

# Modified DOT Strategy for HAART in Beira, Mozambique

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## Issue

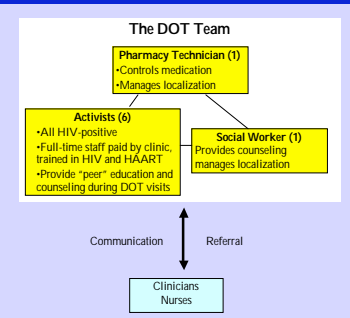
- Treatment adherence is critical to optimize response to HAART
- DOT has been suggested as a method to improve adherence to HAART in resource-limited settings

## Description

- Setting:** The Beira Day Hospital, Beira, Mozambique
- Beira: 2<sup>nd</sup> largest city in Mozambique
  - Located in Sofala Province, Central Region
  - Population ~ 500,000
  - Located on transportation corridor to Zimbabwe
  - Estimated prevalence of HIV 2002 (15-49 yrs of age):
    - Mozambique ~ 13%
    - Sofala Province ~ 27%
  - The Beira Day Hospital = first HIV clinic in Beira
    - Opened Feb 17, 2003
    - 2,930 patients enrolled in care
    - Average 820 consults per month
    - Integrated within the Ministry of Health (location, staff, management), with NGO support
    - Clinical staff includes 5 doctors (1 FTE total), 1 PA (0.5 FTE), 3 nurses (3 FTE), 1 nurse dermatologists (0.5 FTE)
    - Limited availability of HAART

- The Columbia MTCT-Plus Initiative**
- International Initiative supported through Columbia University's Mailman School of Public Health
    - Patients offered comprehensive HIV care, including HAART
    - Enroll HIV+ women identified in pMTCT programs and their families, also may enroll limited number of health care workers
    - Process of enrollment developed by site
      - In Mozambique includes: home visit, attending an HIV+ support group, disclosure of HIV status (later criteria eliminated in 2004)
      - Enrollment not based on immediate need for HAART
      - Limited enrollment of 750 people over 3 years, + 25 HCW
    - Enrollment into project started in April, 2003
    - MTCT-Plus activities integrated into regular clinic activities

- The Modified DOT Strategy (mDOT)**
- Modified DOT<sup>1</sup> required for all patients starting HAART in MTCT-Plus
    - Patients receive morning ARV dose under DOT in clinic, night-time dose self-administered at home
    - Transportation paid by project (~\$ 70 round trip)
    - Patients failing DOT appointment are localized same day by activists
    - Duration initially 12 weeks, shortened to 6 weeks
      - Covers time of most common side effects and NVP dose escalation
      - Adherence may be critical in early phase of treatment
      - Establishes pattern of adherence at beginning of treatment
      - Time extended if problem with adherence
    - Treatment buddy<sup>2</sup> also strongly encouraged
    - After initial mDOT period, patients receive medications directly from pharmacist at increasing intervals
      - 2 weekly
      - monthly
    - Education and counseling continuously available from activists, pharmacist, social worker



- Analysis:**
- All MTCT-Plus enrollees newly started on HAART and finishing DOT phase of treatment prior to July 1, 2004 included in analysis
  - Outcome Measurements
    1. Adherence Rate
      - Adherence rates calculated as the number of doses taken / number of doses prescribed
      - Adherence assessment and recording integrated into normal clinic activities
        - During mDOT
          - DOT doses recorded by activist on DOT adherence form
          - Night and weekend doses measured by self-report, observation of remaining pills
        - Post-mDOT
          - Pharmacist records pill-count and missed doses since last fill
          - Compared to pharmacy refill data
    2. Change in CD4 with HAART
      - Between baseline and 1<sup>st</sup> follow-up at 6 months
      - Viral loads not available as part of routine monitoring
      - Child excluded from analysis

## Lessons Learned

- 312 patients accepted into MTCT-Plus through June, 2004
  - 33 patients newly started on HAART and completed DOT phase by July 1, 2004
  - 32 adults: 19 female, 13 male
  - 1 child (13 months)
- Cumulative time observed for patients on HAART = 276 months
  - Mean time per patient = 8 months (range 3 – 13 months)
- Cumulative time observed on mDOT = 79 months
  - Mean time per patient = 10 weeks (range 4 – 18 weeks)
- Cumulative time observed post-mDOT = 197 months
  - Mean time per patient = 24 weeks (range 3 – 44 weeks)

## Adherence

- Cumulative adherence (total doses taken / total doses prescribed) recorded at >95%
  - Similar adherence rates observed during mDOT and post-mDOT phases
  - 32 of 33 patients with >95% adherence over entire course of HAART therapy
    - One patient with ~ 80% adherence (intervening serious illness)
- Causes of missed doses includes:
  - Serious illness
  - Forgetting
  - Misplacing / losing pills
  - Travel (work related)
  - Vomiting dose (started giving "reserve" doses to keep at home)
- Missed doses during DOT phase almost exclusively at night / weekends

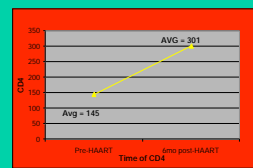
## Adherence Rates, By Phase of Treatment

Phase of Treatment	Adherence Rate (doses taken / doses prescribed)	Proportion with > 95% adherence
mDOT phase	>95%	31/33 (94%)
Post-mDOT phase	>95%	31/33 (94%)
<b>Total</b>	<b>&gt;95%</b>	<b>32/33 (97%)</b>

## CD4 Count Change

- Follow-up CD4 counts available on 19 adults
  - 1 patient temporarily stopping HAART after 2 months due to side effects excluded from analysis
  - Mean time of follow-up CD4 = 6.0 months post-HAART (range 5.3 – 6.7 months)
  - Average CD4 increased from 145 to 301 on follow-up CD4 testing (see chart 2)
    - Average change +156 (range +6\* to +469, p<.001)
    - \*CD4 change in this patient was +185 at month 8 post-HAART

## Average Change in CD4 Counts



## Additional Observations

- Staff and patient acceptance of mDOT high**
- Provides opportunities for close monitoring, teaching
  - Patients see time for DOT as opportunity to ask activists questions, and socialize with activists and other patients
  - "Inconvenience" of daily clinic visits tempered by reimbursing transport costs
- Problems**
- Patients coming daily to clinic may have difficulties explaining absences to family and work
  - Requires flexibility to accommodate patients' schedules (trips for family matters, work, tending to personal food production)
    - If possible, start DOT at a time when patients know they will be present
    - Offer doses for several days – 1 week during necessary trips
  - Requires flexibility to accommodate patients' clinical condition
  - Observe doses at home or hospital if unable to come to clinic (illness, late pregnancy, hospitalization)
- Significant resources required**
- Capitol resources
    - Transportation for patients and activists
    - Payment of activists
  - Human resources required
    - Home visits required on all patients prior to starting HAART
    - 1 activist: 5-10 patients
    - Limited by capacity to perform timely same-day localization
    - Management of mDOT / adherence team

## Limitations

- Alternative and complimentary medicine use is common in this VA population of patients with cancer
- Use of AM by patients with head and neck cancer is associated with a delay of treatment
- There is no association between complimentary medicine use and being treated for cancer with conventional therapy

## Recommendations

- Modified DOT is an effective and acceptable strategy for optimizing adherence to HAART
  - Builds treatment literacy
  - Strengthens patient-clinic linkages
- Trained and supervised "peer" activists can be effective for observing treatment, educating, and counseling patients
- New strategies may be envisioned to accommodate the follow-up of larger numbers of patients
  - Decentralization to provide DOT outside of clinic
  - Using local PLWHA community groups to help with DOT and follow-up
- A randomized controlled trial of mDOT vs. standard care is necessary to determine the effectiveness and cost-effectiveness of mDOT in different situations