR Part 91, as amended.

For More Information Contact: The Community Connections Information Center at 1-800-998-9999, 1-800-483-2209 (TTY), or by internet at: comcon@aspensys.com; or

The HUD State or area Office or the Office of HIV/AIDS Housing, U.S. Department of Housing and Urban Development, 451 Seventh Street, S.W., Room 7154, Washington, D.C. 20410, or phone (202) 708-1934; TTY 1-800-877-8339, fax: (202) 708-1744. Information on HOPWA and other HUD tools is available on the HUD HOME Page at www.hud.gov/home.html.

Information and other support is available under a National HOPWA Technical Assistance Program operated by AIDS Housing of Washington at (206) 448-5242 or by email at: info@aidshousing.org or at www.aidshousing.org.