Trimethoprim-sulfamethoxazole use is a risk factor for nasal colonization with a resident clone of *Staphylococcus aureus* at PSI, an in-patient drug and AIDS/HIV treatment facility.

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Lay Abstract

A. Study Purpose

Staphylococcus aureus (*S. aureus*) is a bacterium commonly responsible for serious, sometimes deadly infections in humans. *S. aureus* can infect almost any part of the body including the lung, blood, heart, bone, and skin, including surgical sites. Although *S. aureus* can cause dangerous infections, it also may live harmlessly in our bodies, mostly in our noses.

This is called nasal colonization. In fact, approximately 30-50% of healthy adults is colonized with *S. aureus*. Nasal colonization is important because it increases the risk of infection with ones own strain of *S. aureus* in the future. It may also facilitate the spread of *S. aureus* in medical settings and can be responsible for outbreaks (2, 3, 6.)

Certain populations are at increased risk for *S. aureus* colonization and infection, including people with HIV/AIDS and histories of drug abuse (1, 4, 5, 7.) The patients we are studying have both HIV/AIDS and histories of drug abuse. They live at PSI, an in-patient residential facility in the Bronx sponsored by Project Samaritan. PSI generally houses about 65 people at a time and residents usually stay for several months. Approximately half of patients come from prison and are mandated by the court to receive drug treatment at PSI

A prospective study was recently conducted at PSI with the following goals: 1) to describe the prevalence of *S. aureus* carriage among PSI residents, 2) to assess risk factors for colonization, and 3) to follow the residents over time to analyze changes in colonization. These goals were achieved by conducting baseline interviews, abstracting data from the medical record at baseline and on a quarterly basis, and by collecting initial and monthly nasal swabs testing for *S. aureus* colonization. Specimens positive for *S. aureus* were tested for antibiotic susceptibility and were examined by Pulsed Field Gel Electrophoresis. (Pulsed Field Gel Electrophoresis or PFGE is essentially a DNA fingerprint for a strain of *S. aureus*.) The data were collected from January 1, 2001 to July 1, 2001.

Preliminary data suggest that there is a very high prevalence of *S. aureus* colonization among PSI residents (about 60%) and that the high prevalence has persisted for several months. PFGE has enabled us to identify two predominant clones (identical strains) of *S. aureus* at PSI, which account for about 2/3 of all samples—a very unusual finding. Furthermore, we have also noted a very high prevalence of resistance to the antibiotic Trimethoprim-Sulfamethoxazole (about 77% compared to 26% in the general U.S. population and 50% in a study of AIDS patients.) In fact, both "resident clones" are resistant to trimethoprim-sulfamethoxazole (TMP-SMX.) Due to common use of TMP-SMX in this population to help prevent PCP, a special kind of pneumonia, we hypothesize the following: There are two "resident clones" of *S. aureus* at PSI. When a new resident arrives at PSI he is either not colonized or colonized with a TMP-SMX sensitive strain (most residents are not treated with TMP-SMX prior to arrival.) The new resident subsequently begins treatment with TMP-SMX and if colonized, the strain is eliminated. The new resident is then vulnerable to colonization with one of the two "resident clones," both of which are TMP-SMX resistant. In short, we believe use of TMP-SMX is a risk factor for colonization with a "resident clone" of *S. aureus* at PSI.

We will test this hypothesis by performing a statistical analysis to see if TMP-SMX is a risk factor for *S. aureus* colonization with either a "resident clone" or another strain. We will also analyze

other possible risk factors for *S. aureus* colonization including CD4 count, time at PSI, and other antibiotic use. We will use the first nasal swab collected for each participant.

B. Study Subjects and Method of Recruitment

The subjects of this study will be the 80 subjects who have already consented and enrolled in the PSI protocol. They are adults with HIV/AIDS and a history of drug abuse. PSI staff advised PSI residents of the study periodically, especially at weekly resident meetings. Anyone expressing interest in participating was invited to participate at his earliest possible convenience. Subjects were given one $6 metro card after the baseline interview and collection of nasal swabs. They were given another metro card approximately six months after initial participation.

C. Study Procedures

The data was collected as described above from 1/1/01 to 7/1/01. An independent interviewer conducted initial interviews and medical record abstractions. Either the staff at PSI or the interviewer collected the nasal swabs. In the laboratory, PFGE as well as antibiotic susceptibilities were conducted on the positive cultures. Sophisticated computer software was used to compare the PFGE samples for percent relatedness. SAS will be used for the statistical analyses.

D. Issues

Collecting nasal swabs is painless and poses no risks to the participant. Confidentiality is carefully maintained. Interview data and medical abstraction data are kept in confidential, encrypted computer files at all times.

IRB Protocol

A. Study Purpose and Rationale:

Staphylococcus. aureus is an important pathogen responsible for serious infections including post-operative wound infections, pneumonia, and endocarditis. However, *S. aureus* is also a commensal organism that colonizes the nares of 30-50% of healthy adults—10-20% are persistently colonized. *S. aureus* colonization is important because it increases the risk of infection with ones own strain of *S. aureus* in the future. It can also facilitate the spread of *S. aureus* in medical settings and be responsible for outbreaks (2, 3, 6.) Several studies suggest an increased risk of both *S. aureus* colonization and infection in HIV/AIDS patients and drug users (1, 4, 5, 7.)

A prospective study was recently conducted at PSI, an in-patient drug treatment facility for AIDS/HIV patients. Preliminary data suggest a very high prevalence of nasal colonization with *S. aureus* (approximately 60%) as well as a very high prevalence of Trimethoprim-sulfamethoxazole (TMP-SMX) resistance (about 77% compared to 26% in general U.S. population and 48% of HIV-infected individuals in one study.) Using Pulsed Field Gel Electrophoresis (PFGE), we have also discovered that two different clones represent the majority of *S. aureus* strains that exist at PSI, a very unusual finding as most of the samples are methicillin sensitive and are not expected to be related. Additionally, the two "resident clones" are resistant to TMP-SMX. We propose that when the untreated patient (most have no prior TMP-SMX exposure) arrives at PSI, he is most likely to be either not colonized or colonized with a TMP-SMX sensitive strain. After beginning treatment with TMP-SMX, any existing colonization is eradicated and the patient is primed for colonization with a resident TMP-SMX resistant clone. We propose to conduct a cross-sectional analysis generating odds ratios, as well as a multiple logistic regression controlling for other risk factors to see if use of TMP-SMX is a risk factor for colonization with a "resident clone."

B. Study Design and Statistical Analysis

This is the baseline data from a prospective study. Subjects will be the 80 subjects already enrolled in the PSI Study conducted from 1/1/01 to 7/1/01. The eighty subjects include all of the consenting residents living at PSI between 1/1/01 and 7/1/01. Only 1 person declined participation and 5 people were discharged before they could be interviewed and swabbed.

For the statistical analysis, we will see if TMP-SMX use is an independent risk factor for the categorical dependent variable "colonization status" with three possible outcomes: 1) no colonization, 2) colonization with a "resident clone", and 3) colonization with a different strain. In univariate analysis, we will employ the chi sqaure test for independence to analyze relationships with TMP-SMX use as well as other independent variables including use of any other antibiotic, length of stay at PSI (<1 month, 1-3 months, and >3 months), and CD4 count (<200 vs. $\geq$200.) Results will be reported as odds ratios with 95% confidence intervals. For multivariate analysis, we will conduct multiple logistic regression for the aforementioned dependent variable "colonization status" and report results as adjusted odds ratios with 95% confidence intervals. We will use SAS to do our analysis.

C. Study Procedures

a. Study Duration

The study was conducted from January 1, 2001 to July 1, 2001. Each participant who consented participated in the study for the duration of his stay at PSI (up to six months.)

b. Interview Data

Baseline interviews among new admissions to PSI

New admissions to PSI who provided informed consent at the time of their initial physical exam, were approached to be interviewed approximately four weeks after they were admitted as residents to PSI. Written informed consent was administered to those residents and if they wished to continue as study participants, then a brief interview (about five to ten minutes) was conducted, followed by the collection of nasal swabs.

c. Baseline interviews among continuing PSI residents

Periodically and particularly at weekly resident meetings, residents were advised and reminded of the study by PSI staff. Residents who expressed interest in participating in the study were invited to participate and be interviewed at their earliest possible convenience. If they agreed to participate, continuing PSI residents were administered informed consent, the interview was conducted, and nasal swabs were collected.

d. Medical Record Data

After obtaining informed consent and on a quarterly basis thereafter, the interviewer completed the computerized medical record abstract form (see attached.) The medical record data was kept confidential on an encrypted computer file.

e. Biological Data

i. Nasal swabs collected by the study staff

The study staff collected nasal swabs at the completion of the baseline interview. All swabs were labeled with the study ID number, the date of specimen collection, and a unique identifier. Nasal swabs were obtained by rotating a sterile rayon-tipped swab (Becton Dickinson, Cockeysville, MD, U.S.A.) in each anterior nare and placing it into transport media. This is neither uncomfortable nor is it harmful to the subject.

ii. Biological specimens collected by PSI staff for the study

If a resident provided consent at the initial or monthly exam, the PSI staff collected a nasal swab. Nasal swabs were labeled with the subject's ID number, the date of specimen collection, and stored in the

PSI specimen refrigerator. The nasal swab specimens were collected every Friday by the study staff and transported to the Lowy Laboratory. Study staff then assigned a unique identifier to each nasal swab specimen.

iii. Microbiologic Evaluation

In the Lowy Laboratory, each nasal swab, appropriately labeled with the subject ID number, date of specimen collection, and unique identifier was plated onto mannitol-salt agar. Positive plates were numerically graded according to the number of colonies: 0, no growth; 1, rare positive colonies; 2, many discrete positive colonies; and 3, a lawn of positive colonies. All positive cultures were confirmed by catalase and the Staphaurex test (Murex Diagnostics Limited, Dartford, Kent, U.K.), which detects clumping factor and protein A. Antibiotic susceptibilities were determined by the Kirby-Bauer disk diffusion method. Antibiotics tested included penicillin, ampicillin, oxacillin, cephalothin, trimethoprim-sulfamethoxazole, erythromycin, clindamycin, rifampin, levofloxacin, vancomycin, gentamicin, and amikacin. Isolated colonies (to obtain a homogenous population of *S. aureus*) were grown in Todd-Hewitt broth (THB) overnight and aliquots frozen in 20% glycerol for future strain typing using Pulsed Field Gel Electrophoresis (PFGE.)

iv. Strain Typing with Pulsed Field Gel Electrophoresis

The homogenous population of *S. aureus* from each swab was pelleted, washed, and resuspended. The samples were embedded in an agarose gel and a DNA prep was done *in stiu.* The DNA was then digested with a restriction enzyme that recognizes a specific DNA sequence found infrequently in the genome. The resulting fragments of DNA (hundreds of kilobases) were then resolved into multiple bands of different sizes using the technology of PFGE (currently the gold standard for *S. aureus* strain typing.) The pattern of these bands gives each strain a distinct genetic fingerprint. The image of each genetic fingerprint was loaded into a computer database and analyzed using sophisticated software. The software assigns a band type based on size to each band within a single strain's banding pattern. The strain's band assignments determine the genetic fingerprint for that strain. We used the computer software to compare percent relatedness of the strains to each other. Using this technology, we were able to identify two distinct clones (each clone has an identical genetic fingerprint) at PSI.

D. Study Drugs

N/A

E. Medical Devices

N/A

F. Study Questionnaires

Please see the "Contact Information" form as well as the "Health History Baseline" form. An independent interviewer obtained this information verbally from each participant and entered his responses directly into a laptop computer.

The independent interviewer was Solimar Curumi. She has a bachelor's degree and several years of experience as a secretary and administrator.

G. Study Subjects

The study includes all consenting residents living at PSI during the course of the study January 1, 2001 to July 1, 2001. There were no exclusion criteria. The study population includes both males and females and various races are represented including African-Americans, Hispanics, and Caucasians.

All of the PSI residents have either HIV or AIDS and a history of drug abuse. About half of the population at PSI are mandated by the court to be there for drug rehabilitation. We included those

residents because they are affected by and play a role in *S. Aureus* colonization at PSI. For all of the study subjects, contact information, health history, and medical record abstractions were kept confidential on encrypted computer files.

H. Recruitment of Subjects

Periodically and particularly at weekly resident meetings, residents were advised and reminded of the study by PSI staff. Residents who expressed interest in participating in the study were invited to participate and be interviewed at their earliest possible convenience, including at the time they expressed interest in participation.

Dr. Barbara Zeller is the primary care physician for the residents at PSI. For all residents, she agreed that the resident was suitable for the study and she established that the resident was willing to discuss the study with the research team before being approached by the investigators.

I. Confidentiality of Study Data

Dr. Barbara Zeller, the primary care physician at PSI, assigned each study participant with a unique study ID number. Only Dr. Barbara Zeller and our interviewer had access to this information. Furthermore, each nasal swab was identified by the study ID number, specimen date, and a unique identifier determined by the study staff. The study staff did not have access to the patients' identities. Additionally, the medical record abstraction data and the interview data were kept on encrypted computer files only accessible to the investigators.

J. Potential Conflicts of Interest

none have been identified.

K. Location of the Study

PSI, where the study participants reside, is where the nasal swabs were obtained and where the medical record abstractions and interviews were conducted. Private rooms were provided for the interviews. PSI is located in the Bronx, NY. Dr. Barbara Zeller approved this study at PSI (there is no institutional IRB at PSI.)

All of the biological studies were conducted in the Lowy Laboratory at Presbyterian Hospital, 9th floor.

L. Potential Risks

None

Nasal swab collection is neither harmful nor uncomfortable.

M. Potential Benefits

Subjects were compensated for participating and are informed of their colonization status, including colonization with methicillin-resistant *S. aureus* at their request. This study may help us understand how TMP-SMX and other factors affect nasal colonization with *S. aureus* in this population of HIV/AIDS patients and drug users. Also, this study may pave the way for future studies investigating whether or not elimination of nasal colonization with *S. aureus* will reduce morbidity and mortality from *S. aureus* infections.

N. Alternative Therapies

N/A

O. Compensation to subjects

Respondents were provided with two (2) metro cards each valued at $6 over the course of the study. The first metro card was given to the resident at the conclusion of the baseline interview and collection of nasal swabs. The exception to this practice was in the case of new admissions to PSI. If the resident had lived at PSI for fewer than eight weeks, compensation was given to the resident's case worker for safe keeping. The second metro card was or will be given to the resident approximately six months after initial participation.

P. Costs to Subjects

N/A

Q. Minors as Research Subjects

N/A

R. Radiation or Radioactive Substance

N/A

S. References

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2. Kluytmans, Jan, van Belkum, Alex, and Henri Verbrugh. Nasal carriage of *Staphylococcus aureus:* Epidemiology, underlying mechanisms, and associated risks. Clinical Microbiology Reviews 1997;10:505-520.

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4. Nguyen, M. Hong, Carol A. Kauffman, et al. Nasal carriage of and infection with *Staphylococcus aureus* in HIV-infected patients. Annals of Internal Medicine 1999;130:221-225.

5. Raviglione, Mario C., Peter Mariuz, et al. High *Staphylococcus aureus* nasal carriage rate in patients with acquired immunodeficiency syndrome or AIDS-related complex. American Journal of Infection Control 1990;18: 64-69.

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Project Samaritan, Inc. (PSI)

The purpose of this consent form is to provide you with the information you need to consider in deciding whether to continuing to participate in this research study.

Study Title*:* *S. aureus* pathogenesis in HIV infection and in drug use

Study Purpose It is the purpose of this study to understand why certain groups of people, such as those who are HIV-infected, are at increased risk of developing bacterial infections caused by *Staphylococcus aureus* and to determine how these infections can be prevented. These infections range in severity from minor skin infections to life-threatening heart infections. We are interested in determining what factors place people at this increased risk. To address this question, the National Institutes of Health has sponsored this study that is being performed at PSI and Columbia University.

Study Procedures Participation in the study involves collection of a culture from your nose to see if there is evidence of staphylococcus. For the nose cultures, a cotton swab will be placed in the front of the nose and gently rotated around each nostril, If you have evidence of infection at another site that might be caused by staphylococcus, a culture of this area will also be obtained. As a reminder, you have already given us one nose culture several weeks ago, when we first told you about this study, This part of the study will include an interview and additional cultures of your nose and any site that may be infected with staphylococcus. The interview concerns your medical history and will take approximately 15 minutes. After the interview we will periodically return (about once a month) to take additional cultures and follow your medical progress in PSI as well as in the hospital if this becomes necessary. If you are hospitalized, we will review your medical record and collect any cultures that are positive for staphylococcus.

Study Risks There are no medical risks associated with this study since only a culture and a medical history will be obtained.

Study Benefits Although there will be no benefits to you directly; the study will provide information on whether you are colonized or infected with staphylococcus. It will also provide information on the factors that increase the risk of staphylococcal infections in HIV-infected patients.

Compensation You will receive a metro card in appreciation of your participation in the study.

Confidentiality All information that is collected will be confidential. No record will be kept that can identify you as a participant in this study.

Participation is Voluntary Participation in this study is voluntary. You can refuse to participate, or withdraw at any time, and such a decision will not affect your medical care at PSI or at Columbia-Presbyterian Medical Center, now or in the future.

Questions If you have any questions concerning this study, please ask and we will. try our best to answer them. For further information feet free to contact Drs. Jessica Justman. at (718) 518-5727 or Frank Lowy at (212) 305-5787. If you have any questions on your rights as a research subject, you can call the Columbia Institutional Review Board at (212) 305-5883,

_____ _____

Signature of Participant Date Signature of Researcher Date

ID#: N__|__|__|__

CONTACT INFORMATION

Personal Information

Name _____

Social Security Number _____/_____/_____

Home Address _____

_____

_____

Home telephone number (____) _____-_____
Beeper number (____) _____-_____
Second telephone number (____) _____-_____

Outside Contact

Name _____

Address _____

_____

_____

Telephone number (____) _____-_____

ID#: N__|__|__|__

Interview Date: ____|____|____
MM/DD/YY

Interviewer: _____

Subject gender:

0. Male
1. Female
2. Transgendered

DEMOGRAPHICS - BASELINE

I'd like to start by asking you some questions about yourself.

B 1. How old are you? ____|____

B4. Were you bom in the United States? ____
0. No
1. Yes (Skip to BX)

B4b. What country were you born in? _____

B4c. How old were you when you came to the United States (in years)? ____|____

B6. What race or ethnic group do you consider yourself to be? ____
I . White
2. African-American or Black (or Caribbean)
3. Latino Non-White
4. Latino
5. Asian
6. Other

B7. What is the highest grade of school or college you have completed? **(enter highest grade)** ____

High school graduate = 12
Some college = 13
College graduate = 14
Post graduate education = 15
Post graduate degree = 16

BX. Did you earn a GED (Graduate Equivalency Diploma if you did not complete HS)?____
0. No
1. Yes

B8. What is your current marital status? ____

1. Single, never married
2. Married / living as married /common law marriage
3. Separated
4. Divorced
5. Widowed

BX. Where were you staying/living before you came here? ____

1. Own apartment
2. With parents
3. In lover's apartment
4. With other friends or family
5. On the streets
6. Shelter, halfway house, other temporary housing/rooms
7. In-patient drug treatment
8. Hospital
9. Jail or prison
10. Someplace else (specify) _____

BX. How many different places have you lived the past 12 months ____|____

B 16. Have you ever been in prison or jail (not including time spent in a Juvenile facility)?

0 No (skip to BX)
1 Yes

B l6b. How much time have you spent in prison or J all in the ***last <u>six months?</u>*** ____

1. Less than one week
2. One week to 30 days
3. One month to 3 months
4. 3 to 6 months

BX. Were you mandated to this treatment program instead of going to prison or jail? ____

0 No
1 Yes

BX. Do you have any tattoos? ____

0 No
1 Yes

BX. When was the last time you got a tattoo? ____|____
MM/YY

BX. Are you pierced anywhere on your body; for example your ears, nose, or anywhere else? ____

0 No
1 Yes

BX. When was the last time you got pierced? ____|____
MM/YY

HEALTH HISTORY BASELINE

Now I would like to ask you about your health history. I'll be asking you a series of questions about diseases and symptoms you may have had in the past or may have now. If you're unsure about any question, please stop me and I'll try to make the question clearer. You can refuse to answer any question you feel uncompfortable answering.

SYMPTOMS IN THE LAST SIX MONTHS

In the last six months have you had any of the following SYMPTOMS?	*Yes*	*No*
Pain, swelling or redness on your skin with either a fever or pus	1	0
A (thick) nasal discharge from your nose	1	0
A bloody nose (if **NO**, skip to __)	1	0
Several bloody noses	1	0
Slin pain with a fever	1	0
Skin rashes Where _____	1	0
Weight loss	1	0

HIV/AIDS

H3. When did you first test HIV positive? ____|____
MM/YY

H7a. What were the results of your most recent T-cell (CD4) test? _____
(DK = 99999, if DK, SKIP to HX) CD4 Count

HX. Is that higher, lower, or about the same as the test before? ____
I Higher
0 Lower
I About the same
2 DK

H7b. What were the results of your most recent viral load test? _____
(DK = 99999, if DK, SKIP to HX) Viral Load

HX. Is that higher, lower, or about the same as the test before? ____
1 Higher
2 Lower
3 About the same
4 DK

H5. Has a doctor or nurse EVER told you that you have AIDS? ____
3 No (Skip to HXX)
4 Yes

H6. In what month and year were you first told that you had AIDS? ____|____
MM/YY

OTHER DISEASES / INFECTIONS

Now I would like to ask you about a few other health conditions.

	Yes	No
Have you ever been treated for endocarditis or heart valve infections?	1	0
Has a doctor told you that you have diabetes (if **NO**, skip to b.)	1	0
Do you take insulin?	1	0
Do you prick your finger to perform a self-blood test on a regular basis?	1	0

HX. In the ***last six months,*** how many times in total have you had an intravenous line or a transfusion? ____|____

H28a. Please show me all of the.places where the intravenous line was injected.

	Yes	No
Arm, Hand, Lower Leg	1	0
Chest, Neck, Groin	1	0
Did you ever noticed an infection at any of these sites, such as redness, swelling or pus?	1	0

DRUG USE HISTORY – BASELINE

DRUG USE HISTORY

1) Have you ever used _____?
If **NO**, SKIP to the next drug/substance.

*2) How old were you the **1st t time** you used _____?*

*3) How old were you the **last time** you used _____?*

4) In the last 6 months, how frequently did you use _____ on average?

INTERVIEWER: For ALL drug questions, if respondent VOLUNTEERS a word or term that he/she uses for the drug (or drug mixture) then use that work THROUGHOUT the questions pertaining to the drug OTHERWISE, USE THE TERMS AS WRITTEN.

	1) Ever		2) Age 1st Used	3) Age Last Used	4) Frequency
	es	o			
a) Cigarettes or tobacco	1	0	_____	_____ ___	1. never 2. < monthly 3. < weekly 4. weekly 5. daily
b) Alcohol	1	0	_____	_____ ___	1. never 2. < monthly 3. < weekly 4. weekly 5. daily
c) Marijuana or hashish (with or without tobacco)	1	0	_____	_____ ___	1. never 2. < monthly 3. < weekly 4. weekly 5. daily
d) Tranquilizers/ downers (not prescribed) e.g., Valium, Elavil, Catapres, Ativan, or Xanax	1	0	_____	_____ ___	1. never 2. < monthly 3. < weekly 4. weekly 5. daily
e) Uppers (not prescribed)	1	0	_____ __	___ _____	1. never 2. < monthly 3. < weekly 4. weekly 5. daily
f) Street methadone	1	0	_____ __	___ _____	1. never 2. < monthly 3. < weekly

					4. weekly

NON-INJECTED DRUG USE

1) Have you ever snorted or smoked _____?
If **NO**, SKIP to next drug.

*2) How old were you the **1st time you** snorted or smoked _____?*

*3) How old were you the **last time** you snorted or smoked _____?*

*4) In **the last 6 months**, how frequently did you snort or smoke , on average?*

	1) Ever		2) Age 1st Used	3) Age Last Used	4) Frequency
	Yes	No			
a) Heroin	1	0	_____	_____	1. never 2. < monthly 3. < weekly 4. weekly 5. daily
b) Crack	1	0	_____	_____	1. never 2. <monthly 3. < weekly 4. weekly 5. daily
c) Cocaine	1	0	_____	_____	1. never 2. < monthly 3. < weekly 4. weekly 5. daily
d) Speedball	1	0	_____	_____	1. never 2. < monthly 3. < weekly 4. weekly 5. daily

In the in the ***last 6 months***, how many people have you usually snorted or smoked with?____

a) Do you use _____ (materials/equipment) when you snort or smoke drugs?
b) Do you share _____ (materials/equipment) with other users?

	a) Use		**b) Share**	
	Yes	**No**	**Yes**	**No**
Straws	1	0	1	0
Matchbooks	1	0	1	0
Spoons	1	0	1	0
Pipe	1	0	1	0
Rolled up bill	1	0	1	0
Other (specify) _____	1	0	1	0

How many people do you usually share with when you use? ____

In the last ***6 months***, have you experienced any of the following when you snorted or smoked drugs?

	Yes	No
A bloody nose	1	0
Sinus pain	1	0
A (thick) nasal discharge	1	0
Any skin infections by your nose	1	0
Any rashes by your nose	1	0

INJECTED DRUG USE

*1) Have you **ever** skin-popped or injected _____into your veins or muscles?*
If **NO**, SKIP to next drug.

*2) How old were you the **1st time** skin-popped or injected _____?*

*3) How old were you the **last time** skin-popped or injected _____ ?*

*1) In the last **6 months**, how frequently have you skin-popped or injected _____ on average?*

	1) Ever		2) Age 1st Used	3) Age Last Used	4) Frequency
	Yes	No			
a) Heroin		0	_____ __	____ ____	1. never 2. < monthly 3. < weekly 4. weekly 5. daily
b) Crack		0	_____ __	____ ____	1. never 2. < monthly 3. < weekly 4. weekly 5. daily
c) Cocaine		0	_____ __	____ ____	1. never 2. < monthly 3. < weekly 4. weekly 5. daily
d) Speedball		0	_____ __	____ ____	1. never 2. < monthly 3. < weekly 4. weekly 5. daily
e. any other drugs? (specify): _____		0	_____ __	____ ____	1. never 2. < monthly 3. < weekly 4. weekly 5. daily

IF NEVER INJECTED, SKIP TO _____

	Yes	No
Have you ***ever*** used a needle or syringe and given it to someone else?	1	0
Have you ***ever*** used a needle or syringe after someone else has used it?	1	0
In the ***last 6 months*** have you used a needle or syringe and given it to someone else?	1	0
In the ***last 6 months*** have you used a needle or syringe after someone else has used it?	1	0

In the ***last 6 months***, did you get your syringes from any of the following? Yes No

1. A sex partner	1	0
2. Friends, family members, or associates	1	0
3. A dealer	1	0
4. Bought them on the street	1	0
5. Syringe exchange program (SEP)	1	0
6. A shooting gallery	1	0
7. A pharmacy	1	0
8. Other (specify)	1	0

In the ***last 6 months***, which of these was your main source of syringes? ____

In the *last 6 months,* have you experienced any abscesses after you injected or skin-popped drugs? ____

0. No
1. Yes

D49. Have you used any other illegal drugs in ***last 6 months,*** such as LSD, methamphetamine, PCP, Special K, Ecstasy (XTC), Mescaline, or Mushrooms? ____

0. No
1. Yes

D49a. In the ***last 6 months,*** which of these other illegal drugs have you used?

_____

DRUG TREATMENT HISTORY

*1)Have you **ever** participated in a(n) _____(type of drug treatment program), not including PSI?*
If **NO**, SKIP to the next treatment program on the list.

*2) Do you **currently** participate in a(n) _____?*

*3) In the **last 6 months** have you participated in a(n) _____?*

*4) In the **last 6 months** how many months were you in a(n) _____ in total?*

	1) Ever		2) Current		3) Last 6 months		4) How long in treatment
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**(last 6 months)**
a) Methadone program (# of months)	1	0	1	0	1	0	_____
b) Out-patient alcohol treatment program (# of months)	1	0	1	0	1	0	_____
c) Out-patient drug treatment program (# of months)	1	0	1	0	1	0	_____

For which drug(s)? _____

INTERVIEWER: Please show the Health Assessment (on the next page) to the patient and ask them to mark off how they feel.

HEALTH ASSESSMENT

|----------|----------|----------|----------|----------|----------|----------|----------|----------|
1 5 10

worst best

ACTIVITIES

Finally, I'd like to ask you a few questions about your day to day life.

Have you ever used a computer? ____
0 No
1 Yes

Have you gone to the movies in the last six months? ____
0 No
1 Yes

Do you enjoy watching sports on television? ____
0 No (If NO, skip to Ax)
I Yes

Which sports do you like to watch?	No	Yes
Football	0	1
Baseball	0	1
Basketball	0	1
Wrestling	0	1
Boxing	0	1
Other (specify)	0	1

Since you moved here, have you decorated your room in any way (eg, with pictures, pillows or something that makes you feel at home?)
0 No
1 Yes

Where would you most like to live? (open ended)

Are there any questions that you would like to ask me about the study?

Instructions for INTERVIEWER:

Get a nasal swab from patient.

Give patient 2 $6 MetroCards.

Say: "Thank you very much for your time and for sharing your story with me."

2. Karnofsky Scale **(to be answered by INTERVIEWER):**

Able to carry on normal activity.	100	Normal; no complaints-, no evidence of disease.
	90	Able to carry on normal activity; minor signs or symptoms of disease
	80	Normal activity with effort; some signs of symptoms of disease
Unable to work; able to care for most personal needs; a varying among of assistance is needed	70	Cares for self, unable to carry on normal activity or do active work
	60	Requires occasional assistance but is able to care for most needs.
	50	Requires considerable assistance and frequent medical care.
Unable to care for self, disease may be progressing rapidly.	40	Disabled; requires special care and assistance.
	30	Severely disabled; hospitalization is indicated, although death is not imminent.
	20	Very sick; hospitalization necessary; active supportive treatment is necessary.
	10	Moribund, fatal processes progressing rapidly.
	0	Dead.

INTERVIEWER, please answer the following questions:

On a scale of I to 10, how would you rate the overall honesty of this patient's interview?____
(I = very honest and 10 = very dishonest)

Are there any particular sections that you consider problematic?	No	Yes
Demographics	0	1
Health history	0	1
Drug use history	0	1
Health assessment	0	1
Activities	0	1

MEDICAL RECORD ABSTRACT FORM

(To be abstracted from the patient's medical record)

Medical Record Sections to be consulted

Care Plans

- • the earliest dated NMS form for demographics and admission data
- • the most recent NMS for all other medical information

History/Physical

- • the most recent blue monthly exam form
- • the white history forms at the end of the section

Physicians Orders

- • lists of medications
- • transfer orders for ER visits

Flow sheet

- provides back up information for CD4 and viral load (VL)

Lab & Special Reports

- toxicology reports from Bendiner

ID#: ___|__|__|__

Interviewer/Data abstractor name _____

CARE PLANS

Minimum Data Set (MDS)

Sections AA & AB: ADMISSION / DEMOGRAPHIC INFORMATION	
Date of medical record abstraction	____|__ __|____ MM/ DD/ YY
Is this the first medical record abstraction for this study participant? 0. No (Skip to section AC) 1. Yes 2.	____
Patient gender I Male 2 Female	____
Date of birth	____|__ __|____ MM/ DD/ YY
Race/ethnicity 1 American Indian/Native American 2 Asian/Pacific Islander 3 Black, not of Hispanic Origin 4 Hispanic 5 White, not of Hispanic Origin	____
Reasons for assessment **0 None of the above (below)** I Admission assessment 2 Annual assessment 3 Significant change in status assessment 4 Significant change of prior full assessment 5 Quarterly review assessment 10 Significant change of prior quarterly assessment	____
Date of entry to PSI	____|__ __|____ MM/ DD/ YY

Admitted from: 1 Private home/apt with no home health services 2 Private home/apt with home health services 3 Board and care/assissted living/group home 4 Nursing home 5 Acute care hospital 6 Psychiatric hospital / MR/DD facility 7 Rehabilitation hospital 8 Other	____
Lived alone prior to entry 0 No 1 Yes 2 In other facility	____

Residential history 5 years prior to entry	No	Yes
None of the above (below)	0	1
Prior stay at this nursing home	0	1
Stay in other nursing home	0	1
Other residential facility - board and care home/assisted living/group home	0	1
MH/psychiatric setting	0	1
MR/DD setting	0	1

Lifetime occupations (list)

Education (highest level completed)

1 No schooling
2 8th grade/less
3 9-11 grades
4 High school
5 Technical or trade school
6 Some college
7 Bachelors degree
8 Graduate degree

Section AC: **CUSTOMARY ROUTINE (in prior year)**

ADL Patterns

	No	**Yes**
R. None of the above	0	1
M. In bedclothes much of the day	0	1
N. Wakens to-toilet all or most nights	0	1
0. Has irregular bowel movement pattern	0	1
P. Showers for bathing	0	1
Q, Bathing in PM	0	1

Section 1: DISEASE DIAGNOSES
(only diseases with relationship to current ADL status, cognitive status, mood and behavior status, medical treatments, nursing monitoring, or risk of death. DO NOT LIST INACTIVE DIAGNOSES)

1. Diseases

	No	Yes
RR. None of the above	0	1
A. Diabetes mellitus	0	1
D. Arteriosclerotic heart disease (ASHD)	0	1
E. Cardiac dysrhythias	0	1
H. Hypertension	0	1
K. Other cardiovascular disease	0	1
L, Arthritis	0	1
R. Aphasia	0	1
T. Cerebrovascular accident (stroke)	0	1
U. Dementia other than Alzheimer's	0	1
V. Hemiplegia/Hemiparesis	0	1
W. Multiple sclerosis	0	1
X. Paraplegia	0	1
Z. Quadriplegia	0	1
AA. Seizure disorder	0	1
CC. Traumatic brain injury	0	1
GG. Schizophrenia	0	1
HH. Asthma	0	1
II. Emphysema/COPD	0	1
NN. Allergies	0	1
PP. Cancer	0	1
QQ. Renal failure	0	1

2. Infections (DO NOT LIST INACTIVE DIAGNOSES)

	No	Yes
M. None of the above	0	1
A. Antibiotic resistant infection (eg Methicillin resistant staph)	0	1
B. Clostridium. difficile (c. diff)	0	1
D. HIV infection	0	1
E. Pnemonia (with fever)	0	1
F. Respiratory infection	0	1
G. Septicemia	0	1
H. Sexually transmitted diseases	0	1
I. Tuberculosis	0	1
L. Wound infection	0	1

3. Other Current Or More Detailed Diagnoses And ICD-9 Codes (DO NOT LIST INACTIVE DIAGNOSES)			
(Interviewer-list infections below)	**No**	**Yes**	**ICD-9**
a.	0	1	
b.	0	1	
c.	0	1	
d.	0	1	
e.	0	1	

Section J: HEALTH CONDITIONS
(List all conditions in the last 7 days, unless other time frame is indicated)

1. Problem Conditions

	No	**Yes**
o. None of the above	0	1
a. Weight gain or loss of 3 or more pounds in 7 days	0	1
b. Inability to lie flat due to shortness of breath	0	1
c. Dehydrated: output exceeds input	0	1
d. Insufficient fluid; did NOT consume all liquids provided in last 3 days	0	1
e. Delusions	0	1
f -Dizziness/Vertigo	0	1
g. Edema	0	1
h. Hallucinations	0	1
i. Internal bleeding	0	1
j. Recurrent lung aspirations in last 90 days	0	1
k. Shortness of breath	0	1
l. Syncope (fainting)	0	1
m. Unsteady gait	0	1
n. Vomiting with weight loss & fever	0	1

Section L: ORAL/DENTAL STATUS

1. Oral Status And Disease Prevention

	No	**Yes**
g. None of the above	0	1
a. Debri's (soft, easily movable substances) present in mouth prior to going to bed	0	1
b. Has dentures or removable bridge	0	1
c. Some/all natural teeth lost-does not have or does not use dentures (or partials)	0	1
d. Broken, loose, or carious teeth	0	1
e. Inflamed gums (gingiva); swollen or bleeding gums; oral abscesses; ulcers or rash	0	1
f Daily cleaning of teeth/dentures or daily mouth care-by resident or staff (not)	0	1

Section M: SKIN CONDITION (Code all the apply during the last 7 days) **1. Ulcers (due to any cause)** **2+ sites at any stage or any stage 3 or 4 (Record the number of ulcerus at each ulcer stage during last 7 days; 0=none, 9=9 or more)**	
a. Stage I A persistent area of skin redness (without a break in the skin) that does not disappear when pressure is relieved.	
b. Stage 2 A partial thickness loss of skin layers that presents clinically as an abrasion, blister or shallow crater.	
c. Stage 3 A full thickness of skin is lost, exposing the subcutaneous tissues-presents as a deep crater with or without undermining adjacent tissue.	
d Stage 4 A full thickness of skin and subcutaneous tissue is lost, exposing muscle or bone.	

History of Resolved Ulcer	
Resident had an ulcer that was resolved in last 90 days 0 No 1 Yes	_____

4. Other Skin Problems Or Lesions Present (Check all that apply during the last 7 days)		
	No	**Yes**
h. None of the above	0	1
a. Abrasions, bruises	0	1
b. Bums (second or third degree)	0	1
c. Open lesions other than ulcers, rashes, cuts (eg cancer-lesions)	0	1
d. Rashes--eg, intertrigo, eczema, drug rash, heat rash, herpes zoster	0	1
e. Skin desensitized to pain or pressure	0	1
f. skin tears or cuts (other than surgery)	0	1
g. Surgical wounds	0	1

6. Foot Problems And Care (Last 7 Days)		
	No	**Yes**
G. None of the above	0	1
A. Resident has one or more foot problems-eg corns, calluses, bunions, hammer toes, overlapping toes, pain, structural problems	0	1
B. Infection of the foot-ea, cellulitis, prurulent drainage	0	1
C. Open lesions on the foot	0	1
D. Nails/calluses trimmed during last 90 days	0	1

Section 0: MEDICATIONS	
1. Number of medications in the past 7 days	___
New medications in the past 90 days? 0. No 1. Yes	____
3. The number of days injections were received 'in the past 7 days.	____

Section P: SPECIAL TREATMENTS AND PROCEDURES
Special treaments, procedures and programs during the last 14 days

	No	Yes
s. None of the above	0	1
a. Chemotherapy	0	1
b. Dialysis	0	1
c. IV medication	0	1
d. Intake/output	0	1
e. Monitoring acute medical condition	0	1
f,Ostomy care	0	1
g. Oxygen therapy	0	1
h. Radiation	0	1
i. Suctioning	0	1
j. Tracheostomy care	0	I
k. Transfusions	0	1
1.Ventilator or respirator	0	1
m. Alcohol/drug treatment program	0	1
n. Alzheimer's/dementia special care unit	0	1
o. Hospice care	0	1
p. Pediatric unit	0	1
q. Respite care	0	1
r. Training in skills required to return to the community	0	1

1. Number of hospital admissions with overnight stay, last 90 days	___|___
6. Number of emergency room visits without overnight stay, last 90 days	___|___
7. Has the resident had any abnormal lab values in the last 90 days (or since admission)? 0. No 1. Yes	____

Section Q: DISCHARGE POTENTIAL AND OVERALL STATUS	
2. Overall change in care needs as compared with status of 90 days ago? 0. No change 1. Improved-receives fewer supports, needs less restrictive level of care 2. Deteriorated-receives more support	____

Section S: STATE SUPPLEMENT		
3.Has resident with HIV engaged in substance abuse behaviors more than one month ago which continue to influence care currently given to the resident? 0. No 1. Yes 2. Resident does not have HIV		
4. Disease diagnoses with relationship to current ADL, cognitive, mood, behavior, medical treatments, nursing monitoring, or risk of death in the last 30 days		
	No	**Yes**
j. None of the above	0	1
a. HIV Dementia	0	1
b. HIV Wasting Syndrome	0	1
c. Non-psychotic disorder following organic brain damage	0	1
d. Psychotic disorder following organic. brain damage	0	1
e. Spinal cord injury	0	1
f. Herniplegia	0	1
g. Herniparesis	0	1
h. Huntington's disease	0	1
i. Dementia Registry reporting 1. County (FIPS) code of prior residence 2. Physician license number	0	1

END OF MINIMUM DATA SET QUESTIONS

HISTORY / PHYSICAL
a) Blue MONTHLY EXAMINATION form

CURRENT PROBLEMS

If most recent monthly exam is crossed out and HO SPITAL RETURN is written in, use the previous MONTHLY EXAMINATION form.

Most recent T-cell (CD4) count _____
CD4 Count

Date of test _____
MM/DD/YY

Most recent viral load _____
Viral Load

Date of test _____
MM/DD/YY

RELAPSE

Review the three (3) most recent MONTHLY EXAMINATION forms.

Was there a drug or alcohol use relapse reported in any of the three most recent MONTHLY EXAMINATION forms?
0 No
I Yes

MEDICAL FINDINGS

Review the three (3) most recent MONTHLY EXAMINATION forms.

Skin ____
0 Normal (skip to ENT)
I Abnormal

Describe findings if abnormal

ENT ____
0 Normal (skip to hospital)
I Abnormal

Describe findings if abnormal

HOSPITAL RETURN CURRENT PROBLEMS
b) Blue MONTHLY EXAMINATION form

Review the three (3) most recent MONTHLY EXAMINATION forms. If MONTHLY EXAMINATION is crossed out and HOSPITAL RETURN is written in for any of the last three months, complete the following.

What was the diagnosis (include all diagnoses, if more than one)?

`

	No	Yes
Did the patient have an IV line or a blood transfusion?	0	1

HISTORY / PHYSICAL
b) White MEDICAL HISTORY form located at the end of section

HIV/AIDS

Date of the first positive HIV test __|___|___ MM/DD/YY

Does the resident have an AIDS diagnosis? ____
0 No (Skip to SPECIFIC HIV...
I Yes

Date of AIDS diagnosis __|___|__ MM/DD/YY

SPECIFIC HIV RELATED DIAGNOSES AND SICKLE CELL

	No	Yes
PCP, (pneumocystis carinii pneumonia)	0	1
MAI/MAC, (mycobactenium aviurn infectionJcomplex)	0	1
Sickle cell anemia	0	1

PHYSICIANS ORDERS-a) Medications

	No	Yes		No	Yes
Abacavir (Ziagen)	0	1	Itraconazole (sporanox)	0	1
Acyclovir (zovirax)	0	1	Kanamycin j	0	1
Amikacin (Amikin)	0	1	Levofloxicin (Levofloxan)	0	1
Amoxicillin (Spectrobid)	0	1	Linezolid	0	1
Amphotericin	0	1	Meropenern	0	1
Ampicillin (Omnipen)	0	1	Mupirocin (Bactroban)	0	1
Amprenavir (Agenerase)	0	1	Metronidozole (Flagyl)	0	1
Atovaguone	0	1	Mycelex (Mycostatin)	0	1
Augmentin (Amoxicillin plus clavulanic)	0	1	Nafcillin (Unipen)	0	1
Azithromycin (Zithromax)	0	1	Nelfinavir (Viracept)	0	1
AZT (zidovudine)	0	1	Nevirapine (Viramune)	0	1
Aztreonam (Azactam)	0	1	Oxacillin	0	1
Bacitracin	0	1	Penicillin G	0	1
Cefazolin (Ancef)	0	1	Penicillin V	0	1
Cefepime (Maxipime)	0	1	Piperacillin (Pipracil)	0	1
Cefixime (Suprax)	0	1	Podofilox	0	1
Cefotetan (Cefotan)	0	1	Primaxin (Imipenem plus Cilastatin)	0	1
Cefpodoxime Proxetil (Vantin)	0	1	Pyrazinamide (PZA)	0	1
Cefprozil (Cefzil)	0	1	Pyrimethamine	0	1
Ceftriaxone (Rocephin)	0	1	Rifabutin	0	1
Ceftazidime (Fortaz)	0	1	Ritonavir (Norvir)	0	1
Ce-fFuroxime axetil (Ceftin)	0	1	Saguinavir	0	1
Cefuroxime (Zinacef)	0	1	Streptomycin	0	1
Cephalexin (Keflex)	0	1	Sulfadiazine	0	1
Ciprofloxacin (Cipro)	0	1	Sulfamethoxazole (Gant nol)	0	1
Clindamycin	0	1	Tetracyclines (Doxycycline, Minocycline)	0	1
Clotrimazole Troches	0	1	Timentin (Tiarcilin plus Cl	0	1
Dalfopristin/Quinupristin (Synercid)	0	1	Tobramycin (Nebcin)	0	1
Dapsone	0	1	Trimethoprim (Trimpex)	0	1
DDC (Zalcitabine, Hivid)	0	1	Trimethoprim-sulfamethoxazole (Bactrim, Septra)	0	1
DDI (Didanosine, Videx)	0	1	Unasyn (Ampicillin plus Sulbactam)	0	1
Dicloxacillin	0	1	Vancomycin (Vancocin)	0	1
Efavirenz (Sustiva)	0	1	Zosyn (Piperacillin plus Tambactarn)	0	1
Ethambutol (EMB)	0	1	3TC (Lamivudine)	0	1
Fluconazole (Diflucan)	0	1			
Foscarnet	0	1			
Ganciclovir (DBPG)	0	1			
Gentarnicin (Garamycin)	0	1			
Indinavir (Crixivan)	0	1			
INH (Isoniazid)	0	1			

PHYSICIANS ORDERS

b) Orders to transfer to the ER

ER
Review PHYSICIANS ORDERS for the past three (3) months.

	No	Yes
Was patient transferred to the ER at any time during the past 3 months?	0	1

LAB & SPECIAL REPORTS
Bendiner toxicology screen reports

DRUG USE RELAPSE
Review the three (3) most recent TOXICOLOGY reports

Date of most recent tox screen ____|____|___
MM/DD/YY

Do any of the urine toxicologies test positive?	**No**	**Yes**
No positive result	0	1
Methadone	0	1
Opiates	0	1
Cocaine	0	1
Barbiturate	0	1
Benzodiazepines	0	1
Cannabinoids	0	1

In the past three (3) months, were there any positive toxicology results (of the six toxicology tests listed above)? ____

0. No (end of medical abstract form)
1. Yes

Which toxicologies were positive?	**No**	**Yes**
Methadone	0	1
Opiates	0	1
Cocaine	0	1
Barbiturate	0	1
Benzodiazepines	0	1
Cannabinoids	0	1

END OF MEDICAL RECORD ABSTRACTION