

# Community statement on the START trial and the change in the US DHHS treatment guidelines

By *moderator*

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The following statement has been sent to the chairs of the United States Department of Health and Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents.

For media comment, please contact:

- Dave Munroe, INSIGHT Community Advisory Board, David Munroe, DavidM4239@AOL.COM
- Nathan Geffen, Treatment Action Campaign, on +27 (0) 84 542 6322
- Simon Collins, HIV i-Base, on +44 (0) 20 7407 8488

## Introduction

The following statement is produced in response to a change in the US treatment guidelines in December 2009 that stated that antiretroviral (ARV) treatment should be universally started at any CD4 count below 500 cells/mm<sup>3</sup>.

The START study is currently enrolling patients to look at whether there is evidence to support such a recommendation. Currently no randomised trial has provided data on the advantages and risks of earlier treatment. This statement affirms both the importance of the START trial and the safety for people who enrol.

We believe that the priority for HIV-positive people is to have accurate, reliable data on both the risks and benefits of earlier treatment in order to base any decision for when to start treatment.

## Statement

When to start antiretroviral treatment is one of the most important outstanding questions for people with HIV and their clinicians. A large clinical trial, Strategic Timing of Antiretroviral Treatment (START), has begun and will hopefully help answer this and other important questions. [1]

The START trial includes antiretroviral-naïve HIV-positive people with CD4 counts greater than 500 cells/mm<sup>3</sup>. It is taking place at about 90 sites in nearly 30 countries. Participants are randomised to either receive antiretroviral treatment immediately or to defer treatment until their first CD4 count less than 350 cells/mm<sup>3</sup> or they have clinical signs of AIDS. Eventually, START will recruit 4,000 people.

The deferred arm is the current standard of care throughout the world, with guidelines recommending treatment at a CD4 count of 350 cells/mm<sup>3</sup>. Clinical trials have demonstrated that once the CD4 count drops to below 350 cells/mm<sup>3</sup>, antiretroviral treatment should begin. [2, 3] However, the recent US guideline change requires a community response for US patients who still want to take part in this study.

On 1 December 2009, the United States (US) Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults

and Adolescents were changed to recommend treatment for patients with CD4 counts between 350 and 500 cells/mm<sup>3</sup>. Of the more than two-thirds of Panel members who supported this recommendation, 55% recommended it strongly and 45% moderately. As explained in the guidelines, this recommendation is based solely on observational data primarily from two large cohorts known as ART CC and NA-ACCORD. As with all observational data the findings from these cohorts could be subject to confounding factors. [4]

Indeed, the ART CC investigators have stated, "We are concerned that some may interpret the new [US] recommendations as implying that the deferral group of this trial is no longer ethical. Such an interpretation would endanger the future of the trial in the [US]." [5]

They further state, "We do not believe that there is convincing evidence to conclude that deferral of initiation of ART to a CD4 count of [350 cells/mm<sup>3</sup>] causes net harm, particularly in terms of mortality, compared with starting at any higher level. We strongly support continued enrolment into START. Large randomised studies represent the only means of eventually obtaining the definitive result we need to properly inform future patient care.

We agree with the ART CC investigators. The available evidence is insufficient to determine if the adherence challenges and long-term side-effects of early antiretroviral treatment are outweighed by reduced risk of illness conferred by these medicines. Only a randomised controlled trial, such as START, can determine this.

The NA-ACCORD data is also challenged by the researchers who originally developed the new statistical methodology. They were not convinced that the application thereof was without problems. [6]

We too are concerned that the new US recommendation:

- (1) raises theoretical concerns about continued enrolment of patients in the US, a substantial source of patients, and
- (2) is based on poor evidence and therefore might not be in the best interests of patients.

We also have further concerns that:

- (3) previous recommendations to use earlier treatment failed to recognise the negative impact of resistance and side effects, and
- (4) a minority of individuals have normal CD4 counts between 350-500 and would therefore be using treatment prior to any significant immune damage.

We support research findings that the absolute risk of HIV-related complications remains very low at a CD4 count 350-500 and that individuals enrolled in START will be carefully monitored and access treatment if their health circumstances change.

We also support the unique importance of sub-studies in START.

These studies have the potential to answer important questions relating to the impact of HIV, treatment and ageing on neurology and mental health, bone health, heart disease, lung disease and behaviour risk.

We support the START investigators, community advocates and HIV-positive people interested in this dynamic research which will help close the essential gap in our current knowledge on the safety and risks of earlier treatment.

Signed:

(Members of the INSIGHT Community Advisory Board in surname alphabetical order)

Peer Aagaard, Denmark

Simon Collins, London

Nathan Geffen, South Africa  
Joseph Hall, USA  
David H. Haerry, Switzerland  
Michael Meulbroek, Spain  
David Munroe, USA  
Dwight Peavy, USA  
Claire Rappoport, USA  
Siegfried Schwarze, Germany  
Mirta Valdez, Argentina  
Jo Watson, Australia

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ACT UP PHILAELPHA, Jose de Marco, Philadelphia, PA, USA  
Adhara-Sevilla, Juan Antonio Reina, Sevilla, Spain  
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AIDS Alliance for Faith and Health, Dawn Womack, Reverend Jamil Willis, Atlanta, GA, USA  
AIDS Care Ocean State, JoAnne Ash, Pamerla Dee, Daniel Zariczny, Providence, RI, USA  
AIDS Care, Jackie Dozier, Rochesterser, NY, USA  
AIDS Community Research Consortium, Megan O'Day, Redwood City, CA, USA  
AIDS Community Research Initiative of America, Daniel Tietz, New York, NY, USA  
AIDS Education Global Information System, Sister Mary Elizabeth, San Juan Capistrano, CA, USA  
AIDS Global Action, Blair Wynkoop, Washington, DC, USA  
AIDS Legal Council of Chicago, Ann Fisher, Chicago, IL, USA  
AIDS Project Los Angeles, Philip Curtis, Los Angeles, CA, USA  
AIDS Project of the East Bay, Damon Powell, Oakland, CA, USA  
AIDS Resource Council, Inc., Frank Tant, Rome, GA, USA  
AIDS Services for the Monadnock region, Arnold Grandell, Gilsum, NH, USA  
AIDS Services of Dallas, Don Maison, Dallas, TX, USA

AIDS/HIV Health Alternatives, Terry Grand, North Hollywood, CA, USA

AIDSmeds.com, Tim Horn, New York, NY, USA

Allies Linked for the Prevention of HIV and AIDS (a.l.p.h.a.), Duane Quintana, Boise, ID, USA

amfAR, The Foundation for AIDS Research , Chris Collins, Washington, DC, USA

Argus Community, Terese Smauldon, Bronx, NY, USA

Australian Federation of AIDS Organisations (AFAO), Don Baxter, Sydney, New South Wales, Australia

AVAC, Kevin Fisher, Mitchell Warren, New York, NY, USA

Beacons of H.O.P.E., Dean Page, West Covina, CA, USA

Black AIDS Memphis, Ernest Donelson, Memphis, TN, USA

Boston Living Center, Wayne Callahan, Mattapan, MA, USA

Care Directions, Jose Alfredo Alvarez, Phoenix, AZ, USA

Center for AIDS, Paul Simmons, Houston, TX, USA

Central City AIDS Network, Johnny Fambro, Macon, GA, USA

CHAIN, Virginia Tonelli, Des Moines, IA, USA

Chicago Womens AIDS Project, Zoe Lehman, Chicago, IL, USA

Choose Life, Patson Phiri, Pretoria, Gauteng, South Africa

Christie's Place, Irene Milton, San Diego, CA, USA

Community Partners CAB Member, Hamilton Richardson, Baltimore, MD, USA

Common Ground - the Westside HIV Community Center, Jeffrey Goodman, Santa Monica, CA, USA

Community HIV/AIDS Mobilization Project (CHAMP), Julie Davids, Walton Senterfitt, Cranston, RI, USA

Community Research Initiative, Anthony Carpinelli, Boston, MA, USA

Coordinadora de asociaciones de VIH de la Comunidad Valenciana, Begoña Bautista Casanova, Spain

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E.C.H.O. Resource Center, Ann Dixon, North Little Rock, AR, USA

European AIDS Treatment Group, Haerry David Hans-Ulrich

European Community Advisory Board, Wim Vandeveld

Foundation for Integrative AIDS Research (FIAR), George Carter, Brooklyn, NY, USA

Gay City News, Doug Ireland, New York, NY, USA

Gay Men's Health Crisis / Client Advisory Board, Joseph Arsenault, Bronx, NY, USA

Global Network of People Living with HIV/AIDS (GNP+/NA), Dr. Frenk Guni, Silver Spring, MD, USA

Grupo de Trabajo sobre Tratamientos del VIH (gTt), Juanse Hernández, Barcelona, Cataluña, Spain

Grupo Português de Ativistas sobre Tratamentos de VIH/SIDA (GAT), Wim Vandevelde, Portugal

Harm Reduction Institute, Larry Pasco, Indianapolis, IN, USA

Health Equities institute, San Francisco State University, Nicholas J. Alvarado, San Francisco, CA, USA

Health GAP (Global Access Project), Paul Davis, Nairobi, Kenya

HealthHIV, Brian Hujdich, Washington, DC, USA

Hepatitis, AIDS, Research Trust, James Hoyt, Florence, CO, USA

HIV Dental Alliance, David Reznik, Atlanta, GA, USA

Hiv-Danmark, Bent Hansen, Copenhagen, Denmark

HIV/AIDS Advocacy Network, Randal Lucero, Albuquerque, NM, USA

HIV/AIDS Law Project, Karen Stuart, Phoenix, AZ, USA

HIV/AIDS Services for African Americans in Alaska, Hugh Brown III, Anchorage, AK, USA

HIV Denmark, Henrik Arildsen

HIV Europe, Henrik Arildsen

HIV i-Base, Polly Clayden, UK

HIVictorious, Inc., Bob Bowers, Madison, WI, USA

Holley Gerald Foundation, Calvin Gerald, Washington, DC, USA

Housing Works, Christine Campbell, Washington, DC, USA

Illinois Alliance for Sound AIDS Policy, J Michael Polasek, Iuka, IL, USA

International AIDS Empowerment, Lorenzo Sias Jr., El Paso, TX, USA

International Treatment Preparedness Coalition (ITPC), Sarah Zaidi

International Community of Women Living with HIV and AIDS-North American Region (ICW-NA), Beri Hull, Washington, DC, USA

International Foundation for Alternative Research in AIDS, Fred Schaich, Portland, OR, USA

Italian League For Fighting Aids - LILA, Alessandra Cerioli, Torino?, Italy

Jo-Ray House Inc, Ida Bythersmith, Chicago, IL, USA

LaGender Inc., Dee Dee Chamblee, Atlanta, GA, USA

Lesbian, Gay, Transexual and Bisexual Spanish Federation (FELGTB),Rubén Sancho

LifeLinc, Wanda Commander, Baltimore, MD, USA

LIGHT Health & Wellness Comprehensive Services, Inc., Debbie Rock, Baltimore, MD, USA

Lion Heart Network Advocates, A. Alberto Abello, San Francisco, CA, USA

Lower East Side Harm Reduction Center, Rev Raquel Algarin, New York, NY, USA

Madrid LGTB Group (COGAM), Rafael Torres Barrio, Spain

Maine General Health Associates - The Horizon Program, Peter Schlosser, Gardiner, ME, USA

McGregor Clinic, Inc., Sharon Murphy, Fort Myers, FL, USA

Metropolitan Community Health Services, Elizabeth Shepherd, Washington, NC, USA

MiamiValleyPoz4Poz, Keith Matthews, Dayton, OH, USA

NAM, Keith Alcorn, London, UK

Nashville CARES, Joseph Interrante, Nashville, TN, USA

National AIDS Housing Coalition, Lola Adele-Oso, Washington, DC, USA

National Association of People Living With HIV/AIDS Australia, Robert Mitchell, Newtown, NSW, Australia

National Coalition for LGBT Health, Kellan Baker, Washington, DC, USA

National Pediatric AIDS Network, Gary Gale, Boulder, CO, USA

New Destiny Recovery Ministry, Rowena Simmons, Baltimore, MD, USA

New York Law School, Arthur Leonard, New York, NY, USA

North American Old Catholic Church, Archbishop Michael Seneco, Washington, DC, USA

Northwestern University, Eric Christoff, Chicago, IL, USA

NW Florida AIDS/HIV Consortium Area (NOFLAC), James Talley, Pensacola, FL, USA

OCASET, Jose Diaz, San Juan, PR, USA

OptimalTrials, James Karin, Gaithersburg, MD, USA

Outer Cape Dental Center, Timothy Martinez, South Wellfleet, MA, USA

Pacientes de Sida pro Politica Sana, Anselmo Fonseca, SJ, PR, USA

PALSS, Carmen Julious, Columbia, SC, USA

PH RockWood.com, Dr. Roscoe M Moore Jr., Rockville, MD, USA

Philadelphia FIGHT, Teresa Sullivan, Philadelphia, PA, USA

Positive East Tennesseans, Larry Frampton, Knoxville, TN, USA

Positive Life NSW, Rob Lake, Darlinghurst, Sydney, NSW, Australia

Positive Women's Network/Oakland/Local, Loren Jones, Berkeley, CA, USA

Positively Positive, Bradford McIntyre, Vancouver, BC, Canada

POZ Charlotte.org, Clinton Woods, charlotte, NC, USA

Progressive Health partners International, Dr. Frenk Guni, Frederick, MD, USA

Projecte dels NOMS-Hispanosida, Michael Meulbrook

Public Personalities Against AIDS Trust, Tendayi Westerhof, Harare, Zimbabwe

PWA Coalition Colorado, Chad Kenney, Denver, CO, USA

Research + Education Group INSIGHT Wash DC ICC CCG Member, Dale Sattergren, Portland, OR, USA

Resource Center Dallas, Bret Camp, Dallas, TX, USA

Roper St. Francis Ryan White Program, Ashley Redmond, Charleston, SC, USA

Ruth M. Rothstein CORE Center, Peter McLoyd, Chicago, IL, USA

Ryan White Part-C, George Martinez-Alicea, Guayama, PR, USA

Shanti, Derrick Mapp, San Francisco, CA, USA

SisterLove, Inc., Lisa Diane White, Atlanta, GA, USA

SomeoneCares of Atlanta, Laurency Gaston, Smyrna, GA, USA

South Carolina Campaign to End AIDS (SC-C2EA), Karen Bates, Columbia, SC, USA

Spanish Community Advisory Board (FEAT), Diego Garcia, Spain

Spanish Federation of AIDS NGOs (CESIDA), Santiago Pérez Avilés,

Status C Unknown, Shari Foster, Medford, NY, USA

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UDCAS, Jose Diaz, San Juan, PR, USA

UKCAB, Michael Marr, London, UK

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Virginia Commonwealth University, Joy Zeh, Richmond, VA, USA

Wayne State University CAB, Janyce Cook, Detroit, MI, USA

West Ohio UMC Conference AIDS Ministry, Lonny LeFever, Conover, OH, USA

Zephyr L.T.N.P. Foundation, Inc., Loreen Willenberg, Sacramento, CA, USA

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Snow William, San Francisco, CA, USA

Bonnie Williams, Saratoga, CA, USA

Seanna Williams, Orem, UT, USA

William Wilson, Chicago, IL, USA

Joe Wright, Cambridge, MA, USA

Louis Zimmerman, Aurora, CO, USA

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