

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

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**SEVERITY OF NEED CORE SERVICES PROJECT
PATIENT COVERAGE PANEL FINAL REPORT**

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Views expressed are those of the meeting participants and do not represent official positions of the Federal Government.

PATIENT COVERAGE PANEL FINAL REPORT

I. Summary of Panel Recommendations

The Patient Coverage Panel recommended including four variables in the severity of need (SON) index:

- Case fatality rate among reported living AIDS patients
- Medicaid adequacy
- Percentage of Federal poverty level (FPL) required for eligibility for the Medicaid Medically Needy program
- AIDS Drug Assistance Program (ADAP) adequacy.

The AIDS case fatality rate is intended to serve as a proxy indicator for severe cases of unmet need for primary medical care services. The Medicaid adequacy variable measures the ability of a State Medicaid program to meet the health care needs of patients with HIV/AIDS. The Medicaid Medically Needy program eligibility variable measures the presence or absence of such a program in a State and the relative generosity of its eligibility requirements. The ADAP adequacy variable measures the ability of a State ADAP program to meet the medication needs of patients with HIV/AIDS.

Panelists identified several variables that they considered important but that they placed on hold for future consideration because the data (1) was currently unavailable but likely to be available in the near future or (2) was currently available, but its validity and reliability could not be accurately assessed given the time constraints of this panel's work.

- Medicaid enrollment
- Rapid progression to AIDS diagnosis
- Receipt of highly active antiretroviral therapy (HAART) (pharmaceutical data)
- Social Area Indicator Analysis based on the Morbidity Monitoring Project (MMP).

The panel identified two variables that they also deemed extremely important but could not determine an acceptable data source that would be reliably available in the near to moderately distant future.

- Unmet need for HIV primary medical care
- Unmet need for substance abuse treatment.

Finally, the panel considered, but did not recommend, several other variables for inclusion in the SON index because they (1) were correlated with one of the variables recommended for inclusion, (2) did not have a sufficient impact on the SON yet, or (3) could not be accurately measured by the publicly available data yet. Variables considered but not recommended for inclusion include:

- Phencyclidine (PCP) incidence
- Hospital discharge data
- The ADAP waiting list
- The Federal medical assistance percentage (FMAP).

II. Overview

A. Purpose of Panel

The Patient Coverage Panel was responsible for identifying variables that describe the degree of medical care currently infected HIV/AIDS patients can expect to have access to in the absence of the CARE Act program. The panel evaluated a wide range of variables, considering the rationale for each variable and whether adequate data existed to measure the concept and proposing potential uses for the measures in an SON index. To accomplish these goals, panel members identified and conducted four sequential tasks:

1. The panel identified an initial set of variables thought to be potential determinants or descriptors of HIV/AIDS patients' existing health coverage and need for services.
2. After identifying the variables to be considered, the panel divided into the following six workgroups to discuss and evaluate the variables in greater depth:
 - Disease Progression: Considered the proxy indicators of unmet need for primary medical care.
 - Medicaid and ADAP Adequacy: Considered a way to measure differences in State Medicaid and ADAP programs.
 - Pharmaceutical Data: Considered the use of proprietary prescription data to measure receipt of HAART.
 - Social Area Indicator Analysis/MMP: Considered the use of a specific methodology for estimating indirect measures of resource needs through area characteristics.
 - Substance Abuse: Considered the potential data sources for estimating the unmet need for substance abuse treatment services among injection drug users.
 - Unmet Need: Considered ways to estimate the number of people living with HIV and AIDS (PLWHA) who were aware of their infection status but currently did not receive medical care.

(Note: The hospital discharge data variable was not discussed exclusively by any of the six workgroups listed above. Panel members did not complete a template for this variable given the unanimous agreement for removal by the group at the first initial meeting in October 2005. The decision to remove this variable from further consideration was based primarily on limitations of the data. Specifically, hospital discharge data are often incomplete and characterized by significant reporting delays, and the AIDS-specific discharge codes are not consistent across States.)

3. The workgroups completed an evaluation template for each variable to help assess the value of each variable and to develop a final set of recommendations for inclusion of variables in an SON index. The templates asked panelists to define each variable; articulate a clear rationale for its inclusion; identify specific data to measure the variable; assess the validity, reliability, and potential biases of each measure; and suggest whether the variable should be forwarded to the larger SON Panel for inclusion.
4. Panelists were then asked to score each variable considered by the six workgroups from 1 to 5, with 1 indicating a variable of the highest importance and 5 indicating a variable

of the lowest importance, based on how well each variable measures the theoretical concept of SON. Panelists were also asked to consider that variables may covary or measure the same concept and were asked to prioritize similar variables as opposed to giving them all the same score. These scores were then compiled, and the averages were ranked (Table 1).

Table 1. Patient coverage variables considered and panelists' priority score (variables forwarded to the full panel highlighted in yellow)

Variable		Average Score
1	Case fatality rate among AIDS patients	1.67
2	Rapid progression to AIDS diagnosis	1.78
3	Medicaid adequacy	2.11
4	Social Area Indicator Analysis/MMP	2.33
5	Unmet need for HIV primary medical care	2.61
6	Receipt of HAART (pharmaceutical data)	3.00
7	Unmet need for substance abuse treatment	3.75
8	PCP incidence	4.00
	ADAP adequacy	*

* Due to the challenging and political nature of the ADAP adequacy variable, the Medicaid and ADAP adequacy subgroup completed much of its work for this variable offline with consistent feedback from the larger group. The measure required significantly more time and effort than the other variables considered and, as a result, was not completed at the time the group made its formal rankings. However, once the subgroup completed its work, there was general consensus among the larger group for the recommendation of the variable.

Variables such as rapid progression to AIDS diagnosis and Social Area Indicator Analysis/MMP received high conceptual rankings by the panel, but were not forwarded to the full panel primarily due to the inadequacy of the data used to measure them.

B. Cross-cutting Issues

The panel also discussed several issues that cut across two or more areas of concentration:

- The panel weighed concerns about creating disincentives or perverse rewards (e.g., penalizing States that make significant financial contributions) through the inclusion of variables related specifically to Medicaid and ADAP against the need to provide health care for needy patients in States that may stint on care. The panel recognized the inherent difficulty in identifying a revenue-neutral way to ensure adequate care for all needy patients nationwide without, to some degree, penalizing areas that invest State resources in caring for HIV/AIDS patients.
- The panel discussed at length the need for a standardized measure of undiagnosed HIV patients that could be applied without State/grantee input (e.g., they wanted to avoid the scenario of “We can’t identify persons with HIV because we don’t have any money”).

- The panel considered assessing only Federal contributions to specific programs, such as ADAP and Medicaid, as opposed to the program's entire funding including State and local contributions.

The panel recommended the inclusion of four variables. Many of the other variables the panel considered were recognized as being important to measuring SON but either lacked adequate data to be measured without bias or covaried strongly with variables forwarded for inclusion. These limitations are described in Section III.

Section III of this report is divided into six sections that correspond to the main areas of investigation by the panel. Sections are then subdivided into two subsections, the first discussing variables that were accepted by the entire group as potential elements for an SON index and the second describing variables that were not. The work on each variable is summarized briefly, followed by the completed evaluation template.

III. Discussion of Variables

A. Disease Progression

Variables Considered: Case fatality rate among reported living AIDS patients, PCP incidence, rapid progression to AIDS

The Disease Progression Workgroup defined variables that would serve as proxy indicators of unmet need for HIV primary medical care. The group argued that case fatality rates among reported living AIDS patients were an indirect measure of unmet need. They theorized that increased mortality among this population in certain States was indicative of a lack of access to and utilization of primary medical care, including antiretroviral drug therapy and opportunistic illness (OI) prophylaxis.

The Workgroup also considered, but (because of data limitations) did not forward for inclusion, two other variables that were also intended to measure poor people's access to medical care services indirectly: the incidence of *Pneumocystis carinii* pneumonia (PCP) and rapid progression from initial HIV infection to symptomatic AIDS illnesses. Reporting of PCP cases to the Centers for Disease Control and Prevention's (CDC) HIV/AIDS Reporting System (HARS) is only required when it constitutes the AIDS-defining condition; therefore, case counts reported in the surveillance data may underestimate incidence of PCP to an unknown and variable degree across jurisdictions. Because no national standards for HIV and laboratory reporting exist, it is impossible to measure the rapid progression from HIV to AIDS in a reliable and consistent way across jurisdictions.

1. Variables forwarded for consideration

Case fatality rate among reported living AIDS patients: The panel recommended a measure of case fatality rates among reported living AIDS patients as a proxy indicator for severe cases of unmet need for HIV primary medical care services. If people living with AIDS (PLWA) die at significantly higher rates in certain States than in others, this may be because of large differences in access to and utilization of primary medical care (e.g., antiretroviral [ARV] drugs, OI prophylaxis).

The panel recommended calculating the case fatality rate by dividing the number of deaths among reported, living AIDS cases by the total number of reported, living AIDS cases alive during the corresponding year. Furthermore, the panel recommended calculating this ratio individually for each of the 5 preceding years and then averaging the estimates for final input into the model. The variable (constructed using data obtained from HARS) represents the observed probability of death over a 1-year period, not considering the cause of death or the background mortality of an area. The Workgroup discussed the extent to which patients infected with AIDS die of unrelated causes and the variability of such background mortality by area and other relevant demographic and risk factor characteristics. The panel explicitly recommended using data from AIDS cases only in place of HIV and AIDS cases primarily because the inclusion of HIV cases would bias systematically States with less mature epidemics (e.g., more HIV-infected patients as compared to AIDS). States with emerging epidemics may experience the same degree of mortality among AIDS cases as compared to States with mature epidemics, but the case fatality rate would be lower due to the larger numbers of HIV cases included in the denominator.

Panel members considered incorporating relative survival analysis to adjust for the background mortality of an area. This common epidemiological approach uses age-, sex-, and race-specific data from published life tables to estimate the expected mortality rate patients would have experienced irrespective of the relevant condition. However, performing a relative survival analysis as discussed by the Workgroup would not be possible because of limitations of HARS data. Such an analysis requires person-level diagnosis data to estimate observed survival time. In addition, AIDS-specific population information is not available in the life tables.

CDC surveillance experts invited to speak to the panel cautioned against attributing deaths reported in HARS to AIDS. CDC surveillance experts noted that jurisdictional variations in death rates depended on the age of the epidemic in an area (as patients with HIV infections of longer duration have a higher probability of death and patients who have been on ARV therapy longer are more likely to develop resistance); the risk characteristics of the HIV-infected group for death from other causes, such as drug overdoses, homicide, suicide, and acute injury; and access to health care. They noted that these differential causes of mortality were probably impossible to separate given existing data.

Despite these limitations, Workgroup members recommended forwarding this variable because regardless of the source of the disparity (e.g., presence of mature epidemic, inadequate access and adherence to treatment, or a disproportionate probability of death from causes unrelated to HIV/AIDS), panel members felt that significantly higher mortality in an area reflected greater resource needs.

Descriptive Characteristics	
Variable Name	Case fatality rate among reported living AIDS patients
Data Elements	Annual deaths of persons with AIDS, for the 5 most recent years with reasonably complete data, divided by the reported living AIDS cases, as of the end of the corresponding year.
Data Sources	HARS
Rationale	Relatively higher death rates may be indicative of a lower average standard of care, later entry into care, and/or comparative difficulties with maintenance in care and adherence to therapy. Alternatively, higher death rates may be indicative of a greater number of advanced cases associated with a comparatively mature epidemic.
Type of Measure	Proxy indicator measure for unmet need for primary medical care
Level of Aggregation	County and State
Frequency of Updates	Annual, although there may be a delay of up to 3 years
Cost	Free
Availability	Public domain (interagency agreement with the CDC required for access to surveillance data)
Quality and Fidelity	
Reliability	<p><i>Does the measurement of this variable differ across units of aggregation?</i></p> <p>Completeness and timeliness of AIDS case reporting and death reporting varies across States, although the CDC imposes certain standards and eventually most deaths are recorded. To minimize error related to reporting delays, the CDC recommends using cumulative deaths over the past 5 years as opposed to deaths in the past year.</p> <p>The panel explicitly recommended using data from AIDS cases only in place of</p>

	HIV and AIDS cases primarily because the inclusion of HIV cases would bias systematically States with less mature epidemics (e.g., more HIV-infected patients than AIDS-infected patients). States with emerging epidemics may experience the same degree of mortality among AIDS cases as compared to States with mature epidemics, but the case fatality rate would be lower due to the larger numbers of HIV cases included in the denominator.
Validity	<p><i>How does the measure capture the rationale for using it?</i></p> <p>This variable represent deaths from all causes, not just HIV/AIDS. This may undermine the validity of the variable because the measure varies by a number of reasons not related to AIDS, including the type of population living with AIDS and the characteristics of the neighborhoods in which they live. However, in the panel's view, background variations in mortality in the age groups of most PLWA are likely to be small enough so that a higher death rate would mostly indicate more AIDS-related deaths. Extra resources would be needed to address whether the reason for these extra deaths was a mature epidemic (i.e., more symptomatic cases) or inadequate access to health care, leading to more acute episodes of AIDS-related opportunistic infections and subsequent deaths.</p>
Bias from Measurement Error	<p><i>Does the measurement of this variable result in systematic biases? If so, how?</i></p> <p>There is no apparent systematic bias in the measurement of the variable, except that States with delayed or incomplete reporting of deaths may show a lower death rate than actual. However, areas with high rates of so-called background mortality may appear to have higher death rates, even if these deaths are not AIDS related.</p>
Usability	<p><i>Are there statistical adjustments that would resolve the reliability, validity, or bias problems of this variable? If so, how?</i></p> <p>AIDS mortality would be a more valid indicator of deaths caused by HIV/AIDS if it could be adjusted for non-AIDS-related causes of death, using relative survival. This cannot be recommended at this time because:</p> <ol style="list-style-type: none"> The data required to calculate relative survival are not available in many to most jurisdictions The majority of the Workgroup felt it would be unnecessary because of the belief that the CARE Act was designed to meet all of the health needs of PLWHA, not just those directly related to HIV/AIDS.
Burden	<p><i>Do the measurement problems with this variable preclude its use? Please indicate if there is disagreement.</i></p> <p>No, measurement problems are not significant enough to preclude its use.</p>
Worth	
Inclusion	Yes
Weight	TBD

2. Variables considered, but not forwarded for consideration

PCP incidence: The panel considered, but did not recommend, the use of PCP incidence as a proxy indicator for severe cases of unmet need for primary medical care services in addition to low levels of HIV counseling and testing. PCP is an opportunistic infection that can easily be prevented with prophylaxis; comparatively increased incidence of PCP would indicate a severe lack of primary

medical care. The panel hoped this measure could be created using information contained in the HARS database.

However, the Workgroup removed this variable from further consideration because reporting of PCP cases to HARS is only required when it constitutes the AIDS-defining condition. This reporting system means the case counts observed in the surveillance data are likely to significantly underestimate the true incidence of PCP. Panel members discussed incorporating a statistical adjustment for the systematic underreporting of PCP, but they determined that calculating such an adjustment across States would be difficult and burdensome without further studying the relative completeness and reliability of PCP reporting in general.

Descriptive Characteristics	
Variable Name	PCP incidence (disease progression)
Data Elements	PCP (<i>Pneumocystis carinii</i> pneumonia) incidence
Data Sources	HARS
Rationale	With adequate primary medical care, incidence of PCP should be low (easily preventable with prophylaxis). Areas with elevated levels of PCP incidence may indicate severe cases of unmet need for primary medical care and consequently higher resource needs.
Type of Measure	Proxy indicator measure for unmet need for HIV/AIDS primary medical care
Level of Aggregation	County and State
Frequency of Updates	Annual
Cost	Free
Availability	Public domain (interagency agreement with the CDC required for access to surveillance data)
Quality and Fidelity	
Reliability	<i>Does the measurement of this variable differ across units of aggregation?</i> Yes.
Validity	<i>How does the measure capture the rationale for using it?</i> Reporting of PCP cases is required only if it is the AIDS-defining condition – the majority of AIDS diagnoses are made on the basis of CD4 counts. Given this reporting limitation, the number of PCP cases reported in HARS is likely to be incomplete. Furthermore, the degree of incompleteness is unknown (e.g., preventing the use of statistical adjustments) and therefore unusable for this variable. This variable could be measured potentially through the CDC’s Morbidity Monitoring Project, which would have the complete medical histories of its participants. However, the number of sites collecting data is limited, making small area estimates difficult.
Bias from Measurement Error	<i>Does the measurement of this variable result in systematic biases? If so, how?</i> Yes (see explanation above).
Usability	<i>Are there statistical adjustments that would resolve the reliability, validity, or bias problems of this variable? If so, how?</i> No.
Burden	<i>Do the measurement problems with this variable preclude its use? Please indicate if there is disagreement.</i>

	Yes (see explanation above).
Worth	
Inclusion	No, this variable should not be included in an SON index because of the incompleteness of the HARS data.
Weight	N/A

Rapid progression to AIDS: The Workgroup also discussed a measure of rapid progression to AIDS – defined as an AIDS diagnosis within 12 months of an HIV diagnosis – as a potential proxy indicator for severe cases of unmet need for primary medical care. Such rapid progression may indicate late testing, issues related to access to care, poor adherence to treatment regimen, or viral resistance. Following this assumption, the availability of testing, Public Health Service (PHS) standard of care, and the provision of treatment adherence monitoring are strongly influenced by the availability of resources in an area.

Panelists were concerned about the variable’s ability to accurately capture the concept of unmet need, and the measure proved difficult if not impossible to construct with existing data sources. The Workgroup noted that the variable could be highly correlated with access to primary medical care (e.g., insurance and poverty status), the availability and utilization of anonymous testing, and viral resistance and therefore might be a strong measure of need. The current variability in name-based HIV and laboratory reporting would make the variable impossible to estimate. In the absence of uniform HIV and laboratory reporting, panel members felt the constructed progression measure would be unacceptably unreliable, inconsistent, and incomparable across States. However, the Workgroup made a specific recommendation to reexamine this variable for inclusion in future SON indices once mature and reliable HIV reporting systems are in place.

Descriptive Characteristics	
Variable Name	Progression to AIDS diagnosis within 12 months of HIV diagnosis
Data Elements	<ol style="list-style-type: none"> 1. Population of individuals newly diagnosed with HIV 2. Percentage of newly diagnosed HIV-infected individuals who are diagnosed with AIDS within 12 months of the HIV diagnosis
Data Sources	HARS
Rationale	This variable measures rapid progression of disease. Progression from an HIV diagnosis within 12 months of an initial HIV diagnosis may be an indication of late testing, access to care issues, poor adherence, or viral resistance. Availability of testing, PHS standard of treatment and care, and provision of adherence monitoring are strongly influenced by the availability of resources.
Type of Measure	Proxy indicator measure for unmet need for primary medical care
Level of Aggregation	County and State
Frequency of Updates	Annual
Cost	Free
Availability	Public domain (interagency agreement with CDC required for access to surveillance data)

Quality and Fidelity	
Reliability	<p><i>Does the measurement of this variable differ across units of aggregation?</i></p> <p>All States have mature AIDS surveillance systems that collect AIDS-related data. However, not all States have surveillance systems that have mature name-based HIV reporting systems. Completeness and timeliness of reporting may vary across and within States, which may affect reliability. However, the CDC has set minimum standards for both.</p>
Validity	<p><i>How does the measure capture the rationale for using it?</i></p> <p>The measure will indicate if a State/county has a larger than average percentage of individuals progressing to an AIDS diagnosis within 12 months of HIV diagnosis. The States/counties with a higher percentage may have fewer resources to offer adequate testing, PHS standard of care, or adherence monitoring.</p>
Bias from Measurement Error	<p><i>Does the measurement of this variable result in systematic biases? If so, how?</i></p> <p>It will be hard to differentiate late testing from lack of access to care. The overall characteristics of the population (i.e., poverty, educational level, other health indicators of the area) also may affect how quickly the population progresses in the disease, and the availability of anonymous testing may impact the reliability of this variable.</p>
Usability	<p><i>Are there statistical adjustments that would resolve the reliability, validity, or bias problems of this variable? If so, how?</i></p> <p>May wish to adjust for characteristics of the population; however, that may defeat the purpose of using this variable.</p>
Burden	<p><i>Do the measurement problems with this variable preclude its use? Please indicate if there is disagreement.</i></p> <p>Yes currently, but maybe not in the future. Until all States have surveillance systems with mature name-based HIV reporting, it would be impossible to make comparisons across jurisdictions.</p>
Worth	
Inclusion	No, not until all States have name-based HIV reporting systems in place.
Weight	N/A

B. Medicaid and ADAP Adequacy

Variables Considered: Medicaid adequacy and enrollment, ADAP adequacy, ADAP waiting list, FMAP

Access to and the quality of State Medicaid and ADAP programs potentially measure the “available resources” portion of the Institute of Medicine (IOM) Report’s (“Measuring What Matters: Allocation, Planning, and Quality Assessment for the Ryan White CARE Act”) SON algorithm. The availability of generous State Medicaid and large State contributions to CARE Act co-financed ADAP programs might substantially alleviate the burden on the CARE Act to provide services in an area because many of the medically needy who in other jurisdictions would need to turn to the CARE Act for assistance would be covered by the State. In States that cannot afford it, do not choose to allocate funds to support a generous Medicaid program, or do not make substantial State contributions to ADAP, many patients may suffer with inadequate medical care. The key issue for this panel to consider was how to allocate additional funds to needy patients in States with poor Medicaid programs without treating generous States unfairly (at best) or creating incentives that might lead generous States to reduce medical services for PLWHA (at worst). (Note that even in a

State that provided very high-quality medical services for all its patients with HIV and AIDS, there would still be a role for the CARE Act because the Act covers several services that are outside the scope of Medicaid.)

The Workgroup and the overall panel had extensive discussions regarding the potential disincentives to States created by linking Medicaid adequacy to funding allocations. Specifically, the panelists did not want to penalize directly States that make generous financial contributions to State Medicaid programs. The panel discussed a number of ways to mitigate or avoid this issue, including adjusting for the FMAP, simply not recommending a Medicaid measure in any form, or applying a weight to the Medicaid adequacy variable once its impact is estimated. However, the panel ultimately moved forward with the variable given its central importance in the IOM Report's definition of resource needs and its practical and significant impact on whether patients receive the medical care they need to survive.

To measure Medicaid, the Workgroup considered two types of variables: (1) those that measure access or enrollment in Medicaid and (2) those that measure the quality of HIV/AIDS services available to those Medicaid recipients who are enrolled. To indicate enrollment, the group investigated using actual estimates of patients with any HIV or AIDS diagnosis, or any prescription for ARVs identified in the medical claims data of each State's Medicaid program in a given calendar year.

However, an initial assessment of such enrollment figures provided by the Centers for Medicaid/Medicare Services (CMS) indicated that such estimates are likely inaccurate at this time, for several reasons, but primarily due to the exclusion of Medicaid Managed Care enrollees in the data (the impact of which varied substantially across States). When the panel compared the Medicaid enrollment numbers to the total number of cases reported by HARS, there was an unacceptable and in some cases, unexplainable amount of variation in the measurement. For example, the percent of total reported cases enrolled in Medicaid ranged from less than 8 percent in one State to greater than 100 percent in four States.

Instead, on an interim basis the panel recommended using percent of FPL required for eligibility for the Medicaid Medically Needy program. For future indexes, the Health Resources and Services Administration (HRSA) should work to develop better measures of HIV or AIDS patients enrolled in State Medicaid programs.

To measure Medicaid adequacy, the group recommended an index variable created from one variable measuring the quantitative amount States spent per Medicaid recipient (adjusting for jurisdictional variation in labor costs) and a second variable measuring the types of special Medicaid programs available for PLWHA.

To measure ADAP adequacy, the panel recommended using the percent of FPL required for eligibility in the program. Although CARE Act Title I supplemental funds do not provide direct reimbursement for drugs directly (paid for primarily through Title II), the panel thought inadequacies in a State ADAP program could result in additional strains on an area's Title I program.

1. Variables forwarded for consideration

Medicaid enrollment and adequacy: Panelists recommended using a Medicaid adequacy scale constructed using two data elements which both the relative benefits available to PLWHA and programs which enhance enrollment or eligibility.

For Medicaid enrollment, the panel recommended using the poverty level required to qualify for the State's Medically Needy program. Specifically, in the absence of an actual count of patients with HIV and AIDS enrolled in Medicaid, the panel elected to measure Medicaid enrollment the percent of the FPL required of eligibility in the program. The variable was created using data collected annually by the Kaiser Family Foundation. The variable was collapsed categorically in the following manner with higher scores indicating more generous ADAP programs:

- 1 = No Medically Needy program in the State
- 2 = 1 to 59 percent FPL
- 3 = ≥ 60 percent FPL.

Future considerations regarding measuring Medicaid enrollment and adequacy –The panel would have preferred to estimate the actual number of patients with HIV and AIDS enrolled in Medicaid, adjusted for the adequacy of the Medicaid program, but found this impossible using currently available data. The panel recommended that HRSA continue to investigate estimate the actual number of patients with HIV and AIDS enrolled in Medicaid by using claims data. They also suggested that HRSA consider requiring States to report the number of PLWHA enrolled in Medicaid, using State data systems. States could achieve this either by requiring Medicaid Managed Care vendors to document HIV- or AIDS-related encounters or, at the State or local level, by comparing the State Medicaid enrollment roster to the names of PLWHA in a jurisdiction. Jurisdictions then would report these numbers in aggregate to HRSA. The panel realized that such a recommendation would create burden for the States, so it also recommended that HRSA continue to work with CMS to investigate how to identify PLWHA in CMS claims data.

Measuring Medicaid Adequacy – The panel created a Medicaid adequacy adjustment factor using the following two data elements:

1. Average Medicaid expenditures per social security income (SSI) beneficiary
2. Presence and number of special Medicaid programs covering PLWHA (four programs total)
 - Targeted case management for people with AIDS
 - Home and Community Based Care Program (HCBC)
 - Pharmacy carve out in capitation rates
 - Differential rates for HIV (capitation, fee-for-service, or risk adjustment pool).

The data used to construct the adequacy adjustment factor were obtained using data from the U.S. Social Security Administration's Office of Policy and the Infectious Disease Society of America.

The average expenditure component of the adequacy adjustment factor was adjusted for State-level differences in the wages of health care professionals common to HIV primary care programs. Following the recommendations of the Associated Costs Panel, the panel used average hourly wage data from the Occupational Employment Statistical Survey (OESS) conducted by the Bureau of

Labor Statistics (BLS) and identified three major labor categories specific to HIV primary care programs:

- Family and General Practitioner (SOC code 291062)
- Registered Nurse (SOC code 291111)
- Licensed Practical and Licensed Vocational Nurse (SOC code 292061).

For each of the three labor categories, the State-level average hourly wage was divided by the national average to create an index normalized to one. The indices for each labor category were then averaged to produce an overall geographic wage index.

After adjusting for regional variations in labor costs, the variable was then collapsed categorically in the following manner based on the number of standard deviations from the mean national expenditure observed in the data:

- 1 = average expenditures more than one standard deviation *below* the mean
- 2 = average expenditures *within* one standard deviation *above and below* the mean
- 3 = average expenditures more than one standard deviation *above* the mean.

The panel assigned a specified number of points to each of the four identified benefit programs based on the program's relative impact on the resource needs of needy patients. The point system was constructed such that the maximum number of points that could be earned was (e.g., all four programs present):

- 0 points = No programs
- 2 points = Targeted case management for people with AIDS
- 1 point = HCBC
- 4 points = Pharmacy carve out in capitation rates *or* differential rates for HIV (capitation, fee-for-service, or risk adjustment pool).

Finally, the overall Medicaid adequacy adjustment factor was calculated by individually dividing each element by the highest possible value (7 and 3 for the special programs and average expenditures variables, respectively), summing the two variables (range = 0–2), and then dividing by the highest combined possible value (2). The net effect of this process was to produce a variable ranging from 0 to 1, such that scores closer to 0 indicated State Medicaid programs with lower per-person expenditures and fewer special programs benefiting PLWHA.

The panel identified several issues related to the data:

- The scale measuring Medicaid Adequacy was based on expert opinion and should be considered as preliminary. HRSA should consider funding research to evaluate the impact of different levels of spending and programs on the adequacy of care for PLWHA, and to evaluate methods (potentially using passively collected data at the Federal level or by requiring reporting by grantees) to enumerate patients with HIV/AIDS enrolled in Medicaid. Although Medicaid adequacy is a crucially important variable in determining regional differences in SON, the subjective nature of the variable

the panel was able to forward limit the potential weight this variable could be given in a resource allocation index.

- The average Medicaid expenditures per SSI beneficiary variable included information collected from all SSI beneficiaries, not specifically data from patients with HIV/AIDS. Although it is possible to construct data for patients with HIV/AIDS, the panel felt this more general SSI number would indicate better the State's overall program generosity and would not be confounded by the variations in the stage of disease of State Medicaid programs.
- The effort required in annually updating the presence and number of the four identified special Medicaid programs benefiting PLWHA could be significant. To the panel's knowledge, these data are not available in a central location, so each State's Medicaid plan would need to be reviewed individually on an annual basis. To compensate for this data limitation, panelists recommend that this information be submitted directly by grantees and consolidated by the HRSA HIV/AIDS Bureau (HAB).

Descriptive Characteristics	
Variable Name	Medicaid adequacy
Data Elements	<p>1. Average expenditures per social security income (SSI) beneficiary</p> <p>a. $= (\text{Total SSI expenditures}) / (\text{total number of SSI beneficiaries})$</p> <p>b. Coding scheme:</p> <ul style="list-style-type: none"> • 1 = average expenditures more than one standard deviation <i>below</i> the mean • 2 = average expenditures <i>within</i> one standard deviation <i>above and below</i> the mean • 3 = average expenditures more than one standard deviation <i>above</i> the mean • Note: Raw expenditures should be adjusted for regional variations in wages before collapsing categorically. <p>2. Special Medicaid programs covering PLWHA (seven programs total)</p> <p>a. Targeted case management for people with AIDS HCBC Pharmacy carve out in capitation rates Differential rates for HIV (capitation, fee-for-service, or risk adjustment pool)</p> <p>b. Coding scheme:</p> <ul style="list-style-type: none"> • 0 points = No programs • 2 points = Targeted case management for people with AIDS • 1 point = HCBC • 4 points = Pharmacy carve out in capitation rates <i>or</i> differential rates for HIV (capitation, fee-for-service, or risk adjustment pool) <p>The overall Medicaid adequacy adjustment factor was calculated by individually dividing each element by the highest possible value (7 and 3 for the special programs and average expenditures variables, respectively), summing the two variables (range = 0–2) and then again dividing by the highest combined possible value (2). The net effect of this process was to produce a variable ranging from 0 to 1, such that scores closer to 0 indicated State Medicaid programs with lower per-person expenditures and fewer special programs benefiting PLWHA.</p>
Data Sources	<p>1. U.S. Social Security Administration; Office of Policy Data</p> <ul style="list-style-type: none"> • “SSI Recipients by State and County, 2004” (most recent report available) • http://www.socialsecurity.gov/policy/docs/statcomps/ssi_sc/2004/index.html <p>Wage adjustment: OESS conducted by the Bureau of Labor Statistics (BLS)</p> <p>2. State Medicaid Plans and Plan Amendments</p> <ul style="list-style-type: none"> • http://www.cms.hhs.gov/medicaid/stateplans/
Rationale	Medicaid is arguably the most important public funder of HIV care (pays for approximately 55% of HIV care), and it is highly variable across States. CARE Act is the payer of last resort for HIV care. It is important to look at how much other payers are contributing in determining an area’s resource needs.
Type of Measure	Proxy
Level of Aggregation	State
Frequency of Updates	<p>1. Annual “SSI Recipients by State and County” reports are updated annually. The next update (release of 2005 data) is expected February 2006. The OESS is conducted every 6 months.</p> <p>2. Annual</p>

Cost	Free
Availability	Public domain
Quality and Fidelity	
Reliability	<p><i>Does the measurement of this variable differ across units of aggregation?</i></p> <p>Yes</p>
Validity	<p><i>How does the measure capture the rationale for using it?</i></p> <p>This scale should measure broad differences in the adequacy of State Medicaid programs. The elements included in the Medicaid adequacy scale are the data elements with the most variation across jurisdictions. The States with higher scores cover most services for most patients, and the States with lower scores cover fewer services for fewer patients. The Medicaid adequacy measure is based on expert opinion and is preliminary. HRSA should consider funding research that evaluates the impact of different levels of spending and programs on the adequacy of care for PLWHA.</p> <p>This measure should be revisited annually and updated based on new information and understanding.</p>
Bias from Measurement Error	<p><i>Does the measurement of this variable result in systematic biases? If so, how?</i></p> <p>The SSI data element does not reflect the cost of delivery of medical care; it may underestimate the resource needs for higher-priced States.</p>
Usability	<p><i>Are there statistical adjustments that would resolve the reliability, validity, or bias problems of this variable? If so, how?</i></p> <p>Adjustment for medical costs across jurisdictions, regionally, etc.</p>
Burden	<p><i>Do the measurement problems with this variable preclude its use? Please indicate if there is disagreement.</i></p> <p>No; collecting State-level estimates for each of these data elements (especially the special Medicaid programs variable) will likely be lengthy and involved (may require a State-by-State search of plans or individual phone calls), but this should not preclude its use. However, this data collection issue could be avoided if this information was required to be submitted on State CARE Act funding applications.</p>
Worth	
Inclusion	<p>Yes; Medicaid is the largest payer of HIV care and explains a significant portion of the variance in resource needs across States. Regardless of the burden associated with annual updates of certain variables, it should be included in an SON index. The question of disincentives is an important but ultimately separate policy issue and should be considered by the larger group.</p>
Weight	TBD

Descriptive Characteristics	
Variable Name	Medicaid enrollment
Data Elements	Percent of Federal Poverty Limit (FPL) required for eligibility for the Medically Needy program. Coding scheme: 1 = No program in State 2 = 1–59% 3 = ≥60%
Data Sources	Kaiser Family Foundation; Kaiser Commission on Medicaid and the Uninsured. <ul style="list-style-type: none"> Data on eligibility by FPL source: Based on a national survey conducted by the Center on Budget and Policy Priorities for the Kaiser Commission on Medicaid and the Uninsured, 2005. http://www.kff.org/medicaid/upload/In-a-Time-of-Growing-Need-State-Choices-Influence-Health-Coverage-Access-for-Children-and-Families-Report.pdf.
Rationale	Medicaid is arguably the most important public funder of HIV care (pays for approximately 55% of HIV care), and it is highly variable across States. CARE Act is the payer of last resort for HIV care. It is important to look at how much other payers are contributing in determining an area's resource needs.
Type of Measure	Proxy
Level of Aggregation	State
Frequency of Updates	Annual
Cost	Free
Availability	Public domain
Quality and Fidelity	
Reliability	<i>Does the measurement of this variable differ across units of aggregation?</i> Yes.
Validity	<i>How does the measure capture the rationale for using it?</i> In the absence of an actual enumeration of patients with HIV and AIDS enrolled in Medicaid, this variable provides a measure of broad differences in enrollment in State programs through the Medically Needy program. States with higher poverty limits cover more patients, and the States with lower poverty limits cover patients. The use of this variable as a proxy indicator for Medicaid enrollment is based on expert opinion and is preliminary. HRSA should consider funding research that evaluates the impact of different levels of spending and programs on the adequacy of care for PLWHA. This measure should be revisited annually and updated based on new information and understanding.
Bias from Measurement Error	<i>Does the measurement of this variable result in systematic biases? If so, how?</i>
Usability	<i>Are there statistical adjustments that would resolve the reliability, validity, or bias problems of this variable? If so, how?</i> No.
Burden	<i>Do the measurement problems with this variable preclude its use? Please indicate if there is disagreement.</i> No.

Worth	
Inclusion	Yes; Medicaid is the largest payer of HIV care and explains a significant portion of the variance in resource needs across States.
Weight	TBD

ADAP adequacy: Panelists recommended using the percent of FPL required for eligibility for the program as a measure of ADAP adequacy for inclusion in an index. Although CARE Act Title I supplemental funds do not provide reimbursement for drugs directly (paid for primarily through Title II), the panel thought inadequacies in a State ADAP program could result in additional strains on an area’s Title I program.

Given that the FPL is uniformly measured nationwide, the panel noted that this variable may tend to underestimate resource needs and the associated costs of meeting those needs in States with higher costs of living, in addition to the added costs that may be incurred if the ADAP program is relatively inadequate.

The panel also discussed, but ultimately did not recommend, using the number of patients enrolled in ADAP, adjusted for the adequacy of the ADAP program. Data for the number of ADAP enrollees could be obtained from the National ADAP Monitoring Project (most recent report available from 2005), National Alliance of State and Territorial AIDS Directors, Kaiser Family Foundation. The panel preliminarily considered an adequacy adjustment factor based on the following two data elements:

1. Average ADAP expenditures per client served
2. Proportion of identified medications included on formulary:
 - ARVs listed in the PHS treatment guidelines
 - OI prophylaxis and treatment listed in the PHS treatment guidelines
 - Other symptom management, adherence-promoting, and comorbidity medications for which the formulary contains at least one drug.

There are other measures, such as per capita expenditures; extensiveness of the formulary; and caps on enrolment, expenditures, or number of prescriptions, that would add additional information on ADAP adequacy. However, these measures are inconsistently available and/or were found to add little differentiation to the financial eligibility criterion. For example, preliminary analyses revealed relatively little variation across States in the coverage of ARVs (Nucleoside Reverse Transcriptase Inhibitors, Protease Inhibitors, Non-Nucleoside Reverse Transcriptase Inhibitors, and Fusion Inhibitors) and only moderate variability in coverage of OI prophylaxis and treatment medication as recommended in the PHS treatment guidelines.

In summary, the panel felt the variable was important because an inadequate ADAP program may increase pressure on Title I funds to supplement ADAP funding or cover additional medical care expenses resulting from inadequate access to drug therapy. However, panelists specifically recommended that the CARE Act develop a second severity adjustment system designed to accommodate the unique characteristics of the ADAP program and patients’ need for antiretroviral therapy.

Descriptive Characteristics	
Variable Name	ADAP Adequacy
Data elements	Eligibility as a percent of the FPL
Sources	ADAP Quarterly Report; HRSA
Rationale	Limited access to a State ADAP program could result in additional financial strains on an area's Title I program through increased need for medication, additional outpatient/inpatient expenses, etc.
Type of measure	Proxy
Level of Aggregation	State
Frequency of Updates	Quarterly
Cost	Free
Availability	HRSA
Quality and Fidelity	
Reliability	<i>Does the measurement of this variable differ across units of aggregation?</i> No.
Validity	<i>How does the measure capture the rationale for using it?</i> This measure captures the adequacy of a State's ADAP program by measuring access through financial eligibility criteria. This measure shows variability across States (range = 125–557% FPL in 2004) indicating significant differences in the relative generosity of programs. There are other measures such as per capita expenditures, extensiveness of the formulary, and caps on enrolment, expenditures or number of prescriptions that would add additional information on ADAP adequacy. However, these measures are inconsistently available and/or were found to add little differentiation to the financial eligibility criterion.
Bias from Measurement Error	<i>Does the measurement of this variable result in systematic biases? If so, how?</i> Since the FPL is uniformly constituted nationwide, this measure may tend to underestimate need and costs of meeting that need in States with comparatively high costs of living, including added costs that may be incurred if ADAP is relatively inadequate.
Usability	<i>Do the measurement problems with this variable preclude its use? Please indicate if there is disagreement?</i> No. Measurement is clear-cut and standard across jurisdictions.
Burden	<i>Does including this variable impose data collection burdens on grantees?</i> No. This information is already being collected from the grantees by HRSA through the ADAP Quarterly Report. It is also summarized at the State-level and readily available online through the Kaiser Family Foundation.
Worth	
Inclusion	Yes – The panel recommends including this variable in a SON index for allocating Title I supplemental funds only. Additional work is required to create a measure of ADAP adequacy for use in allocating funds for other Titles, namely Title II.
Weight	TBD – Given the absence of a corresponding measure of benefits once enrolled in ADAP (see discussion above in “Validity”), this variable should be given a relatively low weight in the index.

3. Variables not forwarded for inclusion

Enumeration of patients with HIV and AIDS enrolled in State Medicaid Programs:

The Workgroup felt that Medicaid enrollment was a crucially valuable indicator of SON. An ideal measure would capture the actual number of PLWHA with Medicaid coverage in a State. The Workgroup used the 2001 Medicaid analytic files supplied by CMS to attempt to estimate this number. Using ICD-9 CM codes for HIV and AIDS and National Drug Code numbers for ARVs, the Workgroup identified all patients in the United States in 2001 with at least one medical claim for HIV, AIDS, or a prescription for an ARV over the calendar year. They then calculated an estimated enrollment rate by dividing this number by the estimated number of living HIV and AIDS cases in each State supplied by the CDC. Panelists expressed some concern regarding the age of the Medicaid enrollment data, although this was not seen as an important enough reason to exclude the data.

However, the calculated enrollment rate exhibited an extremely high range, from as low as 8 percent to as high as 100 percent of estimated living cases. Further variations in the enrollment rate were not consistent with any explanatory rationale, such as the size of State, or the number of HIV cases reported. The panel concluded that this initial CMS analysis likely failed to capture the number of HIV-positive patients enrolled in Medicaid in a reliable manner. Possible explanations for the results include:

- The results are accurate, and enrollment percentages of HIV-positive patients vary dramatically across States
- Across States, Medicaid claims captured patients enrolled in Medicaid Managed Care at varying levels of completeness, from near completeness to virtually total exclusion.
- The current methodology to identify HIV and AIDS patients using claims data is imprecise in a currently unknown manner.

Data measuring the actual number of HIV/AIDS patients enrolled in State Medicaid programs is not being recommended at this time. However this data shows promise and should continue to be evaluated. Some of the specific problems identified with Medicaid enrollment data are.

- Patients enrolled in Medicaid Managed Care (MMC) appear to be inconsistently coded in the data across States. Furthermore, States differ in the percentage of total Medicaid enrollees in managed care, and whether patients with HIV/AIDS are required to enroll in MMC, may opt-out if they like, or are exempt from MMC.
- Patients not eligible for Medicaid under Federal criteria may be enrolled in State-only programs. State-only programs (i.e., programs that do not receive a Federal match) are by definition not Medicaid programs and are not included in the CMS data. Patients enrolled in State-option programs, such as Medically Needy programs, or reside in States that allow patients with a higher level of income than the Federal minimum requirement to qualify for Medicaid are included in the data.

- CMS updates the CMS Medicaid Analytic extract (MAX) data annually, but there is a time delay of approximately 4 years from data collection to general release. However, programmatic changes in Medicaid that directly affect eligibility criteria (and by definition the estimates contained in this data) occur annually.

Descriptive Characteristics	
Variable Name	PLWHA enrolled in Medicaid
Data Elements	Number of unique patients enrolled in Medicaid with at least one prescription for ARVs or a diagnosis for HIV/AIDS
Data Sources	CMS Medicaid MAX data; universe of Medicaid enrollees; 2001
Rationale	Number of HIV-infected patients enrolled in Medicaid provides a direct estimate of the number of patients likely to receive compensation for medical care from the State.
Type of Measure	Direct
Level of Aggregation	State. The number also can be estimated at the eligible metropolitan area (EMA) level, though this process would be more data intensive.
Frequency of Updates	Annual. The data are updated annually, but there is a ~4-year lag between collection and public release.
Cost	Requires substantial effort and cooperation from CMS
Availability	Available to HRSA through data-sharing arrangements between agencies in the Department of Health and Human Services
Quality and Fidelity	
Reliability	<i>Does the measurement of this variable differ across units of aggregation?</i> No. Patients enrolled in Medicaid managed care do not appear to be consistently identified in the data. The level of inconsistency varies to an unknown degree from State to State.
Validity	<i>How does the measure capture the rationale for using it?</i> The variable only represents enrollment in Medicaid and does not make a distinction in terms of the overall adequacy (e.g., covered services, co-payments) of the Medicaid program. To properly assess an area's available resources, this variable may be adjusted for overall adequacy.
Bias from Measurement Error	<i>Does the measurement of this variable result in systematic biases? If so, how?</i> Yes, jurisdictional counts of enrollees will depend on jurisdictional differences in reporting requirements for Medicaid Managed Care companies and State policies that determine the number of HIV/AIDS patients in Medicaid Managed Care (from all to none)
Usability	<i>Are there statistical adjustments that would resolve the reliability, validity, or bias problems of this variable? If so, how?</i> No. This measure could possibly be adjusted based on estimates of the State total percentage of patients in managed care, but such an adjustment would not likely overcome the present deficiencies of this measure.
Burden	Yes. Estimating this variable would create burden for CMS and HRSA.
Worth	
Inclusion	No
Weight	NA

ADAP waiting list: The panel rejected use of the ADAP waiting list primarily because the presence or absence of a waiting list (and the number of patients on such a list) is arbitrary and not necessarily reflective of the true resource needs of a State. The waiting lists depend directly on the States' eligibility criteria (often a politically motivated and subjective decision), making comparisons across States difficult and biased.

Panel members did not complete a template for this variable, given the unanimous agreement for rejection by the group at the first initial meeting in October 2005.

FMAP: FMAP, also known as the Federal financial participation (FFP) rate, refers to the rate at which the Federal Government matches State Medicaid expenditures. FMAP is calculated annually taking into account the State's average per capita income compared to the national average. By law, FMAP cannot be less than 50 percent.

Panel members considered, but ultimately dismissed, incorporating this variable as a means to mitigate potential State-level disincentives associated with the Medicaid adequacy variable such that the lower the FMAP (and theoretically total Medicaid expenditures), the greater the resource needs of an area. However, the Workgroup noted that it would systematically penalize poor States (which by definition have higher FMAPs) for being poor. Panelists also considered incorporating the variable inversely (e.g., the higher the FMAP, the greater the resource needs of an area), but they also rejected this approach because FMAP is calculated using the poverty rate in the general population, and there is substantial variation in income among PLWHA across States. Even though the variable was not forwarded for consideration at this time, the panel is investigating its correlation with the Medicaid enrollment percentage.

Descriptive Characteristics	
Variable Name	FMAP
Data Elements	FMAP, also known as the FFP rate, is the rate at which the Federal Government matches State Medicaid expenditures. FMAP is calculated annually, taking into account the State's average per capita income compared with the national average. By law, FMAP cannot be less than 50%.
Data Sources	Kaiser Family Foundation, StateHealthFacts.org <ul style="list-style-type: none"> Federal Matching Rate (FMAP) for Medicaid and Multiplier http://www.statehealthfacts.org/cgi-bin/healthfacts.cgi?action=compare&category=Medicaid+%26+SCHIP&subcategory=Medicaid+Spending&topic=FMAP+and+Multiplier
Rationale	<ul style="list-style-type: none"> The lower the FMAP (and theoretically lower total Medicaid expenditures), the greater the resource needs of an area. Variable could be used in combination with the Medicaid adequacy variable as a means to mitigate potential State-level disincentives (e.g., reward States that may have higher resource needs simply because they do not contribute or contribute inadequately to Medicaid).
Type of Measure	Proxy. FMAP rates are calculated based on income levels in the general population and therefore are non-HIV/AIDS specific.
Level of Aggregation	State
Frequency of Updates	Annual
Cost	Free
Availability	Public domain

Quality and Fidelity	
Reliability	Does the measurement of this variable differ across units of aggregation? No.
Validity	How does the measure capture the rationale for using it? Its unclear that this variable measures a different concept than poverty.
Bias from Measurement Error	Does the measurement of this variable result in systematic biases? If so, how? Potentially yes; using this variable inversely (e.g., higher FMAP = greater resource needs) to avoid penalizing poor States would result in systematic biases because the variable is based on income levels in the general population. It is well-documented that there is substantial variation in the income levels of PLWHA across States.
Usability	This variable is possibly usable if the variable were used inversely.
Burden	No
Worth	
Inclusion	No
Weight	TBD

C. Pharmaceutical Data

The Pharmaceutical Data Workgroup considered the use of proprietary prescription data to directly estimate the number of patients receiving HIV primary medical care. This focused group considered only one variable, receipt of HAART, and one potential data source, IMS Health, Inc. The panel members also theorized that by combining the number of patients receiving HAART with case loads observed in the surveillance data, an estimate of unmet need or the number of patients not receiving care could be achieved.

Although promising, panel members decided not to forward the variable for further consideration primarily because of several potential data limitations. IMS houses a prescription transaction database that includes information on approximately 90 percent of all retail prescriptions. It maintains patient-level identifiers for medication dispensed through the retail market (allowing for unique patient counts), but for all other channels (including managed care organizations and mail order pharmacies), IMS only collects information on the amount of product supplied to an area. Specific issues regarding the geographic assignment of the supply data across States could not be assessed within the time frame or scope of this project. However, the panel recommended that HRSA/HAB purchase the data and complete an independent review and analysis of these data for possible inclusion in future indices.

1. Variables forwarded for consideration

Not applicable.

2. Variables considered, but not forwarded for consideration

Receipt of HAART: The panel considered, but ultimately did not forward, estimating the number of patients out of care by comparing the number of patient receiving HAART with the case load

observed (adjusted for severity of disease, such as CD4 count below 200) in the surveillance data. Large differences in the number of patients not receiving HAART across jurisdictions indicate differences in the resource needs such that States with fewer patients receiving drug therapy have higher resource needs.

To obtain information on the number of patients receiving HAART, the Workgroup consulted extensively with IMS Health Inc., an international pharmaceutical and health care consulting company headquartered in Fairfield, CT. IMS maintains a prescription transaction database that includes information on approximately 90 percent of all retail prescriptions in the United States. For a subset of these retail prescriptions (~50 percent), IMS has linked patient identifiers that allow for calculations of unique patient case counts. All of the retail prescription data are collected at the zip code level according to the prescribing physician's office location. For prescription medication dispensed through nonretail channels (e.g., mail order companies, bulk pharmacies, public health clinics), IMS assesses the amount of product being supplied to an area but does not collect dispensing information. To overcome this limitation, IMS applies dispensing information gathered through the retail market data (e.g., number of prescriptions per patient per time period) to the supply estimate to calculate the number of unique patients represented through nonretail markets. The proportion of the HAART prescription market covered by these two datasets varies across States.

Panel members identified several limitations for this variable, including concerns regarding the effort required to properly assess any proposed assumptions or statistical adjustments and the added value to a SON index (given an estimated cost of approximately \$20,000 per annual report). Specifically, the proportion of total prescriptions distributed through the retail market (for which IMS has linked patient-level information) compared with other markets (for which IMS has only supplier information on the product) varies substantially across States. The group considered this to be a potentially significant limitation because many HIV-infected patients obtain medication through mail order companies, bulk pharmacies such as Kaiser, and public health clinics. The extent to which low retail coverage for HAART occurs and its impact across States is unknown at this time. Panel members discussed methods for supplementing low retail coverage areas with supply data, but they ultimately could not resolve specific questions within the time frame of the panel's work related to reshipping beyond the initial shipping address within the IMS database, wastage, and free medication distributed by the pharmaceutical companies. In addition, panel members noted that rural patients often travel from outside an EMA to obtain medications. Using the prescribing physician's office location as the geographical marker in these cases would potentially underestimate the resource needs of metropolitan areas where public health clinics are more likely to be located.

Although use of these data is promising, panel members removed this variable from further consideration because of uncertainty regarding the impact of potential measurement biases on any estimates created from the data. The panel considered several statistical adjustments (see discussion above) but ultimately determined the effort required to adequately assess these assumptions was not within the current scope of work or time constraints.

Descriptive Characteristics	
Variable Name	Receipt of HAART (pharmaceutical data)
Data Elements	Number of patients with at least one prescription for antiretroviral drugs compared with total number of patients in need of antiretroviral therapy as determined by estimated case counts (adjusted for CD4 counts above/below 200) reported in the surveillance data
Data Sources	<ul style="list-style-type: none"> • IMS Health, Inc., national longitudinal prescription database <ul style="list-style-type: none"> ○ Number of patients receiving antiretroviral therapy determined two ways: <ul style="list-style-type: none"> ▪ Retail: The national longitudinal prescription database covers approximately 59% of the HAART market nationally. For retail prescriptions, IMS Health has linked patient identifiers to create a count of unique patients by area. ▪ Supply: For those areas not covered or inadequately covered by the retail database, IMS Health has information on the supply of pharmaceuticals from various channels, including mail order and government. These estimates can then be adjusted to create unique patient counts. • HARS
Rationale	Large differences in the receipt of HAART compared to the caseload estimated by the surveillance data would indicate significant differences in resource needs across States (e.g., States with disproportionately fewer patients receiving HAART after adjusting for severity of the epidemic would have comparatively higher resource needs).
Type of Measure	Direct
Level of Aggregation	EMA, State (total and State minus EMA portion)
Frequency of Updates	<ul style="list-style-type: none"> • IMS Health data: Annual estimates constructed using data updated weekly by IMS retail and supply partner organizations • HARS: Annual
Cost	<ul style="list-style-type: none"> • IMS Health data: Approximately \$20,000 per annual report • HARS: Free
Availability	<ul style="list-style-type: none"> • IMS Health data: Proprietary • HARS: Public domain (interagency agreement with CDC required for access to surveillance data)
Quality and Fidelity	
Reliability	<p><i>Does the measurement of this variable differ across units of aggregation?</i></p> <p>Yes. The proportion of total prescriptions distributed through the retail market (for which IMS has linked patient-level information) compared with other markets (for which IMS has only supplier information on the product) varies across States. For antiretroviral therapy, this could be a significant limitation because many patients obtain medication through mail order companies, bulk pharmacies such as Kaiser, or public health clinics. The extent to which this occurs and its impact across States is unknown. In addition, it is unknown whether the supply data include free medication distributed directly by the pharmaceutical companies or has been adjusted for wastage.</p>
Validity	<p><i>How does the measure capture the rationale for using it?</i></p> <p>It directly measures the number of patients in care and, when compared with surveillance data, the number of patients out of care.</p>
Bias from Measurement Error	<p><i>Does the measurement of this variable result in systematic biases? If so, how?</i></p> <p>Yes. There are geographic uncertainties with the supply data such that one mail order company or bulk pharmacy located in one jurisdiction could actually be shipping medication across areas. IMS uses the shipping address provided by the supplier to link the product geographically, but the extent to which the product is reshipped beyond this initial location</p>

	is unknown. Furthermore, the location of the prescription in the retail data is determined by the prescribing physician's address. Rural patients often travel from outside an EMA to obtain medications, potentially underestimating the resource needs of metropolitan areas where public health clinics are more likely to be located.
Usability	<i>Are there statistical adjustments that would resolve the reliability, validity, or bias problems of this variable? If so, how?</i> Yes. Adjustments could be made based on the proportion of total prescription distributed through the different channels relevant to HAART (e.g., mail order, retail, public health clinics). For example, rural areas are likely to have lower retail prescriptions and higher mail order prescriptions.
Burden	<i>Do the measurement problems with this variable preclude its use? Please indicate if there is disagreement.</i> Yes; however, the extent to which the identified data limitations affect certain areas is unknown, and extensive time and effort would be required to properly define any potential statistical adjustments.
Worth	
Inclusion	No. Although the use of these data is promising, more information is needed on potential measurement biases (specifically, assumptions related to translating supply information into patient counts in areas with limited retail market data). Several statistical adjustments were considered (see discussion above), but the effort required to adequately assess the validity of these assumptions was not within the scope or time frame of the panel's work.
Weight	N/A

D. Social Area Indicator Analysis/MMP

The Social Area Indicator Analysis/MMP Workgroup did not recommend any variables for further consideration. Similar to the Pharmaceutical Data Workgroup, this special, focused Workgroup considered only one variable: regional variation in resource needs using Social Area Indicator Analysis. This methodology, recommended by the IOM Committee in its 2003 report, relates the area characteristics of geographically defined populations to variations in disease or the use of services. Social Area Indicator Analysis is particularly informative when data on area-specific resource needs are unavailable or impractical to collect.

Panelists dismissed this method/variable primarily because of the unacceptability and unavailability of potential data sources for resource needs required for such an analysis. Two specific data sources were considered: the HIV Cost and Services Utilization Study (HCSUS) and the MMP. The panel rejected HCSUS data because of concerns regarding the acceptability and relevance of estimates based on data collected more than 10 years ago.

However promising, MMP could not be considered because data collection efforts will not be fully implemented until 2006 (13 of 26 sites collected some data in 2005), with the first release of data anticipated for 2007 at the earliest. In addition, the panel was concerned about the defensibility and acceptability of State-level estimates calculated based on only the 20 State and six MSA project sites included in the MMP; an effort that would most certainly require complex statistical adjustments and a significant amount of time and effort.

1. Variables forwarded for consideration

Not applicable.

2. Variables considered, but not forwarded for consideration

Social Area Indicator Analysis/MMP: Panel members identified and considered extensively the use of Social Area Indicator Analysis, as recommended by the IOM Committee in its 2003 report, to measure regional variation in resource needs specific to PLWHA. The proposed methodology relates the area characteristics of geographically defined populations to variations in disease or the use of services. Specifically, panelists considered the following structure and type of variables useful for such an analysis as defined by IOM Committee:

- Dependent variables = number of resource needs; receipt of HAART
- Independent variables = area characteristics (sociodemographics, medical resource indicators).

The IOM Committee conducted a preliminary analysis using information contained in the Area Resource File (ARF) and data collected by HCSUS. ARF is a national, county-level database containing more than 7,000 variables for each county in the United States, including geographic codes and classifications, health professions supply and detailed demographics, health facility numbers and types, hospital utilization, population characteristics and economic data, environment, and health professions training resources. The file combines data from over 50 primary data sources, including the American Hospital Association, the American Medical Association, the American Dental Association, the American Osteopathic Association, the Census Bureau, CMS, the BLS, and the Veteran's Administration.

Panel members did not recommend using HCSUS data because of concerns regarding the acceptability and relevance of estimates based on data collected more than 10 years ago. However, the Workgroup discussed using data currently being collected by the CDC in 20 States and six metropolitan areas through the MMP. MMP will provide nationally representative estimates of clinical outcomes and HIV-related behaviors of HIV-infected adults (18+ years) receiving primary medical care in the United States through medical record abstractions and patient interviews. Specific measures addressed by the survey include HIV-related illnesses, laboratory values (CD4, HIV viral load), quality of care provided, prescription of and adherence to antiretroviral drugs, and patient risk and care-seeking behaviors. A new cohort of HIV-infected patients is selected annually through a three-stage sampling process involving geographic areas selected based on AIDS prevalence in Stage 1, facilities providing HIV care selected in each geographic area based on the number of HIV-infected patients receiving care in Stage 2, and a random sample of patients seen at facilities selected in Stage 2.

The panel ultimately rejected the use of Social Area Indicator Analysis to estimate regional variations in need because MMP data were not currently available. Release of the partial data (13 of 26 project sites) collected in 2005 is anticipated for 2007 at the earliest. However, the panel recommended a subsequent review of this methodology and any potential statistical adjustments required for future SON indices once the MMP has been fully implemented and data released for public use.

Descriptive Characteristics	
Variable Name	Regional variations in need (Social Area Indicator Analysis/MMP)
Data Elements	<p>1. <u>MMP; CDC</u></p> <ul style="list-style-type: none"> • The potential data elements listed below reflect the findings of the IOM Committee (“Measuring What Matters: Allocation, Planning, and Quality Assessment for the Ryan White CARE Act.”) based on availability from HCSUS. • Resource needs identified by the Committee included the following (summed as a single variable indicating total number of needs): <ul style="list-style-type: none"> ○ Did you need income assistance such as SSI, SSDI, AFDC, or health care benefits from Medicaid or the Veterans Administration in the last 6 months? ○ Did you need to find a place to live in the last 6 months? ○ Did you need home health care in the last 6 months? ○ Did you need mental health or emotional care or counseling? ○ Did you need drug or alcohol treatment in the last 6 months? ○ Receipt of HAART <p>2. <u>ARF</u></p> <ul style="list-style-type: none"> • County-level variables identified by the Committee as important sociodemographic characteristics and/or indicators of medical resources (available from ARF) included the following: <ul style="list-style-type: none"> ○ Total general practitioners divided by the total population ○ Total number of medical specialists divided by the total population ○ Percentage of the population that was African-American ○ Percentage of the population that is foreign born ○ Percentage of the population that lives in urban areas ○ Percentage of the population who live in poverty ○ Percentage of the population who are college graduates
Data Sources	<p>3. <u>MMP</u></p> <ul style="list-style-type: none"> • MMP will provide nationally representative estimates of clinical outcomes and HIV-related behaviors of HIV-infected adults (18+ years) receiving primary medical care in the United States through medical record abstraction and patient interview. • Data collected will include HIV-related illnesses, laboratory values (CD4, HIV viral load), quality of care provided, prescription of and adherence to antiretroviral drugs, and patient risk- and care-seeking behaviors. <p>4. <u>ARF</u></p> <ul style="list-style-type: none"> • National, county-level database containing more than 7,000 variables for each county in the United States, including geographic codes and classifications, health professions supply and detailed demographics, health facility numbers and types, hospital utilization, population characteristics and economic data, environment, and health professions training resources.

- ARF combines data from over 50 primary data sources, including the following:
 - American Hospital Association, the American Medical Association, the American Dental Association, the American Osteopathic Association, the Bureau of the Census, the Centers for Medicare and Medicaid Services (formerly Health Care Financing Administration), Bureau of Labor Statistics, and the Veteran’s Administration
 - <http://arf.hrsa.gov/>.

Social Area Indicator Analysis:

- An analysis method recommended by the IOM Committee to develop indirect measures of resource needs by geographical area. Social Area Indicator Analysis attempts to relate characteristics of geographically defined populations to variations in disease or the use of services.
- MMP/ARF data could be used to estimate regression models that assess how well area characteristics predict resource needs and receipt of HAART.
 - Dependent variable = number of resource needs; receipt of HAART
 - Note: two regression models estimated by the IOM Committee
 - Independent variables = area characteristics (sociodemographics, medical resource indicators)
- Findings from IOM Committee using HCSUS/ARF (see copy of full results below):
 - Significant predictors of *increased* resource needs
 - Fewer college educated persons
 - Fewer general practice physicians
 - Increased number of specialists in an area
 - Significant predictors of *not receiving* HAART
 - Living in a county with a high percentage of African-Americans
 - High percentage of families below the poverty level
 - Areas with more general practitioners.

TABLE 1: Results of Regression Analysis in HCSUS sample

Predictor Variables	Regression coefficient (Standard Errors)	
	Reported Needs	HAART Treatment
Number of general practice MDs per 100 persons	-10.58 (4.04)**	-36.51 (10.20)***
Number of medical specialists per 100 persons	2.45 (.65)***	-2.29 (1.90)
Percent African American	.00 (.00)	-.03 (.01)**
Percent foreign born	-.65 (.53)	-1.41 (.87)
Percent urban	-.46 (.36)	.58 (.91)
Percent of families below poverty level	.01 (.01)	.08 (.03)**
Percent of persons over 25 years of age with 4 or more years of college	-3.27 (1.05)**	3.74 (2.56)
Midwest	.07 (.14)	1.29 (.32)***
South	.14 (.09)	.59 (.30)
West	.22 (.15)	1.10 (.37)**
R-Square	0.02	0.05

*** p < 0.001
 ** p < 0.01
 * p < 0.05

Rationale	The Social Area Indicator Analysis (using MMP survey data) estimates indirect measures of resource needs by linking area characteristics to variability in disease burden and/or use of services. This methodology is useful when data on area-specific needs are unavailable.
Type of Measure	Proxy

Level of Aggregation	<ol style="list-style-type: none"> 1. 26 MMP project areas (20 States, 6 cities) <ul style="list-style-type: none"> ○ MMP data collection in all 26 project areas will not be implemented until 2006 (13 sites collected some level of data in 2005), with release of data anticipated at the earliest in 2007. 2. County
Frequency of Updates	<ol style="list-style-type: none"> 1. <u>Annual</u> Note: A new cohort of HIV-infected patients selected annually for MMP; however, the specific lag time between data collection and release is unknown. 2. <u>Annual</u> ARF updated annually; however, release dates vary because of the dependence on the availability of the major primary data sources.
Cost	<ol style="list-style-type: none"> 1. Unknown (MMP data have yet to be fully collected and released, but they are likely to be available for free) 2. \$500 for 2004 Bureau of Health Professions' ARF \$800 for 2004 Bureau of Health Professions' ARF Access System
Availability	Public domain
Quality and Fidelity	
Reliability	<p><i>Does the measurement of this variable differ across units of aggregation?</i></p> <p>Yes. For the 26 MMP project areas, estimates of resource needs are measured directly. For all other areas, resource needs are measured indirectly through relationships observed through regression analysis.</p>
Validity	<p><i>How does the measure capture the rationale for using it?</i></p> <p>Indirectly; ideally, data on resource needs (for primary medical care and support services) would be directly available for all jurisdictions. This methodology only attempts to fill this gap in available data.</p>
Bias from Measurement Error	<p><i>Does the measurement of this variable result in systematic biases? If so, how?</i></p> <p>MMP directly measures the resource needs of the 26 project areas where data are collected on an annual basis. However, predicting resource needs outside of these areas is less precise and could lead to measurement biases. The impact of this methodology across States cannot be determined, because setup and initial data collection are ongoing.</p>
Usability	<p><i>Are there statistical adjustments that would resolve the reliability, validity, or bias problems of this variable? If so, how?</i></p> <p>Potentially; however, it is difficult to identify and define such adjustment in the absence of collected and cleaned data from all 26 MMP project sites.</p>
Burden	<p><i>Do the measurement problems with this variable preclude its use? Please indicate if there is disagreement.</i></p> <p>Yes (see discussion above).</p>
Worth	
Inclusion	The use of Social Area Indicator Analysis to estimate regional variations in need is not recommended for the initial implementation of the SON index because of data limitations associated with the MMP. However, a subsequent review of this methodology is recommended for future indices once MMP has been fully implemented.
Weight	N/A

E. Substance Abuse

The Substance Abuse Workgroup did not recommend any variables for further consideration. This focused Workgroup considered only one variable: unmet need for substance abuse treatment services among injection drug users (IDUs). The group hoped to create this measure by subtracting the estimated number of IDUs who received substance abuse treatment services from the total number of IDUs in need of treatment during the previous calendar year.

Panelists dismissed this variable primarily because of the uncertainty of one of two data files required to construct the measure. The group hoped to use the Treatment Episode Data Set–Admissions Data System (TEDS) to estimate the number of patients who received treatment. For the total of patients in need of treatment, panelists identified the Substance Abuse Prevention and Treatment (SAPT) Block Grant Funds, Needs Assessment Summary as the most promising data source. Both data files are housed within the Substance Abuse and Mental Health Services Administration (SAMHSA). However, the panel ultimately did not forward this variable for further consideration because of concerns regarding measurement and calculation variability across States in the IDU-specific variables contained in the SAPT data. Furthermore, it was unclear what type of data each State used to construct the variable and to what extent this variability created systematic measurement bias.

1. Variables forwarded for consideration

Not applicable.

2. Variables considered, but not forwarded for consideration

Unmet need for substance abuse services among IDUs: Panelists considered, but ultimately rejected, use of unmet need for substance abuse services among IDUs largely based on variability and uncertainty in the variable’s measurement across States. The group calculated the measure by subtracting the number of drug users who sought treatment during the previous calendar year from the total number of IDUs in need of treatment over the same period. The data used to construct this variable could be obtained from TEDS and the SAPT Block Grant Funds, Needs Assessment Summary, both of which are housed within SAMHSA.

TEDS is a national data reporting system that provides information on the demographic and substance abuse characteristics of nearly 2 million annual admissions to treatment for abuse of alcohol and drugs in facilities that report to individual State administrative data systems. The admissions data have been updated annually since 1992. Although data collected by TEDS are not specific to patients with HIV/AIDS, they do contain information on the patient’s usual route of drug administration (e.g., oral, smoking, injections).

The panel noted that, although comprehensive and reliable, TEDS is an admissions-based system and does not seek to represent unique individuals. For example, a patient admitted for substance abuse treatment services twice within one year would be counted as two admissions in TEDS. To adjust the data for multiple admissions, it is possible to divide the total admissions for all clients by 1.63 (admissions per person in one year) based on information reported in the Alcohol and Drug Services Study (ADSS) Phase II client record abstract data, 1997/1998 discharges.

SAPT summary data include State-level information on the number of IDUs (not specific to HIV/AIDS) in need of substance abuse treatment services. Panel members dismissed SAPT data, and consequently the overall variable, primarily because of incomparability of data collection and calculation methods across States. Individual States often use multiple and different data sources to estimate need, and no uniform calculation methodologies are required or recommended by SAMHSA at this time. Furthermore, information on the sources and calculation methods are not maintained in a central location, making the creation of statistical adjustments difficult and burdensome.

Descriptive Characteristics	
Variable Name	Unmet need for substance abuse
Data Elements	Number of IDUs in need of substance abuse treatment
Data Sources	<p>Uniform Application for SAPT Block Grant Funds, Needs Assessment Summary</p> <ul style="list-style-type: none"> • States are required to use the best available data and indicate how they intend to improve on the reliability and validity of that data. Each State individually determines the methodology for calculating these estimates. • Primary source of data by State is unknown. • Would need to contact individual States to get data. <p>TEDS</p> <ul style="list-style-type: none"> • Admissions-based data file sent from providers to the State; summarized by the State; demographic information self-reported • Not HIV/AIDS specific • State estimates are in the public domain; county-level data are restricted; would need to contact SAMHSA to arrange analyses to comply with confidentiality regulations • Variable and response categories: “usual route of administration (of primary, secondary, and tertiary substances)” <ul style="list-style-type: none"> ○ Oral ○ Smoking ○ Inhalation ○ Injection (IV or intramuscular) ○ Other
Rationale	Approximately 24% of all AIDS cases are directly related to injection drug use, and 7% are attributable to men who have sex with men and also inject drugs (AIDS Surveillance Report, 2004).
Type of Measure	<ul style="list-style-type: none"> • SAPT: Proxy measure determined by the State • TEDS: Direct measure of treatment admission in the general population but a proxy measure in terms of HIV/AIDS; no way to subset the data for HIV/AIDS
Level of Aggregation	<ul style="list-style-type: none"> • SAPT: State and substate planning areas • TEDS: State (note: county-level data can be obtained, but they are restricted to comply with confidentiality standards)
Frequency of Updates	<ul style="list-style-type: none"> • SAPT: Annual. The actual report is submitted annually, but there is no way to know the lag time associated with the primary data. • TEDS: Annual. The lag time in data release is approximately 2 years.
Cost	<ul style="list-style-type: none"> • SAPT: Free • TEDS: Free

Availability	<ul style="list-style-type: none"> • SAPT: Public Domain (note: 42 USC Section 300x-51 requires State to make plan public to facilitate comment) <ul style="list-style-type: none"> ○ SAMHSA’s Division for State and Community Assistance would be able to provide the actual counts. ○ Details on data collection, methods, etc. would be available only from individual States. • TEDS: Public domain <ul style="list-style-type: none"> ○ State-level data are easily accessible (http://www.dasis.samhsa.gov/teds02/TEDS2K2Index.htm). ○ Local and county data are available, but they may require a data use agreement to protect confidentiality of data.
Quality and Fidelity	
Reliability	<ul style="list-style-type: none"> • SAPT: Yes. Each State determines how the data are collected, sources, etc. • TEDS: No.
Validity	Both SAPT and TEDS data report at-risk IDUs either in need of treatment or actually receiving treatment. The need for services can be determined only for this HIV risk factor (e.g., sharing needles).
Bias from Measurement Error	<ul style="list-style-type: none"> • SAPT: Unable to determine because each State’s data collection methodologies are unknown • TEDS: No
Usability	<ul style="list-style-type: none"> • SAPT: Unable to determine because primary source of data and calculation methodologies by States unknown • TEDS: Admission-based system; does not represent unique patient counts. Thus, for example, an individual admitted to treatment twice within a calendar year would be counted as two admissions. <ul style="list-style-type: none"> ○ To adjust for multiple admissions, divide the total admissions for all clients (TEDS total admissions count) by 1.63 (admissions per person in one year) (Source for 1.63 multiplier: ADSS Phase II client record abstract data, 1997/1998 discharges)
Burden	<ul style="list-style-type: none"> • SAPT: TBD • TEDS: No
Worth	
Inclusion	<ul style="list-style-type: none"> • SAPT: No; the extent to which the data limitations identified impact the reliability of the estimates cannot be determined within the scope or time frame of the panel’s work (e.g., each State would need to be contacted individually to determine data collection and calculation methods before any statistical adjustment could be applied). • TEDS: TBD
Weight	<ul style="list-style-type: none"> • SAPT: N/A • TEDS: TBD

F. Unmet Need

The Unmet Need Workgroup worked to estimate of the number of persons who were aware of their infection status that currently did and did not receive medical care. Currently, unmet need is estimated through use of the HRSA Unmet Need Framework, developed by researchers at the University of California at San Francisco (UCSF) and used by all Ryan White Title I and Title II grantees. According to the Framework, unmet need for HIV primary medical care in a geographic area is calculated by subtracting the number of PLWHA who received care from the total number of

PLWHA over a specified 12-month time period. The Framework defines receipt of care as evidence of at least one of the following during the specified time period:

- CD4 count
- Viral load
- Prescription for ARV.

If all States required full reporting of all CD4 counts and viral load test, then the required information for measuring the variable would be contained in the HARS database. However, most States do not have mandatory laboratory reporting.

Although promising, panel members dropped the use variable from further consideration primarily based of the inadequacy of the data used to measure it. Current variability in laboratory reporting and in other data sources used to estimate unmet need for HIV primary medical care would make the variable impossible to measure with adequate reliability. In the absence of uniform, name-based HIV and laboratory reporting, panel members felt the measure would be unacceptably unreliable, inconsistent, and incomparable across States.

1. Variables forwarded for consideration

Not applicable.

2. Variables considered, but not forwarded for consideration

Unmet need for primary medical care services: The group considered, but ultimately dismissed, including a measure of unmet need for HIV primary medical care because of current data limitations associated with HARS. Specifically, the panel reviewed the HRSA Unmet Need Framework as developed by researchers at UCSF and currently used by all Title I and Title II grantees. According to the Framework, a measure of unmet need should be created by subtracting the number of PLWHA-aware with evidence of at least one of three identified markers (evidence of a CD4 count, viral load test, or a prescription for antiretroviral therapy) from the total number of PLWHA-aware over a specified time period. This subtraction approach is used annually by all Title I and Title II grantees to estimate unmet need for HIV primary medical care. However, the data sources and calculation methodologies used to determine the number of PLWHA receiving care vary substantially across States primarily due to availability of appropriate data.

Even though the panel did not forward this variable for further consideration, it did determine that the current Unmet Need Framework continues to be the best approach for measuring unmet need for HIV primary medical care. However, panel members choose not to use the resulting estimates because of the absence of full laboratory reporting across all States. The panel recommended subsequent review of this variable and any potential statistical adjustments required for future SON indices if and when mandatory laboratory reporting has been implemented nationally.

Descriptive Characteristics	
Variable Name	Unmet need for HIV primary medical care
Data Elements	<ul style="list-style-type: none"> • Number (or proportion) of PLWHA and with HIV/non-AIDS/aware (PLWH aware) who have not received any of the following during a defined 12-month period: <ul style="list-style-type: none"> ○ CD4 count ○ Viral load test ○ Antiretroviral therapy (ART) • Calculated by estimating: <ol style="list-style-type: none"> a. Population data: Number of PLWHA and PLWH aware during a specified time period (usually 12 months) b. Care patterns data: Number of PLWHA and PLWH aware with evidence of having received a CD4 count, viral load test, and/or ART during the specified time period c. Difference between a and b = unmet need
Data Sources	<p>Current source of estimates is Title I and Title II grantees.</p> <p>Current sources available to Title I and Title II grantees are varied; frequently used sources include the following:</p> <ul style="list-style-type: none"> • For population data: <ul style="list-style-type: none"> ○ In States using HIV reporting for more than 3–4 years, HARS ○ In States that recently began HIV reporting, HARS for PLWHA, and for PLWH aware; CDC midpoint modeled estimates or State/local estimates (will probably adjust to new CDC estimation methods) • For care patterns data: <ul style="list-style-type: none"> ○ CD4 and VL tests from HARS where State requires ~100% lab reporting. This is simple, quick, and comprehensive. ○ Combination of utilization data (e.g., ADAP and Medicaid claims databases, Ryan White client data, private care data), where possible unduplicated using a unique client identifier or algorithm based on client characteristics. This is more improvisational and incomplete. ○ Private care data may come from individual medical practices, hospital discharges, and other utilization studies. ○ Special studies of varied types
Rationale	<ul style="list-style-type: none"> ▪ Met need provides a measure of the current burden of care in a geographic area. ▪ Unmet need provides a measure of the additional resources needed to address HIV/AIDS in the area.
Type of Measure	Direct indicator of severity of HIV primary medical care need
Level of Aggregation	Varies by source; estimates currently produced by both States and EMAs. Most data sources allow (imperfect) geographic division (e.g., by provider and/or patient zip code).
Frequency of Updates	Annual estimates by grantees (for Ryan White CARE Act applications), using data that vary in frequency of updates from quarterly (e.g., HARS data) to once every several years (e.g., Veterans Administration aggregate data)
Cost	Free if grantee estimates are used
Availability	Estimates from grantees are in the public domain, although often with limited detail / explanation. Some of the data used to estimate met and unmet need (e.g., data on individuals with private health insurance) are not in the public domain. Many of the databases used are available only under strict controls due to the Health Insurance Portability & Accountability Act.

Quality and Fidelity	
Reliability	<p><i>Does measurement of this variable differ across units of aggregation?</i></p> <p>Yes.</p>
Validity	<p><i>How does the measure capture the rationale for using it?</i></p> <p>Poorly, because of differences in estimation sources and methods and difficulty in assessing and comparing data reliability and validity.</p>
Bias from Measurement Error	<p><i>Does the measurement of this variable result in systematic biases?</i></p> <p>Yes, although the net direction is often difficult to determine because of competing tendencies (e.g., missing care sources and imperfect unduplication).</p>
Usability	<p><i>Are there statistical adjustments that would resolve the reliability, validity, or bias problems of this variable?</i></p> <p>No. This variable could become usable only to the extent that States require all labs to report all CD4 counts and viral load tests to HARS, and if HARS had the capacity to maintain all lab reports. This would require higher funding and capacity at the State and county levels, as well as new lab reporting (sometimes requiring changes in law) and enforcement.</p>
Burden	<p><i>Do the measurement problems with this variable preclude its use?</i></p> <p>Yes, at the current time.</p>
Worth	
Inclusion	No – Not unless all States require and implement full laboratory reporting.
Weight	N/A

IV. History of the Panel

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