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Quality of Care Indicators for HIV/AIDS

A Discussion Paper for the Foundation for Accountability

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Table of Contents

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I. Overview

The purpose of this background paper is to review issues related to quality of care assessment for people with HIV/AIDS. The discussion focuses on indicators that could be used to examine the performance of providers and organizations in managed care organizations, to compare organizations, and to inform quality improvement activities. Managed care organizations are increasingly responsible for the health care of people at risk for HIV as well as those with HIV, especially as they are awarded more Medicaid contracts.

This document is intended to help clinical providers, clinical and public health researchers, patients and patient advocates, service organizations, managers, employers, payers, and policy makers consider measures of HIV quality of care. It is hoped that the following discussion will help them to assemble measurement sets that are appropriate to their specific needs and resources.

The selection of candidate indicators attempts to balance the state of the art in science and treatment with practical issues in collecting indicator data. The paper begins with a very brief review of the prevalence and impact of HIV disease, and notes a few existing activities to develop quality of care measures. The paper then moves to a discussion of sampling issues. The longest section reviews potential indicators grouped under measures of outcome, essential

care processes, economic or productivity impact, and satisfaction. The paper concludes with a review of issues related to case mix and the selection of indicators. The appendices include a proposed set of clinical guidelines, key treatment guidelines, a summary of a potential set of accountability measures, a number of available measures.

These data could be used by individuals to help inform choice among provider groups, purchasers of health care to select among health plans, or payers such as Medicaid agencies to negotiate contracts with managed care organizations. Use of some indicators could be restricted to areas with a very high prevalence of HIV. Data could also be used by groups of providers seeking to improve the quality of care they deliver. In addition, the quality indicators described in this paper also could potentially be applied to evaluate the overall quality of care received by individuals who often receive components of their care from several sources.

I. Background

Prevalence

HIV/AIDS is a chronic condition caused by the Human Immunodeficiency Virus (HIV-1) that is characterized by progressive immunosuppression. It is not currently curable. Approximately 650,000-900,000 people in the United States are estimated to have HIV infection, with an estimated one-third being unaware of their seropositive status (Karon, 1996). The average cost of caring for a person with HIV in 1996 was estimated to be $20,000/year (Bozzette, 1998).

Impact of HIV/AIDS

Quality of life for persons with HIV or AIDS is affected by suppression of the immune system with attendant opportunistic infections and complications, and by direct action of the virus, resulting in wasting, neurologic disease, fatigue, etc. People with HIV/AIDS are also affected by discrimination, by comorbid conditions including substance abuse and mental health problems, and by poverty which can be both a cause and effect of infection.

II. Activities to Develop HIV/AIDS Quality of Care Measures

There is consensus that people consider at least three dimensions of quality to be important: the appropriateness of care (i.e., patients should receive a procedure when it benefits them and not get it if it does not), the excellence of care (when something is done to patients, it should be done in a manner that maximizes the benefit-to-risk ratio), and the humaneness of care (including being consistent with societal norms).

Operationally, quality of care is a multidimensional concept that can be assessed by measures of the structure, process and outcome of care (Donabedian). The basic concept is that more effective and more appropriate processes between provider and patient will improve health outcomes. Better facilities, equipment, staffing, and training affect outcomes indirectly by improving processes.

Evaluation of each of the three parameters allows assessment of the quality of care. Important dimensions of clinical quality include efficacy, appropriateness, accessibility, acceptability, effectiveness, efficiency and continuity. Both technical care and management of the interpersonal relationship must be considered.

The goal of quality assurance is to improve the outcomes of patients. This is accomplished in part by attaining a better understanding of which aspects of structure and

process affect outcomes. Ultimately, improving the quality of care can benefit not only individuals, but can improve the health and productivity of communities (Donabedian.)

Guidelines have been proposed for evaluating the quality of HIV care based on a few studies (Agins 1996; Bennett 1995; Bozzette 1995; Marx 1995; Gross 1995). Available recommendations on the use of highly-active antiretroviral medications differ only slightly from each other and have had broad input and support (Carpenter 1997, DHHS 1997;1998). Published guidelines developed by the panel on clinical practices, convened by the Department of Health and Human Services and The Henry J. Kaiser Foundation, are available on the World Wide Web (http://www.hivatis.org/).

There is growing evidence that quality of care measured in terms of structure and processes of care can have an impact on patient satisfaction (Aiken 1997; Stoskoph 1996; Croucher 1997; Katz 1997) and survival (Bennett 1989; Kitahata 1996; Palenicek 1997). Treatment options have expanded rapidly since the introduction of new highly active antiretroviral medications in late 1995 and early 1996. Use of these medications has led to increased survival. This new potential increases the importance of efforts to assess and improve quality of care.

III. Sampling Issues / Scope

There are several potential populations in which one might evaluate quality of care. Previous studies of HIV disease have been limited by the unique set of confidentiality issues that surround testing and test results. This paper will deal primarily with quality of care issues among people already infected with HIV, with an emphasis on adults. Primary prevention and screening will be discussed more briefly, and will be addressed primarily on the level of plan activities.

Because of the confidentiality of individuals at increased risk of HIV, it is difficult to collect data on primary prevention. For example, it would not be possible to know what proportion of high risk individuals received materials or education about HIV prevention. However, it would be possible to assess risk factors for HIV in all adolescent and adult patients by obtaining a sexual history and history of drug use. This population-based measure would not pose confidentiality problems relating to HIV test results. However, providers are often reluctant to record specifics of these data in the medical chart, and are inconsistent in their reporting. It may be possible to collect plan-level data concerning what prevention programs are available to covered individuals, and the absolute number of individuals who utilize any of these services. It would also be possible to ask HIV infected patients if they have received counseling on a variety of topics including routes of transmission, higher and lower risk behaviors (e.g., safer sex and needle sharing).

Because of confidentiality about who is being tested, it is not possible to collect reliable data on screening rates, even among groups of high-risk individuals. Having been tested may convey stigma or discrimination, and some individuals are tested at alternate test sites without the knowledge of their MCO. It may be possible to ask patients within an MCO about the post-test counseling they received from their test site, which might include their MCO.

Data on some subgroups may be difficult to ascertain. HIV infection is relatively uncommon in infants, children and older adults. It is unlikely that many MCOs will possess sufficient numbers of older (e.g. over 45 or 50) subjects or children to derive stable estimates for quality indicators. Rural patients and certain minority groups are also unlikely to be adequately represented. At best, these data would be qualitative. However, it may be practical to target measures to very high prevalence areas.

As the burden of data collection is a major issue for operationalizing performance measures, it would be desirable to employ methods that use administrative data to identify the denominator population. For the numerator, the preferred sources of data are also administrative, with or without augmentation by medical chart reviews and/or surveys. For example, administrative data on use of HIV-specific tests (e.g., CD4 lymphocyte count, HIV RNA) or medications could be used to identify individuals with a high probability of HIV infection. This method results in selection of a sample that is receiving care. As these data elements are also related to quality of care, this kind of procedure could result in a biased sample. However, this approach may still be useful in some cases. For example, if the

denominator is patients with CD4 <200, a measure might be the percentage receiving a prescription for chemoprophylaxis for Pneumocystis carinii pneumonia. In this case, any individual with a CD4 count less than 200 is assumed to be HIV infected.

With the possible exception of a few name-reporting states, to our knowledge there are no databases which could be readily subjected to patient-finding algorithms. Therefore, another method to sample HIV infected adults (and also children) for quality of care studies is to use patient lists compiled by HIV providers. Data on individuals sampled from patient lists of HIV providers could serve as a source of quality indicators extracted using secondary data review or primary data collection. This method is also susceptible to potential biases. For example, there is the possibility that non-adherent or otherwise problematic patients might be excluded, resulting in a biased sample. Another concern with sampling known HIV providers is that low volume providers, who might also be delivering inappropriate care, are unlikely to be sampled. It is comforting that early results from HCSUS (M Shapiro, personal communication) suggest that only 3% of patients are cared for by providers with less than 5 active patients. However, low volume providers may be under-represented by the sampling scheme.

A cross sectional sample could be used from the above mentioned sources for the majority of analyses, perhaps with review of quality indicators and/or collection of survey data within a specified preceding interval (e.g., 3 months to one year). An alternative way to direct data collection would be to evaluate the initial comprehensive HIV evaluation for new patients to the practice. There is general consensus on what the first evaluation should include, and review

of this visit would be efficient. A helpful example for what comprises appropriate care is provided in protocols developed by the AIDS Institute of the New York State Department of Health which include history, screening evaluation, treatment, and preventive measures (appendix).

IV. Measurements

A. Health Outcomes

A range of health outcomes might be considered as quality of care indicators including survival, immunologic measures, disease progression, symptoms, subjective health status, disability and health utility.

Survival

Length of survival or hazard of death has been examined as an outcome measure in studies of quality of care in HIV infected patients (Kitahata 1996, Palenicek 1996). Use of survival as an indicator would require use of a discriminating and well-calibrated risk adjustment method. An important factor to consider is duration of HIV infection, a variable which is not generally known or routinely available. However, collecting survival data on an incident HIV cohort would require an excessively long period of time. Survival data on specific subgroups of patients, such as patients with a nadir CD4 count of <100 cell/mm^3, would require careful risk adjustment strategy that may be beyond the scale and scope of most organizations. This outcome is not listed in the summary of proposed measures.

Measurement tools and items: Not recommended

Patient/member inclusion criteria:

Method for calculating indicator:

Source:

Risk adjustment:

Immunologic and Virologic Measures

Immunologic measures including CD4+ lymphocyte count (cells/mm^3) are most commonly used to describe immunosuppression (with cutoffs at <50, <100, <200, <500 sometimes used) and HIV RNA (number of particles/mm^3) (viral burden or viral load) is the most commonly used measure of viral replication and hence activity (Mellors 1997). Achievement and durability of an "undetectable" viral load has become the primary goal of therapy. However, it may be difficult to measure this across different organizations, particularly when different viral load tests are used, accompanied by different definitions of "undetectable" (e.g. < 500 copies/ml). If used, virologic and immunologic markers would probably need to be adjusted for age and perhaps gender. Viral load may need adjustment for pre-treatment viral load. Importantly, to be interpretable as measures of quality, these outcomes may need to be adjusted for prior experience of treatment with antiretroviral medications. For a viral load measure, this might require limiting the population to patients on their first ART regimen who have received therapy for a minimum period of time (e.g. 12 weeks).

Measurement tool and items: CD4 number

Patient/member inclusion criteria: All

Method for calculating indicator:	Change in CD4
Source:	Chart
Risk adjustment:	Age, gender, prior ART treatment history?

Measurement tools and items:	HIV RNA
Patient/member inclusion criteria:	All; patients receiving ART; initial therapy for $12 weeks
Method for calculating indicator:	% with undetectable viral load
Source:	Chart
Risk adjustment:	age, gender, baseline VL, prior ART treatment history?

Disease Progression

Disease progression may be an indicator of quality of care. Disease progression has been defined using disease stage, and degree of immunosuppression. HIV disease stage has been based on the natural history of progression from asymptomatic to symptomatic disease (formerly AIDS Related Complex or ARC), to AIDS (sometimes following the unfortunate phrase 'full-blown'). Immune suppression was generally irreversible. More recently, treatment with highly active antiretroviral therapy (HAART) has resulted in improvements in physical condition and partial recovery of immune function. Stages of infection are now also referred to as Acute Infection, Intermediate and Advanced Disease.

The 1993 Centers for Disease Control (CDC) classification system is widely used, and is related to the internationally-used WHO System. The CDC system classifies patients into diagnostic and immunologic categories. Category A includes asymptomatic patients with

HIV infection; Category B includes those diagnosed only with milder opportunistic syndromes such as oral thrush or hairy leukoplakia; Category C includes patients who have had an AIDS opportunistic complication. Patients in each disease category are stratified by CD4+ lymphocyte count: 0-199 cells/mm^3, 200-499 cells/mm^3, and >500 cells/mm^3 (MMWR 1992). The major advantages of the CDC system are its relative simplicity and the fact that it is widely used and understood. Rate of progression from intermediate stage disease to AIDS may be a useful outcome measure. In this regard, incidence of specific AIDS defining opportunistic infections might also be used as a measures of progression. It should be recognized that risk adjustment methods for baseline CD4, and perhaps for age and gender may be needed to allow interpretation of these data.

Measurement tools and items:	Progression to AIDS
Patient/member inclusion criteria:	Non-AIDS
Method for calculating indicator:	Incidence of progression
Source:	Chart, administrative data
Risk adjustment:	Age, sex, initial CD4

Symptoms

Symptom indices have been used in several studies. One of the only published measures is a 12 item index developed by Whalen and colleagues (Whalen 1994). Other symptom measures have been used in cohort studies (Revicki 1995) and clinical trials (Bozzette 1995; Justice submitted for publication). A set of 13 items measuring the bothersomeness of symptoms is being used in the HIV Cost And Utilization Study, a national survey of HIV infected patients in care (Berry 1998). An 20 item symptom scale closely related to the Whalen index has been proposed for use in ACTG clinical trials (Justice, personal communication). It would be useful to examine the performance of this index in pilot testing. If used, symptom scores probably need to be adjusted for age, gender and burden of comorbid disease, as well as for indicators of disease stage.

Measurement tools and items:	Whalen Index; ACTG symptom index
Patient/member inclusion criteria:	All
Method for calculating indicator:	Symptom score
Source:	Survey
Risk adjustment:	HIV disease stage, age, gender, comorbidity

Health Status

There are several existing measures of subjective functioning and emotional well-being that could be used as outcome measures. The majority of these are descriptive psychometric measures, and most are based on the Medical Outcomes Study pool of items and scales. The most commonly used measures of patient-reported functional status include the MOS-HIV Health Survey (Wu 1991), and related forms used in AIDS clinical trials (HIV PARSE (Berry 1991; ACTG-95 (Wu 1997); HCSUS instrument (Berry 1998). Measures of basic activities of daily living (ADL)(Katz 1963) have been used clinically and in several studies. Instrumental activities of daily living may show more variability in ambulatory populations and therefore may prove a more useful measure than basic ADLs (Wilson and Cleary 1996, Wilson and Cleary 1997). The provider-reported Karnofsky Performance Status score (Karnofsky 1947) has been used extensively in clinical trials.

Although psychometric measures have been used in a variety of clinical trial populations, it would be useful to have additional data on their performance in sub-populations, particularly those with lower literacy as well as non English speaking populations. There is little experience with measuring subjective health status in adolescents or children, directly or via parents.

An important question for health plans choosing to implement a measurement set is whether to recommend a generic or disease specific set of instruments. HIV targeted measures will probably discriminate better among groups of patients, and may also be more responsive to changes in status over time. In contrast, use of a generic health status measure, such as the

SF-36, would have substantial practical advantages in terms of efficiency and a diminished learning curve if it is being used routinely. A combined approach employing a brief generic health status measure supplemented by an HIV specific symptom battery would offer a third option. A possible solution would be to outline two strategies: the first which uses one or a battery of generic health status measures, the second which uses HIV targeted measures. It would also be possible to use clinically-based measures of health status including body mass index and mini mental status examination (MMSE) (Folstein 1975) and performance testing as indicators. However, the latter are not routinely collected and would be impractical to collect for quality assessment. Health status needs to be adjusted for age, gender, comorbidity and HIV disease stage.

Measurement tools and items:	SF36; MOS-HIV; ACTG QL601-602; HCSUS HRQOL
Patient/member inclusion criteria:	All
Method for calculating indicator:	Score
Source:	Survey
Risk adjustment:	Age, gender, comorbidity, disease stage

Health Utility

Utility information has been collected using several classical and more recently developed instruments including the Standard Reference Gamble (Revicki 1995), the Time Trade Off (Tsevat 1996), magnitude estimation or rating scales, and the EuroQol Instrument (EuroQol 1990; Wu 1997). Studies to date tend to confirm findings from other chronic diseases that different methods yield different answers, with pseudo-utility measures showing stronger relationships to other health status measures. These measures also tend to be less responsive to clinical changes than descriptive measures. Utility measures would also need to be adjusted for age, gender, comorbidity, and HIV disease stage.

Measurement tools and items:	Rating scale
Patient/member inclusion criteria:	All
Method for calculating indicator:	Score
Source	Survey
Risk adjustment:	Age, gender, comorbidity, HIV disease stage

B. Economic or Productivity Impact

Measures of productivity that have been used extensively include self-reports of bed days, days of missed work or reduced activity (adapted from the National Health Interview Survey), and work status (various sources). A few studies have collected data on annual income (Bozzette 1995). However, as many patients with HIV are not in the work force (and may never

have been), traditional measures of role function and work status may only be appropriate for individuals in the labor market. In some populations, generic measures of these concepts have displayed both floor and ceiling effects. This is an area in which health services research would benefit from the development and application of better measures. At the current time, items asking about bed days and days of reduced activity appear to be the most practical. Analyses should be adjusted for age, gender, and comorbidity, and HIV disease stage

Measurement tools and items:	Bed days, days of reduced activity
Patient/member inclusion criteria:	All
Method for calculating indicator:	Mean number of days
Source	Survey
Risk adjustment:	Age, gender, comorbidity, HIV disease stage

C. Satisfaction

There are fewer existing instruments to measure patient ratings of quality of care / satisfaction with various aspects of care. One of the earliest measures was described by Cleary and Fahs 1992. A promising measure is being used in the HIV Cost and Service Utilization Study (see appendix).

Important domains to assess include: access (Cunningham 1995), communication (compassion and information), coordination of services and technical care. As ART becomes a

more essential part of HIV treatment, additional domains may assume greater importance. Questions concerning access and quality of specific services are being used in an evaluation of a Capitated AIDS plan (personal communication), but have not been tested. These may include explanation of medications and expected side effects, and conveyance of strategies to cope with the latter. Cultural competence of providers will be an important consideration in the future, but would be difficult to assess at this time.

As with patient reported health status, an important question will be whether HIV specific satisfaction scales are necessary for use by health plans. Generic measures developed by the GHAA or CAHPS (Hays 1997) may provide adequate coverage of domains most salient to persons with HIV. However, generic measures are likely to be less sensitive to differences among groups or changes in practice over time. Two potential strategies could be recommended: the first which uses a generic satisfaction measure, and a second which applies an HIV targeted measure.

One specific aspect of the process of HIV care is effective communication between physician and patient, both with regard to conveying information, and to delivering care with respect and caring that fosters a climate of acceptance and comfort. These could be evaluated using patient reports of what interactions have occurred, as well as ratings to the degree on which these interpersonal aspects of care are present.

Satisfaction scores might require adjustment for comorbidity and HIV disease stage. As ratings of quality of care are sometimes influenced by cultural and socioeconomic factors, it may be worthwhile to stratify these analyses by race or payer status.

Measurement tools and items:	Cleary Satisfaction; HCSUS satisfaction Questionnaires
Patient/member inclusion criteria:	All
Method for calculating indicator:	Score
Data source	Survey
Risk adjustment:	Comorbidity, HIV disease stage

D. Self-Efficacy

Another potentially important concept to assess is patient self-efficacy for self-management and adherence to medication. Systems of care for chronic diseases should help patients develop both self-management skills and the confidence (self-efficacy) to be collaborators in care. Self-efficacy for disease self-management and for medication use is therefore an important intermediate care outcome. Self-efficacy improvements have been associated with fewer symptoms in HIV patients (Gifford et al., JAIDS in press), and with improved function and quality of life in a number of other chronic diseases (Lorig et al. 1993; Clark et al. 1992; Gonzalez et al. 1990). Measures for evaluating self-efficacy in HIV patients are currently being developed (Shively, Gifford et al. 1998), but no HIV self-efficacy measures have been published to date.

Measurement tools and items: Not recommended

Patient/member inclusion criteria:

Method for calculating indicator:

Source:

Risk adjustment:

E. Essential Care Processes

Information about essential care processes may be obtained from medical records or directly from patient self-report. Areas include prevention, screening and treatment. A general principle for selection of guidelines is that they reflect adequate care. In addition, providers should not be penalized for care processes that are in the vanguard of current practice. In some cases, although published guidelines describe a strict set of treatment criteria, measures applied at the plan level may be more lenient. For example, practices that are not frankly "not recommended" might in some instances be counted as "acceptable" treatment.

Prevention:

Some recommend that all patients should receive counseling about the means of transmission of HIV and high risk behaviors, and risk reduction behaviors (e.g. safer sex, bleaching, use of clean needles)(CDC Guidelines 1994). However, there is little evidence that untargeted education is effective in decreasing HIV transmission.

A more focused recommendation would be to assess HIV risk in all patients, and to counsel those with risks to modify their behavior. The CDC recommends assessment of risk factors for HIV in all adolescent and adult patients by obtaining a sexual history and history of drug use (particularly injection use) and sexually transmitted diseases. The QATool indicators require that all patients be asked about their sexual history, injection drug use, and sexually transmitted diseases. Individuals who have had more than 2 sexual partners in the past 6 months are recommended for counseling. Patients with a history of injection drug use, who are seeking treatment for substance abuse or sexually transmitted diseases, who exchange sex for money, men who have had sex with more than two male partners in the past 6 months, transfusion recipients between 1978 and 1985, and partners of HIV infected persons or injection drug users are recommended for counseling and testing. Currently HIV infected patients should also receive counseling about harm-reducing practices such as safer sex and avoidance of needle sharing.

A tenable strategy for managed care might be to document evidence for obtaining a history for injection drug use, sexual behavior, sexually transmitted diseases and transfusion, and documentation of counseling and/or testing if indicated. Specific programs within managed care

plans, such as STD or substance abuse programs might be an indicator for counseling and offer of testing. However, confidentiality concerns would also be important here, as individuals might not want it known that they have been treated for an STD or substance abuse.

A broader measure would be documentation of an HIV risk assessment for all adults and adolescents from a random sample of charts, with documentation of counseling and testing (but not necessarily HIV test results) of all individuals found to have HIV risk factors.

In the summary table, we have included an indicator that consists of chart documentation that an HIV risk assessment has been performed. The denominator would be all adolescents (age $11) and adults in an MCO. There would be no risk adjustment, but analyses might be stratified by age group, race, insurance status and sampling frame (e.g. methadone clinic).

Measurement tools and items:	Performance of HIV risk assessment
Patient/member inclusion criteria:	All adolescents and adults; Increased risk individuals
Method for calculating indicator:	Percent with documentation
Source:	Chart
Risk adjustment:	None

Screening:

HIV antibody testing should be recommended to anyone at increased risk for exposure to HIV including men who have sex with men, commercial sex workers, injection drug users, partners of injection drug users, people with hemophilia, recipients of blood products, particularly before the early-mid 1980s, and people with occupational exposures. Pregnant women and sexually active individuals may also be considered for testing. HIV-1 ELISA with confirmatory Western Blot, and pre and post test counseling are recommended. (Walters 1993; CDC 199)

A number of organizations including the CDC recommend that all pregnant women be counseled and offered testing for HIV. This is particularly important as it has been demonstrated that ART during pregnancy, labor and the post-partum period dramatically reduce the rate of mother-to-infant HIV transmission. Also, HIV infected women should be counseled not to breast feed their infants (at least in the U.S.) in order to circumvent transmission (MMWR 1998;47: No. RR-2).

In the Summary Table, the proposed indicator is for documentation of HIV counseling and the offer of HIV testing to all individuals at increased risk. For pregnant women, the denominator would be relatively easy to construct, as compared to other risk groups, perhaps making it worthwhile to construct a separate indicator for pregnant women. Analyses could be stratified by age, race, risk factor and insurance status.

Measurement tools and items: Documentation of HIV counseling/offer of testing

Patient/member inclusion criteria:	Pregnant women; Individuals at HIV risk
Method for calculating indicator:	Percent with documentation
Source:	Chart
Risk adjustment:	None

Treatment:

Published treatment guidelines include recommendations for antiretroviral treatment, prophylaxis, acute treatment of opportunistic infections and chronic treatment to follow. These include recommendations that providers address issues related to patient adherence to medications (USPHS; International AIDS Society - USA; DHHS Panel on Antiretroviral Therapy for Adults and Adolescents 1998). Appropriate monitoring and screening for opportunistic infection are also necessary elements of high quality care.

Antiretroviral Treatment

Regimens are classified as preferred, alternative, and not recommended in the Measurement Summary. It is important to note that the DHHS guidelines have been revised three times since the first document was reported on November 4, 1997. In the foreseeable future, these and other guidelines will require periodic updates. To evaluate quality of care, annual review will be necessary to define "acceptable" antiretroviral therapy. One approach would be to evaluate the proportion of patients who are currently receiving acceptable therapy. However, this does not take into account variations in patient preferences for treatment. An alternative would be to define acceptable treatment as "having ever been offered a protease

inhibitor", or "having ever taken a protease inhibitor." However, this discounts the role of the provider to convince patients of the benefit of ART, and their ability to foster long-term maintenance therapy. It may be desirable to record both of these indicators. The measure listed includes acceptable treatment or documentation that treatment was offered and refused. The denominator would be patients with AIDS or a CD4 count < 500, or a viral load > 20,000. A simpler measure might consist of acceptable treatment offered ever, using the same denominator. Risk adjustment would not be used, but analyses could be stratified by age, gender, race, HIV risk factor or insurance status.

It has become apparent that a high degree of adherence to ART is necessary for successful suppression of viral replication. Current multidrug regimens require adherence with the number and timing of pills, as well as dietary requirements. Treatment failure can result if patients are not adequately prepared before starting, the regimen does not fit their lifestyle, or they cannot tolerate drug-related adverse effects. There is no accepted indicator of adherence to medication that can be applied at this time. However, appropriate counseling about adherence to medication is an important element of good process of care. Thus, a potential process measure might be receipt of counseling about adherence to ART. Documentation of the initial discussion about adherence may be the most practical.

Measurement tools and items:	Acceptable or offered ART
Patient/member inclusion criteria:	AIDS or CD4<500 or VL>20,000
Method for calculating indicator:	Percent with acceptable regimen or documentation of offer
Source:	Chart
Risk adjustment:	None

Measurement tools and items:	Ever offered ART
Patient/member inclusion criteria:	AIDS or CD4<500 or VL>20,000
Method for calculating indicator:	Percent with documentation of offer
Source:	Chart
Risk adjustment:	None

Monitoring:

Recommended treatment is determined by evidence of immunosuppression as represented by disease stage, CD4 count and HIV viral load. After a diagnosis of HIV is established, CD4 count and HIV viral load should be measured. However, in practical terms, it is difficult to ascertain when this initial visit occurred. Thereafter, frequency of CD4 and viral load testing should depend on the level of immune suppression. Many guidelines recommend an initial complete blood count, viral load and CD4, then every 4-6 months if CD4 >300, and every 3 months if CD4 <300.

There are additional nuances in recommendations for viral load testing that may be difficult to operationalize as quality measures. For example, guidelines also recommend measurement of viral load around initiation or changing of therapies. However, this level of detail may be difficult to achieve. There is also some evidence that more frequent viral load determinations may be beneficial to the patient (Haubrich R, personal communication). However, measures do not penalize more frequent use of test, and modification of this parameter should await more definitive results.

The measure given in the Summary Table is for CD4 and viral load testing at the initial visit, followed by testing at least every 6 months if CD4 > 300, and every 3 months if CD4 <300. Again only risk stratification is suggested.

Measurement tools and items:	CD4 and VL testing
Patient/member inclusion criteria:	Patients at initial visit
Method for calculating indicator:	Percent with documentation of test or offer
Source:	Chart; administrative
Risk adjustment:	None

Measurement tools and items:	CD4 and VL testing
Patient/member inclusion criteria:	CD4 > 300
	CD4 < 300
Method for calculating indicator:	Percent with at least 1 test in last 12 months (CD4>300)

	Percent with at least 2 tests in last 12 months (CD4<300)
Source:	Chart; administrative
Risk adjustment:	None

Screening:

Recommended screening tests for development of opportunistic infections include at least one measurement of toxoplasma IgG, documentation of syphilis serology and PPD testing for people who have never had a positive test (see Appendix). Additional recommended screening tests include Hepatitis B and C serology, CMV antibody, annual fundoscopic examination for patients with a CD4<100, and Pap smears for women. Detailed recommendations are available for comprehensive evaluation for women with HIV infection.

In the Summary Table, we have listed documentation of PPD (or history of a positive PPD), VDRL and toxoplasma antibody testing, and documentation of an annual Pap test for women. The denominator is all HIV infected patients, with no recommended risk adjustment. Additional screening tests could also be included.

Measurement tools and items:	Documentation of PPD (or history of positive PPD) VDRL, toxoplasma antibody testing; Pap test
Patient/member inclusion criteria:	All; women
Method for calculating indicator:	Percent with documentation

Source: Chart

Risk adjustment: None

Prophylaxis:

Prophylactic medication is recommended to prevent pneumocystis carinii pneumonia, toxoplasma gondii, and mycobacterium avium complex. It should be noted that in some plans, there may not be an adequate number of subjects to evaluate MAC and Toxoplamosis prophylaxis.

A controversial point is whether prophylactic treatment should be based on the patient's lowest CD4 count ever, or on their current CD4 count. This is also a practical issue, as the patient's nadir count may not be recorded on their current patient record which is available for abstraction. A number of randomized clinical trials are underway to determine if prophylactic medications can be safely stopped if the patient has a large and sustained rise in CD4 count in response to HAART. At the current time, use of current CD4 count as a criterion for prophylaxis would be practical and fair.

Although CD4 count is used universally as an indicator of immune status, CD4 percent has also been shown to have prognostic importance. Although less widely used, CD4 percent may also be used as a criterion for prophylaxis. However, it seems inadvisable to judge providers or organizations on the basis of patients who qualify for prophylaxis on the basis of CD4 percent but not total CD4 count.

Recommendations for prophylaxis are changing based on the results of research. For example, a short course regimen of Rifampin and Pyrazinamide for 2 months will likely become an acceptable alternative to 12 months of INH. Thus, what is deemed "acceptable" prophylaxis will require periodic revision.

We have listed chart or pharmacy record of prophylaxis for PCP first, for patients with a current CD4 count <200, as well as MAC and toxoplasmosis for patients with CD4 < 50.

Measurement tools and items:	PCP chemoprophylaxis
Patient/member inclusion criteria:	Current CD4<200
Method for calculating indicator:	Percent with documentation of prophylaxis
Source:	Chart or Administrative
Risk adjustment:	None

Measurement tools and items:	Toxoplasma and MAC prophylaxis
Patient/member inclusion criteria:	Current CD4<50
Method for calculating indicator:	Percent with documentation
Source:	Chart; Administrative
Risk adjustment:	None

<u>Treatment of Opportunistic Complications</u>

Specific recommendations are available for acute treatment of opportunistic infection, and treatment following acute infection (pneumocystis carinii pneumonia, toxoplasma gondii, and mycobacterium avium complex, cytomegalovirus retinitis, cryptococcal meningitis, histoplasmosis, and coccidiodosis) (see Appendix). Quality measures based on these guidelines are not detailed here. It should be noted that as the incidence of opportunistic infection has declined sharply since the advent of HAART, the feasibility of these measures is diminished for lower volume providers. In addition, data may be difficult to collect as care may be delivered in a variety of settings (e.g. inpatient, outpatient, home care). Standards of care in this area are also evolving.

Measurement tools and items:	Appropriateness per explicit criteria
Patient/member inclusion criteria:	Specific opportunistic infection
Method for calculating indicator:	Percent with appropriate therapy
Source:	Chart
Risk adjustment:	None

Symptom Based Measures

Most patients seek medical care because they want relief from symptoms. Therefore, evaluating how providers respond to symptoms can be an important part of quality assessment (Wilson and Cleary, 1995). However, designing measures that evaluate how providers respond to symptoms can be difficult. Identifying records of patients presenting with a specific symptom (e.g. cough, or diarrhea) is beyond the capabilities of most clinical or administrative databases, and the clinical details necessary to evaluate responses to symptoms are unlikely to be present.

The HIV Cost and Services Utilization Study (HCSUS) uses a patient questionnaire with detailed questions that evaluate symptoms and their severity, care seeking for each symptom, and care received for each symptom during the clinical encounter. For example, patients who report having had a cough in the past 6 months are asked a series of questions about symptoms associated with the cough episode (e.g. “Did it hurt to cough?”, Were you coughing anything up?” “Did you also have a fever above 101 degrees or shaking, chills or sweats?”), and questions about diagnostic tests and treatments provided (e.g. examination of the lungs, chest x-ray, sputum analysis, antibiotics). While labor-intensive, this approach allows for detailed, patient-centered evaluations of the quality of care for specific symptoms. Similar symptom “cascades” have been constructed to evaluate care for headache, diarrhea, weight loss, Kaposi Sarcoma lesions, and vaginal discharge in HIV patients.

There is some evidence that reporting of symptoms may vary across different cultures and ethnicity. Thus, it may be important to stratify these analyses by race or language.

Measurement tools and items:	Appropriate per explicit criteria
Patient/member inclusion criteria:	Presence of symptom in medical record
Method for calculating indicator:	Percent meeting criteria
Source:	Chart
Risk adjustment:	None

Vaccination

Recommendations for vaccination include Pneumovax (at least once, and potentially every 7 years), Hepatitis B vaccine (series of 3 injections or documentation of seropositivity), and Influenza (annually). In the summary table, we have listed the first only Pneumovax due to complexity of determining Hepatitis B serostatus from readily available data sources and controversies about the relationship of influenza vaccination to increase viral burden.

Measurement tools and items:	Pneumovax ever received
Patient/member inclusion criteria:	All
Method for calculating indicator:	% with documentation
Source:	Chart
Risk adjustment:	None

V. Field Test

As most of the proposed measures have not been evaluated as quality indicators, data are needed on the feasibility of collecting them. To this end, FACCT will conduct a field test at approximately 3 sites. This test will aim to evaluate the feasiblity of the measures rather than estimating their variation across plans. The sample should include an adequate number of individuals with different risk factors for HIV, women, and members of ethnic minorities (African Americans and Latinos at a minimum).

In cooperation with the HIV Cost and Services Utilization Study (HCSUS), some of the proposed measures will be tested on a nationally representative sample of patients with HIV who are currently in care. In this ongoing project 2,864 respondents were identified using a three-stage stratified random sample of 43 geographic regions, 177 providers and their patients. Data elements include service utilization, symptoms, laboratory data (e.g. CD4 counts and viral loads), costs, patient satisfaction. Data sources include patient interviews, chart reviews, pharmacy and administrative data. As with other efforts in HCSUS, case finding will rely on the use of provider lists.

VI. Case-Mix

Case-mix adjustment will be necessary for comparison of outcomes. Analyses may either be stratified, or adjusted for factors related to the outcome of interest. The desired

case-mix measure may depend on the purpose for which the data are being collected. As a rule of thumb, for measures of outcome, case-mix adjustment should include as many variables as possible that are known to be related to the outcome of interest. However, to answer specific questions, e.g. the health status of African-American patients across organizations, stratification is necessary. In general, it is preferable to consider results in the aggregate, and then to stratify for race, economic status or insurance status rather than adjusting for these variables. This avoids implications that a lower standard of care may be acceptable for certain populations. At the same time, it recognizes the burden of unmeasured severity that accompanies disadvantaged patients (Pincus 1998)

For measures of the process of care, it can be argued that case-mix adjustment is not needed. However, in order to allow fair comparisons among MCOs, it may be desirable to stratify analyses by demographic subgroups (e.g. gender, races, HIV risk group, and insurance status). This avoids comparisons without consideration of factors outside of an MCO's control, e.g., appropriate antiretroviral use in an MCO with a predominantly insured patient populations compared with an MCO serving a largely Medicaid population.

There are several variables that have been shown to predict progression to AIDS and death (Justice, Rabeneck). For people with HIV who have not yet developed AIDS, several of the conditions previously classified as AIDS Related Complex (ARC) such as thrush and oral hairy leukoplakia have been shown to be predictive of progression independent of CD4 cell count.

The probability of death with AIDS is a function of viral activity and immune status, and the condition of other organ systems. Viral load and CD4 cell count are the best available measures of viral activity and immune function. Signs and symptoms of HIV related neurologic disease (dementia, confusion, depression, sleep disturbance, seizures, and paresthesias) carry a poor prognosis. Weight loss and diarrhea relate to nutritional status and functional compromise of the gastrointestinal tract. Albumin is also a prognostic indicator of mortality. Hematologic function and decline of any one of these cell lines and the relative number of lines involved has prognostic significance. General functional status also has prognostic importance (Justice; Stanton). Clinical diagnoses (Kaposi's sarcoma, tuberculosis, pneumocystis carinii pneumonia, toxoplasmosis, cytomegalovirus infection, cryptococcosus, malignancies) are predictive of patient outcomes even after adjustment for CD4 cell count. One study has already showed that CD4, ADL status, bone marrow function as reflected in hematocrit, white blood cell count, and platelet count, albumin, neurologic symptoms, and AIDS-related diagnoses all offer independent prognostic information (Justice).

Comorbidity is likely to become more important in adjusting for severity of illness as people with HIV live longer. One study has already demonstrated that comorbid conditions measured using the Charlson Comorbidity Index (Charlson 1987) partially explain excess mortality among older people with HIV (Welch 1998). Age is also recognized to be independently associated with survival.

Psychiatric disease has not been consistently related to mortality in HIV, but concurrent major psychiatric diagnoses are known to be associated with adherence to treatment regimens and with utilization.

VII. Issues in the Selection of Indicators -

Selection of quality indicators requires balancing medical science and practicality. A measurement set should reflect the best evidence for effective practice. However, costs of the data collection process can not exceed the value of the information to important stakeholders. The labor intensive nature of chart abstraction methods and the multiple sources of data result in uncertainty about the timing of events and make it difficult to evaluate the quality of a specific episode of care. On a national scale, this precludes evaluation using the detailed standards that define good clinical care. A measurement set represents a compromise, consisting of a set of indicators that can be collected efficiently for groups of patients. Since a limited set of data elements can be selected, the indicators should reflect what is important to patients.

To be fair, it is important to select indicators for which organizations are accountable. Indicator data can be used internally by organizations to fuel quality improvement efforts, or for evaluation and comparison to others. For the purposes of evaluation, a reasonable strategy may be to give organizations the benefit of the doubt by selecting relatively low threshold for indicators. Our experience suggests that even a low threshold will reveal substantial distance between optimal and observed practice. However, ideal thresholds should correspond to

treatment with a high probability of being effective. It should also be recognized that areas selected for evaluation are the ones most likely to show improvement. Therefore it is important to create positive incentives.

Focus Groups

As part of an initial process to discern what is important to patients, on May 26, 1998, the Foundation for Accountability (FACCT) conducted the first of four focus groups for people who have been diagnosed with HIV and AIDS. A diverse group of 8 participants attended the focus group in Portland, Oregon. These individuals shared their perceptions of quality of care for persons with HIV/AIDS and revealed their own preference for information about the quality of care for this disease. As part of this exercise, patients were asked to sort candidate quality indicators into groups that were more important vs less important. Based on the sorting process, measures were ranked as follows, (measures mentioned most often as important are indicated in bold):

1. **Prevention of opportunistic diseases**
2. **Involvement in care and treatment decisions**

   Effective relationships with health care providers (tie)
3. **Overall health status**
4. **CD4 counts and viral load testing**

5. **Anti-retroviral treatment**

   Access to health care and medical services (tie)

6. **Self-management education**

7. **Screening and referral for mental health and social services**

8. **Access to social and mental health services**

9. **Processes for effective symptom management (by chart review)**

   Patient reported effective symptom management (outcome) (tie)

10. **Preventive counseling for people at risk of contracting HIV**

11. **Vaccinations**

12. **Days lost from work/school/regular activities**

13. **Regular eye exams**

14. **Achieving undetectable viral load**

15. **Planning for care at the end of life**

People assumed that forming a "partnership" with a physician knowledgeable in treating HIV would lead to many of the right processes and outcomes. When asked whether they would prefer quality information in terms of how often anti-retroviral therapy was offered to people as opposed to how often it was actually received, they said it was important to know both. Several said measures should include information about whether patients felt adequately informed about choices of therapy, side effects and alternatives before deciding about ART.

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APPENDIX 1:

Table 1. PROPOSED CLINICAL GUIDELINES (Adults)

Prophylaxis

Pneumocystis carinii pneumonia

CD4 count <200 or oral thrush or fever≥2 weeks or CD4% <15%

TMP-SMZ 1SS or DS po qd or tiw
or
Dapsone 50mg or 100 mg PO qd, dapsone 100 qd
or
Aerosolized (+/- pyrimethamine, leukovorin),
or
Aerosolized pentamidine 300 mg qm

Mycobacterium tuberculosis

TST ≥5mm or prior + without treatment or contact with active case

INH 300 + pyridoxine 50 x 12 mo
or
INH 900 + pyridoxine 50 mg biw x 12 mo
or
Rifampin 600 qd x 12 mo

Mycobacterium avium complex

CD4<50

azithromycin 1200 qw or

clarithromycin 500 mg bid or

rifabutin 300 mg qd

Toxoplasma gondii

Positive antibody(IgG) and CD4<50

TMP-SMZ 1 ss qd

Dapsone 50 qd + pyrimethamine qw + leucovorin qw

Vaccination

Pneumovax - once (unless CD4 <200 then optional)

Hepatitis B vaccine - series of three shots if HepBAg and HepBAb negative

Influenza vaccine - annually

Screening:

Toxo IgG measured at least once

Syphilis serology measured at least once

PPD testing if never had positive test

Annual Papanicolau test for women

Hepatitis B Ab

Hepatitis C Ab

CMV IgG

Annual fundoscopic exam for CD4 < 100

Monitoring

Initial visit for HIV: CBC, CD4, HIV viral load

If CD4>300: CD4 and viral load every 6 months

If CD4<300: CD4 and viral load every 3 months

Antiretroviral Treatment

Start (offer) anti-retroviral treatment for:

AIDS diagnosis or symptomatic HIV disease

No symptoms, CD4 < 500 or viral load >20,000 (using RT-PCR)

Preferred - 1 highly active protease inhibitor (column A) + 2 NRTIs (column B)

Column A	**Column B**
Indinavir	ZDV + ddI
Nelfinavir	d4T + ddI
Ritonavir	ZDV + ddC
Fortovase	ZDV + 3TC
Ritonavir +	d4T + 3TC
Saquinavir (SGC or HGC)	

Alternative - 1 NNRTI (e.g. Nevirapine, Efavirenz) + 2 NRTIs

Saquinavir + 2 NRTIs

Not generally recommended: clinical benefit demonstrated but initial virus suppression is not sustained in most patients [consider classifying this under “acceptable”]

2 NRTIs

Not recommended: evidence against use, virologically undesirable

All monotherapies

d4T + ZDV

ddC + ddI

ddC + d4T

ddc + 3TC

APPENDIX 2:

Table 2. Proposed Accountability Measurement Summary

	Evaluation Criteria					
Indicators	**Measurement Tools and Items**	**Patient/Member Inclusion Criteria**	**Data**	**Method**	**Risk Adjustment**	
					A	**S**
Health						
Immunologic/ Virologic	CD4, VL	all; on ART; initial ART for $12 wks	annual	change in CD4; % undetectable	age sex	race
Progression	Progression to AIDS	non-AIDS	annual	% with progression	CD4 age sex	race risk ins
Symptoms	Whalen Index	all	annual	score survey	age sex com cdc	race risk ins
Health status	SF36/SF12 MOS/HCSUS	all	annual	score survey	age sex com cdc	race risk ins
Utility	Rating scale	all	annual	score survey	age sex com cdc	race risk ins
Economic	bed days, days reduced activity	all	annual	mean survey	age sex com cdc	race risk ins
Satisfaction	GHAA/CAHPS HCSUS/Cleary	all	annual	score survey	com cdc	age sex race risk ins
Essential Care Processes						
Indicators	**Measurement Tools and Items**	**Patient/Member Inclusion Criteria**	**Data**	**Method**	**Risk Adjustment**	
Screening	History of MSM, blood, std, idu	all or increased risk population (e.g. STD or methadone)	ever	% with documented discussion in chart	no	age sex race ins source
HIV Testing	HIV counseling and testing offered	at incr HIV risk; pregnant women	ever; during pregnancy	% with documented offer in chart	no	age race risk ins
Indicators	**Measurement Tools and Items**	**Patient/Member Inclusion Criteria**	**Data**	**Method**	**Risk Adjustment**	

Treatment	Acceptable* or offered	AIDS,CD4<500, VL>20K	annual	% with acceptable or offered in chart or pharmacy	no	age sex race risk ins
Monitoring	CD4, VL at baseline, then every 3-6 months	all 300 < CD4 >300	annual	% with test in chart or admin	no	sex race risk ins
oi Screening	PPD, VDRL, toxo; Pap	all; women	ever; annual	% documented in chart or admin	no	sex race risk ins
Prophylaxis	PCP prophyl MAC prophyl Toxo prophyl	current CD4<200 current CD4<50	annual	% with acceptable in chart	no	sex race risk ins
Symptom	Per Explicit Criteria	Symptom reported in chart	annual	% meeting criteria in chart	no	sex race lang risk ins
Vaccine	Pneumovax ever	All HIV	annual	% document in chart or admin record	no	sex race risk ins

* Redefined annually **ins** = insurance status, **cdc** = CDC stage, **coM** = comorbidity, **risk** = HIV risk factor, **oi** = opportunistic infection

APPENDIX 3: Examples of Available Patient Reported Outcome Instruments

Symptoms

Whalen Symptom Index

Aids Clinical Trials Group (ACTG)

Utility

Rating Scale

Quality of Life

MOS-HIV Survey

ACTG-95

Health Care Cost and Utilization Survey(HCSUS)

Satisfaction

HCSUS

Utilization

Disability items