

PROGRAM ABSTRACT

TITLE *C-DOT PROGRAM*
COMMUNITY-BASED DIRECTLY OBSERVED THERAPY
For Individuals Living with HIV Beginning Highly Active Antiretroviral Therapy

SUMMARY For HIV positive individuals taking highly active antiretroviral therapy (HAART), the best clinical outcomes (i.e., reduced morbidity and mortality) result from excellent adherence to medication regimens. HAART adherence also helps to prevent the development of costly-to-treat drug-resistant strains of HIV. For these reasons, clinicians encourage patients to adhere as closely as possible to the prescribed doses and schedules for all HAART regimens.

Adherence to HAART may be influenced by the medication regimen, the clinical setting, the provider/patient relationship, and individual characteristics of the patient. Unfortunately, medication adherence in resource-poor settings may be compromised by factors such as poverty, low health literacy, and unstable life situations, necessitating the use of low-cost strategies to increase HAART adherence.

Directly observed therapy (DOT) provides one such low-cost strategy to increase adherence to antiretroviral medication regimens. Individuals beginning HAART are monitored on a daily basis to ensure medication schedules are followed and adherence is maintained. The *Community-based Directly Observed Therapy (C-DOT) Program* originally implemented in Peru, provides supervised medication dosing and medical, social, and economic support as part of a DOT strategy. DOT workers monitor all outpatient HAART doses; report adverse events, missed doses, or psychosocial issues to nurses or providers; and provide participants and family members with emotional support and health education. Program supervisors help participants with other aspects of their medical care and act as an intermediary between participants and the medical organization delivering HIV care. Nurses are responsible for supervising *C-DOT Program* staff and monitoring participant medical care follow-up.

The effectiveness of the *C-DOT Program* in promoting HAART adherence and improving clinical outcomes was evaluated among patients recruited from a public hospital in Lima, Peru. Self-reported medication adherence, psychosocial well-being and clinical outcomes (CD4 count, virologic suppression, tuberculosis treatment outcomes, clinical status) were measured before and 12 months after beginning the *C-DOT Program*. Compared to control participants, *C-DOT Program* participants were significantly more likely to remain on and be adherent to HAART, be cured of tuberculosis, and have a suppressed viral load. *C-DOT Program* participants experienced significant reductions in stigma, significant increases in social support and adherence self-efficacy, and reported fewer difficulties accessing health services than control participants.

*GLOBAL HIV
ARCHIVE
CATEGORY*

- | | | |
|--|---|--|
| <input type="checkbox"/> Sexual risk reduction | <input type="checkbox"/> Community mobilization | <input checked="" type="checkbox"/> Antiretroviral adherence (primary) |
| <input type="checkbox"/> HIV testing and education | <input type="checkbox"/> Reproductive health | <input checked="" type="checkbox"/> High-risk populations (secondary) |

Primary content categories reflect the main focus of the program, while secondary content categories may be addressed in other aspects of the program.

*IMPLEMENTATION
LEVEL*

- | | | |
|---|---|--|
| <input checked="" type="checkbox"/> Individual (implemented one-on-one) | <input type="checkbox"/> Couple/ family (implemented with a couple or family) | <input type="checkbox"/> Group (implemented in small groups) |
| <input type="checkbox"/> Structural (implemented on social, economic, political, or environmental levels) | | |

*IMPLEMENTATION
SETTING*

- | | | |
|---|--|--|
| <input checked="" type="checkbox"/> Community (implemented through community-based organizations) | <input type="checkbox"/> School (implemented in schools) | <input type="checkbox"/> Clinic (implemented in clinics) |
|---|--|--|

The *C-DOT Program* was originally implemented in participants' homes throughout the community. This program may also be feasible in clinics or hospitals serving individuals living with HIV.

*ORIGINAL
TARGET
POPULATION*

Participants in the original implementation of the *C-DOT Program* were HIV positive adults referred from a public hospital providing HIV care and antiretroviral therapy to the region of Lima Este, Peru. Enrolled participants were living in poverty and were starting or had recently started HAART; priority was given to individuals who were co-infected with TB or were female, although males without TB were not excluded.

It may be possible to implement the *C-DOT Program* with populations of HIV positive adults who are not new initiates to HAART. The program's approach may be useful to those having difficulty maintaining medication adherence by helping them address challenges and barriers related to adherence.

*PROGRAM
COMPONENTS*

- | | |
|---|--|
| <input type="checkbox"/> Booster sessions for participants | <input type="checkbox"/> Formalized curriculum |
| <input checked="" type="checkbox"/> Community outreach/mobilization | <input checked="" type="checkbox"/> Medication adherence and routine clinic visits |
| <input checked="" type="checkbox"/> Condom demonstration | <input type="checkbox"/> Motivational interviewing |
| <input checked="" type="checkbox"/> Continual assessment of progress | <input type="checkbox"/> Multi-year program |
| <input type="checkbox"/> Educational materials (e.g., leaflets, posters, comics, magazines) | <input type="checkbox"/> Needs assessment |
| <input type="checkbox"/> Electronic media (e.g., radio, cell phones, internet, videos) | <input checked="" type="checkbox"/> Peer education/ counseling |
| | <input checked="" type="checkbox"/> Presentations |
| | <input checked="" type="checkbox"/> Role Plays |
| | <input type="checkbox"/> Stakeholder investment |
| | <input type="checkbox"/> STI/HIV testing |

*PROGRAM
LENGTH*

The *C-DOT Program* spans 11 months. Participants receive comprehensive support for the first eight months with all outpatient HAART doses monitored daily. For months 9, 10, and 11, DOT workers taper their monitoring activities. The schedule of visits is as follows:

<i>Month(s)</i>	<i>Frequency of visits</i>
1-8	Daily
9	Once every other day
10	Once a week
11	Once every other week

*STAFFING
REQUIREMENTS/
TRAINING*

The *C-DOT Program* team is composed of field supervisors, nurses, and DOT workers. The DOT workers are community members with prior experience working as community health workers for local establishments. They are required to complete a 4-day training session before program implementation. The field supervisors are lay individuals with prior community leadership experience who may also wish to attend the 4-day training session. Nurses are trained health care professionals who work in the HIV clinic conducting the program. They may be involved in implementing or preparing the DOT worker training session.

*PROGRAM
MATERIALS*

The *C-DOT Program* contains most of the materials needed to implement the program; however, there are a few additional materials you will need to obtain prior to the DOT worker training and program implementation.

For the DOT worker training, you will need to obtain the following materials:

- Penis proxy;
- Condoms; and
- Computer/slide projector/screen (if presentations are used).

With guidance provided in the Adaptation Handbook, you will also need to tailor the DOT worker training modules to be relevant to your population and context (e.g., HIV medications, side effects, specific program procedures).

During program implementation, you will need to make copies of each of the following forms (included with program handouts) for DOT workers to use:

- First Home Visit Form (once for the first participant visit);
- Visit and Adherence Form (once a week for the duration of the program);
- DOT Worker Checklist (as needed for every visit); and

- Concordance Plan Form (once at the concordance planning visit).

DOT workers will need one copy of the First Home Visit Form, DOT Worker Checklist, and Concordance Plan Form for each participant. They will need a new copy of the Visit and Adherence Form once a week for each participant. Master copies of these forms are provided as Handouts in the program package. The handouts may need to be adapted to reflect your site's specific procedures and responsibilities of the DOT workers (refer to the Adaptation Handbook for further instruction).

A NOTE ABOUT ADAPTATION

The Global HIV Archive program package includes a Customized Adaptation Handbook to help program staff successfully adapt the *C-DOT Program* for new settings and target populations. The Adaptation Handbook details a set of pragmatic, easy-to-follow steps to facilitate making changes to the program, while preserving the components that made – or are believed to have made – it effective in the first place.

A NOTE ABOUT EVALUATION

Each Global HIV Archive program package contains the original evaluation instruments used to evaluate the program. In the original evaluation of the *C-DOT Program*, a trained native Spanish speaker assessed depression, stigma, social support, quality of life, and self-efficacy using standardized instruments in a one-on-one interview. A separate, non-blinded team collected data using standardized forms from medical charts and patient interviews on adherence and clinical outcomes.

The Intake Form, Mental Health Questionnaire, and Monthly HAART Report are included in the program package for you to review and potentially use during your program evaluation.

The program package also includes an Evaluation Resource Guide, containing select questions to assess relevant HIV outcomes such as adherence to HAART. If you would like to conduct an evaluation with your population, it is important to assess the applicability of the original studies' survey questions to your context/setting. For instance, some questions contain region-specific language and terminology that you might need to adapt to make relevant to your population. Pre-test the instrument with a small group of

individuals representative of your population prior to administering it to the entire group. This pre-test may reveal in advance potentially problematic questions.

*PROGRAM
ACQUISITION
AND
IMPLEMENTATION
COSTS*

Global HIV Archive program packages are available in boxed, flash-drive, and downloadable formats. The cost of this Global HIV Archive program package includes:

- *Quick Guide to Program Package* – a roadmap to get oriented to the *C-DOT Program* and tips for how to get started
- *User's Guide* – an overview of the *C-DOT Program* including information about the original implementation and evaluation
- *Facilitator's Manual* – a guide for how to implement the *C-DOT Program* including how to train DOT workers
- *DOT Worker Training Presentations* – a booklet containing presentations to use or adapt during the DOT worker training, including:
 - General Facts About HIV/AIDS
 - Opportunistic Infections
 - HAART
 - Adherence
 - Adverse Reactions
 - Mental Health
 - Function of a DOT Worker
- *Handouts* – photocopy master forms for DOT workers to use during the program implementation, including:
 - First Home Visit Form
 - Visit and Adherence Form
 - DOT Worker Checklist
 - Concordance Plan Instructions & Form
- *Customized Adaptation Handbook* – a guide to customize adaptations to the *C-DOT Program*
- *Evaluation Resource Guide* – a set of scales to consider using when evaluating HIV prevention program effectiveness
- *Original Evaluation Instruments* – instruments used to measure the effectiveness of the original

implementation of the *C-DOT Program*, including:

- Intake Form
- Mental Health Questionnaire
- Monthly HAART Report

The following *C-DOT Program* materials are also available in Spanish.

- *Checklist of Spanish Materials* - a one-page guide of Spanish documents available
- *DOT Worker Training Presentations* – a booklet containing presentations to use or adapt during the DOT worker training, including:
 - Generalidades en VIH/Sida
 - Infecciones Oportunistas (Io) en VIH/Sida
 - Tratamiento Antirretroviral De Gran Actividad (TARGA)
 - Adherencia (found in previous presentation)
 - Reacciones Adversas
 - Salud Mental en las Pvvvs
 - Función Del Promotor Comunitario en VIH
- *Handout* – photocopy master forms for DOT workers to use during the program implementation, including:
 - Concordance Plan Instructions
- *Original Evaluation Instrument* – instrument used to measure the effectiveness of the original implementation of the *C-DOT Program*, including:
 - Monthly HAART Report

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