

Revised on 11/24/2004 2:41 PM

***NURSING INTERVENTION FOR HIV REGIMEN
ADHERENCE AMONG INDIVIDUALS WITH A SERIOUS
MENTAL ILLNESS***

Policy and Procedure Manual

Center for Mental Health Policy and Services Research
Department of Psychiatry
Center for Health Outcomes and Policy Research
Department of Nursing
University of Pennsylvania
3535 Market Street, 3rd Floor
Philadelphia, PA 19104-3309

TABLE OF CONTENTS

I.	INTRODUCTION	4
	A. Overview	
	B. Aims	
	C. Participants	
	D. Recruitment	
	E. Case Managers and Advanced Practice Nurses	
	F. Team Members	
	G. Team Structure	
	H. Organizational Chart	
	I. Roles and Responsibilities	
II.	POLICY	9
	A. General Protocol for documentation of the APN Intervention	
	B. Safety Protocol for HIV Exposure	
	C. Confidentiality and Security of Clinical and Research Records	
	D. Use of Grant Vehicle	
	E. Documentation of APN costs	
III.	PROCEDURES	
	A. INTERVENTION CASCADE	11
	1. Overview	
	2. Procedures	
	3. Components of the Intervention Cascade	
	B. MEDICATION ADHERENCE PROTOCOL	14
	1. Part I Current Medications	
	2. Part II Adherence Questionnaire	
	3. Part III Adherence Questionnaire	
	4. Part IV Adherence Questionnaire	
	5. Logistical Problems	
	6. Side Effect Profile and Self Care Management	
	7. Perceived Coercion Questionnaire	
	8. Pill count	
	9. Pharmacy Refills	
	C. PATH PROTOCOL	27
	1. Path Session I	
	2. Path Session II	
	3. Path Session III	
	4. Path Session IV	
	D. EDUCATION MODULES	65

E. **COGNITIVE BEHAVIORAL HEALTH**.....82

Appendix

A. Advanced Practice Nurse Job Description.....83
B. Omaha System Assessment.....85
C. Case Study of Facilitators and Barriers.....88
D. Safety Protocol91
E. Event Documentation.....94
F. Common general medical and behavioral CPT codes.....96
G. Confidentiality and Security of Information.....101

A. OVERVIEW

The research team will study effectiveness of integrating advanced practice nursing into ongoing Targeted Case Management (TCM) to enhance adherence to a treatment regimen among persons with serious mental illness (SMI) who are also HIV positive. The investigation will utilize a community health nursing intervention based on outreach interventions and adherence enhancements proven in other HIV populations to test adherence in the SMI. As a consequence, adherence to psychotropic medications should improve.

A growing body of research documents that persons with SMI are at increased risk for contracting and transmitting HIV. This increased risk is thought to be due to high rates of substance use including injection drug use (IDU), risky sexual behavior, sexual victimization, and prostitution among those with SMI. Adherence to HIV regimen is problematic even in the general population, and non-adherence poses a growing public health threat due to development of treatment resistant virus strains. Therefore, the SMI may serve as a particularly dangerous vector of HIV transmission, and methods of improving treatment adherence are of particular significance.

The proposed adherence intervention will be an effective method of secondary HIV prevention for a number of reasons.

1. Philadelphia's mental health system has been an exemplar of public mental health programming, and has received awards from the Ford Foundation for innovative programming in government, the President's Commission on Mental Health, and Robert Wood Johnson Foundation, and others.
2. Integrating community health nursing via advanced practice nurses (APNs) into the existing case management model capitalizes on existing system strengths.
3. There are proven methods of improving treatment adherence that can be translated into the adherence intervention and should be effective with the SMI population.
4. The intervention can be continuously reinforced over an extended period since most SMI have long-term relationships with the public mental health system.

B. Aims

1. Test the effectiveness of a community health nursing intervention added to existing mental health outreach services on adherence to HIV/AIDS medication regimen in a randomized community trial.
2. Demonstrate improvements in HIV knowledge, attitudes and risk behaviors, as well as mental health status and psychosocial outcomes.
3. Demonstrate improved adherence to psychotropic medications as a secondary benefit of the experimental condition.
4. Explore the effectiveness of more intensive intervention strategies for those who do not respond to the basic intervention.
5. Examine the cost-benefit of the intervention.

C. Participants

Persons with SMI co-morbidly infected with HIV at CMHCs in Philadelphia will be approached by their case managers who will obtain permission to release their name and phone number to a member of our research team. A member of the research team will then contact

them to explain more about the study and conduct informed consent for participation. Based upon preliminary Studies, we expect there are approximately 4,000 HIV positive persons among case managed SMI persons in Philadelphia. We estimate that given 16 CMHC's, under equal distribution assumptions there is the expectation of about 250 HIV positive SMI in each clinic.

D. Recruitment

The study will be widely advertised within the CMHC's, and SMI participants who are HIV+ but whose serostatus is not known to the CMHC may self-identify. Further, the study will be advertised at the HIV outpatient clinic at HUP and other sites in Philadelphia, and participants who receive mental health services at one of the participating CMHC's may self-identify. These persons will be given blood tests for baseline viral loads and CD4 counts, as well as the self-report instruments. They will be asked to provide the names of the physician providing HIV treatment as well as to identify the pharmacy where they fill prescriptions. Any participant not currently in treatment will be referred to Dr. Hines at the HUP clinic. All participants will be paid \$40 for each of four interviews over a 12-month period study period, as well as one 24-month follow-up. Blood testing will be completed at baseline, 12 and 24 months only. In order to discourage attrition, a bonus of \$100 will be paid at 24 months to those who provided complete data across all study periods.

We will recruit consumers from clinics where, based on known demographics (proximity to Center City Philadelphia, and a disproportionate number of minority and impoverished persons within their catchment areas), we can reasonably expect to easily recruit a total of at least 400 HIV positive SMI consumers. We expect to be able to serve at least 70 people per year (35 in each of two intervention teams). Extrapolating over a three-year intervention period, we estimate that at least 210 persons will receive the intervention, for a total baseline sample of 420 persons including controls. We expect a very high level of retention since we will offer an incentive for each interview and these are individuals with longstanding relationships with their CMs. We have had longstanding experience with studies in this population, and given the built-in incentive structure, we estimate at least 75% will continue and provide data throughout the study period leaving about 315 persons for longitudinal analyses, including over 150 experimental participants. Our ability to retain participants and reduce attrition will also be enhanced by the outreach component and ability of case managers, nurses, and RAs to travel to participants' homes or other preferred locations. We have based our power analysis on 300 participants, although we expect that actual participation rates could well be higher.

E. Case Management and the APN

The advanced practice nurse (APN)-case manager (CM) dyad is the most appropriate vehicle for HIV adherence interventions for the SMI. First, this combination of expertise can provide comprehensive individual-level intervention tailored to the wide range of cognitive and emotional deficits that characterize the SMI, provide physical care and symptom management for clinical sequelae associated with HIV and its treatment, as well as management of psychotropic drugs. Second, case managers' particular expertise in helping SMI consumers learn despite cognitive and emotional challenges make them particularly well suited to reinforce the adherence intervention. Finally, since many persons with SMI develop longstanding

relationships with case managers and CMHC's, the intervention can be continuously reinforced and updated as needed.

For control participants, case managers will be informed of the results of baseline assessments of co-morbid depression and substance use, so that the control group approximates but is strictly speaking, not treatment-as-usual. However, given the voluminous evidence of how difficult it is to change existing practice patterns in public mental health, we doubt seriously that disclosing this information will have much impact on service delivery for controls, and to fail to inform CMs about findings regarding depression and substance abuse would be a clear ethical violation only in the case where it's danger to self/others. In the experimental group, case managers will be explicitly responsible for coordinating adjunctive treatments for these conditions based on the findings of the baseline assessment, including psychiatric consultation, additional pharmacotherapy, and other appropriate referrals as needed.

F. Team Members

Michael Blank, PhD Principal Investigator
Linda Aiken, PhD, RN, FAAN, Co-Principal Investigator
Julie Tennille, MSW Project Manager
Nancy Hanrahan, PhD, RN, CS Co-Investigator, Nursing Supervisor
Janet Hines, MD Co-Investigator
Robert Gross, MD
Advanced Practice Nurses:
 Patricia Burt, MSN,APRN, BC
 June Roman, MSN,APRN, BC
Research Assistants:
 Ellen Plum
 Kevin Cavanaugh
 Aleya Martin
 Mike Christensen
Consultants:
 William Holzemer, PhD, RN, FAAN
 Catharine Kane, PhD, RN, FAAN
 James Coyne, PhD

G Team Structure

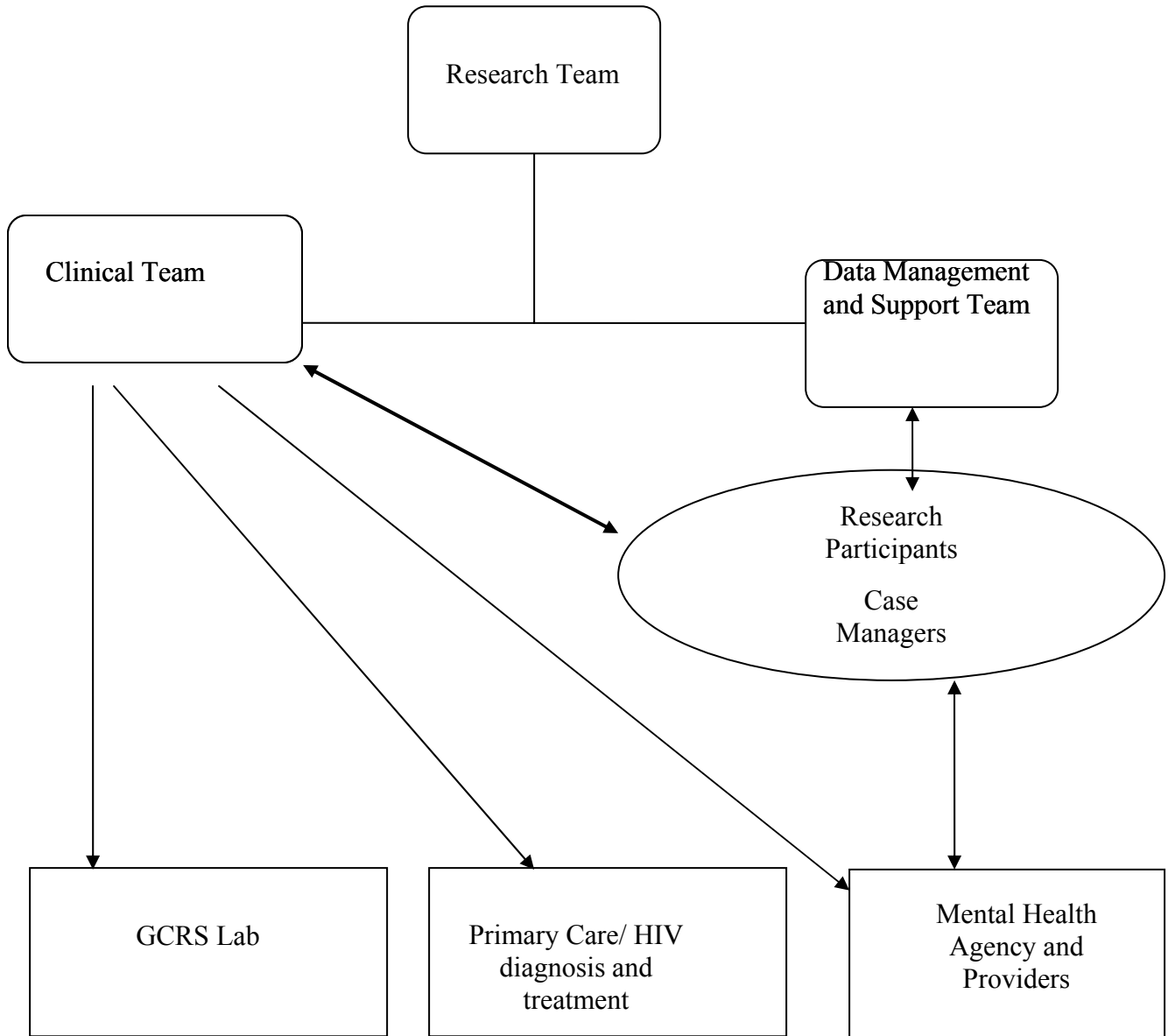
The HIV/SMI REGIMEN ADHERENCE study has three interacting teams: 1) a Clinical Team composed of advance practice nurses and a physician, 2) a Data Collection and Support Team composed of trained and credentialed research assistants, 3) the core Research Team that is employed and guided by the Principal Investigator of the research project is composed of a project manager, co-investigators, and consultants. Specific roles and responsibilities of each team are outlined below.

1. Clinical Team [advanced practice nurses (APN) and physicians (MD)] is composed of those persons who will be responsible for the medication adherence process; reviewing laboratory reports, advising and referring for primary care problems and pharmaco-

therapeutics; and providing clinical follow up to participants with positive test results. This team consists of licensed and trained health professionals who are sensitive to interacting with individuals with serious mental illness and HIV. The APN is also responsible for collecting blood specimens in cases where a client cannot ambulate or leave their home.

2. Data Collection and Support Team (Research Assistants), is made up of those persons who will administer the questionnaires and transport/accompany all individuals to the GCRC lab for blood draws as. The Research Assistants will maintain order while the questionnaires are being completed, be custodians of data, assist the clinical team, assist with recruiting and managing individuals participating in the study. These team members report to the Research Team for additional directives.
3. Research Team (Principal Investigator, Co-Investigators, Project Manager, Research Associates, and Consultants) includes those persons that work together with the Clinical, Data Collection and Support Teams to ensure that appropriate procedures are followed. The Research Team oversees the entire project.

H.ORGANIZATIONALCHART



I. ROLES AND RESPONSIBILITIES

Research Assistant:

Research Assistants (RAs) are responsible for performing a series of tasks related to data collection and monitoring of the study protocol. Tasks range from completing administrative forms, working with study participants to collect data, and interacting with case managers and the clinical team, Project Director, and Research Team. RAs are responsible for maintaining the confidentiality of all study participants.

Advanced Practice Nurses (APNs)

The APN is an independently licensed registered nurse clinician responsible and accountable for the research based knowledge, skills, and experience to assess, diagnose, and treat complex psychiatric and chemical dependency problems and co-morbid medical problems. The APN provides the medication adherence intervention using the protocol in the research study. The APN functions to maximize recruitment potential by identifying barriers to accessing study participants. Along with other research team members, the APN will develop and adapt recruitment strategies commensurate with the research project goals. The APN works with the client's health care and mental health care providers to influence the care of participants, affect change in systems, and enhances the ability of others to provide healthcare. The APN functions as a resource to providers caring for study participants. See job description: Appendix A.

II. POLICY

A. General Protocol for Documenting the APN Intervention

There are three venues for capturing patterns and essential components of the nurse intervention: a) the clinical documentation using the Omaha System, b) the medication adherence and path intervention protocols, and 3) APN journal of facilitators and barriers. The Omaha System consists of three components 1) a problem classification scheme, 2) an intervention scheme, and 3) a problem rating scale for outcomes. The problem classification scheme is a documentation system with consistent language for identifying, sorting, and classifying client problems. The intervention scheme is a taxonomic method for describing nurse actions or activities provided to clients. The problem rating scale for outcomes is an instrument that measures client progress in relation to specific problems. See Appendix B for the Omaha assessment guidelines.

The APN will administer the medication adherence intervention at weekly visits with participants using percent adherence, pill counts, and self reports to calculate the appropriate cascade intervention level. The medication adherence intervention is located in Appendix C. The medication intervention cascade is summarized below. The PATH is an HIV education intervention administered to the participant by the APN. The PATH is located in Appendix D.

The APN will journal about the facilitators and barriers to implementing comprehensive individualized care and highlight the role of the APNs and their clinical knowledge and skills. The APN will journal about each client after every face to face encounter. The APN Case Study Guidelines, below, presents focus areas including facilitators and barriers associated with the complexity of care, clinical priorities, complications, early problem prevention, relationships, and collaborative efforts. See Appendix E for the Case Study Guidelines for the APN journal.

B. Safety Protocol for HIV Exposure

All team members coming into direct or indirect contact with blood samples must use standard precautions at all times and be familiar with OSHA regulations on handling bloods or body fluids. In the case of a needle stick injury or exposure to blood samples, individuals should report within an hour to an emergency room to obtain antiretroviral medications and testing. Questions regarding this policy should be directed to the University of Pennsylvania Infectious Disease Division (215) 662-2222.

The protocol for managing an intervention when exposed to HIV transmission is reviewed in detail in the procedure titled: Post-Exposure Prophylaxis Needle Stick Injury Protocol in Appendix F. Briefly, if exposed to HIV transmission, go immediately to the closest emergency room for treatment. You will be tested and treated with an antiretroviral agent. See Appendix F for the Safety Protocol.

C. Confidentiality and Security of Clinical and Research Records

Pursuant to HIPAA Privacy and Security Rule mandates, all personnel connected to this research study with access to confidential information must adhere to practices that insure the maximum protection of patient/study participant information. These practices extend to the vigilant protection of electronic Protected Health Information (ePHI). Investigators, Research Assistants, APNs and Project management personnel having access to patient identifying information will be held accountable to these safeguards.

All written documents generated by research personnel will be kept under double lock. Paper documents containing patient information not necessary for retaining for research purposes must not be improperly discarded in the trash. These documents must be shredded before being disposed of.

Laptops used to collect patient/study participant data will be stored in locked filing cabinets when not in use. APNs and Research Assistants have coordinated with Project Management to develop strong computer passwords with encryption to include upper and lower case letters and numbers. All data on laptop computers will be de-identified and downloaded to a secure server with access limited to designated research personnel. Links to research subject identification will be under double lock and key and kept by the Senior Research Coordinator.

It is the responsibility of all custodians of patient identifying data not to keep this information on PDAs. Study personnel are also responsible for not sending information that could identify patients over the internet.

All personnel must sign a copy of this policy and procedure as it relates to protection of patient information. Signed copies will be maintained in employee files. See Appendix G.

D. Use of the grant vehicle

The APNs and other designated research team members may use the car for grant related activities as approved by the project manager and the principal investigator. The car is kept in the parking lot by the Nursing Education Building. The APNs will keep the car keys. The APNs will use the vehicle to visit participants at home or other grant related activities.

E. Documentation of APN Costs

In order to effectively capture the costs associated with the delivery of services by the APN, we use the Current Terminology and Procedural Coding (CPT Codes) system. With each direct or indirect participant encounter and activity related to the research, the APN will

Revised on 11/24/2004 2:41 PM

document the event activity. The event activity is defined as the service date, setting, mode of communication, diagnosis, type of service provided, CPT billing code, level of complexity, total time and mileage. See Appendix E.

III. PROCEDURES

A. INTERVENTION CASCADE

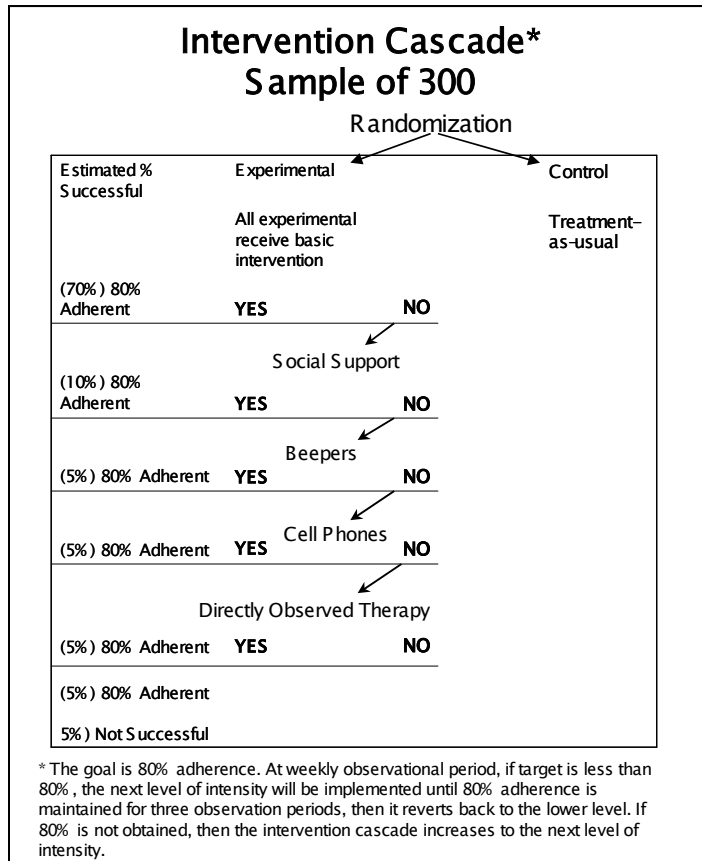
1. Overview

The intervention cascade is an intentional process with the primary goal of actively coping with barriers to adherence and to instill confidence in participants' abilities to self-administer and monitor medication. The intervention cascade is preceded by a baseline assessment to determine HIV sero + status, substance abuse and depression co-morbidities. The intervention cascade procedure is administered only with the experimental group. Participants are randomized into experimental and control groups. Experimental subjects will have APNs coordinate both their HIV and mental health care with case managers and will have face-to-face meetings at least twice a week. In these meetings, nurses and case managers will teach participants to use pill boxes and watches with alarms to arrange their weekly medication regimen. Additionally, nurses and case managers will help to coordinate and monitor attendance for physician and clinic appointments, including providing transportation if needed. A primary goal of the intervention will be to actively cope with barriers to adherence and to instill confidence in participants' abilities to self-monitor.

2. Procedure

a. The intervention will be tailored to the individual needs of the participants. Some participants may require more intensive didactic training to use the memory aids, and more frequent reinforcement and face-to-face meetings. A listing of the components of the intervention, along with the team member primarily responsible for ensuring delivery of that component is given in the figure.

b. Adherence is calculated based on self-report, pill counts, and pharmacist records on a weekly basis. If any of these three methods of measuring adherence fall below 80% the participant will have fallen below threshold. Experimental group participants that fail to maintain the 80% adherence threshold, an intervention cascade will be used to



examine the utility of more intensive methods.

- c. Adherence is assessed weekly by the APN and research team. If the adherence is less than 80%, the next level in the cascade will be implemented until 80% adherence is maintained for three observation periods (weeks), then the intervention reverts to the lower level. If 80% adherence is not obtained, then the cascade increases in intensity to the next level.

3. Components of the Cascade Intervention:

- a. *Social Network:* APN and case manager work with the existing social support network (family, friends, neighbors, and significant others) to assist with reminding participants to take medications, adhere to treatments and attend appointments.

- b. *Wireless devices:* For the estimated 20% who still are not able to maintain 80% adherence, wireless beepers with alphanumeric displays will be employed. These beepers will be used at the actual times a medication should be taken to remind experimental participants as in “take the blue pill now”. Nurses will coordinate this intervention along with case managers. They will rely primarily on the social network to actually make the phone call to send the reminder, but may also need to activate the beepers themselves.

Intervention Components		
Intervention	Levels	Delivered By
1) Memory Aids	*a) pill boxes *b) watches *c) beepers *d) cell phones	Nurse Case Manager
*2) Co-morbid depression	a) dx-CES-D b) Tx coordination	Nurse Case Manager
*3) Tailoring the intervention		Nurse Case Manager
*4) Active substance abuse	a) Dx – ASI light b) Tx coordination	Nurse Case Manager
*5) Attitudes toward medication		Nurse
*6) Monitoring side effects		Nurse
7) Social Support		Family, friends, S.O.
*8) Active coping with barriers and instilling confidence		Team
9) Directly observed therapy		Team
* Components of basic intervention		

- c. *Cellular Phones:* The next step in the intervention cascade will be to give experimental participants prepaid cellular phones to allow phone calls at the times when medications and other treatments need to be had. The rationale here is that those who continue to be non-adherent will need more individualized persuasive communications in order to meet the adherence threshold of 80%. In those cases APNs will coordinate calls by case managers and social network members, as well as making phone calls themselves to encourage adherence.

- a. Note: There is some risk of intentional non-adherence should it become clear to participants that non-adherence to regimen will be rewarded with a cellular phone. In order to discount this possibility, it will not be disclosed that less than 80% adherence trigger the next level of the cascade to participants, nor will the components or ordering of the intervention cascade be revealed. We also expect that only 15% of experimental participants (approximately 23 people) will require this level of intervention. Since these 23 individuals will be should be distributed relatively

evenly over the four year intervention period and over each intervention site ($4 \times 4 = 16$), there should be only one or two participants ($23/16 = 1.4375$) using cell phones at any site during any given week.

- d. *Directly Observed Therapy*: For individuals that continue to be non-adherent, nurses will coordinate the activities of case managers and social support networks, as well as making visits themselves.

B. MEDICATION ADHERENCE PROTOCOL

I.D. NUMBER

I	N			
---	---	--	--	--

DATE OF CONTACT

--	--	--

Month Day Year

TYPE OF SERVICE

	Mode	
--	------	--

- | | |
|---|---|
| <ul style="list-style-type: none">1. Assessment2. Medication Management3. Therapy and Med Management4. Collateral Contact5. Case Management6. Education/Counseling7. Procedure8. Documentation | <ul style="list-style-type: none">1. Face to face2. Phone3. E-mail4. Written |
|---|---|

LEVEL OF SERVICE

TIME SERVICE STARTED (USE 24-HR TIME)

--	--

Hr. Min.

TIME SERVICE ENDED (USE 24-HR TIME)

--	--

Hr. Min.

LOCATION OF SERVICE

 INTERVIEW COMPLETION CODE

- | | |
|---|--|
| <ul style="list-style-type: none">1. Consumer's home2. CMHC3. APN Office4. Other (<i>SPECIFY</i>)5. Community | <ul style="list-style-type: none">1. Respondent terminated interview prematurely2. Respondent refused interview3. Respondent unable to respond4. Interview partially completed; need to schedule another interview5. Interview completed |
|---|--|

MEDICATION ADHERENCE QUESTIONNAIRE COMPETED:

Instructions: APN will complete the following items after participant completes medication adherence form or after you ascertain that this is not possible:

How was the questionnaire completed?

- 1-Self administered by the study participant
- 2-Face-to-face interview that you conducted
- 3-Both self-administered and interview
- 4-Not completed
- 9-Other, specify

a. If you answered "4-Not completed," please indicate the reason why:

- 1-Participant refused
- 2-Participant missed clinic visit
- 3-There was not enough time
- 9-Other reason, specify

If Other, specify

APN INITIALS

--	--

--	--

INSTRUCTIONS FOR ADVANCED PRACTICE NURSE

To be accomplished with weekly contact

- 1.) Introduce self to participant and explain that he/she will be working closely with their case manager to assist them with taking their medications as prescribed
- 2.) Weekly, assess for depressive symptoms and cognitive function. APN will also assess for current use of alcohol and/ or drugs and level of perceived coercion.
- 3.) Gather information about participant's knowledge of medications and assess their attitude toward taking medication as per assessment protocol. This step is to assess the participant's fundamental understanding of their medication regimen and to identify barriers that exist that may prevent the participant from being adherent
- 4.) If participant admits to a change in their medication regimen, call the participants primary care provider to validate the change reported by the participant.
- 5.) Provide participant with instructions for the use of their medications including the action of the medications, the dosage of the medications, the frequency of taking the medications, the side effects of the medications and what to do if a medication is missed
- 6.) Instruct participant to monitor side effects of medications
- 7.) Encourage confidence in participants that they can self-administer and monitor their medications
- 8.) Ask the client if he or she has any questions about the medications and the intervention
- 9.) Initiate the intervention cascade if any HIV, psychotropic or other medication adherence is below 80%.
- 10.) Terminate the visit after establishing the time and place of the next contact.

INTRODUCTION:

Hello. My name is _____ and I am an Advanced Practice Nurse from the study that you enrolled in. I will be working closely with you and your case manager. The purpose of this visit is for me to get to know you. I will ask you a series of questions about your health, take your vital signs and complete a brief physical exam. As a part of your health assessment, I will ask you about your medications and how you manage to take them.

1. Part I CURRENT MEDICATIONS:

APN Instructions: **PART I IS TO BE COMPLETED BY THE PARTICIPANT AND THE NURSE TOGETHER DURING THE INITIAL ASSESSMENT AND UPDATED WHEN MEDICATIONS CHANGE.**

APN Script: **The purpose of this form is to learn about potential influences of treatment adherence. Please answer all questions honestly; you will not be “judged” based on your responses. If you do not wish to answer a question, please draw a line through it. When completed, the form will be quickly reviewed to make sure you didn’t mistakenly skip questions (without crossing them out). Please feel free to ask if you need any of the questions explained to you.**

Write the names of the medications in the boxes	What is the medicine for?	# Pills Each Time you take a dose	#Doses per day	Special Instructions: Do you have any of the following special instructions for taking the pills? Check all that apply	Do you ever have problems taking it?
# of pills on hand Expected Actual				<input type="checkbox"/> With food <input type="checkbox"/> Empty stomach <input type="checkbox"/> Drink plenty of fluids <input type="checkbox"/> No special instructions <input type="checkbox"/> Other, please specify:	<input type="checkbox"/> No <input type="checkbox"/> Yes, please specify_____
# of pills on hand Expected Actual				<input type="checkbox"/> With food <input type="checkbox"/> Empty stomach <input type="checkbox"/> Drink plenty of fluids <input type="checkbox"/> No special instructions <input type="checkbox"/> Other, please specify:	<input type="checkbox"/> No <input type="checkbox"/> Yes, please specify_____

2. Part II ADHERENCE QUESTIONNAIRE

Instructions: Participant fills out the form WEEKLY.

APN Script: The answers you give on this form will be used to plan ways to help other people who must take pills on a difficult schedule. Please do the best you can to answer all the questions. If you do not wish to answer a question, please draw a line through it. Ask if you do not know how to answer a question.

The next section of the questionnaire asks about your medications that you took over the last four days. Most people have many pills to take at different times during the day. Many people find it hard to always remember their pills:

- Some people get busy and forget to carry their pills with them.
- Some people find it hard to take their pills according to all the instructions, such as “with meals” or “on an empty stomach,” “every 8 hours,” “with plenty of fluids.”
- Some people decide to skip pills to avoid side effects or to just not be taking pills that day.

We need to understand how people are really doing with their pills. Please tell us what you are actually doing. Don’t worry about telling us that you don’t take all your pills. We need to know what is really happening, not what you think we “want to hear.” The next section of the questionnaire asks about the medications that you may have missed taking over the last four days. Please complete the following table by filling in the boxes below.

IF YOU TOOK ONLY A PORTION OF A DOSE ON ONE OR MORE OF THESE DAYS, PLEASE REPORT THE DOSE(S) AS BEING MISSED.

<u>STEP 1</u> Drug Names	HOW MANY DOSES DID YOU MISS.....?			
	<u>STEP 2</u> Yesterday	<u>STEP 3</u> Day before yesterday (2 days ago)	<u>STEP 4</u> 3 days ago	<u>STEP 5</u> 4 days ago
	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses
	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses
	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses
	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses
	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses
	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses
	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses
	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses
	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses
	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses
	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses

Revised on 11/24/2004 2:41 PM

	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses	<input type="checkbox"/> Doses
--	--------------------------------	--------------------------------	--------------------------------	--------------------------------

3. Part III Adherence Questionnaire.

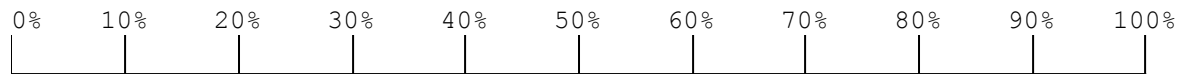
Instructions: After filling out the form above, the participant will continue with the questionnaire below reporting on missed doses of particular drugs. THIS FORM IS FILLED OUT WEEKLY

APN Script: **If you took only a portion of a dose on one or more of these days, please report the dose(s) as being missed.**

MEDICATION ADHERENCE

e.g. **0%** means you have **taken no (DRUG A)**
50% means you have **taken half your (DRUG A)**
100% means you have **taken every single dose of (DRUG A)**

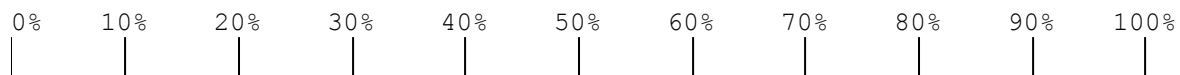
A1. How about (_____)



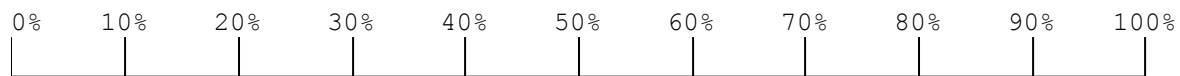
B1. How about (_____)?



C1. How about (_____)?



D1. How about (_____)?



1. During the past 4 days, on **how many days** have you missed taking **all your doses**?

(Check one box)

- None 0
- One day 1
- Two days 2
- Three days 3
- Four days 4

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

Never	Some of the time	About Half the Time	Most of the Time	All of the Time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	1	2	3	4

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

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>
1	2

4. **If Yes, how often did you follow those special instructions over the last four days?**

Never	Some of the time	About Half the Time	Most of the Time	All of the Time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	1	2	3	4

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

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>
1	2

6. **When was the last time you missed any of your medications? (Check one box)**

- Within the past week 5
- 1-2 weeks ago 4
- 2-4 weeks ago 3
- 1-3 months ago 2

More than 3 months ago

IF YOU NEVER MISS YOUR STUDY MEDICATIONS, PLEASE STOP. OTHERWISE, CONTINUE BY ANSWERING THE NEXT SET OF QUESTIONS.

4. PART IV. Adherence Questionnaire

THIS SECTION IS ADMINISTERED WEEKLY WHEN MEDICATIONS ARE MISSED.

APN Script: **People may miss taking their study medications for various reasons. Here is a list of possible reasons why you may miss taking your medications. How often have you missed taking your medications because you: (*Check one*)**

Please check one box for each question.

	Never	Rarely (Monthly)	Sometimes (Weekly)	Often (Daily)
Were away from home?	0	1	2	3
Were busy with other things?	0	1	2	3
Simply forgot?	0	1	2	3
Had too many pills to take?	0	1	2	3
Wanted to avoid side effects?	0	1	2	3
Did not want others to notice you taking medications?	0	1	2	3
Had a change in daily routine?	0	1	2	3
Felt like the drug was toxic/harmful?	0	1	2	3
Fell asleep/slept through dose time?	0	1	2	3
Felt sick/ill from side effect?	0	1	2	3
Felt depressed/ overwhelmed?	0	1	2	3
Had problem taking pills at specific times (with meals, on empty stomach, etc.)?	0	1	2	3
Ran out of pills?	0	1	2	3
Felt good?	0	1	2	3

5. Logistical Problems Related to Medications

Instructions: ADMINISTERED WEEKLY. Often individuals taking medication can have problems with access, storage, payment or other problems. Please respond ‘CHECK’ if you have some trouble related to:

- Getting medication prescriptions filled
- Getting medication prescriptions refilled
- Carrying medications with you when you are out of the house
- Storing medications
- Paying for medications
- Preparing foods suitable for medications

6. SIDE EFFECT PROFILE AND SELF-CARE MANAGEMENT

Instructions: ADMINISTER WEEKLY. Below is a list of potential problems that **you may experience when taking your medications**. If you have had the problem **WITHIN THE LAST WEEK**, select the rating that best describes the extent of the problem. Check one rating per item. If you do not have the problem, do not check a box. Following the completion of the checklist, the nurse will ask you how you manage the problems you have checked.

NONE	MILD	MODERATE	SEVERE	PROBLEM	SELF-CARE ACTIVITIES <i>To be completed by Nurse</i>
	Y	Y	Y	<i>Day sweats</i>	
	Y	Y	Y	Night sweats	
	Y	Y	Y	Fever	
	Y	Y	Y	Chills	
	Y	Y	Y	Weakness	
	Y	Y	Y	Muscle aches	
	Y	Y	Y	Headaches	
	Y	Y	Y	Fatigue	
	Y	Y	Y	Painful joints	
	Y	Y	Y	Painful feet	
	Y	Y	Y	Vomiting	
	Y	Y	Y	Nausea	
	Y	Y	Y	Lack of appetite	
	Y	Y	Y	Gas/bloating	
	Y	Y	Y	Dry mouth	
	Y	Y	Y	Thirst	
	Y	Y	Y	Abdominal pain	
	Y	Y	Y	Loose stools	
	Y	Y	Y	Diarrhea	

Y	Y	Y	Constipation	
Y	Y	Y	Rash	
Y	Y	Y	Oral ulcers	
Y	Y	Y	Taste perversion	
Y	Y	Y	Anemia	Not a subjective symptom
Y	Y	Y	High bilirubin (yellow skin)	This one and the next two are really the same question
Y	Y	Y	Yellow eyes	
Y	Y	Y	Jaundice	
Y	Y	Y	Kidney stones	Not a subjective symptom
Y	Y	Y	Low white blood cells (neutropenia)	Not subjective
Y	Y	Y	Pancreatitis	Not a subjective symptom
Y	Y	Y	Numbness and tingling (peripheral neuropathy)	

7. PERCEIVED COERSION

Instructions: the APN will obtain a perceived coercion score ONE WEEK AFTER THERE HAS BEEN A CHANGE (UP OR DOWN) IN THE CASCADE LEVEL

6.1 I feel free to do what I want about getting mental health treatment.

Strongly Disagree	Somewhat Disagree	Slightly Disagree	Neither	Slightly Agree	Somewhat Agree	Strongly Agree	NANS	NASK
1	2	3	4	5	6	7	8	9

6.2 I choose to get mental health treatment.

Strongly Disagree	Somewhat Disagree	Slightly Disagree	Neither	Slightly Agree	Somewhat Agree	Strongly Agree	NANS	NASK
1	2	3	4	5	6	7	8	9

6.3 It is my idea to get mental health treatment.

Strongly Disagree	Somewhat Disagree	Slightly Disagree	Neither	Slightly Agree	Somewhat Agree	Strongly Agree	NANS	NASK
1	2	3	4	5	6	7	8	9

6.4 I have a lot of control over whether I get mental health treatment.

Strongly Disagree	Somewhat Disagree	Slightly Disagree	Neither	Slightly Agree	Somewhat Agree	Strongly Agree	NANS	NASK
1	2	3	4	5	6	7	8	9

9. PHARMACY REFILL DATA FORM

Instructions: The APN will call the pharmacy to obtain information about refills at the initial visit, 3 months, 6 months, and 12 months.

Pharmacy Refill Data:

Index Drug _____

Dosage _____

Frequency _____

Dates of Refills in last 3 months:

Last refill date ____ / ____ / ____

Refill -1 date ____ / ____ / ____ **Number dispensed** ____

Refill -2 date ____ / ____ / ____ **Number dispensed** ____

Refill -3 date ____ / ____ / ____ **Number dispensed** ____

Refill -4 date ____ / ____ / ____ **Number dispensed** ____

Refill -5 date ____ / ____ / ____ **Number dispensed** ____

Refill -6 date ____ / ____ / ____ **Number dispensed** ____

Refill -7 date ____ / ____ / ____ **Number dispensed** ____

Refill -8 date ____ / ____ / ____ **Number dispensed** ____

C. PATH PROTOCOL

Where will the other teaching modules go? Do we need create more PATH sessions or just fit them into the four sessions already developed?

PATH I

SESSION 1: INTRODUCTORY CARD

Advanced Practice Nurse: Please make sure that you locate a quiet, comfortable space to work with your consumer on PATH. This space should afford privacy and you should plan on spending at least a half an hour for each scheduled session.

Materials Needed:

1. *PATH CARDS & Help Me CARDS*
 2. *Condoms*
 3. *Condom training model*
 4. *Tissues*
 5. *Full supply of pamphlets relating to PATH topics.*
 6. *PATH Weekly form/Invoice*
 7. *Pen*
 8. *Day Planner*
 9. *Referral numbers*
-

PATH CARD 1

The PATH program of education centers on an open and honest discussion about sexually transmitted diseases including HIV.

There are important reasons why this program has come to our agency. Here are a few:

- **As a person with mental illness, you are at a much greater risk for getting sexually transmitted diseases including HIV.**
- **If you are also using drugs and alcohol, your risk is even greater.**

***My goal throughout this process is to help you find out about the resources or information that could help you stay healthy and reduce your risk of getting these diseases.**

To be stated at each session are:

- 1. Thank you for agreeing to meet with me.***
 - 2. Please remember that what you share with me is confidential. I will not share anything that you tell me today with persons unconnected to this project.***
 - 3. I want you to feel that you can be open and honest with me.***
 - 4. If you are uncomfortable with a section, please let me know and we will skip it or come back to it.***
 - 5. This is not a test and any questions that you have are important to me.***
 - 6. Please let me know if I am going too fast or too slow.***
 - 7. Do you have any questions before we begin?***
-

HOW WILL WE DO THIS?

This will be the first of a number of discussions on these health topics.

We will go through the cards together at your pace, and pay special attention to certain topics that are more important to you.

At the beginning of each discussion, I will give you some *HELP ME* cards.

If you want more information, I would be happy to help you with something, like getting condoms. Just tell me or give me a *HELP ME* card.

PATH CARD 2

HAVE YOU HEARD OF SEXUALLY TRANSMITTED DISEASES?

WHAT DO YOU KNOW ABOUT THEM?

PATH CARD 3

NOW THAT WE HAVE TALKED A LITTLE ABOUT WHAT SEXUALLY TRANSMITTED DISEASES ARE, LET'S TALK ABOUT WHAT MIGHT MAKE A PERSON MORE LIKELY TO GET THEM.

WHAT DO YOU THINK MIGHT MAKE A PERSON MORE LIKELY TO GET A SEXUALLY TRANSMITTED DISEASE.

Sexually transmitted diseases are caused by germs that are passed between two people during sex.

Both men and women can get sexually transmitted diseases.

Women are at higher risk for sexually transmitted diseases.

Some examples of sexually transmitted diseases that we will talk about are chlamydia, gonorrhea, syphilis, herpes, genital HPV, Hepatitis, and HIV.

Having unprotected sex makes a person more likely to get sexually transmitted diseases.

Getting drunk or high makes you more likely to have unprotected sex and could also make you more likely to get sexually transmitted diseases.

PATH CARD 4

I HAVE MENTIONED WHAT COULD HAPPEN IF YOU HAVE UNPROTECTED SEX, WHICH IS ALSO CALLED UNSAFE SEX. WHAT DO YOU THINK ARE EXAMPLES OF UNSAFE SEX?

PATH CARD 5

WE HAVE TALKED ABOUT UNSAFE SEX. NOW LET'S TALK ABOUT SAFER SEX.

WHAT DOES SAFER SEX MEAN TO YOU? WHAT DO YOU THINK OF WHEN I SAY SAFER SEX?

UNSAFE sexual activities include:

- **Sharing sex toys without a condom**
- **Oral sex without a condom (blow job, going down on someone)**
- **Vaginal sex without a condom**
- **Anal sex (“in the butt”) without a condom**

Do you have any questions?

The only ‘completely safe’ sex activities are:

- **abstinence (no sex)**
- **masturbation (jerking off)**

Safer sex activities include:

- **mutual masturbation with a partner (jerking each other off)**
- **oral sex with a condom**
- **vaginal sex with a condom**
- **anal (“in the butt”) sex with a condom**

Do you have any questions? Is there anything you would like me to go over again?

PATH CARD 6

IF YOU HAVE SEX, WHAT ARE THE BEST WAYS TO PROTECT YOURSELF FROM SEXUALLY TRANSMITTED DISEASES?

PATH CARD 7

USING CONDOMS IS THE MOST IMPORTANT PART OF HAVING SAFER SEX.

LET'S GO THROUGH THE STEPS OF USING A CONDOM .

***Advanced Practice Nurse needs to be prepared with a condom training model**

If you have sex with one person or multiple people always use proper protection such as a latex condom or female condom (which we will talk about later).

If you use a condom, only use it once.

If you are giving a blow job (giving head), use a condom.

If you are giving oral sex to a woman (eating out, going down on her, etc..), you should always use a dental dam or a barrier like plastic wrap.

Using lubricants, jellies, douches, or sponges, will NOT prevent you from getting sexually transmitted diseases.

IF YOU WANT MORE INFORMATION OR WOULD LIKE ME TO GIVE YOU SOME CONDOMS, YOU CAN GIVE ME A *HELP ME CARD* OR ASK ME NOW.

YOU CAN ALSO ASK ME LATER OR GIVE ME A *HELP ME CARD* AT ANYTIME.

I am going to use a condom training model to demonstrate the correct use of a condom. Does this sound okay to you?

1. Check the date on the condom package to make sure it is not expired.
2. Open the package without tearing the condom.
3. Pinch the tip of the condom to remove the air.
4. Leave space at the tip of the condom for semen (cum).
5. Roll the condom down to the base of the penis.

PATH CARD 8

NOW THAT WE'VE GONE THROUGH THE STEPS OF USING A CONDOM,
LET'S TALK ABOUT WHAT TO DO WITH THE CONDOM WHEN YOU
ARE FINISHED HAVING SEX.

PATH CARD 9

HAVE YOU HEARD ABOUT THE FEMALE CONDOM?

ARE YOU INTERESTED IN LEARNING ABOUT THE FEMALE CONDOM?

IF YES, CONTINUE WITH CARD 9 AND CARD 10

IF NO, PLEASE END SESSION HERE

SESSION I ENDS HERE. PLEASE RECORD....

6. When the man pulls out after cumming, he should hold the condom so that it stays on the penis.
7. Pinch the tip of the condom and keep the semen (cum) inside of the condom.

8. Wrap the condom in a tissue, and throw it in the garbage.
(Do not throw the condom in the toilet)

After completing the demonstration, please ask the consumer to repeat the steps for proper condom use.

The female condom is a small bag-like device that a woman can put inside herself before vaginal or anal (“in the butt”) sex.

Men may also use the female condom when they engage in anal sex, but must remember to remove the ring prior to use. I will show you the ring in a few minutes.

The female condom can prevent HIV, Hepatitis, and other sexually transmitted diseases from being passed.

The female condom should only be used once and then thrown away.

Female and male condoms should never be used at the same time.

PATH CARD 10

LET'S GO THROUGH THE STEPS OF USING A FEMALE CONDOM.

PATH CARD 11

NOW THAT WE HAVE TALKED ABOUT HOW TO INSERT THE FEMALE CONDOM, LET'S TALK ABOUT WHAT TO DO WITH THE CONDOM DURING SEX AND WHEN YOU ARE FINISHED HAVING SEX.

- 1. Check the date on the female condom package to make sure it is not expired.**
- 2. Open the package without tearing the female condom.**
- 3. Be sure that the inner ring is at the bottom, closed-end of the pouch.**
- 4. Grab the inner ring with your thumb and middle finger, and pinch the edges together.**
- 5. Still pinching the edges of the inner ring together, use your other hand to spread the vagina and insert the condom.**
- 6. Use your index finger to guide the condom into the vagina. Be careful not to twist the condom.**

7. Push the ring in until the cervix is completely covered. When this happens, the ring should fall into place.

The female condom can be inserted up to 8 hours before sex.

8. During vaginal sex, make sure the outer ring of the female condom stays outside of the vagina.
9. After partner cums, squeeze and twist the outer ring to keep the semen inside of the pouch.
10. Remove the condom by pulling and be careful not to spill the semen (cum).
11. Wrap the condom in a tissue and throw it in the garbage.
(Do not throw the female condom in the toilet.)

Do you have any questions?

IF YOU WANT MORE INFORMATION OR WOULD LIKE ME TO HELP YOU GET FEMALE CONDOMS, YOU CAN GIVE ME A *HELP ME* CARD NOW.

YOU CAN ALSO ASK ME LATER OR GIVE ME A *HELP ME* CARD AT ANY TIME.

SESSION I ENDS HERE. PLEASE RECORD....

PATH PROTOCOL PATH II

SESSION 2: INTRODUCTORY CARD

Advanced Practice Nurse: Please make sure that you locate a quiet, comfortable space to work with your consumer on PATH. This space should afford privacy and you should plan on spending at least a half an hour for each scheduled session.

Materials Needed:

- 1. PATH CARDS & Help Me CARDS*
 - 2. Condoms*
 - 3. Condom training model.*
 - 4. Tissues*
 - 5. Full supply of pamphlets relating to PATH topics*
 - 6. PATH Weekly form/invoice*
 - 7. Pen*
 - 8. Day Planner*
 - 9. Referral numbers*
-

PATH CARD 12

DURING OUR LAST DISCUSSION, WE TALKED ABOUT SEXUALLY TRANSMITTED DISEASES AND UNSAFE AND SAFER SEX.

TODAY, WE ARE GOING TO TALK ABOUT SPECIFIC EXAMPLES OF SEXUALLY TRANSMITTED DISEASES.

HAVE YOU HEARD ABOUT CHLAMYDIA AND GONORRHEA?

(IF YES, TELL ME WHAT YOU HAVE HEARD?)

To be stated at each session are:

1. *Thank you for agreeing to meet with me.*
2. *Please remember that what you share with me is confidential. I will not share anything that you tell me today with persons unconnected to this project.*
3. *I want you to feel that you can be open and honest with me.*
4. *If you are uncomfortable with a section, please let me know and we will skip it or come back to it.*
5. *This is not a test and any questions that you have are important to me.*
6. *Please let me know if I am going too fast or too slow.*
7. *Do you have any questions before we begin?*

***Chlamydia and gonorrhea are sexually transmitted diseases caused by germs that are passed between partners during sex.**

CHLAMYDIA:

In most people, there are no symptoms of chlamydia. Some women who have chlamydia may have an abnormal vaginal discharge and pain during sex and when peeing. Some men who have chlamydia may have an abnormal discharge from their penis or feel pain when they pee. If untreated, chlamydia can cause sterility in men and women. Sterility is when you are unable to have children. Urine or vaginal discharge can be used to test for chlamydia. There is medicine you can take to treat chlamydia.

GONORRHEA:

Just like with chlamydia, most people have no symptoms of gonorrhea. Some women who have gonorrhea may have abnormal vaginal discharge and pain during urination. Some men who have gonorrhea may have abnormal discharge from their penis. Sometimes, men with gonorrhea get painful or swollen testicles. If untreated, gonorrhea can cause sterility in men and women. Urine is used to test for gonorrhea. There is medicine you can take to treat gonorrhea.

PATH CARD 13

HAVE YOU HEARD ABOUT GENITAL HPV, HERPES, AND SYPHILIS, WHICH ARE OTHER KINDS OF SEXUALLY TRANSMITTED DISEASES?

PATH CARD 14

NOW THAT WE HAVE TALKED ABOUT SOME SPECIFIC EXAMPLES OF SEXUALLY TRANSMITTED DISEASES, WE ARE GOING TO TALK ABOUT HIV/AIDS.

HAVE YOU HEARD OF HIV/AIDS?

HAVE YOU EVER KNOWN ANYONE WITH HIV/AIDS?

GENITAL HPV: In most people, there are no symptoms of Genital HPV. Genital HPV is also know as genital warts. Some men and women who have Genital HPV can get warts on their genitals, in their mouth, or even in the eye. Genital HPV can lead to cancer in some women. A tissue sample is used to test for Genital HPV. There is medicine to treat Genital HPV.

HERPES: In most people, there are no symptoms of Herpes. Some men and women who have Herpes get sores, or “fever blisters”, on their genitals or around the mouth and lips. Sometimes, the genital sores can be very painful. A blood sample can be used to test for Herpes. There is medicine to treat Herpes.

SYPHILIS: In many people, there are no symptoms of Syphilis for many years. Some men and women who have Syphilis may get a sore or sores around their genitals and a skin rash. If untreated, syphilis may lead to death. A blood sample can be used to test for syphilis. There is medicine to treat syphilis.

IF YOU WANT MORE INFORMATION OR WOULD LIKE ME TO HELP YOU GET TESTED FOR ANY OF THE SEXUALLY TRANSMITTED DISEASES WE HAVE JUST TALKED ABOUT, YOU CAN GIVE ME A *HELP ME* CARD NOW OR ASK ME AT ANY TIME.

The Human Immunodeficiency Virus (HIV) is the virus that causes AIDS, or Acquired Immune Deficiency Syndrome.

HIV/AIDS is different than other sexually transmitted diseases. It can be passed during sex and through the blood of people who are infected with HIV/AIDS.

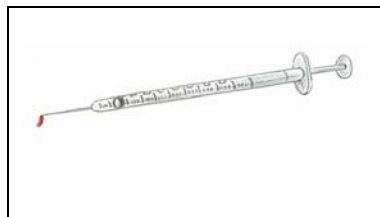
HIV/AIDS makes it harder for your body to fight off infections that can make you very sick.

Although there is no cure for HIV, ongoing treatment for people who have HIV can help them live a longer and healthier life.

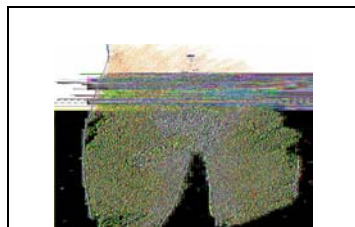
PATH CARD 15

THERE ARE SEVERAL WAYS THAT HIV IS PASSED FROM ONE PERSON TO ANOTHER.

ARE YOU FAMILIAR WITH ANY OF THE WAYS?



HIV is passed through exposure to blood during drug use (e.g. IDU, and snorting drugs)

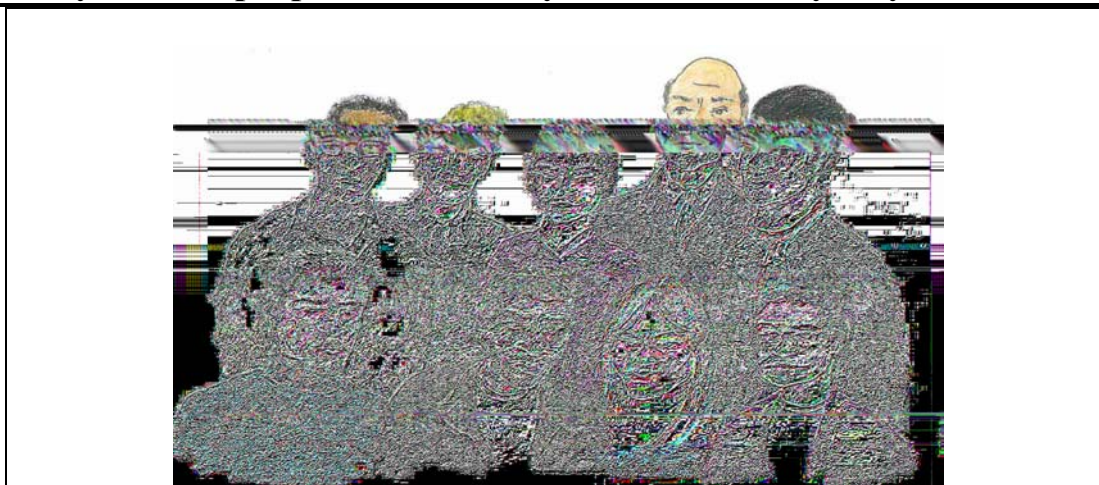


HIV is passed through semen or cum during unsafe sex.

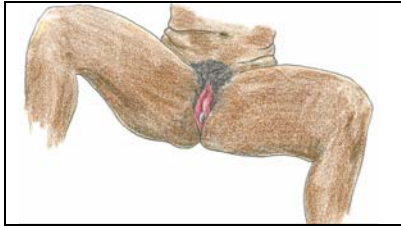
PATH CARD 16

NOW THAT WE HAVE TALKED ABOUT HOW HIV IS PASSED BETWEEN PEOPLE, LETS TALK ABOUT SOME OF THE COMMON MISUNDERSTANDINGS ABOUT HIV?

Do any of these people look like they have HIV? Why do you think that?



YOU CANNOT TELL IF A PERSON HAS HIV FROM THE WAY THAT THEY LOOK.




HIV is passed through vaginal fluid or wetness during unsafe sex.

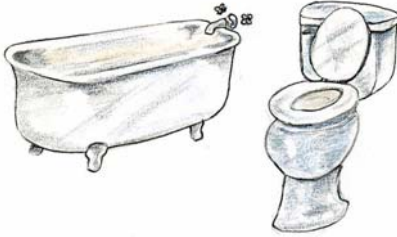


HIV can be passed through breast milk from a mother with HIV to her baby.


Did you know that you cannot get HIV from.....





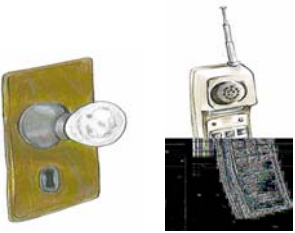
Hugging



Bathtub and toilet seat



Cups and Silverware

 <p>Sharing Food or Drink</p>	 <p>Coughing and Sneezing</p>	 <p>Doorknobs and Phones</p>
---	---	--

PATH CARD 17

WE HAVE TALKED ABOUT HOW HIV MAKES IT HARDER FOR YOUR BODY TO FIGHT OFF INFECTIONS THAT CAN MAKE YOU VERY SICK.

WHY DO YOU THINK THIS HAPPENS?

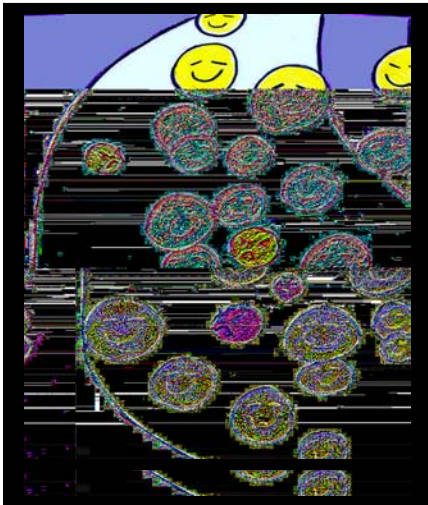
PATH CARD 18

LETS TALK ABOUT SOME DISEASES THAT YOU CAN GET WHEN HIV WEAKENS YOUR IMMUNE SYSTEM.

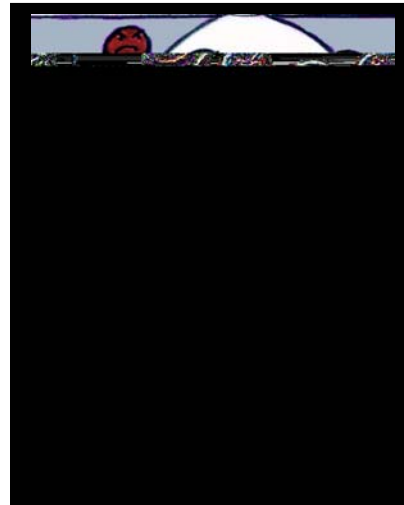
CAN YOU TELL ME WHAT DISEASES YOU THINK MIGHT AFFECT SOMEONE WITH A WEAK IMMUNE SYSTEM

- **The reason this happens is because HIV harms your immune system.**
- **The immune system is a group of cells that people have inside of their bodies to fight off the germs that cause illness and disease.**

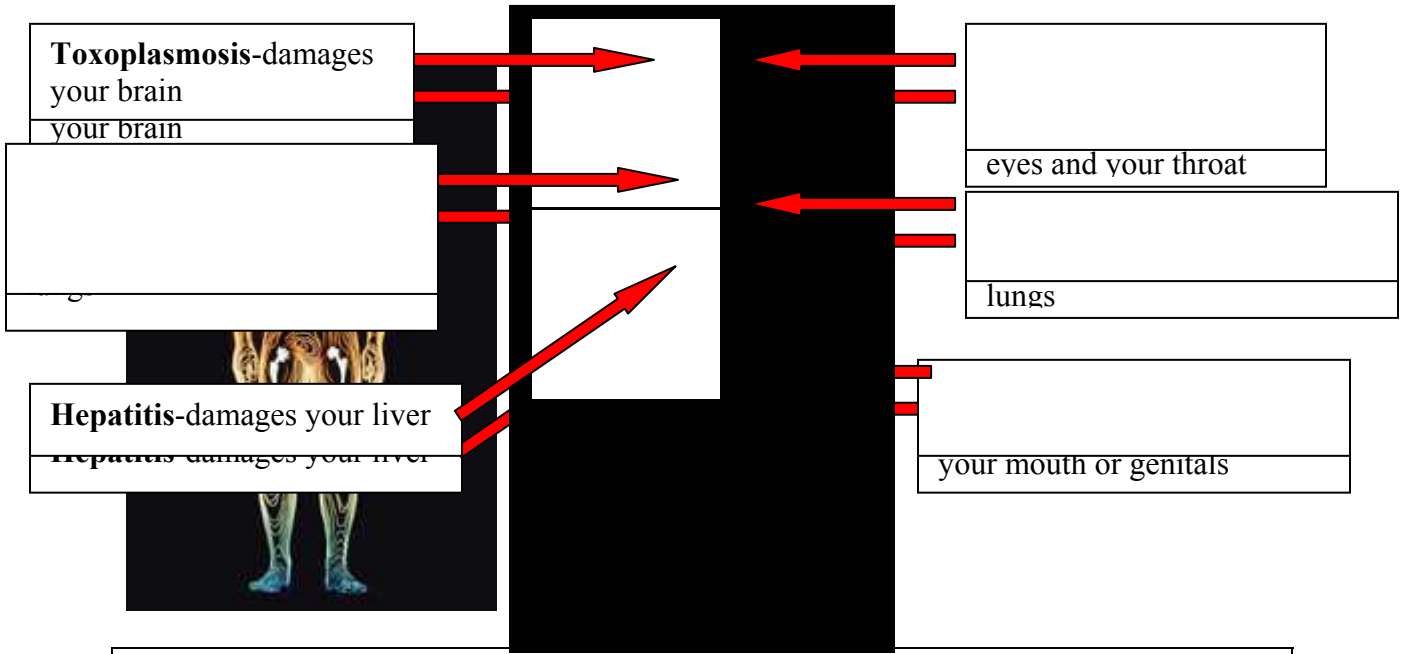
Under normal conditions, your body can get rid of bad invaders or germs that make you sick.



With HIV/AIDS, your body can't fight off those bad germs as well.



DISEASES YOU CAN GET



PATH PROTOCOL PATH III

SESSION 3: INTRODUCTORY CARD

Advanced Practice Nurse: Please make sure that you locate a quiet, comfortable space to work with your consumer on PATH. This space should afford privacy and you should plan on spending at least a half an hour for each scheduled session.

Materials Needed:

1. *PATH CARDS & Help Me CARDS*
2. *Condoms*
3. *Condom training model*
4. *Tissues*
5. *Full supply of pamphlets relating to PATH topics*
6. *PATH Weekly form/invoice*
7. *Pen*
8. *Day Planner*
9. *Referral numbers*

PATH CARD 19

DURING OUR LAST DISCUSSION, I MENTIONED THAT TUBERCULOSIS AND HEPATITIS ARE TWO DISEASES THAT YOU CAN GET WHEN YOUR IMMUNE SYSTEM IS WEAK.

TODAY, WE ARE GOING TO TALK MORE ABOUT TUBERCULOSIS AND HEPATITIS.

HAVE YOU HEARD OF TUBERCULOSIS (TB)?

To be stated at each session are:

- 1. Thank you for agreeing to meet with me.***
- 2. Please remember that what you share with me is confidential. I will not share anything that you tell me today with persons unconnected to this project.***
- 3. I want you to feel that you can be open and honest with me.***
- 4. If you are uncomfortable with a section, please let me know and we will skip it or come back to it.***
- 5. This is not a test and any questions that you have are important to me.***
- 6. Please let me know if I am going too fast or too slow***
- 7. Do you have any questions before we begin?***

Tuberculosis (TB) is a disease that mostly affects the lungs. People who have HIV are at risk for getting TB because they have a weak immune system. People without HIV can also be at risk for TB.

Because TB is passed from person to person through germs in the air, TB is passed more easily in crowded areas. People who live in boarding houses, group homes, prisons, and shelters, are at greater risk for TB.

People with TB may feel sick or weak, lose weight, and have fevers and night sweats. People with TB may also cough a lot, have chest pain, and cough up blood. Or, they may just feel very tired.

There is medicine to treat TB.

IF YOU WANT MORE INFORMATION OR WOULD LIKE ME TO HELP YOU GET TESTED FOR TB, YOU CAN GIVE ME A *HELP ME* CARD NOW.

YOU CAN ALSO ASK ME LATER OR GIVE ME A *HELP ME* CARD AT ANY TIME.

PATH CARD 20

DURING OUR DISCUSSION, I HAVE MENTIONED HEPATITIS.

ARE YOU FAMILIAR WITH HEPATITIS?

(IF YES, WHAT DO YOU KNOW ABOUT HEPATITIS?)

PATH CARD 21

I MENTIONED THREE TYPES OF HEPATITIS. ONE OF THOSE TYPES WAS HEPATITIS A.

HAVE YOU HEARD OF HEPATITIS A?

There are several types of Hepatitis. We will talk about Hepatitis A, Hepatitis B, and Hepatitis C.

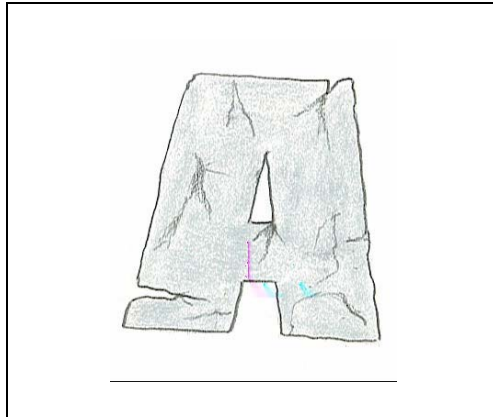
Hepatitis damages the liver. If you have Hepatitis, you could get liver conditions like cancer or cirrhosis, which is scarring of the liver.

If you have Hepatitis, you may feel tired, lose your appetite, feel nauseous, or throw up. Your eyes and skin may also look yellowish.

Hepatitis A is a virus found in the feces (poop, crap) of persons with Hepatitis A.

Hepatitis A is usually passed from one person to another by eating something that is not been cooked correctly, or by putting something in your mouth that has been in contact with the feces of someone who has Hepatitis A.

There is a vaccine to protect you from getting Hepatitis A.



PATH CARD 22

THE SECOND TYPE OF HEPATITIS I MENTIONED WAS HEPATITIS B.

HAVE YOU HEARD OF HEPATITIS B?

PATH CARD 23

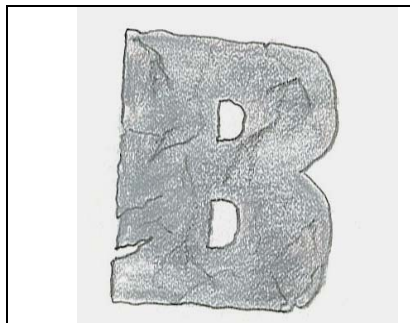
THE LAST TYPE OF HEPATITIS I MENTIONED WAS HEPATITIS C.

HAVE YOU HEARD OF HEPATITIS C?

Hepatitis B is a more serious infection than Hepatitis A. Most people who get Hepatitis B will get better, but some people can become very sick.

People get Hepatitis B from coming into contact with the blood or body fluids of an infected person. This happens most frequently during sex and needle sharing.

There is a vaccine that can protect you against Hepatitis B.



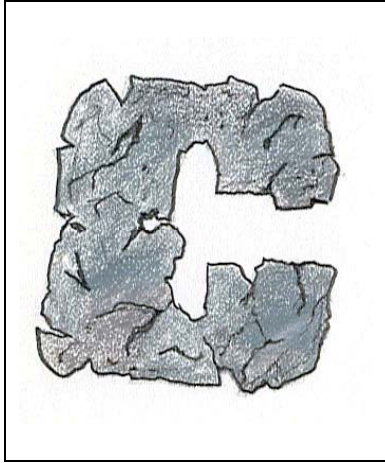
Do you have any questions about Hepatitis A or Hepatitis B?

Hepatitis C is the most common type of Hepatitis. Some people with Hepatitis C can get better, but other people can become very sick and may even die.

People get Hepatitis C from coming into contact with the blood or body fluids of an infected person. This happens most frequently during sex and needle sharing.

People who have Hepatitis C might also be at risk for Hepatitis B and HIV.

There is no vaccine for Hepatitis C.



IF YOU WANT MORE INFORMATION OR WOULD LIKE ME TO HELP YOU GET TESTED FOR HEPATITIS, YOU CAN GIVE ME A *HELP ME* CARD NOW. YOU CAN ALSO ASK ME LATER OR GIVE ME A *HELP ME* CARD AT ANY TIME

PATH CARD 24

ALTHOUGH THERE IS NO VACCINE FOR HEPATITIS C, THERE ARE THINGS YOU CAN DO TO STAY HEALTHY IF YOU HAVE HEPATITIS C.

Things you can do to stay healthy include:

Avoid or minimize alcohol use.

Having safer sex.

If you use drugs, use clean needles. (We will talk about needle use in a little while.)

SESSION III ENDS HERE. PLEASE RECORD.....

Revised on 11/24/2004 2:41 PM

PATH PROTOCOL PATH IV

SESSION 4: INTRODUCTORY CARD

Advanced Practice Nurse: Please make sure that you locate a quiet, comfortable space to work with your consumer on PATH. This space should afford privacy and you should plan on spending at least ½ hour for each scheduled session.

Materials Needed:

- 1. PATH CARDS & Help Me CARDS*
- 2. Condoms*
- 3. Condom training model*
- 4. Tissues*
- 5. Full supply of pamphlets relating to PATH topics*
- 6. PATH Weekly form/invoice*
- 7. Pen*
- 8. Day Planner*
- 9. Referral numbers*

PATH CARD 25

DURING OUR OTHER DISCUSSIONS, WE TALKED ABOUT HOW HIV AND HEPATITIS CAN BE PASSED BETWEEN PEOPLE THROUGH BLOOD.

**IF YOU USE NEEDLES FOR DRUG USE, TATOOING, OR PIERCING,
HOW DO YOU THINK YOU MIGHT PROTECT YOURSELF FROM HIV
AND HEPATITIS?**

To be stated at each session are:

- 1. Thank you for agreeing to meet with me.*
- 2. Please remember that what you share with me is confidential. I will not share anything that you tell me today with persons unconnected to this project.*
- 3. I want you to feel that you can be open and honest with me.*
- 4. If you are uncomfortable with a section, please let me know and we will skip it or come back to it.*
- 5. This is not a test and any questions that you have are important to me.*
- 6. Please let me know if I am going too fast or too slow.*
- 7. Do you have any questions before we begin?*

Never reuse or share needles, water, cottons, or cookers.

Use a new needle every time you inject.

Use clean water.

Disinfect the cooker/spoon with bleach.

Clean the injection site with an alcohol swab.

Safely dispose of needles after every use.

If you do reuse or share syringes, make sure that the needle and all other injection equipment is cleaned with bleach before and after every use.

Do you have any questions?

PATH CARD 26

**WE JUST TALKED ABOUT SOME WAYS TO PROTECT YOURSELF
FROM HIV IF YOU ARE USING NEEDLES.**

NOW, LET'S GO THROUGH THE STEPS OF CLEANING A NEEDLE.

PATH CARD 27

**WE HAVE TALKED ABOUT BOTH THE IMPORTANCE OF USING NEW
NEEDLES AND THE PROPER WAY TO CLEAN NEEDLES DURING DRUG
USE.**

**NEEDLE EXCHANGE PROGRAMS CAN HELP YOU USE NEEDLES
SAFELY. HAVE YOU HEARD OF NEEDLE EXCHANGE PROGRAMS?**

- 1. Fill the needle with clean water and shake the needle.**
- 2. Discard the water into a sink, toilet, or sewer.**
- 3. Fill the needle with full-strength bleach.**
- 4. Keep the bleach in the needle and thoroughly shake up the bleach for 30 seconds to reach all areas of the needle. Avoid having the bleach come into contact with your skin, eyes, and mouth.**
- 5. Discard the bleach waste into sink, toilet, or sewer.**
- 6. After you finish rinsing with one time with water, one time with bleach, and one time with water, remove the plunger from the needle and clean both parts again with bleach and water.**

A needle exchange is a place where you can go to trade your old needles for new needles.

A needle exchange is a place that will also give you condoms.

A needle exchange is a place where you can also get access to doctors, lawyers, and other resources.

IF YOU WOULD LIKE ME TO HELP YOU GET INFORMATION ABOUT THE NEEDLE EXCHANGE IN PHILADELPHIA, YOU CAN GIVE ME A *HELP ME CARD* NOW.

YOU CAN ALSO ASK ME LATER OR GIVE ME A *HELP ME CARD* AT ANY TIME.

PATH CARD 28

WE TALKED ABOUT HOW CONTACT WITH BLOOD DURING NEEDLE DRUG USE PUTS PEOPLE AT RISK FOR HIV AND HEPATITIS.

DO YOU THINK THAT PEOPLE WHO USE COCAINE AND CRACK ARE AT RISK FOR HIV AND HEPATITIS?

PATH CARD 29

NOW THAT WE HAVE TALKED ABOUT SOME OF THE HEALTH RISKS INVOLVED WITH DRUG USE, I THOUGHT WE COULD TALK ABOUT DRUG TREATMENT.

WHAT DO YOU THINK MIGHT BE SOME BENEFITS TO DRUG TREATMENT?

Yes!

People who use crack and cocaine often have more unsafe sex.

People who use crack and cocaine take longer to cum or have an orgasm.

Longer sex can sometimes cause cuts and bleeding. When this happens, a person is more likely to pass HIV and Hepatitis.

People who smoke hot crack pipes can get blisters and cuts on their lips. When this happens, people are more likely to pass HIV and Hepatitis.

Your health will improve.

Your immune system will get stronger.

You will think more clearly.

You will be more likely to take better care of yourself.

You will be more likely to avoid legal problems.

You will save money.

You will feel better.

IF YOU WANT MORE INFORMATION ABOUT DRUG TREATMENT PROGRAMS, YOU CAN GIVE ME A *HELP ME* CARD NOW.

YOU CAN ALSO ASK ME LATER OR GIVE ME A *HELP ME* CARD AT ANY TIME

PATH CARD 30

DURING OUR PAST FOUR DISCUSSIONS, WE HAVE TALKED A LOT ABOUT THE IMPORTANCE OF PROTECTING YOURSELF FROM DISEASES LIKE HIV AND HEPATITIS.

HAVING SAFER SEX IS ONE OF THE MOST IMPORTANT THINGS YOU CAN DO TO PROTECT YOURSELF.

DO YOU REMEMBER WHAT SAFER SEX IS?

Safer sex activities include:

- **mutual masturbation with a partner (jerking each other off)**
- **oral sex with a condom**
- **vaginal sex with a condom**
- **anal (“in the butt”) sex with a condom**

PLEASE REPEAT PATH CARDS 7-9

D. EDUCATION MODULES

TEACHING SESSION # 1

FLASH CARD #1

PURPOSE OF MEDICATIONS

Consistency in taking medications is very important. Each of the medications you are taking has a specific purpose and need to be taken exactly as prescribed. That is, the correct number of times each day, at the correct dose and at the proper time.

Some of these medications have special instructions, such as, either with or without food or before bed only. It is important to take each med exactly as prescribed because they all work differently to control symptoms. Some HIV medications must be taken in combination with others because they are more effective that way than alone.

FLASH CARD #2

STOPPING MEDICATIONS

Psychiatric medications, as well as HIV medications, should never be stopped abruptly. With psychiatric medications, you run the risk of rebound symptoms of depression and /or psychosis and with HIV medications you may end up resistant to medication. Resistance means that the HIV in your blood changes in a way that causes one or more of your medications to stop working the way it should. Your medication can no longer recognize the resistant HIV and will no longer kill it. **Always consult with your doctor or nurse before stopping any medication.**

Let's review the purpose, dose, frequency and special instructions for each of your medications.

FLASH CARD #3

SIDE EFFECTS AND DRUG INTERACTIONS

All medications can have side effects, some mild and some more severe, but all can be managed. Some side effects happen immediately but go away once your body gets used to the medication and some will just stick around for as long as you are taking the medication. Some side effects do not appear until you have been taking the medication for a long period of time. If a side effect is severe, your doctor may be able to help you with another medication or treatment.

FLASH CARD #4

HOW MEDICATIONS WORK

It is important to work with your doctor or nurse and let them know immediately how you are feeling, but to continue with the medication until they can work out a plan with you. The goal is always to get the best results with the fewest side effects.

You also need to be aware of how your medications interact with each other. Prescribed medications, over-the-counter medications and herbal preparations can all interact in an adverse way. Your doctor, nurse or pharmacist can help with this information.

FLASH CARD #5

SKIPPED OR MISSED MEDICATION

If you skip or miss doses of HIV medications, you will increase your chances of becoming resistant to that medication. If you are going to be out over a medication time, remember to take the medication with you. Pill boxes are made so that a day's worth of medication can be easily carried with you. Some medications are large and hard to swallow, but check with your doctor or pharmacist before cutting or crushing them. Taking medications with a thicker liquid, such as milk or orange juice, may help with swallowing.

FLASH CARD #6

ACCESSING AND STORING MEDICATION

Keep medications in a place where you can get to them easily and away from children or animals. Some medications will need to be kept in the refrigerator and some only at room temperature. You may need to consider keeping two pill boxes handy.

It is important that you notify your ICM and health care professional immediately if paying for medications becomes an issue. If coverage changes or insurance is not up-to-date, you might miss important doses of your medication. Sometimes doctors and nurses can supply samples but this is only a temporary solution because samples are limited.

TEACHING SESSION # 2

FLASH CARD # 7

BLOOD TESTING FOR HIV

CD4 COUNT

Normal count is 500-1500 cells in a cubic milliliter of blood (about 1 drop). As HIV disease progresses, your CD4 count will decrease. When your count drops below 200, there is an increased risk of an opportunistic infection. So keeping your CD4 count as high as possible is essential.

VIRAL LOAD

This test is known as a viral load count, a viral burden count or an HIV/RNA count and measures the amount of HIV in a single drop of blood. If only a small amount of virus is present, (less than 50-200), then the test result is “undetectable” meaning that the test did not detect the virus. This does not mean that there is no virus present, but that the amount is so low that the test cannot measure it.

FLASH CARD #8

BLOOD TEST RESULTS

VIRAL LOAD

As HIV disease progresses, the viral load count tends to rise. Someone who starts with a very low viral load count, such as 5,000 copies of virus per drop, may rise to a very high viral load count. Counts can go as high as several hundred thousand or even more than a million copies of virus per drop of blood.

Generally, when your CD4 count goes below 200 and your viral load is high (50,000), your doctor or nurse will start HIV medications

Your doctor will order a routine set of blood tests every 3 or 4 months, however, testing may be more or less frequent depending on how far your HIV has progressed and what medications you are taking.

TEACHING SESSION # 3

FLASH CARD #9

OPPORTUNISTIC INFECTIONS

We carry many types of germs in our bodies all of the time and when our immune system is working, it controls these germs. However, when the immune system is weakened by HIV or by some medications, these germs can get out of control and cause health problems.

When your viral load is high and/or your CD4 count is low, your system is exposed to a variety of infections that use this “opportunity” to take advantage of the weakness in your immune system.

Symptoms of these infections should be reported to your primary care provider immediately.

FLASH CARD #10

TYPES OF OPPORTUNISTIC INFECTIONS I

CANDIDIASIS

- A fungal infection, also known as thrush, that can infect the whole body but often occurs in the mouth and vagina.
- Symptoms include: White patches on gums, tongue or lining of the mouth
Pain Difficulty swallowing Loss of appetite Vaginal irritation, itching, burning and thick white discharge
- Treatment includes creams/lotions or pills depending on the severity of the infection.

FLASH CARD #11

TYPES OF OPPORTUNISTIC INFECTIONS II

CRYPTOCOCCAL INFECTION

- A fungus that primarily affects the brain
- Symptoms include:
Headache, nausea, fever, fatigue, altered mental status, irritability, seizures, coughing and difficulty sleeping.
- Treatment is with IV medication and then maintenance pills for life

HISTOPLASMOSIS

- A fungal infection
- Symptoms include:
- Fever, fatigue, weight loss, difficulty breathing, swollen lymph nodes, pneumonia-like symptoms
- Treatment is with amphotericin B as maintenance therapy

FLASH CARD #12

TYPES OF OPPORTUNISTIC INFECTIONS III

CYTOMEGALOVIRUS (CMV)

- A virus that infects the entire body
- Symptoms are related to various systems in the body and include:
Blurry vision or loss of central vision that can lead to blindness; fever, diarrhea, stomach pain; ulcerations and pain in the throat with difficulty swallowing; pneumonia-like symptoms; confusion, fever, fatigue
- Treatment with antiviral medications

FLASH CARD #13

TYPES OF OPPORTUNISTIC INFECTIONS IV

MYCOBACTERIUM AVIUM (MAC)

- A bacterial infection found in water, dust, soil and bird droppings
- Symptoms include:
Persistent fever, night sweats, fatigue, weight loss, abdominal pain dizziness, diarrhea, weakness
- Treatment is antibiotic therapy. Everyone who has had MAC should be on maintenance therapy and if your CD4 counts stay consistently below 50, you should start preventive therapy

FLASH CARD #14

TYPES OF OPPORTUNISTIC INFECTIONS V

PNEUMOCYSTIS CARINII PNEUMONIA (PCP)

- A parasite that infects the lungs
- Symptoms include:

- Fever, cough, difficulty breathing, weight loss, night sweats, and fatigue
- Treatment with TMP/SMX (Bactrim) Everyone who has had PCP should be on maintenance therapy and if your CD4 counts are at or below 200, you should start preventive therapy

FLASH CARD #15

TYPES OF OPPORTUNISTIC INFECTIONS VI

TOXOPLASMOSIS

- A parasite that primarily infects the brain
- Symptoms include:
Confusion, delusional behavior, severe headaches, fever, seizures and coma
- Treatment is with TMP/SMX (Bactrim) Everyone who has had toxoplasmosis should be on maintenance therapy and if your CD4 counts are below 100, you should start preventive therapy

FLASH CARD #16

TYPES OF OPPORTUNISTIC INFECTIONS VII

TUBERCULOSIS (TB)

- A bacterial infection that primarily infects the lungs
- Symptoms include:
Night sweats, cough, fever, shortness of breath, weight loss.
- Treatment with certain TB drugs Maintenance therapy is not required if your symptoms fully resolve with treatment. All HIV+ clients may be at an increased risk for TB and should be tested for exposure. If the test is + but there is no active disease, preventive therapy should be started

FLASH CARD #17

ROLE OF YOUR PCP

It is important to keep good lines of communication with your doctor or nurse practitioner. Keeping all of your appointments is first and foremost. If you should run into problems between visits, you can call and they will help with prescriptions, medication side effects, or any other medical issues you might have.

Revised on 11/24/2004 2:41 PM

Keep all phone numbers and appointment cards in a prominent place in your home. The refrigerator door is sometimes a good place. Just as long as you know where to get this information quickly when needed.

TEACHING SESSION # 4

FLASH CARD # 18

MEDICAL PROBLEMS ASSOCIATED WITH HIV I

DEPRESSION

Depression is probably the most common type of mental health problem found among HIV infected people. A certain amount of sadness is to be expected; however, if the next 3 factors are present, depression may need treatment:

- Intense sadness
- Lasts longer than a week or two
- Interferes with your day-to-day functioning

If symptoms are present every day for at least 2 weeks, you should ask for help through your health care professional. Do not assume that this is an unavoidable reaction to the diagnosis of HIV. Depression is a separate illness that is treatable.

FLASH CARD # 19

MEDICAL PROBLEMS ASSOCIATED WITH HIV II

DEPRESSION

Symptoms of depression:

- Feelings of sadness, guilt and/or worthlessness
- Difficulty making decisions or concentration
- Difficulty in eating and/or sleeping
- Decrease in energy and motivation to do regular activities
- Lack of interest and pleasure in usual activities
- Physical aches and pains
- Irritability
- Thoughts of death, dying or self-harm
- Feelings of despair or loss of hope in the future

FLASH CARD # 20

MEDICAL PROBLEMS ASSOCIATED WITH HIV III

NERVOUS SYSTEM PROBLEMS

There are two parts to your nervous system:

- Central Nervous System, which is the brain and spinal cord
- Peripheral (around the outside) Nervous System, which takes care of the rest of your nerves and muscles

Central Nervous System problems include memory, thinking, concentration, walking and balance problems, as well as depression which we discussed earlier. These problems are also called dementia. AIDS dementia usually does not show up until later stages of the disease and the antiviral combination therapies that fight HIV seem to protect the Central Nervous System from damage. People with HIV disease can also have peripheral neuropathy which affects the nerves and muscles of the Peripheral Nervous System and causes muscle pain in the feet, legs and hands.

FLASH CARD #21

MEDICAL PROBLEMS ASSOCIATED WITH HIV IV

NERVOUS SYSTEM PROBLEMS

You should report any to the following signs of neurological problems to your doctor:

- Balance or trouble walking
- Problems with vision
- Difficulty remembering
- Difficulty concentrating or completing a task
- Getting lost in familiar places
- Forgetting familiar telephone numbers
- Having trouble with making change or in doing simple math

Some neurological problems are severe and require immediate medical attention. They are: severe headaches with fever, stiff neck, vomiting and severe vision problems.

FLASH CARD #22

MEDICAL PROBLEMS ASSOCIATED WITH HIV IV

METABOLIC PROBLEMS

Diabetes Mellitus

In certain individuals, HIV, hepatitis C and protease inhibitors (type of medication) have been shown to contribute to high blood sugar. This happens when certain cells in the body become resistant to insulin and sugar then spills over into the blood. A simple blood sugar test can be done to make sure that your body is using insulin properly. You should notify your doctor if you experience extreme thirst or hunger, significant increase in urination and fatigue.

Fat Maldistribution

This problem is associated with insulin resistance and high cholesterol. It causes you to lose fat in the face, arms and legs and to gain fat in the stomach, back and breasts. High cholesterol can occur but can be controlled with diet, exercise and certain cholesterol lowering medications called statins.

FLASH CARD #23

MEDICAL PROBLEMS ASSOCIATED WITH HIV V

METABOLIC PROBLEMS

Osteoporosis

This is a loss of minerals in the bone which can be diagnosed by a simple test for bone density. Along with a vitamin and mineral supplement, you should have an adequate intake of calcium and vitamin D. You can also take calcium and vitamin D supplements daily. It is important that you exercise daily and report any injury you might sustain.

FLASH CARD # 24

MEDICAL PROBLEMS ASSOCIATED WITH HIV VII

LIVER PROBLEMS

Unfortunately, the life-extending benefits of the anti-HIV drugs have opened up a new set of problems for HIV+ individuals. Some of the antivirals can decrease the liver's ability to take toxins out of your body efficiently and can even cause your liver to become toxic to your system. Most medications (drugs) have to be broken down by the liver so they can help the body. If the liver is over-worked by drugs, chemicals, foods and other substances that it must detoxify (make safe for the body), it can't do its job and may suffer damage.

Thousands of HIV+ people are also infected or at risk of being infected with one of several hepatitis viruses. These viruses can lead to serious liver damage over time. Use of drugs and alcohol will significantly increase your risk of liver damage and /or a form of hepatitis. Viral hepatitis can cause long term liver problems including liver failure and cancer. HIV, itself tends to speed-up the course of hepatic B and C. This means that symptoms will appear more quickly.

TEACHING SESSION # 5

FLASH CARD #25

DEALING WITH CHRONIC ILLNESS

You are dealing with a “loss” of health right now. The first trick is to understand that the infection can be controlled with changes in lifestyle and meds, but it cannot be cured at this time. The good news is that there are many resources for you and new research is being done all the time. There is a predictable way that people deal with “loss” and as we discuss the stages of loss you may be able to identify feelings that you either have had or are having now.

FLASH CARD #26

COPING WITH LOSS I

Stages of loss

- **Denial** is the refusal to acknowledge or accept that this “terrible thing is happening to me, not me” It is a normal reaction and actually gives the person time to adjust and mobilize resources, although people “in denial” tend to avoid making decisions or taking action and are more likely to isolate themselves at first
- **Anger**, rage and resentment replace denial and decisions are more difficult because energy is placed into being angry rather than into problem solving. It is normal in this stage to ask “why me?” and to be envious of others who are perceived as healthy.

FLASH CARD #27

COPING WITH LOSS II

- **Bargaining** or the “let’s make a deal stage” is an attempt to postpone HIV effects. You may now finally believe that this is happening to you but look to a higher power to offer some exchange for a return to health. At this stage people begin to explore alternatives and re-set goals.
- **Depression**, deep sadness and helplessness make it difficult to make decisions at this stage. If this stage lasts longer than 2-3 weeks, the person should seek professional help.
- **Acceptance** allows the person to successfully fit HIV into his/her life and decision-making becomes possible. The person can now take advantage of support and treatment.

FLASH CARD #28

TALKING ABOUT HIV TO OTHERS I

Sexual Partners

Whether to tell others about your HIV infection, who to tell and how to tell are important questions to resolve. You need to consider why you are telling them, anticipate reactions both good and bad, and prepare your responses. It is important to get support from someone who you trust and make a plan. We can role-play some scenarios. Learn as much as you can about the disease so that you can answer questions but accept that you have no control over reactions, only your response.

It is important to tell people who you may have exposed to the infection so that they can be tested and treated if needed. The Department of Health can tell people you might have exposed without using your name. Employers only need to know if HIV illness and/or treatment will affect your work activities or schedule.

FLASH CARD #29

TALKING ABOUT HIV TO OTHERS II

Family

Family members may or may not be supportive to you. Many people fear that family will be hurt and angry and that telling might weaken their relationship. Family members may go through the same stages that we discussed earlier. Like you, they will need time to adjust to the situation. They may question how you were exposed. Decide ahead of time how to answer that question.

FLASH CARD #30

TALKING ABOUT HIV TO OTHERS III

Care Providers / Social Contacts

Health care providers can provide appropriate health care and also protect themselves more effectively if they are aware of your situation

It is not necessary to tell social contacts unless transmission becomes an issue. However, if a closer relationship begins, you will need to be honest about your HIV status. It will become increasingly more difficult as time progresses.

Revised on 11/24/2004 2:41 PM

If you have a child who is HIV+, you should meet with the principle of his/her school and become acquainted with the school's policy and attitude towards HIV. Meet with the child's teacher and school nurse and have a conversation about confidentiality with them.

TEACHING SESSION # 6

FLASH CARD #31

MIXING SUBSTANCES WITH HIV MEDICATIONS I

People who take street drugs (by mouth or injection) and/or alcohol are potentially at risk from HIV in 2 ways: sexually by having unprotected sex with someone who is already infected and intravenously by sharing needles and syringes.

If you are high, you are more likely to not care or forget about safe practices. The best way to avoid further infection is to not use drugs. If you do use drugs, you can prevent infection by not injecting, not sharing equipment or by cleaning equipment with bleach and water. You could look for a needle exchange program in your area

Studies show that you will have a more beneficial response to HIV medications if you do not use drugs or alcohol. Those individuals who have stopped IV drug use or have never used drugs or alcohol are twice as likely to have CD4 counts below 500 and 4X's as likely to achieve an undetectable viral load.

FLASH CARD #32

MIXING SUBSTANCES WITH HIV MEDICATIONS II

Effects of mixing recreational drugs and alcohol with HIV medications:

- Increased levels of drugs in the system which can lead to over-dose
- Increased risk of kidney stones and pancreatitis
- Increased risk of respiratory distress, high heart rate and blood pressure
- Decrease in the amount of available HIV medication in the body
- Increase in sedative or energizing effect of the recreational drug or alcohol
- Many HIV meds lower the levels of Methadone in the blood which can increase the risk of withdrawal symptoms.

TEACHING SESSION # 7

FLASH CARD #33

HEALTHY CHOICES – HEALTHY FOOD

Good nutrition means getting enough macronutrients (proteins, carbohydrates, fats) and micronutrients (vitamins, minerals). Some medications and many infections can cause weight loss due to anorexia (no appetite), GI upset (nausea/vomiting) and bowel problems (constipation/diarrhea).

Loosing weight can be dangerous for people with HIV. Extra muscle weight will help fight HIV infection. Protein helps build and maintain muscles. Meat, fish, poultry, eggs, beans and nuts are good sources of proteins.

Complex carbohydrates which come from grains, cereals, vegetables and fruits give you energy and are a good source of fiber. They also tend to remain in your system longer than simple carbohydrates like dried fruit, honey, jam or syrup which also give you energy but are broken down in the body more quickly.

FLASH CARD #34

HEALTHY CHOICES – EXERCISE AND FLUIDS

—

It is important to do some form of exercise daily. This will also help to build muscle and decrease bone loss as you age. Walking, swimming, jogging, working with small weights, and aerobics are all good exercises to work into your daily routine.

Drinking fluids, especially water (6-8 glasses daily) can reduce the side effects of medicine and help ease dry mouth and constipation. Some liquids (coffee, tea, cola, chocolate drinks, alcohol) make you urinate more and loose water. So you should drink these in lesser amounts.

TEACHING SESSION # 8

FLASH CARD #35

YOUR RIGHTS

You have the right to know what is happening to your body and to understand what your doctor orders for you and why. Each person is able to make decisions about their health care based on their beliefs, priorities and goals. You deserve a full explanation of all medical procedures and risks involved. You may choose to refuse any type of treatment without jeopardizing your care. You also have the right to quality medical treatment and social services without discrimination of any kind, for example, sexual orientation, gender, diagnosis, economic status or race. You have the right to lead as full and satisfying an emotional life as anyone else and to live with dignity.

FLASH CARD #36

DISABILITY

HIV infection is considered a physical disability by the federal government and the laws that protect the civil right of disabled people will also protect you. It is only necessary to tell your employer about your HIV status if it will affect your job duties, performance or place anyone in danger. You may need to disclose your status if you will need special adjustments in your job requirements to continue your work.

Different states have different laws and it is a good idea to speak with a lawyer about your rights. AIDS service organizations may put you in touch with AIDS legal organizations in your community. Some states and local bar associations offer free legal services to people with HIV who cannot afford to pay.

Revised on 11/24/2004 2:41 PM

E. COGNITIVE BEHAVIORAL HEALTH (CBT)

APPENDIX A

POSITION DESCRIPTION/PERFORMANCE EVALUATION

Project Title: Nursing Intervention for HIV Regimen Adherence among SMI

Job Title: Advanced Practice Psychiatric Nurse (APN)

Qualifications:

- Masters Degree in Nursing with experience in psychiatric mental health working with individuals with serious mental illness
- Licensed as a registered nurse in Pennsylvania
- Board certified by the American Nurses Credentialing Center

Supervisor: Research project identified nursing supervisor

Scope of Practice defined by the:

- American Nurses Association Standards and Scope of Practice for Psychiatric Nurses
- Pennsylvania Nurse Practice Act

Job Summary:

The APN, certified (or eligible) by ANCC in Psychiatric Mental Health Nursing, is an independently licensed clinician responsible and accountable for the research based knowledge, skills, and experience to assess, diagnose, and treat complex psychiatric and chemical dependency problems and co-morbid medical problems. In the current position, individuals with serious mental illness and HIV are the population of focus and referenced as the ‘client’ or the ‘study participant’ in this document. The APN is a research team member who provides the medication adherence intervention using the protocol in the research study. The APN functions to maximize recruitment potential by identifying barriers to accessing study participants. Along with other research team members, the APN will develop and adapt recruitment strategies commensurate with the research project goals. The APN works with the client’s health care and mental health care providers to influence the care of participants, affect change in systems, and enhances the ability of others to provide healthcare. The APN functions as a resource to providers caring for study participants. The APN participates in program development, guiding group decisions, implementing plans, and improving quality of care.

DUTIES AND RESPONSIBILITIES

E=Exceeds the Standard

M=Meets the Standard

NI=Needs Improvement

Demonstrates Competency in the following areas:	E	M	NI
Completes a comprehensive psychiatric assessment by collecting health data which enables the nurse to make sound clinical judgments, diagnose potential and/or actual psychiatric illness and identify co-morbid physical illness(s).			
Completes all the research forms per policy including administering standardized diagnostic tools.			
The APN is a custodian of data and adheres to policy and procedures related to			

Demonstrates Competency in the following areas:	E	M	NI
ensuring data protection, data security, and participant confidentiality,			
Collaborates with other medical and mental health care clinicians on the research team and in the field			
Maximizes recruitment potential of subjects for the study			
Identifies barriers to subject recruitment and seeks innovative ways to overcome the barriers			
Manages medications collaborating with the prescribing physician, monitoring efficacy, reactions, therapeutic responses, toxicity, incompatibilities			
Develops and execute a plan of care (in conjunction with the mental health team and the client) including a problem list, long term, short term goals with measurable outcomes			
Builds effective nurse-client relationships. Works with the client as a partner to review progress towards identified outcomes. The APN designs innovative interventions to assist the client to adhere to medication regimes			
Implements the medication adherence intervention according to the research protocol and creatively uses a wide range of interventions designed to prevent, maintain, and restore mental and physical illness/health.			
Actively pursues contact with study subjects (home, clinic, etc) on the cycle of interventions to offset study attrition.			
Completes documentation in a timely manner			
Provides case management to coordinate comprehensive health service and ensure continuity of care			
Maintains an accurate case list of clients with up to date records			
Participates in team meetings with clients, case managers, and research staff			
Maintains client confidentiality at all times following HIPAA regulations			
Represents the research project in a positive and professional manner in the community. Complies with the University of Pennsylvania policies regarding research code of ethics			
Participates in ongoing supervision with peers and supervisor			
Language Skills: Must possess good oral and written communication skills in the English language			
Skills: Able to work under stressful situations. Able to draw blood safely from HIV positive individuals in clinical and community settings. Has beginning to intermediate computer skills			
Physical Demands: Visual acuity, color vision, hearing acuity, and tactile sensation are necessary to respond to participant response and requests. Must possess the manual dexterity and a degree of body strength and flexibility; to respond to aggressive participant behavior; the ability to reach and stretch intermittently. Time may be spent sitting at a computer, driving to the client's community location, collaborating with other healthcare team members. Standing and walking compromises some of the workday.			
Actively participates in seminars and conferences. Contributes to the body of nursing knowledge by writing and presenting at major nursing conferences			

I have received, read and understand the above Position Description/Performance Evaluation.

Print Name/Signature

Date

APPENDIX B

ADVANCED PRACTICE NURSE ASSESSMENT COMPONENTS

- I. Client Assessment
 - A. Sociodemographic Data
 - B. Functional status
 - 1. personal competency
 - 2. social competency
 - 3. physical competency
 - C. Mental status (Mini-mental status exam)
 - D. Emotional status (depression/anxiety/self-esteem)
 - 1. coping response to HIV+ status-
 - 2. identification/ availability of caregiver-
 - 3. formal/informal support system
 - E. Quality of Life
- II. Primary and Co-Morbidity Health Conditions
 - A. Physical Status
 - 1. Physical health problems, including general and diagnosis specific history
 - 2. Perform baseline physical assessment
 - 3. Daily medication usage, including over the counter medications
 - 4. Diagnosis specific indicators (CD4 and viral load)
 - 5. Client response to pre-intervention treatment plan
 - B. Symptom Status Assessment
 - 1. Diagnosis specific symptoms
 - 2. Predisposing factors
 - a.) physiological
 - b.) treatment regimen related
 - c.) client behavior related
 - d.) support system related
 - 3. Severity as perceived by client-
 - 4. Client and caregiver response-
 - C. Participant General Health Behaviors
 - 1. General Nutritional status
 - 2. Baseline exercise and activity program
 - 3. Need for and use of stress management strategies
 - 4. Evidence of high-risk behaviors
 - 5. Client and caregiver ability to monitor general health pattern
 - 6. Client and caregiver perception of their role in health promotion
 - D. Knowledge Base
 - 1. Medication regimen (identify name of med, purpose, dose, frequency, special instructions, use of devices to remember meds, what does client do if dose is missed?)
 - 2. Prescribed dietary modifications

3. Signs and symptoms to report to physician
 4. Pathophysiology of disease processes and transmission of disease
 - underlying process of HIV turning into AIDS and the role of treatment in slowing process/ symptom management; biological component of mental illness and the role medication has in treatment
 5. Difficulty adhering to prescribed medication regimen and dietary plan
 6. Participant and caregiver effectiveness in self- management of illness
- E. Prior Use of Health Services –
- III. Social Support System Assessment-
- A. Sociodemographic data
 - B. Caregiving role for primary caregiver
 1. Availability
 2. Willingness to assume role
 3. Current caregiving responsibilities
 4. Ability to meet emotional and tangible support needs
 5. Client/ caregiver satisfaction with support system
 - C. Knowledge base related to management of illness and treatment
 - D. Perceived learning needs after intervention termination
 1. Information/teaching
 2. Emergency contact/ informational resources
 3. Services/resources
- IV. Development of Individualized Plan of Care
- A. Identification of client goals (short and long-term)
 1. related to physical and psychiatric symptom management
 2. related to medication education
 3. related to medication adherence
 4. related to functional status
 5. related to quality of life
 - B. Coordination of Services
 - C. Identification of educational and behavioral strategies to increase client's ability to manage physical and psychiatric symptoms and to improve health behaviors with a specific emphasis on medication adherence
 - D. Actively involve client and family/ support system and health care team members in planning process
 - E. Prioritization of problems
 - F. Communicate plan through documentation and collaborative efforts
- V. Implementation of Treatment Plan During the Intervention
- A. Ongoing targeted physical and psychiatric assessment
 - B. Collaborate with healthcare team to ensure that care provided is evidence based, consistent with published guidelines and that the medication adherence intervention is consistent to the outlined procedure
 1. Discuss complex client care issues with members of the multidisciplinary team (ie; medication interactions, connection of treatment plan to client goals)
 2. Discuss client's goals and collaboratively developed treatment plan with client's HIV physician and case manager

- C. Implement appropriate medication intervention consistent with the needs of the Client outlined in the intervention cascade
- D. Provide instruction with validation of learning A
- E. Determine support system understanding and support of symptom management plan and medication adherence plan
- F. Identify and respond to changes in the client's status and post-intervention needs
- G. Coordinate follow-up visits to the client's home
- H. Collaborate with case manager and client's HIV physician
- I. Communicate progress of discharge plan through written documentation in client's record and electronic database
- J. Ensure continuity of care through discourse with HIV physician and case manger
- K. Evaluate effectiveness of intervention process
 - A. Monitor progress
 - B. Modify plan as necessary
 - C. Assess client and social support system's satisfaction with plan

APPENDIX C

APN Case Study Guidelines

The goal is to capture the facilitators and barriers to implementing comprehensive, individualized care. Also, we want to highlight the role of the APNs and their clinical knowledge and skills.

Ideas to highlight

- 1 Complexity of care
 - Number of co-morbidities
 - Number of medications
 - Level of available resources (e.g. personal, community)
 - Environmental factors
 - Number of providers involved (specialists, generalist, disciplines)

- 2 Clinical priorities
 - Primary diagnosis
 - Safety
 - Co-morbidity-physical
 - Co-morbidity-psychological/emotional
 - Depression
 - Anxiety
 - Delirium
 - Dementia
 - Accessing community resources
 - Accessing primary/specialist care
 - Working with the caregiver
 - Quality of life-palliative care
 - Sign/symptom management
 - Pain
 - Fatigue/activity tolerance

- 3 Avoiding complications and/or early problem prevention
 - Fall prevention strategies
 - Medication adjustments-side effects
 - Medication adjustments-new/alternate medication
 - Medication adjustments-decrease poly-pharmacy
 - Pressure ulcer
 - Delirium
 - Restraint-free

- 4 APN-patient/family relationship:

- How did knowing the participant (preference, values, and resources) affect the plan of care?
 - How did the relationship allow specific interventions to be introduced later (e.g. behavior modification)?
- 5 Collaborative efforts
- With whom?
 - Typical topics (e.g. goals setting, accessing referrals/consultations)
- 6 Effects of continuity
- What would have happened if you weren't involved?
 - Delirium wouldn't have been detected
 - Continued poly-pharmacy could have contributed to cognitive impairment?
 - Etc.
 - Is there something that happened in the hospital that affected your management post-discharge?
 - Was there information others may not have known on a referral that was critical to the participant's post-discharge care?

Examples of Facilitators

Participant

- 1 Sufficient Income
- 2 Education level
- 3 Access to primary care
- 4 Access to specialty care
- 5 Sufficient health insurance
- 6 Sufficient pharmaceutical insurance
- 7 Established social network
- 8 Participant motivation to change/adhere to plan
- 9 Mutually set goals
- 10 Needed DME available (including medication compliance aids)
- 11 Available information to manage health plan (e.g. medication schedule, audiotapes)

Caregiver

- 12 Caregiver capable of providing care/has skill set
- 13 Established social network

Provider

- 14 Quick response from physician/health care agency
- 15 Responsive to recommendations
- 16 Good clinical judgment and use of current guidelines

Environment

- 1 Clean
- 2 Safe
 - Heat/air conditioning

- Free of clutter
 - Appropriate refrigeration
 - Stairs/elevator in working order
- 3 Community agencies
 - 4 Access to public transportation

Examples of Barriers

Participant

- 17 Inadequate income and/or insufficient health/pharmaceutical insurance
- 18 Low literacy
- 19 Hard of hearing or visually impaired
- 20 Inadequate access to medical care
- 21 History of non-adherence
- 22 Depression
- 23 Not knowledgeable about when/how to access the health system
- 24 No available transportation

Caregiver

- 25 Not available, or inconsistently so
- 26 Does not have the ability or motivation to learn required skills
- 27 Too many other competing needs (e.g. work, care of another dependent)

Provider

- 1 Lack of knowledge about unique needs of older adults
- 2 Lack of knowledge about specialty care/current standards of practice
- 3 Inaccessible for consultation/collaboration
- 4 Different goals for participant/caregiver
- 5 Not available to participant/family when needed

Environment

- 1 Unsafe home
- 2 Design of home (e.g. no BR on 1st floor, no. of stairs)
- 3 Community unsafe for walking outside, etc
- 4 Neighbors disruptive/disturbing/harassing
- 5 Needed DME not available (e.g. commode)

Health System

- 1 Multiple providers making recommendations
- 2 Poor communication between units/settings
- 3 Conflicting discharge instructions

APPENDIX D

Post-Exposure Prophylaxis Needle Stick Injury Protocol

Background

The risk of HIV transmission to a healthcare worker following needlestick exposure to HIV-infected blood is estimated to be approximately 0.3% (3 cases per 1,000 injuries). The risk of HIV acquisition following exposure of mucous membranes to HIV-infected blood is estimated to be approximately 0.09% (1 case per thousand exposures). HIV transmission following exposure of blood to non-intact skin has been reported, but is thought to be rare. Factors that may increase the risk of HIV transmission following a needlestick injury include: being injured with a needle visibly contaminated with blood, being stuck with a needle that had been placed directly into a participant's vein or artery, receiving a deep injury, and being stuck with a needle from a participant with advanced infection. There is no data that has used a source participant's viral load as a surrogate to assess risk of transmission, but it is assumed that there is a correlation. However, a low or undetectable viral load should not be considered to exclude the possibility of transmission.

Antiretroviral agents are used as post-exposure prophylaxis to prevent HIV acquisition following a needlestick injury to healthcare workers. The efficacy of post-exposure prophylaxis is hard to determine. A retrospective, case-control study of health care workers suggested that the use of a four-week course of zidovudine monotherapy decreased the risk of HIV acquisition by approximately 81%. However, these results are based upon a small number of exposures. Failure of post-exposure prophylaxis to prevent HIV acquisition following a needlestick injury has been reported, including in cases in which the healthcare worker took three or more antiviral medications.

The Centers for Disease Control and Prevention recommend a three-drug antiretroviral combination be administered to health care workers following a needlestick injury resulting in exposure to blood of an HIV-infected individual. Medications should be administered as soon after the exposure as possible. The optimal duration for post-exposure prophylaxis is not known, but a four-week course of medications is typically recommended.

The Centers' for Disease Control and Prevention recommendations for HIV post-exposure prophylaxis and other resources are available at the website: <http://www.aidsinfo.nih.gov/guidelines>.

Hospital of the University of Pennsylvania Post-Exposure Prophylaxis Program

The Hospital of the University of Pennsylvania administers a post-exposure prophylaxis program for healthcare workers through the Department of Occupational Health. Confidential HIV, hepatitis C virus, and hepatitis B virus testing and counseling, antiretroviral therapy, and

hepatitis B immune globulin and vaccine are available through Occupational Health. When this office is closed, the Emergency Department administers this program. Therefore, someone is available for counseling 24-hours-a-day.

What You Should Do if You Experience a Needlestick Injury

The first thing you should do is wash the area that was stuck. Use soap and water or an alcohol wipe if one is available.

Assuming that your injury was from a needle used to take blood from a participant with HIV infection, and that you will be starting on some type of prophylactic combination, the following information would be helpful to have in order to decide what would be the best combination to take:

- Participant's current antiretroviral combination
- Participant's current (most recent) viral load
- Did the participant switch therapy because a previous combination was not suppressing virus replication adequately? If so, what combination was the participant on at that time?
- The participant's HIV provider's name and telephone number.

The antiviral medication includes the 4-drug combination of Combivir (fixed dose zidovudine plus lamivudine), atazanavir (Reyataz) and ritonavir (Norvir). This combination was selected because it is potent, well tolerated, and the some of the drugs in the combination are cleared slowly from the circulation. The immediate side effects you may experience from this combination include headache, nausea, vomiting, stomach upset, and diarrhea. Other side effects that may be encountered with longer term use of this combination will be discussed if you continue on this combination. This may or may not be the best combination for you. The best combination will depend upon the participant's current and previous treatment experience. The medication should be taken as soon as possible after the needlestick injury.

As soon as possible after the needlestick injury, you should report to the Occupational Health Office of the Hospital of the University of Pennsylvania, or the Emergency Department, if the Occupational Health Office is closed. The Occupational Health Office is located adjacent to the Emergency Department on the ground floor of the Silverstein Pavilion. HIV (and hepatitis B virus and hepatitis C virus) testing will be provided in a confidential way, and antiviral medications will be offered. You will return for HIV testing at several time points after you complete the four-week antiretroviral combination. Call to notify the providers that you have been exposed and will require intervention for a needlestick injury.

Being Safe

Needlestick injuries are often preventable. A sharps disposal container should be within reach whenever you draw blood. Never recap a needle after using it to draw blood from a participant. Immediately after removing the needle, place it in the sharps container. Never put the needle on a table or other surface to dispose of later.

Research Practice Controls

Research practice controls will be utilized to eliminate or minimize exposure to the potential for occupational exposure. Personal protective equipment are required.

1. Specimen containers are leak-proof and puncture-resistant.
2. Hand washing facilities are also available to members of the research team who incur exposure to blood or other potentially infectious materials. Anti-infective wipes are available in the field.
3. After removal of personal protective equipment, including gloves, research team members shall wash hands and any other potentially contaminated skin area immediately or as soon as feasible thereafter with soap and water.
4. If a research team member incur exposure to their skin or mucous membranes with blood or other potentially infectious materials, then those areas shall be washed or flushed with water as appropriate immediately or as soon as feasible following contact.
5. Food and beverages **are not** to be kept in refrigerators, freezers, shelves, and cabinets or on counter tops or bench tops where urine or other potentially infectious materials are present.
6. Blood specimens will be placed in a container that prevents leakage during the collection, handling processing, storage, and transport of the specimens.
7. All personal protective equipment required by members of the research team will be provided by the project without cost.
8. All contaminated work surfaces will be decontaminated after completion of procedures and immediately or as soon as feasible when surfaces are overtly contaminated and after any spill of blood.
9. Regulated waste (liquid or semi-liquid blood, urine, or other potentially infectious materials) shall be placed in appropriate containers (red bag labeled with the international biohazard symbol), removed from the point of generation and transported to a designated collection site.

APPENDIX E

EVENT DOCUMENTATION

Advanced Practice Nurse

	Client/Facility Name	Setting*	Mode	Service Date	Diagnosis	Service Provided	Billin g Code	Lev el	Tot al Tim e	Trav el Time	Milea ge
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											
15											
16											
17											
18											
19											
20											
21											
Setting Codes: H=Home; O=Office; S=Street; MHC= Mental Health Center; Hospital=Hosp; Partial Hospital=PH Mode: Face-to-face; Telephone, e-mail, Without face-to-face; team conference											

APPENDIX F

Selected General Medicine and Behavioral Current Procedural Terminology (CPT) Codes for APN Activity

DIAGNOSTIC INTERVIEW

<u>Code</u>	<u>Description</u>
90801	Psychiatric diagnostic interview

PSYCHIATRIC THERAPEUTIC AND MANAGEMENT PROCEDURES

<u>Code</u>	<u>Time</u>	<u>Description</u>
90804	20-30	Therapy only
90505	20-30	Therapy w/med management
90806	45-50	Therapy only
90807	45-50	Therapy w/med management
90808	75-80	Therapy only
90809	75-80	Therapy w/med management
90846		Family psychotherapy (without the patient present)
90847		Conjoint family psychotherapy with patient present
90862		Pharmacologic management
90882		Environmental Intervention for medical management
90885		Psychiatric evaluation of hospital records, reports, tests for diagnostic purposes
90887		Interpretation or explanation of results of exams, procedures to family or responsible persons, or advising them how to assist a patient
90889		Preparation of a report

TEAM CONFERENCE (WITH OR WITHOUT PATIENT PRESENT)

<u>Code</u>	<u>Description</u>
99361	30 Minutes
99362	60 Minutes

EVALUATION AND MANAGEMENT (E&M) CODES

<u>Code</u>	<u>Description</u>
99211	Minimal
99212	Problem Focused
99213	Expanded Focus
99214	Detailed
99215	Highly Complex

PROLONGED APN SERVICES (FACE TO FACE)

<u>Code</u>	<u>Description</u>
99354	First 60 Minutes
99355	Each Additional 30 minutes

PROLONGED APN SERVICES (WITHOUT FACE TO FACE)

<u>Code</u>	<u>Description</u>
99358	First 60 Minutes
99359	Each Additional 30 minutes

APN SUPERVISION

(Work provided in a 30-day period to supervise multi-disciplinary care modalities of patients to include development and/or review of care plans, review reports, communications, etc)

<u>Code</u>	<u>Description</u>
99374	15-29 minutes
99375	Each Additional 30 minutes

CASE MANAGEMENT PHONE

<u>Code</u>	<u>Description</u>
99371	Brief call
99372	Intermediate call
99373	Complex call

NOTE: The following information was taken word for word from (*Current Procedural Terminology 2000, 1999*) published by the American Medical Association.

DIAGNOSTIC INTERVIEW

90801 Psychiatric diagnostic interview examination. Psychiatric diagnostic interview examination includes a history, mental status, and a disposition, and may include communication with family or other sources, ordering and medical interpretation of laboratory or other medical diagnostic studies. In certain circumstances other informants will be seen in lieu of the patient.

PSYCHIATRIC THERAPEUTIC AND MANAGEMENT PROCEDURES

90804 Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient;
90805 with medical evaluation and management services

90806 Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient;
90807 with medical evaluation and management services

90808 Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient;
90809 with medical evaluation and management services

90846 Family psychotherapy (without the patient present)

90847 Family psychotherapy (conjoint psychotherapy) (with patient present)

90849 Multiple-family group psychotherapy

90853 Group psychotherapy (other than of a multiple-family group)

90862 Pharmacologic management, including prescription, use, and review of medication with no more than minimal medical psychotherapy

90882 Environmental intervention for medical management purposes on a psychiatric patients behalf with agencies, employers, or institutions

90885 Psychiatric evaluation of hospital records, other psychiatric reports, psychometric and/or projective tests, and other accumulated data for medical diagnostic purposes

90887 Interpretation or explanation of results of psychiatric, other medical examinations and procedures, or other accumulated data to family or other responsible persons, or advising them how to assist patient

90889 Preparation of report of patient's psychiatric status, history, treatment, or progress (other than for legal or consultative purposes) for other physicians, agencies, or insurance carriers

TEAM CONFERENCE (WITH OR WITHOUT PATIENT PRESENT)

EVALUATION AND MANAGEMENT (E&M) CODES

99211 Office or other outpatient visits for the evaluation and management of an established patient, that may not require the presence of a physician. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.

99212 Office or other outpatient visit for the evaluation and management of an established patient, which requires at least two of these three key components:

- A problem focused history;
- A problem focused examination;
- A straightforward medical decision making.

Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs.

Usually, the presenting problem(s) are self-limited or minor. Physicians typically spend 10 minutes face-to-face with the patient and/or family.

99213 Office or other outpatient visit for the evaluation and management of an established patient, which requires at least two of these three key components:

- An expanded problem focused history;
- An expanded problem focused examination;
- Medical decision making of low complexity.

Counseling and coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs.

Usually, the presenting problem(s) are of low to moderate severity. Physicians typically spend 15 minutes face-to-face with patient and/or family.

99214 Office or other outpatient visit for the evaluation of and management of an established patient, which requires at least two of these three components:

- A detailed history;
- A detailed examination;
- Medical decision making of moderate complexity.

Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs.

Usually, the presenting problem(s) are of moderate to high severity. Physicians typically spend 25 minutes face-to-face with the patient and/or family.

99215 Office or other outpatient visit for the evaluation and management of an established patient, which requires at least two of these three key components:

- A comprehensive history;
- A comprehensive examination;
- Medical decision making of high complexity.

Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs.

Usually, the presenting problem(s) are of moderate to high severity. Physicians typically

spend 40 minutes face-to-face with the patient and/or family.

PROLONGED APN SERVICES (FACE TO FACE)

99354 Prolonged physician service in the office or other outpatient setting requiring direct (face-to-face) patient contact beyond the usual service (e.g., prolonged care and treatment of an acute asthmatic patient in an outpatient setting); first hour (List separately in addition to code for office or other outpatient Evaluation and Management service)

99355 each additional 30 minutes (List separately in addition to code for prolonged physician service)

PROLONGED APN SERVICES (WITHOUT FACE TO FACE)

99358 Prolonged evaluation and management service before and/or after direct (face-to-face) patient care (e.g., review of extensive records and tests, communication with other professionals and/or the patient/family); first hour (List separately in addition to code(s) for other physician service(s) and/or inpatient or outpatient Evaluation and Management service)

99359 each additional 30 minutes (List separately in addition to code for prolonged physician service)

APN SUPERVISION

99374 Physician supervision of a patient under care of home health agency (patient not present) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication (including telephone calls) with other health care professionals involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15-29 minutes.

99375 30 minutes or more

CASE MANAGEMENT PHONE

99371 Telephone call by a physician to a patient or for consultation or medical management or for coordinating medical management with other health care professionals (e.g., nurses, therapists, social workers, nutritionists, physicians, pharmacists); simple or brief (e.g., to report on tests and/or laboratory results, to clarify or alter previous instructions, to integrate new information from other health professionals into the medical treatment plan, or to adjust therapy)

99372 intermediate (e.g., to provide advice to an established patient on a new problem, to initiate therapy that can be handled by telephone, to discuss test results in detail, to coordinate medical management of a new problem in an established patient, to discuss and evaluate new information and details, or to initiate new plan of care)

99373 complex or lengthy (e.g., lengthy counseling session with anxious or distraught patient, detailed or prolonged discussion with family members regarding seriously ill patient, lengthy communication necessary to coordinate complex services of several different health professionals working on different aspects of the total patient care plan)

Current Procedural Terminology 2000. (1999). Chicago: American Medical Association.

APPENDIX G

Confidentiality and Security of Clinical and Research Records

Pursuant to HIPAA Privacy and Security Rule mandates, all personnel connected to this research study with access to confidential information must adhere to practices that insure the maximum protection of patient/study participant information. These practices extend to the vigilant protection of electronic Protected Health Information (ePHI). Investigators, Research Assistants, APNs and Project management personnel having access to patient identifying information will be held accountable to these safeguards.

All written documents generated by research personnel will be kept under double lock. Paper documents containing patient information not necessary for retaining for research purposes must not be improperly discarded in the trash. These documents must be shredded before being disposed of.

Laptops used to collect patient/study participant data will be stored in locked filing cabinets when not in use. APNs and Research Assistants have coordinated with Project Management to develop strong computer passwords with encryption to include upper and lower case letters and numbers. All data on laptop computers will be de-identified and downloaded to a secure server with access limited to designated research personnel. Links to research subject identification will be under double lock and key and kept by the Senior Research Coordinator.

It is the responsibility of all custodians of patient identifying data not to keep this information on PDAs. Study personnel are also responsible for not sending information that could identify patients over the internet.

All personnel must sign a copy of this policy and procedure as it relates to protection of patient information. Signed copies will be maintained in employee files.

I have received, read and understand the above Policy and Procedure.

Print Name/Signature

Date