FIRST LADY HILLARY RODHAM CLINTON
PEDIATRIC AIDS FOUNDATION "KIDS FOR KIDS"
NEW YORK, NEW YORK
SEPTEMBER 25, 1994

INTRODUCTION

As I travelled the country during the past year visiting hospitals and clinics, nothing touched me more than the sight of too many brave children and families struggling to cope with HIV infection and AIDS. I have seen children who have spent most of their short lives in hospitals -- keeping up their courage through one more blood test, one more procedure. And I have been awed by their refusal to give up. By their hope.

No one has inspired me more with the depth of her own hope and courage than Elizabeth Glaser. Day in and day out -- confronting personal tragedy and her own struggle with AIDS -- she carries on, fights back, and gives new hope to so many others.

Today, Elizabeth and the Pediatric AIDS Foundation, Liz Tilberis and Harper's Bazaar magazine, Donna Karan, Chris and Pat Riley and all of you are giving hope to children living with AIDS, and giving the gift of health to children who will be spared from the disease because of successful prevention and research. What a wonderful way to celebrate our power to have hope and to give hope -- even as we face this terrible disease.

STATISTICS ON PEDIATRIC AIDS

- **HIV infection.** In the United States today, HIV infects 1,300 to 2,000 newborns each year and has become one of the top 10 leading causes of death of young children. As many as 10,000 to 20,000 children in the United States may be infected with HIV.

  Worldwide the numbers are even more staggering. In 1990 alone, 1 million children acquired HIV from their infected mother before or during birth. The World Health Organization predicts that by the year 2000, there will be 10 million children infected with HIV worldwide.

- **AIDS cases.** Through June of this year, over 5,700 AIDS cases have been reported in the U.S. among children less than 13 years of age. Of these, more than 3,000 children have already died.

  And the number of children with AIDS is increasing -- 39% of all AIDS cases among children in the U.S. have been reported in the last 2 1/2 years alone.

- **Orphaned children.** In addition to the children who are infected with HIV, many more are affected by HIV and AIDS. Researchers estimate that 20,000 children in the United States have already been orphaned because a parent has died from HIV infection. This number is expected to reach 125,000 to 150,000 by the end of this decade. Across the world, by the end of the 1990s, 10 to 15 million children will be orphaned by the death of one of their parents through AIDS.

WHAT IS BEING DONE

These terribly sad statistics can overwhelm us. But we must not forget that there are many good and courageous people working tirelessly. The Clinton Administration is committed to investing in this work on prevention, treatment, and research.

- **Research.** Funding for pediatric AIDS research at the National Institutes for Health has increased by over 25% under the Clinton Administration's budgets.

  A recent NIH study that some of you may know about tells us that research produces results. The study has shown that when AZT is administered to HIV infected pregnant women, the rate of transmission to their babies drops significantly -- from one chance in 4 of infection to about one in 12. One in 12 is still tragic. But progress is being made, and this news alone tells us that our investment in AIDS research is worth it.

- **Prevention and treatment.** Yet good research is only half the battle. We must also continue to encourage prevention and to make sure that those children and their families who do have HIV disease get treatment and support services.

  The President has supported a 30% increase in funding for Title IV of the Ryan White CARE Act -- which gives grants for community-based, family-centered care programs. And last year the Centers for Disease Control began a major new prevention initiative targeted at adolescents and young adults.

ELIZABETH GLASER AND THE PEDIATRIC AIDS FOUNDATION

Nobody has fought harder and done more in the fight against pediatric AIDS than Elizabeth Glaser. And nobody has fought with such dignity and courage. When Elizabeth discovered that she had contracted the HIV virus from a contaminated blood transfusion after the birth of her daughter Ariel, she could have given up. When she discovered that she had unknowingly passed the virus to Ariel during breast-feeding and then to her son born 3 years later, she could have given up. And when Ariel died of HIV

infection at the age of 7, Elizabeth could have given up. But instead of giving in and giving up, Elizabeth channeled her energy and passion into the fight against pediatric AIDS.

- When Elizabeth helped found the Pediatric AIDS Foundation in 1988, there was no pediatric AIDS research agenda. Since then, the Foundation has raised and invested $13 million in research grants and scholar awards. It has sponsored unique collaborations among government, drug companies, and private research institutions and universities. Its Ariel Project has brought key researchers and clinicians together to find a way to block transmission from an infected mother to her newborn child.

- Elizabeth has had tremendous success in mobilizing private support and getting Republicans and Democrats to put aside partisan bickering and work together against AIDS. She has done this in part because she reminds us that everyone is at risk -- wealthy or poor, black or white. But, more importantly, she has done this because of her enormous tenacity, compassion and intelligence.

CONCLUSION

The fight against pediatric AIDS is not futile. We can improve access to treatment, especially in traditionally underserved African-American and Hispanic communities. We can reach out to our children and teach them about prevention. We can fund research -- to find ways to block transmission, to test new drugs that will lengthen and improve the quality of peoples' lives and, finally, to find a cure for AIDS.

The battle is being fought every day -- by advocates like Elizabeth Glaser and the Pediatric AIDS Foundation, by researchers and doctors, by mothers and fathers, and by so many -- by too many -- remarkably brave and strong children. This is a battle we can win by maintaining hope and working hard. As Elizabeth herself has said, everyone with AIDS is somebody's child. This is a battle we must win for all of our children.

AIDS Foundation

The Pediatric AIDS Foundation

Second Annual

"KIDS FOR KIDS"

DATE:	Sunday, September 25, 1994
TIME:	3:00 to 6:00 pm
LOCATION:	Industria Superstudio, 775 Washington Street
CHAIRS:	**Elizabeth Glaser, Donna Karan, Chris and Pat Riley and Liz Tilberis**

Harper's Bazaar magazine and the **Pediatric AIDS Foundation** are joining forces to bring an extraordinary event to New York City this fall. On Sunday, September 25, 1994, they will be hosting a unique carnival and street fair to benefit the Pediatric AIDS Foundation, an organization co-founded by Elizabeth Glaser, Susan DeLaurentis and Susie Zeegen to fund research designed to confront medical problems unique to children with AIDS. Some of the most talented and exciting artists, designers, sports figures, photographers and celebrities will be donating their time and effort to create an unforgettable afternoon of activities and games for families and children of all ages.

Activities:

STREET FAIR

The street in front of Industria will be closed and tented and a fair consisting of activities and carnival games for children of all ages will be created. Designers, celebrities and other "heroes" will man the booths with such attractions as a dunk tank, hi striker, wheel of fortune, peg toss, face painting and other exciting games. Jugglers, clowns, and other performance artists will wander throughout the carnival space entertaining families. Some of last year's heroes who worked the booths included **Michael Bolton, Tom Brokaw, Michael Douglas, Daryl Hannah, Dustin Hoffman, Ron Howard, Spike Lee, Christopher Reeve, Brooke Shields and Paula Zahn.**

SPORTS - **Captains - Pat and Chris Riley**

One-half of the street fair will be devoted to sports games including football toss, basketball, miniature golf, quarterback challenge, baseball batting and slapshot hockey. Pat and Chris Riley are recruiting sports heroes of past and present to man the booths and pose for pictures and sign autographs. Last year's sport stars included the entire New York Knicks team, Tony Campbell, Donna De Varona, Joe Frazier, Rod Gilbert, Keith Hernandez, Denis Potvin and JoJo Starbuck.

HEROES - Captain - Diane Von Furstenberg

Diane Von Furstenberg will spearhead the effort to enlist celebrity participation. The street fair will be overflowing with a stellar cast of celebrity heroes and their families.

PHOTOGRAPHY - Captain - Fabrizio Ferri

Fabrizio Ferri is organizing world famous photographers to take family portraits of guests in a specially designed studio at Industria. Families will take home a polaroid shot but will receive by mail soon after a beautifully developed print taken by one of the prominent photographers. **Mary Ellen Mark, Francesco Scavullo and Bert Stern** were among the photographers who participated last year.

ART - Co-Captains - Jennifer Bartlett and Robert Rosenblum

An art studio will be set up inside Industria where children will join with distinguished New York artists recruited by Jennifer Bartlett and art historian Robert Rosenblum to paint giant murals to be donated to the pediatrics wards of hospitals in the city. Paper will also be laid out on tables enabling children to create their own smaller drawings. Last year's roster of artists included **Francesco Clemente, Red Grooms, Roy Lichtenstein, Brice Marden, Kenny Scharf and Frank Stella.**

FOOD - Captain - Brian McNally

The upper level of Industria will house a large food court, where some of New York's best restaurants will provide a sampling of their finest cuisine. Restaurant owner Brian McNally will be organizing the restaurants, all of which will be serving food that will be particularly appealing to children. **"44," Cafe Luxembourg, Coco Pazzo, Le Madri, Odeon and Tribeca Grill** were among the many restaurants who participated last year.

PRIZES - John and Dolores Eyler

Wonderful prizes for children of all ages will be donated by leading toy companies for winners of various games. With the world's most beloved toy store at the cornerstone of this effort, F.A.O. Schwarz President and CEO John Eyler and his wife Dolores will ensure that no child leaves empty handed. Toys will also be donated to pediatric wards of New York area hospitals.

MODELS - Captain - Sara Foley Anderson

Model editor Sara Foley Anderson will organize the participation of the world's most unforgettable models in support of the Pediatric AIDS Foundation.

DANCE

The dance studio will be rockin' as children will have the opportunity to participate in a fun dance workshop/disco led by an array of professional dance talents.

RAFFLE

"KIDS FOR KIDS" will feature an irresistible selection of prestige raffle items. Families will have the chance to purchase raffle tickets prior to and during the event.

For further information, please contact **Jeaneane Judelson**, Pediatric AIDS Foundation - (212) 545-2435, fax (212) 545-2468.

FOR IMMEDIATE RELEASE

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(212) 744-2004
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HILLARY RODHAM CLINTON TO SERVE AS HONORARY CHAIR AND ATTEND PEDIATRIC AIDS FOUNDATION SECOND ANNUAL "KIDS FOR KIDS" CELEBRITY STREET FAIR AND CARNIVAL

-- Sunday, September 25th, 1994 --

New York, NY August (DATE), 1994 -- First Lady **Hillary Rodham Clinton** will serve as honorary chair of the Pediatric AIDS Foundation's second annual "KIDS FOR KIDS" carnival in New York City at Industria Superstudio, on Sunday, September 25, 1994. Mrs. Clinton plans to attend the event and man one of the carnival booths herself. **Harper's BAZAAR**, Hearst Magazine's fashion monthly will underwrite the event and **Liz Tilberis**, editor-in-chief of Harper's Bazaar, will co-chair the event with **Elizabeth Glaser, Donna Karan and Chris and Pat Riley**.

The Pediatric AIDS Foundation KIDS FOR KIDS, a festive street fair and carnival which will raise money for pediatric AIDS research, promises to be an extraordinary event bringing together a stellar cast of artists, designers, sports figures, photographers and celebrities, all whom will be donating their time and effort to this worthy cause. For the event, the street in front of Industria will be transformed into a whimsical cornucopia of carnival games and special activities.

Notable celebrities, news broadcasters and designers, organized by "Hero" Captain **Diane Von Furstenberg**, including **Michael Bolton, Tom Brokaw, Katie Couric, Diane Sawyer, Ethan Hawke, Mike Meyers, Phil Donahue, Marlo Thomas, Todd Oldham, Ralph Lauren and Miss America 1995**, will become "heroes" for the day, running the booths with such attractions as dunk tanks, hi striker, wheel of fortune, peg toss, face painting and other exciting games. Jugglers, clowns, and other performance artists will also entertain, engaging participants and passerbys alike. **Sara Foley Anderson**, Harper's BAZAAR Model Editor, has enlisted some of the most sought after fashion models in the world including **Veronica Webb, Natane, Carla Bruni, Elle MacPherson** and many more. They will lend a hand at the games booths and sign autographs.

In addition to a carnival setting, the Industria environment will offer a sporting format, highlighted by the attendance of the **New York Knicks**. **Pat and Chris Riley** will organize sports games including baseball batting, miniature golf, basketball, football toss and slapshot hockey. The sports area will also feature a special interactive sports exhibit. In addition to the New York Knicks team, the sports line-up includes **Mickey Mantle, Red Holtzman, Keith Hernandez, Rod Gilbert,**

Jarrod Bunch and many other athletes. Family portraits will be taken by some of the most internationally recognized photographers such as **Patrick Demarchelier, Arthur Elgort** and **Fabrizio Ferri and Jeanne Moutoussamy-Ashe**, while children will be encouraged to join some of New York's most distinguished artists in the Art Room, organized by **Jennifer Bartlett** and **Robert Rosenblum**. Noted artists including **Roy Lichtenstein, Red Grooms, Frank Stella, Kenny Scharf, Brice Marden, Chuck Close** and others will paint side-by-side with children to create unique murals to be donated to pediatric AIDS wards in city hospitals.

Cowboys and cowgirls from **Denim & Diamonds** will lead a country-western jamboree as they teach the kids to line dance and two-step in the dance room. A food court, organized by **44 at the Royalton's Brian McNally** will take over the upper level of Industria and feature a variety of specialties donated by such acclaimed New York restaurants as **Arcadia, Mesa Grill** and **Matthew's**. The restaurants will also offer a sampling of delicious dishes made especially with children in mind. After playing at the carnival booths, children will be able to choose from a selection of prizes donated by leading toy manufacturers, gathered by Prize Captains **John and Dolores Eyler of F.A.O Schwarz.** All additional prizes will be donated to children with HIV/AIDS. **United Airlines** is the official airline of the Pediatric AIDS Foundation.

The Pediatric AIDS Foundation was co-founded by **Elizabeth Glaser, Susan DeLaurentis** and **Susie Zeegen** in 1988 to fund basic bio-medical pediatric AIDS research. As the leading national organization confronting medical problems unique to children infected with HIV/AIDS, the Pediatric AIDS Foundation offers hope to children living with this disease. "The extraordinary support from Harper's BAZAAR through time, energy and financial commitment means so much to me, and to millions of others. Harper's BAZAAR is helping to bring hope not only to my family, but to so many children and families living with HIV/AIDS," said Elizabeth Glaser, Co-founder. Since it's inception, the Foundation has raised over $25 million to fund research, as well as their Emergency Assistance, Parent Education, and Student Intern Programs. Says Harper's BAZAAR editor-in-chief Liz Tilberis, "With a disease that will account for more years of productive lives lost before the age of 65 than all forms of cancer combined, the need for research is crucial. Harper's BAZAAR is truly proud to sponsor such a talented team effort to raise the resources necessary to pushing critical research forward."

Under the keen editorial direction of Ms. Tilberis, Harper's BAZAAR has received widespread praise since its relaunch in September, 1992. Harper's BAZAAR touches the lives and influences the decisions of millions of women in the United States and overseas. The magazine is published in Great Britain (as Harper's & Queen) and through Hearst Magazines International, nine other editions of the magazine are published in Europe, Asia and Latin America.

Pediatric AIDS Foundation

UPDATE: SPRING 1994

This is a special Update. The foundation has been in existence for over five years, and we want to share some of our accomplishments with you. We also want to introduce you to Art Ammann. He is PAF's Director of Research and heads our Scientific Advisory Board. We couldn't do what we do without him. Art's credentials are impressive-- at the University of California he was Director of the Clinical Research Center and Pediatric Immunology. At Genentech he was Director of Clinical Research, and was one of the first doctors to identify AIDS in children. These are only to be topped by knowing him and working with him in person. We asked Art to say a few words in the Update about what PAF is accomplishing from his point of view. Again, we thank all of you for your continued support.

Susan DeLaurentis Elizabeth Glaser Susie Zeegen

This February we reached an important time in the brief history of the Pediatric AIDS Foundation. After five years of supporting research it was time to reflect and examine. We invited a special group of individuals to our 10th Think Tank entitled "PAF: A Vision for Our Future." These were individuals we could trust to be critical, analytical and imaginative. Their task was to review our progress and programs. It was a time when all aspects of what the foundation does was discussed.

Their analysis and recommendations were clear. The foundation has had an influence beyond its size. Our ability to remain focused is part of the success. The other part is the personal interest of the Co-founders and staff in the research, the scientists, the Think Tanks and the Workshops. The Pediatric AIDS Foundation is not just supporting research, it is intent on finding solutions to critical unanswered questions. PAF's ability to work closely with advisors and researchers, to develop cooperative research and to remain focused is unique in the scientific community.

The challenge for the future is to stay focused. Future research priorities were carefully ordered. A call for continued support of basic investigator initiated research was made. The need for a highly visible Pediatric AIDS Foundation Scholar Program was emphasized to attract and retain the brightest and most innovative young researchers in pediatric AIDS. All our reviewers felt that support for targeted, directed research projects, like the Ariel Project, was essential. The impact of the foundation over the past five years has been dramatic. We look forward to the future with excitement and anticipation as we search for answers.

Most sincerely,

Art Ammann, M.D.
Director of Research

Research produces results. . . the recent results of the NIH study 076 revealed that when AZT is administered to HIV infected pregnant women, the **rate of transmission to their newborns drops** significantly. These results will have an impact on the pediatric and adult communities. But many **questions remain** -- Why do some newborns still become infected? How do we make treatment available to all HIV infected individuals? How do we halt the disease progression in those already infected? **Research must continue** to provide solutions to remaining problems.

Warner Bros. sponsored one of **New York's hottest events to benefit PAF**: the opening of their flagship **Warner Bros. Studio Store**. Warner Bros. helped PAF raise over $150,000 — through ticket sales and the receipts from all merchandise purchased on opening night — and helped raise awareness with an event that attracted great media attention.

As part of their 20th anniversary celebration, **PEOPLE Magazine** has kicked off an exciting year-long charity campaign, entitled **PEOPLE First**, of which PAF is honored to be one of 3 charity beneficiaries. PEOPLE First is an extension of PEOPLE Magazine's efforts to **educate** as well as **entertain** its readers, and will be helping PAF in a variety of ways.

A creative and caring project is the **Kids + Kids = Kids Club**, a group of 6 year old school friends who, wanting to **reach out and help other kids**, got together to work on crafts which they sold during the holiday season, donating $300 in proceeds to PAF.

We also want to share with you some of what PAF has accomplished in its first five years as a result of your support.

- **Research Grants and Scholar Awards**: PAF has funded 171 researchers around the country working on investigator initiated research projects that are in the areas our Think Tanks have determined to be critical to children with HIV infection. To date we have funded $13 million in research grants and scholar awards.
- **Ariel Project**: We have led the way in cooperative, directed research with our 3 year ground breaking *Ariel Project for the Prevention of HIV Transmission from Mother to Infant.* This project, with an annual $3 million commitment, has the potential to create a world in which no additional children will be born with HIV.
- **Parent Education Program**: 70,000 units of this program, "HIV/AIDS: A Challenge to Us All," consisting of 2 videos and a guide book, have been distributed in English or Spanish, without charge, to PTAs, school systems, educational organizations and religious groups nationwide. This program, for parents of preschool and elementary age children, was generously underwritten by the Sega Charitable Trust.
- **Emergency Assistance Grants**: Since this program's inception, PAF has funded 268 grants (totaling over $1 million) to help hospitals and health care facilities address unmet emergency needs for their pediatric AIDS patients, such as transportation, child care, medical equipment and meal vouchers.
- **Student Intern Awards**: To encourage young people to enter the field of pediatric AIDS, this program allows students to spend up to 8 weeks per year working with clinicians and researchers known for their work in pediatric AIDS. PAF has funded 102 Student Interns in 16 states.
- **Think Tanks and Workshops**: PAF has held 10 Think Tanks, 6 One Day Workshops and 2 National Pediatric Research Meetings providing a basis for unique collaborations among members of government, drug companies, private research institutions and universities. These meetings focus on specific issues affecting children with HIV/AIDS.

The Pediatric AIDS Foundation's ability to speak out on many issues surrounding HIV has helped to educate thousands of Americans about how the virus is and is not transmitted, that AIDS is a preventable disease, and that people infected with this virus need and deserve support and compassion.

Printing courtesy of Wolfer Printing • Design courtesy of Parkin Design • Folding courtesy of Roger's Bindery

PAF's phone number is (310) 395-9051. To make a credit card donation call 1-800-488-5000.

This is

Pediatric AIDS Foundation

Hope for Children with AIDS

Pediatric AIDS Foundation
1311 Colorado Avenue
Santa Monica, California 90404

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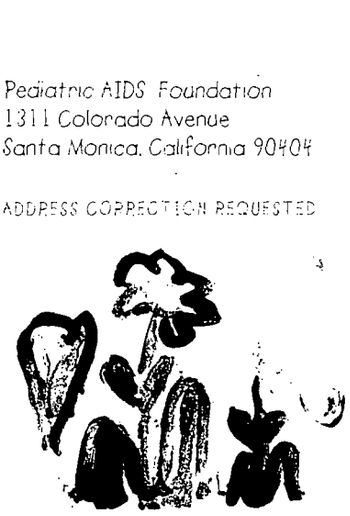

Pediatric AIDS Foundation Programs

Think Tanks and Research Grants

When the Pediatric AIDS Foundation (PAF) was founded in 1988, there was not a pediatric AIDS research agenda. From the beginning, the foundation knew things had to be done quickly and innovatively. The primary goal of PAF became to identify this agenda, establish priorities and fund research. Since its inception, PAF has sponsored nine Think Tanks, bringing together not only the brightest minds on the cutting edge of pediatric AIDS research, but creative minds from other disciplines as well. Doctors from the NIH, the CDC and private industry participate alongside researchers from academia. Think Tank topics have included basic pediatric research priorities, growth and nutrition, opportunistic infections, mucosal immunity and maternal-fetal transmission. The conclusions are used to develop PAF's research priorities which are then funded through our grant awards program. Information of our pediatric agenda is also distributed to applicable government agencies and legislators for action on the federal level.

PAF's Think Tanks and research grants have a direct relationship. Our funding cycles are determined by the outcome of each Think Tank. First, an area of pediatric AIDS research which has critical, unanswered questions is chosen. Then, key people in that area are invited to spend a weekend at our Think Tank, sharing ideas and thinking creatively of ways to find answers. The group prioritizes the steps to be taken. Form this, an RFP (Request for Proposal) is developed and sent to researchers around the world. Scientists then submit grant proposals which are reviewed by PAF's scientific committee. The proposals are scored on scientific merit, and funding is awarded based on scores, the goals of the foundation and the amount of money PAF has available.

> I write to extend my gratitude for one of the most invigorating scientific meetings I have ever attended. The level of interchange was galvanizing. Your insistence on a multi disciplinary approach led to a spontaneity and creativity which I have seldom encountered. I hope that you will continue to recruit the best scientific minds, many of whom are not presently investigating pediatric AIDS. If you can convince these investigators to lend a portion of their talents to the problems of pediatric AIDS, then you will win. I believe that you are on the verge of seeing a logarithmic expansion of results. Science can indeed bring hope.
>
> --Margaret Hostetter, M.D., Associate Professor of Pediatrics and Microbiology, University of Minnesota

For additional information, or a complete list of research grants which have been awarded, please contact PAF.

The Ariel Project for the Prevention of HIV Transmission from Mother to Infant

In February 1992, a Think Tank was held to define priorities for the prevention of HIV transmission from mother to infant since virtually all new cases of pediatric AIDS are from an infected mother passing the virus to her newborn. Out of this, *The Ariel Project for the Prevention of HIV Transmission from Mother to Infant* was conceived. This project is named after Elizabeth Glaser's daughter, Ariel, who died of HIV infection at age 7.

Unprecedented in its scope, *The Ariel Project* is a "Mini-Manhattan project," bringing together key researchers and clinicians collaborating with a single goal of finding a way to block transmission.

The Pediatric AIDS Foundation has committed $3 million a year for three years to fund this project. The director of the project is Arthur J. Ammann, M.D., an exceptionally experienced pediatric AIDS investigator. He has been active in the field of AIDS since 1981, and involved with PAF since its inception.

An Outside Board of Scientists works with the core group of investigators to define the necessary specific aims, determine the validity of the proposed approaches and the significance of results and future directions. This board is composed of individuals who have expertise in specific areas of the project, but who are not funded by the project. These people are recognized for their ability to direct new ideas in areas where creative thinking is required. Funding of this unique project started in September, 1992.

The Pediatric AIDS Foundation Emergency Assistance Program

The Emergency Assistance Program supplies hospitals serving significant pediatric AIDS populations with funds to address their unmet, yet critical, needs.

Presently we are serving close to 100 hospitals around the country with grants up to $6,000 each. Requests may range from funding a partial salary for an extra nurse or social worker, to a needed crib or stroller or piece of medical equipment. This program may also provide transportation funds to help children reach their AIDS treatment centers and not miss appointments due to lack of car fare. A "discretionary fund" is available as well enabling hospital staff to purchase badly needed clothing or food for children who are to be discharged.

This program serves a wide population nationwide. It is a program that every hospital seeing children with AIDS feels is critically needed.

Pediatric AIDS Foundation Student Intern Awards

The goal of the Student Intern program is to encourage students to choose a career in pediatric AIDS research or care. Participants may be undergraduates or graduates and must apply through a sponsor who is their supervisor. This sponsor must be recognized for their contributions to the field of pediatric AIDS. The sponsor must indicate the relevance of their program to pediatric AIDS. The program may be oriented toward fundamental research or clinical research and care.

The total of each award is $2,000 for 8 weeks of work training.

Parent Education Program -- "HIV/AIDS: A Challenge to Us All"

The overall goal of the Pediatric AIDS Foundation Parent Education Program, "HIV/AIDS: A Challenge to Us All", is to establish a guideline for a parent meeting within the context of one school or a small community. This program is geared towards educating the parents of elementary and pre-school students; we do this by providing information and guidelines regarding HIV/AIDS.

The kit, which consists of a parent meeting guide book and two accompanying videotapes, was distributed free of charge in 1992, to 50,000 PTAs and other education organizations across the country. In 1993, an additional 10,000 kits were distributed nationwide, as well as 12,000 Spanish kits which were distributed to Latino communities in major U.S. cities. The guide and one of the videotapes gives all necessary information so any adult can set up a parent meeting in their community. The other videotape demonstrates how parents can answer children's questions about HIV/AIDS with age-appropriate responses.

One Day Workshops

Our One Day Workshops Program began when we realized there were many critical issues which could be addressed in a more targeted way than our weekend Think Tank meetings. Many have arisen from questions facing the Ariel Project. The first workshop was held to develop methods for detecting maternal cells in fetal blood. Others have included Long Tern Survivors, AZT Resistance, and Drug Development for Children.

Our main concern for these meetings is that at the end of the meeting we have a realistic action plan.

Just as our Think Tanks result in a RFP being issued, our workshops must have tangible results.

Pediatric AIDS Foundation

September 12, 1994

Ms. Liz Bowyler
The White House
197 OEOB
Washington, DC 90500

Dear Liz:

At the request of Kathie Berlin, I am sending you background information about the Second Annual Pediatric AIDS Foundation KIDS FOR KIDS benefit and family carnival on September 25th. This package includes an invitation, fact sheet, list of Heroes to date, press clips from last year's event, and background information about the Pediatric AIDS Foundation.

The Pediatric AIDS Foundation headquarters in Santa Monica will be sending you their most recent Annual Report as well as other pertinent information and data regarding their funding, research and other related projects.

On Tuesday, our office will fax to you a list of carnival booths, as we understand that Mrs. Clinton would like to select the booth she will be manning during the event.

Please call me if you have any questions or require additional information. I can be reached at 212-545-2435.

I will contact you shortly to discuss this information in greater detail. Many thanks and I look forward to speaking with you soon.

Kind regards,

Jeaneane Judelson
Event Director
Pediatric AIDS Foundation
KIDS FOR KIDS

CO-FOUNDERS: Susan DeLaurentis/Elizabeth Glaser/Susan Zeegen
1311 Colorado Avenue, Santa Monica, California 90404
TEL: (310) 395-9051 FAX: (310) 395-5149

TARGETS for SEPTEMBER 22:

Kathleen Ambrose (Commerce)

Rajan Anand (Agriculture)

Brent Blakely (DOD- waiting for Judy Miller's confirmation)

✓Sarah Dowling (USIA)

Carmen Diaz (Agriculture)

✓Bill Kincaid (Education)

Barbra Leach (DOT)

Tina Thorne (DOD- maybe next week)

Will Wechler (DOD)

✓Lisa Richards (Federal Maritime Comm)

Charles Marcus (Commerce)

Diana Marino

Sharon Kennedy

Rob Murray (DOT)

Why is Pediatric AIDS Research Important?

Infection by the human immunodeficiency virus (HIV) is different in children than in adults. Infected infants get sicker faster, their immune system may deteriorate more quickly, and treatment may not work the same way or may have different complications. Some treatments may not even be available for children until years after they have been tested in adults.

Almost all new children with HIV infection acquire the virus from their mothers. Once they are infected, they remain infected for the rest of their lives. The time that it takes for the virus to produce symptoms or severe illness (AIDS) varies from child to child. Some children may live a very long time without any symptoms of infection at all.

Not all infants born to HIV infected mothers get infected. Without treatment of the mother during pregnancy and the infant after birth, about one fourth to one third of infants become infected. It has been recently shown that treatment of HIV infected pregnant women with Zidovudine (AZT) can reduce the number of infected infants to less than 10%. That still leaves a significant number of infants who will be infected. But progress is being made and these encouraging results demonstrate the success of research in children.

For children who are infected, there are many remaining questions which will not, or cannot, be addressed by research in adults. The developing brain of children is more susceptible to HIV infection. Children do not mature normally and their growth is impaired. Often, children experience more severe infections. Even ordinary childhood infections may be fatal. When children loose their immunologic function, routine childhood immunizations may not be effective. It is necessary to understand why the immune system deteriorates more rapidly in children infected with HIV.

What is the Relationship Between Pediatric Research and Adult Research?

Certain research questions can only be answered in the mother-infant population. For example, will treatment of HIV infected mothers prevent HIV infection of infants? Or, will an AIDS vaccine given at birth to an infant born to an HIV infected mother prevent HIV infection? These and many other questions can only be answered by studying mothers and infants. But answers to these questions may benefit adults as well. If a vaccine were effective in preventing HIV infection of infants, it might provide some clues to the kind of vaccine needed for adults. And the effectiveness of some drugs might be more quickly seen in children whose disease progresses more rapidly than adults. Positive research results are quickly conveyed to all researchers so that the results of pediatric HIV/AIDS research can be applied to as many individuals as possible. Research that the Pediatric AIDS Foundation supports, while focusing on children is of benefit to all.

Pediatric AIDS Foundation

What is PAF? The Pediatric AIDS Foundation (PAF) is a national non-profit 501 (c) (3) organization confronting medical problems unique to children infected with HIV/AIDS. While our office is in Santa Monica, CA, our funds are distributed worldwide.

How is PAF Unique? PAF is focused on creating a future that will offer hope for children with HIV/AIDS. Many organizations are helping children survive on a day-to-day basis by raising money for food, medicine and lodging. PAF, however, is focused specifically on finding medical answers that will bring this hope.

PAF's Primary Goals: Through our *Think Tanks* PAF identifies and funds critically needed pediatric AIDS research around the world. The majority of the funds we raise go directly to researchers. We fund investigator initiated research, as well as the *Ariel Project*, a directed collaborative effort to identify a way to block transmission from an infected mother to her infant.

PAF addresses these additional objectives:

- Providing funds to hospitals around the country which serve children with HIV/AIDS through our *Emergency Assistance Program.*
- Encouraging students to enter the field of pediatric AIDS through our *Student Intern Award Program.*
- Developing and distributing our national *Parent Education Program* for parents of elementary and pre-school age children.

Administration is provided by a small full-time staff, generous volunteers and in-kind donors committed to PAF's mission and growth. PAF's administrative overhead is currently 5%.

The fight against pediatric AIDS is not futile. This is a battle we can win by working together. This is a battle we must win for our children and for ourselves.

The problem we face is urgency. Every month, indeed every day, is critical. Children are dying who could be saved. Children are suffering whose quality of life could be improved. As new drugs are tested, as lives are lengthened, our hope is strengthened.

1/94

CO-FOUNDERS: Susan DeLaurentis/Elizabeth Glaser/Susan Zeegen
1311 Colorado Avenue, Santa Monica, California 90404
TEL: (310) 395-9051 FAX: (310) 395-5149

Worldwide Statistics

- The World Health Organization (WHO) predicts that by the year 2000, there will be 10 million children infected with HIV world wide.
- By the [illegible] 10-15 million children will be orphaned by the death of one of their parents
- During [illegible] months
- It is conservatively estimated that as many as 10,000 - 20,000 children in the U[illegible] with HIV. According to the CDC definition of AIDS, 4,906 cases of AIDS in infants and children under [illegible]
- The [illegible] high as 240 all HIV cases in the U[illegible] other [illegible] population to have HIV.
- Over 6,000 HIV [illegible] during the last year in the U[illegible] children [illegible]
- Over 50% of [illegible] with AIDS [illegible] among children [illegible] to four.
- By the [illegible]
- [illegible]
- AIDS [illegible]

*Data from the National Institutes of [illegible] Control

Some Other Facts to Know About HIV/AIDS

- HIV/AIDS affects children differently than adults. The manifestations of pediatric AIDS include severe infections, opportunistic infections, as well as failure of growth and development. The variety of manifestations that occur in [illegible] AIDS is much larger than [illegible] with HIV [illegible] problem. [illegible] AIDS [illegible] immune system, children [illegible]
- [illegible]
- Children and adolescents with HIV/AIDS still suffer from [illegible] of this disease.
- When you have a child with HIV/AIDS you almost always have a family with HIV/AIDS. An infected father or mother can transmit the virus to their partner through sex or sharing contaminated needles. Then an infected mother can pass the virus to her newborn in-utero or during childbirth.
- Children and adolescents with HIV/AIDS frequently have difficulty in getting access to diagnosis and treatment [illegible]

LIFE STYLE / COMICS / TRENDS

SECTION E

WEDNESDAY
MARCH 21, 1990

VIEW

Los Angeles Times

A Star in the AIDS War

Elizabeth Glaser has become an unlikely but premier lobbyist in the campaign against a killer

By GERALDINE BAUM
TIMES STAFF WRITER

WASHINGTON—This would be the happy time in Elizabeth Glaser's life if it were not the saddest. She is immersed in the flow of life and having a colossal effect on the world around her, yet this intense, driven woman and her family are fighting AIDS.

"If I didn't have AIDS, if I hadn't lost my daughter to it, if my son didn't have it, if my life wasn't so sad, I would be very fulfilled by what I'm doing," says Glaser, 42.

"I'm realizing my highest potential right now. I am able to communicate about something that I think is important way beyond the scope of my own life."

Even though this wealthy wife of actor/director Paul Michael Glaser is atypical of people confronted by Acquired Immune Deficiency Syndrome—she is not poor, not a minority, not an intravenous drug user, not gay—she has emerged as the most powerful person pressing Washington for more money to fight the epidemic.

"She is the premier lobbyist on this issue now," says Tom Sheridan, whose AIDS Action Council is the largest lobbying group for federal AIDS legislation. "In fact, the thousands of people we represent could all gather under the Capitol Dome and not get half the attention that Elizabeth Glaser gets when she comes to town."

Most AIDS activists simply do not have the cache to go right to then-President Ronald Reagan as Glaser did two years ago when she decided something was wrong with a world that didn't pay enough attention to children dying of the disease.

Most AIDS activists do not begin a day in Washington with ABC's Joan Lunden and end it with ABC's Ted Koppel. They cannot plunk down comfortably in the offices of U.S. senators such as Howard Metzenbaum of Ohio and Orrin Hatch of Utah. Congressmen's wives do not host lunches for them and cry at their compelling stories. And when other AIDS advocates testify before congressional committees, as Glaser did last week, they do not anger the First Lady.

That Elizabeth Glaser is not like most people threatened by this disease is precisely why she has been so effective in Washington, where deep pockets and

Please see GLASER, E6

ALEX STEPHENSON

Elizabeth Glaser: "If I didn't have AIDS, if I hadn't lost my daughter to it, if my son didn't have it, if my life wasn't so sad, I would be very fulfilled by what I'm doing." At left, Glaser and Susan De Laurentis on their way to a meeting in Washington.

GLASER

Continued from E1

glamour go a long way in impressing the powerful.

But while the Hollywood glint has propelled Glaser into an influential spot in the federal bureaucracy, that alone cannot be credited for her success. It has come from a combination of her husband's celebrity, her own determination and the appalling reality of her story.

Glaser contracted the HIV virus that causes AIDS in 1981 from a contaminated blood transfusion after the birth of her daughter Ariel.

During breast-feeding, she unknowingly passed the virus to her daughter, and then passed it to her son, born three years later. Ariel died in 1988. Elizabeth and her son both test HIV-positive, but so far show no symptoms of AIDS. The family continued to try to keep their tragedy private—even after Elizabeth had begun traveling to Washington on behalf of AIDS causes in early 1988.

But then in August, 1989, a year after Ariel's death, the Glasers learned that a national tabloid planned to publish their story. Fearful of distortion, they went to the press themselves.

"If the [tabloid] did anything good, it forced Elizabeth's hand and all the horrible things we all worried about happening didn't happen," says Susan Zeegen, a longtime friend who along with Glaser and another friend, Susan De Laurentis, founded the L.A.-based Pediatric AIDS Foundation two years ago. "Her story has raised enormous awareness and a lot of money too. And all her friends stuck by her."

Joel Johnson, Metzenbaum's legislative director, tries to explain why people in Washington listen to Glaser: "She simply is not like most people who come here, make a case and then go home in hopes that everybody will do the right thing. She doesn't let go of a contact or anybody she can talk to."

AIDS advocates have expressed concern that Glaser's impressive pitch for pediatric AIDS funding—there are 2,055 children younger than 13 who are known to have the disease—might distract politicians from the problems of the other 120,000 people who have AIDS, and who, unlike children, are controversial back in the district.

"Who is going to vote against Elizabeth Glaser?" asks Sheridan of the AIDS Action Council. "She has the public image that members of Congress respond to. Believe me, I've been lobbying for seven years and I can't call members of Congress at home. 'Nightline' isn't interviewing me. She has a lot of power and it's important how she uses it."

Glaser says she tries to "carry this mantle" responsibly. In every speech, every interview, every casual conversation, Glaser says she is not lobbying (she even scoffs at the word, saying it implies she gets paid for her work, which she doesn't) for children alone.

"Every person with AIDS is somebody's child," she lectures a reporter. "AIDS is not a political issue. It's a virus and it kills people, no matter who they are."

During a congressional budget hearing here last week, Glaser called on the federal government to spend $70 million more in 1991 on pediatric AIDS research and care but emphasized that money must not be allocated at the expense of other AIDS programs.

"The overall AIDS budget must have what it needs and within that umbrella a pediatric budget must be identified," she testified. "But the pediatric dollars must not be taken from other AIDS programs already under-funded."

There is an urgency in her voice and an intensity in her stare that belie a warmth she exudes.

To be with her is to wonder: What was it like before tragedy swamped her life?

"Paul Michael Glaser and his beautiful wife were like the Ken and Barbie of Hollywood: gorgeous, successful, loving, great friends, great fun, very private, very consumed with each other," says Zeegen.

And now Elizabeth Glaser is completely consumed by a great struggle for life—marshaling her friends and family to raise money, almost $3 million so far, for the Pediatric AIDS Foundation, flying off to Washington, putting the squeeze on politicians, talking on the phone, making connections and finding new ways to make the world realize that the worst thing that can happen to a mother has happened to her—she lost a child—and no one else should have to face that, particularly not her again.

"Sometimes Elizabeth will be off to Washington and she'll say, 'They want the victim-mother from Hollywood,'" Zeegen explains, "and short of anything that would be harmful to her children and her husband, she's not proud, she'll go out and do it."

It is 8:30 in the morning and a limousine carrying Elizabeth and Paul Michael Glaser and their entourage zooms past the sandstone and marble monuments of Washington to Capitol Hill. Elizabeth and Susan De Laurentis have just appeared on "Good Morning America" and are frenetically reviewing their performances.

"You we're *greeeeeeeeat*," Elizabeth squeals at De Laurentis, slapping her the high five and dissolving into laughter. Then, like a giddy school teacher, Elizabeth points out the sites to Paul, who is sleepily watching the landmarks whiz by.

Although Elizabeth Glaser and De Laurentis have been charging around Washington for two years in an effort to jolt this town into action to help AIDS-inflicted children and families, this is the first time Elizabeth is testifying at a congressional budget hearing before an inferno of television lights.

And this is the first time she has brought Paul along for an appearance.

"This is really big," Elizabeth keeps saying. "Everyone will be there."

Actually, the hearing room is jammed with reporters and pediatric AIDS experts, who are also to testify. But few congressmen show up. Only the two California members of the nine-member Budget Committee are seated on the wooden dais. Glaser doesn't seem dismayed. In fact, she seems thrilled to finally have an audience to present a substantive look at the issues.

Paul is a reluctant accomplice. "I am here to support my wife," he says tersely, the private man annoyed that he is being asked to expose his deepest pain. "I'm the supporting team."

And yet, while Paul is the Hollywood star the cameras have come to gawk at, this is Elizabeth's show. In Washington, among the bureaucrats and politicians, she is the star.

A small, thin woman with green eyes and frosted hair cut in a fashion she admits has been out of style for years, Elizabeth blends well into conservative Washington. She wears a green and black print dress, flesh-colored stockings, low black heels and the requisite string of pearls.

The budget hearing lasts hours but the media stays only long enough to hear the Glasers' testimony. While Paul talks, Elizabeth never takes her eyes off him. His delivery is dramatic and moving.

"I know there are no guarantees," he says, "My family is doing the best they can in a most difficult situation."

Elizabeth is next. Although she had hoped to avoid tears, her voice breaks as soon as she begins talking. "No mother ever really believes her child is going to die," she says tearfully. "I didn't."

After their testimony the Glasers are chased down the halls of the Rayburn Office Building by a media swarm and they submit to a series of interviews in U.S. Rep. Barbara Boxer's crowded office.

It soon becomes apparent that one of the important sound bites of the day will be Elizabeth's comment at the hearing that the Bushes need to get more involved in fighting the epidemic. Elizabeth explains that she had asked to have Mrs. Bush follow in Reagan's footsteps and make a public service announcement about people not discriminating against children with AIDS. But Elizabeth has not received a response from the White House. Later, word comes back from Mrs. Bush's press office that the First Lady feels sideswiped by the Glasers' remarks. "Mrs. Bush is going to hate me, I know," Elizabeth says, "but what I'm saying is important—we have to raise awareness and the Bushes are among the few people who can do it." And in all her interviews she continues to press the need to get the First Lady "on board."

Later, Elizabeth Glaser and De Laurentis begin a marathon of meetings, racing through the labyrinth of federal buildings loaded down with position papers and T-shirts designed by a little boy named Zachary who died of AIDS.

The two women have a series of 15-minute meetings with congressmen or their aides, with whom they deftly discuss the complicated budget negotiations.

Two years ago, Glaser couldn't have found her way from the offices of the Senate to the House, she admits, and she couldn't have differentiated among all the acronyms—like OMB (Office of Management and Budget) or FTE (Full Time Equivalent federal employee).

But now she lights up when a congressman explains to her about "downward negotiations" during budget time and laments how the "peace dividend" will be spent.

"Sometimes, when we're running around like this and talking in this other language I feel like we're in Las Vegas," Glaser says, "and we've completely lost a sense of time and reality."

She also acknowledges that Washington is a fantastic escape: "When I'm here doing business I have to separate myself from emotional reality. I have to close the dam because I can't be effective here if I let all the emotions rule me.

"So I turn it off here and when I go home the emotion I've kept away comes flooding back. It takes two days for me to settle down. We know that now."

By late afternoon of the next day after a lunch meeting with congressional wives, Glaser and De Laurentis regroup in Sen. Metzenbaum's sprawling office, making themselves at home. Sen. Hatch, who sent Glaser flowers after seeing her on television, has an office across the hall and she goes to thank his staff.

Republican Hatch and Democrat Metzenbaum have made a rare bipartisan effort by taking Glaser under their wing. Last year they organized a high-roller fund-raiser for the Pediatric AIDS Foundation in Washington that netted $1 million. The senators provided the premier donors; Glaser brought the stars.

"Are they all using me because of my Hollywood connection?" she asks herself, groping for an explanation for her fantastic success in gaining political access here. "I don't think so. All of these relationships were in place and took a lot of work.

"I have a strong-enough understanding of issues now," she explains on the way back to her hotel, "but sometimes I don't understand the roadblocks we're facing. It's good to have people in these offices to turn to. When I came to Washington that first time, it was Government 101 for me. But it gets easier every time."

Very little in Elizabeth Glaser's life prepared her for her current crusade, but, as she explains it, she was raised to reach out to others.

She grew up in the upper-middle class suburbs of Long Island, the daughter of a businessman and a director of urban renewal.

"I was raised to be politically aware and astute and committed to issues of helping other people," she says. "My mother particularly taught me this. We never talked about those things in fiery debate. My mother simply was an example."

After earning a master's degree in education, Glaser ended up in Los Angeles, where she taught elementary school and fell into what began as a "very L.A." type of romance with Paul Michael Glaser, whom she met while driving down a boulevard. Their life in Hollywood, says Elizabeth, was never glamorous because they chose to be "very private people. It wasn't America's fantasy of Hollywood. I cooked my own meals. I spent a lot of time with my friends. My focus was always children, so when we had our first child I stopped working. I always had wanted to raise my children."

If there was any one moment in which her life was completely transformed, it was not when she found out that she and her children had been exposed to a fatal disease, nor even the day that her daughter died.

Those are surreal memories that she still finds hard to comprehend and discuss.

What remains sharpest in her memory is the day she decided to "change the world." It happened in March, 1988, and she was sobbing on the steps of the hospital where a doctor had just told her that her daughter Ariel had 48 hours to live.

She turned to Lucy Fisher, one of her best friends, and in a haze of tears blurted out, "I have to change the world. I have to see the President. This can't be happening."

An ordinary person would have comforted her pal with a hug, but Fisher was no ordinary friend. She is also the daughter-in-law of Charles Wick, who was Reagan's chief of the U. S. Information Agency and one of his best friends.

"I was so frustrated," recalls Glaser. "I had been fighting for Ari's life, keeping it all quiet from the community . . . yet she was going to die anyway. I felt I had just better do something about it or [my son] and I were also going to die.

"There was so much wrong I didn't know where to begin," she says.

Over the past years, she has not known where to stop.

She will not be "finished," she says, until the government and the doctors take care of the AIDS problem, until there is enough money in the federal budget to root out every possibility and perhaps discover a cure for AIDS.

"You know, there is very little ego involved in all this," she says. "I'm not looking for recognition . . . publicity was the last thing I wanted to have."

But now she is using it to get what she wants:

"One of the things that my life has taught me is that I have nothing to lose by being honest. I don't have the time to play games. I'm also talking about an issue that people really do care about. And until it is handled appropriately, I'm going to keep talking."

National Organizations

[illegible]

For general questions about HIV and to find out about clinical trials:
National AIDS Clearinghouse (800) 458-5231

For statistics regarding HIV/AIDS:
Centers for Disease Control [illegible] (404) 302-2473

[illegible]

Wisconsin Div. of Health AIDS/HIV Program [illegible]

[illegible]

National Association of State Boards of Education [illegible]
Oregon State Health Division (503) 731-4029
Ask for the [illegible]

[illegible]
National Leadership Coalition on AIDS [illegible]

For questions regarding public policy:
[illegible]

[illegible]

For questions about [illegible]
Children with AIDS Project of America [illegible]

For information about [illegible] services for children [illegible]
and families, or for public policy issues:
National Pediatric HIV Resource Center (800) 362-0071

For information about the AIDS [illegible]
The NAMES Project [illegible]

For any questions regarding [illegible]
questions about how the disease [illegible] children differently than [illegible]
or for education materials [illegible]
Pediatric AIDS Foundation [illegible]

If you would like to work with HIV children or
would like to know about AIDS prevention efforts in your area,
call your state or local health department, local hospitals, or your local Red Cross.

1/94

fax

To Jennifer Kline

Org.

Fax 456-9878

Tel.

From

AIDS Policy Center
For Children, Youth & Families

910 Seventeenth Street NW, Suite 422
Washington, DC 20006

Pages 2

Notes Corrected

If you have any questions
regarding this fax, please call
Tel. (202) 785-3564
Fax (202) 785-3579

Pediatric AIDS Foundation

September 13, 1994

Liz Bowyler
The White House
197 OEOB
Washington, D C 90500

Dear Liz,

This information is a compilation of all grants we have awarded in the categories of ARIEL PROJECT, LONG TERM SURVIVORS, and our regular cycle of Research Grants and Scholar Awards.

I am also including our 1993 Annual Report, a pediatric AIDS fact sheet with statistics compiled by the CDC, and one more PAF packet of information.

Thank you so much for your assistance.

Sincerely,

Susie Zeegen

Susie Zeegen
Co-founder

CO-FOUNDERS [illegible] Susie Zeegen
[illegible]
TEL [illegible]

6 1566

cc: Patti
Evelyn

Pediatric AIDS Foundation

Hope for Children with AIDS

We showed Dr R
ARAP re Date

14 March 1994

Mrs. Hillary Rodham Clinton
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Hillary,

This is a follow-up of my earlier letter concerning the Pediatric AIDS Foundation event in New York City. We were so happy when you said you would be the honorary chair and that you plan to attend the event. But now I am writing because, due to complications with dates of the New York Co-chairs, we have changed the date. The event will now be held on September 25th.

Needless to say, we hope this date will work well. We now have underwriting from *Harper's Bazaar*, and already have two $100,000 sponsors.

I know the event will be a huge success -- but nothing means more to me than your participation. It sends so many important messages to so many.

I am hoping to get to Washington the beginning of May. As always, I think you're doing a great job.

With love,

Elizabeth

Elizabeth Glaser
Co-founder

CO-FOUNDERS: Susan DeLaurentis/Elizabeth Glaser/Susan Zeegen
3311 Colorado Avenue, Santa Monica, California 90404
TEL (310) 395-9851 FAX (310) 395-5116

bcc: Evie
Patti

Fall September

THE WHITE HOUSE

March 17, 1994

Elizabeth Glaser
Pediatric AIDS Foundation
1311 Colorado Avenue
Santa Monica, California 90404

Dear Elizabeth:

Thank you for letting me know that the date of the New York event has been changed to September 25th. I am encouraged by your fundraising successes, and will pass on the new date to my scheduling office.

If you are going to be in Washington in May, please let my assistant, Pam Barnett, know and perhaps we can get together for a visit.

It was good to hear from you again.

Sincerely yours,

Hillary

Hillary Rodham Clinton

I think about you all the time. Patti Davis spent a couple of nights with me and we talked about your leadership and example. Hope you feel all our love —

THE WHITE HOUSE

WASHINGTON

September 22, 1994

MEMORANDUM TO LIZ BOYER

From: Jeff Levi, Office of the National AIDS Policy Coordinator

Subject: Q&A on HIV issues

David Harvey of the AIDS Policy Center for Children, Youth and Families has sent a good outline of talking points. There are a few difficult issues that the press might raise:

In light of the findings that giving AZT to pregnant women with HIV dramatically reduces the chances that her baby will be infected, does the Administration support mandatory testing of pregnant women?

The Public Health Service is in the process of reviewing its recommendations for pregnant women with HIV. A meeting on this specific subject was held this week. There are difficult issues to balance in making this policy decision; it is not as simple as mandating a test. If mothers at risk fear that through mandatory testing they might lose custody of their child or be punished in some other way, they might not seek out pre-natal care. That would be a bad solution for both the mother and the child. While a very emotional issue, this is clearly one that the public health professionals and not the political community should resolve.

> Background: Initial studies show that with AZT therapy, transmission from mother to child can be reduced from about 25% to about 8%. But the solution of mandatory testing might, paradoxically, actually reduce the number of high-risk mothers who seek pre-natal care -- for fear that they will be stigmatized for being infected and/or might lose custody of their children after birth. Where quality counseling is offered, 90 percent of pregnant women will accept voluntary testing.

The Public Health Service now supports a program where almost all new borns are tested for HIV in a blinded study. Even though there are now interventions that might delay the onset of disease for the infant, the government has resisted unblinding the results. Why won't the government help these innocent children?

It is certainly the responsibility of the federal government to assist all children with HIV. That is the purpose of Title IV of the Ryan White CARE Act, which provides funding for pediatric care services. The testing of new-borns is a complicated medical and public health issue: the results on new borns tell us more about the mother than about the child. I know that the Public Health Service is constantly re-evaluating this issue in light of the changing science and I think this issue is best left to the public health professionals to decide.

Background: All new-borns are part of a blind screening program funded by the CDC. The testing that is done through this program is designed to teach us about the underlying level of infection among pregnant women in the US. Because the testing is blinded, no informed consent is sought from the mother. The issue that has been raised is whether this should be unblinded so that there can be closer monitoring of the new borns of infected mothers, follwed by early diagnosis and intervention with the new born could occur. The PHS has continued to recommend that these tests not be unblinded for a number of reasons -- including the fact that a positive test from a new born is telling us the infection status of the mother, not the child. Because the infant is carrying the *mother's* HIV antibodies, all infants with HIV-infected mothers will test positive, even though only between one-fourth and one-third of them will actually be infected. Clearly, those infants with infected mothers need close monitoring and follow up. But it has been the consistent recommendation of the PHS that this be accomplished through voluntary testing of the mother -- both for her benefit and for the child's benefit.

Kristine Gebbie, the President's first AIDS Czar, resigned in August. It is now almost October. When is the President going to appoint a replacement?

A search is now under way for a new National AIDS Policy Coordinator. Interviews have been held and, just as importantly, there has been extensive consultation with the HIV community about how this office should be structured and what type of person should fill this important role. In the meantime, this office continues to function -- we have been fortunate to have as interim coordinator Patsy Fleming who is on loan from the Department of Health and Human Services. She has worked on AIDS issues for over a decade; she has made sure that no time is being lost in focusing our national policy. She has already met with the President several times to discuss these issues.

Background: Interviews are expected to be completed next week; a final decision may be forthcoming within a few weeks thereafter.

Cong. Nadler of New York has introduced the AIDS Cure Act, which would mandate a Manhattan Project on AIDS. Why doesn't the Administration support this bill?

While I am not familiar with the specifics of the AIDS Cure Act, I can say that this Administration is fully committed to finding a cure for AIDS and pushing the research agenda as rapidly as possible. We have a new director of the Office of AIDS Research, Dr. William Paul. That office has been given broad new authorities to make budgetary and programmatic decisions and cut through red tape under legislation that this Administration pushed through Congress last year. And just as importantly, we have put money behind this effort: AIDS research (along with other AIDS programs) has been one of very few "investment" areas throughout the government identified as a priority for increased funding in my Administration. In the two budgets since FY 1993, NIH AIDS research funding has increased nearly 25%, more than for any other disease.

Background: The notion of a Manhattan Project that brings together scientists in one place to find a cure is discredited throughout the biomedical community. Better coordination of activities, more discretion in the research budget, etc. are laudable goals -- all of which can be achieved through the new structures created and now in place under the NIH Revitalization Act of 1993. The law requires the OAR to develop a comprehensive plan and budget for all NIH AIDS research. This plan is the first blueprint for the entire NIH AIDS research effort and will determine resource allocation across the NIH. The OAR recently completed the FY 1996 NIH Plan for HIV-Related Research, which was developed through a unique and inclusive process designed to find new approaches. The OAR sought the expertise of the NIH leadership; scientists and researchers from government agencies, academia, foundations, and industry; a number of Nobel laureates; HIV-infected men and women; and AIDS community representatives. The result of this review has been a rededication to basic research -- so that we can learn more about HIV and develop better treatments.

Memorandum to Liz Bowyer

From: Ruby Shamir
Date: 9/20/94
Subj: Pediatric AIDS "Kids for Kids" and "A Time for Heroes"

"Kids for Kids, " New York, N Y; August 18, 1993

This benefit for the Pediatric AIDS Foundation which was held at Industria Superstudio and underwritten by Vogue Magazine raised just over $1 million. Anna Wintour, editor in chief of Vogue magazine, Donna Karan, and Elizabeth Glaser chaired the events whose proceeds went to funding the Ariel project.

Celebrities included Spike Lee, Dustin Hoffman (who also participated in "A Time for Heroes in L.A.), Joan Rivers, Tom Brokaw, Wallace Shawn (actor and playwright), and artist Jennifer Bartlett. For more artist/celebs. see attached article.

"A Time for Heroes," Los Angeles, CA; June 5, 1994

This annual picnic and carnival fundraiser for the Pediatric AIDS Foundation which was held on the grounds of the Brentwood Ranch of Ken Roberts was underwritten by People magazine and the Milken Family Medical Foundation (Michael Milken was able to attend this year for the first time after getting out of jail) . The event, in its fifth year, raised $1.6 million for the charity to fund research and provide care and education.

Celebrities in attendance were: Jack Nicholson and Robin Williams (dunking booth); Candice Bergen and Tom Hanks (Wheel of Fortune); Meryl Streep and Tony Danza (ring toss); Ann Archer (fish pond). Some of the following celebs. brought their kids: Ted Danson, Kim Basinger, Andy Garcia, Dustin Hoffman, Joe Pesci, Jimmy Connors, Oscar De La Hoya, Magic Johnson.

Other celebs. include: Goldie Hawn, Elle MacPherson, Sandy Koufax, Henry Winkler, Mike Myers, Jason Priestly, Michelle Pfieffer, Billy Crystal, Warren Beatty, Richard Gere, Cindy Crawford and more (see articles). O.J. Simpson was there (eight days before the body of Nicole Simpson and her male friend were found).

RY of Level 2 printed in FULL format.

Pediatric AIDS 4 Kids Time & Heroes

Los Angeles Times

8, 1994, Wednesday, Home Edition

SECTIOI ---, Part E; Page 4; Column 3; View Desk

LENGTH: 435 words

HEADLINE: RSVP;
FUN, GAMES, A SERIOUS CAUSE

BYLINE: By BETTY GOODWIN, SPECIAL TO THE TIMES

BODY:

It's more than one colossal Kodak moment, although "A Time for Heroes," the annual picnic and carnival fund-raiser for the Pediatric AIDS Foundation, is most definitely that, too. There were celebrities (categories: sports, movies, television, modeling) everywhere you turned at the former Robert Taylor ranch, now the home of Ken Roberts, in Brentwood on Sunday. Meryl Streep, Andy Garcia and Jimmy Connors would be sauntering across one patch of lawn; Tom Hanks, Elle MacPherson, Sandy Koufax and Kim Basinger across another.

The event, now in its fifth year and underwritten by People magazine and the Milken Family Medical Foundation, was the unusual sort of gathering where paparazzi were barred at the gate, but a phalanx of Polaroid-snapping volunteers encouraged people to pose with their favorite, usually camera-averse, stars.

"It's inspiring," Goldie Hawn said. "Love is very invigorating. If people are happy it gives you energy. This day is about a very positive, loving endeavor."

Over at the dart game booth, Dustin Hoffman was smiling for picture No. 349, or something like that. Next in line was retired Dodger Ron Cey, taking a break from his booth, to grab a family shot with the renowned actor. "Why? He does great work," Cey said.

Although the idea is to have the stars staff old-fashioned carnival booths, the games often get lost in the action. When Jack Nicholson was a no-show for his noon appearance at the dunking booth, no one seemed terribly perturbed.

"Jack usually comes whenever he comes," allowed an event organizer. Robin Williams, who was cast for the 1 p.m. slot, slipped into his Nicholson voice and had the people in line in stitches.

Nicholson finally ambled in about 2, putting on his own show. "Wait till he gets reloaded here now. . . . Let 'er rip," he instructed a ball-thrower hoping to see Mike Myers get dunked. "Man, he's damp," said Nicholson, when the inevitable happened.

Although no one would dispute the display of star power, the event's true centerpiece is Elizabeth Glaser, co-founder of the Pediatric AIDS Foundation with Susan Zeegen and Susan DeLaurentis.

"She is my hero," said Henry Winkler. "I personally love her from my hair to my toes." Glaser, who has been HIV-positive for 13 years, injected the day's

one troubling note when she told the gathering: "For those of you who aren't in my daily life, I've been having a much harder time the last four months." But she added that young HIV-positive survivors she knew gave her hope and strength. "When I'm struggling, I'll remember that miracles happen," she said.

GRAPHIC: Photo, Tom Hanks takes his turn at manning the Wheel of Fortune during picnic and carnival fund-raiser for the Pediatric AIDS Foundation. ; Photo, "Beverly Hills 90210" star Brian Austin Green meets a fan. DONNA GILMARTIN / PAF

LANGUAGE: ENGLISH

LOAD-DATE-MDC: June 9, 1994

10TH STORY of Level 2 printed in FULL format.

June 9, 1993, Wednesday, Home Edition

ECTION: View; Part E; Page 2; Column 3; View Desk

ENGTH: 406 words

EADLINE: 'A TIME FOR HEROES': THE REAL STARS ARE THE KIDS

YLINE: By BETTY GOODWIN, SPECIAL TO THE TIMES

ODY:

Meryl Streep ran a bowling game. Annette Bening took charge at the ring toss. haquille O'Neal instructed kids at basketball. Debbie Allen taught dance. ichelle Pfeiffer and Sandy Koufax took turns heading up a baseball game booth.

The casting didn't always make sense, but you can be sure that the annual ediatric AIDS Foundation "A Time for Heroes" fund-raiser Sunday afternoon was ot your ordinary country fair.

The annual event on the grounds of the sprawling Brentwood home of Ken oberts, the former Robert Taylor ranch, is heavily populated by entertainers nd sports stars. Many come with children and nannies in tow. Among ticket uyers were studio chiefs Sherry Lansing, Peter Guber, Mark Canton, Jeffrey atzenberg and Alan Ladd Jr.

Even Jason Priestly, who attracted a lineup of kids impatiently awaiting a hoto op, was impressed. "Hey, there's Jimmy Connors. Hey, there's Warren Moon. nd Anne Archer. And Michelle Pfeiffer. I get like a little kid out here," he aid. "The turnout is unbelievable."

Magic Johnson, Jack Nicholson, Warren Beatty, Candice Bergen, Billy Crystal, indy Crawford, Richard Gere and Michael Richards of "Seinfeld" (with his hair amed) were among the volunteers explaining the intricacies of games like splish splash" and "fish pond" to the PG-13 crowd. Peter, Paul and Mary, Sheila and Little Richard entertained.

"You can't be a parent and not do it," said Bergen, departing her post at super strike." "I postponed a trip to New York to be here. I'm really grateful or the opportunity to participate."

"I come every year," said Ladd. "It's an extraordinary thing Elizabeth does. xtraordinary woman."

Elizabeth, of course, is Elizabeth Glaser, who received tainted blood during transfusion when her daughter, Ariel, was born and has been HIV positive for 2 years. Ariel died of AIDS, and Glaser's son, Jake, 8, contracted the virus in he womb. Glaser co-founded the Pediatric AIDS Foundation with Susan Zeegen and usan DeLaurentis in 1988.

People magazine and the Milken Family Medical Foundation underwrote the event, and no one seemed to enjoy it more than Michael Milken. His foundation has sponsored the afternoon for three years, but this was his first time

here.

"I had been detained for the last couple of years," said the convicted junk ond king, who was in prison. "It's different being here than having my daughter ell me about it over the phone."

RAPHIC: Photo, Elizabeth Glaser, left, Magic Johnson and Sharon Stone at "A ime for Heroes" fund-raiser for Glaser's Pediatric AIDS Foundation. RANDI ALKIN

ANGUAGE: ENGLISH

DATE: SEPTEMBER 20, 1994

CLIENT:
LIBRARY: NEWS
FILE: CURNWS

OUR SEARCH REQUEST IS:
PEDIATRIC AIDS AND KIDS FOR KIDS AND NEW YORK

UMBER OF STORIES FOUND WITH YOUR REQUEST THROUGH:
LEVEL 1... 11

6TH STORY of Level 1 printed in FULL format.

The New York Times

April 25, 1993, Sunday, Late Edition - Final

ECTION: Section 9; Page 4; Column 1; Styles of The Times

ENGTH: 267 words

EADLINE: EGOS & IDS;
Season For Hope

YLINE: By Degen Pener

ODY:
Last Sunday's welcome spring weather brought out a fun-loving crowd to the Kids for Kids" benefit for the Pediatric AIDS Foundation. Held at the Industria uperstudio and underwritten by Vogue magazine, the event, which was fashioned fter a New York street fair, raised just over $1 million.

Outside, celebrities like Spike Lee, Dustin Hoffman and Joan Rivers worked erchandise and game booths.

Inside, an art room, organized by the painter Jennifer Bartlett, was a big raw, despite its lack of windows. The previous evening, Ms. Bartlett had over d the room with huge sheets of white paper and had drawn a bare-bones map f New York.

Gu ts and their children then added their own visions of the city. The rtist Red Grooms created a collage of Central Park. Tom Brokaw wrote "Marla's ou e" inside an area marked "Future Trump City." The artworks were donated to ediatric AIDS wards around the city.

Wallace Shawn, the actor and playwright, hadn't drawn anything. "I was in harge of keeping order at the materials table," he said, as resolutely t essive as ever.

Had he seen anyone draw anything of interest?

"No," he said. "I was concentrating on maintaining an orderly arrangement of rayons."

Another benefit for children also took place on Tuesday night. Camille Cosby, ove left, the wife of Bill Cosby, was honored at the Plaza by the Northside enter for Child Development, which provides psychiatric counseling and remedial ducation for children in East Harlem. Mrs. Cosby, who last year earned a octorate in education, is working on a film about Winnie Mandela.

ANGUAGE: ENGLISH

OAD-DATE-MDC: April 25, 1993

7TH STORY of Level 1 printed in FULL format.

The New York Times

April 25, 1993, Sunday, Late Edition - Final

SECTION: Section 9; Page 6; Column 1; Styles of The Times

LENGTH: 17 words

HEADLINE: EVENING HOURS;
For Artists Of All Ages

BODY:
A benefit for the Pediatric AIDS Foundation drew supporters to the Industria Super Studio, April 18.

GRAPHIC: Photos: 4:20 P.M.: FRANK STELLA reclined on the floor of Industria Super Studio to draw with JASMIN BARR during the benefit for the Pediatric AIDS Foundation. 4:10 P.M.: RED GROOMS and JENNIFER BARTLETT at the "Kids for Kids" benefit, which raised more than $1 million. Artworks created during the event were donated to pediatric AIDS wards around the city. 5:20 P.M.: ROY LICHTENSTEIN and CAROLYN KOVACS help the cause. Celebrities in art, sports, fashion and entertainment turned out for the event. 6:10 P.M.: ROLANDO BLACKMAN of the New York Knicks and VERNELL, his son. 4:45 P.M.: The Knicks star PATRICK EWING offered some tips to young fans. 6:15 P.M.: The choreographer MARK MORRIS joined a tot in dancing outdoors. 3:30 P.M.: ALEX KATZ collaborating on a drawing with guests at the benefit, which resembled a large street fair. The Pediatric AIDS Foundation helps treat and prevent H.I.V. infection in children. (Bill Cunningham/The New York Times)

LANGUAGE: ENGLISH

LOAD-DATE-MDC: April 25, 1993

Office of the National AIDS Policy Coordinato

Executive Office of the President
750 17th Street, N.W. Suite 1060
Washington, D.C. 20500

Phone: (202)690-5560
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Deliver To: Ex

Sent From: Kathy Lloyd - Soc Forces

Number of Pages: 1 + Cover Fax Number: 202-457-2239 Date: 9/19/94

Message:

Please call upon receipt of this fax.

Thanks,
Kathy

SELECTED CLINTON ADMINISTRATION ACCOMPLISHMENTS FOR HIV/AIDS

* Created the Office of National AIDS Policy (ONAP) to coordinate the national response to HIV/AIDS.

* For FY 1994 there has been a 9% increase in funding for prevention activities at the Centers for Disease Control and Prevention (CDC).

* Since taking office, President Clinton has increased funding by 89.4% for treatment and services through the Public Health Service.

* The National Institute of Health Revitalization Act of 1993 was signed into law to coordinate the monies allocated for HIV/AIDS within the NIH. The appointment of Dr. William Paul as the director of the new NIH Office of AIDS Research.

* The creation of the National Task Force for AIDS Drug Development to streamline drug development and encourage government-private collaborative efforts.

* A Presidential Directive mandating training for the three million federal employees. The training will teach both employees and supervisors about AIDS 101, basic HIV sensitivities, non-discrimination guidelines and progressive workplace policies.

* The appointment of the HIV/AIDS Presidential Advisory Council to continue national community involvement and diverse input on how to implement the National HIV Action Agenda of ONAP.

* President Clinton's Health Security Act will provide guaranteed health benefits for all Americans that can never be taken away, regardless of their HIV - status.

* The launch of the national Preventive Marketing Initiative, which consists of a public information campaign and the creation of a national partners group. The message is aimed at providing necessary information to 18-25 year olds to protect them from HIV infection. In addition, ONAP lent its support to the Country AIDS Awareness Campaign targeted at rural Americans.

* Continued building of strong partnerships between ONAP and various religious, community and business organizations.

* Continued aggressive efforts by the Department of Justice in pursuit of the Americans with Disabilities Act and its relationship to People Living With AIDS.

* Coordinating the HIV/AIDS activities of all government Agencies/Departments more vigorously while encouraging the involvement of those not previously active in HIV/AIDS issues.

* CDC has begun the implementation of the community planning process intended to obtain community input in setting priorities for prevention activities to be conducted locally with federal funding.

Talking Points on Federal Response to Pediatric AIDS

• I am proud to say that the National Institutes of Health is undertaking a full-scale attack on every aspect of pediatric AIDS. This is in no small part due to the tremendous efforts on the part of Elizabeth Glaser -- in getting funding for pediatric research in the early years of the epidemic. We now have new leadership at NIH that is committed to waging a fight for a cure working *with* organizations like the Pediatric AIDS Foundation in developing new strategies for combatting HIV.

• Funding for pediatric AIDS research at the NIH has increased over 25% in the two budgets the Clinton Administration has presented. We inherited a budget of $144 million in FY 1993; it rose to $175 million in the current fiscal year; and it will rise again to $183 million in the appropriations bill that just cleared a conference committee this week. In this two-year period, AIDS research has increased at a faster pace than any other disease -- demonstrating our understanding of the magnitude of the challenge before us.

• Pediatric AIDS research has also been an area where we have seen tremendous pay back on our investment. We now know how to dramatically reduce the likelihood of transmission of HIV infection from pregnant mothers to their children. But we are certainly not resting on those laurels. The NIH funds over 22 pediatric AIDS clinical trials units; there are additional trials under way at other centers. Over 4,200 children were in NIH-sponsored clinical trials last year. Our work will not stop until a successful treatment is found for both children and adults.

• Good research is only half the battle. We also must make sure that those children and their families who do have HIV disease get good treatment -- that they have the chance to take advantage of these new breakthroughs. The federal government has a special role to play in assuring access to care for children with HIV because of the disproportionate impact that HIV has on poor, minority children.

• Our administration has supported a 30% increase in funding for Title IV of the Ryan White CARE Act over the last two years. Title IV is designed to assure comprehensive care systems linked to research for HIV affected children and their families -- through community-based, family-centered care programs. Funding has risen from $20 million in 1993 to $26 million in the new fiscal year starting October 1. We are now funding 49 projects throughout the

country which serve between 45,000 and 50,000 clients.

• There is another group of young people we must be concerned with -- and that is adolescents who are getting HIV at an alarming rate. Over 46,400 -- or 19% of all reported cases of AIDS in the US are among young adults in the 20-29 year old range. That means, given the time lag between infection and becoming sick, that most of them were infected in their teenage years. We as a nation must begin doing something about it. The Centers for Disease Control last year undertook a major new Prevention Marketing Initiative -- a multi-level campaign targeted at adolescents and young adults designed to encourage them to delay sexual activity or, if they choose to be active, to at least be safe. We can, and must, do more in this area -- and I am pleased that the FY 1995 budget about to come to the President for signature will include a $47 million increase in funding for HIV prevention activities at the CDC.

CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION
"The Nation's Prevention Agency"

CENTERS FOR DISEASE CONTROL
AND PREVENTION
Washington Office
202-690-8598
FAX: 202-690-7519

DATE 9/21 **PAGES** 3 + Cover

TO Jennifer Klein

Phone: 202-456-2599

Fax: 202-456-2878

FROM Sharon Kate

Phone: 202-690-8593

COMMENTS/NOTES

Please call to discuss. I have other material you may want to have messengered to you as well. I hope this is helpful.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

AIDS Cases Reported Among U.S. Children

- A dozen years ago, researchers detected the first cases of AIDS in children; in the United States today, HIV infects 1,300-2,000 newborns each year and has become one of the top 10 leading causes of death of young children. Through June 1994, the Centers for Disease Control and Prevention (CDC), the nation's prevention agency, received reports of 5,734 AIDS cases among children less than 13 years of age. And the number of cases among children is increasing: 39% of these total cases have been reported in the last 2-1/2 years.

- Of the 5,734 children with AIDS, 3,100 (54%) reportedly have died. In 1991 (the latest year for which final mortality data are available), HIV/AIDS was the seventh leading cause of death among children 1 to 4 years of age in the United States. HIV/AIDS was the second leading cause of death among black children ages 1 to 4 in Florida, Massachusetts, New Jersey, and New York and the second leading cause of death among Hispanic children ages 1 to 4 in New York (second to unintentional injury).

- Cases of AIDS among children have been reported from 48 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands. Fifty-one percent of the cumulative AIDS cases reported among children are from New York (1,531), New Jersey (522) and Florida (876).

- As with adults and adolescents, children who are members of racial or ethnic minority populations have been disproportionately affected by the HIV/AIDS epidemic. The majority of children reported with AIDS were (non-Hispanic) black (56%) or Hispanic (24%). Nineteen percent of children with AIDS were (non-Hispanic) white, 0.5% were Asian/Pacific Islander, and 0.3% were American Indian/Alaska Native (race was unknown for the remaining 0.2%).

- Thirty-nine percent of children reported with AIDS were diagnosed before their first birthday, 47% were diagnosed between 1 and 5 years of age, and 15% from 6 to 12 years of age. Forty-eight percent of these children were female and 52% were male.

- HIV infection in children is most often acquired through perinatal transmission, i.e., from an HIV-infected mother to her fetus or infant before or during birth. Research has shown that most transmission probably occurs during pregnancy or labor and delivery. HIV infection can also be transmitted through breastfeeding. In the United States, 89% of cumulative AIDS cases were attributable to perinatal

transmission of HIV (and 93% of cases reported in 1993). The majority of mothers of these children acquired HIV infection through injecting drug use (38%) or heterosexual contact (27%).

- Although perinatal transmission accounts for the vast majority of HIV infections in children, a small number of children have become infected through other ways. Before routine screening of the U.S. blood supply began in 1985, some children became infected through blood transfusions or through use of clotting factor to treat hemophilia. Of cumulative pediatric AIDS cases in the United States, children with coagulation disorders account for 4% and children with transfusion-acquired AIDS account for 6%.

- Twenty-seven states conduct surveillance of HIV infection as well as AIDS in children. Through June 1994, these states reported 948 children who are infected with HIV, but have not developed AIDS.

- In addition to collecting data on cases of HIV infection and AIDS and analyzing trends in these data, CDC funds state health departments to conduct surveys of HIV seroprevalence in certain U.S. populations. One of these surveys is among childbearing women. The HIV Survey in Childbearing Women is an ongoing, national serosurvey initiated in 1988. It is designed to measure the prevalence of HIV infection in women delivering infants in the United States and to monitor this rate over time. The survey provides very accurate data for states and health care providers to use in focusing their efforts to provide HIV counseling and testing, prenatal care, and follow-up for women at greatest risk of HIV infection.

- CDC continues to study the course of illness in HIV-infected children and to evaluate ways to prevent serious effects of HIV infection in children. For example, CDC research indicates that the time from infection with HIV to the development of AIDS varies from months to years in children, but on average is about 3 years. It is not possible to predict which children will get sick early and which will survive for a long time before getting sick. Statistical analyses suggest that an estimated one-fourth of perinatally infected children are short-term survivors who are likely to die by age 4 years. The remaining three-fourths are long-term survivors who are likely to survive more than 7-8 years.

- In addition, CDC is currently examining the need to revise its guidelines on preventing *Pneumocystis carinii* pneumonia, the most common serious infection that affects HIV-infected children, especially infants in the first year of life.

- Since the earliest AIDS cases were reported in children,

careful and persistent research conducted with the cooperation of generous and committed families has led up to a recent major breakthrough. An important scientific study has found that we can reduce substantially this deadly infection in the infants of many HIV-infected mothers by using the drug zidovudine (AZT). Recently, researchers have shown that if AZT therapy is given to an HIV-infected woman during pregnancy and delivery, and to the child for a short period after birth, the probability of her child's being infected may be reduced from one chance in four to about one in twelve.

- Investigators found that both mothers and infants tolerated the AZT treatment well, with no significant short-term side effects other than reversible mild anemia (low red blood cell counts) in some infants. The study investigators plan to follow the infants for a number of years because the long-term consequences of AZT therapy are unknown. Researchers will monitor their growth and development and look for any unusual illnesses among them. In addition, they will follow the women in the trial for 6 months after delivery. Longer term follow-up of the mothers is being planned. However, because of the possibility of reducing HIV transmission during pregnancy and birth, women who are or who may become pregnant should know if they are infected with HIV so that specific interventions can be offered early in pregnancy.

- Additional efforts to prevent HIV infection in children must be directed toward preventing infection in adolescents and adults--including childbearing women and their sex partners. CDC has numerous HIV prevention activities directed to the general population, as well as populations at increased risk of HIV infection. For example, CDC is conducting behavioral research under the Comprehensive AIDS and Reproductive Health Education Study (Project CARES) to develop, implement, and evaluate interventions for the prevention of HIV infection and AIDS in women and infants. CDC has also developed a multisite research design and intervention program for the Prevention of HIV in Women and Infants Demonstration Projects to evaluate HIV prevention services in facilities and at the community level. In this project, barriers to prevention and care will be reduced through outreach and the provision of services in nontraditional settings, such as drug treatment centers and homeless shelters.

- In addition to the children who are infected with HIV, many others are "affected" by HIV and AIDS. Researchers estimate that 20,000 children in the United States have already been orphaned because their mothers have died of HIV/AIDS. This number is expected to reach 125,000-150,000 by the end of this decade.

DEPARTMENT OF HEALTH & HUMAN SERVICES

September 21, 1994

Per your conversation with Dr. Lisa Simpson.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Agency for Health Care Policy
and Research
Rockville MD 20852

September 1994

Agency for Health Care Policy and Research (AHCPR)
Clinical Practice Guideline
Evaluation and Management of Early HIV Infection

Dissemination Activities Targeting Pediatric Providers and Caregivers of Children Living with HIV

- In January 1994, Assistant Secretary for Public Health Dr. Philip Lee announced to the American public that they could get free copies of *HIV and Your Child* (in English and Spanish), along with the other guideline materials, by calling the CDC National AIDS Hotline (800/342-AIDS).

- As a result of this promotion and numerous others, 292,729 English language copies, and 59,993 Spanish language copies of *HIV and Your Child* have been distributed.

- The AHCPR worked with the American Academy of Pediatrics to notify most of the nation's pediatricians (47,543 Academy members) of the availability of the clinical guideline on treating children living with HIV, as well as *HIV and Your Child*. AHCPR also notified 30,000 nurse practitioners of the availability of these materials by working with the American Academy of Nurse Practitioners.

- AHCPR formed a partnership with the National Pediatric AIDS Resource Center to distribute copies of the guideline and *HIV and Your Child* through their clearinghouse and network.

American Academy of Pediatrics

141 Northwest Point Blvd
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Elk Grove Village, IL 60009-0927
Phone 708/228-5005
Fax 708/290 5007

April 1994

Dear Colleague:

Primary health care for people living with the Human Immunodeficiency Virus (HIV) can make a difference. Early diagnosis and care are essential. A new information tool for pediatricians and other primary care practitioners is available to help health care providers evaluate and manage patients with early HIV infection effectively and efficiently.

The chairperson of the AAP Provisional Committee on Pediatric AIDS and other members of the Academy served on the federal Agency for Health Care Policy and Research (AHCPR) panel and actively participated in the development of Management and Evaluation of Early HIV Infection. This clinical practice guideline sponsored by the AHCPR and endorsed by the AAP is described in the enclosed brochure.

You may order multiple free copies of the Guideline and the accompanying Quick Reference Guide for physicians to share with your peers. Understanding HIV and HIV and Your Child are for patients and families and may be ordered in quantity for distribution to them. These patient materials are available in both English and Spanish.

The AHCPR Guideline demonstrates that managing HIV in its early stages is not as difficult as it may seem. It contains practical, succinct chapters on selected aspects of early HIV infection to help you develop a regimen of care. It also provides information to share with your patients. Topics include disclosing HIV status, diagnosing specific conditions associated with early HIV infection and coordination of care. There are specific recommendations for women, adolescents and children. Please take the time to review the enclosed material which is available in both English and Spanish. Single copies may be obtained by calling the CDC National AIDS Hotline 1-800-342-AIDS (2437) or you may obtain multiple copies and more information by writing to:

AHCPR HIV Guideline
CDC National AIDS Clearinghouse
PO Box 6003
Rockville, MD 20849-6003

In addition, the Academy has recently developed a compendium of AAP Guidelines on Pediatric Human Immunodeficiency Virus(HIV) Infection. This compendium of AAP policy statements and excerpts from AAP Manuals addresses various topics regarding HIV infection specific to pediatric patients. Included within the compendium are policies on HIV education in schools, pediatric trainees caring for patients with HIV infection, perinatal HIV testing, HIV infection in day care and foster care, athletic participation of the HIV infected patient, administrative policies regarding HIV, preventing transmission of HIV, protecting HIV-infected children, and HIV infected students and school personnel. Copies of the compendium are available through AAP publications (1-800-433-9016) for $9.95 for members ($19.95 for non-members).

As you know, pediatricians play a crucial role in early diagnosis, treatment and care of the HIV-infected child. You are the first line of defense against HIV - for your patients and your community. Men, women and children of all ages, races, and ethnicities are increasingly affected. Statistics show that the rates of infection are increasing most rapidly among women, children, and adolescents. We encourage you to order and make use of the AHCPR guideline Management and Evaluation of Early HIV Infection, the patient brochures, and the compendium of AAP Guidelines on Pediatric Human Immunodeficiency Virus (HIV) Infection.

Sincerely,

Joe M. Sanders, Jr, MD

Joe M. Sanders, Jr, MD
Executive Director
American Academy of Pediatrics

JMS:vku

AMERICAN ACADEMY OF NURSE PRACTITIONERS

Incorporated Lowell, Massachusetts 1985

Administration: Capitol Station, LBJ Building • P.O. Box 12846 • Austin, TX 78711 • (512) 442-4262 • Fax (512) 442-6469
Governmental Affairs: P.O. Box 40013 • Washington, DC 20016

Dear Nurse Practitioner Colleagues:

The American Academy of Nurse Practitioners is assisting the federal Agency for Health Care Policy and Research (AHCPR) in reaching nurse practitioners concerning the recent AHCPR publication regarding HIV management. Primary care for people living with HIV can make a difference. Early diagnosis and care are essential. A new information tool for nurse practitioners and other primary care providers is available to help health care providers evaluate and manage early HIV infection effectively and efficiently.

Management and Evaluation of Early HIV Infection, a clinical guideline sponsored and published by AHCPR.

You may order multiple free copies of this guideline and the accompanying *Quick Reference Guide* for clinicians. Please share these materials with your peers. *Understanding HIV* and *HIV and Your Child* are brochures for patients and may be ordered in quantity. The patient materials are available in both English and Spanish.

Nurse Practitioners play a crucial role in early diagnosis and treatment. You are the first line of defense against HIV -- for your patients and for the public. As you know, people with HIV live everywhere. Men, women, and especially children of all ages, races and ethnicities are increasingly affected. Statistics show that the rates of infection are increasing most rapidly among women, children and adolescents. The good news is that with early diagnosis and treatment, people infected with HIV can remain symptom-free longer.

The AHCPR Guideline will show you that managing HIV in its early stages is not as difficult as it may seem. This guideline provides practical, to-the-point chapters on selected aspects of early HIV infection to help you provide a regimen of care. There are specific recommendations for women, adolescents and children. Please take the time to review the enclosed material. We encourage you to order and make use of the guideline publications. If you wish additional copies, single copies of the set or any part of it, call the CDC National AIDS Hotline, 1-800-342-AIDS (2437). You may obtain multiple copies and more information by writing to:

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

Sincerely,

Judith Dempster, DNSc, NP-C, FNP, President
American Academy of Nurse Practitioners

fax

To Jennifer Kline
Org. Office of The First Lady
Fax 456 2878
Tel. _____

From David Ibarra

AIDS Policy Center
For Children, Youth & Families

910 Seventeenth Street NW, Suite 422
Washington, DC 20006

Pages _____

Notes _____

If you have any questions
regarding this fax, please call
Tel. (202) 785-3564
Fax (202) 785-3579

AIDS Policy Center *For Children, Youth & Families*

MEMO TO: The First Lady
Hillary Rodham Clinton

THRU: Jennifer Kline
Office of the First Lady

FROM: David C. Harvey
Executive Director

SUBJ: Talking Points
Pediatric AIDS Foundation Benefit

DATE: September 21, 1994

CC: Carol H. Rasco
Patsy Fleming

BY FAX: 202-456-2878

Per my phone conversation with Jennifer Kline, attached are talking points for the speech at the Pediatric AIDS Foundation benefit. Please contact me if I can provide any additional information.

I assume you have already covered remarks related to: (1) The White House commitment to AIDS and budget increases for AIDS programs; (2) The White House commitment to helping to provide compassionate care for those individuals and families affected by HIV infection and AIDS and fighting discrimination and stigma; (3) the relationship between AIDS and health care reform; (4) The White House commitment to moving quickly to hire a new national AIDS policy coordinator; and (5) rapidly growing AIDS cases among African-American and Hispanic women who may unknowingly pass the virus to their children if they become pregnant.

Talking Points

1. I am pleased to be here with you today to recognize the work of the Pediatric AIDS Foundation. The Foundation funds vitally needed private sector research to find a cure and find ways of blocking HIV transmission.

AIDS Policy Center *For Children, Youth & Families*

MEMO TO: The First Lady
Hillary Rodham Clinton

THRU: Jennifer Kline
Office of the First Lady

FROM: David C. Harvey
Executive Director

SUBJ: Talking Points
Pediatric AIDS Foundation Benefit

DATE: September 21, 1994

CC: Carol H. Rasco
Patsy Fleming

BY FAX: 202-456-2878

Per your request, attached are talking points that I quickly developed after my phone conversation today with Jennifer Kline. The talking points are brief and to the point. Please contact me if I can provide any additional information on any of the issues mentioned.

I assume you have already covered remarks related to: (1) The White House commitment to AIDS and budget increases for AIDS programs; (2) The White House commitment to helping to provide compassionate care for those individuals and families affected by HIV infection and AIDS and fighting discrimination and stigma; (3) the relationship between AIDS and health care reform; (4) The White House commitment to moving quickly to hire a new national AIDS policy coordinator; and (5) rapidly growing AIDS cases among African-American and Hispanic women who may unknowingly pass the virus to their children if they become pregnant.

Talking Points

1. I am pleased to be here with you today to recognize the work of the Pediatric AIDS Foundation. The Foundation funds vitally needed private sector research to find a cure and find ways of blocking HIV transmission.

2. I also know of the good work of the Foundation and I know of the Foundation's yearly "heroes" benefit that takes place in Los Angeles. All of you are heroes tonight who have come to this event and have donated money for AIDS research. There is no bigger hero that I wish to honor tonight than Elizabeth Glaser who fights with dignity, courage and tenacity. Her work alone has helped so many."

3. I am also pleased to be here with you today following the wonderful news that for the first time, we have made progress in blocking the transmission of the HIV virus. You know better than I the results of a National Institutes of Health research study which has shown that by offering the drug zidovudine -- or AZT -- to pregnant women with HIV infection, that the risk of HIV transmission from mother to child is dramatically reduced. This news alone tells us that our investment in AIDS research is worth it.

4. The task before the federal agencies and The White House is to ensure that this lifesaving treatment is offered to all women with HIV infection who want it. It will require coordination between the various agencies of the Department of Health & Human Services to coordinate outreach, HIV counseling and testing, prenatal care, OB/GYN services, and comprehensive care for women and young women with HIV infection who are pregnant. And it will require the private sector to help us get the word out.

5. And I also know that HIV disproportionately impacts the African-American and Hispanic communities, especially women and children from these communities. We must be sensitive to the cultural issues in providing access to this new promising treatment by building trusting partnerships between providers of services and communities of color where trust may be lacking.

6. And we must not rest on this study alone. NIH and the Pediatric AIDS Foundation must continue to fund studies to assess the safety and efficacy of giving AZT to pregnant women and children over time, and we must carefully counsel women as to their options regarding this new therapy to ensure that all women understand the risks and benefits of this new promising therapy.

7. We must not rest on this study alone. NIH and the private sector must continue to study how to block other routes of HIV transmission through funding vaccine research, behavioral studies to determine what methods of outreach, counseling and testing programs are effective, and other research programs so that we can prevent new HIV infections among children, youth, women and men.

8. We must not rest on this study alone. New HIV infection rates among America's youth is unacceptable and a horrendous failure on our part. We must effectively educate and care for our young people. New HIV infection rates among young gay men are unacceptable and we must address the special needs of this neglected group.

9. Finally, we must not rest on this study alone. In light of this promising new AZT therapy, calls for mandatory HIV testing of all women is not justified. Offering HIV counseling and testing, informed consent, and balanced information about the promising results of AZT therapy for women who may be infected with HIV should be offered to all as a standard medical routine.

10. The real task before all of us today is to discover ways of preventing HIV infection in the first place and to finally discover an absolute cure so that no one has to suffer from diseases associated with HIV infection and AIDS.

MCHB Fact Sheet

Maternal and Child Health Bureau
Health Resources and Services Administration • Public Health Service • U.S. Department of Health and Human Services

Pediatric AIDS

Acquired immune deficiency syndrome (AIDS) in children was first described in 1982 when it became apparent that this then-mysterious disease could be transmitted by blood transfusions or the blood products used to treat hemophilia. Perinatal transmission from mothers infected through intravenous drug use or sexual contact was recognized at about the same time. Initially, it was difficult to distinguish AIDS from the rare and equally puzzling congenital immunodeficiency diseases in children.

By 1984, the numbers of children with AIDS began to escalate, especially in New York City, Newark, and Miami. That year, the Division of Maternal and Child Health (now the Maternal and Child Health Bureau) cosponsored the first National Meeting on Pediatric AIDS which concluded that AIDS did occur in children, that the number of children involved was undercounted in the Centers for Disease Control and Prevention (CDC) surveillance system, and that infected infants and children and their families were subject to discrimination and sometimes barred from basic services.

In 1986, at a second National Pediatric AIDS Meeting, physicians and other health care workers, social workers, and educators shared information about the clinical spectrum and treatment efforts. A new confidence resulted from the increasing knowledge about the etiology and transmission of AIDS. Moreover, it was recognized that most existing approaches to the treatment of children with special health needs were applicable to children with HIV infection.

A third national meeting in 1987, the Surgeon General's Workshop on Children with HIV Infection and Their Families, focused on prevention of human immunodeficiency virus (HIV) infection in children and on the difficulties of caring for children already infected. In addition to summarizing current knowledge about AIDS in children, workshop participants—who included clinical and research physicians, health providers, economists, educators, parents, members of the clergy, and media representatives—presented 82 recommendations for future directions in research, prevention, and services. These recommendations, contained in the workshop report, provide a useful framework for meeting some of the challenges presented by HIV infection in children.

In 1988, the Pediatric AIDS Health Care Demonstration Program was initiated, with funds appropriated under the Public Health Service Act. In 1994, the program is permanently authorized under Title IV of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. The program is administered by the Maternal and Child Health Bureau, which now refers to it as the Pediatric/Family HIV Health Care Demonstration Program, reflecting the fact that projects serve families, not just children, that are infected with or at risk for HIV.

Incidence of Pediatric AIDS

- AIDS is transmitted in several ways: from infected mothers to their infants; through exposure to infected body fluids, primarily blood; and through sexual contact with an HIV-infected partner.
- 4,906 children with AIDS have been reported to CDC through September 1993. About one-third of these cases were reported since 1990 with perinatal transmission the risk factor in 90 percent. The epidemic among children has spread from large metropolitan areas to smaller cities and rural communities, particularly in the Southeastern United States.
- AIDS is already one of the leading causes of death for all children and the ninth leading cause of death among children 1 to 4 years of age.
- 1,167 adolescents with AIDS ages 13–19 years and nearly 13,000 young adults with AIDS ages 20–24 years have been reported to the CDC through September 1993.
- AIDS is the sixth leading cause of death in young people between the ages of 15 and 24 years.
- Women are the fastest growing segment of the AIDS population. The number of women infected with HIV, particularly within communities of color, continues to grow and spread beyond the large urban epicenters to smaller urban and rural settings.

- 40,702 cases of AIDS in female adolescents and adult women have been reported to the CDC through September 1993. Almost one-third of these cases (12,000) were reported in the past year. The majority of women are exposed to HIV through heterosexual contacts, and sexual contact with drug users.
- AIDS is the fifth leading cause of death in women in the United States and the leading cause of death in New Jersey and New York City.

The Pediatric/Family HIV Program

The purpose of the Pediatric/Family HIV Health Care Demonstration Program is to improve and expand the infrastructure of comprehensive care services in order to increase the access of HIV/AIDS-affected women, infants, children, and youth to a comprehensive, community-based, family-centered system of care. As a result of the transfer of the program to Title IV, the focus of the program is further expanded to develop innovative models that link systems of comprehensive community-based medical and social services for the affected population with the National Institutes of Health and other clinical research trials. Funds support innovative strategies and models to organize, arrange for, and deliver comprehensive services through integration into ongoing systems of care and support from appropriate financing mechanisms. The service delivery systems assure the delivery of high-quality care at the appropriate level, with an emphasis on ambulatory care services that may reduce unnecessary hospital stays.

Three categories of projects have been funded: Pediatric AIDS Projects which provide or coordinate comprehensive, family-centered health, social, and support services; Comprehensive Care Consortia with the unique requirement that private sector funding must match public funding; and National Issues Projects which provide information, training, and technical assistance to expand national resource capacity and impact national program development.

In fiscal year 1993, 44 projects were funded in 20 States, the District of Columbia, and Puerto Rico for a total cost of $20.9 million. Thirty-nine of the projects funded were AIDS demonstrations, two were consortia, and three were on national issues. Eighty-four percent of the projects' clients are from poor, minority families with limited access to transportation and housing. Currently, 39 percent are Hispanic and 43 percent are African American. In fiscal year 1994, the program is funded at $22 million.

Program Accomplishments

- The pediatric/family HIV projects have proven to be effective in their ability to organize and improve patient access to a comprehensive system of services. Between 1991 and 1992, the pediatric/family HIV projects have increased the unduplicated number of individual clients served by each project by 87 percent with a total of 28,738 clients served.
- The number of families served more than doubled each year between 1988 and 1990, indicating the program's commitment to maintenance of the family unit in the face of this devastating disease.
- Children in the majority of projects studied were able to participate in clinical trials that gave them access to state-of-the-art treatments. Access to state-of-the-art treatment is provided in coordination with primary medical, social, and family support services which are made available to family members of children served by all of the projects.
- The program has improved the capacity of health and social service professionals, community-based organizations, and families to address the demand of the growing epidemic. In each project, individual grantees have made efforts to strengthen provider capacity within their communities and States through education, training, and peer support.
- A recently completed National Issues Project grant has documented the cost of caring for children with HIV and AIDS, and has proposed reimbursement methodology appropriate to pediatric AIDS financing.
- Projects are identifying HIV-positive pregnant women through outreach, counseling, and testing. These efforts have resulted in earlier identification of both HIV-positive women and HIV-exposed newborns, with appropriate followup care.
- Two national resource centers have been funded by the program. The National Pediatric HIV Resource Center provides information and technical assistance, and has developed curriculum for multidisciplinary training programs for health administrators and care providers. The Institute for Family-Centered Care provides technical assistance to support families affected by HIV and AIDS.

For further information, contact the chief, Hemophilia and AIDS Services Branch, at (301) 443-9051. 1/94

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② 076 DOCUMENTS.

MORE TO COME TOMORROW!

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Table 4. Male adult/adolescent AIDS cases by exposure category and ra[illegible]ethnicity, reported in 1993, and cumulative totals, through December 1993, United States

Exposure category	White, not Hispanic				Black, not Hispanic				Hispanic			
	1993		Cumulative total		1993		Cumulative total		1993		Cumulative total	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Men who have sex with men	32,188	(73)	131,617	(78)	10,509	(36)	36,446	(41)	6,519	(43)	23,146	(45)
Injecting drug use	4,634	(11)	13,483	(8)	10,961	(38)	32,218	(37)	5,872	(38)	19,516	(38)
Men who have sex with men and inject drugs	3,296	(7)	12,933	(8)	1,871	(6)	6,762	(8)	853	(6)	3,458	(7)
Hemophilia/coagulation disorder	868	(2)	2,490	(1)	110	(0)	270	(0)	71	(0)	238	(0)
Heterosexual contact.	707	(2)	1,795	(1)	1,833	(6)	4,207	(5)	752	(5)	1,628	(3)
Sex with injecting drug user	*267*		*875*		*744*		*2,256*		*210*		*650*	
Sex with person with hemophilia	*7*		*14*		*1*		*4*		*4*		*6*	
Sex with transfusion recipient with HIV infection	*26*		*76*		*29*		*50*		*20*		*42*	
Sex with HIV-infected person, risk not specified	*407*		*830*		*1,059*		*1,887*		*515*		*930*	
Receipt of blood transfusion, blood components, or tissue	408	(1)	2,521	(1)	178	(1)	662	(1)	83	(1)	390	(1)
Risk not reported or identified[1]	1,886	(4)	4,231	(3)	3,330	(12)	7,627	(9)	1,151	(8)	2,566	(5)
Total	43,987	(100)	169,080	(100)	28,792	(100)	88,192	(100)	15,301	(100)	50,942	(100)

Exposure category	Asian/Pacific Islander				American Indian/Alaska Native				Cumulative totals[2]			
	1993		Cumulative total		1993		Cumulative total		1993		Cumulative total	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Men who have sex with men	509	(77)	1,699	(80)	177	(63)	432	(63)	49,963	(56)	193,652	(62)
Injecting drug use	33	(5)	87	(4)	27	(10)	74	(11)	21,571	(24)	65,512	(21)
Men who have sex with men and inject drugs	24	(4)	63	(3)	46	(16)	122	(18)	6,098	(7)	23,360	(7)
Hemophilia/coagulation disorder	12	(2)	36	(2)	8	(3)	18	(3)	1,069	(1)	3,058	(1)
Heterosexual contact:	16	(2)	29	(1)	6	(2)	12	(2)	3,317	(4)	7,679	(2)
Sex with injecting drug user	*6*		*12*		*1*		*5*		*1,232*		*3,799*	
Sex with person with hemophilia	—		—		—		—		*12*		*24*	
Sex with transfusion recipient with HIV infection	*1*		*2*		—		—		*76*		*131*	
Sex with HIV-infected person, risk not specified	*9*		*15*		*5*		*7*		*1,997*		*3,575*	
Receipt of blood transfusion, blood components, or tissue	13	(2)	73	(3)	1	(0)	5	(1)	686	(1)	3,660	(1)
Risk not reported or identified	58	(9)	148	(7)	16	(6)	29	(4)	6,461	(7)	14,657	(5)
Total	665	(100)	2,135	(100)	281	(100)	688	(100)	89,165	(100)	311,573	(100)

[1] See Figure 7.
[2] Includes 541 men whose race/ethnicity is unknown.

Table 5. Female adult/adolescent AIDS cases by exposure category and race/ethnicity, reported in 1993, and cumulative totals, through December 1993, United States

Exposure category	White, not Hispanic				Black, not Hispanic				Hispanic			
	1993		Cumulative total		1993		Cumulative total		1993		Cumulative total	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Injecting drug use	1,889	(46)	4,835	(44)	4,420	(48)	12,459	(52)	1,458	(44)	4,317	(48)
Hemophilia/coagulation disorder	16	(0)	51	(0)	7	(0)	16	(0)	3	(0)	7	(0)
Heterosexual contact:	1,557	(38)	3,910	(35)	3,139	(34)	7,613	(32)	1,474	(44)	3,795	(42)
Sex with injecting drug user	*670*		*1,864*		*1,368*		*4,432*		*762*		*2,516*	
Sex with bisexual male	*231*		*600*		*194*		*486*		*81*		*186*	
Sex with person with hemophilia	*56*		*154*		*9*		*21*		*4*		*10*	
Sex with transfusion recipient with HIV infection	*50*		*182*		*33*		*70*		*21*		*56*	
Sex with HIV-infected person, risk not specified	*550*		*1,030*		*1,535*		*2,604*		*606*		*1,021*	
Receipt of blood transfusion, blood components, or tissue	235	(6)	1,429	(13)	187	(2)	659	(3)	90	(3)	362	(4)
Risk not reported or identified[1]	406	(10)	824	(7)	1,459	(16)	3,063	(13)	289	(9)	565	(6)
Total	**4,103**	**(100)**	**11,050**	**(100)**	**9,220**	**(100)**	**23,810**	**(100)**	**3,324**	**(100)**	**9,066**	**(100)**

Exposure category	Asian/Pacific Islander				American Indian/Alaska Native				Cumulative total[2]			
	1993		Cumulative total		1993		Cumulative total		1993		Cumulative total	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Injecting drug use	17	(18)	38	(16)	18	(33)	54	(47)	7,827	(47)	21,744	(49)
Hemophilia/coagulation disorder	1	(1)	1	(0)	—		—		27	(0)	79	(0)
Heterosexual contact:	54	(56)	108	(45)	24	(44)	37	(32)	6,253	(37)	15,497	(35)
Sex with injecting drug user	*17*		*35*		*14*		*24*		*2,833*		*6,883*	
Sex with bisexual male	*15*		*30*		*1*		*3*		*522*		*1,387*	
Sex with person with hemophilia	—		*2*		*2*		*2*		*71*		*183*	
Sex with transfusion recipient with HIV infection	*7*		*11*		—		—		*111*		*322*	
Sex with HIV-infected person, risk not specified	*15*		*30*		*7*		*8*		*2,716*		*6,998*	
Receipt of blood transfusion, blood components, or tissue	13	(13)	59	(25)	3	(5)	9	(8)	529	(3)	1,421	(6)
Risk not reported or identified	12	(12)	34	(14)	10	(18)	14	(12)	2,188	(13)	5,119	(10)
Total	**97**	**(100)**	**240**	**(100)**	**55**	**(100)**	**114**	**(100)**	**16,824**	**(100)**	**48,357**	**(100)**

[1]See Figure 7.
[2]Includes 77 women whose race/ethnicity is unknown.

Table 6. Pediatric AIDS cases by exposure category and race/ethnicity, reported in 1993, and cumulative totals, through December 1993, United States

Exposure category	White, not Hispanic				Black, not Hispanic				Hispanic			
	1993		Cumulative total		1993		Cumulative total		1993		Cumulative total	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Hemophilia/coagulation disorder	17	(11)	145	(14)	3	(1)	27	(1)	3	(1)	33	(3)
Mother with/at risk for HIV infection:	124	(83)	699	(68)	512	(96)	2,734	(95)	248	(94)	1,167	(91)
Injecting drug use	*44*		*300*		*166*		*1,209*		*86*		*522*	
Sex with injecting drug user	*23*		*136*		*72*		*413*		*52*		*340*	
Sex with bisexual male	*4*		*38*		*2*		*29*		*4*		*23*	
Sex with person with hemophilia	*1*		*13*		*1*		*6*		—		*3*	
Sex with transfusion recipient with HIV infection	—		*5*		*1*		*6*		*1*		*7*	
Sex with HIV-infected person, risk not specified	*14*		*55*		*63*		*224*		*33*		*96*	
Receipt of blood transfusion, blood components, or tissue	*6*		*32*		*12*		*58*		*7*		*26*	
Has HIV infection, risk not specified	*32*		*111*		*195*		*789*		*65*		*160*	
Receipt of blood transfusion, blood components, or tissue	8	(5)	166	(16)	6	(1)	74	(3)	8	(3)	77	(6)
Risk not reported or identified[1]	1	(1)	9	(1)	11	(2)	31	(1)	4	(2)	13	(1)
Total	**150**	**(100)**	**1,021**	**(100)**	**532**	**(100)**	**2,866**	**(100)**	**263**	**(100)**	**1,289**	**(100)**

Exposure category	Asian/Pacific Islander				American Indian/Alaska Native				Cumulative totals[2]			
	1993		Cumulative total		1993		Cumulative total		1993		Cumulative total	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Hemophilia/coagulation disorder	—		3	(13)	—		1	(6)	23	(2)	209	(4)
Mother with/at risk for HIV infection:	3	(60)	11	(48)	3	(100)	15	(94)	895	(93)	4,637	(89)
Injecting drug use	*1*		*3*		*2*		*7*		*302*		*2,056*	
Sex with injecting drug user	—		*2*		*1*		*2*		*148*		*895*	
Sex with bisexual male	—		*1*		—		—		*10*		*89*	
Sex with person with hemophilia	—		—		—		—		*2*		*22*	
Sex with transfusion recipient with HIV infection	—		—		—		—		*2*		*13*	
Sex with HIV-infected person, risk not specified	*1*		*2*		—		*2*		*112*		*379*	
Receipt of blood transfusion, blood components, or tissue	—		—		—		—		*25*		*116*	
Has HIV infection, risk not specified	*1*		*3*		—		*4*		*294*		*968*	
Receipt of blood transfusion, blood components, or tissue	2	(40)	9	(39)	—		—		24	(3)	329	(6)
Risk not reported or identified	—		—		—		—		17	(2)	53	(1)
Total	**5**	**(100)**	**23**	**(100)**	**3**	**(100)**	**16**	**(100)**	**959**	**(100)**	**5,228**	**(100)**

[1]See Figure 7.
[2]Includes 13 children whose race/ethnicity is unknown.

Table 7. AIDS cases in adolescents and adults under age 25, by sex and exposure category reported in 1992 and 1993, and cumulative totals through December 1993, United States

	13-19 years old						20-24 years old					
	1992		1993		Cumulative total		1992		1993		Cumulative total	
Male exposure category	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Men who have sex with men	32	(33)	113	(29)	358	(33)	747	(66)	1,654	(59)	7,015	(64)
Injecting drug use	4	(4)	23	(6)	72	(7)	131	(12)	345	(12)	1,391	(13)
Men who have sex with men and inject drugs	4	(4)	10	(3)	47	(4)	109	(10)	241	(9)	1,209	(11)
Hemophilia/coagulation disorder	44	(45)	186	(48)	468	(44)	37	(3)	174	(6)	412	(4)
Heterosexual contact:	6	(6)	11	(3)	22	(2)	47	(4)	129	(5)	311	(3)
Sex with injecting drug user		*2*		*5*		*11*		*19*		*45*		*118*
Sex with person with hemophilia		—		—		—		—		—		1
Sex with transfusion recipient with HIV infection		—		—		—		*1*		*2*		*7*
Sex with HIV-infected person, risk not specified		*4*		*6*		*11*		*27*		*78*		*155*
Receipt of blood transfusion, blood components, or tissue	4	(4)	14	(4)	45	(4)	1	(0)	18	(1)	60	(1)
Risk not reported or identified[1]	4	(4)	30	(8)	58	(5)	55	(5)	227	(8)	529	(5)
Male subtotal	98	(100)	387	(100)	1,070	(100)	1,130	(100)	2,786	(100)	10,947	(100)
Female exposure category												
Injecting drug use	8	(13)	19	(9)	99	(20)	118	(31)	324	(29)	1,034	(35)
Hemophilia/coagulation disorder	—		1	(0)	5	(1)	1	(0)	5	(0)	12	(0)
Heterosexual contact:	36	(61)	120	(60)	254	(52)	210	(56)	571	(51)	1,434	(49)
Sex with injecting drug user		*21*		*47*		*139*		*124*		*275*		*845*
Sex with bisexual male		—		*10*		*13*		*12*		*38*		*124*
Sex with person with hemophilia		*1*		*1*		*6*		*2*		*10*		*28*
Sex with transfusion recipient with HIV infection		—		—		*1*		—		*2*		*6*
Sex with HIV-infected person, risk not specified		*14*		*63*		*93*		*72*		*246*		*431*
Receipt of blood transfusion, blood components, or tissue	4	(7)	13	(6)	44	(9)	10	(3)	19	(2)	95	(3)
Risk not reported or identified	10	(17)	48	(24)	82	(17)	39	(10)	204	(18)	550	(13)
Female subtotal	59	(100)	201	(100)	484	(100)	378	(100)	1,123	(100)	3,943	(100)
Total	**157**		**588**		**1,554**		**1,508**		**3,911**		**14,890**	

[1] See Figure 7.

Table 8. AIDS cases by age at diagnosis and exposure category, reported through December 1993, United States

Age at diagnosis (years)	Men who have sex with men		Injecting drug use		Men who have sex with men and inject drugs		Hemophilia/ coagulation disorder		Heterosexual contact	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Under 5	—		—		—		11	(0)	—	
5–12	—		-		—		190	(6)	—	
13–19	358	(0)	171	(0)	47	(0)	473	(14)	276	(1)
20–24	7,015	(4)	2,425	(3)	1,209	(5)	422	(13)	1,745	(8)
25–29	31,195	(16)	10,472	(12)	4,696	(20)	484	(14)	4,418	(19)
30–34	46,384	(24)	21,325	(24)	6,703	(29)	463	(14)	5,148	(22)
35–39	41,654	(22)	24,294	(26)	5,556	(24)	391	(12)	4,048	(17)
40–44	29,530	(15)	16,221	(19)	2,998	(13)	289	(9)	2,665	(12)
45–49	17,041	(9)	6,989	(8)	1,300	(6)	222	(7)	1,705	(7)
50–54	9,725	(5)	3,051	(3)	508	(2)	117	(4)	1,162	(5)
55–59	5,472	(3)	1,424	(2)	223	(1)	83	(2)	813	(4)
60–64	2,850	(1)	573	(1)	77	(0)	85	(3)	558	(2)
65 or older	1,628	(1)	312	(0)	40	(0)	104	(3)	608	(3)
Total	**193,652**	**(100)**	**87,259**	**(100)**	**23,360**	**(100)**	**3,342**	**(100)**	**23,166**	**(100)**

Age at diagnosis (years)	Receipt of transfusion		Mother with/at risk for HIV infection		Other/risk not reported or identified[1]		Total	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Under 5	147	(2)	4,027	(87)	36	(0)	4,221	(1)
5–12	182	(3)	610	(13)	17	(0)	1,007	(0)
13–19	89	(1)	—		140	(1)	1,554	(0)
20–24	166	(3)	—		909	(5)	13,890	(4)
25–29	434	(7)	—		2,894	(15)	54,593	(15)
30–34	587	(9)	—		3,947	(21)	84,557	(23)
35–39	612	(9)	—		3,375	(18)	79,930	(22)
40–44	577	(9)	—		2,591	(13)	54,871	(15)
45–49	466	(7)	—		1,756	(9)	30,279	(8)
50–54	501	(8)	—		1,296	(7)	16,380	(5)
55–59	539	(8)	—		959	(5)	9,513	(3)
60–64	664	(10)	—		639	(3)	5,446	(2)
65 or older	1,547	(24)	—		679	(4)	4,921	(1)
Total[2]	**6,510**	**(100)**	**4,637**	**(100)**	**19,238**	**(100)**	**361,164**	**(100)**

[1]See Figure 7.
[2]Totals include 2 persons whose age at diagnosis is unknown.

Table 9. AIDS cases by sex, age at diagnosis, and race/ethnicity, reported through Decembe 1993, United States

Male	White, not Hispanic		Black, not Hispanic		Hispanic		Asian/Pacific Islander		American Indian/ Alaska Native		Total[1]	
Age at diagnosis (years)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Under 5	348	(0)	1,247	(1)	527	(1)	9	(0)	8	(1)	2,142	(1)
5–12	247	(0)	191	(0)	158	(0)	7	(0)	1	(0)	605	(0)
13–19	510	(0)	330	(0)	208	(0)	11	(1)	11	(2)	1,070	(0)
20–24	5,096	(3)	3,582	(4)	2,142	(4)	79	(4)	31	(4)	10,947	(3)
25–29	24,694	(15)	12,901	(14)	8,437	(16)	280	(13)	142	(20)	46,530	(15)
30–34	39,628	(23)	20,371	(23)	12,593	(24)	461	(21)	192	(28)	73,349	(23)
35–39	37,545	(22)	20,762	(23)	11,395	(22)	462	(21)	135	(19)	70,439	(22)
40–44	26,949	(16)	14,313	(16)	7,546	(15)	381	(18)	96	(14)	49,378	(16)
45–49	15,948	(9)	7,402	(8)	4,087	(8)	222	(10)	35	(5)	27,743	(9)
50–54	8,541	(5)	4,065	(5)	2,164	(4)	110	(5)	22	(3)	14,926	(5)
55–59	4,887	(3)	2,301	(3)	1,242	(2)	67	(3)	10	(1)	8,534	(3)
60–64	2,865	(2)	1,237	(1)	649	(1)	24	(1)	10	(1)	4,791	(2)
65 or older	2,417	(1)	928	(1)	478	(1)	38	(2)	4	(1)	3,870	(1)
Male subtotal	169,675	(100)	89,630	(100)	51,627	(100)	2,151	(100)	697	(100)	314,325	(100)
Female												
Age at diagnosis (years)												
Under 5	337	(3)	1,233	(5)	494	(5)	1	(0)	7	(6)	2,079	(4)
5–12	89	(1)	195	(1)	110	(1)	6	(2)	—		402	(1)
13–19	104	(1)	300	(1)	77	(1)	1	(0)	1	(1)	484	(1)
20–24	724	(6)	1,508	(6)	679	(7)	15	(6)	13	(11)	2,943	(6)
25–29	2,031	(18)	4,161	(17)	1,794	(19)	23	(9)	24	(20)	8,063	(17)
30–34	2,635	(23)	6,094	(24)	2,374	(25)	49	(20)	35	(29)	11,208	(24)
35–39	2,043	(18)	5,531	(22)	1,838	(19)	41	(17)	15	(12)	9,490	(20)
40–44	1,195	(10)	3,147	(12)	1,091	(11)	40	(16)	11	(9)	5,493	(12)
45–49	658	(6)	1,314	(5)	532	(6)	20	(8)	6	(5)	2,536	(5)
50–54	389	(3)	749	(3)	297	(3)	14	(6)	3	(2)	1,454	(3)
55–59	351	(3)	425	(2)	191	(2)	9	(4)	2	(2)	979	(2)
60–64	270	(2)	276	(1)	92	(1)	12	(5)	3	(2)	655	(1)
65 or older	650	(6)	283	(1)	100	(1)	16	(6)	1	(1)	1,051	(2)
Female subtotal	11,476	(100)	25,238	(100)	[illegible]	(100)	247	(100)	121	(100)	46,838	(100)
Total[2]	**181,151**		**114,868**		**61,297**		**2,398**		**818**		**301,104**	

[1] Includes 545 males, 86 females, and 1 person of unknown sex whose race/ethnicity is unknown.
[2] Includes 1 male and 1 female whose age at diagnosis is unknown, and 1 person whose sex is unknown.

Table 10. AIDS cases and annual rates per 100,000 population, by race/ethnicity, age group, and sex, reported in 1993, United States

Race/ethnicity	Adults/adolescents: Males No.	Males Rate	Females No.	Females Rate	Total No.	Total Rate	Children <13 years No.	Children <13 years Rate	Total No.	Total Rate
White, not Hispanic	43,987	57.3	4,103	5.0	48,090	30.2	150	0.1	[illegible]	25.0
Black, not Hispanic	28,792	266.2	9,220	73.1	38,012	162.2	532	7.2	38,544	125.0
Hispanic	15,301	145.9	3,324	32.2	18,625	89.5	263	3.6	18,888	67.3
Asian/Pacific Islander	665	21.2	97	2.9	762	11.7	5	0.3	767	9.3
American Indian/Alaska Native	281	41.3	55	7.7	336	24.0	3	0.6	339	17.9
Total[1]	**89,165**	**87.8**	**16,824**	**15.4**	**105,990**	**50.1**	**959**	**1.9**	**106,949**	**40.8**

[1]Includes 171 persons whose race/ethnicity is unknown and 1 person whose sex is unknown.

Table 11. AIDS cases by year of diagnosis and definition category, diagnosed through December 1993, United States

Definition category	Period of diagnosis: Before 1990 No.	Before 1990 (%)	1990 No.	1990 (%)	1991 No.	1991 (%)	1992 No.	1992 (%)	1993 No.	1993 (%)	Cumulative total No.	Cumulative total (%)
Pre-1987 definition	115,248	(78)	29,245	(63)	30,892	(56)	29,717	(44)	13,020	(29)	[illegible]22	(60)
1987 definition	29,554	(20)	13,869	(30)	16,508	(30)	18,181	(27)	8,530	(19)	[illegible]612	(24)
1993 definition[1]	2,267	(2)	2,988	(6)	7,366	(13)	19,664	(29)	24,115	(53)	[illegible]400	(16)
Pulmonary tuberculosis		*465*		*407*		*853*		*1,402*		*1,055*		*4,182*
Recurrent pneumonia		*[illegible]*		*85*		*133*		*387*		*615*		*1,291*
Invasive cervical cancer		*23*		*11*		*26*		*54*		*40*		*154*
Severe HIV related immunosuppression[2]		*1,694*		*2,511*		*6,362*		*17,821*		*22,412*		*50,800*
Total	**147,069**	**(100)**	**46,102**	**(100)**	**54,766**	**(100)**	**67,562**	**(100)**	**45,665**	**(100)**	[illegible]164	**(100)**

[1]Persons who meet only the 1993 AIDS surveillance case definition and whose date of diagnosis is before January 1993 were diagnosed retrospectively. The sum of diagnoses listed for the four conditions under the 1993 definition do not equal the 1993 definition total because some persons have more than one diagnosis from the added conditions of pulmonary tuberculosis, recurrent pneumonia, and invasive cervical cancer.
[2]Defined as CD4+ T-lymphocyte count of less than 200 cells/μL or a CD4+ percentage less than 14 in persons with laboratory confirmation of HIV infection.

FULL

DONE - AUGUST 5, 1994

Review of Draft PHS Document, "Recommendations on the Use of Zidovudine to reduce HIV Transmission From Mother to Child" for publication in MMWR".

A. BACKGROUND INFORMATION

Maternal/fetal transmission of HIV

* Worldwide, it is estimated that 15,000 to 20,000 children, 110,00 women, and 1 million men are HIV infected but not yet diagnosed with AIDS. Women are the fastest growing segment of the AIDS population, with 93% of the children with HIV under the age of 13 who contracted the disease from their mother, perinatally.

* In the U.S. serosurveys indicate that annually 7,000 HIV infected women give birth. With a 20-30% transmission rate, that adds up to 1,400 to 2,100 infected infants born each year.

* By 1995, the number of children of children that will be orphaned by AIDS will be 24,600 under the age of 13, 21,000 between the ages of 13-17, and by the year 2000, that number will rise to more than 80,000.

* Preventing HIV transmission among women is ideal, yet new infections still occur. Refraining from breast feeding decreases the risk of mother to infant transmission in the post partum period, but not the pre- or intra-partum periods.

* Prevention of transmission of HIV to the fetus, in utero or intrapartum was the intent of clinical trial 076. There is the possibility of transmission before birth or in the birth process when the child is exposed to copious amounts of the mother's blood and other body fluids which contain HIV.

ACTG- 076

* In February, 1994, The National Institutes of Health released preliminary results of clinical trial ACTG-076. This trial was designed to evaluate the efficacy, safety and tolerance of zidovudine (ZDV; also known as AZT) for the prevention of maternal-fetal transmission of HIV. This study was conducted in 50 sites in the USA and 9 sites in France.

* There were 477 women and 364 infants enrolled in the study at the time of the analysis of the data presented. A total of 421 infants have been born since the study began in 1991. Of those, 364 infants had at least one culture result available.

* The women involved in this study initiated ZDV treatment between 14-34 weeks gestation, had received no other antiretroviral treatment during the pregnancy, had CD4 level greater that 200 cells/mm3 and had no clinical indications for ZDV therapy prior to the pregnancy.

* Under this study, ZDV was given to HIV infected pregnant women with limited or no prior history of antiretroviral therapy. These women were between 14 to 34 weeks gestation. Zidovidine was given during this period and continued throughout pregnancy and the labor period. The infant was given ZDV for six weeks following delivery. Other women were given placebo regiments.

* The results indicated a two-thirds reduction rate---8.3% when both mother and infant received ZDV, compared to a rate of 25.5% among those who received a placebo.

* Even though there was a significant reduction, transmission of HIV occurred despite ZDV therapy in 13 out of 180 infants.

HHS/PHS TASK FORCE

* The Task Force entitled, "The Public Health Service/Health and Human Services Task Force on the Use of Zidovudine to Prevent Perinatal HIV Transmission" has had its first meeting on April 14, 1994. This panel convened to discuss implications of ACTG 076 for the woman and child, specific treatment guideline issues, testing and counseling parameters and propose timelines for the development of recommendations and policies.

* Specifically, NIH would develop draft documents regarding treatment issues and begin evaluation of how on-going natural history studies of HIV infection in women and children could provide information regarding long term effects of this therapy. ~~This document has been drafted and is the subject of this meeting~~.

* CDC would draft a document pertaining to counseling and testing issues for pregnant women, outline issues regarding long term follow up registry for those infants exposed to ZDV in utero, and also begin evaluation of how CDC funded natural history studies could provide further information regarding the impact of this therapy on women and children. The status of this document is still under review. There will be a period for public comment once this document has been drafted.

* HRSA is responsible for developing plans to implement the counseling, testing and clinical care recommendations. The

ON GOING ACTION

implementation of the clinical findings of 076 into broader settings including Ryan White programs will require early identification of HIV infected women. Status unknown at present.

* FDA would review their process of labeling indication assessment or ZDV for use in pregnancy. FDA indicated that Burroughs-Wellcome has submitted an application for new labeling indication for pregnant women after gestational period of 14 weeks for reduction of HIV transmission. Draft of the response has been sent to them for comment. The ACTG 076 review, the treatment draft guidelines, B-W application and response document will be presented to the FDA Antiviral Advisory Committee meeting on July 28, 1994. During this meeting there will also be discussions of possible Phase IV monitoring of long term effects on mothers and infants that may be required of the company. August 24, 1994 is absolute target date for completion of this process.

* August, 1994 is the target month for publication of the recommendations from this task force.

ISSUES OF CONCERN:

* Indications for pregnant women and her child - who may be potentially infected(25%) and potentially unaffected (75%) is confounding. Placement in follow up studies are available for adolescent women and all infants, yet not for the other mothers. Provision of care services for the mothers and their children will require increased allocation of funds for this population.

* The women in the study are already infected with HIV and will develop life threatening diseases, which will increase the orphan population in this country. What policies are being considered to help with the foster care and adoption systems in this country. This will require additional funding streams to assist the social services agencies with placement and financial subsidy for these children.

* What are the long term risks of ZDV exposure in utero and early infancy to the children--those who may have become infected and those who would not have been infected anyway?

* What will the impact of ZDV use during pregnancy have on the woman's ability to use the therapy when it becomes indicated for her own health?

* What about the infected child's ability to use this therapy when indicated for his/her own health?

* ZDV was given in several periods, ante-partum, intra-partum, and post partum. There is no indication that if ZDV is effective if administered in only one or two of these periods. This is especially critical if the woman delivers outside the clinical setting.

* Who will pay for these women to receive ZDV if they are unable to afford this therapy? Who will provide services for the child?

* In some communities there has been a push for policies toward mandatory testing of all pregnant women without regard for their rights, based on the need to "save the babies". This does a disservice to the mother, father, siblings and the baby who may not become infected anyway. Counseling should be offered in all settings. The woman should be allowed to make her own decision regarding her future treatment options.

* There were no significant short term effects to either the mother or infant other than anemia in the infant which was reversed shortly after treatment ended. The women will be only be followed for 6 weeks after delivery and the infants(both HIV+ and HIV-) followed up to 21 years after perinatal exposure to ZDV.

Recommendations

* More extensive research is needed to determine the long term effects of ZDV therapy on the infants, some of whom do not become infected with HIV and those who do in spite of ZDV therapy. Additional studies are indicated to determine the efficacy and safety of ZDV therapy for the mother. The impact on the health and the progression of HIV disease in the mother needs to be considered in subsequent studies.

* The implications of this study highlight the need to broaden our outreach efforts to women of childbearing years to seek HIV counseling and testing. Clinicians who provide services to these women must be alerted to the need to counsel them regarding the potential impact of ZDV therapy, benefits and risks. It is important to note that 8 out of every 100 babies in the study was HIV infected, even though the mother and infant had received ZDV.

* For women who participate in high risk behavior, ie. injecting drugs and unprotected sex with someone whose HIV status is unknown, it is imperative that they have access to

adequate counseling, testing and treatment regardless of whether they are pregnant or not. The rights of the woman to adequate treatment should not be abrogated to the rights of the unborn child.

* Evaluation of Title IV programs demonstrate remarkable success in identifying HIV positive youth and women, retaining them and their newborn infants in comprehensive care and supporting them to participate in early medical treatment. Early identification and follow up care for HIV exposed infants by Title IV programs reduces morbidity and mortality through a coordinated, comprehensive medical, social and family support programs.

* This document by itself is only a portion of the recommendations needed to fully make this therapy available for the women and children it targets. The American College of Obstetrics and Gynecology and the Academy of Pediatrics is also reviewing the data in order to make treatment decisions regarding this therapy. It is therefore, critical that this document be approved for publication in order to give heath care practicioners recommendations on the use of ZDV for HIV infected pregnant women, keeping in mind that CDC, HRSA, HCFA and FDA have crucial roles in the implementation of these therapeutic guidelines.

EXECUTIVE SUMMARY:ABSTRACT ACTG 076

A Phase III Randomized, Placebo-Controlled Trial to Evaluate the Efficacy, Safety and Tolerance of Zidovudine (ZDV) for the Prevention of Maternal-Fetal Transmission

BACKGROUND

Currently, there are approximately 10-20,000 HIV-infected children and approximately 7,000 infants are born annually to HIV-infected women in the United States. It is estimated that by the year 2000, 10 million children globally will have been infected.

The vast majority of HIV-infected infants and children acquire the virus by maternal-infant transmission; either in utero, during labor and delivery, or postpartum via breastfeeding. In the developed world, antepartum and intrapartum routes account for nearly all of the cases. The risk of maternal-infant HIV transmission in pregnant women has been associated with advanced disease stage, low CD4+ lymphocyte count, and high viral burden.

Zidovudine (ZDV) has been demonstrated to be an effective treatment to decrease viral burden and delay disease progression for HIV-infected adults and children. An uncontrolled survey of some pregnant women treated with ZDV for their own medical care revealed no significant untoward effect.

The risk of maternal-infant transmission of HIV theoretically could be reduced by ZDV treatment of pregnant women. To test this hypothesis, in April, 1991, a Phase III randomized, double-blind, placebo-controlled clinical trial (ACTG 076) was initiated to evaluate whether ZDV therapy could reduce the risk of maternal-fetal transmission in HIV-infected pregnant women. An additional study objective was to evaluate the safety of the ZDV regimen for mothers and infants.

METHODS

Eligible patients were HIV-infected pregnant women (between 14 and 34 weeks gestation) who had no antiretroviral treatment during the current pregnancy, had baseline CD4+ lymphocyte counts greater than 200 cells/mm^3, and had no clinical indications for maternal antepartum ZDV therapy. The target sample size was 748 women (636 fully assessable mother-infant pairs). This was chosen so as to provide 80 percent power to detect a reduction in the probability of transmission to 20 percent for the ZDV group compared with 30 percent for the placebo group, using a two sided, alpha=0.05 test. Women were stratified according to gestational age (14-26 weeks; >26 weeks) and randomized to receive either ZDV or placebo.

ACTG 076
EXECUTIVE SUMMARY:ABSTRACT

The ZDV regimen consisted of antepartum ZDV (100 mg p.o. five times daily) plus intrapartum ZDV (IV loading dose, 2 mg/kg, followed by continuous infusion, 1 mg/kg/hr, until delivery) plus newborn ZDV (syrup, 2 mg/kg q. 6 hr for six weeks beginning 8-12 hours after birth). Pregnant women were seen frequently during pregnancy, through delivery, and for six months postpartum, and were carefully assessed for evidence of drug toxicity, HIV disease progression, and fetal well-being. Infants were carefully monitored through 78 weeks of age for evidence of HIV infection and to assess safety. HIV infection status was determined by viral culture from the infants at birth, 12 weeks, and 78 weeks of life, and samples were obtained for HIV serology at 72 and 78 weeks. A protocol modification added an additional culture at 24 weeks. Infants were defined as HIV infected for the primary analysis based on one positive viral culture obtained from peripheral blood.

On February 17, 1994, the ACTG Data and Safety Monitoring Board (DSMB) reviewed the interim analysis based on information in the database as of December 20, 1993, and concluded that there was significant evidence of treatment efficacy. On February 18, 1994, the Pediatric AIDS Clinical Trials Group Executive Committee approved the DSMB recommendations to: (1) discontinue new patient enrollment; (2) offer open-label ZDV as per protocol regimen to all individuals on the study; and (3) continue long term follow-up of all infants participating in ACTG 076 to monitor for possible development of unknown late effects of the study treatment.

RESULTS

Thirty-five NIAID sponsored sites, 15 NICHD sponsored sites, and nine centers in France enrolled patients in ACTG 076. Four hundred seventy-seven women were enrolled as of the December 20, 1993 data cut-off. The median age was 25 years (range, 15-43), the median CD4+ lymphocyte count was 550 cells/mm^3 (range, 200-1818), and 41 percent of women had CD4+ lymphocyte counts between 200 and 500 cells/mm^3. The median gestational age at entry was 26 weeks. Maternal demographics revealed a predominantly minority population: only 19 percent were white/non-Hispanic.

Four hundred twenty-one babies have been born; 409 singletons and 6 sets of twins. The median gestational age at delivery was 39 weeks (range, 27-43 weeks). Three sets of twins and 23 singletons were premature (<36 weeks gestation). The median 1-minute Apgar score was 8 (range, 0-10), the median 5-minute Apgar was 9 (range, 5-10), and the median birth weight was 3160 grams (range, 1040-5267 grams). Seven infants (1.7 percent) weighed <1500 grams at birth, 14 (3.4 percent) weighed between 1500 and 2000 grams, and 44 (10.7 percent) weighed between 2000 and 2500 grams.

Three hundred sixty-four births were included in this interim efficacy analysis, 180 in the ZDV group and 184 in the placebo group. Two hundred thirty-three infants had information about HIV infection status as of 24 weeks

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of life, and 75 of these had confirmation at 18 months. Thirteen babies in the ZDV group and 40 in the placebo group were defined as HIV-infected. The estimated percentages infected based on Kaplan-Meier analysis were 8.3 percent (s.e.: 2.25 percent) in the ZDV group and 25.5 percent (s.e.: 3.60 percent) in the placebo group. The estimated absolute difference in percentage infected between the two groups was 17.2 percent, with 95 percent confidence interval 8.9 to 25.5 percent. This corresponded to a 67.5 relative reduction in transmission risk. This risk reduction is highly statistically significant (z=4.03; two-sided p=0.000056).

Reported maternal and infant side effects were balanced between the two randomized groups, with one exception that hemoglobin levels were lower for infants in the ZDV group. The mean decrease in hemoglobin was less than 1 g/dl, did not require transfusion, and resolved after completion of ZDV therapy.

CONCLUSIONS

A treatment regimen consisting of ZDV given to the mother both antepartum and intrapartum, as well as to the newborn during the first six weeks of life, significantly reduced the risk of maternal-infant transmission of HIV for women with baseline CD4+ lymphocyte counts >200 cells/mm^3. Further follow-up of mothers and infants is being conducted to determine if there are any late adverse effects of this treatment regimen. Any decision to institute therapy regimens for the prevention of maternal-fetal transmission must be made after careful consideration of the potential unknown long term risks.

February 20, 1994
Distributed with Site Instructions

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PRINCIPLES FOR IMPLEMENTATION OF EXPANDED HIV COUNSELING AND TESTING AND ACTG 076 FOR HRSA PROGRAMS

HRSA Constituent Meeting, September 19-20, 1994

HRSA's Working Group on Prevention of Perinatal Transmission of HIV met in Washington, D.C. on May 25, 1994 to initiate discussion of the impact of recently announced findings of the ACTG 076 randomized clinical trial of Zidovudine (ZDV) for the reduction of HIV transmission from infected mothers to their infants. As the first of the two HRSA-sponsored meetings to address the clinical, psychosocial, ethical, financial and legal implications of the study, the meeting brought together women with HIV, providers, advocates, ethicists, and policy makers to explore issues and concerns in an open forum.

The following recommendations were made by this Working Group. These principles form the basis for the discussions of implementation strategies for the September 19-20, 1994 meeting.

- Expanded HIV counseling and testing should be made available in all settings that provide care to women. Existing programs serving women in high, medium and low seroprevalence areas will need to plan and prioritize this service and other service obligations depending on space, staff and financial resources. Testing should only be performed after women give specific informed consent. Informed consent should include a clear, simple presentation of the benefits of early intervention services to woman (and infants, if applicable). Counselors should be aware of local resources and services for women with HIV and arrange for ongoing care when positive serostatus results are given.

- Information on the risks and benefits of Zidovudine use during pregnancy (results of 076) should be made available to all pregnant women in clear, simple language to enable women to make informed choices. PHS should develop a culturally sensitive protocol for presenting the risks and benefits to women.

- Providers of health care and services for women should make the 076 protocol available to women who choose this option, either on site or by referral. It should be clear to all women that their ongoing care will not be influenced by their decision. The protocol is complicated; it requires coordination of care among primary care, obstetric, hospital/delivery and pediatric health professional. This will not occur by chance. It must be developed at the time the 076 protocol is initiated. Staffing, equipment and supply requirements for all component need to be enunciated.

- All women and infants treated according to ACTG 076 protocol should receive long-term follow up care. Infection status for all infants should be documented using available technology. Results should be recorded in a standard database so outcomes of the ACTG 076 protocol in community, as opposed to research, settings can be documented.

  Growth and development of infants with and without HIV infection should be documented in longitudinal client databases. Long term clinical outcomes should be documented for mothers including, where feasible, viral genotype and phenotype.

- Implementation of recommendations regarding ACTG 076 will require substantial community planning and education. Resources should be made available for community planning to develop and coordinate appropriate services and follow-up care for women and families. This will/could involve Medicaid, Medicare, DOD, DVA, SAMSHA, CDC, state and locally funded providers and programs as well as HRSA-funded ones.

- Health care services for women need to be expanded including reproductive health, substance abuse treatment and relapse prevention services.

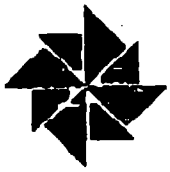
- Caregivers must be sensitive to the high level of distrust and fear that many disenfranchised and minority populations have toward health care providers. Culturally appropriate interventions and provider training must be developed to increase trust, utilization of services and compliance with care.

- Training should be provided for health care workers on: 1) diagnosis and management of HIV disease in women; and 2) counseling and testing for women (issues such as cultural sensitivity; explanations/education for women in simple, clear language; risks and benefits of AZT use during pregnancy; referrals to care and support services and long term care need to be addressed). Without a significant effort devoted to training health professionals who provide care to women, expanded availability of zidovudine for the reduction of perinatal transmission will not occur. Policy discussion and planning should include representation of women with HIV.

- Women with HIV should be considered an important source for community outreach education, policy and planning.

Focus Group on ACTG 076 Preliminary Report

Produced with support from the Maternal and Child Health Bureau through Project # MCU PFC 031-01.



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We acknowledge the generosity of the women who participated in the focus group. By sharing their time, their experiences, and their perspectives they have given us important insights about these complex issues. We thank them.

Preliminary Report

INTRODUCTION

The Institute for Family-Centered Care, with support from the Maternal and Child Health Bureau, HRSA, U.S. Public Health Service, convened a group of 15 women from ten states to discuss issues related to ACTG 076. All of the participants were HIV infected. The group included African-American, Hispanic, and Caucasian women. Several of the women had histories of substance abuse. The group included mothers of infected children, some of whom had died; mothers of affected children; a woman who was pregnant; and younger women who had not yet had children. In preparation for the meeting, participants received written material about ACTG 076.

The day-long meeting was audio taped with permission from the participants. In addition, three recorders kept notes during the meeting. A full report will be developed within the next month for dissemination to policy makers, care providers, and consumers. This report provides a brief summary of the main themes and issues that were addressed at the meeting and presents recommendations based on the discussion.

Overview of the day. The meeting began with a general description of the clinical trial process and a presentation of the specific 076 research by Dr. Marilyn Crain, the pediatric principal investigator for ACTG trials at the University of Alabama at Birmingham and Director of the Family Clinic, a Ryan White Title IV program, jointly sponsored by the University of Alabama, Department of Pediatrics and the Children's Hospital of Alabama. Dr. Crain's presentation was *essential* to the later discussion of issues related to 076. Participants had ample time to ask questions and to express their concerns about both the design of the specific trial and clinical trials in general. The opportunity to receive thorough, unbiased information from a physician who had participated in the study enabled participants to develop a clear understanding of the actual research and also fostered a sense of trust, respect, and candor within the group.

It should be noted that several of the women initially stated they were opposed to AZT treatment of any kind. This is extremely important because it reflects the anti-AZT bias that exists in many communities. After talking with the other participants and Dr. Crain over the course of the day, however, these women seemed willing to evaluate the 076 treatment with a more open mind. This highlights how critically important it is to ensure that women have opportunities to receive accurate information in an unhurried, supportive atmosphere. Not only does it enhance their ability to make informed choices for

themselves and their children, it also fosters more collaborative, trusting relationships with providers.

After Dr. Crain's presentation, a structured focus group was conducted. Participants were asked the following questions:

Focus Group Questions

1. Given Dr. Crain's overview of the ACTG 076 research and results, what issues or questions come to mind?

   - What questions might you and other women have when deciding if you would take the kind of treatment described by Dr. Crain?

2. Who do you think should receive information about the results of 076?

   - What kind of information should be given?

   - Who should present the information and how should they present it, so that women will fully understand the implications for themselves and their infants?

   - Are there special considerations in informing teen-age girls and younger women about the results of 076?

3. Please describe what you think would be the ideal setting and approach to HIV counseling and testing for women.

   - Are there special considerations in providing counseling and testing to teen-age girls and younger women?

4. If a woman is tested and finds she is HIV positive, please describe what counseling, treatments, services, and other supports should be available to her.

5. This focus group has helped us learn about your perspectives on ACTG 076. What other methods could be used to gather information on these issues from a broad group of women ?

At the end of the day, participants voted their responses by secret ballot to the following four questions:

- Should all pregnant women be offered testing, after appropriate pre-test counseling with post-test support, regardless of perceived HIV risk?
- Should there be mandatory testing of all pregnant women?
- Should there be mandatory testing of all women ages 13-50?
- Should HIV infected pregnant women be required to take the 076 treatment?

The full report of the focus group will include a summary of the participants' responses to all of the questions. What is presented here is a discussion of the main themes and issues that emerged during the day, their implications for the implementation of ACTG 076, and a brief set of recommendations based on the women's observations, perspectives, and experiences.

ISSUES AND IMPLICATIONS

Women's Attitudes About Health Care Providers and the Health Care System. An overriding theme of the meeting was the participants' pervasive mistrust of health care providers, both within the research community and within the care system. The women expressed a profound degree of suspicion about AZT and about the design of the 076 study, as well as a deep mistrust about how the 076 findings might be implemented. As one woman said, "When the report came out it scared me, because I know the doctors will now be ready to make recommendations about how to treat all women." Another said, "Now women who are infected will be pressured to take AZT, just as they have been pressured to have abortions." Yet another expressed her concern this way, "What is the 'snowball' effect of this one trial? Will women who won't participate be found 'unfit'– will it be used to blackmail women?" This wariness and skepticism about providers' attitudes toward HIV infected women was prevalent throughout the discussion.

Among the specific questions that were raised about the 076 findings were:

- What are the long term effects of AZT on the babies in the study?
- What about the design of the study – "If you change any part of the puzzle, does it change the results?"
- Is there any follow-up care for the women? Are there any follow up studies on the women?
- If women participate in 076 treatment will they jeopardize a later opportunity to take AZT when their own health might benefit from it?
- Will the treatment work for more than one pregnancy?
- Why is there such a great hurry to implement 076 treatment when there are still so many unanswered questions?
- Can a woman trust her health provider to have the woman's best interest in mind when making recommendations?

- If it turns out that AZT really works will it be made available to all women? Who will pay for it?

A number of the participants stated that the 076 study pitted their rights as women against the rights of their babies. One woman described the difficult choice 076 presents to women this way, "It's very important to me that my child not be born with this virus, but I also have to think about if I want to have a child and then not be around to be there for the child. Do I want to have a baby and then a year after taking AZT my immune system shuts down and I die within the year, and then not be able to be there for my child?"

Others expressed anger at being considered "vessels." One woman poignantly said, "It seems that women – as real, thinking, responsible, contributing adults – were overlooked." Another said, "It seems like in the whole study women were ignored." However, participants also pointed out that if providers continued to ignore the rights and concerns of women they and their babies would be lost to treatment. "Unless you're going to strap us down, you need our cooperation. If you don't care about me, I don't care about you. You need to be partners with women in order to get this care to the baby." Another participant added, "If you don't take care of the mother, she won't be there in the future for the baby."

Many of the women, especially those with a history of substance abuse, expressed concern that women will be coerced into agreeing to the 076 treatment. A number of the women said they were fearful that refusal to take AZT could result in a referral to child protective services. There was real concern that 076 might be used as a way to take their children away.

Finally, the participants expressed concern about how information about 076 will be conveyed to women. These concerns again stemmed from the women's suspicions of providers – that providers would not give complete or accurate information, that they would not provide information in ways that women could understand, and that they would not support women in making informed choices for themselves.

Implications: It is clear that many of the participants in the focus group feel powerless and undervalued by the medical community. They describe having limited input in decisions affecting their own care and no input in policy and program decisions affecting women's health care in general. The resulting mistrust of providers has major implications for the acceptance of the ACTG 076 findings by HIV infected women. It is incumbent upon health care providers to establish trusting relationships with these women, to develop forums where information can be shared, and to provide the necessary practical and emotional supports for women to make informed decisions about their treatment options.

Information and Informed Decision-Making. Although the participants had concerns and questions about the 076 research, there was strong agreement that information about the trial and its results should be made widely available. In response to a question about who should receive information about 076, the women said: "women, women, women"; all HIV positive women; all women of childbearing age; all women; OB/GYNs; pediatricians; male partners; women's families and other supports; the ACLU; community-based organizations; the media; anyone connected with family planning; adolescents; and Boards of Education.

Similarly, when asked what kind of information should be made available, the women said, "Every little thing that is known." They urged that complete information about the study – the specific results as well as the unanswered questions – be given to women in understandable terms. They emphasized that both the pros and the cons of the treatment must be presented, and that the main facts of the study should be presented with neutrality and clarity.

Participants pointed out that the way the information is presented is as important as what is presented. They urged that information be offered in understandable terms, in many languages, by people women can relate to, and in places where women typically get and exchange information (markets, churches, schools). Some suggested a national media campaign, others an 800 number that women could call to get information on 076 (perhaps as part of the existing 1-800-TRIALS-A hotline).

There was agreement in the group that the information will have the greatest impact if it is separated from HIV, and presented as part of women's health care in general. Several women said that information about 076 would be overwhelming if given as part of HIV counseling and testing – "You can't concentrate on the diagnosis of HIV and this information at the same time." (see section on counseling and testing for additional comments).

The participants were unanimous in the belief that every woman should have the right to decide for herself about the 076 treatment. **They voted 15 - 0 against mandatory 076 treatment for HIV infected pregnant women.** They urged health care providers to give women complete, comprehensible information about 076 and then to support them in making their own decision regarding treatment. They recommended that consent forms be carefully developed in collaboration with women who are HIV infected and be written in understandable ways.

The participants cautioned that the power dynamics between providers and women – especially younger women, women who do not speak English, and women with a history of substance abuse – make it very difficult for women to make their own decisions. In addition, they warned that women who put "blind trust" in health care providers may have their rights to informed decision

making "greatly compromised." Providers, they said, must take responsibility for presenting the pros *and* the cons of the 076 study. One participant said, "Many women aren't going to think it through. They're going to reach out for hope. We already feel guilty, and we'll be made to feel even more guilty for not taking AZT. The doctors must give us the information about both the risks and the benefits."

The participants' ardent belief in a woman's right to make decisions about her own treatment is reflected in the statements they wrote when asked, "If you could tell policy makers one thing related to 076, what would it be?"

Among their responses were the following:

- "Give the public education on 076. Let the women make the final decision."
- "As an HIV infected woman, I feel that 076 and its results are very overwhelming, but at the same time I feel it is too inconclusive. Please leave this choice to me. Educate me and help me to make an educated decision."
- "All HIV infected pregnant women should be fully informed on the results of the 076 study and given the option of taking AZT during their pregnancy."
- "Give all women the understanding and the choice to decide."
- "Please recognize me as a human being, who wants to make the right decision based on my needs, wants, abilities, and freedom of choice. I am not a vessel, I am not a disease, I am not an "undesirable." I have strengths, abilities, desires, and rights. Let me love, help me to grow and be as productive as possible, for as long as possible. Acknowledge and respect me, we both lose when you ignore or dismiss me. Thank you for listening."

Implications: It is essential that information about ACTG 076 be widely disseminated and presented in an accessible, unbiased form. Because of the mistrust that many women have of the health care system, it will be especially important to build in ample time and opportunities for women who are HIV infected to learn about 076, to express their concerns, and to have their questions answered. Women must be supported in the decisions they make about the 076 treatment. Any suggestion of mandated 076 treatment will drive women away from the care system.

Counseling and Testing. The participants provided a wealth of information about counseling and testing. Their stories provided powerful testimony about the devastation of receiving a positive test result. After learning her diagnosis, one woman said, "I found out and I don't remember driving home that day." Another said, "I wanted to kill myself." And another, "I learned I was positive and I ran away for four years." Still another spoke of relapsing upon learning the diagnosis and using crack for another year and a half before returning to the care system.

These stories point out how critical a supportive counseling and testing system can be in linking women to comprehensive care. Unfortunately, however, the stories the women told of receiving their test results were largely negative. "I was tested in a private doctor's office. I heard the results over the phone at work. It's been over a year and I'm still waiting to hear from him again." Another woman described her experience this way, "When I came back for the results no one spoke to me, they just walked me down a long hall deep in the basement. I knew something wasn't right."

These stories demonstrate that in many instances current approaches to counseling and testing are not working well and, in fact, often drive women away from the system instead of bringing them in during this highly stressful time. These stories also point out that the time of diagnosis, even if handled in the most supportive manner, is a very difficult time to have to make complex decisions (e.g. about 076 treatment) – "You're asking the brain to be clear at a time when it can't."

Approaches to counseling and testing for women must be improved. The participants in the focus group provided eloquent descriptions of how the testing process could be more humane and supportive. Their comments again reflected their desire to be treated respectfully by providers and to have their psychosocial and emotional needs acknowledged and supported. Among the specifics offered by the women in the focus group were:

- Provide testing in sites where women get other health care services.
- The testing site should be pretty, bright, and cheerful.
- The people who are doing the testing should be women. They should come from the same community and speak the same language as the people being tested. They should be warm, caring, and non-judgmental.
- HIV positive women should be available for support when the test results are given.
- Because teens learn and relate differently, peer counselors should be used.
- Both the pre-test and post-test session should be at least two hours. There should be an interim meeting during the time the woman is waiting for the results to build rapport and continuity and ensure support.
- Give important information about care and support during pre-test phase since some women don't return for post-test follow up.

- Use the time between the pre and post test meetings to educate people. Offer an interim educational session on HIV.
- Give information about resources, care, and support at the time of diagnosis.
- Make sure people doing testing have been properly trained.
- Testing sites must be linked to services -- "If you can't treat, you shouldn't test."
- Provide a psychosocial assessment and several counseling sessions prior to testing to determine if woman will be able to handle positive results.
- Link mental health services, substance abuse treatment, and peer support to counseling and testing.
- Provide a range of test sites, from regular health clinics to anonymous test sites.
- There should be a stronger link between HIV education and prevention efforts and testing.
- If the woman tests negative, take the opportunity to reinforce risk reduction education -- "Some people think if they test negative once, they'll always be negative -- like an immunization."
- Shorten time between having blood drawn and getting results -- "We have one hour service for photographs, why not one hour service for an HIV test?"
- Women need to be there for other women during the testing process -- "We're all family."

Implicit in all the suggestions about an ideal counseling and testing system was the need for psychological support and an immediate connection to a care system. Participants stressed that special care must be taken with younger women and adolescents who are especially vulnerable and who may have very few social supports. HIV education and information about testing for teens should be provided by young people in the community.

The women also stressed that more public education about HIV was needed to reduce the stigma around HIV. With less stigma, more women would come for testing. One participant's comment reflects the degree of stigma still associated with HIV, "It's better to go out as a drug addict than as an HIV positive woman. There's more acceptance in society of drug abuse."

Finally, in response to three questions about universally offered/mandated testing for women the participants answered:

Should all pregnant women be offered testing, after appropriate pre-test counseling with post-test support, regardless of perceived HIV risk?
Yes - 13 No - 2

Should there be mandatory testing of all pregnant women?
Yes - 4 No - 11

Should there be mandatory testing of all women 13-50?
Yes - 3 No - 12

Implications: Because of the overwhelming emotional impact of receiving a positive test result, many of the participants felt it would be extremely difficult to make an informed choice about the 076 treatment at that time. Therefore, opportunities for testing must be made more available to women during routine health care encounters and as part of pre-conception care. In addition, the testing process needs to be humanized, and the psychosocial aspects of receiving a positive diagnosis must be comprehensively addressed.

CONCLUSIONS AND RECOMMENDATIONS

The focus group provided a tremendous amount of information on women's opinions about ACTG 076 and related issues including information dissemination, counseling and testing, and the components of a comprehensive care system for women with HIV infection. The participants' perspectives and comments provide important guidance on how information about 076 can be effectively communicated and how women can and should be supported in making care and treatment decisions for themselves and their children.

The following recommendations are based on the information, concerns, and experiences shared by the women in the focus group discussion.

- There is a high degree of suspicion among women about the medical community and about the efficacy of antiretroviral treatments. As a result, policy makers and clinicians must allow ample time for women to become informed about the study and ensure that there are opportunities for them to discuss their concerns. Without this kind of supportive, educational framework, many women will not consider the 076 treatment.

- All women have a fundamental right to complete, unbiased information about 076 so they can make a fully informed decision about accepting or declining treatment. No woman should ever be explicitly or implicitly coerced into treatment.

- The devastating impact of a positive HIV test result can potentially compromise a pregnant woman's ability to make an informed decision about 076 treatment. Therefore, there must be increased efforts to offer supportive, appropriate HIV testing to women as part of general health care and during preconception care.

- Because of the enormous emotional burden of receiving an HIV diagnosis, all HIV counseling and testing for women must be linked to mental health services, peer support, substance abuse services, and comprehensive health care. Without these kinds of supports women will be lost to care and treatment.

- Too often, women (and other consumers) have been excluded from participation in the health care decisions that affect their lives. In the future, these consumers must be at the table when all research and clinical decisions are being made. This kind of collaboration will foster trust between the recipients of care and the providers of care and ensure that decisions are made in the best interest of those living with HIV.

While the information in this report pertains primarily to the ACTG 076, the observations and experiences of the women reflect problems in the overall health care system. Their very powerful commentary about the lack of trust they have in providers and in the health care system goes far beyond HIV and AIDS. Similarly, their clear, well-articulated vision of how the care system could be restructured to be more respectful and more responsive to the needs of women, children, and families applies to all settings where health care is delivered.

One participant in the focus group said, "When making policy choices, you must include HIV positive women and adolescents in the entire decision making process, from beginning to end." By incorporating her perspectives and experiences, and the perspectives and experiences of other women in policy and program development, the system of care will be improved. The principles of collaborative planning and decision making are essential to designing an effective, humane health care system, in HIV care and in care for all the nation's citizens.

For copies of the full report, contact: Institute for Family-Centered Care, 5715 Bent Branch Road, Bethesda, MD 20816, (301)320-2686.

The Institute for Family-Centered Care provides essential leadership on family-centered issues. It serves as a central resource for policy makers, program planners, direct service providers, design professionals and family members. The Institute seeks to increase understanding and practice of family-centered care through resource development, information dissemination, policy and research initiatives, training, and technical assistance.

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MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

Recommendations and Reports

Recommendations of the U.S. Public Health Service Task Force on the Use of Zidovudine to Reduce Perinatal Transmission of Human Immunodeficiency Virus

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta, Georgia 30333

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Executive Committee and U.S. Public Health Service Task Force

On June 6, 1994, the U.S. Public Health Service convened a workshop in Bethesda, Maryland, to develop recommendations for the use of zidovudine to reduce the risk for perinatal transmission of human immunodeficiency virus (HIV). The recent results of AIDS Clinical Trials Group Protocol 076, a controlled clinical trial sponsored by the National Institutes of Health in collaboration with the National Institute of Health and Medical Research and the National Agency of Research on AIDS in France, indicate that zidovudine administered to a selected group of HIV-infected women and their infants can reduce the risk for perinatal transmission of HIV by approximately two-thirds. The implications of these results for use of zidovudine in HIV-infected pregnant women and neonates were discussed at the workshop. The following persons participated in the workshop and either served as the Executive Committee writing group that developed the recommendations or were members of the U.S. Public Health Service Task Force on the Use of Zidovudine to Reduce Perinatal HIV Transmission.

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ened a workshop in Bethesda, zidovudine to reduce the risk virus (HIV). The recent results clinical trial sponsored by the National Institute of Health and h on AIDS in France, indicate HIV-infected women and their of HIV by approximately two- udine in HIV-infected pregnant The following persons partici- tive Committee writing group ers of the U.S. Public Health Perinatal HIV Transmission.

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BOX 3. Summary: Clinical situations and recommendations for use of zidovudine* to reduce perinatal HIV transmission

I. Pregnant HIV-infected women with CD4+ T-lymphocyte counts ≥200/µL who are at 14–34 weeks of gestation and who have no clinical indications for ZDV and no history of extensive (>6 months) prior antiretroviral therapy.

Recommendation:
The health-care provider should recommend the full ACTG Protocol 076 regimen to all HIV-infected pregnant women in this category. This recommendation should be presented to the pregnant woman in the context of a risk-benefit discussion: a reduced risk of transmission can be expected, but the long-term adverse consequences of the regimen are not known. The decision about this regimen should be made by the woman after discussion with her health care provider.

II. Pregnant HIV-infected women who are at >34 weeks of gestation, who have no history of extensive (>6 months) prior antiretroviral therapy, and who do not require ZDV for their own health.

Recommendation:
The health-care provider should recommend the full ACTG Protocol 076 regimen in the context of a risk-benefit discussion with the pregnant woman. The woman should be informed that ZDV therapy may be less effective than that observed in ACTG Protocol 076, because the regimen is being initiated late in the third trimester.

III. Pregnant HIV-infected women with CD4+ T-lymphocyte counts <200/µL who are at 14–34 weeks of gestation, who have no other clinical indications for ZDV, and who have no history of extensive (>6 months) prior antiretroviral therapy.

Recommendation:
The health-care provider should recommend initiation of antenatal ZDV therapy to the woman for her own health benefit. The intrapartum and neonatal components of the ACTG Protocol 076 regimen should be recommended until further information becomes available. This recommendation should be presented in the context of a risk-benefit discussion with the pregnant woman.

IV. Pregnant HIV-infected women who have a history of extensive (>6 months) ZDV therapy and/or other antiretroviral therapy before pregnancy.

Recommendation:
Because data are insufficient to extrapolate the potential efficacy of the ACTG Protocol 076 regimen for this population of woman, the health-care provider should consider recommending the ACTG Protocol 076 regimen

*These recommendations do not represent approval by the Food and Drug Administration (FDA) or approved labeling for the particular product or indications in question.

BOX 3. Summary: Clinical situations and recommendations for use of zidovudine to reduce perinatal HIV transmission (Continued)

on a case-by-case basis after a discussion of the risks and benefits with the pregnant woman. Issues to be discussed include her clinical and immunologic stability on ZDV therapy, the likelihood she is infected with a ZDV-resistant HIV strain, and, if relevant, the reasons for her current use of an alternative antiretroviral agent (e.g., lack of response to or intolerance of ZDV therapy). Consultation with experts in HIV infection may be warranted. The health-care provider should make the ACTG Protocol 076 regimen available to the woman, although its effectiveness may vary depending on her clinical status.

V. Pregnant HIV-infected women who have not received antepartum antiretroviral therapy and who are in labor.

Recommendation:
For women with HIV infection who are in labor and who have not received the antepartum component of the ACTG Protocol 076 regimen (either because of lack of prenatal care or because they did not wish to receive antepartum therapy), the health-care provider should discuss the benefits and potential risks of the intrapartum and neonatal components of the ACTG Protocol 076 regimen and offer ZDV therapy when the clinical situation permits.

VI. Infants who are born to HIV-infected women who have received no intrapartum ZDV therapy.

Recommendation:
If the clinical situation permits and if ZDV therapy can be initiated within 24 hours of birth, the health-care provider should offer the ACTG Protocol 076 postpartum component of 6 weeks of neonatal ZDV therapy for the infant in the context of a risk-benefit discussion with the mother. Data from animal prophylaxis studies indicate that, if ZDV is administered, therapy should be initiated as soon as possible (within hours) after delivery. If therapy cannot begin until the infant is >24 hours of age and the mother did not receive therapy during labor, no data support offering therapy to the infant.