Monitoring Patient Adherence: Recommendations from and for Practice

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Slide Set from IAPAC 2009 Monitoring Adherence Workshop

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INTRODUCTION

- **Settings**
  - Context for monitoring adherence.

- **Goals**
  - Why monitor adherence?

- **Current Practices**
  - How is adherence currently monitored in your practice, clinic, or service?
Potential impact of adherence on success of ART noted early on
- 30% to 70% of HIV+ patients prescribed ART in clinical care did not achieve the success demonstrated in well controlled trials

Need to examine and explore impact of adherence rests on ability to measure adherence reliably and validly
- Reliably— in a manner that is consistent over time and over people
- Validly— in a manner that reflects actual medication taking behavior

Altice & Friedland, 1998; Pradier et al., 2001
Behavior of Interest

- *As prescribed medication taking behavior*
  - At all (total pills per day or per time period)
  - In specified time intervals
  - Consistently over longer periods of time (patterns)
  
*As with many behaviors, these are not typically directly observed (exception—DOT, mDOT)*

- **Proxies**
  - Self-report of the behavior (exposure)
  - Bottle or pill container opening (exposure)
  - Prescription refill behavior (availability)
  - Pill counts (availability)
ONGOING DEBATE

Which of these proxies are the best method for reliably and validly characterizing adherence to ART is an ongoing debate.

In establishing the validity of measures, frequently the relation between adherence defined by the measure and disease progression indices are used as supportive of validity.
What research has to offer

Common Measures and Methods used to Monitor Adherence
- DOSES/PILLS TAKEN/MISSED APPROACHES
- SINGLE ITEM MEASURES
- SCALE MEASURES
- COUNTING PILLS
- PHARMACY RECORDS (REFILL)
- ELECTRONIC MONITORING

- Each medication
- All medications (ART regimen in general)
- One Medication
DOSES/PILLS TAKEN/MISSED APPROACHES

ACTG and other dose/pills taken or missed measures are likely the most commonly used measure of adherence in research conducted to date.

<table>
<thead>
<tr>
<th>Step 1</th>
<th>HOW MANY DOSES DID YOU MISS...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Names of your anti-HIV drugs</td>
<td>Step 2</td>
</tr>
<tr>
<td></td>
<td>Yesterday</td>
</tr>
</tbody>
</table>

- [ ] Doses
- [ ] Doses
- [ ] Doses
- [ ] Doses
- [ ] Doses
- [ ] Doses
- [ ] Doses
- [ ] Doses
- [ ] Doses
- [ ] Doses

Chesney et al 2000
CPCRA form also looks at each agent in a regimen but instead of counting doses taken, adherence to rated on a scale.

<table>
<thead>
<tr>
<th></th>
<th>ALL my pills every day</th>
<th>MOST of my pills</th>
<th>About ONE-HALF of my pills</th>
<th>VERY FEW of my pills</th>
<th>NONE of my pills</th>
</tr>
</thead>
<tbody>
<tr>
<td>During the last 7 days, I took:</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

Mannheimer et al 2002,
SINGLE ITEM BY AGENT

VISUAL ANALOG SCALE

How much of this medication have you taken as prescribed in the last three to four weeks?

0% means you have taken none of this medication
50% means you have taken half of this medication
100% means you have taken every single dose of this medication

Giordano et al., 2004; Oyugi et al. 2004; Walsh et al, 2002
By Agent

- Discrete data can be used to assess exact number missed, proportion of adherence or non-adherence, and relative rates of adherence with different cutoffs.
- Can also speak to differential attrition

CONS:
- Need to know agents
- Time consuming for count recall
- High recall demand
- May not be necessary to gather this level of data—depending on goal of assessment
SINGLE ITEM – OVERALL ADHERENCE

VISUAL ANALOG SCALE

About how much of your HIV medications have you taken as prescribed in the last three to four weeks?

0% means you have taken none of this medication
50% means you have taken half of this medication
100% means you have taken every single dose of this medication

Likert Single Item

About how much of your HIV medications have you taken as prescribed in the last week?

□ □ □ □ □
ALL   MOST   HALF   FEW   NONE
**Single Item**

- Time efficient, has some support for relation with disease progression outcomes and other adherence measures, do not need data on specific agents and does not make as high recall demands

- CONS: Less developed history of support but growing, will miss differential adherence, may or may not provide subtle rates, may be conceptually difficult, will need careful follow-up to get more details
CASE (Center for Adherence Support and Evaluation) Adherence Index questionnaire

A1. How often do you feel that you have difficulty taking your HIV medications on time? By ‘on time’ we mean no more than two hours before or two hours after the time your doctor told you to take it.

A2. On average, how many days per week would you say that you missed at least one dose of your HIV medications?

A3. When was the last time you missed at least one dose of your HIV medications?

SCALES FOR OVERALL ADHERENCE

Morisky Scale

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you ever forget to take your medicine?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Are you careless at times about taking your medicine?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. When you feel better do you sometimes stop taking your medicine?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Sometimes if you feel worse when you take your medicine, do you stop taking it?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mannheimer et al 2007
**Scales for Overall Adherence**

*Swiss HIV Cohort Study- Adherence Questionnaire (SHCS-AQ)*

**Over the last 4 weeks**

- How often did you miss a dose of your HIV-medication?
  1) Daily
  2) More than once a week
  3) Once a week
  4) Once every second week
  5) Once a month
  6) Never

- Did you forget 2 doses one after the other
  o Yes
  o No

**Scoring**

< 100% Taking adherence or ≥ 1 drug holiday
SCALES FOR OVERALL ADHERENCE

- The Simplified Adherence Questionnaire (SAQ)

1. Do you ever forget to take your medicine? (y/n)
2. Are you careless at times about taking your medicine? (y/n)
3. Sometimes if you feel worse, do you stop taking your medicines? (y/n)
4. Thinking about the last week. How often have you not taken your medicine? Never, 1±2 times, 3±5 times, 6±10 times, >10 times
5. Did you not take any of your medicine over the past weekend? (y/n)
6. Over the past 3 months, how many days have you not taken any medicine at all? ≤2 days > 2 days

(Knobel et al., 2002)
Scale Measures

- Allow for multiple items to quantify adherence, can be straightforward to complete, appears to correlate with disease progress and other measures of adherence.

- CONS: Short but growing body of validation support, will not flag differential adherence specifically, may by too global or gross level an assessment, will obviously require careful follow-up.
SELF REPORT MEASURES

**Packets**

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What research has to offer

- Common Measures and Methods used to Monitor Adherence
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- Each medication
- All medications (ART regimen in general)
- One Medication
What research has to offer

- **PILL COUNTS**
  - Tends to be for one medication but can be all
  - Can be done in person, home visits, on site, or over the telephone
  - Involves instructing patient to dispense all pills in one’s medication bottle
  - Counting the pills (typically train people how to do this most effectively, with least error)
What research has to offer

- **PILL COUNTS**
  - Record date of count
  - Record date medication was obtained from pharmacy (from label)
  - Record amount dispensed and amount prescribed (from label)
  - Inquire about start date for this particular medication fill (any medication still on hand at time of refill would impact anticipated amount needed as would pills lost, so on).
  - Calculate number of pills taken (number dispensed minus number on hand) and divide by number of pills that should have been taken in the matched time period (date of refill to current date)
What research has to offer

- PHARMACY REFILL

Calculate
1. **COVERED**
   Pills – Doses – Days covered from medication dispensed

2. **REQUIRED**
   DAYS elapsed from START FILL DATE to END FILL DATE (as days, total pills required, or total doses required depending on metric used in numerator)

Rate of adherence = \( \frac{\text{Covered}}{\text{REQUIRED}} \)

DATA REQUIRED
- Fill date
- Prescribed dose
- Pills dispensed
What research has to offer

- ELECTRONIC MONITORING
What research has to offer

- ELECTRONIC MONITORING

![Graph showing time and days of the month with data points for different times.]
What research has to offer

- ELECTRONIC MONITORING
Other devices

MedSignals  SimPill

EMMA
Other devices

Integrated Real-time Adherence Monitoring and Care

InforMedix

Med-eXpert

Monitoring Center(s)

Patients

Medical Professional

Pharmacist

Family Member

Ambulance

Bangsberg et al– IAPAC 2008
Methods and Devices

- May allow for easier tracking of adherence on the part of the participant and minimize demands on accurate recall, has a long history of demonstrated relationships with outcomes in most cases, can provide more “objective” measurement

- CONS: Can be more expensive in equipment or time/effort, can be experienced as intrusive, may not be superior to “easier” measures, requires return or devices or bottles or tracking strategies for pharmacy refill
What research has to offer.

- A long history of careful evaluation of multiple strategies for monitoring of adherence.
  - Each with pros and cons
  - Many with a demonstrated track record of association with other measures and with disease progression indices
  - Best strategy adopted for a given patient, client, or practice should be based on what is the best fit to client needs and what will provide the most accurate data in the long run.
What research has to offer.

- ADHERENCE is best understood, and most predictive of many outcomes, when it is considered as a *pattern*.
- A single instance or single monitoring outcome is not as powerful as helping people to see their patterns of adherence over time.
- Monitoring of adherence, regardless of the method selected, should be consistent and ongoing.
What research has to offer.

DISCUSSION

◦ What methods or measure appear most feasible in your practice, agency, or for your needs?
◦ Are there some that would be out of the question?
◦ How can you increase the odds of accurate, reliable reporting?
◦ Other observations?
How can we communicate better with patients?

Applying Principles of Cultural Competence and Motivational Interviewing
Four principles

- Resist the Righting Reflex
- Understand your patient’s motivations
- Listen to your patient
- Empower your patient
Resist the Righting Reflex
Resist the Righting Reflex

- The natural instinct
  - Helping professions: desire to set things right, heal, prevent harm, promote well-being, teach, educate
  - Urge to correct another’s course is automatic, reflexive
Resist the Righting Reflex

The problem

- All people have the tendency to resist persuasion, particularly about something about which they have some knowledge and experience
- Attempts to correct and fix problems, misunderstandings, faulty information can lead to verbalization of counter arguments, and defense of the status quo
D– What are you going to do with you? You keep on missing appointments
P– I came that day but I thought it was earlier in the day.
D– Well, you missed in August and July. My concern is that back when I saw you in June, we knew then that we pretty urgently needed to make some changes…. What’s up?
P– I’ve been busy with the kids… looking for work because I’m unemployed now.
D– So what happens if you get sick and aren’t there to even look for work or be busy with the kids if you don’t care for yourself.
P– I promise I am going to be better.
D: Well, these have the time, you have pretty much chronology that you’re taking them around the same time. They’re a couple here that you took in the late, uh later. Uh, in May, the times are off. But this is the big, this is the big, you hafta be, you hafta do better and I don’t want to make this the focus of your life, when to take your medications and when not to take your medications, it should be routine. It should be part of the day, taking your medications because there’s gonna be a time, when you’re gonna, when these medications are gonna fail, when this happens and if they fail then there’s nothing, you know there’s nothing we can do.

P: Mmhmm

D: All of us who practice have patients that have so much drug resistance and that there’s no drugs. You hafta take shots, you have to take T20 and that doesn’t give you a very good lifetime. You know, my goal with you is to keep you healthy for as long as possible.

P: Mmhmm.

D: But you have to, you gotta, really hafta help me.

P: Mmhmm.

D: And I worry, I truly, truly, truly worry because I think that you’re 90% is good, I think there is a way that you could, you could do better. Total percent taken 91%. Percent taken on time 88%. Days with correct doses taken 82%. Total days with all doses taken on time 78%. If it’s not a hundred percent or ninety-five percent it’s just gonna get worse because you’re not dealing with me, you’re not dealing with anybody else, you’re dealing with nature. Mother nature. And Mother Nature is, is, is something you can’t, you cannot deal with, you cannot change. The virus is not a living thing, you know it’s a pathogen. It’s constantly making mutations, looking at ways to fool the body so it can grow and kill you and what you’re doing is you’re battling, that, that, that machine, that nonliving machine and that’s what Nature’s doing to you and what you can, this is very, very good, we’re checking this. You can get anything you want from me, you can get anything you want from a lot of people. You can deal with people, you can deal with, um, bad situations, you know the electric company and uh, you know, the insurance company this that and the other thing. You can’t deal with Nature.

P: Mmhmm.

D: You can’t deal with Nature. The only way to deal with nature is to take these medications and uh, I really truly am concerned. If you think you can go to bed and forget to take the medications. You think you can do all these things and still stay alive, it’s a mistake because at some point, you’re gonna come back and you’re gonna tell me, why didn’t you tell me doctor, when I had the chance to take the meds or a hundred percent. Well I’m doing that now. I’m just telling you can’t do this.

P: Mmhmm.
Resist the Righting Reflex

- What can happen if you don’t Resist the Righting Reflex?
  - People never tell you the truth because when they do they get corrected, or get a lecture

- So when and how do you inform, educate, teach?
  - When you are sure you have the right diagnosis (what the real problem is)
  - How: with respect for what they do know
What to do instead of correcting?

- Ask for more information
  - “So tell me more about what’s been going on with you.”
- Reflect back what the patient has just told you
  - “It sounds like your life just got so stressful for a time that you just didn’t have time to take your medications. It just fell to the bottom of your priority list”
Understand Your Patient’s Motivations
Understand Motivations

- Diagnose before you treat
- Need to understand the nature of the problem before you attempt to ‘solve’ it
D: What do you do in the mornings? Do you eat something?
P: No.
D: You’re going to have to take the time. So I want you to get a cover for your toothbrush. I want you to, whether it’s a piece of paper or something, that you can not brush your teeth, until you think about taking that cover off, cause you can’t stick it in your mouth with the paper cover on it or a case on it or something.
P: mm hmm.
What’s Wrong?

- Failure to explore or diagnose
- Framework to think about nonadherence: intentional vs. non-intentional
Voluntary Non-adherence

- Not convinced it is really needed
- Doesn’t think it is working
- Having a side effect or possible side effect
- Stigmatized by the diagnosis
- Stigmatized by medication taking
- Bad press for other medicines: Vioxx and Avandia
- Thinks they are on too many medicines
- Just doesn’t like taking medications
- Misunderstandings
- Conspiracy theories
Resist the Righting Reflex
Respect patients’ experiences, views, judgments, and opinions
Ask them what they hear people saying and what they think about what they hear
Explore how they deal with the conflict between biomedical and cultural paradigms
Ask how you can help
Involuntary Non-adherence

- Cost problems
- Forgetting doses
- Forgetting to get refills
- Irregular schedule
- Working, childcare, etc.
- Problems with personal organization
The Hard Part

- Multiple reasons for non-adherence
- Voluntary and non-voluntary reasons coexist
- Hierarchy or dependency
  - If a patient doesn’t believe that ARVs will be good for them, focusing on remembering won’t help much
  - Believing that ARVs are good for you is necessary but not sufficient
- Look for reasons for voluntary non-adherence
Listen to your patient
“When you are listening, even if it is just for a minute, you have no other immediate agenda than to understand the other person’s perspective and experience.”

Rollnick et al. Motivational Interviewing in Healthcare
Listen to your patient

- When you take the time to listen, patients feel as though that you’ve spent a longer time with them than you actually have.
- Reflective listening: paraphrase
- Acknowledge feelings/ express empathy
What is Empathy?

Empathy is a response that demonstrates an accurate understanding and acceptance of the patient’s feelings or concerns.

Patient: After I had my hysterectomy. I was taking estrogen, right?

Physician: Yeah?

Patient: You know how your breast get real hard and everything? You know how you get sorta scared?

Physician: How long were you on the estrogen?

Patient: Oh, maybe about six months.

D– What are you going to do with you? You keep on missing appointments
P– I came that day but I thought it was earlier in the day.
D– Well, you missed in August and July. My concern is that back when I saw you in June, we knew then that we pretty urgently needed to make some changes…. What’s up?
P– I’ve been busy with the kids…looking for work because I’m unemployed now.
D– So what happens if you get sick and aren’t there to even look for work or be busy with the kids if you don’t care for yourself.
P– I promise I am going to be better.
Are we good at empathy?

- Physicians ‘missed’ empathic opportunities in 47/65 (72%) patient visits
- Visits with ‘missed’ empathic opportunities averaged 3 minutes LONGER than visits in which empathy had been expressed
- In 25/47 visits with missed opportunities, the patient brought up the same concern more than once

Empower your patient
P: You wait and see. You’ll see me pick up my weight, you’ll see, you’ll be proud of me again. You wait, and I’ll be proud of myself too because I feel better than life.

D: I hate to say this but I just, I keep hearing this over and over again.

P: I understand.

D: and it’s time to walk the walk as they say.

P: I know I understand ok.
Empower your patient

- Support adherence self-efficacy
  - "Tell me more about the time when you were able to take your meds every day."

- Identify and build on their strengths
  - "I think it’s great that you came in today…"

- Help patients explore how they can make a difference in their own health
  - "What do you think you want to do?"
  - "What can I do to help"
Reflections on the Approach

- Take more time?
- Make medical practice more fun?
  - Your job is not to ‘make’ patients more adherent...just understand and help them problem-solve
Higher quality patient–provider communication and relationships can lead to better outcomes among patients with HIV.

We can enhance patient–provider relationships and communication about medication adherence:
- Resist the Righting Reflex
- Understand motivations
- Listen
- Empower
How to catch nonadherence in practice?

Ann Deschamps MSN, University Hospitals Leuven, Belgium
IAPAC/NIMH Adherence Workshop April 5th 2009, MIAMI
Practice?

- Research project
- HIV clinical practice
Focus?

- HIV/AIDS in general
  Adherence assessment = secondary aim

- Adherence
  Adherence assessment = primary aim
Resources?

- Assessment tools: SR, interview, EM, appointment nonadherence...
- Money
- People
- Training
- Time/space

Research practice >> clinical practice
## Overview

<table>
<thead>
<tr>
<th>Research Project</th>
<th>Clinical Practice</th>
</tr>
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<tbody>
<tr>
<td>HIV General</td>
<td>HIV General</td>
</tr>
<tr>
<td>Adherence</td>
<td>Adherence</td>
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<table>
<thead>
<tr>
<th>Setting</th>
<th>Intervention Effect</th>
<th>Clinic Visit</th>
<th>Adherence Counseling</th>
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<tbody>
<tr>
<td>RCT ARV drug</td>
<td></td>
<td>Clinic Visit</td>
<td>Adherence Counseling</td>
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<table>
<thead>
<tr>
<th>Adherence Assessment</th>
<th>Secondary</th>
<th>Primary</th>
<th>Secondary</th>
<th>Primary</th>
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<tbody>
<tr>
<td>Secondary Assessment</td>
<td>Brief SR</td>
<td>Detailed SR</td>
<td>Brief SR</td>
<td>Detailed SR</td>
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<tr>
<td>Tool</td>
<td></td>
<td>EM, Pill Count, Prescription Refill</td>
<td>Appointment Nonadherence</td>
<td>EM, Pill Count, Prescription Refill</td>
</tr>
</tbody>
</table>

1. Adapted from Chesney MA. JAIDS 2006; 43:S149-S155
Validation study¹

- 3 Self Reports
  - VAS: % of overall doses taken
  - SHCS–AQ: % of overall doses missed and DH
  - EHTQ: % of doses missed and DH for each ARV

- EM during 3 months

- Prediction of virological failure at 1 year

Design

Time 1: baseline
Self report: SHCS-AQ
VAS
EHTQ
Viral load

Time 2:
Electronic Monitoring
3 months

Time 3: completion
Self report: SHCS-AQ
VAS
EHTQ
Viral load

Time 4:
Assessment for virological failure
12 months

Month 0
3
15
End of Study
## Ranking

<table>
<thead>
<tr>
<th>Diagnostic value</th>
<th>Measurement</th>
<th>Remarks</th>
</tr>
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<tbody>
<tr>
<td>Best</td>
<td>SR (SHCSA-Q) after EM</td>
<td>Costly (US $ 100)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Labor intensive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>↑ Refusal rate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- disclosure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- unpractical</td>
</tr>
<tr>
<td>Second best</td>
<td>EM</td>
<td>Cf. supra</td>
</tr>
<tr>
<td>Third best</td>
<td>SR (SHCS-AQ + VAS) combined before EM</td>
<td>Feasible in daily practice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt; 3’ time</td>
</tr>
<tr>
<td></td>
<td></td>
<td>↓ Refusal rate</td>
</tr>
</tbody>
</table>

Findings

- Simple questions about overall doses taken perform better than questions about individual ARV.

- Combining simple questions improves their diagnostic value.

- Combining objective and subjective measures improves their diagnostic value.

SR and appointment NA¹

- VAS or SHCS–AQ
- Appointment nonadherence last 2 years
- Virological failure last 2 years

Design

- Assessment for appointment nonadherence
- Assessment for virological failure

Months: -24, -21, -18, -15, -12, -9, -6, -3, 0

VL VL VL VL VL VL VL VL

Self-report: VAS SHCS-AQ

Conclusions

- Appointment NA predicts virological failure better than self-reported NA

- Appointment NA patients = 4.5 times more at risk for virological failure
Conclusion\textsuperscript{1-3}

- No gold standard available
- Depends on practice, aim and resources
- Research on adherence: EM + SR
- Daily clinical practice: SR + APP NA

NOTES (added by authors)

- Workshop also included presentation by J Devieux and R Malow (see IAPAC site or contact these authors directly for information) focusing on adherence monitoring in Haiti.
- Workshop material included set of measures reviewed in Amico and Simoni presentation at start of workshop (contact Amico for a copy).
- As with any slide set, the material provided in the slide set complements, but does not substitute for, the oral presentations and interactive discussions of the workshop.

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Tailoring Adherence Monitoring to the Cultural Context in a Resource-Poor Setting

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&
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Purpose of Presentation

- Describe the Antiretroviral (ARV) Program at the GHESKIO Centers in Haiti and measures of adherence used in the clinical setting.

- Discuss difficulties in measuring adherence in resource-poor countries, the unique challenges to effective ART in Haiti, and strategies used at GHESKIO to enhance adherence among the populations served.

- Briefly share some results from our Cognitive Behavioral Stress Management (CBSM) pilot study with HIV-infected adults at GHESKIO.
INTRODUCTION

Haiti, located on western third of the Caribbean island of Hispaniola

In the Western Hemisphere it is both, the poorest nation and the country with highest HIV burden: estimated prevalence 2.2% among adults

Over past the 25 years country has suffered near constant political and social unrest

Only an estimated 60% of the population has access to health care services (PAHO, 2005)

In 2001 the per capita total expenditure on health was US$56
THE GHESKIO CENTERS

Established in 1982 by a group of Haitian Clinicians as the Haitian Group for the study of Kaposi’s Sarcoma & Opportunistic Infections (GHESKIO):

Groupe Haitien d’Etude du Sarcome de Kaposi et des Infections Opportunistes

In 1983, published their experiences in NEJM documenting first case of AIDS in a developing country

GHESKIO’s commitment to service, research, & training has led to expansion of many GHESKIO models at the national level (E.g.: HIV care and prevention, treatment of STI’s, care for diarrheal diseases, blood safety, AIDS treatment, prevention of congenital syphilis.)
Currently GHESKIO receives about 100,000 patient visits annually

Health care is provided free of charge, including services and medications

Primary care for HIV and related diseases include:

- HIV Counseling and Testing,
- Adult AIDS Care,
- Adolescent Care,
- Pediatric Care,
- STIs,
- Rape Counseling,
- Tuberculosis Treatment,
- Reproductive Health
In 1998 ART introduced to small group of patients using donated drugs

By 2003 with funds from GFATM and PEPFAR the program expanded

Currently ARV treatment is provided at 4 GHESKIO clinics:
- Adult Clinic – 5608
- PMTCT Clinic – currently 326 [2919 already delivered]
- Pediatric Clinic – 405
- Adolescent Clinic - 326
GHESKIO ARV PROGRAM (2)

- Promotes multidisciplinary team approach

- View patients as part of the Adherence Team

- Doctors, nurses, psychologists, social workers, pharmacists, laboratory technicians, and field workers play supportive role to patients
Measures of Adherence at GHESKIO

- CD4 count at enrollment and every 6 months thereafter. Viral load measures not offered routinely due to cost
- Pill counts at every visit
- Pharmacy refill records (every Friday generates lists of missed appointments. Patients who missed appointments are contacted by field workers via phone or home visits for follow-up)
- Self-report of pills taken/doses missed recorded by MD at every visit and reinforcement of importance of adherence to regimen
- Weekly case conferences by adherence team where each patient seen in clinic in given week is discussed and patients who are failing ART identified. Decisions made then whether switch to second-line ART justified.
Difficulties in Measuring Adherence in Resource-Poor Countries

- Few laboratory facilities to test viral load and drug resistance
- Shortage of trained staff, unreliability of electricity supply, and costly reagents
- Most HIV patients do not have access to such testing
- Models used for monitoring ART in resource poor settings use patients’ clinical and treatment Hx, adherence to treatment and lab indices (e.g., hemoglobin level and total lymphocyte count) to identify virological treatment failure
Difficulties in Measuring Adherence in Resource-Poor Countries (2)

- Decision to change ART is based on rise in viral load, fall in CD4+ lymphocyte counts, and presence of drug resistance.

- Focus for measuring adherence in a resource poor environment should be to diagnose virological Tx failure early enough to allow a switch to second-line regimens in order to prevent resistance from developing further in individual and population.
Flowchart showing System for assessing the risk of virological failure for a first-line regimen. To be used after at least 6 months of treatment; treatment failure is estimated as probable if at least one major or at least three minor criteria from different categories are met.
**Table**: System for assessing the risk of virological failure for a first-line regimen. To be used after at least 6 months of treatment; treatment failure is estimated as probable if at least one major or at least three minor criteria from different categories are met.

<table>
<thead>
<tr>
<th>Risk factors for virological factors</th>
<th>Predictive value of the criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TREATMENT HISTORY</strong></td>
<td></td>
</tr>
<tr>
<td>1. Previous monotherapy or bi-therapy with NRTI's for more than 6 months</td>
<td>MINOR</td>
</tr>
<tr>
<td>2. Previous exposure to nevirapine for the prevention of mother-to-child transmission of HIV</td>
<td>MINOR</td>
</tr>
<tr>
<td>3. Infected with HIV by partner with a history of anti-retroviral exposure</td>
<td>MINOR</td>
</tr>
<tr>
<td>4. Current “weak” antiretroviral regimen (e.g., 3NsRTI or 2 NsRTI and 1 NtRTI)</td>
<td>MINOR</td>
</tr>
<tr>
<td>5. Long term use of drugs that could reduce antiretroviral drug level levels in the system</td>
<td>MINOR</td>
</tr>
<tr>
<td><strong>ADHERENCE HISTORY</strong></td>
<td></td>
</tr>
<tr>
<td>1. Day-to day adherence score (&lt;95% but ≥ 80%)</td>
<td>MINOR</td>
</tr>
<tr>
<td>2. Day-to day adherence score (&lt;80% but ≥ 60%)</td>
<td>MAJOR</td>
</tr>
<tr>
<td>3. History of stopping an NNRTI containing regimen without continuing NRTI's for at least 5 days</td>
<td>MINOR</td>
</tr>
<tr>
<td><strong>CLINICAL HISTORY</strong></td>
<td></td>
</tr>
<tr>
<td>1. Appearance or worsening of unexplained prurigo</td>
<td>MINOR</td>
</tr>
<tr>
<td>2. Reappearance of unexplained prurigo and atleast one other HIV-related symptom/sign (not in 1st 6 months or not thought to be IRIS)</td>
<td>MAJOR</td>
</tr>
<tr>
<td>3. Reappearance of atleast 2 other HIV-related symptoms/signs (not in 1st 6 months or thought to be IRIS)</td>
<td>MINOR</td>
</tr>
<tr>
<td>4. Body weight equal / lower than the patient’s weight before starting HAART, or more than 10% weight loss from peak values in the absence of signs of lipoatrophy</td>
<td>MINOR</td>
</tr>
<tr>
<td>5. Development of new WHO stage IV opportunistic infections (including extra-pulmonary TB &amp; IRIS) or malignancy (not in 1st 6 months or not thought to be IRIS)</td>
<td>MAJOR</td>
</tr>
<tr>
<td>6. A recurrent WHO stage III opportunistic infection</td>
<td>MINOR</td>
</tr>
<tr>
<td>7. Tuberculosis and no evidence of TB IRIS(abscess/cavity formation)</td>
<td>MINOR</td>
</tr>
<tr>
<td>8. Worsening Kaposi’s sarcoma</td>
<td>MINOR</td>
</tr>
<tr>
<td>9. Worsening after initial improvement of Kaposi’s sarcoma</td>
<td>MAJOR</td>
</tr>
<tr>
<td><strong>LABORATORY HISTORY</strong></td>
<td></td>
</tr>
<tr>
<td>1. Unexplained fall of haemoglobin of 10% on 2 occasions and a reducetio in TLC of 50% from peak values on consecutive testing or haemoglobin and TLC falling below baseline on 2 consecutive tests.</td>
<td>MINOR</td>
</tr>
<tr>
<td>2. A reduction in CD4+ count to &lt;50% from peak values on 2 consecutive tests or a CD4+ count below baseline on 2 consecutive tests</td>
<td>MINOR</td>
</tr>
</tbody>
</table>

NRTI=nucleoside reverse transcriptase inhibitors, singly phosphorylated (NsRTI) or triply phosphorylated (NtRTI); NNRTI=non nucleoside reverse transcriptase inhibitors; TLC=total lymphocyte count. * These tests should ideally be done in the absence of an acute intercurrent illness.
Challenges to Adherence

- Poverty
- Stigma & Traditional beliefs
- Violence and Insecurities
- Unreliable Stock of ARV
- Tuberculosis
Poverty: Challenge & Solutions

- Poverty affects patients’ ability to feed themselves

- Although first-line regimen not dependent on food for absorption, cultural belief is that taking meds without food will cause further illness

- GHESKIO provides a monthly ration of food to patients on ARV

- Inability to pay for transportation to clinic for regular follow-up appointments and refills is also a barrier to adherence

- GHESKIO offers travel reimbursement for all patients on ARV as well as prepaid phone cards to call the clinic

- When patients are too sick to travel, field workers conduct home visits and deliver meds

- Female patients at high risk for partner violence/abuse and eligible to participate are referred to micro credit program
Stigma & Traditional Beliefs: Challenges & Solutions

- HIV-related stigma is unfortunately common in Haiti. Can prevent patients from accessing health care.

- Counseling with members of the adherence team, social workers, psychologists, peer educators, nurses, and physicians as well as participation in clinical studies can alleviate problem. Successful ARV treatments have been shown to lower stigma in Haitian communities (Shaw, 2004).

- Religious/traditional beliefs about magical cures and modes of transmission can interfere with adherence.

- Counseling by traditional healers working in concert with physicians have at times yielded positive results.
Violence/Insecurities: Challenge & Solutions

- At times, volatile social and political situation affects ARV patients and staff, making clinic and home visits difficult.

- GHESKIO has developed an emergency plan to continue care during times of general insecurity:
  - A skeleton crew works at the main clinic, even during the worst violence.
  - Staff who can visit patients at home or receive patients in their home are designated in each city neighborhood.
  - During worst periods of violence 2005-2006 GHESKIO purchased and stored an emergency supply of medicines in sites throughout the city.

- Although located in one of the worst slum areas of Port-au-Prince, the GHESKIO Centers have never experienced any acts of vandalism or lost “one pencil” even during the worst periods of violence (Pape, 2008).
Although financial barriers to ARV access are decreasing, non-financial barriers to dependable pharmacy stock of ARVs exist.

**Medications from generic manufacturers arrive 4-12 months late.**

**Concerns about manufacturer quality control of generic medications.**

**Delays of more than 6 weeks can occur at customs offices.**

**Difficulties in maintaining reliable pharmacy supply force doctors to make decisions about whether to do a “structured interruption” or switch medications in order to maintain suppressed viral load.**

**Haitian government leading efforts with international agencies to develop a national pharmacy system to assure reliable source of ARVs in Haiti – a critical component of scale up efforts.**
Tuberculosis: Challenge & Solutions

- In Haiti, TB found to be most common presentation of symptomatic HIV and AIDS-defining illness (Deschamps, 2000)

- At ARV clinic 15% patients started on ARV are also on TB meds. Presents challenges including drug interactions, toxicities, and risks of decreased adherence with high pill burden

- In patients receiving co-treatment, drugs used to treat TB complicate ARV treatment. Also, there is increased risk of Immune Reconstitution Syndrome (IRS). In resource-poor setting with limited lab capacity, clinical management of a patient on ARV with symptoms suggestive of IRS can be challenging

- With funding from the French foundation Rodolphe Mérieux, GHESKIO recently built a state-of-the-art laboratory facility that should be operational by the end of 2009 or early 2010
Our CBSM Pilot study

- Received supplemental funds to our NIH funded Cognitive Behavioral Stress Management (CBSM) grant to conduct a pilot study at GHESKIO

LES CENTRES GHESKIO
Demographic Characteristics

- Our study sample consisted a total of 56 adults
  - 28 ♂ = mean age 40 years
  - 28 ♀ = mean age 38 years

- Education

  - Most (n=50; 89%) were unemployed and had total annual income of HA$ 10,000 (US$ equivalent $1,250) in the past year.

- Chart showing:
  - GED/Diploma: 9
  - High School: 24
  - < 8th Grade: 20

Most (n=50; 89%) were unemployed and had total annual income of HA$ 10,000 (US$ equivalent $1,250) in the past year.
Demographic Characteristics (contd...)

Marital status of study sample

- Single: 21
- Married: 11
- Common-law: 10
- Separated: 7
- Widowed: 6
- Divorced: 1

 Married status of study sample

75% had children. Average: 3.4 children.
They had a regular place to stay with living arrangements either
- at their partner’s apartment (n=27; 48%), or
- at someone else’s apartment (n=18; 32%), or
- rented a room (n=3; 6%).

Lived with

- Alone: 3
- Others: 8
- Friend: 9
- Husband/Wife/Girlfriend/Boyfriend: 11
- Children: 22
- Immediate/Extended family member: 23
MEDICATION ADHERENCE

- Average time since diagnosis of HIV: 8.43 years (range 3-21 years)
- Average time on ART: 5.86 years (range 3-8 years)
- Average number of pills taken per day: 4 (range 2-12).
- 90% reported perfect adherence in previous 4 days.
Beliefs About Medications Questionnaire (BMQ)

Beliefs about medications questionnaire (BMQ) was used to assess participants’ perceptions about medications in general and Anti-Retroviral Therapy (ART) which has an influential role on their medication adherence behavior.

BMQ consisted of 31 items responded on a 5-point scale (1=Strongly Agree, 2=Agree, 3=Uncertain, 4=Disagree, 5=Strongly Disagree).

With 4 subscales in total, Trust (8 items) and Benefit (5 items) subscales assessed perceptions about medications in general; while Necessity (8 items) and Concern (11 items) assessed perceptions about ART.
Trust about medications in general increased significantly from baseline to 3-month follow-up \((p \leq 0.01)\).

Participants’ concerns about the ART decreased significantly from baseline to 3-month follow-up \((p \leq 0.01)\).

The high level of trust about medications in general, the low level of concern about ART, and generally good adherence to prescribed regimens found in our sample were validated by qualitative data collected from a subsample of participants in our study.
Results

Qualitative data from 4 focus groups conducted with male (n=10) and female (n=12) participants from our pilot study reveal that:

Prior to the initiation of ARV treatment most had extremely low CD4 counts and suffered from a variety of OIs

“I was so weak I could not walk. I was loosing weight and went down to 114 lbs from 165. I had fever and diarrhea all the time. In February ‘96 my CD4 count had gone down to 19”

“When I came to the Center my count was around 30. Since I started the meds it went up and is now at 710”

“I was so sick that my younger brother said he was bringing me here for a test. I was so weak that they had to carry me in a chair. When I started ARV treatment I began to gain weight. To combat this illness you need to eat too. When I eat and take my meds I feel strong.”
Due to the prevailing stigma, the majority of participants manage their HIV infection alone and use a variety of strategies to keep their status secret (e.g., remove their meds from their original containers)

“I live with my 2 children and my niece. I use a technique to hide the meds I take. I remove them from their box and place them in a container of Centrum so they would think that I’m taking vitamins. To keep them from touching them, I tell them that those vitamins are made for people who are at least 50.”

“My family and children know that I’m taking meds but they don’t know why. Even though I eat with them every day, the minute they would learn I’m infected, things would not be the same.”

“Before when I lived with my sister when it came time to eat I felt that she was uncomfortable. She did not drink water in the glass I used. Now I live alone and have a room by myself.”

“I live alone and I eat alone at home but my entire support is here at the clinic. I don’t have one relative who knows my status. It’s been a long time since I live alone. I only have 6 uncles but they never try to see me; I am the one that has to go visit them. I have no one to help me; I must do everything for myself.”
Participants view the access to ARVs as a miracle from God that has transformed their lives. Those who experienced side effects say they were short-lived.

“My experience with the meds, I say that it’s a miracle from God. I am still taking the same meds that they gave me the first day I came here.”

“The meds are really good for me. I never had any bad reactions. They never bothered me.”

“The meds did a lot for me. First I thank God; secondly, I thank the researchers, and thirdly I thank the doctors because I did not have any hope of living. Those who were infected before me did not have the chance to find meds but God made it a priority for researchers to discover these meds.”

“Before I started taking the meds, I spent one year inside my house. I was so small that when I went out, people ran away from me; it as if they saw a ghost. With the meds I began to regain my strength and I found a support group. I regained confidence in myself.”

“When I just started the meds, one of them gave me vertigo. But this effect went away. I’ve now been on the same meds for 3 years.”
Participants view their ARV treatment as a gift and described strict adherence to their regimens as important. They used striking terms to describe the importance of the meds to them (e.g., their life line; the tube that keeps their heart beating):

“I don’t feel I can live without them (meds). I don’t want to die. Life is too beautiful. I know if I don’t take them I will die. I have to take them.”

“For me, the meds are like a tube that keeps my heart beating. If I get rid of the tube my heart will stop beating and I will die. Wherever I go I keep my meds in my pocket. If the time arrives for me to take them and I don’t have access to water, I generate saliva in my mouth in order to swallow them, then when I find water I drink it to make them go down. These meds are my life. If I don’t take them, my heart will stop and I will die.”

“I cannot not take my meds because after God, they are my life.”

“I have no problem with my meds. When I go out or I travel, I always take them with me in this briefcase because you never know when you might be spending more time away than you thought. Once I had gone away for 2 days but ended spending 1 week; fortunately, I had taken extra meds with me and did not miss any doses.”
Results (5)

Some of the participants identified situations that disrupted their strict adherence to the ARV treatment:

death of a close parent

“Since my father died I live alone. He used to cook for me. Sometimes it’s 12 noon and I haven’t had anything to eat so I don’t feel I can take the med.”

“My mother’s death affected me a lot. She was everything to me. I felt I was done. When I woke up I used to find that the food was prepared and on the table. Now I had to do everything myself and sometimes I was feeling weak.”

Lack of food, although a major problem for most, affected adherence only for a few. Most say they take their meds even without food

“Rain or shine I take my meds. Sometimes I take them at 6a.m. and it’s sometimes 2p.m. that I haven’t found anything to drink or eat, not even a cup of coffee.”

Lack of financial resources/unemployment

“Owing money can affect you. Sometimes I am so preoccupied I forget to take them on time”

Lack of privacy from living with a friend or relative

“Sometimes when I am at someone’s house it’s very difficult for me to take my med. I have to watch when they go to sleep to get up. Sometimes I fall asleep too and I miss my dose.”
Conclusion

- With increased support for resource-poor nations in the fight against HIV/AIDS Haiti has made great strides in ARV treatment.

- Resource-poor nations such as Haiti have demonstrated the ability to use this support to successfully treat large numbers of patients with ARV, despite multiple challenges.

- Integrated model of primary care for HIV developed at GHESKIO is being implemented throughout the country.

- Lessons learned can be used to expand access to care, treat more poor AIDS patients, and achieve treatment coverage rates comparable to developed nations.
THANK YOU!!!

QUESTIONS PLEASE???