

# **Ending AIDS: Considering the Human Element**

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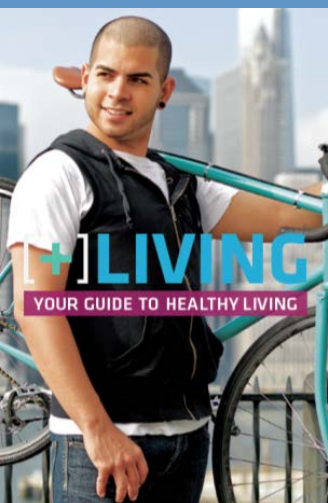
**HIV CENTER** for Clinical and Behavioral Studies  
at the New York State Psychiatric Institute and Columbia University



# *HIV in 2016*

- ART (range of potent antiretroviral treatments, including long-acting injectibles)
- New, emerging treatments, including “cure” research

- Living longer
- Improved quality of life
- Chronic disease model
- Treatment as Prevention (TasP)
- PrEP (oral & topical)
- “The End of AIDS” – Hype or Hope?!



# Ending HIV /AIDS Initiatives

- 90-90-90
- Fast Track Cities Initiative
- US National HIV/AIDS Strategy
- US Local Initiatives; for example:
  - NY State Ending the Epidemic (EtE) Initiative
  - End AIDS Washington Campaign
- Others, and those emerging

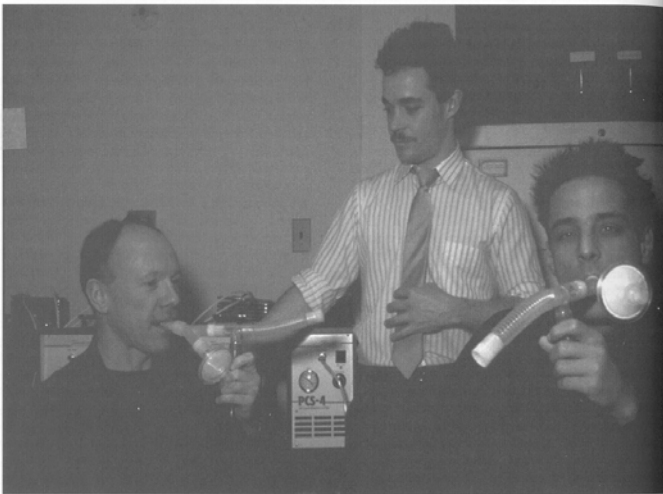
Hillary Clinton talking about the possibility of achieving an AIDS-free generation;  
National Institutes of Health: November 8, 2011



# Adherence & Survival

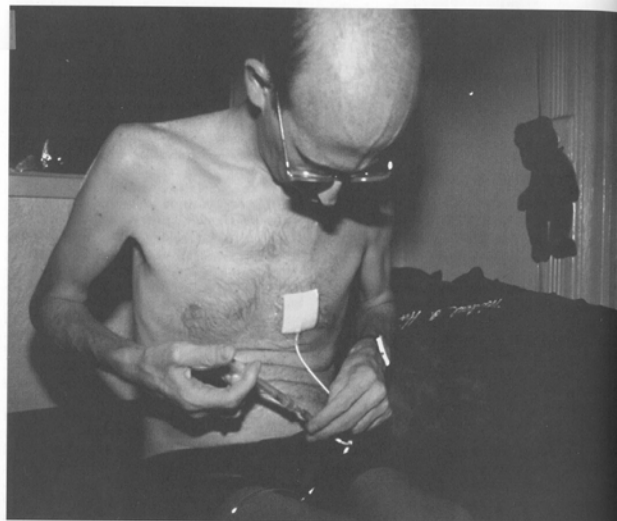
- Aerosolized pentamidine;  
Nutritional supplements (Hickman catheters); Experimental therapies

392 PNEUMOCYSTIS CARINII PNEUMONIA (PCP)



*Pneumocystis carinii pneumonia (PCP) was the major cause of death among people with AIDS during the early years of the epidemic. The first clinical trials for aerosolized pentamidine (AP) as prophylaxis against PCP were sponsored not by the federal government but by two community-based organizations: New York's Community Research Initiative (CRI) and San Francisco's County Community Consortium (CCC).*

340 MALNUTRITION



*Michael Hirsch, founder of the New York AIDS service organization Body Positive, infuses a nutritional supplement into a Hickman catheter in his chest in order to combat AIDS-related malnutrition.*

COMPLEMENTARY AND ALTERNATIVE MEDICINE 141



*Numerous experimental treatments have been unsuccessfully attempted to remove HIV from the body, including plasmapheresis, in which the blood is removed, filtered, and reinfused.*

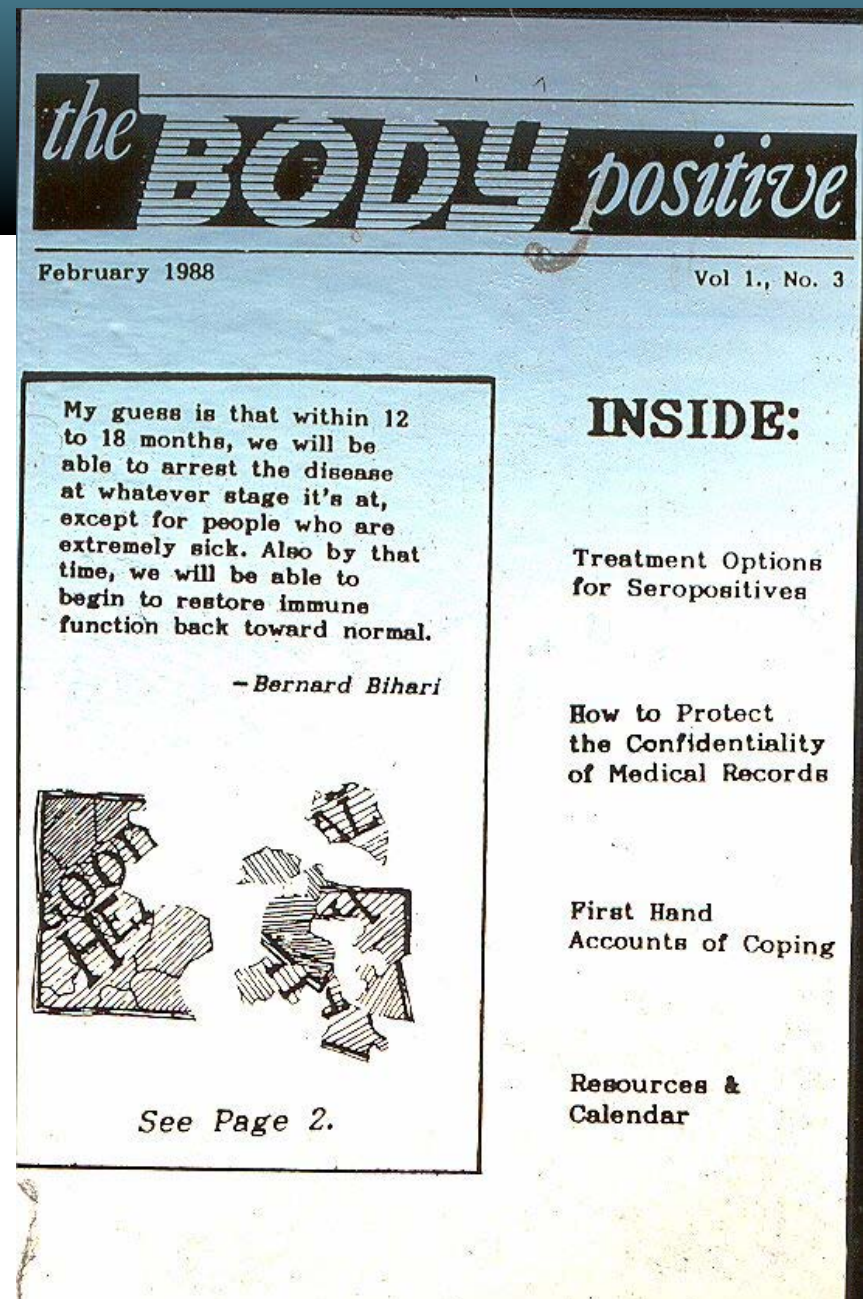
**PWA Coalition Newslines**  
September 1988 Published By And For People With AIDS And AIDS Related Conditions Issue #36



*PWArc: Belinda Mason with her army of vitamins and minerals attended the recent Boston AIDS conference sponsored by the Lesbian & Gay Health Foundation. Photo: © 1988 Jane Rosett*

# HOPE (in the “dark” days)

- Announced at a large community forum by a well-known community physician in 1988
- Many of us thought the nightmare would be over soon



But, the epidemic raged on and the deaths continued



# Multiple loss and grief



# Including (my) personal network

## A Tribute To The Life Of Charles D. Armstrong



June 13, 1953 - April 4, 1995

"Charlie: A bright light of life who touched everyone with his wit, charm, intelligence, style, grace and warmth through his art and his being. Charlie always added his unique personal touch to every encounter, making it a delight to know and love him."

Robert De Angelis

### Dr. Peter Jepson-Young, 35, Dies; Educated Canadians About AIDS

By CLYDE H. FARNSWORTH  
Special to The New York Times

### John Martin, 38, a Researcher Who Studied the Impact of AIDS

By BRUCE LAMBERT  
John Martin, a Columbia University professor and an AIDS researcher who started a pioneering study on the sexual behavior of gay men and the impact of the AIDS epidemic on the community, died on Friday at his home in New York City.

### Andr  Bossard, 47, a Founder of a Mime Trio

By ANNA KISSELGOF

Andr  Bossard, a founding member of Mummenschoen, the Swiss mime trio that achieved international popularity with its sophisticated commentary on the human condition, died on March 9 in Brunnen, Switzerland.

### Willard Ching, 50, A National Leader Of Interior Designers

By BRUCE LAMBERT

Willard Ching, a national leader of interior designers, died on March 9 in New York City.

### John Haber, an Opera Director, Teacher and Zen Buddhist Monk

John Haber, an opera director, teacher and Zen Buddhist monk, died on March 9 in New York City.

### Robert L. Cecchi, 49, AIDS-Care Advocate

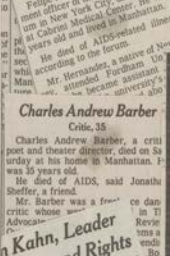
Robert L. Cecchi, founder of the program at the New York City Department of Health and Mental Hygiene, died on March 9 in New York City.

### Her  Guibert, 36, French Novelist, 36

Her  Guibert, a French novelist who wrote about his struggle against AIDS, died on March 9 in Paris.

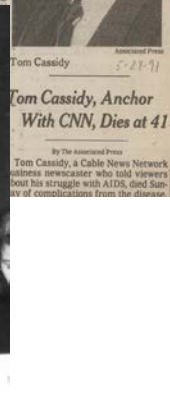
### Melvin Dixon, 42, Professor and Author

Melvin Dixon, a professor of English at the University of California, died on March 9 in Stanford, Calif.



In Celebration

WILLIAM A. BAILEY



# AZT

- The first promise of a new medical agent to treat HIV directly

## The New England Journal of Medicine

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Volume 323

OCTOBER 11, 1990

Number 15

### A RANDOMIZED CONTROLLED TRIAL OF A REDUCED DAILY DOSE OF ZIDOVUDINE IN PATIENTS WITH THE ACQUIRED IMMUNODEFICIENCY SYNDROME

MARGARET A. FISCHL, M.D., CORETTE B. PARKER, M.S.P.H., CARLA PETTINELLI, M.D., Ph.D.,  
MICHAEL WULFSOHN, M.D., MARTIN S. HIRSCH, M.D., ANN C. COLLIER, M.D., DIANA ANTONISKIS, M.D.,  
MONTA HO, M.D., DOUGLAS D. RICHMAN, M.D., EDWARD FUCHS, P.A.-C.,  
THOMAS C. MERIGAN, M.D., RICHARD C. REICHMAN, M.D., JONATHAN GOLD, M.D., NEAL STEIGBIGEL, M.D.,  
GIFFORD S. LEOUNG, M.D., SURAIYA RASHEED, Ph.D., ANASTASIOS TSATSIS, Ph.D.,  
AND THE AIDS CLINICAL TRIALS GROUP\*

**Abstract Background.** The initially tested dose of zidovudine for the treatment of patients with advanced disease caused by the human immunodeficiency virus type 1 (HIV) was 1500 mg. Although this dose is effective, it is associated with substantial toxicity.

**Methods.** To evaluate the efficacy and safety of a reduced dose, we conducted a randomized controlled trial in 524 subjects who had had a first episode of *Pneumocystis carinii* pneumonia. The subjects were assigned to receive zidovudine in either a dose of 250 mg taken orally every four hours (the standard-treatment group, n = 262) or a dose of 200 mg taken orally every four hours for four weeks and thereafter 100 mg taken every four hours (the low-dose group, n = 262).

**Results.** The median length of follow-up was 25.6 months. At 18 months the estimated survival rates were 52 percent for the standard-treatment group and 63 percent for the low-dose group (P = 0.012 by the log-rank test). At 24 months the estimated survival rates were 27 percent for the standard-treatment group and 34 percent for the low-

dose group (P = 0.033). In both groups, 82 percent of the subjects had another opportunistic infection, and the length of time to that infection was similar in the two groups (P = 0.56 by the log-rank test). CD4 T-lymphocyte counts improved transiently in both groups, and serum levels of HIV antigen decreased in the subjects with antigenemia. The hemoglobin level declined to less than 5 mmol per liter (80 g per liter) in 101 subjects in the standard-treatment group and in 77 in the low-dose group (39 vs. 29 percent, P = 0.0009 by the log-rank test). The neutrophil count declined to less than  $0.750 \times 10^9$  per liter in 134 subjects in the standard-treatment group and in 96 in the low-dose group (51 vs. 37 percent, P = 0.0001).

**Conclusions.** The reduced daily dose of zidovudine used in this study was at least as effective as the standard dose and was less toxic; however, with the use of a four-week induction period with a high dose followed by low-dose treatment, severe anemia and neutropenia were common complications of treatment with zidovudine. (N Engl J Med 1990; 323:1009-14.)

ZIDOVUDINE (3'-azido-2'-deoxythymidine; formerly azidothymidine, or AZT) is a thymidine analogue that inhibits the replication of the human immunodeficiency virus type 1 (HIV) in vitro.<sup>1</sup> The administration of zidovudine to patients with advanced HIV disease over a 6-to-24-month period prolongs survival, decreases the frequency and severity of opportunistic infections, improves neurologic function, transiently improves CD4 T-lymphocyte counts, and decreases the rate of HIV antigenemia.<sup>2,3</sup>

Despite these benefits, zidovudine therapy is frequently associated with adverse reactions, including both anemia and neutropenia.<sup>2,3</sup> Although the serum half-life of zidovudine is one hour, the intracellular half-life of its 5'-triphosphate form approaches three hours, suggesting that lower daily doses or longer intervals between drug administration may be adequate.

To evaluate the safety and efficacy of a lower daily dose of zidovudine, we conducted a randomized, con-

trolled trial in which the initially tested dose of zidovudine (250 mg every four hours)<sup>2</sup> was compared with a lower dose (100 mg every four hours). This report details the preliminary findings of the study.

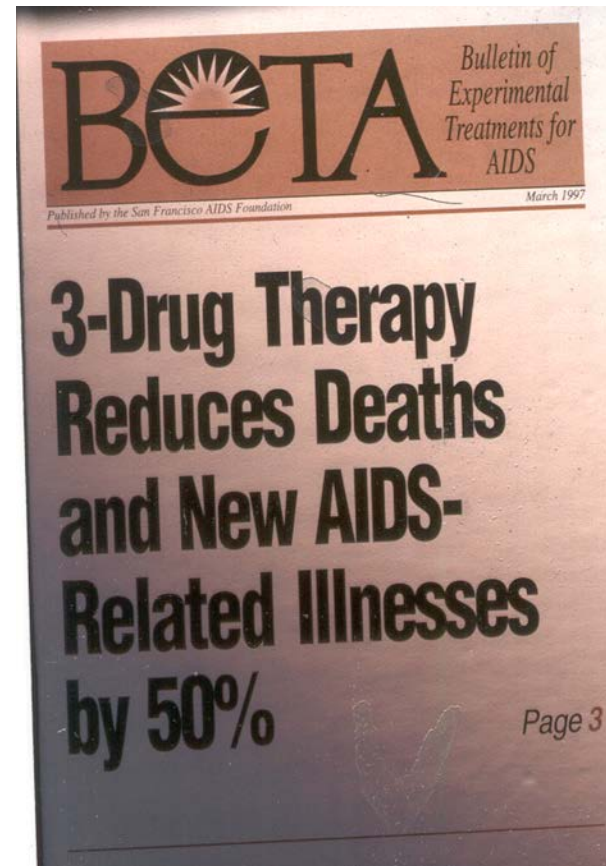
#### METHODS

##### Study Population

The study population consisted of subjects who had had a first episode of histologically confirmed *Pneumocystis carinii* pneumonia at least two weeks before enrollment. Subjects who had previously received zidovudine, who had had multiple episodes of *P. carinii* pneumonia, or who had any further infection or a neoplasm indicating the presence of the acquired immunodeficiency syndrome (AIDS), other than minimal cutaneous Kaposi's sarcoma, were excluded. The criteria for eligibility also included a hematocrit of 30 percent or more, a total neutrophil count of  $1.0 \times 10^9$  per liter or more, a platelet count of  $75 \times 10^9$  per liter or more, a serum aspartate or alanine aminotransferase level that was less than five times the upper limit of normal, a Karnofsky performance score of 60 or more, and serum positive for HIV antibody as determined with any licensed enzyme-linked immunosorbent assay. The use of other anti-HIV drugs, biologic-response modifiers, prophylaxis for *P. car-*

# Finally, good news on the treatment front (1996)

- Combination therapy which came to be known as HAART



# When to Start?

- Hit Hard, Hit Early?
- Wait and preserve your options?
- What combination to start with?

## San Francisco AIDS Foundation New Federal Guidelines for the Treatment of HIV Infection



In November 1997, the federal government released new guidelines for anti-HIV treatment based on research showing the benefits of combination regimens. The recommendations offer expert opinions about when to start anti-HIV therapy, what drugs to consider, how to use HIV viral load and CD4 T-cell testing, and when to stop or change therapy.

The use of highly active antiretroviral therapy (HAART) has produced clinical improvements and a better quality of life for many people living with HIV/AIDS. The guidelines recommend that all people choosing treatment should use combination regimens that include nucleoside analogs and potent protease inhibitor drugs. People also may benefit from other 3- and 4-drug combinations, including certain double protease inhibitor combinations and regimens that contain a non-nucleoside reverse transcriptase inhibitor (NNRTI) drug. The guidelines discourage using 2 nucleoside analogs by themselves.

### Viral Load and CD4 T-Cell Testing

An HIV viral load test should be done when a person is first diagnosed with HIV infection and then every 3-4 months afterwards. The CD4 T-cell count should be measured at the time of diagnosis and every 3-6 months afterward. Monitoring viral load and CD4 T-cell counts is important even if a person is not taking any anti-HIV drug treatment, because this allows for rapid and effective drug intervention if HIV levels rise or CD4 T-cells decrease significantly.

When a person decides to start treatment, HIV viral load should be measured immediately before and again 4 weeks after starting therapy. After about 4-8 weeks of treatment with HAART, most

people should experience a greater than 10-fold decrease in viral load.

People taking anti-HIV drugs should have an HIV viral load test every 3-4 months. If the treatment is working well, within 6 months HIV levels will be "undetectable." "Undetectable" does not mean that there is no HIV in the body. Rather, it means that the amount of HIV genetic material in the blood plasma is "below the level of detection" of the particular viral load test used.

### When to Start Therapy

Table 1 below shows guidelines for when to start anti-HIV therapy based on disease stage and the results of viral load and CD4 T-cells tests. Table 2 lists FDA-approved anti-HIV drugs.

HAART works best when it includes at least 2 drugs that a person has never used before. Because many people with AIDS have already exhausted the benefit from most or all of the nucleoside analog drugs, it may be difficult for them to find effective long term combinations. Currently 3 experimental drugs are available to people who have no remaining nucleoside analog treatment options. See the summary sheet on "Promising New Drugs in Development."

### When to Interrupt or Change Therapy

There are reasons (such as drug interactions or pregnancy) for briefly interrupting therapy. If treatment is interrupted, stop all anti-HIV drugs at the same time to reduce the risk of developing drug-resistant HIV.

A person may need to change a drug regimen for several

Table 1. When to Start Anti-HIV Therapy

Stage of Infection	HIV Viral Load and CD4 T-Cell Count	Treatment Recommendation
Asymptomatic	Greater than 500 CD4 T-cells and HIV RNA less than 10,000 (bDNA) or less than 20,000 (RT-PCR)	Some experts would wait; others would use HAART indefinitely
Asymptomatic	350-500 CD4 T-cells and HIV RNA less than 10,000 (bDNA) or less than 20,000 (RT-PCR)	Begin HAART or wait
Asymptomatic	Less than 500 CD4 T-cells or HIV RNA more than 10,000 (bDNA) or 20,000 (RT-PCR)	Begin HAART
Symptomatic (thrush, unexplained fever, weight loss, AIDS diagnosis)	Any level	Begin HAART

# Still Seeking New Drugs

## Among other things: concern about toxicities and drug resistance

THE DOCTOR'S WORLD

### To Combat the Wily H.I.V., Newer and Safer Drugs Are Necessary

By LAWRENCE K. ALTMAN, M.D.

CHICAGO, Feb. 10 — An arsenal of 15 drugs would seem ample to treat a disease successfully. But not AIDS.

Since the mid-1980's, scientists have developed 15 drugs directed against H.I.V., the AIDS virus. Combinations of three or more of the anti-H.I.V. drugs have reduced the number of deaths and allowed thousands of infected people to maintain relatively good health. With improved obstetrical care, the drugs have sharply reduced the incidence of mother-to-child transmission of H.I.V. in the United States and Europe to less than 2 percent from earlier highs of 25 percent.

Pharmacologic advances have simplified some regimens by lifting restrictions for pills that once had to be swallowed only with food, or without it. Some pills, like indinavir, can now be taken twice daily instead of three times a day, easing the burden on people who had to adhere to rigid intake schedules built around meals.

Nevertheless, H.I.V. is so wily that the drugs are still failing thousands of infected people, including many who have taken each of the 15 at one time or another. Viral resistance that severely compromises drug use is common. Even effective regimens can be complicated and must be followed for a lifetime, which could be 50 years or longer for young infected people.

"That is unrealistic for most people," Dr. Fred T. Valentine, an AIDS expert at New York University, said in an interview at the Eighth Annual Retrovirus Meeting here.

New, safer drugs are urgently needed for people already infected and the millions who are expected to become infected, speakers at the meeting said. Ultimate goals include developing a once-daily combination that avoids irreversibly damaging the im-

mune system and delays disease progression.

Indeed, many candidate drugs are in various stages of the experimental pipeline.

Dr. Roy M. Gulick of the Weill Medical College of Cornell University in Manhattan discussed a partial list. Many were known only by initials and numbers like T-20, T-1249, TMC-126 and BMS 232632, and others had names like capravirine, tenofovir and tipranavir.

Still other candidates are in earlier stages of drug development and have not left the laboratory, have been tested only in animals or have been given only to a few people for purposes of monitoring safety more than determining effectiveness.

Some experimental drugs are chemically related to members of the three licensed classes. Other candidates that belong to new classes offer the hope of substantial therapeutic benefits because they disrupt different parts of the H.I.V. cycle left unscathed by the available 15 drugs. One new class inhibits the binding of H.I.V. to a receptor, known as CCR5, situated on a cell surface. A second new class inhibits fusion of H.I.V. to a cell after it gains entry.

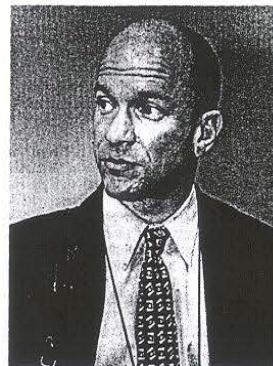
When and if the Food and Drug Administration will license a 16th anti-H.I.V. drug is unknown. Experience has shown that many promising candidates unexpectedly fall by the wayside in the lengthy series of animal and human tests needed to meet federal licensing requirements.

"The fundamental issue in the field right now is toxicity of our drugs," Dr. Diane Havlir of the University of California at San Diego said at the meeting.

Experts did not predict most toxicities of the available drugs, and they poorly understand why they develop. Among the problems: fat accumulations in the neck and abdomen that create buffalo humps and pot-



Dr. Anthony Fauci, left, and Dr. Roy Gulick, participants in the retrovirus conference, discussed possible anti-H.I.V. drugs now in experimentation and trial therapy cycles.



Photographs by Steve Kagan for The New York Times

bellies, weakened bones, dangerous increases in cholesterol levels, anemia, kidney stones and diabetes. Still, Dr. Havlir said, "The full spectrum may not yet be realized."

A common, painful toxicity spotlighted at the meeting is a type of nerve damage known as peripheral neuropathy. It causes a pins-and-needles sensation in the soles of the feet and legs, but spares motor function and usually does not weaken muscles. Still, constant pain makes life miserable for many. The pain limits drug choices and leads many affected people to skip doses, increasing risk for developing viral resistance, said Dr. Justin McArthur of the Johns Hopkins University School of Medicine.

A main hope is that new classes of drugs will overcome such toxicities and also the increasingly common problem of viral resistance. Resistance can develop for a variety of reasons as diverse as patients' not taking drugs on schedule and doctors' prescribing drugs in wrong combinations.

Efforts to find effective drug combinations for people with highly resistant viruses are called salvage therapy. A new hope is to learn how to use two tests, known as phenotyping and genotyping, before prescribing anti-H.I.V. drugs to identify resistant strains early, thus preventing treatment failures and the need for salvage therapy.

Dr. Susan J. Little of the University of California at San Diego said that no one

could know whether new drugs would be marketed in time to rescue many of those infected by resistant strains but that she believed there was "reason for great pessimism."

Dr. Havlir said doctors were paying a price for having been too certain about anti-H.I.V. treatment. A pressing problem, Dr. Havlir said, is to learn the best time to start therapy and how to optimize use of available drugs.

Some infected people are known as long-term nonprogressors because they have controlled H.I.V. without therapy for as long as 20 years. Researchers are seeking to identify what in their immune systems is responsible for the phenomenon. Continuing studies are designed to learn whether starting drug treatment soon after infection occurs and then stopping it might allow the immune system to produce a similar protective effect.

The approach is known as structured treatment interruption and is one of the hottest and most controversial areas of AIDS research. But because the studies are being run in different ways, direct comparison of findings is impossible. Those reported at the meeting were sobering and inconsistent. In summarizing the work of his and other teams, Dr. Bruce D. Walker of Harvard Medical School said such therapy could not be generally recommended because it had not shown real benefits so far.

Participants at that session "did not walk away with a good feeling" about the goal of ultimately stopping therapy, said Dr. Anthony S. Fauci, the director of the National Institute of Allergy and Infectious Diseases. Dr. Fauci is conducting two small trials in which participants stop and restart therapy for specified periods in well-defined cycles. The aim is, to give infected people long

*Continued on Page 12*

- HIV Medical Care – as much “art” as it was “science.”
  - New antiviral agents
  - Role of prophylaxis?
  - Role of newly approved VL test?
  - \*Lack of data!

## Flying by the Seat of Our Pants

by Dave Gilden

### Deciding How to Treat

In the absence of sufficient information, doctors are using their personal experience to develop new treatment modalities 1

### Treatment Issues Survey

Thirty-six physicians describe the way they incorporate the new medical tools in their HIV/AIDS practice 4

### Preventing Yeast

Women's study finds once weekly fluconazole reduces thrush and vaginal yeast by half 6

### Economic Pressures on HIV/AIDS Care

Sometimes reducing costs improves the quality of care, but mostly it just means cutting corners 7

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Minimizing the perils of the new economic order 8

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### Viral Load Testing

FDA and International AIDS Society panel differ on its role. Questions persist as to the value and place of viral load testing in treatment strategy 21

### Nevirapine Approved

Surprise! Surprise! New data impress the FDA 25

### Eradicating HIV

The new giddy optimism meets the old hard realities 26

### Fusin II

More on how HIV fuses to cells 28

Last March, the United States Food and Drug Administration authorized the sale of two additional protease inhibitors, indinavir and ritonavir. This makes for eight anti-HIV drugs currently on the U.S. market, compared to only four as recently as last fall. Continuing this historic expansion, nevirapine will shortly join the ranks (see page 25). On the heels of nevirapine are two more protease inhibitors and five reverse transcriptase inhibitors in advanced human testing. AIDS-related opportunistic conditions also have seen significant developments. In particular, new agents have been proffered over the past year for preventing CMV and MAC as well as for combating AIDS-related weight loss.

Tests for viral load—the Roche PCR version is newly approved in the U.S. (see page 21)—may help make some sense of this therapeutic kaleidoscope. Unfortunately, research on the relation of HIV levels to disease has been inadequate. Viral load tests' potential for settling questions of overall therapeutic strategy and for guiding individuals' treatment decisions requires further delineation. Opinion differs in the meantime about the optimal starting point for pharmacological intervention, when to change therapy and which regimens have the best therapeutic indices and duration of effect.

When patients and doctors lack sufficient carefully collected study data, they can only rely on their own and others' clinical experience to guide them. In an effort to further disseminate that experience, we at *Treatment Issues* surveyed a group of prominent HIV specialists in North America, Europe and Australia. We recapitulate their answers in the pages that follow.

Our respondents have large AIDS practices conducted in diverse care settings—public clinics, private practice, health maintenance organizations and university hospitals. Many work within the constraints of managed care, payer formularies, Medicaid and ADAP programs. The questions they answered were open-ended and intended to stimulate discussion of diverse treatment strategies.

Our goal was to uncover the range of approaches followed today by experts in the field rather than to systematically reflect the opinions of all physicians who treat HIV and AIDS. We therefore have included answers illustrating both dominant trends and contrarian views. Statements attributed to individuals may be paraphrased and are not necessarily the complete response to any given question. The tables do provide a quick overview of all the responses, but because of the survey's eclectic nature, we urge that readers carefully look at the individual responses rather than just peruse the summaries.

### Associating Viral Load and Physical Health

The most striking observation to come from these respondents is the remark by several that they are seeing clinical improvement in

Results of the  
Treatment Issues'  
survey of current  
medical practice

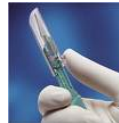
Literally – Flying by the Seat of my Pants!



# The Use of Antiretrovirals for Primary Prevention as well as Treatment



## Male circumcision



Auvert B, PloS Med 2005  
Gray R, Lancet 2007  
Bailey R, Lancet 2007

## Treatment of STIs



Grosskurth H, Lancet 2000

## Female Condoms



## Male Condoms



## HIV Counseling and Testing



Coates T, Lancet 2000  
Sweat, Lancet ID, 2011  
Coates, CROI, 2013

## Behavioral Interventions



## Vaccines



Rerks-Ngarm S, NEJM 2009

# COMBINATION HIV PREVENTION

## Microbicides for women



Abdool Karim Q, Science 2010

## Treatment as prevention



Donnell D, Lancet 2010  
Cohen M, NEJM 2011

## Prevention with positives



Fisher J, JAIDS 2004

## Oral pre-exposure prophylaxis

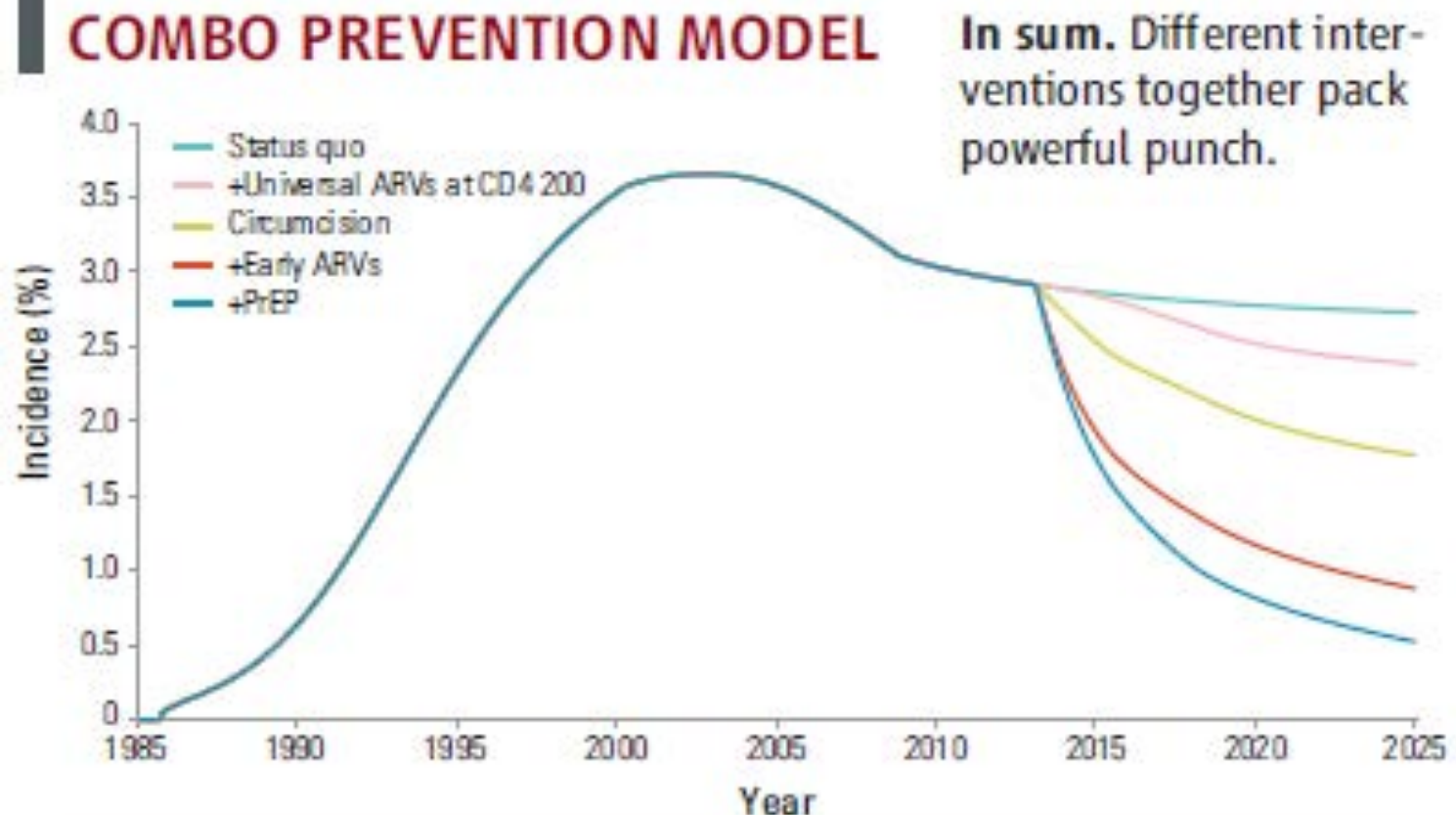
Grant R, NEJM 2010 (MSM)  
Baeten J, 2011 (Couples)  
Paxton L, 2011 (Heterosexuals)

## Post Exposure prophylaxis (PEP)



Scheckter M, 2002

Mathematical modeling anticipates the greatest impact will be with implementing effective strategies together



**VIEWPOINT**

Gregory K. Folkers, MS, MPH

## FUTURE DIRECTIONS

**ANALYSIS & COMMENTARY**  
**The World Must Build On Three  
 Decades Of Scientific Advances  
 To Enable A New Generation  
 To Live Free Of HIV/AIDS**

DOI: 10.1377/hlthaff.2012.0275  
HEALTH AFFAIRS 30,  
NO. 7 (2012): 1529-35  
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The People-to-People Health  
Foundation, Inc.

**Gregory K. Folstein** is chief of staff to the director and a senior advisor on policy, communications, and programmatic issues at the National Institute of Allergy and Infectious Diseases.

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### Addressing Gender and HIV/AIDS



Addressing gender norms and inequities, increasing access to services for every woman and girl, and strengthening interagency Gender Technical Working Groups will help UN Women address gender norms and inequities on five key areas:

- [Full Text»](#) [Fact Sheet \(PDF\)»](#) [Blog post by Ambassador Goosby](#)  
[Commitment: Zero Tolerance to Gender-Based Violence»](#) [Collect](#)  
[issues in HIV/AIDS»](#)

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## Charlotte Tuck

### Excerpt

In the early day  
method" to tell  
Abstain. Be faith  
Copyright The N

## 'Don't Think of Ugly People': 19th-Century Parenting Advice

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## How Close Are We to an AIDS-Free Generation?

## Blueprint for fighting HIV aims for global AIDS-free generation: Plotting future of US PEPFAR program

**JAIDS** JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROMES

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J AIDS Journal of Acquired Immune Deficiency Syndromes:

1 August 2012 - Volume 60 - Issue - p S19-S21

doi: 10.1097/QAL.0b013e31826028d5

Introduction

## Engaging to End the Epidemic: Seven Essential Steps Toward an AIDS-Free Generation

Marlink, Richard MD<sup>a,\*</sup>; El-Sadr, Wafaa MD, MPH, MPA<sup>b,§,||</sup>; Simao, Mariangela MSc, MD<sup>b</sup>; Katabira, Elly MD, FRCP<sup>c,\*\*</sup>

# The Cities Report



## Targets

By 2020

By 2030

90-90-90  
Treatment

95-95-95  
Treatment

500 000  
New infections  
among adults

200 000  
New infections  
among adults

ZERO  
Discrimination

ZERO  
Discrimination

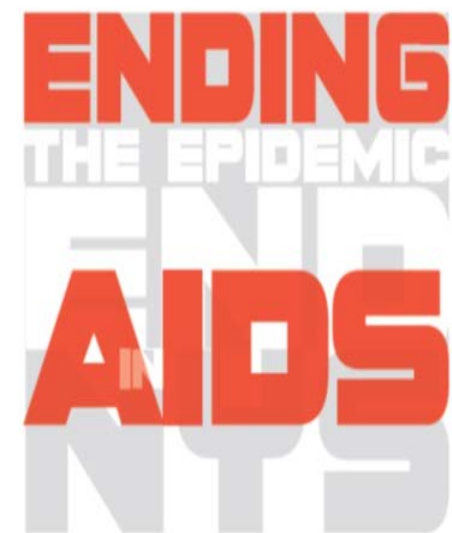


HIV CENTER for Clinical and Behavioral Studies  
at the New York State Psychiatric Institute and Columbia University

# Ending the Epidemic

- Identifying persons with HIV who remain undiagnosed and linking them to health care
- Linking and retaining persons with HIV to health care, getting them on antiretroviral therapy to improve their health and prevent transmission
- Providing Pre-Exposure Prophylaxis (PrEP) to high-risk persons to keep them HIV-negative.





GET TESTED.  
TREAT EARLY.  
STAY SAFE.

NEW YORK STATE DEPARTMENT OF HEALTH

2015

# BLUEPRINT

For achieving the goal set forth by Governor Cuomo to end HIV as an epidemic in New York State by 2020

1 | PAGE

12/27/2014

[http://www.health.ny.gov/diseases/aids/ending\\_the\\_epidemic/index.htm](http://www.health.ny.gov/diseases/aids/ending_the_epidemic/index.htm)



On January 13, 2015 the NYS Ending the Epidemic Task Force completed its charge and finalized 44 committee recommendations that address HIV related prevention, care and supportive services.

Committee Recommendations were informed by 294 community recommendations and 17 statewide stakeholder meetings.

**The final Blueprint contains  
30 Blue Print Recommendations and  
7 Getting to Zero Recommendations.**

# Blueprint to End AIDS by 2020

On April 29<sup>th</sup>, 2015 Gov. Cuomo announced the launch of the Blueprint at the LGBT Center in Manhattan.

"Thirty years ago, New York was the epicenter of the AIDS crisis -- today I am proud to announce that we are in a position to be the first state in the nation committed to ending this epidemic".

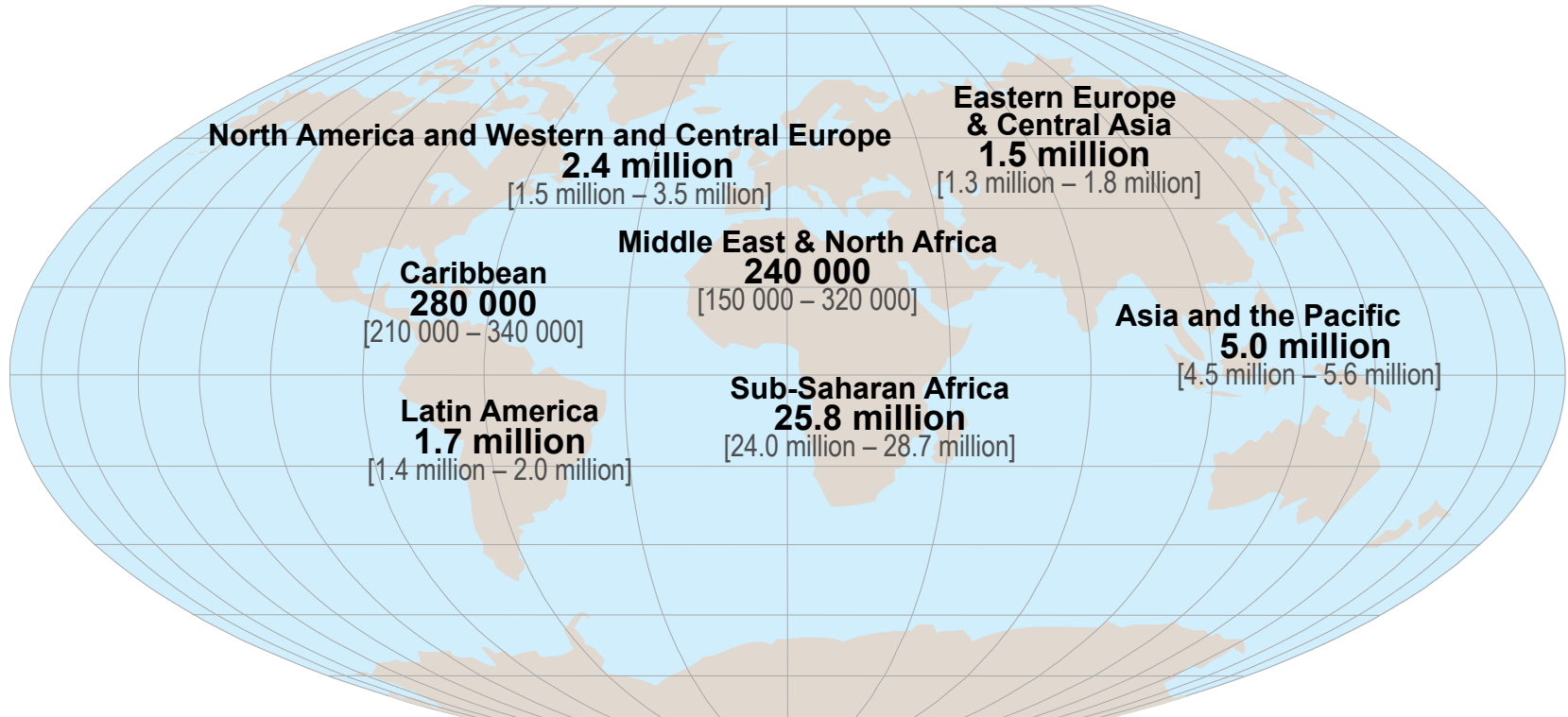


Positive  
Trajectory  
for  
Over a  
Decade

	New infections (children)	New HIV infections (millions)	AIDS related deaths (millions)	People accessing treatment (millions)
2001	550 000	3.4		
2002	560 000	3.3		
2003	560 000	3.1		
2004	550 000	3.0	2.3	
2005	540 000	2.9	2.3	1.3
2006	520 000	2.8	2.3	2.0
2007	480 000	2.7	2.2	2.9
2008	450 000	2.6	2.1	4.1
2009	400 000	2.6	2.0	5.3
2010	360 000	2.5	1.9	6.6
2011	310 000	2.5	1.8	8.1
2012	260 000	2.3	1.6	9.7



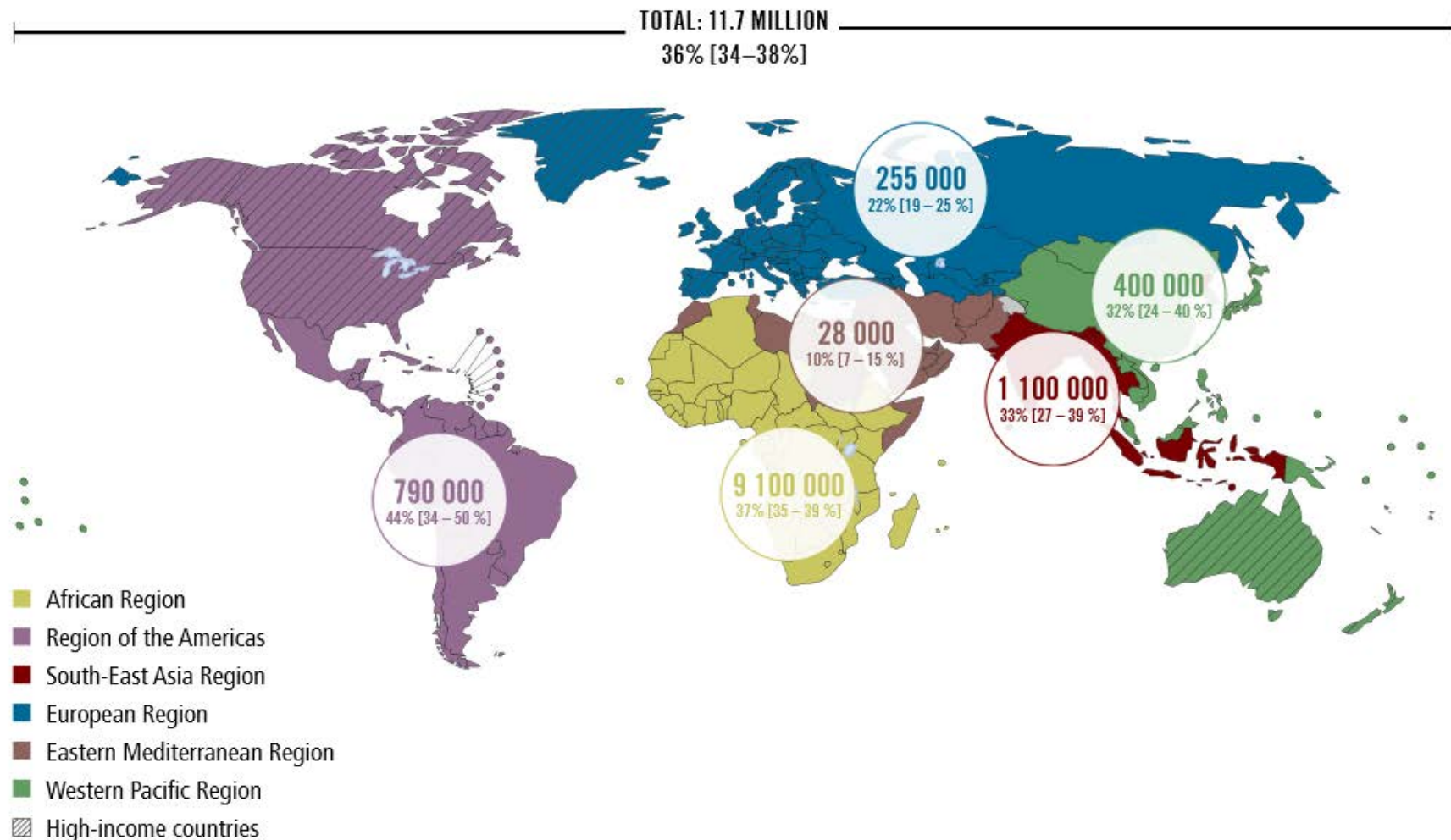
# Adults and Children Estimated to be Living with HIV: 2014



**Total: 36.9 million** [34.3 million – 41.4 million]

Source: UNAIDS; July 2015

## Number of people receiving ART and percentage of all people living with HIV receiving ART in low- and middle-income countries overall and by WHO region, 2013<sup>a</sup>



<sup>a</sup>Country income classification by the World Bank at the time of the 2011 Political Declaration on HIV and AIDS.

Source: Global AIDS Response Progress Reporting (WHO/UNICEF/UNAIDS).

# Long-term psychosocial challenges for people living with HIV: let's not forget the individual in our global response to the pandemic

Robert H. Remien and Claude A. Mellins

Since the beginning of the HIV epidemic, people living with HIV have faced numerous psychological and behavioral challenges. With the advent of antiretroviral therapy (ART) there have been dramatic shifts in some of these key challenges and new ones have come to the forefront. This paper highlights several critical psychological and behavioral aspects of HIV disease, a few of which require focused attention, including mental health, stigma and disclosure, adherence, and sexual behavior. Although the focus is primarily on adults living with HIV, we also comment on some of the additional challenges for children and young people. Our critical examination in these areas draws upon the lessons learned in contexts in which ART has been available for a decade, and we explore what is currently happening in settings with more recent treatment access. In the end we offer our insights into what we may expect in the future, and provide recommendations for ongoing prevention and care initiatives with adults, children, and young people affected by this disease.

© 2007 Wolters Kluwer Health | Lippincott Williams & Wilkins

*AIDS* 2007, 21 (suppl 5):S55–S63

**Keywords:** HIV, psychosocial, coping, behavior, mental health, community

## Introduction

Most individuals with serious, progressive illness confront a range of psychological and behavioral challenges, including adherence to complex and sometimes toxic medication regimens, the prospect of real and anticipated losses (at the personal, familial, and community levels), changes in quality of life, the fear of significant physical decline and death, and coping with the uncertainty of the course of the illness. HIV/AIDS brings additional challenges. It is unusual in the extent of stigma associated with the disease and the modes of transmission, and the fact that it is both infectious and potentially fatal. As a result of the risk of HIV transmission and the potential for the development and transmission of treatment-resistant virus when adherence is poor, there are individual psychological and behavioral challenges, with significant public health consequences that must be addressed.

Although the patterns of HIV infection have varied with the social and economic conditions of affected countries

25 years into the epidemic, HIV and poverty are inextricably linked. Most HIV-positive individuals are living in impoverished communities, have lower levels of education than the general population, and face challenging life circumstances such as unemployment, homelessness, a lack of adequate health insurance, incarceration, and other social vulnerabilities [1,2]. Contextual forces involving race, class, and sex intersect in vulnerable communities to shape HIV/AIDS risks, which in turn influence individual-level physical and mental health outcomes [3,4]. Many individuals living in extreme poverty, particularly women, must weigh the risk of becoming HIV infected against other risks associated with poverty, including the loss of income, food, shelter, safety, and support for children [5]. They may have little choice but to engage in sexual risk behavior or put themselves in potentially violent situations in order to meet their own or their family's basic living needs [6]. In many countries, substance use is also a third factor in the mix. Many HIV-infected individuals are thus living in vulnerable communities and

From the HIV Center for Clinical and Behavioral Studies, New York State Psychiatric Institute and Columbia University, New York City, New York, USA.

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E-mail: rhr1@columbia.edu

# Disparities in The Treatment Cascade

There remains an urgent and vital *Behavioral & Social Science (human) Agenda* for each step in the Cascade!

**Black MSM:** worse outcomes at each step compared to White MSM

**Young Adults** (age 25-30) are ~ 10% lower than older groups at each step

**Heterosexual Men and Women and Transgendered women:** worse outcomes compared to MSM overall, and male IDUs

*Mental Health*

*Stigma & Discrimination*

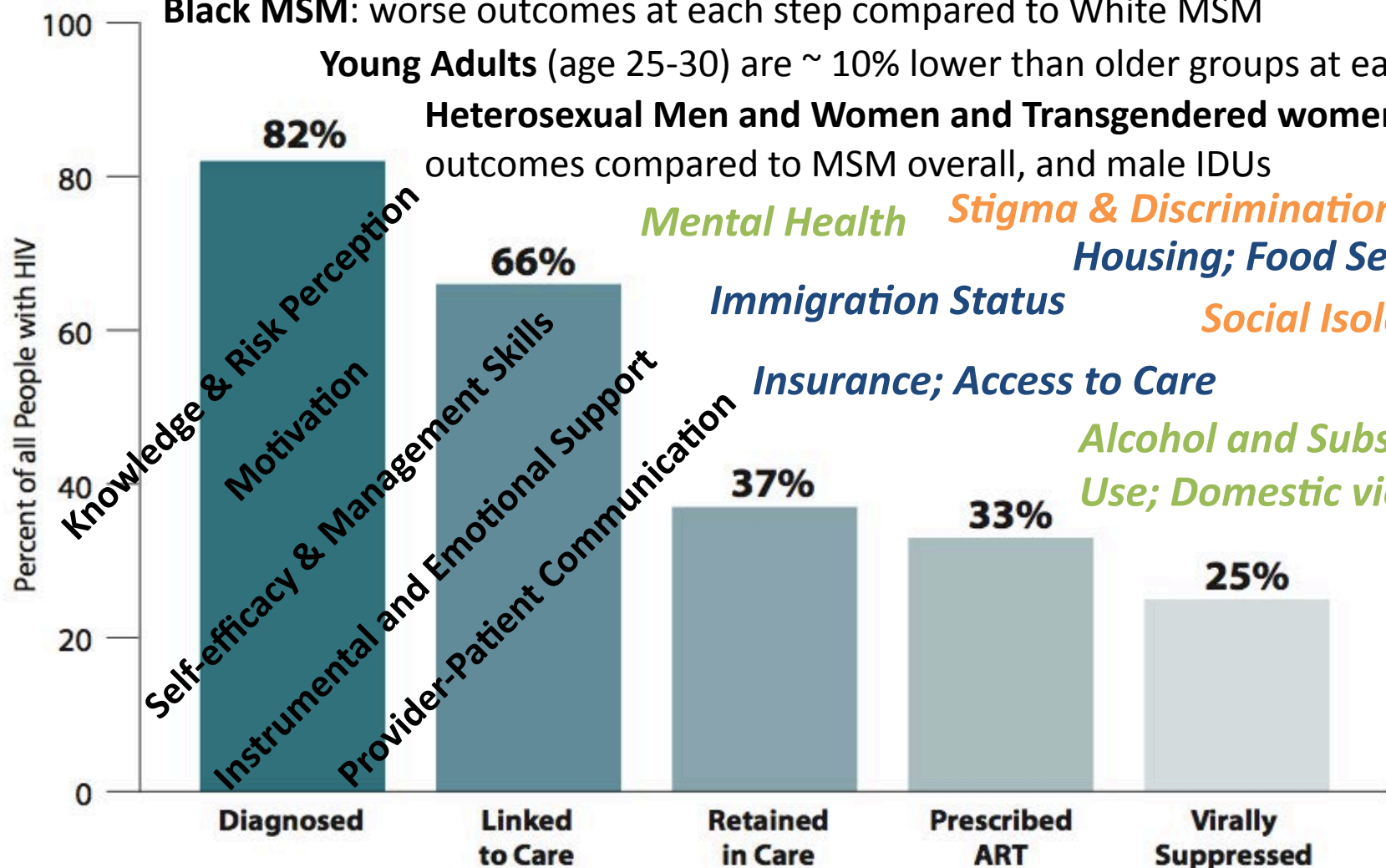
*Housing; Food Security*

*Immigration Status*

*Social Isolation*

*Insurance; Access to Care*

*Alcohol and Substance Use; Domestic violence*



# The Implementation Cascade: Seek, Test, Link, Treat, Adhere, Retain

What part of speech are these words?

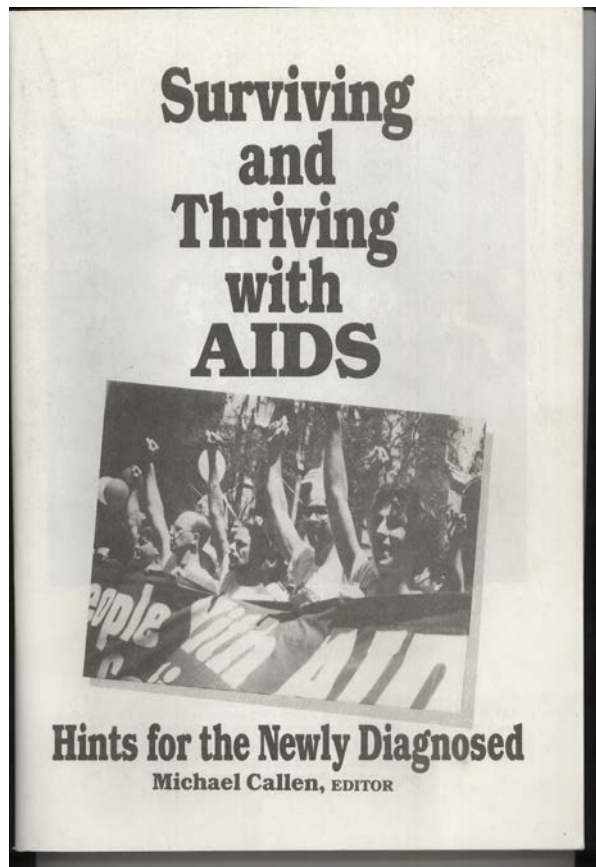
CORRECT: Verbs --- i.e., Behaviors!

In fact, they are Action verbs, requiring action:

On the part of patients

AND their providers

# Long-Term Survivors (prior to HAART)



Research

## Learning to Live With AIDS

*Why Do Some Survive Longer—and Others Die Sooner?*

By Malcolm Gladwell  
Washington Post Staff Writer

FLORENCE, Italy

After presenting the results of his study on long-term survivors of AIDS at the Seventh International AIDS Conference here last week, New York City psychologist Lewis Katoff tapped to the audience and made a confession.

"My interest in this study does not derive from scientific curiosity," he told the packed lecture hall. "I was diagnosed with AIDS five years ago. At the time I believed that I had only a year to live."

The research helped Katoff understand how he and others infected with human immunodeficiency virus that causes AIDS could co-exist and even live well with the disease ravaging their bodies.

"This study," he said, "is part of my search for answers."

If the International AIDS meeting two years ago in Montreal was dominated by flashy science—such as the first AIDS vaccine data from Jacques Salit—and last year's San Francisco meeting was marked by political controversy, this year's conference was symbolized by close attention to the treatment and concerns of people living with AIDS.

In a variety of papers and presentations, clinicians and researchers expressed new hope that the lives of those living with the disease could be improved and extended. Vaccine experts spoke of using vaccine preparations to treat the already infected. The bulk of the drug research papers focused on treating opportunistic infections that plague AIDS patients and finding less toxic combinations of existing drugs, rather than looking for a magic bullet to cure the disease.

Many delegates said this gathering reflected the maturation of the epidemic in the West. There was a growing sense among clinicians that AIDS could be treated

ments for patients who cannot tolerate the current drugs.

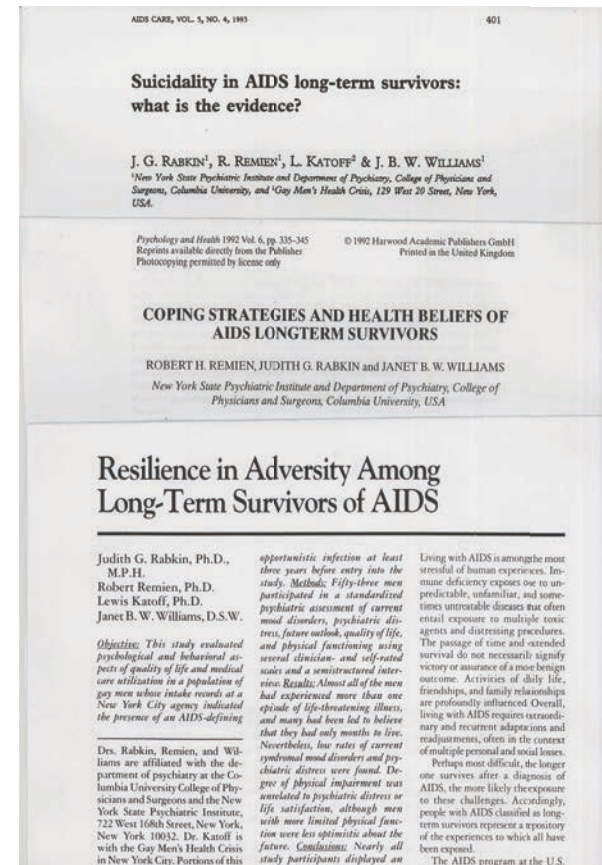
For example, a paper presented by National Institutes of Health researcher Henry Masur showed that of 100 patients who

cago epidemiologist John Phair reported, those who progress quickly from infection to developing the disease and succumbing to AIDS and death had on average more

ILLUSTRATION BY DAVID DINE FOR THE WASHINGTON POST

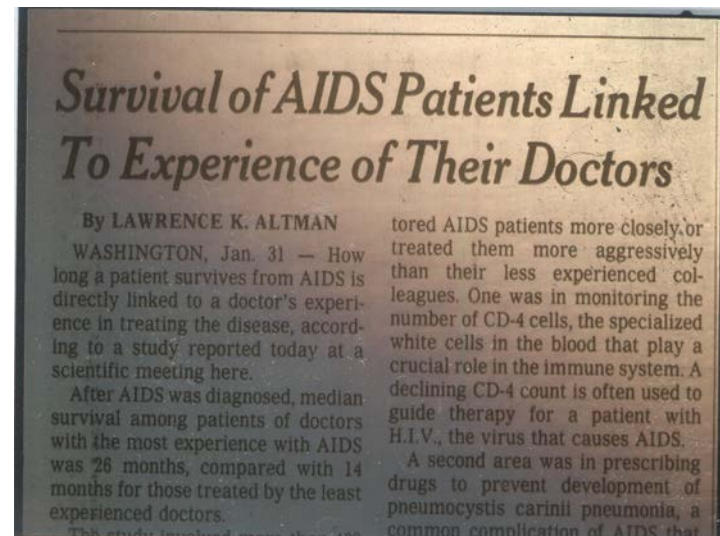
# Long-term Survivor Research

- Psychological resilience
- Positive attitude
- Maintaining goals
- Pro-active coping style
- Assertive in health-care behaviors



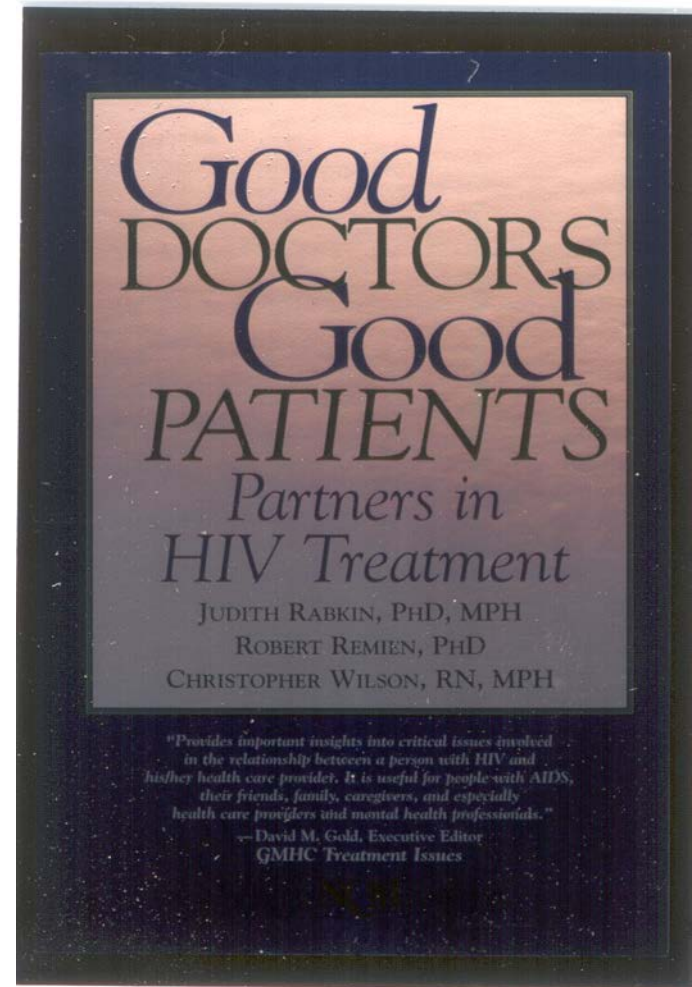
# Long-term Survivor Research (cont.)

- A key finding in our research: the importance of finding and working closely “in partnership with” their medical provider

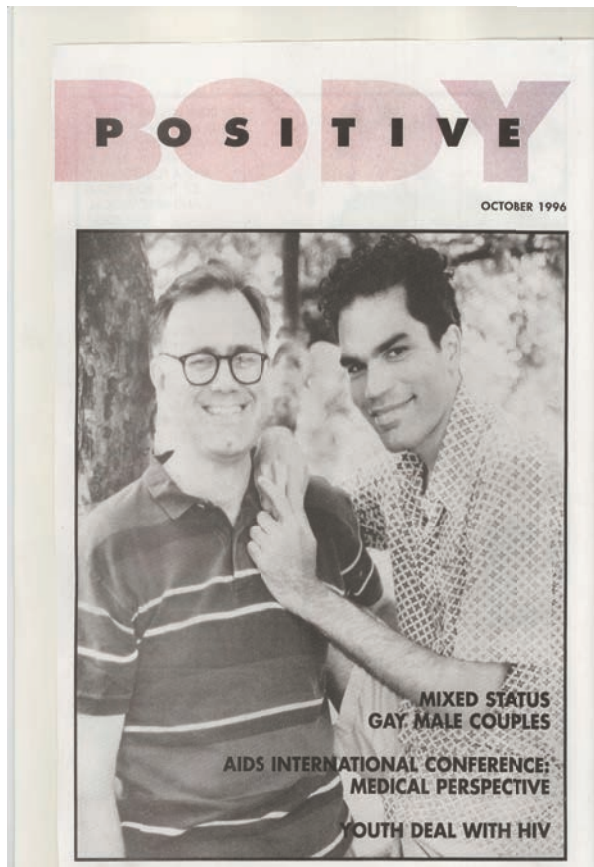


# Long-term Survivors and Doctor-Patient Relationship

- Matching styles
- Joint-decision making
- Aggressive care and management
- Balancing hope and candor



# Partner Support: HIV Serodiscordant Couples



- First NIMH study focused on serodiscordant male couples
- Group intervention trial to address care-taking and risk
- Collaboration with Body Positive

# The First IAPAC Patient Panel: 2007

## Workshops and Specialty Topics 2

10:45 am – 12:00 pm

### Implementing Effective Modified Directly Observed Therapy (M-DOT) Programs

- o Moderator: Kathy Goggin, PhD, University of Missouri, Kansas City
- o Julia Arnsten, MD, Montefiore Medical Center & Albert Einstein College of Medicine
- o Heidi L. Behforouz, MD, Harvard Medical School & Brigham and Women's Hospital
- o Mindy Ma, PhD, Jackson State University
- o Billy Brown, PharmD, GV (Sonny) Montgomery Medical Center
- o Christopher Mitchell, DSW, University of Illinois Chicago
- o Jennifer Mitty, MD, Brown University/Miriam Hospital
- o B. Anna Mullen, MSN, AACRN, John Hopkins University
- o Derek Spencer, MS, CRNP, University of Maryland, JACQUES Project

### Intervention Demonstration: A CD-ROM-Delivered Program to Improve Adherence in Clinic Patients

- o Jeffrey Fisher, PhD, University of Connecticut
- o K. Rivet Amico, PhD, University of Connecticut
- o Paul Shuper, PhD, University of Connecticut

### International Priorities for HIV Treatment Adherence among Children and Adolescents

- o Moderator: Susannah Allison, PhD, National Institute of Mental Health
- o Glenda Grey, MD, Chris Hani Baragwanath Hospital, South Africa
- o John Farley, MD, MPH, University of Maryland

### Patient Perspectives on Maintaining Long-Term Treatment Adherence

- o Moderator : Robert H. Remien, PhD, Columbia University

### Adherence Program Priorities & US Federal Grant Applications

- o Michael J. Stirratt, PhD, National Institute of Mental Health
- o Martha Hare, PhD, RN, National Institute of Nursing Research



1<sup>st</sup> Patient Panel; IAPAC 2<sup>nd</sup> International Conference; Jersey City, NJ; 2007

# Subsequent Panels

Continued as a Workshop and/or Coffee Talk session **2008-2011**

In **2012** the “Patient Panel” was elevated to the **Main Stage**

Michael Stirratt (NIMH) and IAPAC staff helped identify and invited participants with me

In **2013** the panel included an individual who may have been the first to stand up in front of a major scientific conference audience to publically acknowledge that he **was taking PrEP**. He had used the pseudonym “Juan Carlos,” and he was a participant in the Miami site of the US PrEP Demonstration Project.



Baton pass: Phill Wilson (2014, 2015); Moisés Agosto-Rosario (2016)

# Adherence: The Importance of the Provider-Patient Relationship

AIDS PATIENT CARE and STDs  
Volume 29, Number 12, 2015  
© Mary Ann Liebert, Inc.  
DOI: 10.1089/apc.2015.0156

BEHAVIORAL AND PSYCHOSOCIAL RESEARCH

AIDS Behav  
DOI 10.1007/s10461-012-0143-z

ORIGINAL PAPER

## The Influence of Trust in Physicians and Trust in the Healthcare System on Linkage, Retention, and Adherence to HIV Care

James L. Graham, DrPH,<sup>1</sup> Lokesh Shahani, MD, MPH,<sup>2,3</sup> Richard M. Grimes, PhD,<sup>4</sup> Christine Hartman, PhD,<sup>3</sup> and Thomas P. Giordano, MD, MPH<sup>2,3</sup>

## Provider-patient Adherence Dialogue in HIV Care: Results of a Multisite Study

M. Barton Laws · Mary Catherine Beach · Yoojin Lee · William H. Rogers · Somnath Saha · P. Todd Korthuis · Victoria Sharp · Ira B. Wilson

AIDS Behav  
DOI 10.1007/s10461-016-1340-y



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ORIGINAL PAPER

## Retaining HIV Patients in Care: The Role of Initial Patient Care Experiences

Bich N. Dang<sup>1,2,3,4</sup> · Robert A. Westbrook<sup>5</sup> · Christine M. Hartman<sup>1,2</sup> · Thomas P. Giordano<sup>1,2,3,4</sup>

## Physician-Patient Communication in HIV Disease: The Importance of Patient, Physician, and Visit Characteristics

\*Ira B. Wilson and †Sherrie Kaplan

\*Department of Clinical Care Research, New England Medical Center; and †Department of Family and Community Medicine, Tufts University School of Medicine, Boston, Massachusetts, U.S.A.

## Better Physician-Patient Relationships Are Associated with Higher Reported Adherence to Antiretroviral Therapy in Patients with HIV Infection

John Schneider, MD, MPH, Sherrie H. Kaplan, MPH, PhD, Sheldon Greenfield, MD, Wenjun Li, PhD, Ira B. Wilson, MD, MSc



HIV CENTER for Clinical and Behavioral Studies  
at the New York State Psychiatric Institute and Columbia University

# 2015 *JAIDS* Publication: Qualitative Study of Four Special Populations in NYC

## Barriers and Facilitators to Engagement of Vulnerable Populations in HIV Primary Care in New York City

*Robert H. Remien, PhD,\* Laurie J. Bauman, PhD,† Joanne E. Mantell, PhD,\* Benjamin Tsoi, MD,‡  
Javier Lopez-Rios, BA,\* Rosy Chhabra, PsyD,† Abby DiCarlo, MPH,\* Dana Watnick, MPH, MSSW,†  
Angelic Rivera, MPH, MBA,† Nehama Teitelman, MPH,† Blayne Cutler, PhD, MD,§  
and Patricia Warne, PhD\**

In-depth interviews with **four populations**, all of whom had **experienced challenges linking and staying in HIV care**:

**African Immigrants (AI)**

**Persons who were previously incarcerated (PI)**

**Young MSM (YMSM)**

**Transgendered women (TGW)**

*A collaboration with the NYC Department of Health and Mental Hygiene*

# Provider/Clinic Treatment can Facilitate/ Impede Retention & Adherence

**Willingness to collaborate and allow the patient to be an active participant in their own healthcare; having knowledge and understanding of life circumstances; showing respect, caring, and compassion**

*“I would love for my doctor to have...have an open courteous malleable mind when talking to patients... be empathetic. [But] don't be sympathetic... **I need you to reason and be real with me.**” (YMSM)*

*“You don't want [a doctor to] just to come in, take your blood pressure, take your pants down, lift up, cough. **You need a doctor [to whom you can say]** – ‘Well, Doc, I'm homeless, so I wasn't eating right, so if I take my medicine, will it affect me, my stomach?’” (TGW)*

*“[My HIV care clinic] has a real good doctor. I guess maybe the training that they do, even with the interns, [I've] never had a problem...They call me by the name that I want to be called and I've been doing well....A lot of people are not trained to do that. Many people just -- they call you ‘he’ by mistake and make you feel uncomfortable; **it makes you feel not to want to come back to that place.**” (TGW)*

Remien, Bauman, Mantell et al., *JAIDS*, 2015



**HIV CENTER** for Clinical and Behavioral Studies  
at the New York State Psychiatric Institute and Columbia University

# Provider/Clinic Treatment can Facilitate/ Impede Retention & Adherence (con't)

## Caring --- Concern --- Compassion

*"... Like, if I have questions. **She just really cares.** It's like a mom. We talk about everything. We talk about my relationships. I can check in with her." (YMSM)*

*"He's very blunt. Straightforward. He likes to tell it how it is; he doesn't hold anything back. He gives you the best advice that I've probably ever had from any doctor, **and he just makes you feel really comfortable.** He treats you kind of like a friend, mostly. (YMSM)*

*"... my doctor, **he takes care of me.** He also give me his cell phone number just in case." (AI)*

*"**Don't trust doctors in prison.** They are not well qualified, do not care about the patient. I just didn't trust his judgment because we were a bunch of criminals **and they treat us like shit.**" (PI)*

Remien, Bauman, Mantell et al., *JAIDS*, 2015



HIV CENTER for Clinical and Behavioral Studies  
at the New York State Psychiatric Institute and Columbia University

# Vulnerable Populations: Globally

## 12 populations being left behind



### **I am a person living with HIV.**

Worldwide, 19 million of the 35 million people living with HIV today do not know that they have the virus.



### **I am a young woman.**

76% of adolescent girls in sub-Saharan Africa do not have comprehensive and correct knowledge about HIV.



### **I am a prisoner.**

HIV prevalence among prisoners in some settings is 50 times higher than among the general population.



### **I am a migrant.**

Around the world, 39 countries have an HIV-related travel restriction.



### **I am an injecting drug user.**

Only 55 of 192 countries offer a needle-syringe programme.



### **I am a sex worker.**

HIV prevalence among sex workers is 12 times greater than among the general population.



### **I am a man who has sex with other men.**

Same-sex sexual conduct is criminalized in 78 countries.



### **I am a transgender woman.**

Transgender women are 49 times more likely to acquire HIV than all adults of reproductive age.



### **I am a pregnant woman.**

Only 44% of pregnant women in low- and middle-income countries received HIV testing and counselling in 2013.



### **I am a child.**

Of the 3.2 million children under the age of 15 living with HIV, 2.4 million are not accessing antiretroviral therapy.



### **I am a displaced person.**

At the end of 2013, there were 51.2 million people forcibly displaced worldwide.



### **I am a person living with a disability.**

23% of men with a disability do not return to seek health care because they were treated badly at a previous visit.



### **I am 50+.**

The life expectancy of people aged 50 and older living with HIV and accessing treatment is the same as the life expectancy of others of the same age.

# Mental Health & Adherence

Am J Community Psychol (2006) 38:275–285  
DOI 10.1007/s10464-006-9083-y

## ORIGINAL PAPER

### Depressive Symptomatology among HIV-Positive Women in the Era of HAART: A Stress and Coping Model

Robert H. Remien · Theresa Exner · Robert M. Kertzner · Anke A. Ehrhardt · Mary Jane Rotheram-Borus · Mallory O. Johnson · Lance S. Weinhardt · Lauren E. Kittel · Rise B. Goldstein · Rogério M. Pinto · Stephen F. Morin · Margaret A. Chesney · Marguerita Lightfoot · Cheryl Gore-Felton · Brian Dodge · Jeffrey A. Kelly · NIMH Healthy Living Project Trial Group

Published online: 13 September 2006  
© Springer Science+Business Media, LLC 2006

*AIDS Care*

Vol. 21, No. 2, February 2009, 168–177



### Adherence to antiretroviral medications and medical care in HIV-infected adults diagnosed with mental and substance abuse disorders

Claude Ann Mellins<sup>a\*</sup>, Jennifer F. Havens<sup>b</sup>, Cheryl McDonnell<sup>c</sup>, Carolyn Lichtenstein<sup>d</sup>, Karina Uldall<sup>e</sup>, Margaret Chesney<sup>f</sup>, E. Karina Santamaria<sup>a</sup>, and James Bell<sup>c</sup>

<sup>a</sup>HIV Center for Clinical and Behavioral Studies, New York State Psychiatric Institute and Columbia University, New York, US; <sup>b</sup>Department of Child and Adolescent Psychiatry, New York University School of Medicine, New York, US; <sup>c</sup>James Bell Associates, Arlington, Virginia, US; <sup>d</sup>Walter R. McDonald & Associates, Inc., Rockville, Maryland, US; <sup>e</sup>Department of Psychiatry and Behavioral Sciences, University of Washington School of Medicine, Washington, US; <sup>f</sup>Center for AIDS Prevention Studies, University of California, California, US

(Received 6 December 2007; final version received 20 February 2008)

### Description and Demonstration of Cognitive Behavioral Therapy to Enhance Antiretroviral Therapy Adherence and Treat Depression in HIV-Infected Adults

Michael E. Newcomb, *Massachusetts General Hospital and Harvard Medical School and Northwestern University, Feinberg School of Medicine*  
C. Andres Bedoya, Aaron J. Blashill, Jonathan A. Lerner,  
Conall O'Cleirigh, *Massachusetts General Hospital and Harvard Medical School*  
Megan M. Pinkston, *Miriam Hospital and Warren Alpert Medical School of Brown University*  
Steven A. Safren, *Massachusetts General Hospital and Harvard Medical School*

## CLINICAL SCIENCE

### Psychiatric Risk Factors for HIV Disease Progression: The Role of Inconsistent Patterns of Antiretroviral Therapy Utilization

Adam W. Carrico, PhD,\* Elise D. Riley, PhD, MPH,\*† Mallory O. Johnson, PhD,\* Edwin D. Charlebois, PhD, MPH,\* Torsten B. Neilands, PhD,\* Robert H. Remien, PhD,‡ Marguerita A. Lightfoot, PhD,\* Wayne T. Steward, PhD, MPH,\* Lance S. Weinhardt, PhD,§ Jeffrey A. Kelly, PhD,§ Mary Jane Rotheram-Borus, PhD,|| Stephen F. Morin, PhD,\* and Margaret A. Chesney, PhD¶

## CRITICAL REVIEW: CLINICAL SCIENCE

### Alcohol Use and Antiretroviral Adherence: Review and Meta-Analysis

Christian S. Hendershot, PhD,\* Susan A. Stoner, PhD,† David W. Pantalone, PhD,‡ and Jane M. Simoni, PhD\*

AIDS Behav (2015) 19:981–986  
DOI 10.1007/s10461-014-0925-6



## ORIGINAL PAPER

### Psychosocial Syndemics are Additively Associated with Worse ART Adherence in HIV-Infected Individuals

Aaron J. Blashill · C. Andres Bedoya · Kenneth H. Mayer · Conall O'Cleirigh · Megan M. Pinkston · Jocelyn E. Remmert · Matthew J. Mimiaga · Steven A. Safren

Published online: 21 October 2014  
© Springer Science+Business Media New York 2014

# Mental Health & Adherence (con't)

AIDS Behav (2012) 16:2101–2118  
DOI 10.1007/s10461-011-0087-8

## SUBSTANTIVE REVIEW

### Depression, Alcohol Use and Adherence to Antiretroviral Therapy in Sub-Saharan Africa: A Systematic Review

Etheldreda Nakimuli-Mpungu · Judith K. Bass ·  
Pierre Alexandre · Edward J. Mills · Seggane Musisi ·  
Malathi Ram · Elly Katabira · Jean B. Nachega

AIDS PATIENT CARE and STDs  
Volume 23, Number 6, 2009  
© Mary Ann Liebert, Inc.  
DOI: 10.1089/apc.2008.0184

### Prevalence and Clinical Implications of Interactive Toxicity Beliefs Regarding Mixing Alcohol and Antiretroviral Therapies among People Living with HIV/AIDS

Seth C. Kalichman, Ph.D., Christina M. Amaral, B.A., Denise White, B.A., Connie Swetsze, L.P.N.,  
Howard Pope, B.A., Moira O. Kalichman, M.S.W., Chauncey Cherry, M.P.H., and Lisa Eaton, M.A.

AIDS Behav (2013) 17:142–147  
DOI 10.1007/s10461-011-0124-7

## ORIGINAL PAPER

### Association Between Use of Specific Drugs and Antiretroviral Adherence: Findings from MACH 14

M. I. Rosen · A. C. Black · J. H. Arnsten ·  
K. Goggin · R. H. Remien · J. M. Simoni ·  
C. E. Golin · D. R. Bangsberg · H. Liu

ann. behav. med. (2011) 42:352–360  
DOI 10.1007/s12160-011-9295-8

## ORIGINAL ARTICLE

### A Closer Look at Depression and Its Relationship to HIV Antiretroviral Adherence

Glenn J. Wagner, Ph.D. · Kathy Goggin, Ph.D. ·  
Robert H. Remien, Ph.D. · Marc I. Rosen, M.D. ·  
Jane Simoni, Ph.D. ·  
David R. Bangsberg, M.D., M.P.H. ·  
Honghu Liu, Ph.D. · MACH14 Investigators

Published online: 13 January 2012  
© Springer Science+Business Media, LLC 2012

Published online: 5 August 2011  
© The Society of Behavioral Medicine 2011

# What Evidence Exists for Effective ART Adherence Interventions?

- 1. IAPAC ART Adherence Guidelines**
- 2. Centers for Disease Control and Prevention (CDC) Compendium**
- 3. Meta Analyses**



## Guidelines for Improving Entry Into and Retention in Care and Antiretroviral Adherence for Persons With HIV: Evidence-Based Recommendations From an International Association of Physicians in AIDS Care Panel

Melanie A. Thompson, MD; Michael J. Mugavero, MD, MHSc; K. Rivet Amico, PhD; Victoria A. Cargill, MD, MSCE; Larry W. Chang, MD, MPH; Robert Gross, MD, MSCE; Catherine Orrell, MBChB, MSc, MMed; Frederick L. Altice, MD; David R. Bangsberg, MD, MPH; John G. Bartlett, MD; Curt G. Beckwith, MD; Nadia Dowshen, MD; Christopher M. Gordon, PhD; Tim Horn, MS; Princy Kumar, MD; James D. Scott, PharmD, MEd; Michael J. Stirratt, PhD; Robert H. Remien, PhD; Jane M. Simoni, PhD; and Jean B. Nachega, MD, PhD, MPH

- Systematic literature search for evidence-based interventions used to improve linkage, retention and ART adherence
- Recommendations based on quality of the evidence
- 37 evidence-based recommendations made
- Only 5 recommendations on linkage and retention

### IAPAC recommendations for linkage and retention strategies

- a) Systematic monitoring of entry into care for all diagnosed
- b) Systematic monitoring of retention into care for all PLWH
- c) Intensive outreach/engagement for newly diagnosed not in care
- d) Use of peer or paraprofessional patient navigators
- e) ARTAS: brief strengths-based case management for newly diagnosed

# The Medication Adherence Chapter of the CDC *Compendium*\*

- 12 HIV medication adherence evidence-based behavioral interventions (EBIs), identified from the scientific literature (through 2015)
- Interventions focus on medication adherence behaviors among persons living with HIV and represented the strongest behavioral interventions in the literature to date that were rigorously evaluated and had demonstrated efficacy in reducing HIV viral load or improving HIV medication adherence behaviors

\*Department of Health and Human Services Centers for Disease Control and Prevention: <http://www.cdc.gov/hiv/topics/research/prs/ma-chapter.htm>

# The Medication Adherence Chapter of the CDC *Compendium (cont.)*

- **Adherence Through Home Education and Nursing Assessment (ATHENA)** (Ann B. Williams, RN, EdD)
- **Care+** (Ann E. Kurth, PhD, MSN, MPH)
- **Directly Administered Antiretroviral Therapy (DAART) for Drug Users** (Frederick Altice, MD)
- **Directly Administered Antiretroviral Therapy (DAART) in Methadone Clinics** (Gregory M. Lucas, MD, PhD)
- **Healthy Living Project (HLP)** (NIMH Multi-site AIDS Research Centers)
- **Helping Enhance Adherence to antiRetroviral Therapy (Project HEART)** (Linda Koenig, PhD)

# The Medication Adherence Chapter of the CDC *Compendium (cont.)*

- **In the Mix** (Seth Kalichman, PhD)
- **Managed Problem Solving (MAPS)** (Robert Gross, MD, MSCE)
- **Pager Messaging** (Jane Simoni, PhD)
- **Partnership for Health** (Joel Milam, PhD)
- **Peer Support** (Jane Simoni, PhD)
- **Sharing Medical Adherence Responsibilities Together (SMART Couples)** (Robert H. Remien, Ph.D.)



# Effective ART Adherence Behavioral Interventions (RCTs)

The most effective interventions were based on ***cognitive-behavior models*** and shared a core set of ***psycho-educational components***:

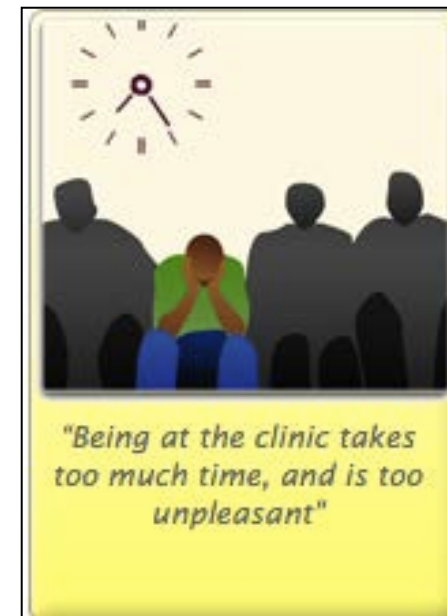
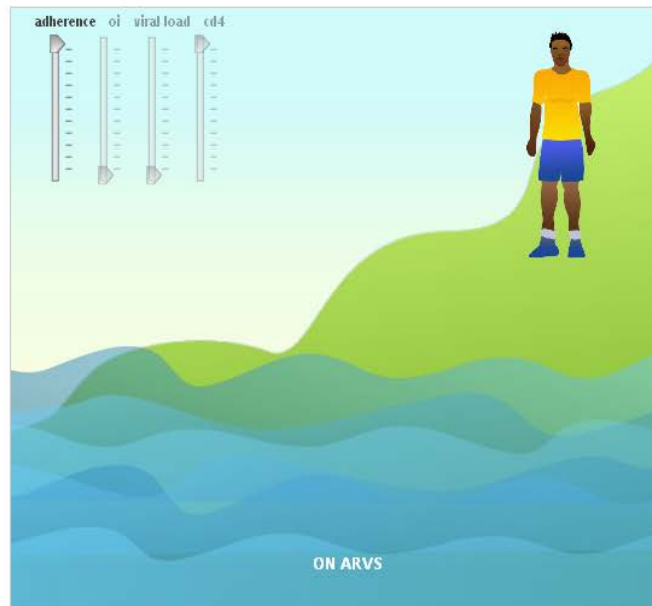
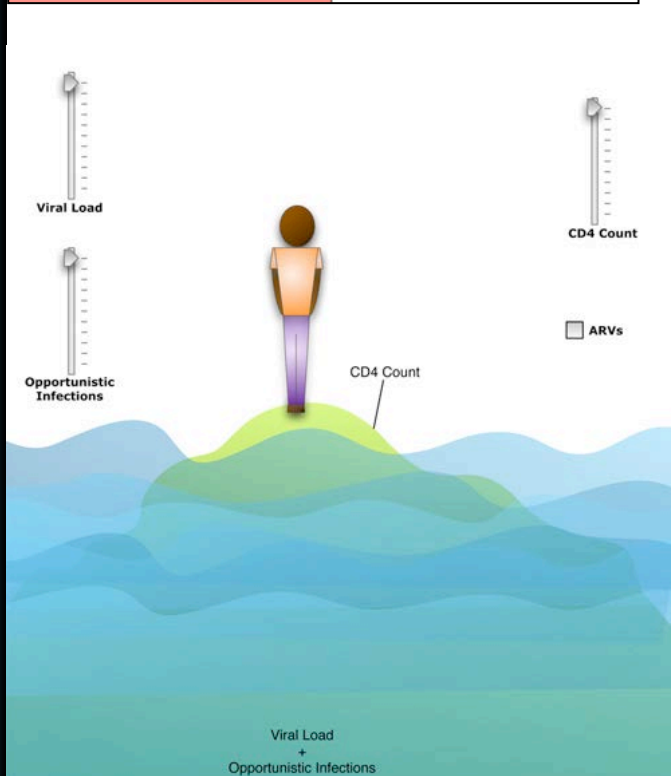
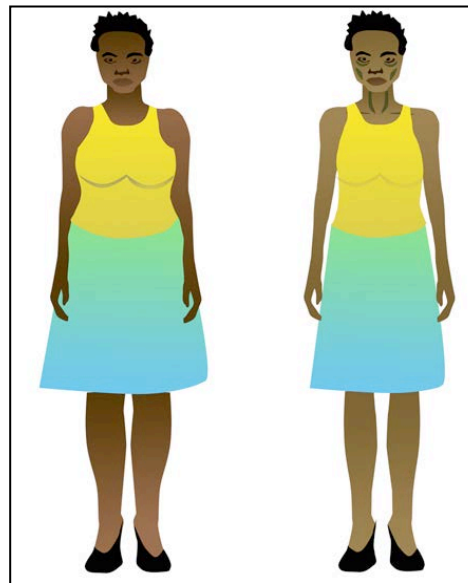
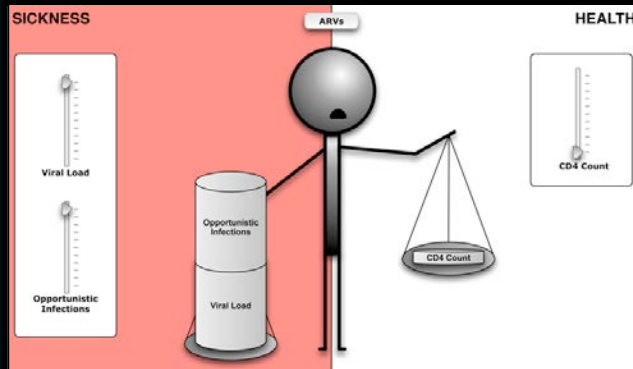
- educating about HIV, its treatment, and the importance of adherence;
- teaching self-monitoring skills;
- identifying barriers to adherence and improving problem-solving skills for those barriers;
- reframing treatment beliefs and attitudes to improve adherence self-efficacy; and
- facilitating positive social support for adherence, including “provider-patient” communication

Simoni, Pearson, Pantalone et al., 2006; Robbins, Spector, Mellins et al., 2014

# Examples of Ongoing Research

- *“Masivukeni: A Multimedia ART Adherence Intervention for Resource-Limited Settings”* (NIMH R01 MH95576; PI: Remien)
  - ▶ Can the use of multimedia support scale-up of adherence counseling in resource constrained settings?
  - ▶ Focus is on enhancing the human interaction between “lay counselors” and patients
  - ▶ Need for local / cultural tailoring

# Adaption to the local population



# Counseling in resource-constrained settings

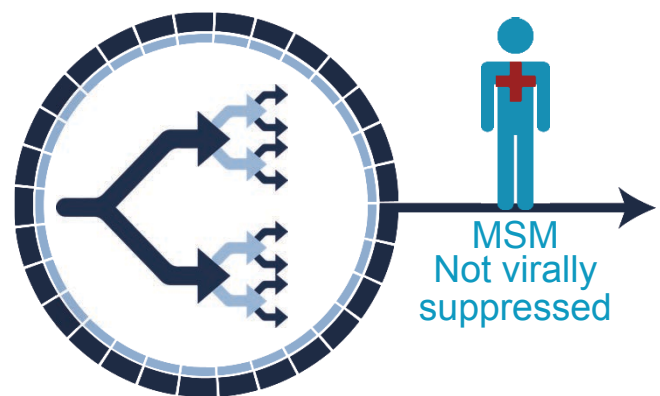


# Examples of Ongoing Research

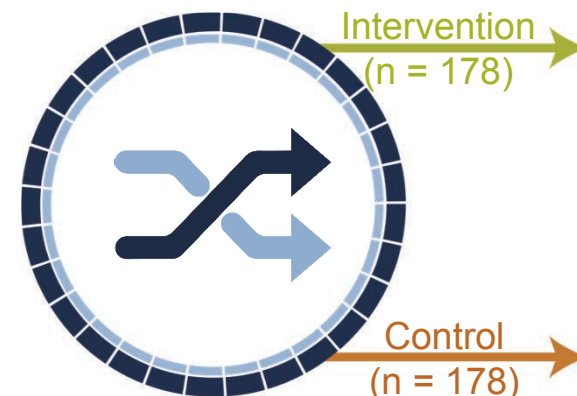
- HPTN 078: *“Enhancing Recruitment, Linkage to Care and Treatment for HIV-Infected Men Who Have Sex with Men (MSM) in the United States”* (NIAID UM1 AI068619; Protocol Chair: Chris Beyrer, MD, MPH; Co-Chair: Robert H. Remien, PhD)
  - ▶ Integrating evidence-based approaches in community settings (Deep-chain RDS; and intensive Case Management)
  - ▶ Need for individual-level tailoring

Screened population	Enrolled participants
2700	356
MSM $\geq$ 16 yo	MSM/ HIV+
Study Duration:	12 M Enrollment 24 M Follow-up

## HPTN 078: Enhancing Recruitment, Linkage to Care and Treatment for HIV-Infected Men Who Have Sex with Men (MSM) in the United States



Deep-Chain Respondent Driven Sampling



Individual Randomization

Case Manager Intervention Package

SOC for Linkage and Treatment

# Examples of Ongoing Research

- *“Structural Intervention to Increase Screening and Testing for Acute HIV Infection”* (NIMH R01 MH92187; PI: Remien; in collaboration with NYC and NYS Departments of Health)
  - ▶ To develop and test a multi-level, multi-component structural intervention for AHI screening and detection.
  - ▶ Raising awareness and providing tools and support for both Providers and Patients



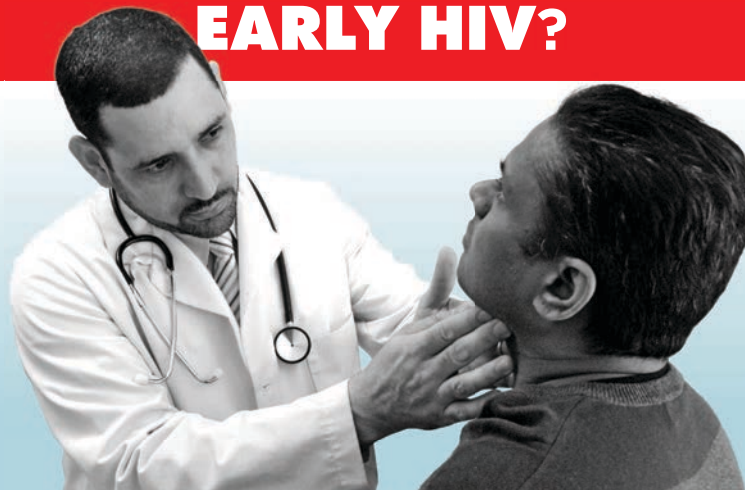
## KEY FACTS TO KNOW BEFORE GETTING AN HIV TEST

- HIV is the virus that causes AIDS. It can be spread through sex with someone who has HIV, through contact with HIV-infected blood by sharing needles (piercing, tattooing drug equipment) and by pregnant women to their infants during pregnancy or delivery, or by breastfeeding.
- There are treatments for HIV/AIDS that can help a person stay healthy.
- People with HIV or AIDS can use safer practices to prevent others from becoming infected. Safer practices also protect people with HIV/AIDS from being infected with different strains of HIV.
- Testing is voluntary and can be done at a public testing center without giving your name (anonymous testing).
- By law, HIV test results and other related information are kept confidential (private).
- Discrimination based on an individual's HIV status is illegal. People who are discriminated against can get help.
- Consent for HIV-related testing remains in effect until it is withdrawn verbally or in writing. If the consent was given for a specific period of time, the consent applies to that time period only. You may withdraw your consent at any time.



✓ FEVER ✓ RASH ✓ MOUTH SORES  
✓ SORE THROAT ✓ TIRED

**COULD IT BE  
EARLY HIV?**



Please answer the questions on this form and give it to your provider at the start of the visit.

**KNOW YOUR HIV STATUS NOW**



# Examples of Ongoing Research

- PCCP: *“Patient Centered Care Project (PCCP) Phase 1: Qualitative Interviews to Identify Drivers of HIV-testing and HIV-care Utilization in Target Populations in Kenya”* (Planned collaboration among PEPFAR, NIMH, IAPAC, KEMRI (Kenya), NY (Columbia) HIV Center, University of Michigan)
  - ▶ To identify individual, community and structural level factors influencing uptake, use and patient-centered delivery of HIV-testing and HIV-care services from the perspective of groups at elevated risk for HIV-infection or transmission.

# Patient Centered Care Project

A photograph of a sign for the Ministry of Medical Service, listing various services and their costs. The sign is titled "MINISTRY OF MEDICAL SERVICE" and "AMULETA BUS DISTRICT HOSPITAL". It lists services such as REGISTRATION, PATIENT BOOKLET, and EMERGENCY TREATMENT, along with their respective costs in KSh and US\$.

In "Fishing" and "Non-fishing" communities:  
*In-depth interviews: Young women, Het men, MSM*  
*Focus groups with providers and other key stakeholders*

# (Atypical) Case Study

- Gay male in early 20's → NYC in 1977 to attend Graduate School
- 1977: volunteered in NYC Blood Center Hepatitis B efficacy vaccine trial
- 1984: discovered HIV+ antibody status - dating back to a seroconversion in 1980 - by testing stored serum
- 1990's: labeled a "long-term non-progressor;" Dr. David Ho; Aaron Diamond; *NEJM* seminal paper (1 of 10 cases)\*
- 2000: after 20 years - rising VL; decline in CD4+ cells
  - ART recommended; patient resisted; eventually initiated
- Surviving & Thriving (36 years with HIV)

\*Cao Y, Qin L, Zhang L, Safrit J, Ho DD. Virologic and immunologic characterization of long-term survivors of human immunodeficiency virus type 1 infection. *N Engl J Med*. 1995 Jan 26;332(4):201-8.

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**THANK YOU** to all of the “patients” on past IAPAC panels and in my practice, and the providers who have cared for them; and all of the early pioneers, activists, and advocates in the fight – including Gary Reiter and Andy Kaplan - they all have taught me so much!

**THANK YOU** to the following people who have contributed to/inspired this talk:

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Thomas Giordano  
Ira Wilson  
Glenn Wagner  
Jeremiah Johnson  
Chris Beyrer  
Benjamin Young

**THANK YOU**, the audience for your time & attention.

And YES, I believe we can end AIDS, if we move forward together with **Humanity, Compassion & Quality Care** for **ALL** people living with HIV worldwide!

