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COMPARING SEVERAL SELF-REPORT MEASURES OF ADHERENCE WITH MEDICATIONS FOR HIV WITH ELECTRONICALLY MONITORED MEDICATION ADHERENCE.

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COMPARING SEVERAL SELF-REPORT MEASURES OF ADHERENCE WITH MEDICATIONS FOR HIV WITH ELECTRONICALLY MONITORED MEDICATION ADHERENCE.

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ABSTRACT

Objective: Self-report of medication adherence is commonly used in research studies, but the information is lacking about the sensitivity, specificity, reliability and clinical validity of this method. The purpose of this study was to test the sensitivity, specificity and reliability of several methods for accessing medication compliance using patient self-report of adherence. The Medication Event Monitoring System (MEMS) was used as a standard against which self-report measures were compared.

Design: Cross sectional study.

Data Collection: A self-reported questionnaire accessed compliance of Anti-retroviral therapy (ART) and Protease inhibitors (PI) used by the patients with HIV infection during the year 1996-1997. The eligibility criteria included ages between 18-74 years, a current prescription of ART or PI. One hundred and forty- five patients completed the questionnaire out of which a subset of 86 patients were randomly selected to receive a 30-day supply of their prescribed anti-retroviral in a vial with MEMS Track cap. After a period of one month the data was retrieved using MEMS-4 communicator. Data on demographics, mood status, medical status and clinical characteristics was also obtained by survey.

Methodology: Sensitivity, specificity and reliability were calculated for the following self-report measures: number of doses missed in past one month, number of doses missed in past three months, Medication Adherence Scale (MAS) and temptation to skip medication scale. The patient population was divided into two groups, i.e., the patients on PI and patients on ART. MEMS report was used as a standard for

comparison of the self-reported compliance. Two different gold standards were set. >80% compliance MEMS and >90% compliance MEMS to test the compliance at 80% and 90% cutoffs.

Results: For patients on Protease inhibitors, the agreement between Self-report and MEMS-report according to kappa statistics was K= 0.14 (for >80% compliance MEMS) and K=0.11 (for >90% compliance MEMS) indicating only slight agreement between the two measures of compliance. Number of doses missed in past one month and number of doses missed in the past three months had the highest sensitivity of 1.00, but the specificity of these measures was very poor. MAS had the highest values of kappa (K=0.26) indicating a fair amount of agreement with MEMS. Temptation to skip medication scale showed a good balance of sensitivity and specificity, indicating good accuracy. For patients on ART the agreement between the Self-report and MEMS-report according to the kappa statistics was K=0.15 (for >80% compliance MEMS) and K=0.20 (for >90% compliance MEMS) indicating only slight agreement between the two measures of compliance. In congruence with the results for PI patients, number of dose missed in past one month and number of doses missed in past three months overestimated adherence. MAS had the highest kappa value of K=0.33 indicating fair agreement with MEMS and temptation to skip medication showed a good balance between sensitivity and specificity, similar to PI patients.

Conclusion: Sensitivity and specificity are the measures of accuracy of the data. Number of doses missed in past one month and number of doses missed in the past three months showed highest sensitivity, indicating that this measure correctly

classified the complaint patients in the complaint category. At the same time these measures had a very low specificity indicating that the non-compliant patients were also incorrectly classified as compliant, causing overestimation of compliance behavior, leading to erroneous results. MAS and temptation to skip medication measures also overestimated adherence, concluding a very low accuracy of these measures in detecting compliance. Kappa statistics is an index of reliability. All the self-report measures only showed a slight to fair agreement with MEMS reported compliance indicating a very low reliability of these self-report measures in measuring compliance. Additional studies will be required to determine if these findings also apply to other populations.

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INTRODUCTION

Adherence, often used interchangeably with compliance, is "the act, action, or quality of being consistent" [1] with administration of prescribed medications. Adherence is preferred because it affirms that a patient actively participates in choosing and maintaining a medication regimen. Nonadherence may mean not taking medication at all, taking reduced amounts, not taking doses at prescribed frequencies or intervals or not matching medication to food requirements [2]. Typical rates of medication adherence for persons with chronic disease are about 50%, with a range from 0% to 100% [3].

A] Importance of Adherence

As protease inhibitors and triple drug combinations have become the standard of care for most HIV patients, adherence to HIV medication regimens has become an important issue [4]. Since HIV has the ability to mutate rapidly in absence of drug or at sub- therapeutic doses, taking anti-retroviral medication exactly as prescribed is the required the success of antiretroviral therapy [5,2].

Adherence to anti-retroviral therapy for the treatment of HIV infection and AIDS has become one of the most important clinical challenges among HIV health care providers and patients [4,6]. One hundred percent adherence to current anti-retroviral regimen however is not easy to achieve. Research on adherence of HIV therapy ranges from 46% to 88% [7-10]. It has also been shown that adherence normally decreases over time and with greater number of pills that one is required to take.

Improvement of adherence is key to preventing the emergence of drug-resistant viruses that compromise therapeutic benefits and may be transmitted to others. Furthermore, the cost of interventions to enhance adherence is minimal as compared to the cost of the therapy [2].

B] Measuring Adherence:

The measurement of adherence poses a challenge to researchers and clinicians. There are a number of ways to measure adherence or compliance [11,16].

Current detection methods include indirect measures, such as self-report, interviews, therapeutic outcomes, pill count, change in the weight of meter-dose inhaler canisters, medication refill rate and computerized compliance monitors, and direct measures, such as biologic markers, tracer compounds, and biologic assay of body fluids [12].

Plasma and urinary drug levels provide useful objective assessment of adherence but are often subject to wide individual variation in drug pharmacokinetics [13]. Drug levels may only reflect doses taken the previous day rather than adherence over the previous week or month [14]. This problem is particularly true for medications with short half-lives. In addition, most drug assays are expensive and subject to multiple confounding sample methods [14,15].

Pill count is another common detection method used to measure compliance. It is frequently used in clinical drug studies, but the results can be confounded if unused bottles are misplaced or deliberately not returned to the providers also called "pill-

dumping" [16]. In addition, pill counts do not reveal whether a medication is taken consistently or at correct dosing intervals.

Refill records at pharmacies capture the quantity of medication presumably consumed between visits but cannot verify correct timing of doses or the actual taking of medication [17].

Self-report and interviews with patients are the most common and simplest methods of attempting to determine compliance with the therapy [12]. It is the only method that can detect the underlying issues related to non-adherence behavior, and it is therefore critical to incorporate some type of self-report in evaluating an adherence strategy [18].

This method has an advantage of low cost, results are easily obtainable and the method can be tailored to the language and reading competency of the subjects. Disadvantages of this method include: overestimation of adherence, recall bias and the fact that this method often gives information only on short-term adherence or average adherence. One of the ways suggested to improve self-reporting methods is to include computer-assisted interviews, which may give more accurate results especially on sensitive questions [19].

The method in which 'self-report' is administered is an important aspect of getting useful information from patients. The way in which the questions are asked also plays a role in the quality of information received. Phrasing the question in a non-judgmental way and asking for specific information has been found to be critical in obtaining important information on how the patient is managing with adherence.

Some examples of this are: "It is sometimes difficult to take these medications exactly on time. How many doses have you missed in the past 24 hours?" and "Do you miss some of your medications each week?" [18].

One study found that phrasing question to elicit a "yes" response to non-adherence behavior allowed patient to disclose actual behavior more readily because the patients have the tendency to answer providers in the affirmative [20]. This supports the notion that providers will get more accurate information if they give their patients permission to be honest about their difficultly in taking medication.

An ideal method for measuring compliance should measure compliance at the time and place of medication-taking event. It should, therefore, possess perfect sensitivity and specificity. Although direct observation of the patient would come closest to satisfying the definition, this method is not practical.

Computerized compliance monitors are the most recent and reliable source of indirect detection methods. Hence they were used in this study as a gold standard to compare self-report measures. The principle of electronic monitoring of compliance was pioneered by Kass et al., [21,22] with the development of an electronic eye-drop dispenser. Electronic monitoring also has been used to measure compliance with solid dosage forms (Medication Event Monitoring Systems [MEMS] available from Aprex Corporation, Fremont, California.)[21,22]. This technique uses a computer chip in the cap to record the time when the medication bottle is opened and presumably a pill is taken. This method has the disadvantages of underestimating the adherence if multiple doses are removed at one time or estimating adherence if the

medication is not actually taken, it is expensive and it also requires specific software for interpretation.

C] Measurement Error

A certain amount of error is intrinsic to any measurement process. In the conduct of epidemiologic research, measurement error is potentially a major problem that may invalidate the results of otherwise well-designed studies. Although measurement error can never be eliminated, the methods for minimizing the impact can contribute greatly to the quality of epidemiologic studies and to the appropriateness of the conclusions drawn from them.

Indices of accuracy of measurement:

The accuracy, or validity, of a measurement refers to the extent to which the measurement represents the true value of the attribute being assessed. In order to obtain something more than an impressionistic idea of the quality of a measurement of a given variable, it is useful to calculate quantitative indices of the accuracy of measurement. For a discrete variable there are two separate aspects of the accuracy of measurement. One is *sensitivity*, which is defined as the proportion of those who truly have the characteristic that are correctly classified as having it by the measurement technique [23]. The other is *specificity*, which is defined as the proportion of those who truly do not have the characteristic that are correctly classified as not having it by the measurement technique [23]. Measurement of a binary characteristic is perfect when both sensitivity and specificity are 100%. When sensitivity is equal to 100%

minus specificity, then the measurement technique is no better than an entirely random mean of classifying individuals, which indicated that the probability of being identified as having characteristic is same for those who do not have the characteristic. In order for a measurement technique to be useful in epidemiologic research, it must be substantially better than a random method of classification.

Indices of reliability:

In many epidemiologic studies, it is important to assess the degree of correspondence of two qualitatively differently methods of measurement, such as information on use of medications obtained through interviews compared with similar information obtained through review records. The extent of their agreement in classifying the individuals would then reflect the reliability of the measure used.

The kappa coefficient is appropriate for comparing agreement between discrete variables. The kappa coefficient, which was first proposed by Cohen (1960), has the important characteristic of correcting for the chance agreement that would be expected to occur if the two classifications were completely unrelated. Failure to take into account chance agreement can lead to erroneous conclusions about the quality of measurement.

The relationship of kappa to sensitivity and specificity under the assumption of independent error is more complex and is a function not only of these two indices of accuracy, but also of the true proportion of the population that in fact has the characteristic of interest (compliant) [24,25]. Consequently, even for fixed values of

sensitivity and specificity, the value of kappa can vary widely, so that inferences about accuracy based on the value of kappa are difficult to draw.

METHODOLOGY

Study Sample

The sample consisted of 145 patients who were currently prescribed medication for HIV. Eligibility criteria included age between 18 and 74 years, a current prescription of approved anti-retroviral medication or protease inhibitors or use of approved medication for HIV-related complications and prophylaxis of opportunistic infections (for example, trimethoprim, sulfamethoxazole used in the prophylaxis of Pneumocystic carinii pneumonia), ability to read English, and positive HIV status. The purpose of the original study for which the data was gathered was to develop measures of stages of change for medication adherence. The study was funded by NIH and conducted by Dr. Cynthia Willey, at the University of Rhode Island during the year 1995-1998.

The study sites are described below:

1. **The Miriam Hospital Immunology Center**, which has the largest number of ambulatory visits of HIV seropositive individuals and serves the majority of HIV+ women in Rhode Island.
2. **Stanley Street Treatment and Resources,** which provides primary care for the indigent and intravenous drug using population in the greater Fall River Massachusetts area.
3. **Veterans Affairs Medical Center in Providence RI,** which currently provides care to approximately 60 HIV seropositive men.

Data Collection

Patients meeting the above criteria who visited one of the three sites were asked to fill out a standardized questionnaire. The patients were told that the questionnaire was about how they think and feel about the HIV related medications that they were taking, and about different strategies that people use to take their medications. They had the choice to complete it at home and mail it in return to the clinic, or complete it right at the clinic. They were told they would receive a gift certificate of $20 after they had turned in the questionnaire. The data was collected during the year 1996-1997. After completion of the questionnaire, a subset of patients (n=86) were randomly selected to receive a 30-day supply of their prescribed medication in a vial with Medication Event Monitoring System (MEMS) TrackCap™ (APREX Corporation, Union City, California). A second appointment was scheduled for 1 month later, and data from the MEMS TrackCap were read using a MEMS-4 Communicator. All patients were offered a $50 gift certificate for their participation in the MEMS portion of the study.

The survey questionnaire administered to patients included data on demographics, living arrangements, education, employment, income, insurance, social support, side effects and a psychological measurement scale. It was a self-reported questionnaire. The answers were checked for completeness.

Measures and Variables Assessed

The questionnaire included the following questions:

- Demographics: age, gender, race, years of education, income, insurance, number in household, current health status and employment.
- Mood status.
- Economic status: cost of regimen, insurance coverage.
- Physical functioning: weeks in bed, hospitalization.
- Medical status: self reported disease and medication history, # of doses missed.
- Coping: coping with normal work outside and at home.
- Social support: support from family and friends and other health care providers.
- Side effects.

Sensitivity and Specificity were calculated for the following self-report measures.

1. Number of dosed missed in past one month.
2. Number of doses missed in past three months.
3. Medication adherence scale.
4. Temptation to skip medication scale.

1. Number of doses missed in past one month: This was a self-reported answer to the question "how many doses of medication have you missed in the past one month". Higher numbers indicate worse compliance.

2. Number of doses missed in past three months: This was a self-reported answer to the question "how many doses of medication have you missed in the past three months".

Higher numbers indicate worse compliance.

3. *Medication Adherence Scale*: MAS or Medication Adherence Scale is a previously validated scale to measure compliance [26]. It contains six questions that are answered "yes" or "no". Each patient scored two for every 'yes' and one for every 'no'. A positive response indicates a problem with adherence and the total score range from 6-12, with higher scores indicating poorer adherence. The following questions are included in this scale:

- During the ***last 3 months***, have you ever stopped taking your protease inhibitor/ antiretroviral medication because you **felt better**?
- During the ***last 3 months***, have you ever stopped taking your protease inhibitor/ antiretroviral medication because you **felt worse**?
- During the ***last 3 months***, have you ever forgotten to take your protease inhibitor/ antiretroviral medication?
- During the ***last 3 months***, have you at times been careless about taking your protease inhibitor/ antiretroviral medication?
- During the ***last 3 months***, have you ever taken less of your protease inhibitor/ antiretroviral medicine than your doctor prescribed because you **felt better**?
- During the ***last 3 months***, have you ever taken less of your protease inhibitor/ antiretroviral medicine than your doctor prescribed because you **felt worse**?

4. Temptation to skip medication scale: This scale was developed to measure self-reported likelihood of non-compliance (Willey, C et al., manuscript in progress). The items on the temptation scale were based upon predictors of compliance from the literature and included situations that might affect the taking of protease inhibitors or anti-retrovirals as directed. Responses for each situation rated how tempted the patient would be to skip their protease inhibitor medication. The responses were measured on a five-point Likert scale (continuous) with 1=not tempted to 5=extremely tempted.

A few of the items on temptation to skip medication scale include:

- When you feel good and think you don't need it.
- When you are anxious about the side effects.
- When you want to save on the cost of medication.
- When your doctor doesn't seem interested in whether you take your medication.
- When you start feeling better.

3 categories were developed:

<u>a. Temptation to skip medication due to side effects</u>

- When you are anxious about side effects.
- When you experience minor side effects.
- When you feel you should give your body a rest.
- When you worry that the chemicals in the medication might harm your body.

b. Temptation to skip medication due to lack of support

- When your family and friends don't seem concerned enough about your condition.
- When your doctor doesn't seem concerned enough about your condition.
- When your insurance doesn't cover the cost of your medication.
- When you lose confidence in your doctor.

c. Temptation to skip medication when feeling good

- When you feel good and think you don't need it.
- When your medical condition doesn't seem that bad.
- When it seems too complex to keep track of all your medications.
- When you aren't sure if the medication is really helping you.

d. Total Scale

Scores on each sub-categories were obtained by adding items under each subscale. Score on total scale was obtained by summing all the items under all the sub-categories.

Variables Used:

The variables were coded as follows:

Demographic characteristics

Age: Categorical (AGEGRP)

≤ 25yrs: 1

26-35yrs: 2

36-45yrs: 3

46-55yrs: 4

Sex: Categorical

Male: M

Female: F

Race: Categorical

White, non-Hispanics: 1

Hispanics: 2

African American: 3

Native American: 4

Asian: 5

Others: 6

Years of education: Categorical (EDU)

>12yrs: 1

12yrs: 2

13-15yrs: 3

16+yrs: 4

Annual Income: Categorical

Less than $15,000: 1

$15,000 to $24,000: 2

$25,000 to $34,000: 3

$35,000 to $44,000: 4

$45,000 to more: 5

***Current health status*:** Categorical

Excellent: 1

Very good: 2

Good: 3

Fair: 4

Poor: 5

Insurance: Categorical

No insurance: 1

Insurance: 2

Employment status: Categorical (EMP)

Employed: 1

Not employed: 2

T-Cell count last tested: Categorical

>500: 1

201-500: 2

50-200: 3

Less than 50: 4

There were three different classes of drugs prescribed to the patients, DRUG 1, DRUG 2 and DRUG 3. DRUG 1 mostly comprised of protease inhibitors and DRUG 2 mostly comprised of ART and DRUG 3 comprised of anti-infectives.

Total Population on Protease Inhibitors (PI): All the patients who were prescribed protease inhibitor in DRUG 1 (thrice day) class comprised the total patient population on protease inhibitor. This set of patients was used for further analysis of patient population PI (n=82).

Total Population on Anti-retrovirals (ART): All the patients who were prescribed anti-retrovirals in DRUG 2 class comprised the total patient population on ART. This set of patients was used for further analysis of patient population ART (n=66). All the drugs in DRUG 2 class had different dosing schedule ranging from 2 times a day to 5 times a day, so the measures number of doses missed in past one month and number of doses missed in past three months were difficult to calculate for patient population on ART and so were not used for them.

Statistical Analysis:

Descriptive statistics were calculated for all self-report measures of compliance and for MEMS data. The data was analyzed using the Statistical Analysis System (SAS) Version 8.0 on IBM compatible computer at the University of Rhode Island.

Compliance coding strategies

A) Coding of self-report measures:

For all the measures 0 = Compliant and 1= Non-compliant.

1. <u>Number of dosed missed in the past one month</u>:

This was converted to % of doses missed in the past one month (OM) using the following formula:

OM = [(90 - # of dosed missed in the past one month) / 90] * 100

This measure was divided into two sub measures to test compliance at two different cutoffs ≥ 80% compliance and ≥ 90% compliance.

OMI: ≥ 80% Compliance

OM2: ≥ 90% Compliance

OM1: Categorical

≥ 80%: 0

<80%: 1

OM2: Categorical

≥ 90%: 0

<90%: 1

2. <u>Number of doses missed in the past three months</u>: This was converted to % of doses missed in the past three months (TM) using the following formula:

TM = [(270 - # of dosed missed in the past three months) / 270] * 100

This measure was divided into two sub measures to test compliance at two different cutoffs ≥ 80% compliance and ≥ 90% compliance.

TMI: ≥ 80% Compliance

TM2: ≥ 90% Compliance

TM1: Categorical

≥ 80%: 0

<80%: 1

TM2: Categorical

≥ 90%: 0

<90%: 1

3. Medication Adherence Scale (MAS): This scale consisted of six questions to be answered yes/no. Where the patient scored 1- for every yes and 2- for every no. With the total score ranging from 6 to 12.

This scale was recoded as 1 for every 'yes' and 0 for every 'no' to get the range from 0-6.

Total Score = Sum of the scores for all 6 answers.

***For patient population Protease inhibitors*:** The measure MAS was further divided in three sub-measures (PIM1, PIM2 and PIM3) to help determine the optimal scoring procedure for this self-report measure.

PIM1: Categorical

MAS Scores: 0= 0

MAS Scores: 1-6= 1

PIM2: Categorical

MAS Scores: 0 and 1= 0

MAS Scores: 2-6=1

PIM3: Categorical

MAS Scores: 0, 1 and 2 =0

MAS Scores: 3-6 = 1

***For patient population on Antiretrovirals*:** The measure MAS was further divided in three sub-measures (AVM1, AVM2 and AVM3) to determined the optimal scoring procedure for this self-report measure.

AVM1: Categorical

MAS Scores: 0= 0

MAS Scores: 1-6= 1

AVM2: Categorical

MAS Scores: 0 and 1= 0

MAS Scores: 2-6 = 1

AVM3: Categorical

MAS Scores: 0, 1 and 2=0

MAS Scores: 3-6 = 1

4. <u>Temptation to skip medication scale</u>: The responses for this scale were measured on a five point Likert scale (continuous) with 1= not tempted to 5= extremely tempted.

This scale was further divided into two sub-scales:

a. <u>Temptation to skip medication 12 scale</u> (TEMP 12): This scale included the twelve questions listed on pages 11-12. The total score ranged from 12 to 60 (each question contributing 1-5 points) with higher score indicating worse compliance.

b. Temptation to skip medication 13 scale (TEMP 13): This scale included the twelve questions listed in the above section with the addition of the question "When you feel like giving up". The purpose of including this particular question was to test the importance of this variable in measuring compliance.

The total score ranged from 13 to 65 with higher score indicating worse compliance with each question contributing 1-5 points.

For patient population PI: TEMP 12 and TEMP 13 scales were coded as follows on the bases of the scores obtained. The cutoffs were determined on the basis of adequate distribution of patients in each category.

PI12T1: Categorical

Temp 12 Score: 12 = 0

Temp 12 Score: 13-60 = 1

PI13T1: Categorical

Temp 13 Score: 13 = 0

Temp 13 Score: 14-65 = 1

***For patient population ART*:** TEMP 12 and TEMP 13 scales were coded as follows on the bases of the scores obtained. The cutoffs were determined on the basis of adequate distribution of patients in each category.

AV12T1: Categorical

Temp 12 Score: 12 = 0

Temp 12 Score: 13-60 = 1

AV12T2: Categorical

Temp 12 Score: 12 and 13 = 0

Temp 12 Score: 14-60 = 1

AV12T3: Categorical

Temp 12 Score: 12, 13 and 14 = 0

Temp 12 Score: 15-60 = 1

AV13T1: Categorical

Temp Score: 12 = 0

Temp Score: 13-65 = 1

AV13T2: Categorical

Temp 13 Score: 12 and 13 = 0

Temp 13 Score: 14-65 = 1

AV13T3: Categorical

Temp 13 Score: 12, 13 and 14 = 0

Temp 13 Score: 15-65 = 1

B) Coding of MEMS measures:

For all the MEMS measures 0 indicates compliant and 1 indicates non-compliant. Two MEMS measures were used as different gold standards. One indicating ≥ 80% doses taken as prescribed, the other indicating ≥ 90% of doses taken as prescribed.

MEMS1 (Gold standard I): Tested the compliance at 80% cutoff. This measure was coded as follows:

MEMS1: Categorical

≥ 80%= 0

<80%= 1

MEMS2 (Gold standard II): Tested the compliance at 90% cutoff. This measure was coded as follows:

MEMS2: Categorical

≥ 90%= 0

<90%= 1

Comparison of self-report measures with MEMS:

For each patient a comparison of compliance behavior was made between self-report measures and MEMS reported compliance. True positive (A) indicated both the self-report and the MEMS gold standard show compliance. False positive (B) indicated the self-report indicates compliance but the MEMS gold standard indicates noncompliance. False negative (C) indicated that the self-report indicates noncompliance but MEMS gold standard indicates compliance. True negative (D) indicated that both the self-report and MEMS gold standard both indicate noncompliance.

Example considering Gold standard I (MEMS ≥ 80% doses taken) and Self-report measure # 1 (% of doses taken in the past one month):

		MEMS	
		≥80% Compliant	<80% Compliant
SELF-REPORT	≥ 80% of doses taken in the past one month	**A**	**B**
	< 80% of doses taken in the past one month	**C**	**D**

Where A= True positive, B= False positive, C= False negative and D= True negative. Sensitivity and Specificity were calculated for all the measures. Sensitivity is defined as the proportion of the population who truly has the characteristics that are correctly classified as having it.

$$\textbf{Sensitivity} = \frac{\textbf{(true-positive)}}{\textbf{(true positive + false-negative)}} = \frac{A}{(A+C)}$$

Specificity is defined as the proportion of the population who truly do not have the characteristic that are correctly classified as not having it.

$$\textbf{Sensitivity} = \frac{\textbf{(true-negative)}}{\textbf{(true negative + false-positive)}} = \frac{D}{(B+D)}$$

Sensitivity and Specificity are the quantitative indices of the accuracy of measurement [27].

The overall agreement between the self-report and MEMS was measured using kappa statistics. Kappa statistics an index of reliability. Reliability, or reproducibility, refers to the extent to which results of a measurement can be replicated [27,23].

$$\text{Kappa coefficient (K)} = \frac{\text{Observed agreement} - \text{Expected agreement}}{1 - \text{Expected agreement}}$$

The kappa coefficient is an important characteristic of correcting for the chance agreement that would be expected to occur if two classifications were completely unrelated. Failure to take into account chance agreement can lead erroneous conclusions about the quality of measurement. Kappa performance was analyzed using standard nomenclature <0 poor; 0 to 0.2 slight; 0.21 to 0.4 fair; 0.41 to 0.6 moderate; 0.61 to 0.8 substantial; 0.8 to 1 almost perfect [27,23].

RESULTS

A total population of 145 patients was enrolled in the original study. A sub-population of 86 patients participated in the MEMS monitoring. Demographic data is shown in table A. Eighty two of these were on protease inhibitors (PI), and 66 patients were on anti-retroviral therapy (ART). The median age was 38.5 years and age ranged from 26-55 years. White-non-Hispanics represented 80% of the 86 patient population, Hispanics 3.5%, African American 3.5% and Native Americans 6%. Most of the patients were uninsured (95%) and 58% were unemployed. Eighty six percent had at least high school education. More than half of the study population had an annual income of less than $15,000. Thirty-five percent had very good health status and 43% had good health status.

I. For Population on Protease Inhibitor:

A) Comparison between MEMS and % of doses missed in the past one month.

For this measure n=68. This measure was compared with two different compliance levels i.e. • 80% compliance and • 90% compliance as determined by MEMS.

Table 1-2 and Tables 12-13: Shows the agreement between compliance as measured by MEMS and by self-report % doses missed in the past one month. All the patients (68/68) were classified as compliant for ≥ 80% compliance # of doses missed in the past one month. In contrast, only (47/68) 69% were classified as ≥ 80% compliance level by MEMS. This shows a clear indication of overestimation of adherence by self-report.

The highest sensitivity i.e.100% was recorded for both ≥ 80% compliance number of doses missed in the past one month and ≥ 90% compliance of doses missed in the past one month, at both 80% and 90% cutoffs for MEMS. The specificity remained low, at all the above levels indicating a low accuracy of the measure. The value of kappa was 0.00 and 0.13 for >80% number of doses missed in the past one month and >90% number of doses missed in the past one month respectively at >80% compliance determined by MEMS and 0.00 and 0.06 for >80% # of doses missed and >90% number of doses missed respectively at >90% compliance determined by MEMS indicating low reliability of the measure.

B) Comparison between MEMS and % of doses missed in the past three months.

For this measure n=68. The measure was studied at 2 different compliance levels i.e. >80% compliance and >90% compliance.

Table 3-4 and Tables 14-15: Shows the agreement between MEMS and % doses missed in the past three months. 99% of the population was classified as compliant at >90% number of doses missed in the past three months, in contrast to 69% by MEMS report.

The highest sensitivity i.e.100% was recorded for both >80% compliance number of doses missed in the past three months and >90% compliance number of doses missed in the past three months, at both 80% and 90% cutoffs for MEMS. The specificity remained low, at all the above levels indicating a low accuracy. The value of kappa was 0.00 and 0.05 for >80% number of doses missed in the past three months and >90% number of doses missed in the past three months respectively at >80%

compliance determined by MEMS and 0.00 and 0.03 for >80% number of doses missed in the past three months and >90% number of doses missed in the past three months respectively at >90% compliance determined by MEMS indicating low reliability of the measure.

C) Comparison between MEMS and Medication Adherence Scale (MAS).

For this measure the total population was n=67. Three different cutoff scores were used to determine which was the most useful.

Table 5-7 and Tables 14-16: Shows the agreement between MEMS and Medication Adherence Scale. The highest sensitivity was seen when the score of 0,1 and 2 on MAS was set as compliant and the score 3 or more as noncompliant for both >80% and >90% of doses taken as measured by MEMS. The highest specificity was observed when the score of 0 was set as compliant and the score of 1or more as non-complaint at both 80% and 90% cutoff values for MEMS. The agreement with MEMS data was highest when scores of 0,1 and 2 was set as compliant and 3 or more as non-complaint (K=0.37) for >80% compliance MEMS and when the score of 0 was set as complaint and 1 or more as non-compliant (K=0.31) for >90% compliance MEMS indicating fair reliability.

D) Comparison between MEMS and Temptation to skip medication scale 12 (TEMP12).

For this measure the total population was n=64.

Table 8 and 17: Shows the agreement between MEMS and Temptation to skip medication scale 12. The total score on the scale ranged from 12-60. Two different

cutoff scores were used to determine the most useful level. When the cutoff score of 12 was set as complaint and 13 and more as non-compliant, the sensitivity remained i.e. 0.52 for both >80% compliance and >90% compliance MEMS, but the specificity was higher at the >80% cutoff for MEMS (0.61) as compared to >90% cutoff for MEMS (0.55). This measure showed a low reliability at kappa values of 0.06 (>80% compliance MEMS) and 0.11 (>90% compliance MEMS).

E) Comparison between MEMS and Temptation to skip medication scale 13 (TEMP13).

For this measure the total population was n=64.

Table 9 and 18: Shows the agreement between MEMS and Temptation to skip medication scale 13. The total score on the scale ranged from 13-65. Two different cutoff scores were used to determine the most useful level. When the cutoff score of 13 was set as complaint and 14 and more as non-compliant, the sensitivity remained the same i.e. 0.52 for both >80% compliance and >90% compliance MEMS, but the specificity was higher at the >80% cutoff for MEMS (0.61) as compared to >90% cutoff for MEMS (0.55). This measure showed a low reliability at kappa values of 0.06 (>80% compliance MEMS) and 0.11 (>90% compliance MEMS).

For patients on Anti-retroviral therapy:

F) Comparison between MEMS and Medication Adherence Scale (MAS).

For this measure the total population was n=62. Three different cutoff scores were used to determine which one was the most useful.

Table 19-21 and Tables 27-29: Shows the agreement between MEMS and Medication Adherence Scale. The total score on the scale ranged from 6-36. The highest sensitivity of 0.98 was seen when the score of 0, 1 and 2 was set as compliant and the score of 3 and more as non-compliant for both >80% and >90% of doses taken as measures by MEMS. The highest specificity was observed when the score of 0 was set as compliant and 1 or more as non-complaint for both 80% and 90% cutoff values for MEMS. The agreement with MEMS was highest when the score of 0 was set as complaint and 1 or more as non-complaint (K=0.16) for >80% compliance MEMS and (K=0.33) for >90% compliance MEMS indicating fair reliability.

G) Comparison between MEMS and Temptation to skip medication scale 12 (TEMP12).

For this measure the total population was n=64. Three different cutoff scores were used to determine which one was the most useful.

Table 22-24 and Tables 30-32: Shows the agreement between MEMS and Temptation to skip medication scale 12. The total score on the scale ranged from 12-60. The highest sensitivity of 0.61 and 0.66 was seen when the score of 12, 13 and 14 was set as compliant and the score of 15 and more as non-compliant for both >80% and >90% of doses taken as measured by MEMS respectively. The highest specificity of 0.68 and 0.64 was observed when the score of 12 was set as compliant and 13 or more as non-compliant for both 80% and 90% cutoff values for MEMS respectively. The agreement with MEMS was highest when the score

of 12 and 13 was set as complaint and 14 or more as non-compliant i.e. K=0.16 for >90% compliance MEMS.

H) Comparison between MEMS and Temptation to skip medication scale 13 (TEMP13).

For this measure the total population was n=56. Two different cutoff scores were used to determine which one was the most useful.

Table 25-26 and Tables 33-34: Shows the agreement between MEMS and Temptation to skip medication scale 13. The total score on the scale ranged from 13-65. The highest sensitivity of 0.57 and 0.61 was seen when the score of 13 and the score of 14 was set as compliant and the score of 15 and more as non-compliant for both >80% and >90% of doses taken as measured by MEMS respectively. The highest specificity of 0.68 and 0.64 was observed when the score of 13 was set as compliant and 14 or more as non-complaint for both 80% and 90% cutoff values for MEMS respectively. The agreement with MEMS was highest at the when the score of 13 and 14 was set as compliant and 15 or more as non-complaint i.e. K=0.21 for >90% compliance, indicating fair reliability of the measure at this particular cutoff.

DISCUSSION

There is little debate that adherence to treatment recommendations has a major impact on health outcomes and the cost of health care. For medications, the health effect of deviations from recommended therapy is a function of the pharmacological properties of the medication prescribed. The methods used to estimate adherence in research or practice must be sensitive variations in adherence that meaningfully affect health outcomes.

Formal validation of the many alternative methods of adherence assessment has not been extensive. No published study has evaluated all these measures against electronic monitoring in the same population.

In this study we examined the accuracy of various self-report measures of adherence with electronically monitored adherence.

Number of doses missed in past one month:

The results for the second measure i.e. numbers of doses missed in the past three months were very much similar to the first measure. The sensitivity was 100% indicating that the complaint patients were correctly classified, as being complaint, at the same time the specificity was zero, indicating that the non-compliant patients were incorrectly classified, as complaint. Therefore there was only a slight agreement between the compliance reported using this measure and MEMS report, indicating low reliability of this measure.

Number of doses missed in the past three months:

The results for the second measure i.e. numbers of doses missed in the past three months were very much similar to the first measure. The sensitivity was 100% indicating that the complaint patients were correctly classified, as being complaint, at the same time the specificity was zero, indicating that the non-compliant patients were incorrectly classified as complaint. Therefore there was only a slight agreement between the compliance reported using this measure and MEMS report (K= 0.05 and 0.03) indicating low reliability of this measure.

Medication Adherence Scale:

The third measure MAS was studied at three different cutoff scores, for both subsets of population i.e. patients on PI and patients on ART.

In the PI population when the MAS was coded as, score of 0 as compliant and 1 or more as non-compliant, it underestimated adherence as compared to MEMS report and showed low sensitivity and high specificity. This indicated that the non-compliant patients were correctly classified as non-adherent, but at the same time the all the compliant patient were not correctly classified as compliant. Both the sensitivity and specificity were higher at ≥ 90% compliance MEMS then at ≥ 80% compliance MEMS, indicating greater accuracy at higher cutoff compliance values. The agreement of this measure was better with ≥ 90% compliance MEMS (K=0.26) as compared to ≥ 80% compliance MEMS (K=0.31), indicating better reliability at 90% cutoff i.e. more stringent conditions. When the MAS was coded as, score of 0 and 1 as compliant and 2 or more as non-compliant, it showed good sensitivity compared to

specificity, indicating poor accuracy of this method, also greater accuracy was seen at 90% cutoff as compared to 80%. The agreement with MEMS was fair (K=0.22) when compared with ≥ 80% compliance MEMS and (K=0.25) with ≥ 90% compliance MEMS.

When the MAS was coded as, score of 0, 1 and 2 as compliant and 3 or more as non-compliant, it showed a very high sensitivity and a low specificity leading to overestimation of compliance. The reliability and accuracy results were opposite at this level of compliance on MAS, the agreement at ≥ 90% compliance MEMS (K=0.15) was lower than at ≥ 80% compliance MEMS, also the accuracy was lower at 90% cutoff compared to 80%. This indicated that as compliance level become less stringent the accuracy and reliability of the measure decreases.

In the patients with ART, when the MAS was coded as, score of 0 as compliant and 1 or more as non-complaint, it showed a higher sensitivity as compared to specificity. Both the sensitivity and specificity was higher at ≥ 90% compliance MEMS then at ≥ 80% compliance MEMS. The agreement of this measure with ≥ 90% compliance MEMS (K=0.33) was greater then with ≥ 80% compliance MEMS (K=0.16). When the score of 0 and 1 was coded as compliant and 2 or more as non-compliant, it showed higher sensitivity and lower specificity as compared to the score of 0 as compliant and 1 or more as non-complaint. When the MAS scale was coded as, score of 0,1 and 2 as compliant and 3 or more as non-compliant, the measure showed highest sensitivity as compared to the other two cutoffs. A higher sensitivity was observed at 90% cutoff MEMS and compared with 80% cutoff MEMS. The reliability

of this measure was similar both at ≥ 90% compliance MEMS and ≥ 80% compliance MEMS i.e. 0.15.

Temptation to skip medication scale 12:

In patients on PI, when the TEMP 12 scale was coded as, score of 12 as compliant and 13 or more as non-complaint this measure showed average sensitivity and specificity indicating fair accuracy of this measure, similar results were seen for both 80% and 90% cutoff MEMS. But according to the kappa statistics agreement of this measure with MEMS was only slight indicating a poor reliability (K=0.11 and 0.06).

For patients on ART, this measure was studied at three different cutoffs to determine which one is more useful. When the TEMP 12 scale was coded as, score of 12 as compliant and score of 13 or more as non-complaint, it showed lower sensitivity as compared to specificity. Indicating that the compliant patients were wrongly categorized as non-compliant. Thus indicating poor accuracy. There was a slight agreement with MEMS report both at ≥ 80% compliance (K=0.16) and ≥ 90% compliance.

When the TEMP 12 scale was coded as, score of 12 and 13 as complaint and 14 or more as non-compliant, it showed average sensitivity and specificity, at ≥ 90% compliance MEMS indicating good accuracy of this method. But the agreement with MEMS was slight both at 80% (0.19) and 90% cutoff (K=0.16). When the TEMP 12 scale was coded as score of 12, 13 and 14 as complaint and 15 or more as non-compliant, the reliability at ≥80% compliance MEMS (K=0.18) was slight as compared to ≥ 90% compliance MEMS (K=0.21), these kappa values indicated fair

agreement between the two measures i.e. temptation to skip medication scale and MEMS reported compliance. The sensitivity and specificity were higher at this level as compared to other two cutoffs.

Temptation to skip medication scale 13:

In patients on PI when the TEMP 13 scale was coded as, score of 13 as complaint and 14 or more as non-complaint, the measured showed average sensitivity and specificity indicating fair accuracy of this measure. Similar results were seen for both 80% and 90% cutoff MEMS at this cutoff value on TEMP 13 scale. At the same time the agreement of this measure with MEMS was only slight indicating a poor reliability.

There was no difference in both the accuracy and reliability of temptation to skip medication 12 scale and temptation to skip medication 13 scale at both ≥ 80% and ≥ 90% compliance measures by MEMS for this particular cutoff.

For patients on ART this measure was studied at two different cutoffs to determine which one was more useful. When the TEMP 13 scale was coded as, score of 13 as compliant and 14 or more as non-complaint, it showed low sensitivity as compared to specificity. This indicated that the compliant patients were wrongly categorized as non-compliant. Thus indicating low accuracy. There was only a slight agreement between the MEMS reported compliance and this measure at both ≥ 80% compliance MEMS (K=0.17) and ≥ 90% compliance MEMS (K=0.18) according to the kappa statistics.

When the TEMP 13 scale was coded as, score of 13 and 14 as compliant and 15 or more as non-complaint, it had average sensitivity and specificity (0.61), at ≥ 90%

compliance MEMS indicating good accuracy of this method. The agreement with MEMS was fair (0.21) at ≥ 90% compliance MEMS indicating average reliability. There was only slight agreement with MEMS report at 80% compliance MEMS (0.18).

The ideal measure of compliance is the one, which has both, good sensitivity and specificity. For the patients on PI, MAS indicated to be a good measure of compliance. When the score was set as 0 as complaint and 1 or more as non-compliant, it showed both good accuracy and fair reliability. Temptation to skip medication had good accuracy but only slight reliability.

For patients on ART, good accuracy and reliability was seen only at ≥ 90% compliance MEMS. MAS subscale (score of 0 as complaint and 1 or more non-compliant) had good sensitivity and specificity and also average reliability. Temptation to skip medication scale 13 indicated good accuracy at the same time had fair reliability.

Limitations

Generalizability: The study population was not randomly selected. This puts limitation on extrapolating the results for the entire population. The results of this study do not demonstrate the extent of discrepancies between the self-report and electronic measure of adherence as previously demonstrated in the literature. There are two possible explanations for these findings. First patients in this study were asked to document unintentional opening of their MEMS cap on the blank calendar dispensed

to them at the baseline. As a result, some patients documented missed doses or late doses, which may have increased their recall and self-report of non-adherence over previous month. Second, the adherence findings from the study are from a young, educated, and motivated population with very high degree of adherence, according to dose percentage calculations. It is possible that self-report, in general, may exceed MEMS report to a large extent in a markedly nonadherent population and to a lesser degree in a very adherent patient group.

CONCLUSION

The objective of this study was to test the sensitivity, specificity and reliability of various self-report measures, considering MEMS report as the standard.

Self-reported number of doses missed in the past one month and number of doses missed in the past three months overestimated adherence as compared to MEMS report. Both these self-report measures showed high sensitivity and low specificity, which indicated low accuracy of this measure. A probable reason for low accuracy may be recall memory errors such as forgetting (underreport) and telescoping (overestimation).

It is also seen that in comparison to number of doses missed in the past one month, number of doses missed in the past three months had even lower accuracy and reliability, though not very significant. This might be due an even greater the recall bias, as the memory of the person becomes weaker over long period of time.

These results were contradictory to a published report which found reported that self-reports were more accurate measures than when number of missed doses was used to measure compliance (Chesney et al., 1999).

Medication Adherence Scale was divided into three sub-categories to access compliance at various levels. It was observed that as the criteria for assessment became less stringent, more non-compliant patients were incorrectly categorized as compliant leading to decrease in the accuracy of the method. The reliability also decreased simultaneously.

Higher accuracy and reliability was obtained at the more (higher) stringent levels of compliance and MEMS ≥ 90% compliance as compared with others.

Overall this measure showed a fair agreement with the MEMS report at all higher cutoff points (stringent conditions). The reliability and the accuracy of this measure were better in the PI population than in the ART population.

Temptation to skip medication scale was also broken down into sub categories to test compliance at various levels. Similar results as those for MAS were obtained, except for temptation to skip medication scale 13 (Score of 13 coded as compliant and 14 or more as non-compliant) were there was an increase in the reliability along with the increase in sensitivity and decrease in specificity. This might be due to setting up very high (stringent) levels of compliance, that even most of the compliant patients were classified as non-complaint.

The addition of the additional question in temptation to skip medication scale 13 did not make a significant difference in the assessment of compliance. The results of these studies regarding the accuracy and reliability of self-report measures of medication adherence are disappointing, particularly given the reliance on self-report methodology among the clinical and research communities.

The overall results of all the self-report measures were consistent with the literature on compliance that self-report methods consistently overestimate patient adherence (Cramer et al., 1989; Waterhouse et al., 1993).

The study found that measuring compliance on continuous scales like MAS or temptation to skip medication scale, where the patients were asked about their general

attitude towards the medication regimen, are more accurate and reliable measures to detect compliance as compared with number of doses missed. Therefore, these scales could be further developed in future research to yield better measures to detect compliance.

In general it was seen for all the measures, that when the criteria for compliance was set more stringent, it gave more accurate and reliable results.

Additional studies will be required to replicate these findings in other HIV populations.

TABLE A: Demographics of population used N=86

Demographics	N (%)	Mean	SD†	Min††	Max†††
Age					
>= 25 yrs	0 (0%)	2.8953	0.7825	2.0000	4.0000
26-35 yrs	31 (36.05%)				
36-45 yrs	33 (38.37%)				
46-55 yrs	22 (25.58%)				
SEX					
Males	75 (87.21%)	–	–	–	–
Females	11 (12.79%)				
Race					
White, non-Hispanics	69 (80.23%)	1.6744	1.5219	1.0000	1.0000
Hispanics	3 (3.49%)				
African American	3 (3.49%)				
Native American	6 (6.98%)				
Asian	0 (0%)				
Others	5 (5.81%)				
Education					
> 12 yrs	14 (16.28%)	2.4186	0.9262	1.0000	4.0000
12 yrs	34 (39.53%)				
13-15 yrs	26 (30.23%)				
16 + yrs	12 (13.95%)				
Annual Income					
Less than $15,000.	45 (54.88%)	2.0121	1.4271	1.0000	5.0000
$15000 to $24,000.	17 (20.73%)				
$25,000 to $34,000.	5 (6.10%)				
$35,000 to $44,000.	4 (4.88%)				
$45,000 or more	11 (13.41%)				
Current health status					
Excellent	9 (10.47%)	2.5581	0.8346	1.0000	4.0000
Very Good	30 (34.88%)				
Good	37 (43.02%)				
Fair	10 (11.63%)				
Poor	0 (0%)				
T-Cell count					
< 500	20 (23.81%)	2.1547	0.8572	1.0000	4.0000
201-500	36 (42.86%)				
50-200	23 (27.38%)				
Less than 50	5 (5.95%)				
Employment Status					
Employed	36 (41.86%)	1.4186	0.4962	1.0000	2.0000
Unemployed	50 (58.14%)				
Insurance					
No insurance	82 (95.35%)	1.0465	0.2118	1.0000	2.0000
Some insurance	4 (4.65%)				

SD†: Standard deviation.
Min††: Minimum
Max†††: Maximum

Table B:

Self-report measures of adherence for patients on protease inhibitors.

Nos.	Self-report measures	N	Mean	SD†	Min††	Max†††
1.	Number of doses missed in past one month.	72	1.60855	2.48843	0	12
2.	Number of doses missed in past three months.	71	3.57746	5.38957	0	30
3.	Medication Adherence Scale.	71	1.09859	1.28901	0	6
4.	Temptation to skip medication scale 12	68	16.3235	8.01387	12	60
5.	Temptation to skip medication scale 13	68	17.7941	8.81748	13	65

SD†: Standard deviation.
Min††: Minimum
Max†††: Maximum

Table C:

Self-report measure of adherence for patients on anti-retroviral therapy.

Nos.	Self-report measures	N	Mean	SD†	Min††	Max†††
1.	Medication Adherence Scale	64	0.8437	0.9955	0	4
2.	Temptation to skip medication 12	59	15.745	5.2966	12	33
3.	Temptation to skip medication 13	58	17.086	5.9773	13	38

SD†: Standard deviation.
Min††: Minimum
Max†††: Maximum

TABLE D:

Compliance coding strategies for patients on protease inhibitors.

Self-report measures	Coding 0=†C and 1=††NC	N (%)	Mean	SD†	Min††	Max†††
1)% of doses missed in past one month.						
a. OM1	≥ 80%=0 and < 80%=1.	72	0	0	0	0
b. OM2	≥ 90%=0 and < 90%=1.	72	0.02777	0.1654	0	1
2) % of doses missed in past 3 months.						
a. TM1	≥ 80%=0 and < 80%=1.	71	0	0	0	0
b. TM2	≥ 90%=0 and < 90%=1.	71	0.01408	0.11867	0	1
3) Medication Adherence Scale (MAS) 0-6						
a. PIM1	0 = 0 and 1+ = 1.	71	0.57746	0.49747	0	1
b. PIM2	0 and 1=0 and 2+ = 1.	71	0.30985	0.46572	0	1
c. PIM3	0,1 and 2= 0 and 3+ = 1.	71	0.12676	0.33507	0	1
4) Temptation to skip medication Scale 12 (12-60)						
a. PI12TI	12 = 0 and 13+ = 1.	68	0.51470	0.50349	0	1
5) Temptation to skip medication Scale 13 (13-65)						
b. PI13TI	13= 0 and 14+ = 1.	68	0.51470	0.50349	0	1

†C= Compliant and ††NC = Non Compliant
SD†: Standard deviation.
Min††: Minimum
Max†††: Maximum

TABLE E:

Compliance coding strategies for patients on Anti-retroviral therapy.

Self-report measures	Coding 0=†C and 1=††NC	N	Mean	SD†	Min††	Max†††
1) Medication Adherence Scale (MAS) 0-6						
a. AVM1	0 = 0 and 1+ = 1.	71	0.57746	0.49747	0	1
b. AVM2	0 and 1=0 and 2+ = 1.	71	0.30985	0.46572	0	1
c. AVM3	0,1 and 2= 0 and 3+ = 1.	71	0.12676	0.33507	0	1
2) Temptation to skip medication Scale 12 (12-60)						
a. AV12TI	12 = 0 and 13+ = 1.	68	0.51470	0.50349	0	1
b. AV12T2	12 and 13 = 0 and 14+ = 1.					
c. AV12T3	12, 13 and 14 = 0 and 15+ = 1					
3) Temptation to skip medication Scale 13 (13-65)						
a. AV13TI	13= 0 and 14+ = 1.	68	0.51470	0.50349	0	1
b. AV13T2	13 and 14 = 0 and 15+ = 1.					
c. AV13T3	13, 14 and 15 = 0 and 16+ = 1					

†C= Compliant and ††NC = Non Compliant
SD†: Standard deviation.
Min††: Minimum
Max†††: Maximum

TABLE F:

Compliance coding strategies for MEMS data for patients on protease inhibitors.

MEMS Measures	Coding 0=†C and 1=††NC	N	Mean	SD†	Min††	Max†††
1) Gold Standard I MEMS 1	≥ 80%=0 and < 80%=1.	64	0.34375	0.47871	0	1
2) Gold Standard II MEMS2	≥ 90%=0 and < 90%=1.	64	0.48437	0.50370	0	1

†C= Compliant and ††NC = Non Compliant
SD†: Standard deviation.
Min††: Minimum
Max†††: Maximum

TABLE G:

Compliance coding strategies for MEMS data for patients on Anti-retroviral therapy.

MEMS Measures	Coding 0=†C and 1=††NC	N	Mean	SD†	Min††	Max†††
1) Gold Standard I MEMS 1	≥ 80%=0 and < 80%=1.	64	0.34375	0.47871	0	1
2) Gold Standard II MEMS2	≥ 90%=0 and < 90%=1.	64	0.48437	0.50370	0	1

†C= Compliant and ††NC = Non Compliant
SD†: Standard deviation.
Min††: Minimum
Max†††: Maximum

TABLE H:

Sensitivity, Specificity and Kappa statistics for various Self-report measures for patients on Protease inhibitors. ≥ 80% Compliance by MEMS (Gold Standard I)

Nos.	Self-report measures	Sensitivity	Specificity	Expected agreement	Observed agreement	Kappa
1	# of doses missed in past one month (≥ 80%=C† & <80%=††NC)	1.00	0.00	0.69	0.69	0.00
2	# of doses missed in one past month (≥ 90%=C† & <90%=††NC)	1.00	0.10	0.72	0.72	0.13
3	# of dosed missed in past three months (≥ 80%=C† & <80%=††NC)	1.00	0.00	0.69	0.69	0.00
4	# of doses missed in three past month (≥ 90%=C† & <90%=††NC)	1.00	0.05	0.69	0.71	0.06
5	Medication Adherence Scale (0=C† & 1+=††NC)	0.53	0.80	0.61	0.61	0.26
6	Medication Adherence Scale (0 & 1=C† & 2+=††NC)	0.77	0.45	0.67	0.67	0.22
7	Medication Adherence Scale (0,1&2=C† & 3+=††NC)	0.96	0.35	0.78	0.78	0.37
8	Temptation to skip medication scale 12 (12=C† &13+=††NC)	0.52	0.61	0.55	0.55	0.11
9	Temptation to skip medication scale 13 (13=C† &14+=††NC)	0.52	0.61	0.55	0.55	0.11

† C= Compliant
†† NC= Noncompliant

TABLE I:

Sensitivity, Specificity and Kappa statistics for various Self-report measures for patients on Protease inhibitors. ≥ 90% Compliance by MEMS (Gold Standard II)

Nos.	Self-report measures	Sensitivity	Specificity	Expected agreement	Observed agreement	Kappa
1	# of doses missed in past one month (≥ 80%=C† & <80%=††NC)	1.00	0.00	0.50	0.50	0.00
2	# of doses missed in one past month (≥ 90%=C† & <90%=††NC)	1.00	0.06	0.50	0.53	0.06
3	# of dosed missed in past three months (≥ 80%=C† & <80%=††NC)	1.00	0.00	0.50	0.50	0.00
4	# of doses missed in three past month (≥ 90%=C† & <90%=††NC)	1.00	0.03	0.50	0.51	0.03
5	Medication Adherence Scale (0=C† & 1+=††NC)	0.59	0.73	0.50	0.66	0.31
6	Medication Adherence Scale (0 & 1=C† & 2+=††NC)	0.82	0.42	0.50	0.63	0.25
7	Medication Adherence Scale (0,1&2=C† & 3+=††NC)	0.94	0.21	0.51	0.58	0.15
8	Temptation to skip medication scale 12 (12=C† &13+=††NC)	0.52	0.55	0.50	0.53	0.06
9	Temptation to skip medication scale 13 (13=C† &14+=††NC)	0.52	0.55	0.50	0.53	0.06

† C= Compliant
†† NC= Noncompliant

TABLE J:

Sensitivity, Specificity and Kappa statistics for various Self-report measures for patients on Anti-retroviral therapy. ≥ 80% Compliance by MEMS (Gold Standard I)

Nos.	Self-report measures	Sensitivity	Specificity	Expected agreement	Observed agreement	Kappa
1	Medication Adherence Scale (0=†C & 1+=††NC)	0.51	0.67	0.48	0.56	0.16
2	Medication Adherence Scale (0 & 1=†C & 2+=††NC)	0.83	0.29	0.59	0.65	0.13
3	Medication Adherence Scale (0,1 &2=†C & 2+=††NC)	0.98	0.14	0.64	0.69	0.15
4	Temptation to skip medication scale 12 (12=†C &13+=††NC)	0.50	0.68	0.48	0.56	0.16
5	Temptation to skip medication scale 12 (12 & 13=†C &14+=††NC)	0.55	0.63	0.50	0.58	0.16
6	Temptation to skip medication scale 12 (12,13&14=†C&15+=††NC)	0.61	0.47	0.53	0.56	0.07
7	Temptation to skip medication scale 13 (13=†C &14+=††NC)	0.51	0.68	0.48	0.57	0.17
8	Temptation to skip medication scale 13 (13 & 14=†C &15+=††NC)	0.57	0.63	0.50	0.59	0.18

†C= Compliant
††NC= Noncompliant

TABLE K:

Sensitivity, Specificity and Kappa statistics for various Self-report measures for patients on Anti-retroviral therapy. ≥ 90% Compliance by MEMS (Gold Standard II)

Nos.	Self-report measures	Sensitivity	Specificity	Expected agreement	Observed agreement	Kappa
1	Medication Adherence Scale (0=†C & 1+=††NC)	0.61	0.72	0.50	0.66	0.33
2	Medication Adherence Scale (0 & 1=†C & 2+=††NC)	0.88	0.31	0.52	0.61	0.20
3	Medication Adherence Scale (0,1 &2=†C & 2+=††NC)	1.00	0.14	0.53	0.60	0.15
4	Temptation to skip medication scale 12 (12=†C &13+=††NC)	0.52	0.64	0.50	0.58	0.16
5	Temptation to skip medication scale 12 (12 & 13=†C &14+=††NC)	0.59	0.61	0.50	0.60	0.19
6	Temptation to skip medication scale 12 (12,13&14=†C&15+=††NC)	0.66	0.50	0.50	0.58	0.16
7	Temptation to skip medication scale 13 (13=†C &14+=††NC)	0.54	0.64	0.50	0.59	0.18
8	Temptation to skip medication scale 13 (13 & 14=†C &15+=††NC)	0.61	0.61	0.50	0.61	0.21

† C= Compliant
†† NC= Noncompliant

Table 1:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure # 1 (≥ 80% of doses taken in past one month) for patient population on protease inhibitor.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	≥ 80% compliance (≥ 80% of doses taken in the past one month)	47	21	68
	< 80% compliance (≥ 80% of doses taken missed the past one month)	0	0	0
	Total	47	21	68

Sensitivity = 47/47 * 100 = **100%**

Specificity = 0/21 * 100 = **0%**

Table 2:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure # 2 (≥ 90% of doses taken in past one month) for patient population on protease inhibitor.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	≥ 90% compliance (≥ 90% of doses taken in the past one month)	47	19	66
	< 90% compliance (≥ 90% of doses missed in the past one month)	0	2	2
	Total	47	21	68

Sensitivity = 47/47 * 100 = **100%**

Specificity = 2/21 * 100 = **10%**

Table 3:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure # 3 (≥ 80% of doses taken in past three months) for patient population on protease inhibitor.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	≥ 80% compliance (≥ 80% of doses taken in the past three months)	47	20	67
	< 80% compliance (≥ 80% of doses missed in the past three months)	0	1	1
	Total	47	21	68

Sensitivity = 47/47 * 100 = **100%**

Specificity = 1/21 * 100 = **5%**

Table 4:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure # 4 (≥ 90% of doses taken in past three months) for patient population on protease inhibitor.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	≥ 90% compliance (≥ 90% of doses taken in the past three months)	47	21	68
	< 90% compliance (≥ 90% of doses missed in the past three months)	0	0	0
	Total	47	21	68

Sensitivity = 47/47 * 100 = **100%**

Specificity = 2/21 * 100 = **10%**

Table 5:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure #5 (Medication Adherence Scale) for patients on Protease Inhibitor.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Medication Adherence Scale 0 = †C	25	4	29
	Medication Adherence Scale 1+ = ††NC	22	16	38
	Total	47	20	67

Sensitivity = 25/47 * 100 = **53%**

Specificity = 16/20 * 100 = **80%**

† C= Compliant
†† NC= Noncompliant

Table 6:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure #6 (Medication Adherence Scale) for patients on Protease Inhibitor.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Medication Adherence Scale 0 and 1= †C	36	11	47
	Medication Adherence Scale 2+ = ††NC	11	9	20
	Total	47	20	67

Sensitivity = 36/47 * 100 = **77%**

Specificity = 9/20 * 100 = **45%**

† C= Compliant
†† NC= Noncompliant

Table 7:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure # 7 (Medication Adherence Scale) for patients on Protease Inhibitor.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Medication Adherence Scale 0,1 and 2= †C	45	13	58
	Medication Adherence Scale 3+ = ††NC	2	7	9
	Total	47	20	67

Sensitivity = 45/47 * 100 = **96%**

Specificity = 7/20 * 100 = **35%**

† C= Compliant
†† NC= Noncompliant

Table 8:

Agreement between Gold Standard I (≥ 90% compliance MEMS) and Self-report measure #8 (Temptation to skip medication scale 12) for patients on Protease Inhibitor.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Temptation to skip medication Scale 12 12 = †C	24	7	31
	Temptation to skip medication Scale 12 13+ = ††NC	22	11	33
	Total	46	18	64

Sensitivity = 24/46 * 100 = **52%**

Specificity = 11/18 * 100 = **61%**

† C= Compliant
†† NC= Noncompliant

Table 9:

Agreement between Gold Standard I (≥ 90% compliance MEMS) and Self-report measure #9 (Temptation to skip medication scale 13) for patients on Protease Inhibitor.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Temptation to skip medication Scale 13 13= †C	24	7	31
	Temptation to skip medication Scale 13 14+ = ††NC	22	11	33
	Total	46	18	64

Sensitivity = 24/46 * 100 = **52%**

Specificity = 11/18 * 100 = **61%**

† C= Compliant
†† NC= Noncompliant

Table 10:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 1 (≥ 80% of doses taken in past one month) for patient population on protease inhibitor.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	≥ 80% compliance (≥ 80% of doses taken in the past one month)	34	34	68
	< 80% compliance (≥ 80% of doses taken missed the past one month)	0	0	0
	Total	34	34	68

Sensitivity = 34/34 * 100 = **100%**

Specificity = 0/34 * 100 = **0%**

Table 11:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 2 (≥ 90% of doses taken in past one month) for patient population on protease inhibitor.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	≥ 90% compliance (≥ 90% of doses taken in the past one month)	34	32	66
	< 90% compliance (≥ 90% of doses taken missed the past one month)	0	2	2
	Total	34	34	68

Sensitivity = 34/34 * 100 = **100%**

Specificity = 2/34 * 100 = **6%**

Table 12:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 3 (≥ 80% of doses taken in past three months) for patient population on protease inhibitor.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	≥ 80% compliance (≥ 80% of doses taken in the past one month)	34	34	68
	< 80% of doses taken in the past three months=††NC	0	0	0
	Total	34	34	68

Sensitivity = 34/34 * 100 = **100%**

Specificity = 0/34 * 100 = **0%**

Table 13:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 4 (≥ 90% of doses taken in past three months) for patient population on protease inhibitor.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	≥ 90% compliance (≥ 90% of doses taken in the past one month)	34	33	67
	< 90% of doses taken in the past three months=††NC	0	1	1
	Total	34	34	68

Sensitivity = 34/34 * 100 = **100%**

Specificity = 1/34* 100 = **3%**

Table 14:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 5 (Medication Adherence Scale) for patients on Protease Inhibitor.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	Medication Adherence Scale 0=†C	20	9	29
	Medication Adherence Scale 1+=††NC	14	24	38
	Total	34	33	67

Sensitivity = 20/34 * 100 = **59%**

Specificity = 24/33 * 100 = **73%**

†C= Compliant
††NC= Noncompliant

Table 15:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 6 (Medication Adherence Scale) for patients on Protease Inhibitor.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	Medication Adherence Scale 0 and 1= †C	28	19	47
	Medication Adherence Scale 2+=††NC	6	14	20
	Total	34	33	67

Sensitivity = 28/34 * 100 = **82%**

Specificity = 14/33 * 100 = **42%**

† C= Compliant
†† NC= Noncompliant

Table 16:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 7 (Medication Adherence Scale) for patients on Protease Inhibitor.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	Medication Adherence Scale 0,1 and 2=†C	32	26	58
	Medication Adherence Scale 3+=††NC	2	7	9
	Total	34	33	67

Sensitivity = 32/34 * 100 = **94%**

Specificity = 33/7 * 100 = **21%**

†C= Compliant
††NC= Noncompliant

Table 17:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 8 (Temptation to skip medication scale 12) for patients on Protease Inhibitor.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	Temptation to skip medication Scale 12 12=†C	17	14	31
	Temptation to skip medication Scale 12 13+=††NC	16	17	33
	Total	33	31	64

Sensitivity = 17/33 * 100 = **52%**

Specificity = 14/31 * 100 = **55%**

† C= Compliant
†† NC= Noncompliant

Table 18:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 9 (Temptation to skip medication scale 13) for patients on Protease Inhibitor.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	Temptation to skip medication Scale 13 13=†C	17	14	31
	Temptation to skip medication Scale 13 14+=††NC	16	17	33
	Total	33	31	64

Sensitivity = 17/33 * 100 = **52%**

Specificity = 17/31 * 100 = **55%**

†C= Compliant
††NC= Noncompliant

Table 19:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure # 1 (Medication Adherence Scale) for patients on Anti-retroviral.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Medication Adherence Scale 0=†C	21	7	28
	Medication Adherence Scale 1+=††NC	20	14	34
	Total	41	21	62

Sensitivity = 21/41 * 100 = **51%**

Specificity = 14/21 * 100 = **67%**

† C= Compliant
†† NC= Noncompliant

Table 20:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure # 2 (Medication Adherence Scale) for patients on Anti-retroviral.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Medication Adherence Scale 0 and 1= †C	34	15	49
	Medication Adherence Scale 2+=††NC	7	6	13
	Total	41	21	62

Sensitivity = 34/41 * 100 = **83%**

Specificity = 6/21 * 100 = **29%**

† C= Compliant
†† NC= Noncompliant

Table 21:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure # 3 (Medication Adherence Scale) for patients on Anti-retroviral.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Medication Adherence Scale 0,1 and 2=†C	40	18	58
	Medication Adherence Scale 3+=††NC	1	3	4
	Total	41	21	62

Sensitivity = 40/47 * 100 = **98%**

Specificity = 3/21 * 100 = **14%**

† C= Compliant
†† NC= Noncompliant

Table 22:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure # 4 (Temptation to skip medication scale 12) for patients on Anti-retroviral.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Temptation to skip medication Scale 12 12=†C	19	6	25
	Temptation to skip medication Scale 12 13+=††NC	19	13	32
	Total	38	19	57

Sensitivity = 19/38 * 100 = **50%**

Specificity = 13/19 * 100 = **68%**

† C= Compliant
†† NC= Noncompliant

Table 23:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure # 5 (Temptation to skip medication scale 12) for patients on Anti-retroviral.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Temptation to skip medication Scale 12 12 and13=†C	21	7	28
	Temptation to skip medication Scale 12 14+=††NC	17	12	29
	Total	38	19	57

Sensitivity = 21/38 * 100 = **55%**

Specificity = 12/19 * 100 = **63%**

†C= Compliant
††NC= Noncompliant

Table 24:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure # 6 (Temptation to skip medication scale 12) for patients on Anti-retroviral.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Temptation to skip medication Scale 12 12, 13 and 14=†C	23	10	33
	Temptation to skip medication Scale 12 15+=††NC	15	9	24
	Total	38	19	57

Sensitivity = 23/38 * 100 = **61%**

Specificity = 9/19* 100 = **47%**

†C= Complian·
††NC= Noncor pliant

Table 25:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure # 7 (Temptation to skip medication scale 13) for patients on Anti-retroviral.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Temptation to skip medication Scale 13 13=†C	19	6	25
	Temptation to skip medication Scale 13 14+=††NC	18	13	31
	Total	37	19	56

Sensitivity = 19/37 * 100 = **51%**

Specificity = 13/19 * 100 = **68%**

† C= Compliant
†† NC= Noncompliant

Table 26:

Agreement between Gold Standard I (≥ 80% compliance MEMS) and Self-report measure # 8 (Temptation to skip medication scale 13) for patients on Anti-retroviral.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Temptation to skip medication Scale 13 13and 14=†C	21	7	28
	Temptation to skip medication Scale 13 15+=††NC	16	12	28
	Total	37	19	56

Sensitivity = 21/37 * 100 = **57%**

Specificity = 12/19 * 100 = **63%**

† C= Compliant
†† NC= Noncompliant

Table 27:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 1 (Medication Adherence Scale) for patients on Anti-retroviral.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	Medication Adherence Scale 0=†C	20	8	28
	Medication Adherence Scale 1+=††NC	13	21	34
	Total	33	29	62

Sensitivity = 20/33 * 100 = **61%**

Specificity = 21/29 * 100 = **72%**

† C= Compliant
†† NC= Noncompliant

Table 28:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 2 (Medication Adherence Scale) for patients on Anti-retroviral.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	Medication Adherence Scale 0 and 1= †C	29	20	49
	Medication Adherence Scale 2+=††NC	4	9	13
	Total	33	29	62

Sensitivity = 29/33 * 100 = **88%**

Specificity = 9/29 * 100 = **31%**

† C= Compliant
†† NC= Noncompliant

Table 29:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 3 (Medication Adherence Scale) for patients on Anti-retroviral.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	Medication Adherence Scale 0,1 and 2=†C	33	25	58
	Medication Adherence Scale 3+=††NC	0	4	4
	Total	33	29	62

Sensitivity = 33/33 * 100 = **100%**

Specificity = 4/29 * 100 = **14%**

† C= Compliant
†† NC= Noncompliant

Table 30:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 4 (Temptation to skip medication scale 12) for patients on Anti-retroviral.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	Temptation to skip medication Scale 12 12=†C	15	10	25
	Temptation to skip medication Scale 12 13+=††NC	14	18	32
	Total	29	28	57

Sensitivity = 15/29 * 100 = **52%**

Specificity = 18/28 * 100 = **64%**

† C= Compliant
†† NC= Noncompliant

Table 31:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 5 (Temptation to skip medication scale 12) for patients on Anti-retroviral.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	Temptation to skip medication Scale 12 12 and13=†C	17	11	28
	Temptation to skip medication Scale 12 14+=††NC	12	17	29
	Total	29	28	57

Sensitivity = 17/29 * 100 = **59%**

Specificity = 17/28 * 100 = **61%**

†C= Compliant
††NC= Noncompliant

Table 32:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 6 (Temptation to skip medication scale 12) for patients on Anti-retroviral.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Temptation to skip medication Scale 12 12, 13 and 14=†C	19	14	33
	Temptation to skip medication Scale 12 15+=††NC	10	14	24
	Total	29	28	57

Sensitivity = 19/29 * 100 = **66%**

Specificity = 14/28 * 100 = **50%**

† C= Compliant
†† NC= Noncompliant

Table 33:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 7 (Temptation to skip medication scale 13) for patients on Anti-retroviral.

		MEMS		
		≥ 80% Compliant	< 80% Noncompliant	**Total**
SELF-REPORT	Temptation to skip medication Scale 13 13=†C	15	10	25
	Temptation to skip medication Scale 13 14+=††NC	13	18	31
	Total	28	28	56

Sensitivity = 15/28 * 100 = **54%**

Specificity = 18/28 * 100 = **64%**

†C= Compliant
††NC= Noncompliant

Table 34:

Agreement between Gold Standard II (≥ 90% compliance MEMS) and Self-report measure # 8 (Temptation to skip medication scale 13) for patients on Anti-retroviral.

		MEMS		
		≥ 90% Compliant	< 90% Noncompliant	**Total**
SELF-REPORT	Temptation to skip medication Scale 13 13and 14=†C	17	11	28
	Temptation to skip medication Scale 13 15+=††NC	11	17	28
	Total	28	28	56

Sensitivity = 17/28 * 100 = 61%

Specificity = 17/28 * 100 = 61%

†C= Compliant
††NC= Noncompliant

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APPENDIX

- Questionnaire
- SAS Program

Managing Your Medications Questionnaire

Please answer the following questions thoughtfully and completely. This questionnaire is about how you think and feel about the HIV related medications that you are taking, and about the different strategies that people use to take their medications. When you turn it in, we will give you a gift certificate for $20 to thank you for your participation.

PATIENT ID: _____

CODE FOR THIS QUESTIONNAIRE:

A) What are the first 3 letters of your mother's first name? _____

B) What is your birth date? ☐☐/☐☐/☐☐

SECTION I
BACKGROUND INFORMATION

The first section of this questionnaire asks about your background.

⇒ *Please circle or fill in the correct response for each question.*

1. What is your age? ☐☐ years

2. What is your gender? M F

3. How would you describe your current health status? *(Please check one answer)*

   ☐ Excellent ☐ Very Good ☐ Good ☐ Fair ☐ Poor

4. Which of the following best describes your ethnic background?

   ☐ White, non-Hispanic ☐ Hispanic ☐ African American
   ☐ Native American ☐ Asian ☐ Other

5. How many years of education have you finished? ☐☐
   (for example, for high school, fill in "12")

6. Do you currently work either part-time or full time?

   ☐ Full-time ☐ Part-time ☐ I am not currently employed

7. Do you live by yourself or with other people?

☐ By myself ☐ With others

8. If you live with others, how many (besides you) are in your household? ☐☐

9. If you live with others, what is their relationship to you? *(Check all that apply)*

☐ Husband or wife
☐ Intimate partner
☐ Other adults 18 or older
☐ Parents
☐ Grandparents
☐ Children under age 18
☐ Children over age 18

10. Do you have any children? If so, how many? *(If none, put 0)* ☐☐

11. Do any of your adult children live nearby (within a half hour drive)?

☐ Yes ☐ No ☐ Not applicable

12. How many of your family or friends can you count on for emotional support? ☐☐

13. How many of your family or friends can you count on for financial help? ☐☐

14. How many of your family or friends can you count on for physical assistance, or a place to stay? ☐☐

15. Do you feel confident that your family or friends will continue to help you with your everyday needs?

☐ Very confident
☐ Fairly confident
☐ Somewhat confident
☐ Less than somewhat confident
☐ Not at all confident

16. If you were to need more help with every day needs, do you feel confident that your family or friends could provide it?

☐ Very confident
☐ Fairly confident
☐ Somewhat confident
☐ Less than somewhat confident
☐ Not at all confident

17. How many of your family & friends have you told about your HIV infection?

☐ None ☐ Less than half ☐ About half ☐ More than half ☐ All

18. What type of health insurance coverage do you currently have?

- ☐ NONE
- ☐ Rhode Island Elderly Assistance Program
- ☐ Blue Cross
- ☐ Harvard Pilgrim Health Care (RIGHA, HCHP)
- ☐ Ocean State
- ☐ Other private insurer
- ☐ Medicare
- ☐ VA
- ☐ Other
- ☐ Medicaid

19. Which of the following best estimates your total (family) income during the past 12 months?

- ☐ Less than $15,000
- ☐ $15,000 to $24,000
- ☐ $25,000 to $34,000
- ☐ $35,000 to $44,000
- ☐ $45,000 or more

20. About how far do you live from this treatment center?

- ☐ Within walking distance
- ☐ Within a ten minute drive or less
- ☐ Within a twenty minute drive or less
- ☐ Within a thirty minute drive
- ☐ More than thirty minutes away

21. When you have questions about medications for your HIV infection, who do you usually ask?
(Please check all that apply)

- ☐ Pharmacist
- ☐ Physician
- ☐ Social Worker
- ☐ Nurse
- ☐ Other persons with HIV infection
- ☐ Family members
- ☐ Friends
- ☐ Other; please specify_____

22. Which health care provider is most helpful to you in taking your medications as directed?

- ☐ Nurse
- ☐ Pharmacist
- ☐ Physician
- ☐ Social Worker
- ☐ Other; please specify_____

23. Is there someone living with you or close to you who helps or reminds you to take your medications on time?

- ☐ Yes
- ☐ No

24. How much bodily pain have you had during the past four weeks?

☐ None ☐ Moderate
☐ Very mild ☐ Severe
☐ Mild ☐ Very Severe

25. During the past 4 weeks, how much did HIV-related symptoms interfere with your normal work (including both work outside the home and housework)?

☐ Not at all ☐ A little bit ☐ Moderately ☐ Quite a bit ☐ Extremely

26. During the past two weeks, how many days did you stay in bed all or most of the day? ☐☐

27. How many times have you been hospitalized in the past year? *(If none, put 0)* ☐☐

28. These questions are about how you feel and how things have been with you during the past 4 weeks.

⇒ *For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...*

	NONE OF THE TIME	A LITTLE BIT OF THE TIME	SOME OF THE TIME	A GOOD BIT OF THE TIME	MOST OF THE TIME	ALL OF THE TIME
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

29. How long ago were you diagnosed as HIV positive?

- ☐ Less than a month
- ☐ One to six months
- ☐ More than six months, but less than a year
- ☐ 1 to 2 years
- ☐ 3 to 4 years
- ☐ 5 years or more

30. How do you think you got your HIV infection?
Please check all that apply

- ☐ Injection (IV) drug use
- ☐ Heterosexual contact
- ☐ Homosexual contact
- ☐ Blood transfusion
- ☐ Other: _____

31. What was your T cell count (CD4 count) the last time you were tested?

☐ Greater than 500 ☐ 201-500 ☐ 50-200 ☐ Less than 50

SECTION II
MEDICATION HISTORY

1. WHICH OF THE FOLLOWING MEDICATIONS ARE PRESCRIBED FOR YOU NOW?
   ⇒ *PLEASE CHECK ALL THAT APPLY:*

- ☐ AZT (Retrovir®, zidovudine)
- ☐ DDI (Videx®, didanosine)
- ☐ DDC (Hivid®, zalcitabine)
- ☐ D4T (Zerit®, stavudine)
- ☐ 3TC (Epivir®, lamivudine)
- ☐ Nevirapine (Viramune®)
- ☐ Delavirdine (Rescriptor®)
- ☐ Saquinavir (Invirase®)
- ☐ Ritonavir (Norvir®)
- ☐ Nelfinavir (Viracept®)
- ☐ Indinavir (Crixivan®)
- ☐ Trimethoprim or Sulfamethoxazole (Bactrim®, Septra®)
- ☐ Clarithromycin (Biaxin®)
- ☐ Dapsone
- ☐ Fluconazole (Diflucan®)
- ☐ Itraconazole (Sporanox®)
- ☐ Rifabutin (Mycobutin®)

2. How long have you been taking your protease inhibitor medication?
   [Saquinavir (Invirase®), Ritonavir (Norvir®), Nelfinavir (Viracept) or Indinavir (Crixivan®)]

- ____ Less than 1 month
- ____ 1 to 3 months
- ____ 4 to 6 months
- ____ 6 months to 1 year
- ____ 1 to 2 years
- ____ more than 2 years

3. *During the last 3 months*, have you ever stopped taking your protease inhibitor medication because you felt better?
   ☐ YES ☐ NO

4. *During the last 3 months*, have you ever stopped taking your protease inhibitor medication because you felt worse?
   ☐ YES ☐ NO

5. *During the last 3 months*, have you ever forgotten to take your protease inhibitor medication?
   ☐ YES ☐ NO

6. *During the last 3 months*, have you at times been careless about taking your protease inhibitor medication?
   ☐ YES ☐ NO

7. *During the last 3 months*, have you ever taken less of your protease inhibitor medicine than your doctor prescribed because you felt better?
   ☐ YES ☐ NO

8. *During the last 3 months*, have you ever taken less of your protease inhibitor medicine than your doctor prescribed because you felt worse?
   ☐ YES ☐ NO

9. *Since you began taking* your protease inhibitor medication, have you ever purposely:

	YES	NO
a) taken more of the medicine than your physician prescribed?	☐	☐
b) taken less of the medicine than your physician prescribed?	☐	☐
c) discontinued or stopped taking your medication?	☐	☐

If yes,

⇒ 10.a) How many times have you discontinued your protease inhibitor medication for more than 3 days? _____

b) What were your reasons for discontinuing your protease inhibitor medication?
Please check all that apply

- ☐ My doctor recommended it
- ☐ Too many side effects
- ☐ I didn't want to be reminded of my illness
- ☐ Problems with insurance coverage
- ☐ I didn't think it was working
- ☐ Other: _____

11. Sometimes it is difficult to take prescribed medicine all the time. During the past week, how many times did you miss a dose of your protease inhibitor? _____

12. During the past month, about how many times did you miss a dose of your protease inhibitor? _____

13. During the past three months, about how many times did you miss a dose of your protease inhibitor? _____

14. Please check any side effect(s) you are having that you believe are caused by your protease inhibitor medicine:

☐ nausea	☐ shortness of breath	☐ headaches
☐ dizziness	☐ muscle aches	☐ anxiety/worry
☐ vomiting	☐ fatigue	☐ depression
☐ abdominal pain	☐ tingling in hands/feet	☐ rash
☐ diarrhea	☐ numbness in hands/feet	☐ sensitivity to sun

☐ other: _____

15. How long have you been taking your antiviral medication?
[AZT (Retrovir®, zidovudine), DDI (Videx®, didanosine), DDC (Hivid®, zalcitabine), D4T (Zerit®, stavudine), 3TC (Epivir®, lamivudine), or Nevirapine (Viramune)]

____ Less than 1 month
____ 1 to 3 months
____ 4 to 6 months
____ 6 months to 1 year
____ 1 to 2 years
____ more than 2 years

16. *During the last 3 months*, have you ever stopped taking your antiviral medication because you felt better?
☐ YES ☐ NO

17. *During the last 3 months*, have you ever stopped taking your antiviral medication because you felt worse?
☐ YES ☐ NO

18. *During the last 3 months*, have you ever forgotten to take your antiviral medication?
☐ YES ☐ NO

19. *During the last 3 months*, have you at times been careless about taking your antiviral medication?
☐ YES ☐ NO

20. *During the last 3 months*, have you ever taken less of your antiviral medicine than your doctor prescribed because you felt better?
☐ YES ☐ NO

21. *During the last 3 months*, have you ever taken less of your antiviral medicine than your doctor prescribed because you felt worse?
☐ YES ☐ NO

22. *Since you began taking* your antiviral medication, have you ever purposely:

	YES	NO
a) taken more of the medicine than your physician prescribed?	☐	☐
b) taken less of the medicine than your physician prescribed?	☐	☐
c) discontinued or stopped taking your medication?	☐	☐

If yes,

⇒ 23.a) How many times have you discontinued your antiviral medication for more than 3 days? _____

b) What were your reasons for discontinuing your antiviral medication?
Please check all that apply

- ☐ My doctor recommended it
- ☐ Too many side effects
- ☐ I didn't want to be reminded of my illness
- ☐ Problems with insurance coverage
- ☐ I didn't think it was working
- ☐ Other: _____

24. Sometimes it is difficult to take prescribed medicine all the time. During the past week, how many times did you miss a dose of your antiviral medication? _____

25. During the past month, about how many times did you miss a dose of your antiviral medication? _____

26. During the past three months, about how many times did you miss a dose of your antiviral medication? _____

27. Please check any side effect(s) you are having that you believe are caused by your antiviral medicine:

☐ nausea	☐ shortness of breath	☐ headaches
☐ dizziness	☐ muscle aches	☐ anxiety/worry
☐ vomiting	☐ fatigue	☐ depression
☐ abdominal pain	☐ tingling in hands/feet	☐ rash
☐ diarrhea	☐ numbness in hands/feet	☐ sensitivity to sun

☐ other: _____
_____

SECTION III
ANTIVIRAL MEDICATIONS

REMINDER: ***FILL OUT THIS SECTION IF YOU HAVE EVER TAKEN ANY OF THESE ANTIVIRAL MEDICATIONS: AZT (Retrovir®, zidovudine), DDI (Videx®, didanosine), DDC (Hivid®, zalcitabine), D4T (Zerit®, stavudine), 3TC (Epivir®, lamivudine), Nevirapine (Viramune®), or Delavirdine (Rescriptor®).***

⇒ *If you are taking more than one antiviral medication NOW, please answer these questions for the medicine that is most difficult for you to take, and fill in the name of that medicine here* _____

⇒ *If you have discontinued your antiviral medication, please answer these questions for the medicine that you took most recently, and fill in the name of that medicine here* _____

Taking medications as directed (the prescribed amount taken at the right time) is not always easy. At one time or another most people simply forget to take a dose of their medication, and sometimes people discontinue taking their medications for a while. The following is a list of possible advantages and disadvantages of taking antiviral medications as directed.

⇒ *For each numbered statement, please mark one box with an "X" to rate HOW IMPORTANT that statement is to you when you are thinking about whether to take your antiviral medication as directed.*

	NOT IMPORTANT	SLIGHTLY IMPORTANT	MODERATELY IMPORTANT	VERY IMPORTANT	EXTREMELY IMPORTANT
1. If I take my antiviral medication as directed, I can avoid possible complications of HIV infection.	☐	☐	☐	☐	☐
2. When I take my antiviral medication as directed, it makes me feel depressed about having HIV infection.	☐	☐	☐	☐	☐
3. Taking my antiviral medication as directed causes too many annoying side effects.	☐	☐	☐	☐	☐
4. Taking my antiviral medication as directed will slow down this illness.	☐	☐	☐	☐	☐
5. I worry that taking all the doses that are prescribed might not be good for me.	☐	☐	☐	☐	☐

	NOT IMPORTANT	SLIGHTLY IMPORTANT	MODERATELY IMPORTANT	VERY IMPORTANT	EXTREMELY IMPORTANT
6. Taking my antiviral medication as directed gives me hope.	☐	☐	☐	☐	☐
7. I worry that the antiviral medication is doing more harm than good.	☐	☐	☐	☐	☐
8. Taking my antiviral medication as directed may help me stay well longer.	☐	☐	☐	☐	☐
9. It may be hard on my system, if I take my antiviral medication as directed.	☐	☐	☐	☐	☐
10. Taking my antiviral medication as directed will help me feel better.	☐	☐	☐	☐	☐

Sometimes people take their medications as directed for a while, and then stop taking them for a while.

⇒ *The following 2 questions are about how you are taking your antiviral medication RIGHT NOW.*

11. Do you consistently take your antiviral medication as directed? ("as directed" means taking your medication at the right time and taking the prescribed amount)

____ a. No, I do not, and *I am not considering* taking my antiviral medication as directed.
____ b. No, I do not, but *I am considering* taking my antiviral medication as directed.
____ c. No, I do not, but *I am planning to start* taking my antiviral medication as directed within the next month.
____ d. Yes, I consistently take my antiviral medication as directed.

If yes,

⇒ *12.* How long have you been taking your antiviral medication as directed?

____ a. 0-3 months
____ b. 4-6 months
____ c. 6-12 months
____ d. more than 12 months

Now here are some situations that might affect whether you take your antiviral medication for HIV infection as directed.

⇒ *For each situation, please mark one box with an "X" to rate HOW TEMPTED you would be to skip your antiviral medication or take a dose which is different from the one prescribed.*

	NOT AT ALL TEMPTED	SLIGHTLY TEMPTED	MODERATELY TEMPTED	VERY TEMPTED	EXTREMELY TEMPTED
13. When you feel good and think you don't need it.	☐	☐	☐	☐	☐
14. When you are anxious about side effects.	☐	☐	☐	☐	☐
15. When you experience minor side effects.	☐	☐	☐	☐	☐
16. When your medical condition doesn't seem that bad.	☐	☐	☐	☐	☐
17. When it seems too complex to keep track of all your medications.	☐	☐	☐	☐	☐
18. When you feel like giving up.	☐	☐	☐	☐	☐
19. When you aren't sure if the medicine is really helping you.	☐	☐	☐	☐	☐
20. When your family or friends don't seem concerned enough about your condition.	☐	☐	☐	☐	☐
21. When your doctor doesn't seem concerned enough about your condition.	☐	☐	☐	☐	☐
22. When your insurance doesn't cover the cost of your medication.	☐	☐	☐	☐	☐
23. When you lose confidence in your doctor.	☐	☐	☐	☐	☐
24. When you feel you should give your body a rest.	☐	☐	☐	☐	☐
25. When you worry that the chemicals in the medication might harm or hurt your body.	☐	☐	☐	☐	☐

SECTION IV
PROTEASE INHIBITOR MEDICATIONS

REMINDER: ***FILL OUT THIS SECTION IF YOU HAVE EVER TAKEN ANY OF THESE PROTEASE INHIBITOR MEDICATIONS: Saquinavir (Invirase®), Ritonavir (Norvir®), Nelfinavir (Viracept®) or Indinavir (Crixivan®).***

⇒ ***If you are taking more than one protease inhibitor medication NOW, please answer these questions for the medicine that is most difficult for you to take, and fill in the name of that medicine here*** _____

⇒ ***If you have discontinued your protease inhibitor medication, please answer these questions for the medicine that you took most recently, and fill in the name of that medicine here***

_____

Taking medications as directed (the prescribed amount taken at the right time) is not always easy. At one time or another most people simply forget to take a dose of their medication, and sometimes people discontinue taking their medications for a while. The following is a list of possible advantages and disadvantages of taking protease inhibitor medications as directed.

⇒ ***For each numbered statement, please mark one box with an "X" to rate HOW IMPORTANT that statement is to you when you are thinking about whether to take your protease inhibitor medication as directed.***

	NOT IMPORTANT	SLIGHTLY IMPORTANT	MODERATELY IMPORTANT	VERY IMPORTANT	EXTREMELY IMPORTANT
1. If I take my protease inhibitor medication as directed, I can avoid possible complications of HIV infection.	☐	☐	☐	☐	☐
2. When I take my protease inhibitor medication as directed, it makes me feel depressed about having HIV infection.	☐	☐	☐	☐	☐
3. Taking my protease inhibitor medication as directed causes too many annoying side effects.	☐	☐	☐	☐	☐
4. Taking my protease inhibitor medication as directed will slow down this illness.	☐	☐	☐	☐	☐
5. I worry that taking all the doses that are prescribed might not be good for me.	☐	☐	☐	☐	☐
6. Taking my protease inhibitor medication as directed gives me hope.	☐	☐	☐	☐	☐

	NOT IMPORTANT	SLIGHTLY IMPORTANT	MODERATELY IMPORTANT	VERY IMPORTANT	EXTREMELY IMPORTANT
7. I worry that the protease inhibitor medication is doing more harm than good.	☐	☐	☐	☐	☐
8. Taking my protease inhibitor medication as directed may help me stay well longer.	☐	☐	☐	☐	☐
9. It may be hard on my system, if I take my protease inhibitor medication as directed.	☐	☐	☐	☐	☐
10. Taking my protease inhibitor medication as directed will help me feel better.	☐	☐	☐	☐	☐

Sometimes people take their medications as directed for a while, and then stop taking them for a while.

⇒ *The following 2 questions are about how you are taking your protease inhibitor medication RIGHT NOW.*

11. Do you consistently take your protease inhibitor medication as directed? ("as directed" means taking your medication at the right time and taking the prescribed amount)

____ a. No, I do not, and ***I am not considering*** taking my protease inhibitor medication as directed.
____ b. No, I do not, but ***I am considering*** taking my protease inhibitor medication as directed.
____ c. No, I do not, but ***I am planning to start*** taking my protease inhibitor medication as directed within the next month.
____ d. Yes, I consistently take my protease inhibitor medication as directed.

If yes,

⇒ *12.* How long have you been taking your protease inhibitor medication as directed?

____ a. 0-3 months
____ b. 4-6 months
____ c. 6-12 months
____ d. more than 12 months

Now here are some situations that might affect whether you take your protease inhibitor medication for HIV infection as directed.

⇒ *For each situation, please mark one box with an "X" to rate HOW TEMPTED you would be to skip your protease inhibitor medication or take a dose which is different from the one prescribed.*

	NOT AT ALL TEMPTED	SLIGHTLY TEMPTED	MODERATELY TEMPTED	VERY TEMPTED	EXTREMELY TEMPTED
13. When you feel good and think you don't need it.	☐	☐	☐	☐	☐
14. When you are anxious about side effects.	☐	☐	☐	☐	☐
15. When you experience minor side effects.	☐	☐	☐	☐	☐
16. When your medical condition doesn't seem that bad.	☐	☐	☐	☐	☐
17. When it seems too complex to keep track of all your medications.	☐	☐	☐	☐	☐
18. When you feel like giving up.	☐	☐	☐	☐	☐
19. When you aren't sure if the medicine is really helping you.	☐	☐	☐	☐	☐
20. When your family or friends don't seem concerned enough about your condition.	☐	☐	☐	☐	☐
21. When your doctor doesn't seem concerned enough about your condition.	☐	☐	☐	☐	☐
22. When your insurance doesn't cover the cost of your medication.	☐	☐	☐	☐	☐
23. When you lose confidence in your doctor.	☐	☐	☐	☐	☐
24. When you feel you should give your body a rest.	☐	☐	☐	☐	☐
25. When you worry that the chemicals in the medication might harm or hurt your body.	☐	☐	☐	☐	☐

For information on the "Medication for The Needy–Assistance Program" at The University of Rhode Island, call 1-800-215-9001.

This completes this survey. Thank you for your assistance with this project & for sharing your thoughts on HIV related medications.

```
libname research 'd:\research';
data research.new;
set research.hivshrt;

*new variable for age called agegrp coded as 1,2,3 and 4;

if 20 le qi1 le 25 then agegrp=1;
else if 26 le qi1 le 35then agegrp=2;
else if 36 le qi1 le 45 then agegrp=3;
else if 46 le qi1 le 55 then agegrp=4;

*new variable for education called edu coded as 1 2 3 and 4;

if qi5<12 then edu=1;
else if qi5=12 then edu=2;
else if 13 le qi5 le 15 then edu=3;
else if qi5 ge 16 then edu=4;

*new variable for employment called emp coded as 1 2 ;

if qi6=1 or qi6=2 then emp=2;
else if qi6=3 then emp=1;

*recoding for drugnam1  drunam2 and drugnam3 1=pi 2=ar and 3=ai;

if drugnam1='saqinavir' or drugnam1='invirase' or drugnam1='ritonavir
or drugnam1='norvir' or drugnam1='crixivan' or drugnam1='nelfinavir'
then drugnam1=1;

else if drugnam1=' ' then drugnam1='.';

else if drugnam1= 'AZT' or drugnam1= 'retrovir' or drugnam1= 'zidovud
or drugnam1='videx' or drugnam1= 'didanosine'or drugnam1='DDC' or dru
drugnam1= 'zalcitabine' or drugnam1= 'D4T' or drugnam1= 'zerit' or dr
drugnam1= '3TC' or drugnam1='epivir' or drugnam1='lamivudine' or drug
or drugnam1='viramune' or drugnam1='delavirdine' or drugnam1= 'rescri

else drugnam1=3;

if drugnam2='saqinavir' or drugnam2='invirase' or drugnam2='ritonavir
or drugnam2='norvir' or drugnam2='crixivan' or drugnam2='nelfinavir'
then drugnam2=1;
```

```
else if drugnam2=' ' then drugnam2='.';

else if drugnam2= 'AZT' or drugnam2= 'retrovir' or drugnam2= 'zidovud
or drugnam2='videx' or drugnam2= 'didanosine'or drugnam2='DDC' or dru
drugnam2= 'zalcitabine' or drugnam2= 'D4T' or drugnam2= 'zerit' or dr
drugnam2= '3TC' or drugnam2='epivir' or drugnam2='lamivudine' or drug
or drugnam2='viramune' or drugnam2='delavirdine' or drugnam2= 'rescri

else drugnam2=3;

if drugnam3='saqinavir' or drugnam3='invirase' or drugnam3='ritonavir
or drugnam3='norvir' or drugnam3='crixivan' or drugnam3='nelfinavir'
then drugnam3=1;

else if drugnam3=' ' then drugnam3='.';

else if drugnam3= 'AZT' or drugnam3= 'retrovir' or drugnam3= 'zidovud
or drugnam3='videx' or drugnam3= 'didanosine'or drugnam3='DDC' or dru
drugnam3= 'zalcitabine' or drugnam3= 'D4T' or drugnam3= 'zerit' or dr
drugnam3= '3TC' or drugnam3='epivir' or drugnam3='lamivudine' or drug
or drugnam3='viramune' or drugnam3='delavirdine' or drugnam3= 'rescri

else drugnam3=3;
*recoding the variables included in the mas scale as 0 and 1;

if qiiav16=1 then qiiav16=0;
else if qiiav16=2 then qiiav16=1;
else qiiav16='.';

if qiiav17=1 then qiiav17=0;
else if qiiav17=2 then qiiav17=1;
else qiiav17='.';

if qiiav18=1 then qiiav18=0;
else if qiiav18=2 then qiiav18=1;
else qiiav18='.';

if qiiav19=1 then qiiav19=0;
else if qiiav19=2 then qiiav19=1;
else qiiav19='.';

if qiiav20=1 then qiiav20=0;
else if qiiav20=2 then qiiav20=1;
```

```
else qiiav20='.';

if qiiav21=1 then qiiav21=0;
else if qiiav21=2 then qiiav21=1;
else qiiav21='.';

if qiipi3=1 then qiipi3=0;
else if qiipi3=2 then qiipi3=1;
else qiipi3='.';

if qiipi4=1 then qiipi4=0;
else if qiipi4=2 then qiipi4=1;
else qiipi4='.';

if qiipi5=1 then qiipi5=0;
else if qiipi5=2 then qiipi5=1;
else qiipi5='.';

if qiipi6=1 then qiipi6=0;
else if qiipi6=2 then qiipi6=1;
else qiipi6='.';

if qiipi7=1 then qiipi7=0;
else if qiipi7=2 then qiipi7=1;
else qiipi7='.';

if qiipi8=1 then qiipi8=0;
else if qiipi8=2 then qiipi8=1;
else qiipi8='.';

MAS_AV= qiiav16+qiiav17+qiiav18+qiiav19+qiiav20+qiiav21;
MAS_PI= qiipi3+qiipi4+qiipi5+qiipi6+qiipi7+qiipi8;

TEMP13AV= qiii23+qiii24+qiii28+qiii34+qiii36+qiii37+qiii40+
qiii44+qiii47+qiii48+qiii49+qiii51+qiii52;

TEMP12AV= qiii23+qiii24+qiii28+qiii34+qiii36+qiii40+
qiii44+qiii47+qiii48+qiii49+qiii51+qiii52;

TEMP13PI=qv23+qv24+qv28+qv34+qv36+qv37+qv40+qv44+qv47+qv48+qv49+qv51+

TEMP12PI= qv23+qv24+qv28+qv34+qv36+qv40+qv44+qv47+qv48+qv49+qv51+qv52
*avm1 avm2 avm3 are three sub categories for mas_av and pim1 pim2 pim
```

```
if mas_av=0 then avm1=0;
else if 1 le mas_av le 6 then avm1=1;
else avm1='.';

if mas_av=0 or mas_av=1 then avm2=0;
else if 2 le mas_av le 6 then avm2=1;
else avm2='.';

if mas_av=0 or mas_av=1 or mas_av=2 then avm3=0;
else if 3 le mas_av le 6 then avm3=1;
else avm3='.';

if mas_pi=0 then pim1=0;
else if 1 le mas_pi le 6 then pim1=1;
else pim1='.';

if mas_pi=0 or mas_pi=1 then pim2=0;
else if 2 le mas_pi le 6 then pim2=1;
else pim2='.';

if mas_pi=0 or mas_pi=1 or mas_pi=2 then pim3=0;
else if 3 le mas_pi le 6 then pim3=1;
else pim3='.';
if temp12av=12 then av12t1=0;
else if 13 le temp12av le 38 then av12t1=1;
else av12t1='.';

if temp12av=12 or temp12av=13 then av12t2=0;
else if 14 le temp12av le 38 then av12t2=1;
else av12t2='.';

if temp12av=12 or temp12av=13 or temp12av=14 then av12t3=0;
else if 15 le temp12av le 38 then av12t3=1;
else av12t3='.';


if temp12av=12 or temp12av=13 or temp12av=14 or temp12av=15 then av12
else if 16 le temp12av le 38 then av12t4=1;
else av12t4='.';

if temp13av=13 then av13t1=0;
```

```
else if 14 le temp13av le 42 then av13t1=1;
else av13t1='.';

if temp13av=13 or temp13av=14 then av13t2=0;
else if 15 le temp13av le 42 then av13t2=1;
else av13t2='.';

if temp13av=13 or temp13av=14 or temp13av=15 then av13t3=0;
else if 16 le temp13av le  42 then av13t3=1;
else av13t3='.';

if temp13av=13 or temp13av=14 or temp13av=15 or temp13av=16 then av13
else if 17 le temp13av le 42 then av13t4=1;
else av13t4='.';

if temp12pi=12 then pi12t1=0;
else if 13 le temp12pi le 60 then pi12t1=1;
else pi12t1='.';

if temp13pi=13 then pi13t1=0;
else if 14 le temp13pi le 65 then pi13t1=1;
else pi13t1='.';

if 80 le dosepct1 le 100 then mems1=0;
else if dosepct1=. then mems1=.;
else mems1=1;

if 90 le dosepct1 le 100 then mems2=0;
else if dosepct1=. then mems2=.;
else mems2=1;
* new variable for # doses missed;

OM= (90-qiipi12)/90*100;
TM= (270-qiipi13)/270*100;

if 80 le om le 100 then om1=0;
else if om=. then om1=.;
else om1=1;

if 90 le om le 100 then om2=0;
else if om=. then om2=.;
else om2=1;
```

```
if 80 le tm le 100 then tm1=0;
else if tm=. then tm1=.;
else tm1=1;

if 90 le tm le 100 then tm2=0;
else if tm=. then tm2=.;
else tm2=1;
run;
```

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