Monitoring Patient Adherence:
Recommendations from and for Practice

AGENDA

**Introduction**- Exploration of areas of service, monitoring needs, and goals of workshop participants (R. Amico and J. Simoni)

**Common Strategies** for Monitoring Adherence Developed in the Context of Research (R. Amico and J. Simoni)

**Interview-based Strategies**- Provider and health professionals interview and discussions of adherence (I. Wilson)

**Tailoring adherence monitoring to the cultural context**- Example of monitoring approaches adapted to Haiti (R. Mallow and J. Devieux)

**Positioning monitoring adherence strategies to specific goals**- Tailoring adherence monitoring strategies to the specific goals of monitoring (A. Deschamps)

**Summary and Conclusions**

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NOTE:

PLEASE SEEK APPROPRIATE PERMISSION TO USE MEASURES INCLUDED IN THIS PACKET. MEASURES ARE PROVIDED HERE TO SUPPORT DISCUSSIONS AMONG WORKSHOP PARTICIPANTS AND DO NOT IMPLY PERMISSION FOR USE FOR OTHER PURPOSES.
**MONITORING/ASSESSING DOSES TAKEN/MISSED RELATIVE TO THOSE PRESCRIBED EXAMPLE 1: INTERVIEWER DELIVERED**

(ACTG and other dose based recall measures where days recall can range from yesterday to one week ago)

**MEDICATIONS**

Complete based on prescribed regimen.

<table>
<thead>
<tr>
<th>Drug Name/Dose</th>
<th># Pills Each Time</th>
<th># Times Per Day</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>(Pills in Each Dose)</td>
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</table>

How long have you been on this regimen? (number of days, weeks, months, or years)

**INSTRUCTIONS:**

“Most people with HIV have many pills to take at different times during the day. Many people find it hard to always remember their pills: Some people get busy and forget to carry their pills with them. Some people find it hard to take their pills according to all the instructions, such as “with meals,” or “on an empty stomach,” “every 8 hours,” “with plenty of fluids.” Some people decide to skip doses to avoid side effects or to just not be taking pills that day. We need to understand how people with HIV are really doing with their pills. Please tell us what you are actually doing. Don’t worry about telling us that you don’t take your pills. We need to know what is really happening, no what you think we want to hear.”
This section asks about the medications that you may have missed taking over the last four days.

**IF YOU TOOK ONLY A PORTION OF A DOSE, REPORT IT AS MISSING THE DOSE.**

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4</th>
<th>Interviewer Comments</th>
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</thead>
<tbody>
<tr>
<td>Names of your anti-HIV drugs</td>
<td>HOW MANY DOSES DID YOU <strong>MISS</strong>...</td>
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<tr>
<td>Step 2</td>
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<td>Yesterday</td>
<td>Day before Yesterday (2 days ago)</td>
<td>3 Days ago</td>
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</table>

If you took only a portion of a dose on one or more of these days, please report the dose(s) as being missed.
In the past 3 days, on how many days have you missed taking all your pills?

- [ ] None
- [ ] One day
- [ ] Two days
- [ ] Three days
- [ ] Four days

Most anti-HIV medications need to be taken on a schedule, such as “2 times a day” or “3 times a day” or “every 8 hours.” How closely did you follow your specific schedule over the last 3 days?

- [ ] Never
- [ ] Some of the time
- [ ] About half of the time
- [ ] Most of the time
- [ ] All of the time

Do any of your anti-HIV medications have special instructions, such as “take with food” or “on an empty stomach” or “with plenty of fluids?”

- [ ] Yes
- [ ] No
If Yes, how often did you follow those special instructions over the last three days?

<table>
<thead>
<tr>
<th>Never</th>
<th>Some of The Time</th>
<th>About Half of The Time</th>
<th>Most of The Time</th>
<th>All of The Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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</tbody>
</table>

Some people find that they forget to take their pills on the weekend days. Did you miss any of your anti-HIV medications last weekend—last Saturday or Sunday?

1 Yes  2 No

When was the last time you missed taking any of your medications? Check one box.

5 Within the past week

4 1-2 weeks ago

3 2-4 weeks ago

2 1-3 months ago

1 More than 3 months ago

0 Never skip medications
### ANTIRETROVIRAL MEDICATION SELF-REPORT

**FORM 646**

### Instructions – RESEARCH STAFF:

Attach a PID label and record the form date on both pages of this form. Mark the “Sequence” box with “1.” Check Method of Data Collection for Sections B and C. If no AR drugs are prescribed check box 3, skip sections A-C, and FAX this page to the SDMC.

If AR drugs are prescribed complete Section A of this form with the patient. If more than 7 AR drugs are prescribed, include another copy of page 1 of this form, marking the “Sequence” box with “2.”

Method of Data Collection for Sections B and C:
1. [ ] Patient filled out these sections
2. [ ] Staff member (or other person) assisted patient with completion of these sections
3. [ ] Not completed because patient not prescribed any AR drugs. (Do not check this box for patients lost to follow-up.) Skip Sections A-C, FAX this page to the SDMC.

### SECTION A

TO BE COMPLETED BY RESEARCH STAFF WITH STUDY PARTICIPANT.

Complete the following information with the patient for each antiretroviral drug prescribed during any of the past 7 days.

Please write in the name of the drug that the patient uses and the drug code from the key below. For liquid ritonavir, alpha interferon and T-20, record “Drug Name,” “Drug Code,” “No. Doses Per Day” only. Charts and stickers may be used to ensure the patient’s prescribed regimen is well understood. (Do not put stickers on this form.) For drugs that are temporarily discontinued, record “00” for “Total No. of Pills Per Day.”

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Code</th>
<th>No. Pills Per Dose</th>
<th>No. Doses Per Day</th>
<th>Total No. Pills Per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<td>7.</td>
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</tbody>
</table>

During the last 7 days, I took:

- ALL my pills every day
- MOST of my pills
- About ONE-HALF of my pills
- VERY FEW of my pills
- NONE of my pills

If you took all your pills every day during the last 7 days for every drug listed, DO NOT ANSWER ANY MORE QUESTIONS. Otherwise, go to Section C on the last page.

*Drug Codes:
- ABC=abacavir
- DDI=didanosine
- EMV=Emtricitabine
- IL2=Interleukin 2
- $GQV=sagamivir
- T20=T-20 (Fuzone)
- ADV=adefovir dipivoxil
- DDC=calcitabine
- FTC=Covarin
- LPV=rinavitepravir (Kaletra)
- 3TC=lamivudine
- ZDV=zidovudine
- APV=rampinavir
- D4T= stavudine
- IDV=indinavir
- NFV=nefuvir
- ATV=ATV
- AZT=aziteranavir
- DEX=oxifrotin
- ERV=efavirenz
- NVP=nevirapine
- TIR=rilevir
- CBV=cravir
- IFI=interferon
- RON=rinavitepravir
- TZR=atrovir
- TAZ=traver

CPCRA Form 646 V4 (1-2) AUG 2003
SECTION G
TO BE COMPLETED BY STUDY PARTICIPANT. Do not answer these questions if you took all your pills every day during the last 7 days for every drug listed.

1. During the last 7 days, what part of the day did you usually MISS taking your antiretroviral drugs? (Check all that apply.)
   - □ In the morning (upon waking until 12 noon)
   - □ In the afternoon (between 12 noon and 5 p.m.)
   - □ In the evening (between 5 and 9 p.m.)
   - □ At night (9 p.m. until waking the next morning)

2. Below are some reasons why people miss taking their antiretroviral drugs. Check “Yes” or “No” to indicate whether or not each of the following reasons describes why you usually MISSED taking your antiretroviral drugs during the last 7 days:
   a. I feel worse when I take the pills  □ Yes □ No
   b. There are too many pills to take  □ Yes □ No
   c. I forget to take the pills  □ Yes □ No
   d. I ran out of pills  □ Yes □ No
   e. I don’t think I need the pills  □ Yes □ No
   f. I was away from home  □ Yes □ No
   g. I did not want others to notice  □ Yes □ No
   h. I am too busy  □ Yes □ No
   i. I had problems taking pills at specified times (with meals, on empty stomach, etc.)  □ Yes □ No
   j. I was confused or uncertain about how to take the pills  □ Yes □ No
   k. Other (please explain):

   ____________________________________________________________________

_____________________________________________________________________

CPCRA Form 848 V4 (2-2) AUG 2003
MONITORING/ESTIMATING ADHERENCE TO ART SPECIFIC ART AGENTS

VAS (Visual Analog Scale)

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

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

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

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

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

0% means you have taken none of this medication
50% means you have taken half of this medication
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How much of this medication have you taken as prescribed in the last three to four weeks?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

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

********************************************************************************

MONITORING/ESTIMATING ADHERENCE TO ART SPECIFIC ART AGENTS

Single Item Measures (extracted from CPCRA form- Likert scale)

About how much of this medication have you taken as prescribed in the last week?

- ALL
- MOST
- HALF
- FEW
- NONE

About how much of this medication have you taken as prescribed in the last week?

- ALL
- MOST
- HALF
- FEW
- NONE
MONITORING/ESTIMATING ADHERENCE TO ART IN GENERAL

VAS (Visual Analog Scale)

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

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

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

Gifford et al. PRESENTLY USED IN PROJECT AT VA NEW ENGLAND AND BOSTON UNIVERSITY DELIVERED VIA COMPUTER

MONITORING/ESTIMATING ADHERENCE TO ART IN GENERAL

Single Item (Likert Scale)

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

ALL MOST HALF FEW NONE
MONITORING/ESTIMATING ADHERENCE TO ART IN GENERAL

Case Adherence Index Questionnaire
(Mannheimer et al., 2007)

CASE (Center for Adherence Support and Evaluation) Adherence Index questionnaire
Please ask each question and circle the corresponding number next to the answer, then add up the numbers circled to calculate Index score.

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.
   4  Never
   3  Rarely
   2  Most of the time
   1  All of the time

A2. On average, how many days per week would you say that you missed at least one dose of your HIV medications?
   1  Everyday
   2  4-6 days/week
   3  2-3 days/week
   4  Once a week
   5  Less than once a week
   6  Never

A3. When was the last time you missed at least one dose of you HIV medications?
   1  Within the past week
   2  1-2 weeks ago
   3  3-4 weeks ago
   4  Between 1 and 3 months ago
   5  More than 3 months ago
   6  Never

INDEX SCORE: __________

>10 = good adherence
≤ 10 = poor adherence
MONITORING/ESTIMATING ADHERENCE TO ART IN GENERAL

The Morisky Scale
(Morisky, 1983)

The Morisky Scale (original, developed for antihypertensive medication adherence)

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

SCORING: Score all NO answers as 1 and sum all responses (range 0 to 4 total). Low scores indicate greater risk for nonadherence.
MONITORING/ESTIMATING ADHERENCE TO ART IN GENERAL

The Swiss HIV Cohort Study Adherence Questionnaire (SHCS-AQ)
(Glass et al., 2006)

Over the last 4 weeks

- How often did you miss a dose of your HIV-medications?
  - Daily
  - More than once a week
  - Once a week
  - Once every second week
  - Once a month
  - Never

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

SCORING

< 100% Taking adherence or ≥ 1 drug holiday/maand

MONITORING/ESTIMATING ADHERENCE TO ART IN GENERAL

The Simplified Adherence Questionnaire (SAQ)
(Knobel et al., 2002)

1. Do you ever forget to take your medicine?  
   - Yes  
   - No

2. Are you careless at times about taking your medicine?  
   - Yes  
   - No

3. Sometimes if you feel worse, do you stop taking your medicines?  
   - Yes  
   - No

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?  
   - Yes  
   - No

6. Over the past 3 months, how many days have you not taken any medicine at all?
   - ≤2 days
   - > 2 days

SCORING: A positive response to any of the qualitative questions, more than two doses missed over the past week, or over 2 days of total non-medication during the past 3 months = non-adherent (Knobel et al., 2002).
MONITORING/ESTIMATING ADHERENCE VIA PILL COUNTS

In person or by phone but required training of the patient or participant to be able to do this on their own if over the phone. Alternatively, asking patients to simply bring in their medications can work but can be very difficult for some patients who are at increased risk for unintentional status disclosure by carrying medications.

- 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)
- 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)

MONITORING/ESTIMATING ADHERENCE VIA PHARMACY REFILL RECORDS

Closed systems work best (example): Refill data include date of fill, dose instructions (pills per dose and doses per day) and total number of pills (or doses) dispensed

\[
\begin{align*}
\text{FILL DATE} & \quad \text{FILL DATE} \\
\text{FILL DATE} & \quad \text{FILL DATE}
\end{align*}
\]

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)

\[
\text{Rate of adherence} = \frac{\text{Covered}}{\text{REQUIRED}}
\]
MONITORING/ESTIMATING ADHERENCE ELECTRONICALLY
Monitoring devices - downloaded and real-time

One of several available devices that tracks pill bottle or other device (pill box) opening either on a chip for download at a later date or on a chip and in real time through wireless transmission of data to a server.

The following are available systems (more may be available but here is a short list):

Medication Events Monitoring System (trademarked by Aadex Ltd) [http://www.aardexgroup.com/]

Informex’s Med-eMonitor or medimonitor [http://www.informedix.com/]


SimPill [http://www.simpill.com/thesimplesolution.html]

From Wired’s list of 10 Top Technology Breakthroughs of 2008

**Edible Chips**

Grandma’s pillbox with the days of the week neatly marked is set to go high tech. Tiny edible chips will replace the organizer, tracking when patients take their pills (or don’t) and monitoring the effects of the drugs they’re taking. Proteus, a Redwood City, California, company, has created tiny chips out of silicon grains that, once swallowed, activate in the stomach. The chips send a signal to an external patch that monitors vital parameters such as heart rate, temperature, state of wakefulness or body angle.

The data is then sent to an online repository or a cellphone for the physician and the patient to track. Proteus says its chips can keep score of how patients are responding to the medication. That may be just the beginning, as the chips could improve drug delivery and even insert other kinds of health monitors inside the body. Now doctors may have a better answer to a common patient complaint — they will know exactly how it feels.

Outlook: If proven in clinical trials, edible chips could let physicians look into a patient’s system in a way that could change how medicine is prescribed and how we take the drugs.

MONITORING ADHERENCE THROUGH FOCUSED CONVERSATIONS

RULE -- Four Principles to follow when discussing adherence with clients or patients

R esist the Righting Reflex

U nderstand your patient’s motivations

L isten to your patient

E mpower your patient

TIPS:
• 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”
• 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”