

**Severity of Need Core Services Project
Patient Characteristics Panel Final Report**

Prepared for:

**U.S. Department of Health and Human Services
Health Resources and Services Administration
HIV/AIDS Bureau**

Prepared by:

**Health Systems Research, Inc.
an Altarum Company**

RTI International

March 2007

**SEVERITY OF NEED CORE SERVICES PROJECT:
PATIENT CHARACTERISTICS PANEL FINAL REPORT**

Table of Contents

I.	Introduction	1
	A. Panel Purpose and Process	1
	B. Discussion of Data Sources	3
	C. Conceptual Framework and Guiding Principles	4
II.	Subpanel Discussions and Variable Templates	10
	A. Clinical Characteristics Subpanel.....	10
	B. Comorbidities Subpanel.....	13
	C. Sociodemographic Subpanel.....	22
III.	Citations	31
IV	History of the Panel	32
	A. Members and Affiliations	32
	B. HSR/RTI Contact Information	32

Views expressed are those of the meeting participants and do not represent official positions of the federal government.

PATIENT CHARACTERISTICS PANEL FINAL REPORT

I. Introduction

A. Panel Purpose and Process

The Patient Characteristics panel was charged with identifying specific characteristics of HIV/AIDS patients that result in a greater need for services. To determine these characteristics, the panel members identified and conducted three sequential tasks:

1. To ensure that the panel considered a comprehensive set of variables prior to assessing their validity, feasibility, and interdependence, the panel identified an initial set of variables thought to be important determinants of severity of need (SON).
2. The panel members split into three groups to better focus their efforts on measuring three types of patient-specific factors that may significantly increase the depth, scope, or necessary utilization of care and services for people with HIV:
 - A clinical subpanel
 - A comorbidities subpanel
 - A demographic subpanel.
3. Each subpanel was responsible for completing a template for each variable in their area of consideration. The template defined the variable; identified the rationale for its inclusion; identified the potential sources of data for measuring the variable; assessed the validity, reliability, and potential bias of each variable; and suggested ways to address any underlying bias. The goal was to evaluate the value of each variable and develop a final set of recommendations for inclusion in the SON index. The full Patient Characteristics panel then reconvened to discuss the recommendations of the subpanel and identify the variables that should be included in the panel's final recommendation to the larger SON expert panel.

Within each subpanel, the variables were evaluated based on their importance in determining resource needs for CARE Act services and in determining the current quality, cost, and availability of data used to measure the variables. The variables would then be forwarded to either the Area Characteristics panel, so they could consider how the variables might be better measured or applied at the area level, or to the Associated Costs panel, so they could cost out the impact of the characteristics on SON.

As identified in *Table 1*, the panel evaluated 20 variables, 5 of which were forwarded for possible inclusion in a SON index. Variables were excluded based on either a lack of sufficient data, or a lack of a sufficient rationale for inclusion. Variables that simply lacked sufficient data should be reconsidered in the future for possible inclusion if data becomes available. One variable the panel considered (insurance) was not forwarded because it was being considered by another panel.

Table 1. Variables considered and forwarded for possible inclusion in an HIV/AIDS SON index, by the Patient Characteristics Subpanel

Patient Characteristics Subpanel	Variables Forwarded for Further Consideration for Use in an SON Index	Variables Excluded Due to Insufficient Data	Variables Excluded Due to Insufficient Rationale for Inclusion
Clinical Characteristics	<ul style="list-style-type: none"> HIV/AIDS disease progression * Insurance (considered by another panel) 	<ul style="list-style-type: none"> Drug resistance HIV exposure categories 	<ul style="list-style-type: none"> Non-IDU HIV risk behaviors
Comorbidities	<ul style="list-style-type: none"> IDU exposure category 	<ul style="list-style-type: none"> Age-related comorbidities (e.g., diabetes, cardiovascular disease) Hepatitis C Mental illness Substance abuse 	<ul style="list-style-type: none"> Gonorrhea Syphilis Tuberculosis (TB)
Demographic Characteristics	<ul style="list-style-type: none"> Age Race/ethnicity Sex 	<ul style="list-style-type: none"> Educational status Socioeconomic status (SES) Immigration status 	<ul style="list-style-type: none"> Urban/rural differences

In an effort to prioritize their work before breaking into smaller subpanels, panelists first met as a full group to develop a list of variables to evaluate subjectively each variable’s contribution to SON. Before voting to rate the variables, the group eliminated 12 of 20 variables. Panelists were asked to score each variable from 1 to 5 based on how well each measured the theoretical concept of SON, with 1 indicating a variable of the highest importance and 5 indicating a variable of the lowest importance. These scores were then compiled and the averages ranked. The results are presented in *Table 2*.

Table 2. Area characteristics variables (considered important by the panel with sufficient data currently available) forwarded to the full panel and panelists’ priority score

	Variable	Average Score
1	HIV/AIDS disease progression	1.0
2	Race/ethnicity	1.9
3	IDU exposure category	2.0
4	Age	2.5
5	Sex	3.5

B. Discussion of Data Sources

Once the variables were defined, the panel then identified the potential sources of data. Panelists were able to share knowledge of the existing sources, discuss challenges inherent in using the sources, and identify critical gaps within the sources. As part of this discussion, the panel asked for clarification on the use of past studies and asked if they could recommend new data to collect, either through surveys or by adding data elements to existing surveys. Health Systems Research (HSR) and RTI International (RTI) clarified that the panel should focus on existing data sources, with an emphasis on those that are of high quality, lower in cost, and available and updated on a regular basis. Although past studies were used in part to determine the relevance of data elements, the Panel agreed that future data would need to come from sources that are regularly updated. The panel could make recommendations to the Health Resources and Services Administration (HRSA) to collect new data, but the inclusion of a variable could not be dependent upon proposed collection of new data.

The panelists identified various challenges associated with using the data sources considered, and did not include key elements or cofactors. In general, many data sources:

- Did not identify people with HIV
- Did not appropriately capture CD4 counts
- Did not involve a large enough sample
- Were not available at the county level
- Were not complete and accurate for other reasons
- Did not include those “not in care”
- Did not provide unduplicated counts
- Were not updated quickly and consistently.

Ultimately, the panel felt that the following four Centers for Disease Control and Prevention (CDC) data sources, despite their limitations, might be the most appropriate:

- ***HIV/AIDS Reporting System (HARS) National Surveillance Database.*** HARS contains the records of all persons confidentially reported by name that have HIV/AIDS
 - *Advantages:* Captures race/ethnicity, sex, disease status, insurance data, in care/not in care, some clinical data, zip code, and county; states are coming online constantly.
 - *Limitations:* Degree of completeness varies; CDC does not accept HIV data from 13 states that are using coded identifiers (must be name-based data); data are based on information at time of initial diagnosis.
- ***Morbidity Monitoring Project (MMP).*** MMP is a surveillance system designed to collect information from HIV/AIDS patients who received care from randomly selected HIV care providers.

- *Advantages:* Locally representative (19 states, 1 territory, 5 cities, LA county); supplements core HIV/AIDS surveillance data with linked medical record abstractions and patient interviews; provides data to estimate quality of care, clinical outcomes, risk behaviors, health care utilization, and unmet needs among HIV-infected persons receiving medical care.
- *Limitations:* Not nationally representative; county-level data unavailable except for LA county. Data may not be available for several years.
- ***National Health Interview Survey (NHIS).*** NHIS is the principal source of information on the health of the civilian noninstitutionalized population of the United States.
 - *Advantages:* Displays health characteristics by many demographic and socioeconomic characteristics.
 - *Limitations:* Does not identify people with HIV; only publishes national-level data.
- ***National Health and Nutrition Examination Survey (NHANES):*** NHANES is a unique data source in that it combines interview survey data with physical examination data. It is the primary source of national-level serologically-based estimates.
 - *Advantages:* Allows the estimation of serologic prevalence among self identified risk groups (for example those who have ever injected drugs, or those who have ever had a same-sex attraction); includes demographic, socioeconomic, nutrition, and health-related data, as well as biomedical measurement data, prevalence, and risk factors; identifies people with HIV.
 - *Limitations:* Only provides national estimates; estimates among some subgroups are too unstable to use due to sample size limitations.

C. Conceptual Framework and Guiding Principles

The panel developed a conceptual framework and series of guiding principles that guided the subsequent discussions of the panel. The panel started by describing the patient-specific factors they believed would significantly increase the depth, scope, or necessary utilization of care and services for people with HIV. When creating this list, the panel used the following seven guiding principles:

- ***Defining target level of care:*** Recommendations would differ depending on whether the group considered the impact of patient characteristics on **optimal care** versus **usual care**. For instance, active injection drug use may result in lower outpatient costs (and predictably poor outcomes) because the usual level of care by these patients is low, but may result in much higher cost to provide **optimal** care for the same patient if outreach, harm reduction, counseling, on-site methadone or buprenorphine, and multiple other services are provided. When identifying the factors that affect utilization, the panel used a criterion of impact on **usual care**, assuming those data might be more available.
- ***Focusing on direct medical services and those that support access to care and treatment:*** Although the panel would have preferred to use optimal care, the established guidelines and the limited ability to estimate additional costs required for

optimal care, restricted their consideration to the usual medical services. Panelists chose to focus on the likely impact on categories of service that are funded by the CARE Act within the scope of ambulatory care services, including antiretroviral (ARVs) therapies, case management, mental health care, substance use/harm reduction services, adherence services, and oral health care. The final SON estimates of care utilization will need to take into account the entire spectrum of critical services, including those provided outside the medical clinic (e.g., referrals for mental health treatment, drug abuse treatment, adherence support), to be reasonable criteria for determination of funding. The panel recognized that limited data may exist on how to estimate the impact on resource needs for several of these measures.

- ***Type of increased need:*** Increases in SON may be manifested as increased need for care visits, screening, monitoring, or treatment and may take the form of higher costs for medications, laboratory tests, or human resources.
- ***Duration of need:*** We have only included those conditions that increase SON over time or those with potential for chronic increased SON. This assumption considers that acute conditions will likely be less cost-intensive over time and be more evenly distributed across all HIV populations (e.g., HIV-related acute pneumonias or medication-related hepatitis or acute sexually transmitted infections [STIs]). The one exception would be hospitalization for new opportunistic infections (OIs); however, because inpatient services are not paid for by the CARE Act, this exception is not relevant to the model. This assumption is critical because funding allocations based on severity will likely be based on retrospective data that will affect allocations over several years.
- ***Exclusion of unrelated comorbidities:*** Only comorbidities caused by or complicated by HIV and its treatment have been included in the list. This list is incomplete; additional categories may determine whether specific conditions result in increased need because of increased monitoring (visits and/or labs), treatment (services, medication, or screening tests to confirm diagnosis), or supportive services important for successful treatment (mental health, adherence services, drug treatment, case management), as well as any correlation between these services.
- ***Impact of late entry to care and poor adherence to care:*** The panel considered factors resulting in late entry into care and poor treatment adherence because both are associated with higher morbidity, more frequent complications, and more expensive monitoring and medications. Panelists asserted that these factors would balance the savings from visits, labs, and medications foregone during the period when the patient was out of care.
- ***Medication complexity and interactions:*** Panelists initially considered any factor that increased a patient's number of prescriptions as a factor that also increases cost of care and complexity, because additional work is required to (1) coordinate prescribing with other clinicians, (2) increase monitoring frequency and types of laboratory tests, (3) manage more side effects with advice, visits, and symptom-controlling medications, (4) and monitor and manage drug–drug interactions.

The group then used these seven guiding principles to identify and characterize the patient-specific factors they believed would significantly increase the depth, scope, or necessary utilization of care and services for people with HIV. The patient-specific determinants of resource needs are summarized in *Table 3*.

Table 3. Patient-specific factors increasing the depth, scope, or necessary utilization of care and services for people with HIV

Category	Characteristic	Rationale for Inclusion	Data Sources and Limitations	HSR/RTI Research Questions
<p>MENTAL HEALTH</p>	<ul style="list-style-type: none"> Severe, Persistent Mental Illness (SPMI) Schizophrenia Bipolar Disorder Affective Disorders Post-traumatic stress disorder (PTSD) Adjustment Disorders/ Anxiety related to HIV diagnosis 	<ul style="list-style-type: none"> Late entry into care ↓ adherence Need for mental health services by licensed mental health practitioners ↑time to coordinate with mental health services or necessity to provide mental health treatment within HIV program ↑ medication complexity ↑ frequency of drug monitoring as a result of drug-drug interactions Medication costs for psych meds if uninsured Additional support (CM, adherence) ↓ adherence Need for mental health services by licensed mental health practitioner ↑time to coordinate with Mental Health Services or necessity to provide mental health treatment within HIV program Medication costs for psych meds if uninsured 	<p>Local availability of mental health treatment resources varies greatly and will have an enormous impact on these costs.</p> <p>Data sources:</p> <ul style="list-style-type: none"> -Medicaid -RW databases -VAH -Private? -Medicare? -NIMH studies? 	<p>Cross cutting question: What is the net effect of late entry into care on cost and utilization of outpatient HIV care?</p> <p>What is the frequency of the listed psych diagnoses in PWHIV? If no direct measure, what surrogates exist?</p> <p>What impact do SPMI and Affective Disorders have on cost of delivery of HIV medical care and other targeted services noted above? Can we learn from data on this in non-HIV patients?</p> <p>How should we be considering cost of non-HIV, non-ADAP medications in this analysis?</p>
<p>SUBSTANCE USE</p>	<ul style="list-style-type: none"> Active injection drug use Noninjection drug use (non-IDU; illicit and abuse of prescriptions) 	<ul style="list-style-type: none"> Late entry into care High rate of comorbidity with mental health, HCV ↓ adherence Need for drug treatment, harm reduction services provided by drug treatment counselors and addiction services professionals ↑time to coordinate with substance abuse treatment services ↑ medication complexity ↑ likelihood of developing resistance Additional support (CM, adherence) Drug-related comorbidities need workup and treatment (e.g. wasting, abscesses, dental complications), ↑ visits, ↑ labs, and ↑ symptom control medications 	<p>Local availability of substance abuse treatment resources varies greatly and will have an enormous impact on these costs.</p> <p>Data sources:</p> <ul style="list-style-type: none"> -Medicaid -RW databases -VAH -Private? -Medicare? -Cohort studies with substance users? 	<p>Are resistance rates higher in active drug users? How much higher?</p> <p>What is the impact of substance use (probably differs by drug type) on utilization and cost of HIV services?</p>

Table 3. Patient-specific factors increasing the depth, scope, or necessary utilization of care and services for people with HIV

Category	Characteristic	Rationale for Inclusion	Data Sources and Limitations	HSR/RTI Research Questions
PREVIOUS ARV HISTORY	<ul style="list-style-type: none"> Increased risk of resistance or side effects which require second or higher line treatment 	<ul style="list-style-type: none"> More expensive drugs in second and third line regimens More frequent visits More frequent and more expensive laboratory monitoring, including resistance testing More expert care, extra visits to strategize and consult More medication to treat side effects of second and third line regimens Direct provision of adherence support services Funding of community based resources to support treatment adherence 	<p>Caveat: There are likely significant differences between communities in the frequency of resistance and of patients with extensive ARV histories</p> <p>Data sources: -Cohort studies -Cost effectiveness models</p>	<p>Can we quantify on a per-patient basis the impact on cost of care of developing resistance?</p> <p>What is the cost of a second line regimen as compared to a first line? Third compared to second?</p> <p>What are the costs and needs associated with care of patients who have exhausted available treatment options (beyond 2nd and 3rd line options)?</p>
HCV AND HBV COINFECTION	<ul style="list-style-type: none"> Decreased tolerability of some HIV meds Impact on response to HIV treatment Progressive liver disease to be managed Need for HCV treatment 	<ul style="list-style-type: none"> More specialty care, hepatologist or ID referrals and need to coordinate care ↑ medication complexity More frequent routine visits ↑ Monitoring for liver-related complications of HIV treatment Hepatitis-related symptoms (fever, wasting, rashes and headaches) need workup to rule out HIV complications and need treatment, ↑ visits and ↑ labs HCV treatment in appropriate patients, including drug cost, cost of ancillary meds, extra visits, and labs/studies 	<p>Data sources: -Medicaid -RW databases -VAH HCV and IDU cohorts -Private? -Medicare?</p>	<p>What is the total cost of a year of HCV and/or HBV treatment?</p> <p>What are the effects of HCV and its treatment on the cost and utilization of HIV services?</p>
OTHER COMORBID CONDITIONS	<ul style="list-style-type: none"> Cardiovascular disease Renal disease DM Others 	<ul style="list-style-type: none"> ↑ medication complexity More frequent routine visits Symptoms needing workup to rule out HIV complications and needing treatment, so ↑ visits and ↑ labs ↑ demand for other medications Referrals to specialty care and need to coordinate 	<p>Data sources: -Medicaid -RW databases -VAH -Private? -Medicare? -VACS Cohort Study -Other cohorts (ex. Kaiser)</p>	<p>What are the associated costs and utilization needs with treatment for these various diseases?</p>

Table 3. Patient-specific factors increasing the depth, scope, or necessary utilization of care and services for people with HIV

Category	Characteristic	Rationale for Inclusion	Data Sources and Limitations	HSR/RTI Research Questions
OLDER AGE (>50)	<ul style="list-style-type: none"> Proxy for increase risk of age-related conditions: CAD, osteoporosis, cancer 	<ul style="list-style-type: none"> Increased need for screening (mammogram, colon, etc) Lipid lowering Other health services Better adherence 	Data sources: -Medicaid -RW databases -VAH -Private? -Medicare? -VACS cohort study	Studies showing different utilization and cost patterns associated with different age groups
HOUSING STATUS	<ul style="list-style-type: none"> Homeless or unstably housed 	<ul style="list-style-type: none"> Not certain 	Need to review: -Andrew Moss -Cohort studies which include homeless	See above for homeless patients
DISTANCE FROM CLINIC	<ul style="list-style-type: none"> Distance and potentially use as proxy for difficulty (?) 	<ul style="list-style-type: none"> Transportation Need to utilize and support low volume MDs 	HCSUS (S Cohn)	What is impact of transportation/distance, rural versus urban? See also below
INSURANCE STATUS		Increased need for ADAP Associated with poorer outcomes in some settings and delay in accessing care	Data sources: -HCSUS (old) -Other cohorts	How to define (ever/never/current/this year)? How adjust for state use of ADAP to cover insurance? What are rates (or is there a proxy)?
RURAL VS. URBAN	<ul style="list-style-type: none"> Combined transportation, reflecting other levels of services? 		Data sources: - HCSUS (S Cohn) - Data from other non-HIV national data sets	

II. Subpanel Discussions and Variable Templates

The following section outlines the rationale for recommending each of the selected variables and explains why other variables were excluded. The section is divided into two subsections: the first subsection discusses variables forwarded by the panel as potential elements for a SON index, and the second subsection discusses variables that were not forwarded. A short description is provided for each variable followed by a standardized data evaluation template that guided the investigation and discussion.

A. Clinical Characteristics Subpanel

The Clinical Characteristics subpanel was charged with identifying clinical variables measured at the patient level that would be predictive of need. The subpanel forwarded the HIV/AIDS disease progression variable, which all members agreed was most important. They felt ARV drug resistance was likely predictive of higher need, but was unable to identify a data source to measure it. The subpanel recommended that the comorbidities subpanel evaluate the risk behavior and exposure categories. The full panel agreed with the recommendations of the subpanel, which are outlined in *Table 4*.

Table 4. Clinical Characteristics Subpanel variables for consideration

Included Variables	Inclusion	Data Source/Comments	Rank
HIV/AIDS disease progression	Yes	MMP/HARS	1.0
Drug resistance	No	<i>Deemed important, but no potential data set to measure it</i>	N/A
HIV clinical variables	No	<i>Determined to include disease progression and drug resistance</i>	N/A
HIV risk behaviors	No	<i>Recommended for consideration by the comorbidities subpanel</i>	N/A
HIV exposure categories	No	<i>Recommended for consideration by the comorbidities subpanel</i>	N/A

1. Variables forwarded for consideration

HIV/AIDS disease progression: The subpanel forwarded HIV disease progression based on the assessment that patients with more advanced destruction of their immune system would require greater resources. Panelists identified the CDC HIV/AIDS reporting system (HARS) as a data source that currently provided information on patient CD4 counts as well as HIV/AIDS designation. Although the variable was forwarded, panelists were concerned that CD4 counts as reflected in HARS might not reflect current severity of need as they were only a measure of the patient's low point (nadir) of immune destruction. Many patients in fact rebound quite dramatically from this nadir following the use of ARVs. The panel agreed that to measure disease progression requires repeated observations. In addition, HARS provides only a snapshot and does not reflect the ongoing costs over time. Finally, some states have limited data due to less-sophisticated reported systems. However, despite these limitations, the subgroup felt that nadir measures of CD4 counts provide better information on disease progression than no information at all.

It is important to note that CDC is currently transitioning states to reporting of HIV/AIDS cases through eHARS. A complete transition is expected within the next 2 years. Implementation of eHARS will allow states to report repeated CD4 observations for individual patients into the database. This will be especially beneficial for states with lab-based reporting for they will always have the most current CD4 counts for infected patients in their state. States currently have different levels of CD4 reporting which include those who report all counts, <500, <200, <50. However, all states with lab based reporting of CD4 counts, report CD4 counts of at least <50 which will catch persons most in need of ARV.

As a related issue to using CD4 counts, the panel noted that antiretroviral (ARV) therapy is helping HIV-positive persons live longer, meaning patients now need more care for chronic illness rather than for acute terminal illness. CARE Act grantees are more likely to be disabled (and less likely to have access to other kinds of resources) and are more likely to experience increased utilization in terms of visits, complications, and resources than in the past. Some panelists recommended use of the Morbidity Monitoring Project (MMP), along with HARS, to look at HIV/AIDS disease progression as a proxy for resource utilization.

In contrast other panelists were concerned that data from the MMP would not be useful for allocating CARE Act resources because it is currently fielded in only a subset of areas (i.e., 19 states, 1 territory, 5 cities, and 1 county), and because data from it may not be available for several years.

Further, the panel was concerned that rewarding jurisdictions with a greater number of cases with advanced HIV disease might penalize jurisdictions that successfully identify infections earlier or prevent people from progressing to advanced disease states. The panel noted that this may not be a major concern because the CARE Act does not pay for inpatient services, so a large portion of the shift of costs from early-stage patients to late-stage patients would not be included in the allocation. However, they recommended that HRSA remain cognizant of the issue. Potentially, the panel thought that jurisdictions that make an effort to diagnose people and identify HIV cases early could receive a supplemental allocation.

Nonetheless, the panelists agreed that the CARE Act should ultimately pay extra for patients in need, even if they are in need because of their State’s poor health policies. Therefore, the panel voted to forward disease stage variable to the Associated Cost panel to cost out the potential impact on SON.

HIV Disease Progression Template

Group	Item	Example
Descriptive Characteristics	Variable Name	HIV disease progression
	Data Element	1) Nadir CD4—percentage of people in an area who have ever had an AIDS diagnosis (under 200) 2) Nadir/CD4 count during time period and highest viral load 3) Whether diagnosed with an opportunistic infection
	Source	MMP—all three; HARS—more limited
	Rationale	Increased utilization in terms of visits, complications, resources, need for care; patients are also more likely to be disabled (and less likely to have access to other kinds of resources)
	Type of Measure	Disease progression is a proxy for resource utilization
	Level of Aggregation	MMP—state level; HARS—county level data
	Frequency of Updates	MMP—annually; HAR—continuously
	Cost	Both free

	Availability	Both require interagency cooperation
	Limitations	MMP—state level would be lowest level; does not include data from all states but is representative of the national epidemic
		HARS—it is passive; although HIV/AIDS reporting in all states, data are not updated with the same frequency in all areas
Quality and Fidelity	Reliability	Measurement does not vary across units of aggregation
	Validity	There is a well-documented link between utilization and stages of illness
	Bias from Measurement Error	This measure may overestimate the percentage of people with HIV in the United States who have advanced disease but will not overestimate the percentage in care with advanced disease
	Adjustments Possible	None noted
	Usability	Errors do not preclude use
	Burden	No additional burden to grantees
Worth	Inclusion	Yes—the panel forwarded the variable with a recommendation to use the MMP, along with the HARS, to look at disease progression as a proxy for resource utilization
	Weight	The panel feels that this is the most important variable for consideration and it should be weighted highly

2. Variables not forwarded for consideration

The Clinical subpanel did not believe that *risk behaviors* and *exposure categories* would have an ongoing contribution to the SON, except as they manifest as comorbidities. Therefore, they recommended that the Comorbidities subpanel consider both factors among their other variables.

Drug resistance: Panel members concluded that the increased risk of resistance from previous ARV history would require more intensive clinical care including more expensive drugs, more frequent outpatient visits and laboratory tests, a higher level of expert care, and additional medications to treat side effects of ARVs. They also agreed that there are probably significant differences among communities in terms of the frequency of resistance and frequency of patients with extensive ARV histories. Potential data sources for looking at these issues include cohort studies and cost-effectiveness models. However, the panel had the following unresolved questions regarding ARV drug resistance:

- The panel doubted that the per-patient impact on costs of developing drug resistance could be quantified given present data sources.
- The panel did not think a consensus existed on what would constitute appropriate care and drug therapy for patients with drug resistance.

The panel was uncertain that the costs associated with care of patients who have exhausted available treatment options could be estimated with present data sources. The subpanel discussed whether existing studies could be used to at least estimate the proportions of patients with primary drug resistance. They also recommended that future studies evaluate the costs of secondary resistance, which they thought was even more difficult to assess than primary resistance.

The panel felt drug resistance was important to consider, but due to data limitations did not forward it for inclusion.

Drug Resistance Template

Group	Item	Example
Descriptive Characteristics	Variable Name	Drug resistance
	Data Element	Percentage of clients whose genotype or phenotype demonstrates resistance to at least one class of retrovirals
	Source	1) MMP—denominator is number of people received resistance testing
		2) CDC Not-in-Care study
	Rationale	Utilization—more frequent visits, more laboratory work, more drugs (including more expensive drugs)
	Type of Measure	Proxy for increased utilization
	Level of Aggregation	MMP—state; CDC Not-in-Care study—five areas; not all are states
	Frequency of Updates	Both updated annually
	Cost	Both are free
	Availability	Both require interagency cooperation
National or Local	1) MMP—state level; more likely testing people who we suspect are resistant	
	2) Not-in-Care—project area level; small number of areas; not all jurisdictions; limited to people that are not in care	
Quality and Fidelity	Reliability	Measurement does not vary across units of aggregation
	Validity	Makes intuitive sense but we are not aware of data that link utilization to resistance directly
	Bias from Measurement Error	Because not all patients will receive disease resistance testing and the rate that testing occurs may vary substantially across jurisdictions, areas with higher rates of resistance testing will appear to have more drug resistance
	Adjustments Possible	None noted— there is not enough uniformity in the testing (e.g., related to cost, more likely to get it in private care, length of time in care)
	Usability	Yes, errors probably do preclude use
	Burden	No additional burden to grantees
Worth	Inclusion	No—although the panel considered drug resistance to potentially have a significant impact on utilization of resources, they felt there was no way to effectively measure drug resistance. The panel recommended that the SON council and other panels consider potential data sources
	Weight	N/A

B. Comorbidities Subpanel

The Comorbidities subpanel was charged with identifying specific comorbidity variables measured at the patient level that would potentially increase need. They agreed that as a complex, multisystem illness, HIV is influenced by other factors, such as general health and behaviors. Research indicates that the number of people with co-occurring conditions, such as coinfection with hepatitis C, is rising. Mental illness and substance abuse in particular, create unique challenges and can impact entry into care, adherence to treatment, level of risk behaviors, and utilization of services. Access to primary care, mental health, and substance abuse treatment, in addition to food, transportation, and housing, can in turn encourage entry and retention in care (Messeri et al., 2002; Lo et al., 2002; Wells et al., 2001).

The panel felt that certain comorbidities can significantly impact resource needs for CARE Act services. Unfortunately, it is difficult to measure the impact of comorbidities on SON, because challenges exist in the source, validity, reporting period, and definitions used to document them.

Because of data limitations, estimates are largely reported among the general population instead of among the HIV-positive population. Keeping these limitations in mind, the panel made the recommendations outlined in *Table 5*.

Table 5. Comorbidities Subpanel Variables for Consideration

Included Variables	Inclusion	Data Source/Comments	Rank
IDU exposure category	Yes	CDC surveillance data	2.0
Age-related comorbidities	No	<i>Deemed important, but no potential data set to measure it</i>	N/A
Hep C	No	<i>Deemed important, but no potential data set to measure it</i>	N/A
Mental illness	No	<i>Deemed important, but no potential data set to measure it</i>	N/A
Substance abuse	No	<i>Deemed important, but no potential data set to measure it</i>	N/A
TB	No	<i>Deemed not highly relevant to resource needs and poorly measured</i>	N/A
Gonorrhea	No	<i>Deemed not highly relevant to resource needs and poorly measured</i>	N/A

Of the comorbidities considered, the group only recommended including the intravenous drug use (IDU) exposure category. Several variables, including age-related comorbidities (including diabetes and cardiovascular disease), hepatitis C (which was seen largely as a subset of IDU exposure), mental illness (initially added by the panel for consideration), and substance abuse other than IDU, were not forwarded because the panel felt that data sources did not currently exist to measure them adequately. The panel was particularly conflicted about excluding mental illness and substance abuse because of their heavy impact on cost of care. There was also significant discussion surrounding the inclusion of IDU as a variable without also adjusting for need for other substance abuse services. Ultimately, the panel agreed to submit the IDU and other substance abuse and mental illness variables to the SON working group for further discussion. The panel strongly suggested that these variables should be considered in the future when better data become available.

Other variables, including tuberculosis (TB), gonorrhea, and syphilis, were not forwarded because the occurrence of illness is rare or because treatment is relatively cheap and available. There was some debate about whether to forward gonorrhea and syphilis because epidemiologically they are measures of risky behavior and possibly surrogate measures of HIV infection. However, the panel was not able to identify any potential data set that appropriately measures prevalence of gonorrhea and syphilis among HIV-positive persons.

It should be noted that the panel spent time discussing the potential use of Centers for Medicare and Medicaid (CMS) data before deciding to rely solely on CDC data for the included variables. Panelists acknowledged that it is theoretically possible to create a valid and reliable measure of comorbidities in AIDS patients who are eligible for Medicaid via the disability mechanism, but the measure is not feasible for this project. Challenges to using CMS data include the following:

- The data might accomplish what the group ideally wants (i.e., a consistent measurement of comorbidities within a defined and consistent population), but the process would be technically complex, and therefore time consuming and costly. Assuming the data could be acquired for free, the panel would recommend that HRSA dedicate future resources

to think through the issues of identifying comorbidities using claims data, and develop such estimates using the MAX data. These estimates could be updated annually or biannually if resources allowed.

- A few issues of validity would persist regardless of the quality of the analysis:
 - The MAX files may not include patients enrolled in Medicaid managed care. This could create systematic bias in the estimates between states.
 - The MAX files obviously do not include any information on patients who do not enroll.
 - It might be impossible to identify AIDS patients in the MAX files if patients received services only for comorbidities and not directly for HIV/AIDS during the year, or if they received treatment for comorbidities (e.g., sexually transmitted diseases) anonymously or at a facility that did not submit a claim to Medicaid.

1. Variables forwarded for consideration

IDU exposure category: Intravenous drug use is related to resource needs in several ways. IDU exposure increases the need for substance abuse services, the likelihood of extremely high rates of hepatitis C, the tendency to enter care at a late stage of disease progression, and the overall cost of primary care. The IDU exposure category is measured in the CDC HARS data, although the precise exposure category is missing for many patients. The panels felt strongly that the IDU-exposure category as measured by HARS was a strong indicator of severity of need.

However, the panel struggled with including a measure of IDU use without also including a measure of other substance abuse. The panel was concerned that adjusting for IDU use but not for other drug use (such as methamphetamines or crack cocaine) would weight the index in favor of the Northeastern US, because that is the region with the greatest number of IDUs.

In an attempt to address this issue the contractor worked with the CMS representative to evaluate the number of patients in Medicaid who had an HIV or AIDS diagnosis and who had a claim for substance abuse or mental health services. This data was not available for inclusion in this report.

The contractor also worked with Substance Abuse and Mental Health Services Administration (SAMHSA) to determine sources for measuring substance abuse and mental health services. Currently, the National Survey on Drug Use and Health (NSDUH) does not capture HIV infection. It is possible to estimate need for substance abuse services for several fairly general groups, but it is not possible to generate an estimate aggregated at a lower than national level. Fortunately, starting in 2007, NSDUH added a question asking respondents if a medical professional had ever told them they had HIV/AIDS. Assuming reasonably valid reporting on this question is available they will be able to cross substance use and mental health treatment need data with the HIV/AIDS variable.

In light of these issues and findings, the panel recommended including an estimate of IDU risk based on exposure category from the HARS data, with the caveat that the NSDUH data will be available soon and will potentially provide a reliable, valid source of data to estimate drug abuse of all substances among people with HIV. They felt this data should be evaluated as soon as it is ready and incorporated into the SON index if possible. They also recommended that data from CMS Medicaid files be evaluated once available.

Injection Drug Use Template

Group	Item	Example
Descriptive Characteristics	Variable Name	Need for substance abuse treatment services among IDUs
	Data Element	1. Estimate of IDU risk based on HIV exposure category from HARS data 2. National estimate of proportion of those who use injecting drugs who need substance abuse treatment services from NSDUH
	Source	1. HARS; 2. NSDUH
	Rationale	Substance abuse treatment services are a component of services paid for by the CARE Act, so greater service need will be related to greater resource need
	Type of Measure	1. Direct measure of number of IDUs with HIV 2. Proxy measure for the need of substance abuse treatment services among those with HIV
	Level of Aggregation	1. HARS —state/EMA; 2. NSDUH—national
	Frequency of Updates	1. HARS—annual; 2. NSDUH —annual but based on 3-year moving average
	Cost	Free
	Availability	1. HARS —requires data use agreement 2. NSDUH—estimates must be obtained through communications with the NSDUH research team
Quality and Fidelity	Reliability	1. Yes—HARS measures reported use of IDU but has reporting biases that differ systematically by state 2. No—NSDUH is reliable in the information it obtains
	Validity	1. HARS—valid but an underestimate 2. NSDUH—is not particularly valid because it is not true to say that the need for substance abuse treatment services is the same for IDUs in all areas of the country
	Bias from Measurement Error	Yes—there is systematic error in the measurement of IDU cases that is difficult to sort out
	Adjustments Possible	Yes—CDC does adjust exposure category to try to estimate the true number of IDU exposures based on historical trends; however, the accuracy of this adjustment is unclear
	Usability	Yes—it is very difficult to justify using this variable without also adjusting for need for other substance abuse services; there was some disagreement among the panelists, because some think this variable should still be used
	Burden	No additional burden to grantees
Worth	Inclusion	Yes—with the caveat that if the model only adjusts for services among IDUs (because of lack of adequate data for others) then the index will be weighted in favor of the Northeast, with a known bias (that we are simply not counting need for SA service among non-needle users). The panel recommended further research into cohort studies and other potential data sources. They also stressed that NSDUH data will be available soon and will potentially provide a reliable, valid source of data to estimate IDU prevalence among people with HIV
	Weight	No specific weight is recommended

2. Variables not forwarded for consideration

Age-related chronic illness: The panel did not recommend inclusion of diabetes prevalence and any cardiovascular condition. Panelists believed that these age-associated chronic diseases might be more explanatory of increased resource needs than simply an age adjustment. The prevalence of these conditions within the general population can be identified stratified by age, race, and gender using data from the National Health Interview Survey (NHIS) and the American Heart Association (AHA). However, they did not feel that adequate data, particularly at the client level, exist to measure diabetes and CVD as comorbid conditions among the HIV positive population. The clinical subpanel had also originally considered including renal failure and liver failure but decided not to include them because of lack of data, and because liver failure was thought to be encompassed by the hepatitis C variable.

Age-related Chronic Illness Template

Group	Item	Example
Descriptive Characteristics	Variable Name	Age-related chronic illnesses that are covered by the CARE Act
	Data Element	1) Diabetes prevalence 2) Any cardiovascular condition
	Source	1) CDC National Health Interview Survey (NHIS) 2) American Heart Association (AHA)
	Rationale	This is a direct way to quantify the impact of advancing patient age and different case mix in terms of race and gender
	Type of Measure	Direct
	Level of Aggregation	Age x race x gender estimates are calculated at the national level (and can apply to a case mix for each state)
	Frequency of Updates	Annual
	Cost	Free
	Availability	Public domain
Quality and Fidelity	Reliability	The measure does not differ across units of aggregation, but national-level estimates do obscure local-level heterogeneity
	Validity	Measures are based on self-reported illness but represent the best estimate of the prevalence of these conditions; however, they do not measure the prevalence of comorbid conditions among the HIV positive population
	Bias from Measurement Error	There is no bias from measurement error
	Adjustments Possible	No adjustments are desirable
	Usability	Errors do not preclude use
	Burden	No additional burden to grantees
Worth	Inclusion	No-- adequate data, particularly at the client level, does not exist to measure diabetes and CVD as comorbid conditions among the HIV positive population
	Weight	N/A

Hepatitis C: The subpanel discussed how hepatitis C may impact a patient's care in terms of decreased tolerability of some HIV medications, need for management of progressive liver disease and hepatitis C (including more specialty care), increased medication complexity, and more frequent routine visits. The panel did not recommend hepatitis C for inclusion because they felt current data sources could not appropriately measure hepatitis C within the HIV positive population and because the costs associated with it represent a subset of the costs associated with IDU exposure category.

They suggested that the Associated Cost panel may wish to adjust only for IDU exposure category, which would consider the impact of hepatitis C and other costs.

The subpanel evaluated data from NHANES to estimate the proportion of hepatitis C among people who had ever used a needle to inject drugs, as well as a measure of hepatitis C prevalence among MSMs. This analysis identified a prevalence of 56.7% among people who had ever used a needle to inject illegal street drug, and 6.2% among men who reported ever having a romantic attraction to another male. However, the panel noted that NHANES may represent an underestimate of the prevalence of hepatitis C within the HIV positive population (because hepatitis C is not always linked to IDU). In addition, NHANES is only updated every 2 to 3 years and is only available at the national level.

Hepatitis C Template

Group	Item	Example
Descriptive Characteristics	Variable Name	Hepatitis C
	Data Element	Proportion of hepatitis C among people who have ever used a needle to inject drugs
	Source	NHANES—does not include regional information, but it does allow the calculation of hepatitis C prevalence by reported IDU. NHANES also has HIV-positive patients, though the total number of these is small (<i>CDC surveillance data and MMP data are inadequate</i>)
	Rationale	Infection with hepatitis C directly increases patient outpatient and drug costs
	Type of Measure	Direct—serologic survey
	Level of Aggregation	Single national estimate of infection rate among IDUs. The proportion of HIV patients infected via IDU-exposure differs by jurisdiction
	Frequency of Updates	Semiannual (every 2 or 3 years)
	Cost	Minor fee
	Availability	Public domain
Quality and Fidelity	Reliability	Imprecise estimate of local trends
	Validity	No—cannot assume that hepatitis C is always linked to IDU
	Bias from Measurement Error	Yes—regional prevalence of hepatitis C among IDUs is set to the national value in all areas
	Adjustments Possible	None possible
	Usability	No—errors may preclude use
	Burden	No additional burden to grantees
Worth	Inclusion	No—data is insufficient; recommendation is to only include IDU-exposure category and to ask the Associated Cost panel to consider the costs of hepatitis C
	Weight	N/A

Mental Illness: The panel felt that mental illness was an important determinant of resource needs for a variety of reasons, including its impact at the patient level on late entry into care, decreased adherence to HIV/AIDS medications, increased complexity of medications, and potential medication costs for psych meds if uninsured. At the program level, mental illness also impacts resources needs because of the need for mental health services by licensed mental health practitioners, the increased amount of time it takes to coordinate with mental health services or the necessity to provide mental health treatment within HIV program, and the increased frequency of drug monitoring as a result of drug-drug interactions. Finally, the panel stressed that local availability of mental health treatment resources varies greatly and will have an enormous impact on costs.

The Comorbidities subpanel considered data sources such as Medicaid and Medicare, the CADR, Veterans Administration data, National Institute of Mental Health studies, and private sources, but subpanel could not identify an appropriate national data sources related mental illness within the HIV positive population and therefore did not complete a template. The panel ultimately recommended that the Area Characteristics panel explore measurement at the population level, and also strongly urged HRSA to develop a plan for exploring additional data sets and for including mental illness in the severity of need index in the future.

Substance Abuse other than IDU: The panel felt substance abuse was an important determinant of resource needs, partly because substance abuse treatment services are a component of services paid for by the CARE Act, and partly because substance abusers have greater complications associated with their illness and are more labor intensive to care for. However, the panel was unable to identify any national data sets that could provide estimates of the need for substance abuse treatment services for HIV infected individuals who abuse non-injecting drugs. The panel was particularly concerned about omitting substance abuse services required by crack cocaine and non-injecting methamphetamine users. The panel recommended referring the variable to the Area Characteristics panel to see if it could be measured at the population level. The panel also suggested using the National Survey on Drug Use and Health (NSDUH) small-area estimates of those in need of substance abuse services who also report having HIV from the NSDUH, as soon as those estimates become available.

The subpanel evaluated the following data sets, but none were deemed satisfactory at this time. They strongly urged the HRSA to develop a plan for exploring additional data sets and for including substance abuse in the model in the future.

- ***National Survey on Drug Use and Health (NSDUH)*** may be able to provide some estimates in the future. The panel felt it would not be an adequate data source currently because the survey measures the need for substance abuse treatment services among the general population, which may be totally unrelated to the need for substance abuse treatment services among the HIV-positive population.
- ***MAX data*** from CMS may potentially be used to measure substance abuse in people with HIV who are eligible for Medicaid via the disability mechanism. However, the MAX data is fairly complex and premature use of it could lead to substantial errors if the data's limitations are not well understood. In general, the MAX data appears to be a problematic source of information for prevalence estimates, but an adequate data set to measure individual costs. The panel recommends that HRSA continue to work in partnership with CMS to evaluate and develop methodologies to use the MAX data for epidemiological research.
- The ***Behavioral Risk Factor Surveillance System (BRFSS)***, which provides state-level estimates of health risk behaviors among U.S. adult populations. The panel felt that it would not be an adequate data source because it includes only alcohol abuse but not other substance abuse.
- ***Adolescent Health (AdHealth)*** data is a representative sample of the U.S. population aged 18 to 26 and includes several different measures of drug use. For example, the contractor used the data to look at usage of crack/cocaine and meth by males who reported a "romantic attraction" to other males during the past 30 days and past 12

months. Within the past 30 days, the results showed a significantly higher likelihood only for crack/cocaine in the West and for crystal meth in the West and Midwest. Within the past 12 months, the results were similar, except boys with a “romantic attraction” used significantly more coke and meth in both the West and the Midwest, and used slightly more meth in the South. Ultimately, the panel felt that because the AdHealth data focused on substance use in only one small segment of the general population, it would not be an adequate data source for estimating substance use among the larger HIV-positive community.

Substance Abuse Template

Group	Item	Example
Descriptive Characteristics	Variable Name	Need for substance abuse treatment services for non-IDUs
	Data Element	Age × gender × race estimates of the need for substance abuse treatment services from NSDUH (for the whole population)
	Source	NSDUH
	Rationale	Substance abuse treatment services are a component of services paid for by the CARE Act, so greater need will be related to greater resource need
	Type of Measure	Proxy
	Level of Aggregation	National, possibly regional
	Frequency of Updates	NSDUH —annual but based on 3-year moving average
	Cost	Free
	Availability	NSDUH estimates must be obtained through communications with the NSDUH research team
Quality and Fidelity	Reliability	Measurement does not vary across units of aggregation
	Validity	1. National or even regional estimates may grossly over- or underestimate estimates in a particular area
		2. Need for substance abuse treatment services among the general population may be totally unrelated to the need for substance abuse treatment services among the HIV-positive population
	Bias from Measurement Error	No—except that regional estimates may be inaccurate measures of state or local trends
	Adjustments Possible	None noted
	Usability	Yes—errors do preclude use
Burden	No additional burden to grantees	
Worth	Inclusion	No—the subpanel felt substance abuse was important, but could not identify any national data sets for HIV-positive persons that could provide estimates. Better data will potentially be available in the future, because NSDUH added a question in 2005, asking respondents if they had ever been told by a medical professional that they had HIV/AIDS. The panel also recommended that the Area Characteristics Panel explore measurement at the population level
	Weight	N/A

Tuberculosis: The panel agreed that if common enough, TB, particularly Multiple-Drug Resistant (MDR) TB, could potentially increase HIV patients’ needs. However, in evaluating existing data on TB, the subpanel found TB prevalence not to be a significant factor for the following reasons:

- The overall rate of TB has declined in every year since 1993.
- In 2003, the most recent reporting year, there were only a little over 14,000 cases of total TB nationally, of which only 1,128 reported coinfection with HIV.
- Only 10 cases of MDR were reported with HIV coinfection in 2003.

The subpanel discussed that more detailed information might be available from CDC’s Division of TB Prevention, in which each verified case is an active case of TB, and counts of TB cases with HIV are available for every state. However, additional data will most likely not show any significant increase.

In addition, the panel felt that although there may be some relative increase in cost, the bulk of TB medication costs are often covered by non-CARE act sources, therefore the value added to the model would be small.

Tuberculosis Template

Group	Item	Example
Descriptive Characteristics	Variable Name	Diagnosed with TB
	Data Element	Report of verified TB Case
	Source	wonder.cdc.gov
	Rationale	If common enough, TB, particularly MDR TB, can potentially increase needs of HIV patients
	Type of Measure	Direct
	Level of Aggregation	Person
	Frequency of Updates	Ongoing
	Cost	Free
	Availability	Public domain
Quality and Fidelity	Reliability	Within HIV coinfection fields, plurality is not populated; in most states the plurality of HIV cases do not report HIV status
	Validity	Yes, if reported
	Bias from Measurement Error	Yes—proportion that do not report HIV coinfection varies from place to place
	Adjustments Possible	None recommended, but if adjusting model for TB would suggest potentially using non-U.S. born as surrogate
	Usability	Yes—errors do preclude use
	Burden	No additional burden to grantees
Worth	Inclusion	No: 1) In most states, the plurality of reported cases does not report HIV status (positive or negative)
		2) In 2003, the most recent reporting year, there were only a little over 14,000 cases of total TB nationally, of which only 1,128 reported coinfection with HIV
		3) The overall rate of TB has declined every year since 1993
		4) Only 10 cases of MDR were reported with HIV coinfection in 2003
		5) There may be some relative increase but the bulk of TB medication costs are often covered by non-CARE Act sources, adding little value to the model
Weight	N/A	

Gonorrhea and syphilis: The panel felt that at the individual patient level, gonorrhea and syphilis do not necessarily indicate increased SON because treatment is relatively simple, cheap, and available. They thought gonorrhea and syphilis may be more useful measures at the area level because epidemiologically these diseases are measures of risky behavior and could potentially be surrogate measures of HIV infections.

Keeping this in mind, the comorbidity subpanel immediately ruled out gonorrhea because of the availability of inexpensive and simple treatment. They felt syphilis was correlated with a potentially higher need for and use of outpatient services and therefore spent some time developing a rationale for inclusion, considering data sources, and completing a template. This process helped the subpanel, and subsequently the panel, determine that although syphilis is likely to be important in determining need, no potential data set appropriately measured the prevalence of syphilis infection among people with HIV.

Syphilis Template

Group	Item	Example
Descriptive Characteristics	Variable Name	Syphilis infection among HIV patients
	Data Element	1. Overall population rate of syphilis 2. Male-to-female syphilis case ratio
	Source	CDC STD surveillance data
	Rationale	Syphilis may be related to higher outpatient services, but the extent of the problem is unclear
	Type of measure	Proxy measure of syphilis within the HIV population
	Level of Aggregation	County
	Frequency of Updates	Annual updates
	Cost	Free
	Availability	The state- and MSA-level estimates are public domain, but some contact with CDC would be needed to get the county-level data
Quality and Fidelity	Reliability	Reported cases is a known underestimate of true cases, so level of underreporting varies from place to place
	Validity	Unclear
	Bias from Measurement Error	Reported cases is a known underestimate of true cases, so level of underreporting varies from place to place
	Adjustments Possible	There are potentially ways to adjust for underreporting
	Usability	Yes—errors do preclude use
	Burden	No additional burden to grantees
Worth	Inclusion	No—although syphilis was considered to be important in determining need, there was no potential data set identified to appropriately measure the prevalence of syphilis infection among people with HIV
	Weight	N/A

C. Sociodemographic Subpanel

Although the current public system of care has provided care to many people with HIV of lower socioeconomic status (SES), significant disparities remain in ensuring access to the standard of care for HIV across demographic populations (Institute of Medicine [IOM], 2004). For example, people newly infected with HIV are more often poor, from racial and ethnic minority groups, female, and either lack insurance or are more publicly insured than in the past (Levi and Hildago, 2001). Also, despite substantial improvements in access to care in the late 1990s, some disparities by race,

insurance status, and sex still exist (Shapiro et al., 1999). **Table 6** outlines the variables thought to measure, or indicate sociodemographic characteristics, and the panel’s recommendations regarding them.

Table 6. Variables Considered by the Sociodemographic Subpanel

Included Variables	Inclusion	Data Source	Rank
Race/Ethnicity	Yes	HARS	1.9
Age	Yes	HARS	2.5
Immigration Status	No	No adequate data	2.6
Sex	Yes	HARS	3.5
Socioeconomic Status (SES)	No	Refer variable to Area Characteristics panel for consideration within the “poverty” variable because there is a high correlation	N/A
Urban/Rural	No	Refer variable to Area Characteristics panel for consideration within the “access to care” variable because there is a high correlation	N/A
Educational Status	No	Refer variable to Area Characteristics panel for consideration within the “poverty” variable because there is a high correlation	N/A

The panel recommended that variables measuring age, race/ethnicity, and sex of HIV/AIDS infected patients be evaluated by the Associated Costs panel to determine their impact on costs. Each of these variables has a good to moderate rationale regarding why it may impact costs, and each can be directly measured among patients with HIV/AIDS using CDC HARS data.

The panel viewed immigration status as being important in determining need for CARE act services, but could not identify an adequate data source to measure this variable among either the general or the HIV infected population. Panelists did not consider the “Country of birth” variable drawn from the HARS data to be a valid indicator of immigration status.

Like immigration status, the panelists through the socioeconomic status of HIV/AIDS infected patients was important in determining severity of need, but could not identify adequate data to measure it. The panel suggested that sociodemographic status be evaluated through a measure of poverty at the area level (which has been done by the Area Characteristics panel). The panel felt that after adjusting for access to care and poverty (variables forwarded by the Area Characteristics panel) there was insufficient rationale to also move forward the urban/rural and education status variables.

1. Variables forwarded for consideration

Race and ethnicity: The panel felt it was important to include race and ethnicity as a marker of lack of access to care because racial disparities in the quality and quantity of health services received have been documented in a number of settings. The 2003 IOM report, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, lays out several key issues in relation to health disparities as a whole:

- First, evidence of racial and ethnic disparities are consistent across range of illnesses and health services, and are associated with socioeconomic differences (Smedley et al., 2003)

- Second, although some differences diminish significantly or disappear when socioeconomic factors are controlled, most studies indicate that racial and ethnic differences remain after adjustment (Kressin et al., 2004).

Further research conducted by the contractor indicates that where HIV is concerned, the results are somewhat less clear. As the *Table 7* highlights, studies have shown that racial and ethnic underserved populations (as well as injection drug users, women, and the uninsured) experience less favorable patterns of use of needed HIV services than whites, although these differences may be diminishing with time.

Table 7. Summary of Research on the Impact of Race/Ethnicity on Access to and Utilization of HIV Care

Source	Findings
Moore et al., 1994 Baltimore Clinical Study	In 1994, a clinical study in Baltimore found that although there were no racial differences in stage of HIV disease when the clients entered the HIV clinic, racial disparities did exist in the receipt of ARV therapy. Factors such as age, sex, mode of transmission, type of insurance, income, and education made no significant difference in resource utilization.
Shapiro et al., 1999 HIV Cost and Services Utilization Consortium	Another study found that even by 1998, fewer blacks, women, uninsured, and Medicaid-insured had started taking ARV medications, and although care improved, they all had “less desirable patterns of care.” Race, ethnicity, and insurance status, in particular, impacted a woman’s chance of accessing quality of care. In the first stage of the study, insurance status, race, ethnicity, and age were considered to be the most important explanatory variables, and in the second stage sex, exposure group, insurance, and region were more significant factors.
Gebo et al., 2003 HIV Research Network (HIVRN)	In 2000, a study found that African Americans, women, and IDUs were less likely to receive HAART; however, after adjusting for outpatient utilization, race was not statistically significant. Yet the same groups had higher hospitalization rates.
Gebo et al., 2005 HIV Research Network (HIVRN)	Finally, newer, unpublished data indicate that the major cost driver is CD4 count (more so than sex, age, or race). The sociodemographic variables did not demonstrate statistically significant differences in the receipt of combination therapy, although further analysis will explore the contributions of these variables.

In light of this mixed evidence, the Patient Characteristics panel struggled with how to effectively address differential access to and quality of care. They discussed potentially using poverty as a proxy because of the high correlation between low SES and race. The panelists felt that although it might be possible to measure the poverty variable at the area level, it could not be measured at the patient level. In addition, they felt the evidence did not consistently support that controlling for sociodemographic status would completely diminish the relevance of race/ethnicity.

The panel believed that HARS data at the individual level did provide a valid measure of race and ethnicity. They did note that some inconsistencies exist in how the data are recorded, such as the occasional lack of an appropriate or consistent “box” to check on forms if a person is multiracial. CDC clarified that the current race/ethnicity categories on the HIV/AIDS case report form were implemented for federal use by OMB on January 1, 2003. The current HIV/AIDS case report form allows for the collection of race/ethnicity data for persons reporting multiple race/ethnicities. The previous case report form only allowed for the selection of one race/ethnicity. Consequently, case

reports for persons reported through December 2002, only allowed for the selection of one race/ethnicity even if a person is multiracial. The race/ethnicity data currently in the HARS database has been collected under two systems. CDC currently maintains the race/ethnicity categories used through December 2002 when publishing data for most case reports were submitted under that system.

Ultimately, the panel felt strongly that race/ethnicity be considered separately by the Associated Costs panel when estimating the cost of care because of: 1) the disparities in patterns of care that may be decreasing yet still exist in some of the studies cited above, 2) the larger body of literature citing various studies of disparities in health outcomes and the quantity and quality of health care, and 3) the availability of credible data on race/ethnicity available from the HARS data set. The panelists do understand that this may be one of the more difficult variables to address when attempting to gain consensus among all SON panelists and in creating the final model(s). They stressed the need for more research on the impact of race and ethnicity on severity of need.

Race and Ethnicity Template

Group	Item	Example
Descriptive Characteristics	Variable Name	Race/ethnicity
	Data Element	Individual level (from case report form; includes African American or black, white, Asian Pacific Islander, American Indian or Alaskan Native; then ethnicity box and can choose Hispanic; if multiracial, the current form allows for the collection of multiple race data)
	Source	HARS - race/ethnicity, individual level
	Rationale	1) Persons of minority races may have lower SES 2) Independent of SES, both race and ethnicity may be related to disparities in health care, access, and health outcomes
	Type of Measure	Direct
	Level of Aggregation	Person level but could be aggregated up to county
	Frequency of Updates	CDC gets monthly updates for each state and they do get information if a particular case changes
	Cost	Free
	Availability	Interagency cooperation—approval from the state; will need one overall data use agreement to cover all data from HARS (will need to enumerate data elements)
	Limitation	None, except that not all data is self-reported
Quality and Fidelity	Reliability	Measurement does not vary across units of aggregation
	Validity	Very valid measure
	Bias from Measurement Error	There is no bias from measurement error
	Adjustments Possible	None noted
	Usability	Errors do not preclude use
	Burden	No additional burden to grantees
Worth	Inclusion	Yes—the panel felt it was important to include race and ethnicity because increased costs related to poor health outcomes and more variations in access to care have been documented in a number of settings among racial and ethnic minorities
	Weight	No specific weight is recommended

Age: Age, as it relates to HIV, is important for two primary reasons: first, the body’s ability to fight off infection decreases as age increases, and second, older people tend to have more medical problems, or comorbidities, that are unrelated to HIV, such as diabetes, cardiovascular disease, and high blood pressure. The panel recommended including age because treatment of these comorbidities will in turn increase the cost of care and because the HARS data accurately captures the variable. They did briefly discuss recent HIV Care Network findings that age does not have a large impact on patient resource needs once CD4 is controlled for, but felt that further research was required to substantiate this finding. The panel recommended forwarding the variable to the Associated Costs panel for evaluation of the impact on cost.

Age Template

Group	Item	Example
Descriptive Characteristics	Variable Name	Age
	Data Element	HARS: Individual level
	Source	Date of birth, individual level
	Rationale	1) Persons of older age may have more comorbidities and consequently require more services; 2) Cost of services are different by ages
	Type of Measure	Direct
	Level of Aggregation	Person level, but could be aggregated up to county level
	Frequency of Updates	CDC gets monthly updates for each state and they do get information if particular case changes
	Cost	Free
	Availability	Interagency cooperation—approval from the state; will need one overall data use agreement to cover all data from HARS (will need to enumerate data elements)
Quality and Fidelity	Reliability	Measurement does not vary across units of aggregation
	Validity	Valid measure
	Bias from Measurement Error	There is no bias from measurement error
	Adjustments Possible	None noted
	Usability	Errors do not preclude use
	Burden	No additional burden to grantees
Worth	Inclusion	Yes—the panel recommended including age because treatment of these comorbidities will in turn increase the cost of care
	Weight	No specific weight is recommended

Sex: The panel agreed that there are documented differences in cost of care and complexity of care for women, most likely because the majority of women living with HIV are within child-bearing age and require more support services to care for their families (Bozette et al., 2001). In short, they felt that sex is related to resource needs because of “associated gynecological conditions and obstetric issues.” The sociodemographic subpanel highlighted the U.S. Public Health Service (USPHS) recommendations (optimal care) that gynecological care includes a pap smear and pelvic exam as part of an initial exam. They also stressed that rates of abnormal pap smears are 10 to 11 times greater among HIV-positive women. The panel agreed that all of these factors add to the treatment costs (A Guide to Clinical Care of Women with HIV, 2005). They also noted that most new HIV cases in women (more than 75%) are among women of color, indicating that sex is clearly interrelated with the race/ethnicity variable.

The panel felt the HARS data would appropriately capture this variable. One limitation in the data is that they do not report on transgendered persons because the question only asks about sex at birth. However, CARE Act Data Report (CADR) data indicate that the percentage of transgendered persons is small (1%), so the panel felt the variable would not have a major impact on SON.

Sex Template

Group	Item	Example
Descriptive Characteristics	Variable Name	HARS: Sex; CADR: gender
	Data Element	HARS: Individual-level; does not report out transgendered—question is about sex at birth CADR: Not recommended because it does not include unduplicated data; does include transgendered, but less than 1% are transgendered
	Source	Sex, individual-level
	Rationale	There has been a well-documented difference in care provided to women with HIV (e.g., for support services related to complexity of taking care of family). There is also a belief that transgender persons are not adequately provided with care
	Type of Measure	Direct
	Level of Aggregation	Person-level but could be aggregated up to county-level
	Frequency of Updates	CDC gets monthly updates for each state and they get information if a particular case changes
	Cost	Free
	Availability	Interagency cooperation and approval from the state; HRSA will need one overall data use agreement to cover all data from HARS
	Limitation	None—except this will not tell us about transgender persons, but these are only a small percentage of the population
	Quality and Fidelity	Reliability
Validity		Very valid measure
Bias from Measurement Error		There is no bias from measurement error
Adjustments Possible		None noted
Usability		Errors do not preclude use
Burden		No additional burden to grantees
Worth	Inclusion	Ye—the panel agreed that there are documented differences in cost of care and complexity of care for women. It is also worth noting that most new HIV cases among women (more than three-quarters) are women of color, so sex is interrelated with the race/ethnicity variable
	Weight	No specific weight is recommended

2. Variables not forwarded for consideration

Immigration Status: The sociodemographic subpanel felt that the immigration status variable may be particularly important because many undocumented people, especially clients with no green card, may be using CARE Act dollars. They also felt that it is more difficult to provide services to non-English speakers.

However, although the subpanel felt this was an important variable in terms of access to care and barriers to care, they struggled with how to assess immigration status at the client level. The full panel felt that the variable “country of birth,” which is included in the HARS, would not be a good

proxy for immigration status—being foreign born does not necessarily indicate higher need for resources. The Census was another potential source for data on legal immigration, but no reliable state level estimates of undocumented immigration exist.

In the absence of nationally available data for immigration status of the HIV population, the panel does not recommend its inclusion at this time. However, the panel believes immigration status to be an important indicator of resource needs and would encourage the future inclusion of this variable if new data permits.

Immigration Status Template

Group	Item	Example
Descriptive Characteristics	Variable Name	Immigrant status
	Data Element	HARS—individual-level for country of birth
	Source	HARS—individual-level for country of birth
	Rationale	1) If undocumented or no green card, may be more likely to rely on CARE Act as payer of last resource; 2) May be greater resource needs at clinic for those for whom English is not the first language
	Type of Measure	Proxy
	Level of Aggregation	Person-level, but could be aggregated up to county-level
	Frequency of Updates	CDC gets monthly updates for each state and they get information if a particular case changes
	Cost	Free
	Availability	Interagency cooperation and approval from the state; HRSA will need one overall data use agreement to cover all data from HARS
	Limitations	Country of birth is not necessarily reflective of immigration status
Quality and Fidelity	Reliability	Yes—it might differ based on how frequently the question is asked
	Validity	TBD—country of birth does not necessarily indicate immigrant status
	Bias from Measurement Error	Providers might be more likely to ask question in areas with higher immigrant populations
	Adjustments Possible	None noted
	Usability	Potentially in the future
	Burden	No additional burden to grantees
Worth	Inclusion	No
	Weight	No specific weight is recommended

Socioeconomic, urban/rural, and education status: The panel stressed that these remaining variables were highly correlated and important factors in determining SON, yet all were also extremely difficult to measure among patients with HIV/AIDS. Panelists reached consensus on the following issues:

- *Socioeconomic status:* The panel agreed that persons with lower SES are usually not able to afford medication, so there would be an additional need for CARE Act resources. However, they felt that SES could not be measured adequately at the patient level because HARS and CADR data do not capture this variable. In addition, although population level Census data may be available to determine socioeconomic status within an area, such data may not be representative of the HIV population.

- *Urban/rural status:* The panel agreed that persons who live in rural areas may require more funding for services, therefore, this variable can highlight the limits of health care infrastructure. However, they felt that nothing uniquely different exists between urban/rural status at the patient level versus the area level and therefore recommended that only the access to care variable from the Area Characteristics panel be forwarded. This would be a direct measure of access to care for HRSA-funded clinics and primary care providers in general.
- *Education status:* The panel agreed that various studies indicate that HIV treatment compliance, followup, and other issues fall off dramatically for those with less than high school education. However, they felt that HARS, CADR, and Census data do not capture this variable. Because education is correlated with income, the panel suggested using the poverty variable developed by the Area Characteristics panel.

The following templates outline the discussion above concerning SES and urban/rural status. The subpanel did not complete a template for education.

Socioeconomic Status (SES) Template

Group	Item	Example
Descriptive Characteristics	Variable Name	Socioeconomic status
	Data Element	This data is not collected in HARS
	Source	CADR: Report on federal poverty level of people they serve, by grantee by state is included but not unduplicated, therefore, the panel would not recommend use
	Rationale	Persons with low SES are not able to afford medication and there would be an additional need for CARE resources
	Type of Measure	Unknown
	Level of Aggregation	
	Frequency of Updates	
	Cost	
	Availability	
	Limitation	Insurance status changes more frequently and rules regarding coverage are also subject to ad hoc changes. This is especially true in state Medicaid programs
Quality and Fidelity	Reliability	The federal poverty level does not take cost of living into account. This changes from urban to rural, and from area to area. Similarly, coverage under state Medicaid programs differs significantly from state to state. Furthermore, despite regulations to the contrary, there are states where access to Medicaid is limited by asset tests
	Validity	Population level estimates of poverty are potentially a proxy measure for poverty levels among HIV-positive patients, but this is not a very good proxy
	Bias from Measurement Error	Unknown
	Adjustments Possible	
	Usability	
	Burden	
Worth	Inclusion	No—SES cannot be measured adequately at the patient level. There is nothing overt about income that directly affects SON, although costs are higher if on Medicaid or Medicare. Therefore, it is recommended that the Area Characteristics panel's poverty variable be used
	Weight	N/A

Urban/Rural Template

Group	Item	Example
Descriptive Characteristics	Variable Name	Urban/rural
	Data Element	HARS: County of residence CADR: Not recommended because it does not include unduplicated data
	Source	County of residence, individual level
	Rationale	1) Persons who live in rural areas may require more funding for services; 2) this can show the limits of health care infrastructure
	Type of Measure	Direct
	Level of Aggregation	Person level but could be aggregated up to county
	Frequency of Updates	CDC gets monthly updates for each state and they get information if a particular case changes
	Cost	Free
	Availability	Interagency cooperation and approval from the state; HRSA will need one overall data use agreement to cover all data from HARS
Quality and Fidelity	Reliability	Measurement does not vary across units of aggregation
	Validity	Very valid measure
	Bias from Measurement Error	There is no bias from measurement error
	Adjustments Possible	None noted
	Usability	Errors do not preclude use
	Burden	No additional burden to grantees
Worth	Inclusion	No—the Area Characteristics panel has a direct measure of access to care for HRSA-funded clinics and primary care providers in general. There is nothing uniquely different between urban/rural status at the patient level versus the area level, therefore, it is recommended that only the access to care variable be used
	Weight	N/A

III. Citations

1. Anderson Jr (Ed.) (2005) A Guide to Clinical Care of Women with HIV. *MD and HIV/AIDS Surveillance Report*, Volume 16, CDC.
2. Aktan GB, Calkins RF, and Johnson DR (2001) Substance use, need, and demand for substance user treatment services in patients treated for STDs in Michigan. *Substance Use & Misuse* 36(12), 1651-1676.
3. Bozzette SA, Joyce G, McCaffrey DF, et al. (2001) Expenditures for the care of HIV-infected patients in the era of highly active antiretroviral therapy. *New England Journal of Medicine* 344:11;817-823.
4. Gebo KA, Moore RA, Fleishman JA (2003) The HIV Research Network: A unique opportunity for real time clinical utilization analysis in HIV. *Johns Hopkins AIDS Services: The Hopkins HIV Report*. November.
5. Gebo K, Fleishman J, Conviser R, et al. (2005) *Contemporary costs of HIV HEALTH Care in the HAART Era*. Poster presentation at the 13th Conference on Retroviruses and Opportunistic Infections, Denver, Colorado, February 5-9.
6. Institute of Medicine (IOM) (2004) *Public Financing and Delivery of HIV/AIDS Care: Securing the Legacy of Ryan White*. Washington, DC: The National Academies Press.
7. Kressin NR, Bei-Hung C, Whittle J, et al. (2004) Racial differences in cardiac catheterization as a function of patients' beliefs. *American Journal of Public Health* 94(12):2091-2097.
8. Levi J, Hildalgo J (2001) Financing and delivery of HIV care. *Minority Health Today: Mobilizing to Fight HIV/AIDS in the African-American Community* April (Suppl):33-43.
9. Lo W, MacGovern T, Bradford J (2002) Association of ancillary services with primary care utilization and retention for patients with HIV/AIDS. *AIDS Care* 14 (Suppl 1):545-557.
10. Messeri PA, Abramson DM, Aidala AA, Lee F, Lee G (2002) The impact of ancillary HIV services on engagement in medical care in New York City. *AIDS Care* 14(Suppl 1):515-529.
11. Moore RD, Stanton D, Gopalan R, Chaisson RE (1994). Racial difference in the use of drug therapy for HIV disease in an urban community. *New England Journal of Medicine* 330(11):763-768.
12. Johns Hopkins University (2004) *Multicenter AIDS Cohort Study (MACS), fielded in Baltimore, Chicago, Pittsburgh, and Los Angeles*. Available at: <http://www.statepi.jhsph.edu/macs/mac.html>.
13. Shapiro MF, Morton S, McCaffrey D, et al. (1999) Variations in the care of HIV-infected adults in the United States: results from the HIV Cost and Services Utilization Study. *Journal of the American Medical Association* 281(24):2305-2315.
14. Smedley BD, Stith AY, Nelson AR (Eds.) (2003) *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*. Institute of Medicine. Washington, DC: The National Academies Press.
15. Wells K, Klap R, Koike A, Sherbourne C (2001) Ethnic disparities in unmet need for alcoholism, drug abuse, and mental health care. *American Journal of Psychiatry* 158(12):2027-2032.

IV. History of Panel

A. Members and Affiliations

Bruce Agins

AIDS Institute
New York State Department of Health

Stephen Blumberg (*later withdrawn*)

Division of Health Interview Statistics
Centers for Disease Control and Prevention

Kathleen Clanon

Health Equity Partnership

Michael Evanson

HIV AIDS Bureau
Health Resources Services Administration

Lisa Hirschhorn

John Snow International

Margaret Korto

Office of Minority Health Resource Center

Alice Kroliczak

Division of Science and Policy
Health Resources and Services Administration

A.D. McNaghten

Division of HIV/AIDS Prevention Centers
for Disease Control and Prevention

José Morales

HIV/AIDS Bureau
Health Resources and Services Administration

Anna Satcher

National Center for HIV, STD, and TB
Research and Dissemination Team
HIV Incidence and Case Surveillance Branch
Prevention
Centers for Disease Control and Prevention

Fikirte Wagaw

Chicago Department of Public Health
STD/HIV/AIDS Policy and Programs

Tia Zeno

Division of Community Based Programs
Health Resources and Services Administration

B. HSR/RTI – Contact Information

Jamie Hart

Health Systems Research, Inc.
jhart@hsrnet.com
512-343-1086

David Rein

RTI International
drein@rti.org
770-234-5035