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**NATIONAL
SKILLS
BUILDING
CONFERENCE**

February 24, 1997

Patsy Fleming
National AIDS Policy Office
750 17th St., #600
Washington, DC 20503

Dear Patsy,

On behalf of the sponsors of the National Skills Building Conference (NSBC) -- AIDS National Interfaith Network (ANIN), National Association of People With AIDS (NAPWA) and National Minority AIDS Council (NMAC) -- enclosed is a copy of the '96 Conference Final Report.

The report will provide you with detailed information about the conference -- sponsors, program format, keynote speakers and special guests, faculty, scholarship program, exhibitors, participants statistics and evaluation results.

As the enclosed document details, the '96 NSBC was the largest skills building conference convened to date. It was also a programmatic and logistical success. Much of that success was due to your support and/or contributions.

Thank you for your belief in and support of our program. I look forward to your continued support in the future.

Sincerely,

Vicente L. Rodriguez

Vicente L. Rodriguez, CMP
Conference Director

Enclosure

PRESENTED BY:

AIDS
NATIONAL
INTERFAITH
NETWORK
REV. KENNETH T. SOUTH
EXECUTIVE DIRECTOR

NATIONAL
ASSOCIATION
OF PEOPLE
WITH AIDS
WILLIAM J. FREEMAN
EXECUTIVE DIRECTOR

NATIONAL
MINORITY
AIDS
COUNCIL
PAUL AKIO KAWATA
EXECUTIVE DIRECTOR

1931 13TH ST., NW
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1996 NATIONAL SKILLS BUILDING CONFERENCE ✦ OCTOBER 10-13 ✦ WASHINGTON, DC

OUR LEGACY OF COURAGE

FINAL REPORT

AIDS NATIONAL INTERFAITH NETWORK ✦ NATIONAL ASSOCIATION OF PEOPLE WITH AIDS ✦ NATIONAL MINORITY AIDS COUNCIL

**NATIONAL
SKILLS
BUILDING
CONFERENCE**

E. Hoasby

February 24, 1997

Bruce Reed
The White House - Domestic Policy Council
1600 Pennsylvania Ave, NW
Washington, DC 20500

Dear Bruce

PRESENTED BY:

AIDS
NATIONAL
INTERFAITH
NETWORK
REV. KENNETH T. SOUTH
EXECUTIVE DIRECTOR

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NATIONAL
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WITH AIDS

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WILLIAM J. FREEMAN
EXECUTIVE DIRECTOR

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NATIONAL
MINORITY
AIDS
COUNCIL

Thank you for your belief in and support of our program. I look forward to your continued support in the future.

PAUL AKIO KAWATA
EXECUTIVE DIRECTOR

Sincerely,

Vicente L. Rodriguez

Vicente L. Rodriguez, CMP
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NATIONAL SKILLS BUILDING CONFERENCE

February 24, 1997

Jeff Levi
National AIDS Policy Office
750 17th St., #600
Washington, DC 20503

Dear Jeff,

PRESENTED BY:

AIDS
NATIONAL
INTERFAITH
NETWORK
REV. KENNETH T. SOUTH
EXECUTIVE DIRECTOR

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Sincerely,

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Vicente L. Rodriguez, CMP
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OUR LEGACY OF COURAGE FINAL REPORT

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Public Vocational Rehabilitation

The oldest and most successful Federal/State program
in American History

People with Disabilities:
Want to work, Can work, Do work!



Presented by The Council
of State Administrators of
Vocational Rehabilitation

*Celebrating the
Rehabilitation Act!*

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A look at the **REHABILITATION ACT** *and the* **AMENDMENTS OF 1992**

ADMINISTRATION AND VOCATIONAL REHABILITATION SERVICES **Declaration of Policy (Section 100)**

FINDINGS. — Congress finds that:

- (1) Millions of Americans have one or more physical or mental disabilities and the number of Americans with such disabilities is increasing;
- (2) Individuals with disabilities constitute one of the most disadvantaged groups in society;
- (3) Disability is a natural part of the human experience and in no way diminishes the right of individuals to:
 - (A) live independently;
 - (B) enjoy self-determination
 - (C) make choices;
 - (D) contribute to society;
 - (E) pursue meaningful careers; and
 - (F) enjoy full inclusion and integration in the economic, political, social, cultural, and educational mainstream of American society;
- (4) Increased employment of individuals with disabilities can be achieved through the provision of individualized

training, independent living services, educational and support services, and meaningful opportunities for employment in integrated work settings through the provision of reasonable accommodations;

- (5) Individuals with disabilities continually encounter various forms of discrimination in such critical areas as employment, housing, public accommodations, education, transportation, communication, recreation, institutionalization, health

services, voting, and public services; and

- (6) The goals of the Nation properly include the goal of providing individuals with disabilities with the tools necessary to:

- (A) make informed choices and decisions; and

- (B) achieve equality of opportunity, full inclusion and integration in society, employment, independent living, and economic and social self-sufficiency, for such individuals.

"Disability is a natural part of the human experience and in no way diminishes the right(s) of individuals ..."

THERE ARE 43 MILLION AMERICANS WITH DISABILITIES.

**COUNCIL OF STATE ADMINISTRATORS OF VOCATIONAL REHABILITATION
AND
UNITED STATES DEPARTMENT OF EDUCATION
REHABILITATION SERVICES ADMINISTRATION**

PRESS RELEASE

FOR IMMEDIATE RELEASE

**COUNCIL OF STATE ADMINISTRATORS
OF VOCATIONAL REHABILITATION**

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**NATIONAL EFFORT LAUNCHED TO STREAMLINE
EMPLOYMENT SYSTEM FOR PEOPLE WITH DISABILITIES**

Washington, D.C. - A nationwide effort to streamline the state system responsible for placing persons with disabilities into competitive employment was announced today. The effort began with the signing of an agreement between State Officials and the Federal Government with specific deadlines for accomplishing its purpose.

The purpose of the agreement signed by the Council of State Administrators of Vocational Rehabilitation (CSAVR) and the Rehabilitation Services Administration (RSA) is to reduce overly burdensome rules, regulations, and reports in order for the program to focus on its true purpose - putting more people with disabilities into good jobs.

The Vocational Rehabilitation Program is a 76-year old Federal-State partnership which has assisted millions of people with disabilities in getting jobs. Vocational rehabilitation programs offer a broad range of services aimed at lessening the impact of a mental and/or physical disability on a person's ability to work in a meaningful job. Services include, but are not limited to, counseling, training, technology assistance and job placement. Service plans are designed for each person the program serves in recognition of the diversity of disabilities and individual needs.

(more)

"The program has succeeded for 76 years, largely because it has maintained a focus on ability and employment", says Jeanne Munro, CSAVR President. "This streamlining effort addresses the elimination of State and Federal paperwork and process that over time became an impediment to professional staff and to persons with disabilities in their joint efforts to reach employment outcomes."

Last year, the CSAVR and RSA laid out a plan for change for a more responsive and interactive program. The Plan eliminates unnecessary bureaucracy, emphasizing consumer involvement in the services they receive, and refocuses it on employment in good jobs.

"I am excited about this plan and optimistic about what it means for people with disabilities", stated Commissioner Fredric Schroeder. "It has probably never been more important for a person with a disability to be competitive in the job market. Despite success in the Vocational Rehabilitation program, unemployment for persons with disabilities remains at an alarming rate of more than 60%. I am pleased that the states have taken the initiative to identify specific ways to improve and help more people become more independent and employed in competitive work".

In Fiscal Year 1995, more than 209,000 people with disabilities went to work through the State-Federal Vocational Rehabilitation program. An estimated 90% of these people worked for minimum wage or more. Almost 84% rely on their earnings as their primary source of income.

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Rehabilitation Services Administration
Mary Switzer Building
330 C Street, SW
Washington, D.C. 20202
(202) 205-5482



Streamlining

THE PUBLIC VOCATIONAL REHABILITATION SERVICE DELIVERY SYSTEM

*a joint initiative of the
Council of State Administrators of Vocational Rehabilitation (CSAVR) and the
U.S. Department of Education Rehabilitation Services Administration (RSA)*

Purpose:

The Public Vocational Rehabilitation Program will assist more eligible people with disabilities to obtain real jobs at real wages.

Vision:

The future of the Public Vocational Rehabilitation Service Delivery System is dependent, in part, upon streamlining that system to work in partnership with consumers to achieve meaningful employment outcomes. The primary focus of this effort must be on achievement of **gainful employment outcomes** rather than on process.

Background:

Many aspects of the public vocational rehabilitation (VR) "process" evolved over time into impediments to an efficient system. In 1993, the Council of State Administrators of Vocational Rehabilitation (CSAVR) developed and adopted recommendations and strategies to streamline the program to make it more responsive to the people with disabilities it serves, and to enhance employment outcomes of people with disabilities.

Many state agencies have since begun streamlining their service delivery systems. The Rehabilitation Services Administration (RSA) has helped state agencies identify practices and policies hindering the rehabilitation process from the perspective of consumers, advocates and rehabilitation professionals.

Recognizing the need to simplify "process" requirements throughout the nation's Public VR System, the CSAVR and RSA commit to a national effort geared toward consumer-responsive, high-quality, efficient public vocational rehabilitation service delivery, leading to employment outcomes for people with disabilities.

Strategies:

To help state agencies meet the goals of the streamlining initiative, the RSA and the CSAVR will:

-  provide support and technical assistance to help state VR agencies adopt more consumer-friendly policies and procedures;
-  commit resources to train state agency staff to meet streamlining objectives;
-  focus on the four important steps in vocational rehabilitation service delivery: *eligibility, employment planning, service implementation and employment outcome*.
-  assure that state plans and federal reporting requirements for VR agencies are consistent with those four important steps;
-  maintain and utilize a new monitoring system that assures compliance with the law and the streamlining initiative; and
-  provide guidance in refining and improving the streamlining initiative.

COUNCIL OF STATE ADMINISTRATORS OF VOCATIONAL REHABILITATION

Streamlining the Process of Public Vocational Rehabilitation

QUESTIONS AND ANSWERS

QUESTION: What led to the streamlining effort to make vocational rehabilitation more "user friendly"?

ANSWER: In 1990, as State Rehabilitation Agencies approached the Reauthorization of the Rehabilitation Act, the **Council of State Administrators of Vocational Rehabilitation (CSAVR)** convened a leadership meeting to address criticism of the Public VR Program. Those attending found that, rather than the law creating problems, the VR **process** had become cumbersome, lethargic and unresponsive. These problems were due to Federal regulations, statistical and reporting requirements, various state and federal policy directives, as well as antiquated practices.

Determined to resolve these issues, the CSAVR convened a national conference which, after in-depth deliberations, produced what is now known as the **Aspen Document**. This Policy Paper proposed streamlining the Public Vocational Rehabilitation Service Delivery System in order to place more eligible persons with disabilities into competitive employment by making the "system" more "user friendly" and more "customer friendly."

The CSAVR approached the Rehabilitation Services Administration (RSA) in the Department of Education with this proposal. As a result of negotiations, the Streamlining Agreement was adopted by both of the Governmental Partners, the CSAVR and the RSA, with its signing on February 1, 1996. This important endeavor attempts to eliminate all unnecessary processes and to focus on the four steps of vocational rehabilitation, i.e.: eligibility, employment planning, delivery of employment services and job placement.

QUESTION: What do you hope to accomplish with this streamlining initiative?

ANSWER: To provide higher quality service to more persons with disabilities with essentially the same amount of federal and state resources. That is, to assist more people with disabilities get good jobs at appropriate wages.

(more)

QUESTION: How many state agencies have implemented this streamlining effort?

ANSWER: State agencies are in various stages of implementing the agreement. We know that a majority of the 82 state agencies are moving quickly toward implementation which will affect service delivery to millions of people with disabilities.

QUESTION: What has been the result of streamlining so far?

ANSWER: The Public Vocational Rehabilitation Program has increased the number of people with disabilities who have gone to work annually by 13% between 1992 and 1996, with little, if any, new federal or state monies. Approximately 1 million more people with disabilities are working in 1996 than in 1991.

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**JOINT RSA/CSAVR VISION AND
STRATEGIES FOR STREAMLINING
THE PUBLIC VOCATIONAL
REHABILITATION
SERVICE DELIVERY SYSTEM**

JOINT RSA/CSAVR VISION AND STRATEGIES FOR STREAMLINING THE PUBLIC VOCATIONAL REHABILITATION SERVICE DELIVERY SYSTEM

PURPOSE: IN ORDER THAT THE PUBLIC VOCATIONAL REHABILITATION PROGRAM WILL ASSIST MORE ELIGIBLE PEOPLE WITH DISABILITIES TO OBTAIN REAL JOBS AT REAL WAGES.

VISION:

The future of the Public Vocational Rehabilitation Service Delivery System is dependent, in part, upon streamlining the Public Vocational Rehabilitation Service Delivery System to work in partnership with consumers to achieve meaningful employment outcomes. The primary focus of this effort must be the achievement of gainful employment outcomes in integrated settings rather than a focus on process.

BACKGROUND:

In 1993, The Council of State Administrators of Vocational Rehabilitation (CSAVR) convened a conference of national leaders of the Public Vocational Rehabilitation Program.

The purpose of the meeting was to develop recommendations and strategies to Streamline the Public Vocational Rehabilitation Service Delivery System, in order to make it more responsive to the persons the system serves and to enhance employment outcomes of persons with disabilities. As a result of this meeting, many of the State Agencies have implemented Streamlining Initiatives.

Over the past two years, the Rehabilitation Services Administration (RSA) has assisted these State Agencies in carrying out streamlining activities. These streamlining efforts sought to identify practices and policies impeding the rehabilitation process and outcomes from the perspective of consumers, advocates, and rehabilitation professionals.

Recognizing the need to simplify "process" requirements throughout the nation's Public Vocational Rehabilitation System, the RSA in collaboration with the CSAVR commits to a National effort designed to facilitate consumer-responsive, high quality, efficient Public Vocational Rehabilitation outcomes. Many of the "process" requirements generally considered to be impediments to an efficient, responsive System have evolved over time and have become institutionalized in the Service Delivery System. To facilitate an effective National Streamlining Initiative, State Vocational Rehabilitation Agencies will be asked to undertake a review of current Agency practices and processes. The Rehabilitation Services Administration will provide Technical Assistance and resources to assist State Vocational

Rehabilitation Agencies in these streamlining efforts. Additionally, the RSA commits to ensuring that Federal Regulations and Policies minimize "process" requirements and support a clear focus on quality employment outcomes.

Further, the RSA commits to incorporate this philosophy into its monitoring practices. Comprehensive Monitoring will focus on areas of concern identified by consumers in individual states.

The RSA and CSAVR Streamlining Initiative represents a joint commitment to ensuring a clear focus on quality employment outcomes for people with disabilities.

The success of the Streamlining Initiative is rooted in a philosophy of a consumer-driven, outcome-based System of Public Vocational Rehabilitation.

SCOPE OF AGREEMENT:

Each of the steps to implement the above Vision has specific Actions associated with them and Dates by which they are to be accomplished.

The CSAVR and RSA commit their respective resources to the accomplishment of these Strategies and Actions within the Time Deadlines agreed upon. These Actions and Time Frames recognize the opportunity at hand and the significance of timely implementation.

It is also important to recognize that the CSAVR and Member State Vocational Rehabilitation Agencies are prepared to assist, through the availability of State Vocational Rehabilitation staff, in the work on specific action steps.

This Streamlining Effort is a joint effort between the RSA and the CSAVR which will require appropriate and available Federal and State staff time and expertise.

The RSA and CSAVR will encourage all State Rehabilitation Agencies to review this Plan with their Rehabilitation Advisory Councils, and other stakeholders, to seek their involvement in, and support of, this Plan and its implementation in the State Agencies.

Date: February 1, 1996; Completed: April 1, 1996.

WORKPLAN

STRATEGIES OF IMPLEMENTATION TO STREAMLINE THE STATE/FEDERAL VOCATIONAL REHABILITATION SERVICE DELIVERY SYSTEM

THE REHABILITATION SERVICES ADMINISTRATION AND THE COUNCIL OF STATE ADMINISTRATORS OF VOCATIONAL REHABILITATION WILL:

1. Promote State Vocational Rehabilitation Agency self-evaluations in order to identify and promote the adoption and use of policies and procedures that result in a Streamlined Service Delivery System that is focused on "employment outcomes."

ACTION: The CSAVR will notify all Member State Vocational Rehabilitation Agencies of this Agreement and recommend that this is an opportunity for each agency to further streamline its service delivery with the support and technical assistance of the RSA and with the involvement of stakeholders in the review for its planning and implementation.

Date: February 1, 1996. Status Report: August, 1996.

ACTION: The RSA Staff will provide support and technical assistance to State Vocational Rehabilitation Agencies for the purpose of streamlining the vocational Rehabilitation Service Delivery process in each State Agency.

Date: Beginning March 1, 1996.

ACTION: The State Rehabilitation Directors will develop Regional Support Networks, facilitated by each CSAVR Regional Representative, to work collaboratively in support of the Region's individual and collective State Streamlining Initiatives.

Date: Begin March 1, 1996.

ACTION: The RSA recognizes that State Agencies may, as appropriate, implement this Streamlining Plan utilizing resources from the 1.5 percent set-aside which is required for uses described in Section 123 "Innovation and Expansion" of the Rehabilitation Act.

Date: February 1, 1996.

2. Commit personnel and discretionary resources, including the Regional Rehabilitation Continuing Education Program (RRCEP) and In-Service Training, to achieve the Streamlining Objectives.

ACTION: The RRCEP's will be directed to provide training and technical assistance to State Vocational Rehabilitation Agencies staff that are tailored to the needs of the Region and the States which adopt the Streamlining Agenda.

Date: Beginning April 1, 1996.

ACTION: The RSA In-Service Training Plans in State Vocational Rehabilitation Agencies will be revised under the continuation grant for FY 97 and will include the Streamlining Initiative.

Date: February 1 to April 1, 1996.

3. Focus on the important steps in the Vocational Rehabilitation Service Delivery Process: Eligibility, Employment Planning, Service Implementation, and "Employment Outcome."

ACTION: The RSA Commissioner will issue a clear and concise Policy Statement on Streamlining to RSA staff and State Vocational Rehabilitation Agencies, defining the new Four Step System and requiring its use. The RSA will provide adequate lead time for State Vocational Rehabilitation Agencies to implement changes in Reporting Requirements in a consistent, uniform and accurate manner. The Policy Statement will be written so that it supports caseload management and the new Streamlining Initiative.

Date: Available for review by April 15; Begin Clearance by May 1, 1996.

Implementation: Upon Clearance.

ACTION: The CSAVR will work with the RSA to establish the Priority of Issues to be addressed under Policy Streamlining.

Date: Completion within 30 days of final Title I Regulations.

4. Utilize the recommendations of the "RSA-CSAVR Section 140 Work Group," when relevant and appropriate, to establish a Statistical and Fiscal Reporting System that supports an employment outcomes-oriented Service Delivery System and the RSA/CSAVR Streamlining Initiative.

ACTION: Revise the RSA-113 Cumulative Caseload Report, (PD-95-03).

Date: April 15 to CSAVR; May 1 to Federal Government Clearance.

ACTION: The CSAVR will share the Streamlining Strategies with the CSAVR members of the "Section 140 Work Group" and request them to develop a Work Plan and to recommend and develop proposed Report changes and instructions, in order to address the goals of the Streamlining Initiative.

Date: March 1, 1996.

5. Maintain and utilize the collaborative State-Federal Vocational Rehabilitation Monitoring System, including the Case Review Instrument, to assure compliance with the Law and consistency with the RSA/CSAVR Streamlining Initiative.

ACTION: Adopt the new Monitoring System.

Date: COMPLETED.

ACTION: Adopt the new Case Review System focused on employment outcomes.

Date: COMPLETED.

ACTION: Train reviewers in the utilization of the Monitoring System and the Case Review Instrument in order to reflect the new Streamlining Initiative.

Date: Beginning March 1, 1996.

ACTION: The CSAVR/RSA Task Force on Monitoring and Case Review will review the RSA Monitoring System and make recommendations from the states' perspective that will enhance and support the Streamlining Initiative.

Date: May 1, 1996.

ACTION: The CSAVR's comments in response to the "Vocational Rehabilitation Notice of Proposed Rulemaking" (NPRM) will include a proposed definition of "substantial services" with supporting rationale.

Date: February 23, 1996.

6. Assure that the RSA State Plan Requirements and Policy Directives are consistent with the RSA/CSAVR Streamlining Initiative and reflect on outcomes.

ACTION: The RSA will take steps to assure that State Plan Requirements and Policy Directives developed, are consistent with the Law, Regulations and the Streamlining Initiative.

Date: Upon finalization of the Title I and related regulations.

ACTION: The CSAVR will develop model Eligibility and Individualized Written Rehabilitation Program (IWRP) Forms which reflect the new Streamlining Initiative and the experiences of states which have implemented Streamlining.

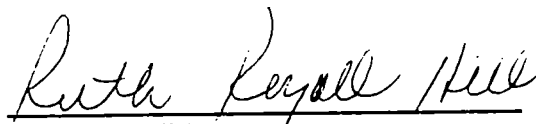
Date: August, 1996.

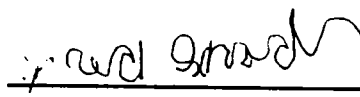
7. Utilize the Institute on Rehabilitation Issues (IRI) and other effective approaches as vehicles for the continuous refinement and enhancement of improved employment outcomes through the State-Federal Vocational Rehabilitation Program.

ACTION: The RSA and the CSAVR will identify and communicate proposed Streamlining issues to the IRI for study and development of useful guidance and training materials in order to sustain, expand and improve the Streamlining Initiative.

Date: March 1, 1996.

SIGNATURES:


Ruth Royall Hill
President, CSAVR


Fredric K. Schroeder
Commissioner, RSA

Date: 2/1/96

Date: 2/1/96

**COUNCIL OF STATE ADMINISTRATORS
OF
VOCATIONAL REHABILITATION**

**RECOMMENDATIONS FOR A
MODEL SERVICE DELIVERY SYSTEM
FOR PUBLIC VOCATIONAL REHABILITATION**

COUNCIL OF STATE ADMINISTRATORS
OF
VOCATIONAL REHABILITATION

RECOMMENDATIONS FOR A
MODEL SERVICE DELIVERY SYSTEM
FOR PUBLIC VOCATIONAL REHABILITATION

I. ISSUES ADDRESSED:

- A. In the Public State-Federal Vocational Rehabilitation Program, there has been a pronounced drift from employment outcomes to an over-emphasis on process.
- B. We need to move people through the Vocational Rehabilitation process more expeditiously and effectively.
- C. Our goal is to enhance the economic independence of consumers.
- D. Limited resources must be targeted to employment outcomes.

II. VISION STATEMENT:

Our vision is of a streamlined service-delivery system which works in partnership with consumers to achieve meaningful employment outcomes. This vision focuses not on "process" but on consumer empowerment, which facilitates the achievement of gainful employment outcomes in integrated work settings.

III. RECOMMENDATIONS:

It is the recommendation of the Council of State Administrators of Vocational Rehabilitation that the Public Vocational Rehabilitation Program in the United States focus primarily on employment outcomes rather than the process used to assist people in achieving those outcomes.

The Program focus appears to have drifted over the years from employment outcomes to the provision of "services."

However, passage of the "Americans with Disabilities Act" (ADA) and the 1992 Amendments to the Rehabilitation Act of 1973, combined with the current fluid status of regulation writing, make this an opportune time to streamline the current service delivery system, and thereby, to enhance employment outcomes.

Three significant factors affect the "practices" which State Rehabilitation Agencies utilize to achieve outcomes. They are: 1) local and state economies; 2) the new emphasis on consumer choice; and 3) the responsibility of consumers and employers to advise Agencies as they implement the 1992 Amendments to Title I of the Rehabilitation Act. Additionally, the Congressionally-mandated evaluation standards and performance indicators emphasize employment outcomes.

It is the opinion of the CSAVR that process often controls practice. Therefore, the decision has been made to concentrate, at this point, on the "process" and on other recommendations which facilitate increased numbers of people with disabilities entering employment, rather than upon "practice" issues.

Further, it has been assumed that State Rehabilitation Agencies have, and must retain, broad flexibility to structure their financial resources, staffing, practices, and services, while emphasizing their philosophy for maximizing employment outcomes with consumers.

Therefore, the CSAVR recommendations for enhancing employment outcomes are made in the following areas:

A. RECOMMENDATIONS REGARDING PROCESS:

1. Eligibility Determination (The use of existing data and a sixty-day maximum to determine eligibility):

IT IS RECOMMENDED:

- a. That, to the maximum extent possible, existing data for the determination of eligibility be used to reduce the time and costs of enabling people with disabilities to obtain employment;

- b. That State Rehabilitation Agencies and the Rehabilitation Services Administration (RSA) revise their monitoring instruments to reflect only the essential requirements of the statute pertaining to eligibility determination; and
- c. That the sixty-day maximum time period for determining eligibility begin when the Agency receives a signed application and that State Agency personnel encourage consumers and referral resources to provide all relevant and available documentation at the time of application.

2. Development of the Individualized Written Rehabilitation Program (IWRP):

IT IS RECOMMENDED:

- a. That the IWRP requirements not extend beyond existing law and that the IWRP be made less complicated and "legalistic." The IWRP is an agreement, or "living document," which is flexible and does not require extensive specificity (i.e. all digits of the Dictionary of Occupational Titles (DOT) code) in establishing a consumer's initial vocational goal. Excessive specificity too often results in excessive IWRP amendments. Only a broad, suitable vocational goal and rationale, that can last the life of the IWRP, are required;
- b. That the IWRP follow the needs of the person, not the review requirements of the RSA or of individual states. It is often unrealistic to set specific suitable employment outcomes (i.e. six digit DOT codes) at the outset of the rehabilitation program; and
- c. That the reviews of the IWRP's focus on outcome, not on the process of the plan's implementation.

3. Case DOCUMENTATION System (Status System):

IT IS RECOMMENDED:

- a. That the case management and documentation system be simplified by reducing the current number of statuses;
- b. That the proposed statuses include, at least:
 - 1) Eligibility,
 - 2) Services (See Title I, Section 103), and
 - 3) Outcomes.

This simplification would remove the "seams" or presumption that the consumer must have completed one service status before beginning another; and

- c. That tracking and management systems follow the consumer, rather than the consumer having to follow the existing system. This will result in a significant reduction in documentation and a shift of resources from record-keeping to service provision, with the focus on employment outcome.

4. Documentation:

IT IS RECOMMENDED:

- a. That the regulations and monitoring practices reflect only the essential documentation required by the Rehabilitation Act, as amended;
- b. That State Agencies and the RSA revise their audit and review process to focus on employment outcomes instead of on "process." This will result in reduced documentation, which will enable more resources to be expended on consumers; and
- c. That the CSAVR and the RSA clarify the Federal law and regulations in order to minimize case documentation requirements, while, at the same time, allowing individual states the right to retain flexibility to establish their own case management

systems, if they meet or exceed the Federal requirements.

B. RECOMMENDATIONS WHICH ARE NOT DIRECTLY RELATED TO "PROCESS:"

1. Informed Choice:

IT IS RECOMMENDED:

- a. That, as states and the RSA develop policy and regulations around the issue of "choice of services and providers," they consider the responsibility of the states to support sound professional judgement.

Agencies must retain responsibility to establish and maintain reasonable criteria for the selection of services and providers, including costs, leading to employment outcomes. For example, an Agency may limit its financial responsibility to the payment of tuition for a state-supported university program (which is available and appropriate), when its curriculum is equivalent to that of a private university.

Consistent with the principle of "informed choice," consumers need to be given information about the Vocational Rehabilitation process and how to participate in it in order to most effectively achieve gainful employment outcomes; and

- b. That the RSA obtain input from State Rehabilitation Agencies on issues such as "state wideeness" and on Agency experience with "equal or comparable services," prior to the writing of regulations on "choice."

2. Employment Outcomes:

IT IS RECOMMENDED:

- a. That the RSA and the states devise a system which recognizes and appropriately credits significant services provided to help consumers enter, engage in, or retain gainful employment. If a consumer has been placed into gainful employment but requires

limited services to retain employment, those services are to be provided as Post-Employment Services; however, if a consumer requires significant services to retain or regain employment or advance in employment (and advancement limitations are imposed by disability) those services are to be provided under a new plan.

Goals, as well as available employment, frequently change in our society. Therefore any consumer employment outcome, which meets the intent of the law, would be considered a successful outcome. Gainful employment is the goal; and

- b. That the CSAVR and the RSA jointly develop a definition of "significant services" to meet the intent of the preceding recommendation, for "significant services" are interpreted differently across the Nation.

IV. IMPLEMENTATION STRATEGIES:

While the preceding Recommendations deal with "process" or procedural changes to facilitate delivery of services leading to gainful employment, several additional actions are recommended.

These are in the arena of "practice" and need to be addressed by the CSAVR Task Force on Employment.

Therefore,

IT IS RECOMMENDED THAT THE CSAVR TASK FORCE ON EMPLOYMENT:

- a. Develop a model for placing consumers into gainful employment, recognizing that each State Agency may have wide variations in incorporating the elements of the model;
- b. Develop guidelines for State Agencies to implement employer services designed to promote employer-agency relationships. These services may include disability management, ADA technical

assistance, job accommodation, affirmative action, employee assistance programs, advancement in employment, second injury (workers' compensation) certification, etc. The development of a comprehensive employer-agency relationship will enhance the placement of workers with disabilities;

- c. Help State Rehabilitation Agencies establish community "employer advisory" councils;
- d. Develop National Cooperative Agreements, and support the development of local agreements with Chambers of Commerce, manufacturers' associations, etc;
- e. Serve as liaison with Projects with Industry (PWI), the President's Committee on Employment of Persons with Disabilities, and other employer-related groups, and;
- f. Analyze and advise how "services to groups" might better be used to enhance employment outcomes.

OVERWHELMINGLY ADOPTED BY THE FULL COUNCIL OF STATE ADMINISTRATORS OF VOCATIONAL REHABILITATION, ON MONDAY, SEPTEMBER 27, 1993, DURING THE CSAVR FALL CONFERENCE

November 1996

Dear Colleague:

Protease inhibitors are a new type of drug to treat HIV infection. These drugs, when taken in combination with other HIV therapies, offer great promise for people with AIDS. However, in order for these drugs to be most effective, doctors and patients must know how to use them properly. Enclosed is a packet of materials to provide information about protease inhibitors and other anti-viral drugs for you and your fellow staffworkers, clients, patients, health care providers, friends, etc. The packet contains materials created by four leading HIV treatment education programs. Please use them, photocopy them, call and ask for more as you need them. There is an enclosed card that tells you how to order more of these packets. Without the proper information, we will not be able to realize the promise that these new drugs may provide to people with AIDS.

Because these drugs are new, we still do not know enough about how to use them most effectively. There are three different protease inhibitors and five different nucleoside analogs. We do not yet know when is the best time to start therapy, which combinations are best to use first, how long the effect of these drugs can last, and what are the long-term side effects. The answers to these questions will come through continued clinical research and experience. But that takes time. Meanwhile, people with HIV are faced with treatment decisions today. Many people have no time to wait and must consider whether or not they will start an anti-viral regimen now or in the near future. This packet provides the information that is currently available to assist doctors and patients in making and following through on these difficult decisions.

In sending out this packet, none of our organizations are endorsing any of these drugs or a particular regimen. The decision to use these drugs is one that only each patient, in consultation with his or her doctor can make. However, without the necessary information, patients cannot begin to decide for themselves what they think is best. That is why we are sending this packet out all over the country.

These materials are meant to reach people at different reading levels. Several of them are in both English and Spanish. We are working to translate many of these materials into other languages. Feel free to copy any and all of them. We will keep supplying them until we have no more. We will update the packets as new information becomes available.

This is the first time that our organizations have worked in collaboration to provide treatment education materials. The mailing house that is coordinating this mailing for us is handling the mailing lists from each of our organizations. The mailing lists remain strictly confidential. The mailing house will not allow anyone to have access to these lists and we are not sharing our lists with each other.

We feel that the information provided is very important and we are committed to doing everything we can to help people learn about HIV treatment as quickly as possible. If you have any suggestions or comments on this packet, please call any of our organizations at the numbers listed below. Thank you for your support.

Yours truly,

Moises Agosto - National Minority AIDS Council
David Barr - Gay Men's Health Crisis
Martin Delaney - Project Inform
Ken Fornataro - AIDS Treatment Data Network

PROTEASE INHIBITOR: INVIRASE (SAQUINAVIR)

What are Protease Inhibitors?

Protease inhibitors are a new type of anti-retroviral (drugs that stop the reproduction of HIV in your body). Protease drugs work by blocking a part of HIV called protease. Without protease, HIV makes copies of virus that cannot infect new cells. Studies (clinical trials) of protease inhibitors have shown that these drugs, taken alone or in combination with other anti-viral drugs (AZT, ddI, ddC, d4T, 3TC), can lower viral load (the amount of HIV in your blood) and raise T-cells (CD4 cells). The greatest effect was seen in people taking combination therapy. However, it is important to remember that more studies are needed to better understand how to use these drugs.

When Should I Start Taking Protease Inhibitors?

No one knows yet the best time to begin taking protease inhibitors. One study of people with AIDS who have low T-cells (100 or lower) showed that those who took a protease inhibitor lived longer (by approximately six months) than those who did not take a protease inhibitor. Based on these results, if you have: 1) low T-cells, 2) high viral load, 3) symptoms of illness, and/or 4) have had HIV disease for a long time, you may want to talk with your doctor about starting a protease combination.

Doctors do not yet know whether taking these drugs early in HIV disease—when T-cells are high and viral load is low—will help prolong life or prevent the development of AIDS. In theory, starting a protease drug when viral load is low could allow the drug to be more effective.

Can Drug Resistance Occur with Protease Inhibitors?

HIV eventually learns to work around the effect of the drug. This is called drug resistance. Resistance causes the drug to work less well or not to work at all. Resistance does not go away. Also, developing resistance to one protease drug will often mean that you are resistant to other protease drugs as well. This is called cross-resistance.

Some studies show that taking protease inhibitors in combination with other anti-HIV drugs may greatly reduce the chance of developing resistance. But the best way, at this time, to avoid or delay the development of drug resistance, is to make sure you take the drugs properly. Skipping doses, taking lower than prescribed doses, not following food guidelines, and not taking the drugs on schedule, all encourage the development of drug resistance. If you think that you are not able to follow the treatment routine which you and your doctor have put together, then you might want to wait until you feel you really need the drugs or are better prepared to take the drugs properly.

Invirase (also called saquinavir):

Dose

Three 200 mg capsules taken three times a day within two hours after eating a full meal preferably high in fat. Invirase must be taken on a full stomach to be effective. Some healthier foods that are high in fat include: lean red meat, peanut butter, avocado, cheese, bread with butter, whole or 2 percent milk products.

Unlike other protease inhibitors, Invirase has been shown to be effective only when used in combinations with other anti-viral drugs, including AZT, ddC or AZT/ddC. Talk with your doctor about which combination and at which doses is best for you.

Clinical studies have shown that Invirase is not as potent as other protease inhibitors in lowering the level of virus in the blood. This may be due in part to the fact that Invirase is not absorbed or metabolized very well by the body. A new, improved version of Invirase will be available over the next year.

Studies have shown that development of cross resistance between Invirase and Crixivan or Invirase and Norvir may occur more slowly than with the other protease drugs. Although more studies need to be done, this is good news for people already taking Invirase who may wish to switch from Invirase to Crixivan or Norvir.

Invirase in combination with Norvir or Crixivan has not been tested and the safety is not known. Screening for an upcoming trial with Invirase and Norvir is occurring now. For clinical trial information call: Abbott Labs Consumer Hotline at 1-800-441-4987.

Storage

Keep capsules in their bottle at room temperature.

Side Effects

Invirase has fewer side effects than the other protease drugs. Side effects might include diarrhea, stomach upset and nausea. However, most people in the clinical studies did not develop these problems.

Cost

Invirase sells for about \$7,800 a year. Most Medicaid programs and private insurers cover the cost of the drug. Invirase is covered by the ADAP program in New York. Hoffman-LaRoche, the maker of Invirase, has a patient assistance program for people who are not covered by insurance and who cannot pay for Invirase. For further information, call 1-800-282-7780.

Availability

Invirase is an approved drug and is available through any pharmacy. Speak to your doctor about other possible drug interactions.

Drug Interactions

Invirase should NOT be taken with: rifampin or rifabutin (Mycobutin), terfenadine (Seldane), astemizole (Hismanal), phenobarbital, phenytoin (Dilantin), dexamethasone (Decadron), carbamazepine (Tegretol).

Speak to your doctor about other possible interactions.

INHIBIDORES DE PROTEASA: INVIRASE (SAQUINAVIR)

¿Qué son los inhibidores de Proteasa?

Los inhibidores de Proteasa son una nueva clase de medicamentos anti-retrovirales (drogas que bloquean la reproducción del VIH en su cuerpo). Los inhibidores de Proteasa bloquean una parte del VIH llamada proteasa. Sin proteasa, el VIH produce copias imperfectas de sí mismo que no pueden infectar nuevas células. Varios estudios clínicos de inhibidores de Proteasa han demostrado que estas drogas, tomadas solas o en combinación con otras drogas anti-virales (AZT, ddI, ddC, d4T, 3TC), pueden disminuir la carga viral (la cantidad de VIH presente en su sangre). También pueden aumentar el conteo de células T (células CD4). Los mejores resultados se han observado en personas que han tomado una terapia de combinación de drogas. Es importante mencionar que se necesitan más estudios para comprender mejor el uso de esta nueva clase de drogas.

¿Cuándo debo comenzar a tomar los Inhibidores de Proteasa?

Todavía no sabemos cual es el mejor momento para comenzar el tratamiento con los Inhibidores de Proteasa. Un estudio de personas con SIDA quienes tenían un conteo de células T menor de 100, demostró que los que tomaron Inhibidores de Proteasa sobrevivieron más tiempo (aproximadamente seis meses más) que las personas que no tomaron el Inhibidores de Proteasa. En base a estos resultados sabemos que si usted tiene: 1) Un conteo bajo de células T; 2) Un conteo viral alto; 3) Síntomas de enfermedad, y/o; 4) Ha tenido la enfermedad del VIH por mucho tiempo, usted debe hablar con su doctor sobre la posibilidad de comenzar tratamiento de combinación que incluya un Inhibidor de Proteasa.

Los doctores no saben todavía si tomar estas drogas en la etapa temprana de la infección (cuando el conteo de células T es alto y la carga viral es baja) ayude a prolongar su vida o a prevenir el desarrollo del SIDA. (En teoría, se piensa que el comenzar el tratamiento con un Inhibidor de Proteasa cuando la carga viral es baja debe ayudar a la droga a trabajar mejor.)

¿Es posible el desarrollo de la resistencia viral con los Inhibidores de Proteasa?

Eventualmente el VIH aprende a "sobrepasar" o a "resistir" los efectos de las drogas anti-virales. Este fenómeno es llamado resistencia viral. La resistencia ocasiona que la droga no funcione bien o no funcione completamente. La resistencia no desaparece. Es posible que cuando usted desarrolla resistencia a un tipo de Inhibidor de Proteasa también haya desarrollado resistencia a otras drogas Inhibidoras de Proteasa (recuerde: existen varias Inhibidores de Proteasa diferentes). Este fenómeno se llama resistencia cruzada.

Algunos estudios han demostrado que el tomar Inhibidores de Proteasa en combinación con otras drogas anti-retrovirales puede reducir las posibilidades de desarrollar resistencia viral. La mejor manera de evitar o retardar el desarrollo de la resistencia es el tomar las drogas de la manera indicada. Las siguientes condiciones promueven el desarrollo de la resistencia hacia las drogas: El tomar las drogas irregularmente, no tomarlas como son prescritas, y el no seguir las direcciones con respecto a cuales comidas debe o no debe tomar con su medicamento. Si usted piensa que no puede cumplir con su tratamiento, entonces debe de esperar hasta que usted se sienta preparado para tomar las drogas correctamente.

Interacciones con otros drogas

Invirase no debe ser ingerido con los siguientes medicamentos:

Rifampin o rifabutin (Mycobutin), Terfenadine (Seldane), Astemizole (Hismanal), Phenobarbital, phenytoin (dilatín), dexamethasone (decadron), Carbamazepine (Tegretol).

Hable con su doctor sobre otras posibles interacciones.

Invirase (también llamado Saquinavir)

Dosis

La dosis recomendada para tomar Saquinavir es de tres cápsulas de 200mg (cada una) tres veces al día. Invirase se debe tomar después de cada comida y no más de dos horas después de haber ingerido una comida prefiblemente alta en grasas. Para que el Invirase sea efectivo, debe tomarlo con el estómago lleno. Los siguientes son ejemplos de comidas altas en grasas: Carne roja, mantequilla de maní (cacahuates), aguacate, queso, pan con mantequilla, leche completa o desnatada.

A diferencia de otros Inhibidores de proteasa, Invirase es efectiva solamente cuando se utiliza en combinación con otras drogas antivirales. Estas drogas incluyen a: AZT, ddC, o AZT/ddC. Hable con su doctor sobre cuál combinación y qué dosis es mejor para usted.

Varios estudios clínicos han demostrado que Invirase no es tan potente como otros Inhibidores de Proteasa en bajar los niveles del VIH en la sangre. El cuerpo no absorbe muy bien el Invirase, y puede que esto explique el porqué no sea tan potente. En el transcurso de este año, una nueva formula mejorada de Invirase vá a estar disponible.

Se ha demostrado que la resistencia cruzada entre Invirase y Crixivan, e Invirase y Norvir puede ocurrir mucho más lentamente que entre otros Inhibidores de proteasa. Esta es una buena noticia para aquellas personas que están tomando Invirase actualmente y quieren cambiar a Crixivan o a Norvir.

La combinación de invirase con Norvir o Crixivan todavía no se sometido a pruebas experimentales y no sabemos si es una combinación segura. Actualmente se está reclutando personas para un estudio experimental con Invirase y Norvir. Para más información sobre este estudio y otras pruebas experimentales llame a la línea caliente de consumidores de los Laboratorios Abbott al 1-800-441-4987.

Almacenaje

El Invirase debe mantenerse bajo temperatura ambiente.

Efectos secundarios

El invirase tiene menos efectos secundarios que otros Inhibidores de Proteasa. Los efectos secundarios más comunes con Invirase son los siguientes: diarrea, molestia estomacal, y nausea. La mayoría de los participantes en las pruebas experimentales no desarrollaron estos problemas.

El costo

Invirase se vende a un costo de \$7,800 al año. La mayoría de los programas de Medicaid, y las casas aseguradoras privadas cubren el costo de la droga. El programa ADAP de Nueva York cubre el costo de Invirase. Hoffman LaRoche, la casa manufacturera de Invirase, ha establecido un programa de asistencia económica para personas que no pueden pagar por la droga y quienes llenan ciertos requisitos de elegibilidad. Para más información llame al 1-800-282-7780.

Disponibilidad

Invirase ha sido aprobado por el FDA para personas con la infección del VIH y está disponible mediante varias farmacias.

PROTEASE INHIBITOR: CRIXIVAN (INDINAVIR)

What are Protease Inhibitors?

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No one knows yet the best time to begin taking protease inhibitors. One study of people with AIDS who have low T-cells (100 or lower), showed that those who took a protease inhibitor lived longer (by approximately six months) than those who did not take a protease inhibitor. Based on these results, if you have: 1) low T-cells, 2) high viral load, 3) symptoms of illness, and/or 4) have had HIV disease for a long time, you may want to talk with your doctor about starting a protease combination.

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HIV eventually learns to work around the effect of the drug. This is called drug resistance. Resistance causes the drug to work less well or not to work at all. Resistance does not go away. Also, developing resistance to one protease drug will often mean that you are resistant to other protease drugs as well. This is called cross-resistance.

Some studies show that taking protease inhibitors in combination with other anti-HIV drugs may greatly reduce the chance of developing resistance. But the best way, at this time, to avoid or delay the development of drug resistance is to make sure you take the drugs properly. Skipping doses, taking lower than prescribed doses, not following food guidelines, and not taking the drugs on schedule all encourage the development of drug resistance. If you think that you are not able to follow the treatment routine which you and your doctor have put together, then you might want to wait until you feel you really need the drugs or are better prepared to take the drugs properly.

Crixivan (also called indinavir):

Dose

Two 400mg capsules taken every eight hours (3 times a day—e.g. 8 A.M., 4 P.M., 12 MID.). Must be taken on an empty stomach or, if necessary, with a light, low-protein, low-fat meal (e.g. corn flakes, skim milk, apple juice, dry toast, coffee or tea; do not take with grapefruit juice). Take each dose with a large glass of water and drink at least six more large glasses of liquid throughout the day.

In studies, the greatest effect was seen with Crixivan in combination with AZT/3TC. Other combinations may also be useful but have not been tested yet. In deciding which combination to take, think about possible side effects and, if possible, look for a combination that you have not taken before.

Storage

Keeping capsules dry in their bottle is very important. To do this, put the small cloth package or cotton that comes in the bottle, back after every use.

Side Effects

Nephrolithiasis (defined as pain in the sides, blood in urine or kidney stones) occurred in 4 percent of people in clinical studies. Drinking at least eight large glasses of water throughout the day can help prevent nephrolithiasis. Other side effects include nausea, abdominal pain, headache, weakness/fatigue, diarrhea, taste changes and back pain. Less than 2 percent of patients reported having these side effects in clinical studies.

Cost

Crixivan sells for about \$6,000 a year. Most Medicaid programs and private insurers cover it. Crixivan is covered by the ADAP program in New York. Merck, the company that makes Crixivan, runs a patient-assistance program that will supply the drug at no cost if you meet certain qualifications. **Call 1-800-927-8888 Mon.-Fri. 9 A.M.-8 P.M.** for more information regarding patient assistance.

Availability

Because of a temporary limit on drug supply, Crixivan is only available through one pharmacy, **Stadtlanders**, which can fill prescriptions all over the country. **Call 1-800-238-1548** for more information and to enroll in the program. By November 1996, all pharmacies should have Crixivan available.

Drug Interactions

Most drugs can be taken with Crixivan. Rifabutin and ketoconazole (Nizoral) will require a change in the amount of medication taken.

Rifampin, terfenadine (Seldane), astemizole (Hismanal), cisapride (Propulsid), triazolam (Halcion) and midazolam (Versed) **SHOULD NOT** be taken with Crixivan.

Speak to your doctor about other possible drug interactions.

INHIBIDORES DE PROTEASA: CRIXIVAN (INDINAVIR)

¿Qué son los inhibidores de Proteasa?

Los inhibidores de Proteasa son una nueva clase de medicamentos anti-retrovirales (drogas que bloquean la reproducción del VIH en su cuerpo). Los inhibidores de Proteasa bloquean una parte del VIH llamada proteasa. Sin proteasa, el VIH produce copias imperfectas de sí mismo que no pueden infectar nuevas células. Varios estudios clínicos de inhibidores de Proteasa han demostrado que estas drogas, tomadas solas o en combinación con otras drogas anti-virales (AZT, ddI, ddC, d4T, 3TC), pueden disminuir la carga viral (la cantidad de VIH presente en su sangre). También pueden aumentar el conteo de células T (células CD4). Los mejores resultados se han observado en personas que han tomado una terapia de combinación de drogas. Es importante mencionar que se necesitan más estudios para comprender mejor el uso de esta nueva clase de drogas.

¿Cuándo debo comenzar a tomar los Inhibidores de Proteasa?

Todavía no sabemos cual es el mejor momento para comenzar el tratamiento con los Inhibidores de Proteasa. Un estudio de personas con SIDA quienes tenían un conteo de células T menor de 100, demostró que los que tomaron Inhibidores de Proteasa sobrevivieron más tiempo (aproximadamente seis meses más) que las personas que no tomaron el Inhibidores de Proteasa. En base a estos resultados sabemos que si usted tiene: 1) Un conteo bajo de células T; 2) Un conteo viral alto; 3) Síntomas de enfermedad, y/o; 4) Ha tenido la enfermedad del VIH por mucho tiempo, usted debe hablar con su doctor sobre la posibilidad de comenzar tratamiento de combinación que incluya un Inhibidor de Proteasa.

Los doctores no saben todavía si tomar estas drogas en la etapa temprana de la infección (cuando el conteo de células T es alto y la carga viral es baja) ayude a prolongar su vida o a prevenir el desarrollo del SIDA. (En teoría, se piensa que el comenzar el tratamiento con un Inhibidor de Proteasa cuando la carga viral es baja debe ayudar a la droga a trabajar mejor.)

¿Es posible el desarrollo de la resistencia viral con los Inhibidores de Proteasa?

Eventualmente el VIH aprende a "sobreponerse" o a "resistir" los efectos de las drogas anti-virales. Este fenómeno es llamado resistencia viral. La resistencia ocasiona que la droga no funcione bien o no funcione completamente. La resistencia no desaparece. Es posible que cuando usted desarrolla resistencia a un tipo de Inhibidor de Proteasa también haya desarrollado resistencia a otras drogas Inhibidoras de Proteasa (recuerde: existen varias Inhibidores de Proteasa diferentes). Este fenómeno se llama resistencia cruzada.

Algunos estudios han demostrado que el tomar Inhibidores de Proteasa en combinación con otras drogas anti-retrovirales puede reducir las posibilidades de desarrollar resistencia viral. La mejor manera de evitar o retardar el desarrollo de la resistencia es el tomar las drogas de la manera indicada. Las siguientes condiciones promueven el desarrollo de la resistencia hacia las drogas: El tomar las drogas irregularmente, no tomarlas como son prescritas, y el no seguir las direcciones con respecto a cuales comidas debe o no debe tomar con su medicamento. Si usted piensa que no puede cumplir con su tratamiento, entonces debe de esperar hasta que usted se sienta preparado para tomar las drogas correctamente.

Crixivan (también llamado Indinavir)

Dosis

Dos cápsulas de 400mg tomadas cada ocho horas (tres veces al día por ejemplo 8 A.M., 4 P.M., 12 MED). Es necesario que se tome con el estómago vacío. Si es necesario, puede tomarla con comida baja en grasa y baja en el contenido de proteínas (Hojuelas de maíz (Corn Flakes), leche desnatada, zumo de manzana, tostadas sin mantequilla, café o té. No tome el Crixivan con zumo de toronja.) Tome cada dosis con un vaso grande de agua. Debe tomar por lo menos seis vasos grandes de agua u otros líquidos durante el día.

En estudios clínicos, se observó un mayor efecto beneficioso con la combinación de Crixivan, 3TC y AZT. Otras combinaciones de drogas puede que sean útiles pero todavía estan por ser estudiadas. Antes de decidir el tratamiento de combinación que usted debe de tomar, piense en los posibles efectos secundarios y escoja una combinación que usted no haya tomado anteriormente.

Almacenaje

Es muy importante el mantener las cápsulas secas. Asegurese de reponer el algodón que acompaña la botella cada vez que abra y cierre el envase.

Efectos secundarios

Episodios de piedras en los riñones ocurrió en cuatro por ciento de las personas que participaron en estudios clínicos. Es muy importante tomar por lo menos ocho vasos grandes de agua durante el día para prevenir esta condición. Otros efectos secundarios son: náusea, dolor abdominal, dolor de cabeza, debilidad, cansancio, diarrea, cambio en el sabor de las comidas, y dolor de espalda. Menos de el dos por ciento de los pacientes que participaron en pruebas experimentales reportaron tener efectos secundarios.

El costo

Crixivan se vende por \$6,000 al año. La mayoría de los programas de Medicaid, y las casas aseguradoras de salud privadas cubren el costo de la droga. El programa ADAP de Nueva York cubre el costo de Crixivan. Merck, la casa manufacturera de Crixivan, ha establecido un programa de asistencia que suple la droga sin costo alguno para personas que llenen ciertos requisitos de elegibilidad. Para más información sobre este programa llame al 1-800-927-8888 de Lunes a viernes entre las horas de 9 A.M. a 8 P.M.

Disponibilidad

Debido a un limite temporero en la disponibilidad de la droga, Crixivan está disponible solamente por medio de una farmacia llamada Stadtlanders, la cual puede suplir recetas en cualquier parte de los USA. Llame al 1-800-238-1548 para más información y para obtener la droga. Se espera que para el mes de Noviembre todas las farmacias tendrán Crixivan disponible para la venta.

Crixivan y otros medicamentos

La mayoría de los medicamentos se pueden tomar con Crixivan. El Rifabutin y el Ketoconazole (Nizoral) requieren un cambio en la cantidad que se toma.

Rifampin, terfenadine (Seldane), astemizole (Hismanal), cisapride (Propulsid), triazolam (Halcion) y midazolam (Versed) NO DEBEN SER TOMADOS CON CRIXIVAN.

Hable con su doctor sobre posibles problemas con otras drogas.

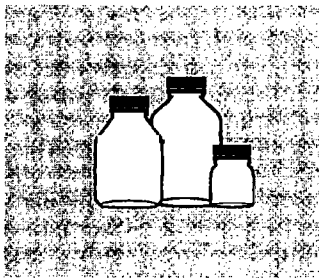
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COMBINATION THERAPY



THE SIMPLE FACTS PROJECT

Combinations of protease inhibitors are now being studied for the treatment of HIV infection. A study of ritonavir and saquinavir is ongoing, and a study of saquinavir and indinavir is planned. Data from just six weeks of the saquinavir and ritonavir study has been presented. Doses studied so far have been 400 mg of saquinavir twice daily with ritonavir at either 400 mg twice daily, or the standard ritonavir dose of 600 mg twice daily. The combination seems safe so far, but researchers recommend waiting for further results before trying combinations of protease inhibitors.

The Simple Facts Project is a program of the AIDS Treatment Data Network (The Network). This information does not intend to promote or endorse any specific treatment for any health related condition.

The most commonly prescribed anti-HIV treatment has been the drug AZT (brand name Retrovir). Other anti-HIV drugs that work in a similar way to AZT are ddI (Videx), ddC (Hivid), d4T (Zerit), and 3TC (Epivir). These drugs are known as nucleoside analogs. A newer class of anti-HIV drugs are protease inhibitors. The approved protease inhibitors are saquinavir (Invirase), zalcitabine (ddC), didanosine (ddI), and zalcitabine (ddC). Recently completed studies clearly show that combinations of these anti-HIV drugs are much more effective than AZT alone in preventing disease progression and death.

The first studies to show the benefits of combination therapy were called DELTA and ACTG 175. These studies compared combinations of AZT with ddI and AZT with ddC to AZT taken alone. Several thousand people took part in these studies. People taking the combinations survived longer and had less disease progression than those taking AZT alone.

Since these studies were done, protease inhibitors have become available. A new test for measuring how well anti-HIV drugs are working is also available. The test is called the viral load test, and measures the amount of HIV in the blood. Researchers are finding that the level of HIV in the blood is linked to a person's risk of getting sick. A study has shown that using drug treatments to lower the level of HIV can reduce the chances that a person will get sick.

These new discoveries are changing the way doctors think about HIV treatment. Combination anti-HIV treatment is now the standard of care for people with HIV. We still don't have enough experience to know which anti-HIV drug combination works best, or for the longest time. What is known is that the stronger the anti-HIV effects of a combination therapy, the less likely it is that HIV will become resistant to the effects of the drugs. When HIV becomes resistant to a drug, that drug no longer works against the virus. This has led many doctors to use three drug combinations. Combinations usually include a protease inhibitor, 3TC, and one other nucleoside analog anti-HIV drug such as AZT or d4T.

The decision about which combination of anti-HIV drugs may work best for an individual is usually based on several factors:

- Which combination has the best chance of reducing the amount of HIV in my body for the longest time?
- Which combination will best increase my T4 cell count or keep it stable and hopefully prevent disease progression?
- What are my options if this combination stops working?
- What are the possible side effects of the drug combination?
- How many pills will I need to take?
- What symptoms do I have now?

Each of these questions may be part of the decision making process.

The best time to start combination therapy is not yet known. The new viral load tests may be helpful, as studies have shown the risk of disease progression is higher when the viral load is above 10,000. Most trials of anti-HIV drugs have also found benefits to treatment when the T4 cell count has dropped below 500. Because medication to prevent an opportunistic infection called PCP is needed when the T4 cell count goes below 200, anti-HIV treatment is usually considered before the T4 cell count gets this low.

Studies of different combination therapies are ongoing. Call the Network if you need a referral. The Network also has up-to-date fact sheets on the individual anti-HIV drugs and the newly approved viral load tests. Call us to receive free copies.

September 1996

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Protease Inhibitors Come of Age

by Theo Smart

The big news at the Third Conference on Retroviruses was the extraordinary antiviral and clinical effects achieved by protease inhibitors when administered along with nucleoside analogs. The reports, although limited in their scope, suggested that combinations of anti-HIV drugs now available will be considerably more effective than the mediocre HIV treatment options of the past.

In one study, Abbott's ritonavir (brand name Norvir) was found to dramatically prolong survival and slow disease progression in people with advanced AIDS. Other trials found that Merck's indinavir combined with several nucleoside analogs can hold HIV blood levels for many months below minimum detectable levels (less than 500 copies of HIV genes (RNA) per ml of plasma).

Findings from the Ritonavir Clinical Study

Abbott, which was running behind Merck and Hoffmann-La Roche in the race to develop protease inhibitors, is so far the first and only company to show that its drug extends survival and delays opportunistic infections (abstract LB6a). The company accomplished this feat by counting the clinical events that occurred in 1090 volunteers with advanced HIV disease—CD4 cell counts of 100 or below—randomized to take either ritonavir (600 mg) or placebo twice daily. The participants had a history of more than nine months of prior anti-HIV therapy and added ritonavir to their existing regimen of nucleoside analogs (most commonly AZT or d4T—3TC was not yet approved).

At baseline, the median CD4 cell count was 18 in the ritonavir arm and 22 in the placebo group. The median HIV plasma viral load was over 250,000 copies per milliliter. After completing four months on the study, trial participants who reached an AIDS-defining event were given open-label ritonavir.

When planning the study, Abbott researchers had calculated that it would take only 191 clinical events (the appearance of new opportunistic infections) or deaths to show definitively that ritonavir had an effect. That figure was reached within one month, although

the trial continued while the company confirmed each event. When the results were analyzed, it became clear that the people on ritonavir were doing better than those on placebo within ten days. After one month, only 69 opportunistic infections or deaths had occurred in those receiving ritonavir as opposed to 149 in those on placebo, a statistically significant difference. Forty-four of these events were deaths—seventeen on ritonavir, and 27 on placebo.

After a median of six months follow-up (see table), 26 people on ritonavir versus 46 people on placebo had died, a 43 percent reduction in mortality. New OIs or death occurred in 85 people on ritonavir and 181 on placebo.

Viral load response was analyzed in 159 patients from the trial. Levels of virus decreased by 96 percent in the ritonavir arm but over time returned back upwards toward baseline. The trial's rapporteur, John Leonard, M.D., of Abbott, argued that virologic responses might have been more sustained if trial participants had begun their concurrent therapies at the same time as they started ritonavir. CD4 and CD8 cell responses (followed in 215 participants) were also significantly better in those taking ritonavir (47 CD4 cells and more than 200 CD8 cells above baseline at week sixteen).

An Australian team led by David Cooper, M.D., performed a more in depth exploration of the immunologic effects of ritonavir in 21 patients from an earlier trial by analyzing the functional responses of the new CD4 and CD8 cells (abstract 232). The team determined that the new CD4s acquired during the first four weeks of therapy were primarily clones of existing memory cells (lymphocytes that respond to previously encountered pathogens), and that new "naive" cells (which might be able to mount an immune response to infections for which there is no pre-existing defense) were noted only after the first four week period.

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Treatment ALERT

FALL 1996

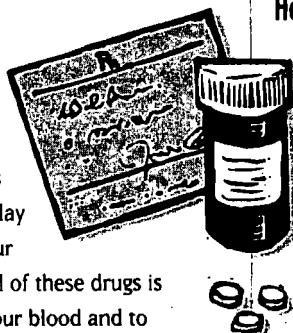
HOW TO USE PROTEASE INHIBITORS THE RIGHT WAY

by Moisés Agosto

This issue of NMAC's Treatment Alert focuses exclusively on protease inhibitors and the best way to use them, to maximize their benefit. We encourage you to read this carefully and to distribute copies to people living with HIV who are taking or considering protease inhibitors.

Treating HIV infection

People living with HIV who are considering treatment must always be informed about their options. To treat HIV infection, doctors use drugs called antiretrovirals. These drugs delay the production of the virus inside your body in different ways. The main goal of these drugs is to decrease the amount of virus in your blood and to increase the number of T₄ cells for as long as possible.



What kind of treatments are available?

There are three kinds of drugs used to treat HIV infection. The first kind are the nucleoside analogues: AZT or Retrovir™, ddI or Videx™, ddC or HIVID™, D4T or Zerit™ and 3TC or Epivir™. The second kind are non-nucleoside analogues such as nevirapine or Viramune™. The third and the newest kind are the protease inhibitors. The names of the protease inhibitors that are approved are saquinavir or Invirase™, ritonavir or Norvir™ and indinavir or Crixivan™. Notice that each of these drugs has two names. One is the generic name and the other is the brand™ name.

What are protease inhibitors?

Protease inhibitors are a new class of drugs that are used to treat HIV infection. People living with HIV have the option of using three protease inhibitors currently available with a prescription from your doctor. They are Invirase™ (saquinavir),

Norvir™ (ritonavir) and Crixivan™ (indinavir). In order to benefit from the use of these new protease inhibitors, people living with HIV must look for information and be aware of a few things:

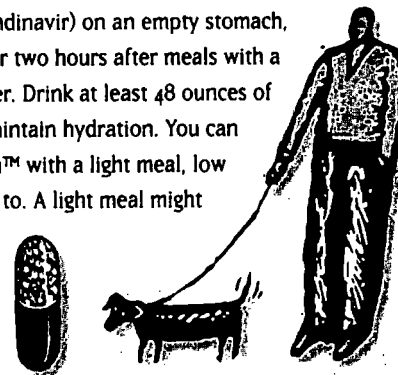
How can Protease Inhibitors improve my health?

Protease inhibitors slow the replication of HIV in your body. So far, the use of protease inhibitors in combination with other drugs like AZT, ddC, 3TC, D4T or ddI may significantly reduce the amount of virus in your blood and give you a remarkable increase of T₄ cells. If your T₄ cells have a significant increase and the amount of virus is reduced considerably, your health may improve.

What is the best way to use Protease Inhibitors?

To make sure your body gets the full benefit from protease inhibitors, you must be aware of the things you can do to help your body to better absorb these drugs.

- Take Invirase™ (saquinavir) within two hours of a full meal or substantial snack.
- Take Norvir™ (ritonavir) with a full meal that is high in fat and protein.
- Take Crixivan™ (indinavir) on an empty stomach, one hour before or two hours after meals with a large glass of water. Drink at least 48 ounces of liquids daily to maintain hydration. You can take your Crixivan™ with a light meal, low in fat. If you need to. A light meal might be plain toast with juice or skim milk.



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Update on Protease Inhibitors

tease inhibitors appear to suppress HIV replication and increase CD4+ cell counts to a greater degree and for a longer time than any previous therapies. Three protease inhibitors have been approved by the FDA - indinavir (Crixivan® from Merck), zidovudine (Retrovir® from Abbott), and zalcitabine (Hivid® from Hoffman La-Roche) - and several more are in development. All have been tested in a variety of ways and are widely available. They are not, however, interchangeable and there is nothing magic in the fact that a drug is a protease inhibitor. In the end, what matters is how well it works, not what label it wears.

Each of the drugs offers a different level of benefits and side effects. Each must be used wisely and with greater care than the previous generation of drugs if people are to get the maximum benefit offered by these therapies. Knowledge of how best to

use them is limited but it grows with each month as additional studies report new data. The purpose of this article is to summarize the most important data from clinical trials. A second Project Inform document, entitled "Developing Long Term Treatment Strategies" discuss how to incorporate these drugs and other drugs into a treatment strategy.

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Indinavir Studies

Results from new studies of indinavir show that it combines particularly potent antiviral activity with a quite modest side effect profile. The studies evaluated the drug in people with little or no history of antiretroviral therapy use as well as in people who had been on AZT for six months or longer.

What is a protease inhibitor?

A protease inhibitor is an antiviral drug designed to reduce the amount of HIV being produced in the body.

How are they different from other antiviral drugs, like AZT, ddI, d4T, 3TC and ddC?

Protease inhibitors attempt to stop HIV-infected cells from making effective new copies of the virus. The other drugs attempt to stop the virus from taking over a cell in the first place. By using such drugs together, the virus is blocked in two separate ways.

Why are they used in combination with the older drugs?

Combination therapy increases the overall effectiveness of the drugs and suppresses the development of drug resistance.

Are all protease inhibitors alike? Does it matter which one I use?

The three available protease inhibitors differ widely in their effectiveness, toxicity, and ease of use. They are similar in name only. Your choice of a protease inhibitor matters a great deal.

Study 1

Seventy-eight people with CD4+ counts between 50 and 200, viral load greater than 20,000 copies of HIV RNA and less than two week prior use of AZT or ddI received either AZT + ddI, indinavir alone, or indinavir + AZT + ddI. Results are seen in **Table 1**. The data suggest that people using all three drugs will fare better than those using indinavir alone or AZT + ddI.

Study 2

Ninety-seven volunteers with CD4+ counts between 50 to 400, viral load above 20,000 and at least six months prior use of AZT received either AZT + 3TC, indinavir, or a combination of all three. Results are shown in **Table 2**.

It is clear that those receiving the triple

Table 1 - Indinavir (IND), AZT, ddI

Therapy group	Maximum VL drop	Median VL drop @ 24 wks	Med. CD4+ increase @ 24 wks	% with at least 2 log VL drop	% with virus below LD
AZT + ddI	1.6 logs*	0.5 logs	30	20%	15%
IND	2.0 logs	0.5 logs	100	20%	15%
IND + AZT+ddI	2.9 logs	2.9 logs	100	80%	60%

Table 2 - Indinavir (IND), AZT, 3TC

Therapy group	Median VL drop @ week		Med. CD4+ gain @ week		% with virus below LD @ week	
	24	48	24	48	24	48
AZT + 3TC	-0.6 logs	-0.4 logs	14	14	0% (0 of 27)	0% (0 of 8)
IND	-1.3 logs	-1.6 logs	106	158	41% (11 of 27)	56% (5 of 9)
IND+AZT +3TC	-2 logs	-2.3 logs	127	218	90% (27 of 30)	89% (6 of 7)

VL = viral load LD = Limit of Detection

November 1996

Dear Colleague:

Protease inhibitors are a new type of drug to treat HIV infection. These drugs, when taken in combination with other HIV therapies, offer great promise for people with AIDS. However, in order for these drugs to be most effective, doctors and patients must know how to use them properly. Enclosed is a packet of materials to provide information about protease inhibitors and other anti-viral drugs for you and your fellow staffworkers, clients, patients, health care providers, friends, etc. The packet contains materials created by four leading HIV treatment education programs. Please use them, photocopy them, call and ask for more as you need them. There is an enclosed card that tells you how to order more of these packets. Without the proper information, we will not be able to realize the promise that these new drugs may provide to people with AIDS.

Because these drugs are new, we still do not know enough about how to use them most effectively. There are three different protease inhibitors and five different nucleoside analogs. We do not yet know when is the best time to start therapy, which combinations are best to use first, how long the effect of these drugs can last, and what are the long-term side effects. The answers to these questions will come through continued clinical research and experience. But that takes time. Meanwhile, people with HIV are faced with treatment decisions today. Many people have no time to wait and must consider whether or not they will start an anti-viral regimen now or in the near future. This packet provides the information that is currently available to assist doctors and patients in making and following through on these difficult decisions.

In sending out this packet, none of our organizations are endorsing any of these drugs or a particular regimen. The decision to use these drugs is one that only each patient, in consultation with his or her doctor can make. However, without the necessary information, patients cannot begin to decide for themselves what they think is best. That is why we are sending this packet out all over the country.

These materials are meant to reach people at different reading levels. Several of them are in both English and Spanish. We are working to translate many of these materials into other languages. Feel free to copy any and all of them. We will keep supplying them until we have no more. We will update the packets as new information becomes available.

This is the first time that our organizations have worked in collaboration to provide treatment education materials. The mailing house that is coordinating this mailing for us is handling the mailing lists from each of our organizations. The mailing lists remain strictly confidential. The mailing house will not allow anyone to have access to these lists and we are not sharing our lists with each other.

We feel that the information provided is very important and we are committed to doing everything we can to help people learn about HIV treatment as quickly as possible. If you have any suggestions or comments on this packet, please call any of our organizations at the numbers listed below. Thank you for your support.

Yours truly,

Moises Agosto - National Minority AIDS Council
David Barr - Gay Men's Health Crisis
Martin Delaney - Project Inform
Ken Fornataro - AIDS Treatment Data Network

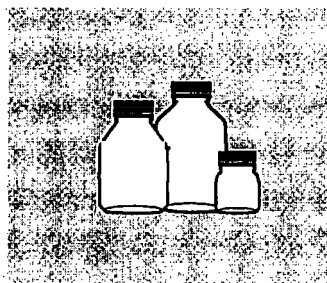
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Treatment ALERT

FALL 1996

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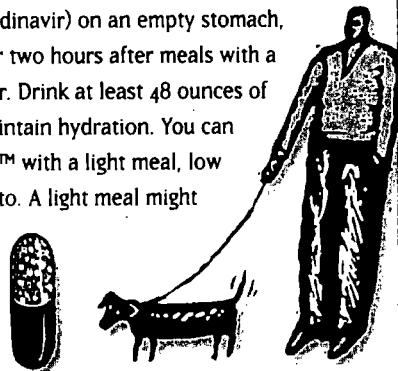
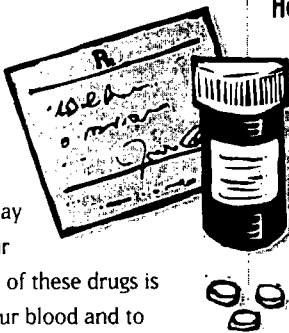
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What is the best way to use Protease Inhibitors?

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Project Inform Fact Sheet Protease Inhibitors

9/96

Update on Protease Inhibitors

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use them is limited but it grows with each month as additional studies report new data. The purpose of this article is to summarize the most important data from clinical trials. A second Project Inform document, entitled "Developing Long Term Treatment Strategies" discuss how to incorporate these drugs and other drugs into a treatment strategy.

Indinavir Studies

Results from new studies of indinavir show that it combines particularly potent antiviral activity with a quite modest side effect profile. The studies evaluated the drug in people with little or no history of antiretroviral therapy use as well as in people who had been on AZT for six months or longer.

Study 1

Seventy-eight people with CD4+ counts between 50 and 200, viral load greater than 20,000 copies of HIV RNA and less than two week prior use of AZT or ddI received either AZT + ddI, indinavir alone, or indinavir + AZT + ddI. Results are seen in **Table 1**. The data suggest that people using all three drugs will fare better than those using indinavir alone or AZT + ddI.

Study 2

Ninety-seven volunteers with CD4+ counts between 50 to 400, viral load above 20,000 and at least six months prior use of AZT received either AZT + 3TC, indinavir, or a combination of all three. Results are shown in **Table 2**.

It is clear that those receiving the triple

What is a protease inhibitor?

A protease inhibitor is an antiviral drug designed to reduce the amount of HIV being produced in the body.

How are they different from other antiviral drugs, like AZT, ddI, d4T, 3TC and ddC?

Protease inhibitors attempt to stop HIV-infected cells from making effective new copies of the virus. The other drugs attempt to stop the virus from taking over a cell in the first place. By using such drugs together, the virus is blocked in two separate ways.

Why are they used in combination with the older drugs?

Combination therapy increases the overall effectiveness of the drugs and suppresses the development of drug resistance.

Are all protease inhibitors alike? Does it matter which one I use?

The three available protease inhibitors differ widely in their effectiveness, toxicity, and ease of use. They are similar in name only. Your choice of a protease inhibitor matters a great deal.

Table 1 - Indinavir (IND), AZT, ddI

Therapy group	Maximum VL drop	Median VL drop @ 24 wks	Med. CD4+ increase @ 24 wks	% with at least 2 log VL drop	% with virus below LD
AZT + ddI	1.6 logs*	0.5 logs	30	20%	15%
IND	2.0 logs	0.5 logs	100	20%	15%
IND + AZT+ddI	2.9 logs	2.9 logs	100	80%	60%

Table 2 - Indinavir (IND), AZT, 3TC

Therapy group	Median VL drop @ week		Med. CD4+ gain @ week		% with virus below LD @ week	
	24	48	24	48	24	48
AZT + 3TC	-0.6 logs	-0.4 logs	14	14	0% (0 of 27)	0% (0 of 8)
IND	-1.3 logs	-1.6 logs	106	158	41% (11 of 27)	56% (5 of 9)
IND+AZT +3TC	-2 logs	-2.3 logs	127	218	90% (27 of 30)	89% (6 of 7)

VL = viral load LD = Limit of Detection

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