HIV/AIDS CLINICAL CARE QUALITY ASSURANCE PROJECT

Trends in Clinical Performance & Clinical Outcomes at

Enhanced Medical Management Services Sites

Funded by the Massachusetts Department of Public Health HIV/AIDS Bureau

2001 to 2006



JSI Research & Training Institute, Inc.

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BACKGROUND

Since 2002, JSI has conducted biannual reviews of HIV/AIDS primary medical care provided in 21 sites for a clinical care quality assurance project funded by the Massachusetts Department of Public Health HIV/AIDS Bureau as part of their Enhanced Medical Management Services (EMMS). The purpose of this project is to evaluate performance in HIV clinical services and to identify opportunities for improving care and health outcomes for people living with HIV/AIDS.

Data elements and methods used in this project were adopted from a data collection strategy initially developed by JSI for the Massachusetts Department of Public Health ACT Now Program, which pre-dated EMMS. Same methods were used in data collection at both EMMS and Boston Public Health Commission's Ryan White Part A clinics.

Three cycles of review have been completed and seven years of data are available (2000 to 2006) for each participating site (Appendix). Our sample includes the original cohort of a random set of patients reviewed since 2000, patients newly entering care at the sites in 2001 and 2002, and patients newly diagnosed with HIV and entering care between 2003 and 2006.

JSI nurses and trained research assistants performed detailed medical chart reviews on a random sample of all active patients at each site (all patients were reviewed at sites with smaller HIV caseloads). In more recent years, many clinics have converted to electronic medical records and thus both paper and electronic sources were used to ensure the fullest data capture.

EVALUATION METHODOLOGY

The current report summarizes clinical performance and outcome measures that are emphasized by the Health Resources and Services Administration-HIV/AIDS Bureau (HRSA-HAB) and focuses on prevention, screening, and treatment services in HIV clinical care management.

With six annual years of data (2001 to 2006), we highlight the aggregate clinical performance of all EMMS sites reviewed. Using established national treatment guidelines and IHI and HRSA benchmarks where available, we present aggregate site changes in performance and outcome measures from 2001 to 2006. Clinical performance indicators include provider visits, antiretroviral treatment, PCP prophylaxis, CD4 counts, and viral hepatitis screening. Outcome measures include viral load suppression, CD4 counts, and all cause hospitalizations.

We also present clinical performance and outcome data based on patient demographics including gender, foreign born vs. US born, and race and ethnicity, to identify potential opportunities for improving care. Chi-square analyses were used to test for statistical significance. Further, for select clinical and outcome indicators, we display data for each of the EMMS sites reviewed as well as data for the aggregate sample to illustrate potential variations across the sites.

To test for statistically significant differences across sites, we calculated 95% confidence intervals (CI) for the aggregate mean proportion of select indicators for years 2005 and 2006. Individual sites may use the 95% CI to evaluate their performance with aggregate sites' performance. Estimates within the bounds of the 95% confidence interval are not statistically significant and sites are assumed to be performing on par with all EMMS sites. Sites with

estimates that lie below the lower bound of the 95% CI have significantly lower performance than all sites. Similarly, sites with estimates that are above the upper bound of the 95% CI have significantly higher performance than all sites on a given indicator. The following formula was used for calculating 95% CI:

95% CI: p ± 1.96*sqrt((p-(1-p))/n)

Where p = Aggregate mean proportion and n = aggregate sample size

Performance measures or clinical outcome indicators with more narrow or tighter confidence intervals imply that the observed aggregate mean proportion closely approximates the true estimate of the aggregate performance of all sites combined.

POTENTIAL LIMITATIONS

As with any medical chart review project, the validity of findings depends on the clarity, accuracy, and completeness of data maintained in patient records. Differences in documentation procedures across clinics and among providers may affect results. Referrals to other providers or care received elsewhere including hospitalizations that are not systematically documented in patient medical records may lead to an underestimate of services provided. Further, results may also be underestimated if there were incomplete documentation or incomplete data transfers during the conversion period to electronic medical records at some sites.

While patients were randomly selected for observation during the first review cycle, oversampling of patients newly diagnosed with HIV in recent years may have reduced the overall generalizability of results presented.

Data presented for the various demographic subgroups were tested for statistical significance using chi-square analysis. While differences in certain clinical performance and outcome indicators were observed among various demographic subgroups in some years, findings should be interpreted with caution as these differences may be attributable to other potential confounding factors. Therefore, even statistical significant differences may not reflect actual disparities in care and further investigation is warranted prior to making conclusions about these trends.

Finally, due to some variability in sample sizes across individual sites, due caution should be exercised when making site to site comparisons and it is advisable to consult the sample size for each clinic provided in Appendix B.

REPORT OUTLINE

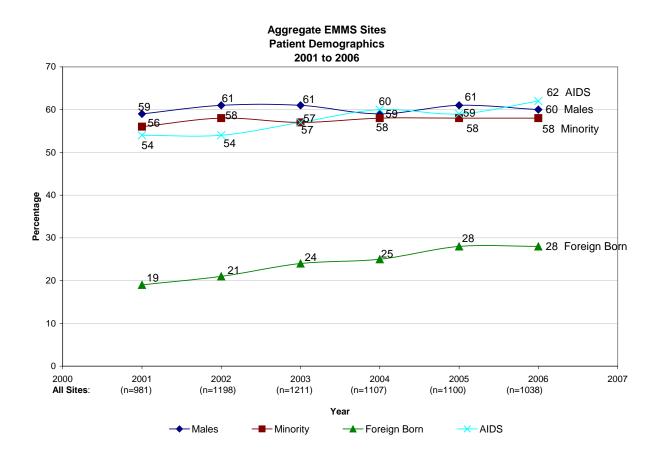
This report summarizes:

- 1) Trends or changes in patient demography across all MDPH-EMMS sites reviewed from 2001 to 2006.
- 2) Annual data on select clinical performance measures from 2001 to 2006 for all patients diagnosed on or before December 31, 2005, who were alive with at least 2 visits at the end of a given review year.
 - Aggregate EMMS sites' clinical performance between 2001 and 2006
 - Aggregate EMMS sites' clinical performance between 2001 and 2006 by select demographic subgroups (gender, place of birth: foreign born vs. US born, and race/ethnicity) with p-values where statistically significant
 - Comparisons among sites and aggregate EMMS sites: 95% CI
- 3) Annual data on select outcome measures including viral load, CD4 count, and allcause hospitalizations
 - Outcome measures for aggregate EMMS sites between 2001 and 2006 by select demographic subgroups (gender, place of birth: foreign born vs. US born, race/ethnicity) with p-values where statistically significant
 - Comparisons among sites and aggregate EMMS sites: 95% CI

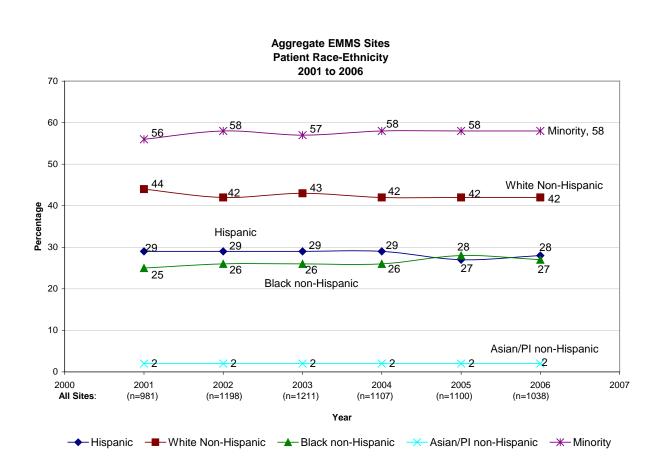
Data presented include all patients reviewed who were diagnosed on or before December 31, 2005, alive at the end of the year, with at least 2 visits during the review year.

PART I. PATIENT CHARACTERISTICS

EMMS/Ryan White Part A sites serve diverse patient populations that are traditionally disenfranchised and underserved. Thus, it is important to continuously monitor and recognize demographic trends for the planning and delivery of HIV clinical care to ensure that services and interventions are culturally and linguistically appropriate to changing client needs. Data on patient demographics including gender, age, race/ethnicity, nativity (foreign-born vs. US born), and HIV risk factors were collected. The figure below highlights the characteristics of all patients sampled at all sites from 2001 to 2006.

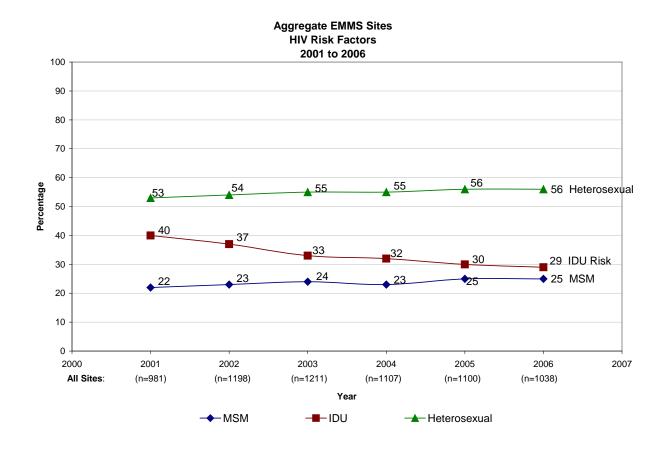


Consistently about 58% of all patients sampled at MDPH-EMMS funded sites were racial or ethnic minorities throughout the 6 review years. During the same period, we observed a gradual increase in the proportion of foreign born patients, from 19% in 2001 to 28% in 2006. Males represented about 60% of the patients sampled. The proportion of patients with an AIDS-defining condition increased slightly from 54% in 2001 to 62% in 2006.

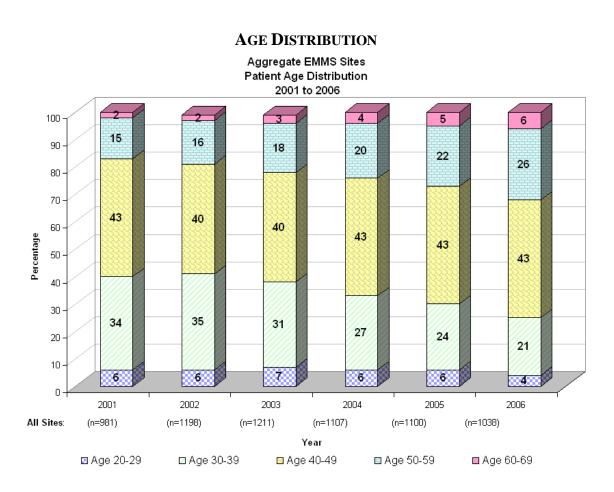


White non-Hispanic patients consistently represented about 42% of the patient sample. Among racial or ethnic minorities, Hispanic patients made up nearly 30% of all patients from 2001 to 2004, with a slight decrease noted in 2005 and 2006 (27%). The proportion of Black non-Hispanics patients increased slightly to 28% in 2005 and 2006, from 26% in prior years. Two percent of patients were Asian or Pacific Islanders.

Patient factors such as intravenous drug use and presumed HIV exposure risk (MSM/heterosexual) were also examined during the chart review process. Patients may be categorized in more than one risk group due to multiple transmission factors, and thus percentages may add to more than 100%.



Throughout the 6 review years, approximately 25% of patients sampled at all sites had MSM as a documented HIV risk factor. The proportion of patients with heterosexual transmission risk also remained constant around 55%. However, we did observed a gradual decrease in the proportion of patients with documented IDU risk from 40% in 2001 to 29% in 2006.



As a group, the proportion of patients between 50-59 and 60-60 nearly doubled from 17% in 2001 to 32% in 2006, reflecting aging in our cohort. In 2006, patients ages 50 and over represented 26% of the patient sample, compared to 15% in 2001. The proportion of patients ages 40-49 remained constant at roughly 43% throughout the 6 review years. However, we observed declines in the proportion of patients ages 30 to 39. In 2006, 21% of patients were ages 30 to 39, compared to 34% in 2001. Four percent of patients were ages 20-29 in 2006.

Table 1. Mean Age of Patients Sampled at All Reviewed EMMS Funded Sites, 2001 to 2006

	2001	2002	2003	2004	2005	2006
Total Sample Size	N=981	N=1198	N=1211	N=1107	N=1100	N=1038
Mean Age in Years	41.8	41.8	42.2	43.2	44.1	45.5
Continuing Cohort (n) New Patients (n)	41.8 (943) 40.1 (38)	43.0 (904) 38.1 (294)	42.9 (1022) 38.7 (189)	43.2 (1101) 47.0 (6)	44.4 (994) 41.3 (106)	45.5 (1038) -
Standard Deviation Age Range	8.1 13-72	8.7 14-79	8.9 15-74	9.0 16-78	9.2 17-76	9.1 18-77

Note: Patients newly diagnosed in 2006 were excluded from the analysis for this report since they may not necessarily have been in care long enough to meet the performance standards.

In 2006, the mean age of patients in the continuing cohort was about 46 years old, compared to a mean of 42 years in 2001. In all years except 2004, patients newly entering into care or newly diagnosed tended to be younger than patients in the continuing cohort.

AGGREGATE & SITE-SPECIFIC SAMPLE SIZE 2001 TO 2006

The table below provides the aggregate sample included in the analysis for this report as well as the site-specific sample sizes for each year reviewed from 2001 to 2006. Only patients reviewed who were diagnosed on or before December 31, 2005, alive at the end of the year, with at least 2 visits during the review year were included in the analysis.

	2001	2002	2003	2004	2005	2006		
Aggregate Sample Size	981	1198	1211	1107	1100	1038	Site Code	Size
Site-Specific Sample Size								
Clinic A	34	49	33	29	36	37	Α	S
Clinic B	35	56	40	35	32	28	В	S
Clinic C	48	62	58	55	60	57	С	М
Clinic D	61	74	77	75	68	56	D	М
Clinic E	49	54	57	55	53	53	Е	М
Clinic F	52	63	68	62	67	61	F	М
Clinic G	56	61	56	51	47	42	G	S
Clinic H	49	56	61	47	53	58	Н	М
Clinic I	61	61	64	63	63	60	Ι	М
Clinic J	59	68	66	59	54	52	J	М
Clinic K	36	57	63	57	63	63	К	М
Clinic L	43	43	43	37	40	36	L	S
Clinic M	105	137	172	160	147	141	М	L
Clinic N	53	84	107	92	84	71	Ν	L
Clinic O	32	32	39	36	26	29	0	S
Clinic P	68	71	66	70	65	63	Р	М
Clinic Q	58	78	68	55	59	46	Q	М
Clinic R	41	41	33	29	29	30	R	S
Clinic S	73	83	79	76	80	84	S	L

Table 2. Aggregate & Site-Specific Sample Sizes* from 2001 to 2006

*Sample sizes presented for each site above include all patients reviewed who were diagnosed on or before December 31, 2005, alive at the end of the year, with at least 2 visits during the review year.

*For certain clinical or outcome indicators presented in this report, a smaller number or a subset of the patient sample were used as the denominator. For example, a subset or only those patients who were on ART at last visit were included in the denominator for the clinical indicator "last viral load ≤ 400 ".

In the report for distribution to individual clinics, site names and site-specific sample sizes are not included to preserve anonymity. Instead, sites are arbitrarily assigned a letter code and are categorized by size of caseload in 2005 and 2006 as follows:

 Small
 ≤50/patients

 Medium
 51-74

 Large
 >75 patients

 THIS TABLE IS ALSO PROVIDED IN APPENDIX B

PART II. CLINICAL PERFORMANCE INDICATORS

For all patients in the original cohort and newly diagnosed patients, JSI collected data for each review year on the following process indicators that correspond with HRSA's HAB HIV Tier 1-Clinical Performance Measures:¹

- Visit with an HIV provider every trimester (4-month periods of Jan-Apr, May-Aug, and Sept-Dec)
- Immune function monitoring: CD4 counts
- PCP prophylaxis for patients with CD4 cell count < 200 cells/mm3
- ART Management
 - On ART when patient met CD4 count or viral load eligibility criteria current during the year of review
- Pregnant women with HIV on ART

Additional measures collected that will also be presented in this section include:

- Hepatitis Screening and vaccination:
 - Receipt of at least one dose of Hepatitis A vaccine if HAV antibody negative
 - Receipt of at least one dose of Hepatitis B vaccine if no evidence of prior hepatitis B infection (defined as any test for HBV antibody or antigen negative)
 - Hepatitis C treatment (of potential candidates)
- Pneumovax ever administered
- Cervical cancer screening
 - Annual Pap smears (women)
 - Pap smear results
 - Referrals for management of abnormal Pap smears

Additionally, we provide data on select performance indicators by demographic subgroups (gender, place of birth, race or ethnicity) to identify potential opportunities for improving care. Furthermore, for certain indicators, we display a listing of each site's performance in relation to the aggregate performance. Due to differences in the number of patients sampled at individual clinics, however, some caution must be exercised when making comparisons across sites.

Data presented include all patients reviewed who were diagnosed on or before December 31, 2005, alive at the end of the year, with at least 2 visits during the review year.

¹ HRSA HAB HIV Measures... <u>ftp://ftp.hrsa.gov/hab/1stTierPMs.pdf</u>

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A. CLINICAL PERFORMANCE MEASURES Aggregate Sites Reviewed & By Select Demographic Sub-Groups

MEDICAL VISITS

Medical visits with an HIV care provider with prescribing privileges are necessary for management of HIV disease and monitoring of clinical status via routine laboratory work. Current guidelines continue to recommend a medical visit every 3-4 months. In 2007, HRSA/HIV AIDS Bureau HIV Core Clinical Performance Measures defined the medical visit performance measure as being seen "two or more times at least 3 months apart during the measurement year". Patients recently diagnosed with HIV and those with complications or disease progression may require more frequent visits.

During our data collection process, we determined whether patients had a visit in each 4-month period (defined as Jan-Apr, May-Aug, Sept-Dec) or "trimester". Since we did not collect actual dates of visits until this last cycle, for the purpose of measuring site performance on this new HRSA indicator, we considered patients with visits in all three trimesters or any two trimesters as fulfilling the criterion set by HRSA in 2007 as described above.

Table 3. Percentage of Patients with Visits in 2 or more 4-month periods, Aggregate & by Subgroups									
	2001	2002	2003	2004	2005	2006			
Total Sample Size	n=981	n=1198	n=1211	n=1107	n=1100	n=1038			
	11-001	11-1100		11-1101	11-1100	11-1000			
Aggregate Sites									
Seen in ≥ TWO	90%	85%	89%	93%	91%	94%			
4-month periods									
By Condor									
By Gender			88%		90%				
Male	92%	85%	(p=0.01)	93%	(p=0.002)	94%			
Female	91%	86%	92%	94%	95%	96%			
By Place of Birth									
U.S. Born	92%	86%	90%	93%	92%	94%			
Familian Dama				(p=0.01)					
Foreign Born	92%	83%	88%	97%	91%	95%			
By Race or Ethnicity		000/			000/				
Minority	93%	83%	88%	94%	90%	96%			
White non-Hispanic	0.00/	(p=0.003)	000/	0 404	(p=0.08)	2 224			
White Holl-I hspanic	90%	89%	90%	94%	93%	93%			
Hispanic	92%	84%	87%	93%	91%	97%			
Black non-Hispanic	000/	(p=0.0004)	000/	0.40/	000/	(p=0.02)			
•	93%	82%	89%	94%	89%	94%			
Asian/PI non-Hispanic	100%	84%	95%	95%	95%	100%			
Other non-Hispanic	100%	44%	83%	100%	100%	93%			

In most years, at least 90% of patients reviewed at all sites combined had visits in at least two trimesters with an HIV medical provider with prescribing privileges. Female patients were significantly more likely to have consistent provider visits than males in 2003 and 2005, with no differences observed in other years. Foreign born patients were significantly more likely to have visits in at least 2 trimesters in 2004, though this difference disappeared in 2005 and 2006. In

2002, White non-Hispanic patients were significantly more likely to have regular provider visits than minority patients, but this difference disappeared from 2003 onwards. Overall, there appeared to be no consistent trends from year to year to suggest any differences by demographic subgroups.

able 4. Percentage	of Patients wit	h Visits in 2	or more 4-mor	nth periods, A	ggregate & Sit	e-Specific	
		2001	2002	2003	2004	2005	2006
Total Sample Size		n=981	n=1198	n=1211	n=1107	n=1100	n=1038
	n in ≥ TWO nth periods	90%	85%	89%	93%	91%	94%
By Site							
Clinic A		88%	78%	78%	86%	86%	97%
Clinic B		92%	75%	83%	94%	94%	93%
Clinic C		98%	82%	91%	91%	92%	98%
Clinic D		93%	85%	96%	91%	92%	96%
Clinic E		86%	86%	86%	96%	96%	96%
Clinic F		88%	89%	93%	97%	91%	97%
Clinic G		91%	95%	96%	87%	83%	91%
Clinic H		98%	91%	93%	97%	95%	94%
Clinic I		92%	83%	97%	94%	92%	90%
Clinic J		98%	94%	93%	97%	95%	92%
Clinic K		92%	89%	87%	95%	92%	96%
Clinic L		86%	86%	89%	98%	98%	100%
Clinic M		86%	82%	88%	94%	88%	92%
Clinic N		88%	83%	83%	95%	94%	96%
Clinic O		94%	94%	82%	94%	81%	93%
Clinic P		94%	95%	88%	97%	90%	96%
Clinic Q		93%	78%	79%	97%	85%	96%
Clinic R		91%	73%	94%	79%	97%	94%
Clinic S		95%	93%	93%	92%	95%	95%

Note: Total sample size for each site is provided in Appendix B.

In the table above, we present the percentage of patients with visits with an HIV prescribing provider in two or more trimesters each year by site. Due to the variability in sample sizes across the clinics, some site to site comparisons should be interpreted with caution.

In 2005, the aggregate mean percentage of patients with medical visits in 2 or more 4-month periods was 91% (95% CI: 89% to 93%). Based on the 95% confidence interval, Clinic O (81%), Clinic G (83%), Clinic Q (85%), Clinic A (86%), and Clinic M (88%) patients were less likely to have consistent medical visits with a provider compared to patients at all sites in 2005.

In 2006, the aggregate mean percentage of patients with medical visits in 2 or more 4-month periods was 94% (95% CI: 93% to 95%). Although rates were high, Clinic I (90%), Clinic G (91%), Clinic J and Clinic M (92%), and Clinic O and Clinic B (93%) patients were less likely to have provider visit(s) in 2 or more trimesters relative to patients at all sites combined.

CD4 COUNTS

According to DHHS Guidelines, monitoring of **CD4 counts** is an essential component of quality HIV care. As a measure of immune function, CD4 counts inform treatment decisions including the need for ART initiation, modification, or PCP prophylaxis. CD4 counts are also associated with disease prognosis and survival outcomes. Current US PHS guidelines recommend that CD4 counts be measured at least every three to six months. The 2007 HAB HIV Core Clinical Performance Measure for CD4 counts is 2 or more CD4 counts in a year that are at least 3 months apart (\geq 90 days).

This HRSA/HAB indicator was used for evaluating performance on this measure and is shown in the figure below for all EMMS clinics. Patients who were newly enrolled in the last months of the review year were excluded as they would not have been in care long enough to necessarily meet the performance standard. Proportions shown below represent patients meeting this criterion.

Table 5. Percentage of Patients with 2 or more CD4 (≥ 3 months apart), Aggregate & by Subgroups									
	2001	2002	2003	2004	2005	2006			
Total Sample Size	n=973	n=1131	n=1139	n=1107	n=1064	n=1038			
Aggregate Sites 2 or more CD4s,	81%	77%	82%	86%	85%	86%			
≥ 3 months apart									
By Gender	0.40/				000/				
Male	84% (p=0.02)	77%	81%	85%	86% (p=0.05)	88%			
Female	76%	77%	84%	86%	85%	84%			
By Place of Birth									
U.S. Born	80%	76% (p=0.01)	81% (p=0.08)	84% (p=0.07)	86%	86% (p=0.07)			
Foreign Born	84%	80%	87%	90%	85%	88%			
By Race or Ethnicity									
Minority	79%	73%	80% (p=0.03)	85%	83% (p=0.05)	86%			
White non-Hispanic	83%	82%	86%	87%	88%	87%			
Hispanic	76%	75%	78% (p=0.10)	81%	85% (p=0.006)	85% (p=0.06)			
Black non-Hispanic	81%	71%	81%	88%	80%	86%			
Asian/PI non-Hispanic	89%	88%	95%	89%	95%	95%			
Other non-Hispanic	86%	38%	75%	86%	94%	93%			

Between 77% and 86% of patients at all sites combined had two or more CD4 counts that were at least 3 months apart during 2001-2006. In 2001 and 2005, males were more likely to have at least 2 CD4 counts measured. In most years, foreign born patients were more likely to have regular CD4 counts than US born patients, with statistically significant differences in 2002 (p<0.05) and 2003, 2004, and 2006 (p<0.10). In 2005 and 2006, a greater percentage of White non-Hispanics had regular CD4 counts than racial or ethnic minorities.

	2001	2002	2003	2004	2005	2006
Total Sample Size	n=973	n=1131	n=1139	n=1107	n=1064	n=1038
Aggregate Sites 2 or more CD4s, ≥ 3 months apart	81%	77%	82%	86%	85%	86%
By Site						
Clinic A	74%	77%	83%	72%	92%	95%
Clinic B	86%	77%	76%	89%	97%	89%
Clinic C	67%	59%	68%	71%	80%	91%
Clinic D	87%	84%	96%	91%	91%	91%
Clinic E	85%	75%	88%	95%	94%	94%
Clinic F	26%	44%	46%	52%	55%	54%
Clinic G	88%	90%	95%	90%	88%	83%
Clinic H	92%	89%	92%	85%	92%	84%
Clinic I	80%	81%	91%	89%	93%	82%
Clinic J	88%	85%	89%	90%	79%	88%
Clinic K	97%	86%	92%	95%	95%	94%
Clinic L	74%	80%	78%	84%	90%	89%
Clinic M	90%	84%	84%	88%	51%	85%
Clinic N	96%	78%	86%	90%	94%	93%
Clinic O	84%	87%	81%	89%	84%	79%
Clinic P	76%	71%	73%	80%	83%	90%
Clinic Q	78%	70%	76%	96%	77%	83%
Clinic R	71%	68%	73%	79%	79%	77%
Clinic S	88%	79%	88%	91%	96%	92%

Table 6. Percentage of Patients with 2 or more CD4 (≥ 3 months apart), Aggregate & Site-Specific

In the table above, we present the percentage of patients with undetectable last viral loads each year by site. Due to variability in sample sizes across the clinics, some site to site comparisons should be interpreted with caution.

In 2005, the aggregate mean percentage of patients with 2 or more CD4 counts that were at least 3 months apart was 85% (95% CI: 83% to 87%). Based on the 95% confidence interval, patients at Clinic F (55%), Clinic M, Clinic Q, Clinic J, Clinic S, Clinic R (<80%), Clinic C, Clinic O and Clinic P (<85%) were less likely to have regular CD4 counts than all patients combined.

In 2006, the aggregate mean percentage of patients with 2 or more CD4 counts that were at least 3 months apart was 86% (95% CI: 84% to 88%). At Clinic F, only 54% of patients had regular CD4 counts. Further, patients at Clinic R, Clinic O, Clinic I, Clinic G, Clinic Q, and Clinic H and Clinic M were less likely to have regular CD4 counts relative to all patients.

PCP PROPHYLAXIS

Pneumocystis jiroveci pneumonia (PCP) is an opportunistic infection that is preventable with appropriate use of **PCP prophylaxis** when indicated. US PHS guidelines state that all patients should receive PCP prophylaxis when CD4 is below 200, percent < 14% or there is prior history of PCP. PCP prophylaxis is included as one of the 2007 HRSA/HAB HIV Clinical performance measures, and the IHI goal is that at least 95% of all patients who meet these criteria be prescribed PCP prophylaxis. Because of potential gaps in documentation of prior OIs or CD4 percent, CD4 count < 200 cells/mm3 for greater than 3 months was set as the criteria for eligibility for PCP prophylaxis. Due to effective ART, the number of patients eligible for PCP was small for individual sites.

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	2001	2002	2003	2004	2005	2006
Total Sample Size						
(PCP prophylaxis eligible)	n=309	n=369	n=334	n=293	n=242	n=226
Aggregate Sites	95%	94%	96%	96%	89%	91%
On prophylaxis (of eligible)	90 /6	9470	90 %	90 /0	0970	9170
By Gender						
Male	95%	95%	97%	97%	90%	92%
Female	92%	95%	96%	94%	88%	94%
By Place of Birth						
U.S. Born	94%	94%	96%	95%	90%	92%
Foreign Born	94%	98%	99%	97%	89%	95%
By Race or Ethnicity						
Minority	94%	96%	98%	95%	89%	92%
White non-Hispanic	95%	93%	95%	97%	90%	93%
1.0.				050/		
Hispanic	96%	96%	98%	95% (p=0.02)	86%	94%
Black non-Hispanic	88%	96%	97%	97%	93%	90%
Asian/PI non-Hispanic	100%	100%	100%	100%	100%	75%
Other non-Hispanic	100%	100%	100%	100%	67%	100%

Table 7. Percentage of Patients on PCP prophylaxis (among eligible), Aggregate & by Subgroups

Prescription of PCP prophylaxis for eligible patients at all sites reviewed in this project was impressively high overall, ranging from 93% to 95%. Further, as illustrated in the table above, there appears to be no significant differences in rates of being on PCP prophylaxis among eligible patients by gender, place of birth, or race-ethnicity. All patients eligible for treatment were equally likely to be on PCP prophylaxis. In 2005 and 2006, twenty-five and 19 eligible patients respectively were not on PCP prophylaxis, averaging 2% to 3% of patients across all sites combined. Where there were documented reasons for not being on treatment, most often progress notes indicated that PCP prophylaxis was being considered pending further monitoring of CD4 counts.

Given the high rates of PCP prophylaxis among eligible patients across all sites, clinic level comparisons are not displayed

ANTIRETROVIRAL THERAPY

USPHS guidelines recommend **antiretroviral therapy** for all patients with a diagnosis of AIDS (CD4 count < 200 cells/mm3 or prior AIDS-defining condition), or who meet specific thresholds for CD4 cell count, or viral load. The USPHS criteria for CD4 count and viral load thresholds changed during the review period, and the guidelines in place during the year of review were used. The IHI target for this performance measure is for at least 90% of all patients eligible for ART to be prescribed ART.

Table 8. Percentage of Patients on ART (among eligible), Aggregate & by Subgroups								
	2001	2002	2003	2004	2005	2006		
T (10) 1 0								
Total Sample Size (ART eligible)	n=872	n=1028	n=1008	n=942	n=932	n=903		
	11=072	11=1020	11=1000	11-042	11=332	11-300		
Aggregate Sites								
% On ART	91%	90%	93%	94%	94%	95%		
(of ART indicated)								
By Gender								
	95%	91%	93%	94%	92%	95%		
Male Female	(p=0.001) 88%	88%	91%	94%	95%	94%		
remaie	00 /0	00 /0	9170	94 /0	9378	94 /0		
By Place of Birth								
U.S. Born	91%	90%	91%	93%	93%	95%		
Foreign Born	(p=0.04) 96%	90%	(p=0.04) 95%	95%	94%	96%		
By Race or Ethnicity	5078	3078	5576	3070	5470	3070		
Minority	92%	89%	94%	95%	95%	95%		
	92 /0	0976	9470	90 /0	(p=0.02)	90 /0		
White non-Hispanic	92%	92%	91%	92%	91%	95%		
		• • • • •						
Hispanic	90%	91% (p=0.10)	94%	96%	94% (p=0.004)	95%		
Black non-Hispanic	93%	87%	94%	94%	96%	95%		
Asian/PI non-Hispanic	100%	100%	100%	100%	100%	100%		
Other non-Hispanic	83%	78%	82%	100%	70%	75%		

As a group, all sites reviewed performed well in meeting the IHI target of providing ART to at least 90% of the eligible patient population. After 2001, males and females were equally likely to be on ART when clinically indicated. In most years, foreign born patients tended to have higher rates of being on ART than U.S. born patients, however, statistically significant differences were only observed in 2001 and 2003. While racial or ethnic minorities were more likely to be on ART than White non-Hispanic patients in 2005, no statistically significant differences were observed in other years.

In 2005 (63/932) and 2006 (46/903), about 6% of patients eligible for ART were not on ART. Progress notes indicated that ART was discussed with 97% of patients in 2005 and 91% of patients in 2006. In 2005, of the patients not on ART where clinically indicated, 50% (32/63) refused ART. In 2006, 40% (18/46) refused treatment. Of the remaining patients eligible but not on ART, clinical notes revealed that treatment was in progress. In most cases, treatment was pending further examination of CD4 or viral load laboratory results or stabilization of concurrent

medical problems (including substance abuse, psychiatric illness, or medical care non-compliance).

USPHS guidelines recommend use of ART for all pregnant women even if they do not meet ART treatment criteria to prevent HIV transmission from mother to child. Of the few patients pregnant during each review year across all sites, all were on ART. Some pregnancies were terminated and thus ART was not indicated.

Table 9. Percentage	of Patients o	n ART (amor 2001	ng eligible), Ag 2002	gregate & Site 2003	2004	2005	2006
Total Sample Size)	n=872	n=1028	n=1008	n=942	n=932	n=903
		11=072	11=1020	11=1000	11=942	11=932	11=903
Aggregate Sites	On ART	91%	90%	93%	94%	94%	95%
(of ART	indicated)	9170	90%	93%	94%	94 70	90%
	,						
By Site		770/	700/	000/	000/	010/	0.40/
Clinic A		77%	78%	83%	96%	91%	94%
Clinic B		87%	91%	97%	100%	91%	94%
Clinic C		91%	81%	88%	92%	98%	92%
Clinic D		92%	97%	98%	95%	90%	96%
Clinic E		86%	93%	92%	96%	98%	100%
Clinic F		94%	89%	95%	90%	93%	100%
Clinic G		96%	96%	100%	98%	88%	95%
Clinic H		96%	98%	96%	98%	96%	98%
Clinic I		98%	94%	92%	92%	100%	98%
Clinic J		98%	93%	95%	95%	96%	98%
Clinic K		91%	94%	98%	98%	89%	95%
Clinic L		85%	89%	87%	94%	97%	92%
Clinic M		91%	84%	91%	94%	97%	97%
Clinic N		89%	80%	82%	89%	86%	88%
Clinic O		93%	86%	94%	94%	92%	100%
Clinic P		92%	97%	98%	97%	95%	91%
Clinic Q		98%	90%	89%	91%	91%	95%
Clinic R		94%	92%	97%	88%	96%	92%
Clinic S		92%	92%	90%	90%	89%	91%

Table 9. Percentage of Patients on ART (among eligible), Aggregate & Site-Specific

In the table above, we present the percentage of patients (eligible for ART) who were on ART each year by site. Due to variability in sample sizes across the clinics, some site to site comparisons should be interpreted with caution.

In 2005, the aggregate mean percentage of patients who were on ART among those eligible was high at 94% (95% CI: 92% to 96%). Based on the 95% confidence interval, about half of all sites performed better than the average. Sites that performed below the average included Clinic N, Clinic G, Clinic S, Clinic K, Clinic D, Clinic A, Clinic B, and Clinic F.

In 2006, 95% (95% CI: 94% to 96%) of all eligible patients were on ART. Eleven of the 19 sites performed on par or higher than the average. Relative to all sites combined, however, Clinic N, Clinic P, Clinic S, Clinic R, Clinic L, Clinic C, Clinic B, and Clinic A had significantly lower proportions of patients on ART when clinically indicated, although the IHI target of 90% was met.

VIRAL HEPATITIS PREVENTION, SCREENING & TREATMENT

HEPATITIS B VACCINATION

Screening for hepatitis A, B and C viruses is important to ensure vaccination of patients at risk (for Hepatitis A and B) and for assessment of potential treatment for HCV. Rates of **hepatitis B and hepatitis C** screening across all sites during 2001-2006 were close to 100%. Hence, we present information on hepatitis A and B vaccination and hepatitis C treatment.

In 2004, the HIV Outpatient Study (HOPS) published a report on the rates of hepatitis A and hepatitis B vaccination among a sample of eligible HIV+ patients receiving care at 9 clinics located in 7 US cities.² In their sample:

- \circ 32% of eligible patients had documented receipt of ≥ 1 dose of hepatitis B vaccine
- \circ 23% of eligible patients had documented receipt of ≥ 1 dose of hepatitis A vaccine

Compared to this study's estimates, eligible patients at all sites reviewed were more likely to have had received at least one dose of hepatitis B or hepatitis A vaccination.

able 10. Percentage	of Patients	with any Hep	<u>atitis B Vaccir</u>	<u>ie (among HB'</u>	V-), Aggregate	& Site-Specif	ic
		2001	2002	2003	2004	2005	2006
Total Sample Size	(HBV-)	441	540	561	525	546	508
Aggregate Sites Any Hepatitis E	3 Vaccine	78%	78%	81%	80%	82%	81%
By Site							
Clinic A		79%	83%	89%	92%	94%	94%
Clinic B		81%	78%	91%	87%	100%	100%
Clinic C		81%	75%	85%	83%	87%	79%
Clinic D		92%	88%	89%	89%	83%	79%
Clinic E		89%	89%	100%	100%	92%	96%
Clinic F		32%	31%	41%	36%	45%	47%
Clinic G		75%	83%	78%	84%	89%	88%
Clinic H		96%	93%	90%	88%	93%	94%
Clinic I		71%	75%	81%	81%	85%	82%
Clinic J		74%	77%	82%	85%	83%	84%
Clinic K		92%	77%	83%	80%	71%	75%
Clinic L		79%	83%	76%	76%	76%	76%
Clinic M		66%	65%	66%	63%	62%	61%
Clinic N		83%	89%	89%	90%	91%	86%
Clinic O		90%	92%	94%	100%	100%	100%

Table 10. Percentage of Patients with any Hepatitis B Vaccine (among HBV-), Aggregate & Site-Specific

² Tedaldi EM, Baker RK, Moorman AC, Wood KC, Fuhrer J, McCabe RE, Holmberg SD; HIV Outpatient Study (HOPS) Investigators. Hepatitis A and B vaccination practices for ambulatory patients infected with HIV. Clin Infect Dis. 2004 May 15;38(10):1478-84.

Clinic P	88%	87%	83%	87%	89%	86%
Clinic Q	81%	84%	88%	90%	88%	90%
Clinic R	88%	88%	91%	90%	90%	77%
Clinic S	79%	72%	74%	77%	79%	79%

In the table above, we provide rates of receipt of at least one dose of **HBV vaccination** among patients who have had no evidence of prior HBV infection on screening across all sites reviewed. Between 83% and 89% of all eligible patients had ever received any HBV vaccine during the 6 year period. At the site level, a few clinics had relatively lower rates of providing HBV vaccinations. Due to the variability in sample sizes across clinics, some site to site comparisons should be interpreted with caution.

While we only collected and presented data on the receipt of at least one dose of HBV vaccination, please note that the proposed draft 2nd Tier HAB HIV Clinical Performance Measures requires the complete hepatitis B vaccination series.³

The aggregate mean percentage of patients with documented receipt of any dose of hepatitis B vaccine among those HBV negative was 82% (95% CI: 79% to 85%) in 2005 and 81% (95% CI: 78% to 84%) in 2006. The majority of sites performed better than the average.

In both years, about 75% of eligible patients at Clinic K and Clinic L received any dose of the HBV vaccine. Compared to the aggregate, eligible patients at Clinic F and Clinic M were less likely to have documented receipt of any dose of the HBV vaccination regimen in both years (with less than 50% of eligible patients vaccinated).

³ HRSA HAB HIV Draft Performance Measures...<u>ftp://ftp.hrsa.gov/hab/draftperfmeasure.pdf</u>

HEPATITIS A SCREENING AND VACCINATION

Hepatitis A screening rates are lower across all sites combined relative to hepatitis B and C screening. Between 2001 and 2004, about 85% of patients reviewed have ever been screened for HAV and in 2005 and 2006, 90% of patients were screened.

As described above, in 2004, the HIV Outpatient Study (HOPS) published a report on the rates of hepatitis A and hepatitis B vaccination among eligible patients in a sample of HIV patients receiving care at 9 clinics located in 7 US cities. In this study, about 23% of eligible patients had documented receipt of ≥ 1 dose of hepatitis A vaccine.

Table 11. Percentage of Patient	ts with any Hep	atitis A Vaccir	e (among HA	V-), Aggregate	e & Site-Specif	ic
Tatal Camala Cina	2001	2002	2003	2004	2005	2006
Total Sample Size (HAV-)	n=436	n=544	n=556	n=517	n=517	n=487
Aggregate Sites Any Hepatitis A Vaccine	70%	67%	72%	71%	71%	71%
By Site	700/	000/	000/	770/	000/	000/
Clinic A	73%	88%	93%	77%	89%	86%
Clinic B	41%	40%	63%	58%	65%	60%
Clinic C	62%	70%	82%	82%	89%	88%
Clinic D	94%	85%	81%	78%	74%	71%
Clinic E	75%	73%	86%	91%	88%	88%
Clinic F	46%	45%	49%	41%	45%	48%
Clinic G	91%	84%	83%	89%	91%	100%
Clinic H	93%	93%	94%	93%	85%	87%
Clinic I	43%	48%	60%	56%	50%	50%
Clinic J	72%	68%	79%	84%	89%	86%
Clinic K	92%	74%	73%	74%	61%	63%
Clinic L	64%	54%	57%	64%	60%	58%
Clinic M	59%	53%	44%	45%	53%	49%
Clinic N	83%	87%	92%	93%	94%	95%
Clinic O	38%	14%	50%	63%	67%	67%
Clinic P	64%	61%	58%	66%	64%	70%
Clinic Q	75%	83%	96%	95%	84%	88%
Clinic R	75%	68%	75%	71%	79%	67%
Clinic S	78%	71%	77%	79%	79%	79%

Patients who are hepatitis A negative should receive the **hepatitis A vaccination** regimen to prevent viral infection. Of patients who were screened and have no evidence of hepatitis A infection, approximately 70% had received at least one dose of the hepatitis A vaccine in any given year between 2001 and 2006.

In the table above, we also present the percentage of patients (HAV-) who had received any dose of hepatitis A vaccine each year by site. Rates of receiving any dose of hepatitis A vaccination

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were variable across sites and across years. Due to some differences in sample sizes across the clinics, some site to site comparisons should be interpreted with caution.

While we only collected and presented data on the receipt of at least one dose of HAV vaccination, please note that the proposed draft 3rd Tier HAB HIV Clinical Performance Measures requires the complete 2 dose hepatitis A vaccination regimen.

The aggregate mean percentage of HAV negative patients with any dose of Hepatitis A vaccination was 71% (95% CI: 67% to 75%) in both 2005 and 2006. Among eligible patients (HAV-), those Clinic F, Clinic M, Clinic I, and Clinic L (\leq 50%) were least likely to have any dose of the hepatitis A vaccine. Clinic K, Clinic B, Clinic Q, and Clinic R (<71%) patients were also less likely to have received any HAV vaccine in both 2005 and 2006.

HEPATITIS C TREATMENT

Among patients who are HCV antibody positive, we determined whether **HCV treatment** had ever been provided. We excluded patients with undetectable HCV viral load (viral load measured), since this would be a contraindication for treatment. Of potential candidates, we examined rates of ever receiving HCV treatment across all sites. Non-adherence to care and other select medical co-morbidities (significant liver disease, active substance abuse, psychiatric problems) could also be reasons for no treatment.

Table 12. Percentage of Patients	who ever ha	d HCV treatm	ient (among H	ICV+), Aggreg	ate	
	2001	2002	2003	2004	2005	2006
HCV Positive	44%	40%	37%	35%	33%	32%
Potential candidates for						
HCV treatment	n=397	n=434	n=367	n=320	n=292	n=270
Aggregate Sites						
HCV treatment (Ever, of candidates)	5%	9%	14%	15%	20%	21%
By Site						
Clinic A	5%	4%	8%	8%	11%	11%
Clinic B	0%	0%	10%	14%	14%	25%
Clinic C	0%	0%	4%	5%	11%	10%
Clinic D	5%	5%	11%	9%	11%	14%
Clinic E	0%	6%	0%	0%	0%	20%
Clinic F	21%	23%	21%	25%	22%	24%
Clinic G	0%	10%	14%	25%	25%	33%
Clinic H	0%	0%	19%	11%	13%	0%
Clinic I	8%	9%	9%	10%	22%	26%
Clinic J	4%	10%	26%	23%	17%	19%
Clinic K	0%	4%	12%	17%	10%	24%
Clinic L	0%	6%	7%	0%	0%	0%
Clinic M	8%	9%	11%	6%	28%	32%
Clinic N	0%	20%	33%	60%	80%	67%
Clinic O	0%	0%	6%	17%	22%	44%
Clinic P	0%	5%	10%	23%	22%	24%
Clinic Q	9%	11%	4%	13%	15%	11%
Clinic R	13%	25%	38%	14%	17%	0%
Clinic S	12%	14%	22%	29%	30%	30%

Table 12. Percentage of Patients who ever had HCV treatment (among HCV+), Aggregate

The proportion of patients with hepatitis C declined throughout the 6 year period from 44% in 2001 to 33% in 2006. Among patients who were HCV antibody positive each year, the rate of ever having received HCV treatment increased from 5% in 2001 to 21% in 2006 overall. This increase may likely reflect the availability of better treatment options (including combination therapy of oral ribavirin and pegylated interferon) during this time period.

PNEUMOCOCCAL VACCINATION

Patients with HIV infection are at greater risk for pneumococcal infection. It is recommended that all HIV patients be given **pneumococcal vaccine** soon after HIV diagnosis. For each patient reviewed, we determined whether pneumococcal vaccine was ever administered. While some guidelines now recommend revaccination, there remained enough ongoing controversy that the measure of ever vaccinated regardless of time since administration was used.

	2001	2002	2003	2004	2005	2006
Total Sample Size	n=981	n=1198	n=1211	n=1107	n=1100	n=1038
Aggregate Sites Pneumovax	91%	88%	90%	92%	92%	92%
By Site						
Clinic A	88%	84%	85%	90%	89%	92%
Clinic B	91%	77%	88%	97%	97%	96%
Clinic C	88%	895	86%	87%	90%	91%
Clinic D	100%	100%	99%	99%	96%	96%
Clinic E	65%	61%	79%	82%	85%	85%
Clinic F	92%	90%	93%	94%	94%	93%
Clinic G	89%	87%	89%	88%	94%	98%
Clinic H	96%	98%	98%	98%	96%	97%
Clinic I	92%	93%	95%	97%	97%	95%
Clinic J	98%	94%	95%	98%	98%	98%
Clinic K	97%	91%	94%	93%	89%	87%
Clinic L	95%	93%	98%	95%	93%	94%
Clinic M	90%	90%	81%	83%	82%	84%
Clinic N	83%	83%	87%	90%	90%	87%
Clinic O	100%	97%	92%	97%	92%	90%
Clinic P	99%	99%	94%	93%	97%	98%
Clinic Q	97%	88%	93%	96%	97%	96%
Clinic R	90%	88%	88%	97%	100%	87%
Clinic S	89%	81%	89%	92%	89%	87%

Table 13. Percentage of Patients with Documented Pneumococcal Vaccination, Aggregate & Site-Specific

Approximately 90% of all patients have ever received a pneumococcal vaccination in any given year throughout the review period. Rates were equally high across most sites.

The aggregate mean percentage of patients who had ever received a pneumococcal vaccine was 92% (95% CI: 90% to 94%) in both 2005 and 2006. About one half of all sites performed better than the average in both years. Patients at Clinic M, Clinic E (\leq 85%), Clinic K, Clinic N, Clinic S, and Clinic C were significantly less likely than patients at all sites combined to have ever received a pneumococcal vaccine in 2005 and 2006.

CERVICAL CANCER SCREENING (PAP SMEARS)

Women with HIV infection are at higher risk for cervical cancer, and regular screening through Pap smears is recommended. While risk of anal cancer related to HPV infection is also increased, no specific guidelines exist for screening, and low rates of anal Pap smears were seen across clinics. Therefore, we only present data on cervical cancer screening. Although criteria have changed during the 6 year period, we used receipt of a documented Pap smear in the year as the indicator, even though more frequent screenings have been recommended in some years. Information on performance of Pap smears, results of the screening, and referrals for follow-up of abnormal Pap smears were collected for each patient reviewed.

Under the 2nd Tier HAB HIV Clinical Performance Measures, it is recommended that Pap smears are done every 12 months. While there is no current national benchmark or target from HRSA for this measure, we found a study published in 2001 by the HIV Cost and Service Utilization Study (HCSUS) that reported on the rates of Pap smears, abnormal Pap smears, and referral rates among a national sample representing over 43,000 women receiving HIV treatment.⁴ Data were gathered during the first follow-up interview of the HCSUS cohort from December 1996 to July 1997. Of this representative sample of female patients with HIV:

- o 81% had a Pap smear in the past 12 months
- o 27% of Pap smears were abnormal
- 95% of patients with abnormal Pap smears were scheduled for a repeat Pap or colposcopy (however, only 85% followed through with the referral)

	2001	2002	2003	2004	2005	2006
Total Females	n=399	n=465	n=456	n=439	n=417	n=403
PAP Smears	62%	56%	63%	62%	69%	63%
% Abnormal PAP	31%	28%	28%	27%	18%	20%
% Referred of Abnormal PAPs	79%	75%	85%	76%	98%	95%

These statistics may serve as a comparison for EMMS sites.

Table 14. Percentage of Patients Receiving PAP Smears, Rates of Abnormal PAP, and Referrals

Note: Percentage of PAP smears is inclusive of females who may have had colposcopies.

About 60% of all female patients in our sample had received a Pap smear during each review year over the 6-year period. About 30% of Pap smears were abnormal from 2001 to 2004 and about 20% were abnormal in 2005 and 2006. Referral rates for abnormal Pap smears were generally high ranging from 75% to nearly 100% across all sites throughout the 6 years.

⁴Stein MD, Cunningham WE, Nakazono T, Turner BJ, Andersen RM, Bozzette SA, Shapiro MF; HCSUS Consortium. Screening for cervical cancer in HIV-infected women receiving care in the United States. J Acquir Immune Defic Syndr. 2001 Aug 15;27(5):463-6.

Table 15. Percentage of Female Patients Receiving Pap Smears, Aggregate & Site-Specific								
	2001	2002	2003	2004	2005	2006		
Total Sample Size	n=399	n=465	n=456	n=439	n=417	n=403		
Aggregate Sites								
Pap Smears	62%	56%	63%	62%	69%	63%		
By Site	71%	E 00/	649/	E 90/	71%	62%		
Clinic A		58%	64%	58%				
Clinic B	65%	68%	67%	20%	76%	69%		
Clinic C	56%	69%	77%	83%	91%	71%		
Clinic D	72%	55%	75%	51%	61%	48%		
Clinic E	65%	50%	86%	79%	80%	71%		
Clinic F	44%	30%	54%	46%	63%	48%		
Clinic G	83%	88%	100%	57%	71%	60%		
Clinic H	81%	61%	63%	59%	95%	65%		
Clinic I	50%	41%	70%	72%	68%	21%		
Clinic J	25%	24%	14%	21%	53%	50%		
Clinic K	86%	38%	52%	74%	80%	85%		
Clinic L	42%	40%	44%	62%	23%	69%		
Clinic M	58%	56%	60%	63%	65%	65%		
Clinic N	-	-	-	-	-	-		
Clinic O	80%	79%	59%	75%	67%	70%		
Clinic P	72%	78%	59%	62%	70%	72%		
Clinic Q	44%	42%	44%	55%	45%	67%		
Clinic R	74%	60%	83%	78%	68%	67%		
Clinic S	59%	67%	78%	70%	86%	79%		

In the table above, we present the percentage of female patients who have received a Pap smear each year by site. Due to differences in number of female patients across clinics, some site to site comparisons should be interpreted with caution.

In 2005, the aggregate mean percentage of female patients who had received a Pap smear was 69% (95% CI: 65% to 73%). Based on a 95% confidence interval, the majority of sites performed better or equal to all sites combined. Female patients at Clinic F (63%), Clinic D (61%), and Clinic J (53%), and Clinic Q (45%) were significantly less likely to have documented receipt of a Pap smear in 2005, compared to all sites.

In 2006, the aggregate mean percentage of female patients who had ever received a Pap smear was 63% (95% CI: 58% to 68%). Clinic D (48%), Clinic F (48%), and Clinic J (50%) patients were less likely than patients at all sites combined to receive a Pap smear in 2006. Further, only 21% of patients at Clinic I had documented receipt of a Pap smear in year.

PART III. CLINICAL OUTCOME INDICATORS

In addition to using process indicators to evaluate adherence to HIV/AIDS clinical care standards and treatment guidelines, JSI also collected data on clinical outcomes to assess the health status of patients sampled at EMMS sites. Thus, for each review year, information for the following outcome indicators was collected:

- Viral suppression throughout Year (among patients on ART at all anytime during year)
- Last viral load \leq 400 (among patients on ART at last visit)
- Last CD4 count > 200
- All-cause hospitalizations

This section presents aggregate and site-specific data on these outcome measures. Further, for select indicators, clinical outcomes by demographic subgroups (gender, place of birth, race-ethnicity) are also provided.

VIRAL LOAD SUPPRESSION THROUGHOUT YEAR (Among patients on ART at anytime during year)

Viral load is an important measure of ART effectiveness, and suppression below the level of detection is the goal of treatment. All viral loads obtained during the year were collected for every patient reviewed. We used the cutoff of \leq 400 copies/ml due to variability in the use of ultrasensitive viral load tests across sites during a number of review periods. A patient has achieved viral suppression if all viral loads obtained during the year were undetectable. Only patients with documentation of being on ART during the review year were included.

Table 16. Percentage of Patients on ART who Always and Never Had Viral Suppression, Aggregate								
	2001	2002	2003	2004	2005	2006		
Always viral suppressed (VL always ≤ 400, On ART)	49%	44%	44%	58%	59%	68%		
HIVRN*	34%	35%	37%	42%	47%	51%		
Never viral suppressed (VL never ≤ 400, On ART)	24%	26%	21%	14%	14%	12%		
HIVRN*	33%	33%	28%	27%	24%	21%		

Overall improvements in viral suppression were observed from 2001 to 2006, with an increase in the proportion of patients who always maintained an undetectable viral load throughout the year each year, and a decrease in the percentage of patients with consistently detectable viral loads. Specifically, in 2006, 68% of patients maintained viral suppression throughout the year, compared to only 49% in 2001.

On the other hand, about a quarter of patients at all sites had viral loads that were always greater than 400 between 2001 and 2003. From 2003 onwards, however, there has been a decline in the proportion of patients with consistently detectable viral loads throughout a given year. In 2006, 12% of all patients never achieved viral suppression.

*Throughout the 6 review years, patients at EMMS/Ryan White Part A sites reviewed were more likely to have achieved viral suppression and less likely to have detectable viral loads compared to patients in the HIV Research Network, a consortium of 19 sites across the US that provide medical care to adult HIV patients.

	2001	2002	2003	2004	2005	2006
otal Sample Size	n=803	n=927	n=932	n=883	n=869	n=857
Aggregate Sites % of Patients with Always VL ≤ 400	49%	44%	44%	58%	59%	68%
HIVRN*	34%	35%	37%	42%	47%	51%
By Site						
Clinic A	29%	34%	42%	52%	55%	66%
Clinic B	58%	49%	58%	71%	67%	65%
Clinic C	33%	32%	53%	48%	53%	65%
Clinic D	48%	48%	47%	59%	50%	51%
Clinic E	68%	51%	52%	77%	67%	71%
Clinic F	55%	31%	28%	29%	18%	74%
Clinic G	64%	77%	83%	89%	89%	91%
Clinic H	63%	60%	66%	77%	74%	65%
Clinic I	60%	55%	52%	56%	60%	63%
Clinic J	20%	19%	22%	42%	63%	65%
Clinic K	41%	30%	26%	60%	63%	73%
Clinic L	39%	44%	26%	59%	73%	82%
Clinic M	50%	46%	34%	61%	58%	71%
Clinic N	58%	48%	45%	69%	75%	76%
Clinic O	40%	17%	32%	74%	78%	71%
Clinic P	47%	34%	32%	39%	53%	68%
Clinic Q	58%	45%	34%	48%	44%	69%
Clinic R	55%	36%	50%	52%	57%	65%
Clinic S	44%	46%	57%	61%	62%	67%

In the table above, we present the percentages of patients (on ART at any time during year) who always had viral suppression or undetectable viral loads throughout the year each year by site. Due to some variability in sample sizes across the clinics, site to site comparisons should be interpreted with caution.

Among patients on ART, 59% (95% CI: 56% to 62%) in 2005 and 68% (95% CI: 65% to 71%) in 2006 had viral load suppression throughout the year. In 2005, Clinic D, Clinic C, Clinic P, and Clinic Q patients were less likely to maintain viral suppression throughout year compared to all patients combined. Clinic F patients were the least likely to maintain viral suppression, with only 18% of patients always with VL \leq 400. By 2006, patients at the majority of sites had similar rates of viral suppression. However, Clinic D patients were least likely to achieve viral suppression, with only 51% maintaining undetectable viral loads in the year.

LAST VIRAL LOAD IN YEAR (Among patients on ART at Last Visit)

To determine the effectiveness of ART, we also examined the last viral load measured each year for patients who were on ART at last visit at all sites. Suppression or an undetectable viral load is defined as ≤ 400 copies/ml. The cutoff of ≤ 400 copies/ml was used due to variability in the use of ultrasensitive viral load tests across sites.

Table 18. Percentage of F	Patients with	last VL ≤400 (d	on ART at last	visit), Aggreg	ate & by Sub	groups
	2001	2002	2003	2004	2005	2006
Total Sample Size	n=747	n=863	n=854	n=831	n=829	n=837
Aggregate Sites % of Patients with Last VL ≤ 400	66%	64%	72%	77%	78%	83%
By Gender						
- Male Female	65% 66%	64% 66%	73% 71%	79% 77%	78% 79%	87% (p=0.06) 81%
By Place of Birth U.S. Born	64% (p=0.02)	62% (p=0.02)	71%	77%	78%	84%
Foreign Born By Race or Ethnicity	73%	71%	77%	81%	81%	87%
Minority	62% (p=0.03)	61% (p=0.01)	70%	76% (p=0.06)	78%	84%
White non-Hispanic	70%	69%	75%	81%	80%	86%
Hispanic	54%	53% (p<0.0001)	66% (p=0.06)	73%	77%	84%
Black non-Hispanic	70%	. 69%	73%	78%	77%	85%
Asian/PI non-Hispanic	80%	82%	89%	87%	88%	94%
Other non-Hispanic	50%	33%	67%	83%	83%	50%
By Year of Diagnosis						
Diagnosed in Year Diagnosed Previously	-	60% 65%	57% (p=0.0003) 75%	-	63% (p=0.003) 80%	73% (p=0.003) 85%

*Due to the small number of newly diagnosed patients reviewed in 2001 and 2004, no relevant data are presented for those years. Patients newly diagnosed in a given year are compared to patients diagnosed in all years prior to that year.

From 2001 to 2006, a substantial increase is noted in the proportion of patients who achieved viral suppression at the end of each year. Among patients who were on ART at last visit, 83% had undetectable last viral loads in 2006, compared to 66% in 2001.

In examining rates by demographic subgroups, there were no patterns to indicate any differences in last viral load by gender, and any significant differences by race-ethnicity and place of birth was eliminated after 2002.

- While rates were similar in most years, in 2006, males were more likely to have achieved a last viral load of 400 or less compared to females, although this difference is significant only at p<0.10.
- Although foreign born patients tended to have undetectable last viral loads than U.S. born patients in all years, there were no statistically significant differences after 2002.

- White non-Hispanic patients were also more likely to have achieved viral suppression than minority patients throughout the 6 year period, although these differences were not significant after 2002.
- Among minorities, Hispanics were less likely to have undetectable viral loads than other racial or ethnic minorities, although these differences no longer existed after 2002.
- Furthermore, patients newly diagnosed with HIV in any given year were significantly less likely to achieve viral suppression than patients diagnosed in previous years.

ble 19. Percentage of Patient		,		00 0		2000
	2001	2002	2003	2004	2005	2006
Fotal Sample Size	n=747	n=863	n=854	n=831	n=829	n=837
Aggregate Sites % of Patients with VL ≤ 400		64%	72%	77%	78%	83%
HIVRN	53%	53%	56%	62%	64%	67%
By Site						
Clinic A	58%	67%	80%	68%	81%	84%
Clinic B	67%	74%	84%	81%	89%	75%
Clinic C	45%	56%	72%	70%	73%	75%
Clinic D	61%	68%	69%	84%	80%	67%
Clinic E	82%	71%	84%	93%	89%	93%
Clinic F	71%	57%	66%	60%	26%	86%
Clinic G	64%	77%	83%	89%	89%	91%
Clinic H	73%	79%	88%	92%	93%	86%
Clinic I	73%	71%	78%	79%	67%	72%
Clinic J	35%	33%	38%	66%	76%	74%
Clinic K	81%	55%	75%	84%	86%	89%
Clinic L	59%	76%	70%	82%	94%	94%
Clinic M	70%	65%	67%	75%	78%	85%
Clinic N	69%	69%	84%	88%	85%	90%
Clinic O	54%	42%	74%	86%	87%	86%
Clinic P	57%	46%	49%	56%	75%	88%
Clinic Q	73%	58%	69%	82%	71%	94%
Clinic R	62%	52%	59%	57%	65%	68%
Clinic S	68%	78%	80%	82%	87%	87%

In the table above, we present the percentages of patients (on ART at last visit) with undetectable last viral loads each year by site. Due to variability in sample sizes across the clinics, some site to site comparisons should be interpreted with caution.

In 2005, the aggregate mean percentage of patients who were on ART and had undetectable last viral load at last visit was 78% (95% CI: 75% to 81%). Based on a 95% confidence interval, in 2005, Clinic F (26%), Clinic I (67%), Clinic R (65%), Clinic Q (71%), Clinic P (75%), and Clinic C (73%) patients were significantly less likely to have last VL \leq 400, compared to patients at all sites combined.

In 2006, the aggregate mean percentage of patients who were on ART and had undetectable last viral loads was 83% (95% CI: 80% to 86%). Based on a 95% confidence interval, in 2006, Clinic D (67%), Clinic R (68%), Clinic I (72%), Clinic J (74%), Clinic C (75%), and Clinic B (75%) patients were significantly less likely to have last VL \leq 400, compared to patients at all sites.

LAST CD4 COUNT > 200 IN YEAR

CD4 counts are a direct measure of immune function and HIV-related progression. Achieving a CD4 count > 200 significantly reduces the risk of AIDS-related conditions such as PCP and other opportunistic infections, and further disease progression. Therefore, the last CD4 count collected for each patient each year was selected for use as an outcome indicator.

Table 20. Percentage of	Patients with la	ast CD4>200,	Aggregate & I	by Subgroups		
	2001	2002	2003	2004	2005	2006
Total Sample Size	n=981	n=1198	n=1211	n=1107	n=1100	n=1038
Aggregate Sites						
Aggregate Sites % of Patients with Last CD4 >200	81%	80%	84%	83%	85%	85%
By Gender						
By Gender					85%	87%
Male	81%	82%	85%	85%	(p=0.01)	(p=0.04)
Female	85%	83%	87%	87%	89%	89%
By Place of Birth						
U.S. Born	82%	82%	86%	84%	86%	86% (p=0.009)
Foreign Born	85%	82%	87%	88%	87%	
By Race or Ethnicity						
Minority	78% (p=0.0001)	79% (p=0.002)	83% (p=0.006)	83% (p=0.008)	84% (p=0.03)	86%
White non-Hispanic	88%	86%	89%	88%	89%	89%
Hispanic	75% (p=0.0002)	77% (p=0.005)	81% (p=0.03)	79% (p=0.01)	83%	83%
Black non-Hispanic	83%	82%	86%	86%	86%	88%
Asian/PI non-Hispanic	83%	74%	80%	84%	90%	84%
Other non-Hispanic	60%	67%	82%	83%	81%	93%
By Year of Diagnosis		700/	700/		700/	700/
Diagnosed in Year Diagnosed Previously	-	73% (p=0.003) 83%	79% (p=0.004) 87%	-	70% (p<0.0001) 88%	72% (p<0.0001) 88%

*Due to the small number of newly diagnosed patients reviewed in 2001 and 2004, no relevant data are presented for those years. Patients newly diagnosed in a given year are compared to patients diagnosed in all years prior to that year.

Overall, the proportion of patients who achieve a last CD4 of greater than 200 at the end of each year remained somewhat consistent around 80% to 85% throughout the 6 year period, with a slight increasing trend noted.

- In 2005 and 2006, females were significantly more likely to have last CD4>200 than males.
- Although a greater or similar proportion of foreign born patients tended to have last CD4>200 than U.S. born patients, this difference was statistically significant in only 2006.
- In all years except 2006, racial or ethnic minorities were significantly less likely to achieve a last CD4>200 compared to White non-Hispanics. Among minorities, Black non-Hispanics were more likely to have CD4>200 than Hispanics.
- Patients newly diagnosed in year were less likely to have a last CD4 >200 compared to patients diagnosed in previous years.

Table 21. Percentage of Patient	s with last CD4	4>200, Aggreo	gate & Site-Sp	ecific		
	2001	2002	2003	2004	2005	2006
Total Sample Size	n=803	n=927	n=932	n=883	n=869	n=857
Aggregate Sites						
% of Patients with Last CD4 >200	81%	80%	84%	83%	85%	85%
*HIVRN	67%	71%	72%	73%	74%	78%
D 0%						
By Site Clinic A	59%	86%	79%	62%	86%	84%
Clinic R	74%	75%	83%	86%	91%	75%
	65%	69%	71%	67%	78%	77%
Clinic C	82%	85%	91%	91%	85%	88%
	88%	80%	82%	82%	85%	91%
Clinic E						
Clinic F	77%	76%	78%	81%	81%	84%
Clinic G	56%	61%	56%	51%	47%	42%
Clinic H	88%	82%	95%	94%	94%	93%
Clinic I	79%	82%	91%	90%	87%	92%
Clinic J	81%	76%	82%	80%	87%	87%
Clinic K	86%	82%	87%	84%	83%	87%
Clinic L	81%	77%	79%	70%	78%	72%
Clinic M	86%	83%	81%	87%	84%	85%
Clinic N	87%	92%	92%	95%	93%	92%
Clinic O	84%	81%	85%	83%	81%	86%
Clinic P	75%	73%	73%	69%	82%	81%
Clinic Q	88%	78%	88%	89%	86%	91%
	80%	73%	88%	76%	76%	87%
Clinic R	82%	83%	87%	89%	84%	90%
Clinic S	02 /0	0370	01 /0	03/0	04 /0	30 /0

In the table above, we present the percentage of patients with last CD4 >200 each year by site. Due to some variability in sample sizes across the clinics, site to site comparisons should be interpreted with caution.

The aggregate mean percentage of patients who achieved a last CD4 of greater than 200 at the end of both 2005 and 2006 was 85% (95% CI: 83% to 87%). Based on a 95% confidence interval, Clinic G, Clinic C, Clinic F, Clinic L, and Clinic P patients were significantly less likely than patients at all sites combined to achieve a last CD4>200 in both years.

ALL-CAUSE HOSPITALIZATIONS

Hospitalizations for all causes were documented during the chart review process. Presented below are the percentages of patients with documentation of ever having been hospitalized each year across all sites. Since we also included hospitalizations for non-HIV related conditions, data should not be used to infer trends in HIV-related morbidity. However, studies have found that HIV-related hospitalizations are decreasing while hospitalizations due to other causes have remained stable. Differences in documentation and missing or incomplete data on hospitalizations in patient records may also have reduced measures of hospitalization rates in some sites.

Table 22. Percentage of	Patients with de	ocumented Ho	spitalizations,	Aggregate & E	By Subgroups	
	2001	2002	2003	2004	2005	2006
Total Sample Size	n=981	n=1198	n=1211	n=1107	n=1100	n=1038
	11=901	11=1190	11=1211	11=1107	11=1100	11=1030
Aggregate Sites % Ever Hospitalized in Year	15%	18%	17%	16%	13%	13%
By Gender						
Male	14%	17%	15%	13% (p=0.06)	10% (p=0.04)	11% (p=0.05)
Female	16%	17%	18%	19%	15%	16%
By Place of Birth						
U.S. Born	16% (p=0.07)	19% (p=0.01)	19% (p<0.0001)	18% (p=0.002)	14% (p=0.0003)	14% (p=0.08)
Foreign Born	11%	12%	8%	10%	7%	10%
By Race or Ethnicity		400/	400/	470/	450/	
Minority	16%	19% (p=0.06)	18% (p=0.08)	17% (p=0.09)	15% (p=0.0004)	14%
White non-Hispanic	14%	15%	14%	14%	8%	11%
1.12		040/			470/	
Hispanic	15%	21% (p=0.08)	18%	18%	17% (p=0.002)	11%
Black non-Hispanic	18%	18%	17%	17%	15%	17%
Asian/PI non-Hispanic	6%	5%	15%	6%	5%	11%
Other non-Hispanic	14%	9%	29%	21%	6%	7%
By HIV Stage	100/	0.4.07	000/	100/		4 = 0 (
AIDS	19% (p=0.0009)	21% (p<0.0001)	20% (p=0.0001)	19% (p<0.0001)	13%	15% (p=0.004)
HIV	10%	12%	12%	10%	11%	9%

Overall hospitalization rates remained the same across all-sites. Thirteen to 18% of patients sampled from all sites combined have ever been hospitalized each year between 2001 and 2006, with slightly lower rates from 2004 onwards.

- Similar rates of documented hospitalizations were observed, except in 2005 and 2006, when females were significantly more likely than males to ever have been hospitalized in year.
- US born patients were significantly more likely to have at least one documented hospitalization than foreign born patients in all years. In any given year, about 10% of

foreign born patients had experienced a hospitalization, compared to 14% to 19% of US born patients.

- Racial or ethnic minorities were more likely to ever have been hospitalized in year compared to White non-Hispanic patients in most years (p<0.10).
- Patients with an AIDS-defining condition were also significantly more likely to have ever been hospitalized in year than HIV patients.

In 2005, a study was published using data from the HIV Research Network, a consortium of 19 sites across the US that provide medical care to adult HIV patients.⁵ Specifically, it examined data on health care utilization, including hospitalization admissions and outpatient visits. Among over 13,000 patients in 2000, 15,000 in 2001, and 14,000 in 2002, 22.2%, 20.4%, and 19.7% of patients had at least one hospital admission respectively.

Estimates from this study are higher than the aggregate rate at EMMS sites during those same years. As discussed, differences in documentation and missing or incomplete data on hospitalization admissions may have underestimated the rates we observed. Thus, interpretation of findings should be made cautiously.

⁵ Fleishman JA, Gebo KA, Reilly ED, Conviser R, Christopher Mathews W, Todd

Korthuis P, Hellinger J, Rutstein R, Keiser P, Rubin H, Moore RD; HIV Research Network. Hospital and outpatient health services utilization among HIV-infected adults in care 2000-2002. Med Care. 2005 Sep;43(9 Suppl):III40-52.

PART IV. CONCLUSIONS

Sites reviewed as part of this HIV/AIDS clinical care quality assurance project assume a challenging task in providing medical care to patients who are traditionally disadvantaged and underserved. In examining aggregate data and select measures by demographic subgroups, we have highlighted areas of success as well as potential opportunities for quality improvement.

From 2001 to 2006, overall clinical performance and outcomes have improved across all sites. Clinical performance in areas such as ART management, PCP prophylaxis, and CD4 counts has met national guidelines. An impressive improvement was also observed in patient health outcomes, specifically viral suppression, likely reflecting enhanced ART effectiveness and ART management.

In evaluating aggregate performance on select clinical care measures by demographic subgroups, we found no consistent trends throughout the 6 review years to suggest disparity in care. For example, disparities in viral suppression rates by race-ethnicity noted in 2001 and 2002 were absent from 2003 onwards. While some differences were detected in certain years, further investigation is needed to determine whether these were actual representations of clinical performance, as there may potentially be confounding factors. These findings may be used to inform the development of quality improvement projects targeted towards patient groups that may benefit from additional intervention.

Furthermore, we also presented site-specific performance data to allow for site to site and site to aggregate data comparisons. On many indicators, aggregate performance was quite high and thus no apparent differences were found at individual sites. Variations in performance by site were observed for a few indicators, such as hepatitis vaccinations and Pap smears. Given the variability in patient and site characteristics, these comparisons may not necessarily imply different levels of care across clinics. However, sites are advised to investigate areas where their performances were lower than the average and to initiate quality improvement projects as appropriate.

Nevertheless, overall improvements in performance and outcome measures between 2001 and 2006 provide evidence of the efficacy of any quality improvement projects or clinical care initiatives implemented during these years. Clinics should recognize their accomplishments, continue existing quality management practices, and adapt systems as appropriate to changing guidelines and patient needs. Clinics may also share best practices, set goals for continued improvement, or identify strategies to sustain the progress achieved.

By continuously monitoring and responding to changes in clinical care performance and patient health outcomes, MPHD-EMMS sites will continue to deliver quality care, reduce disparities, and support optimal health and quality of life for persons living with HIV/AIDS.

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APPENDIX A

EMMS/Ryan White Part A Sites Reviewed

Clinic A Clinic B Clinic C Clinic D Clinic E Clinic F Clinic G Clinic H Clinic I Clinic J Clinic K Clinic L Clinic M Clinic N Clinic O Clinic P Clinic Q Clinic R Clinic S

Aggregate	&	Site-	Spec	ific	Sam	ble	Sizes*	from	2001	to	2006

	2001	2002	2003	2004	2005	2006		
Aggregate Sample Size	981	1198	1211	1107	1100	1038	Site Code	Siz
Site-Specific Sample Size								
Clinic A	34	49	33	29	36	37	Α	S
Clinic B	35	56	40	35	32	28	В	S
Clinic C	48	62	58	55	60	57	С	٨
Clinic D	61	74	77	75	68	56	D	٨
Clinic E	49	54	57	55	53	53	Е	N
Clinic F	52	63	68	62	67	61	F	٨
Clinic G	56	61	56	51	47	42	G	S
Clinic H	49	56	61	47	53	58	Н	٨
Clinic I	61	61	64	63	63	60	Ι	٨
Clinic J	59	68	66	59	54	52	J	٨
Clinic K	36	57	63	57	63	63	К	٨
Clinic L	43	43	43	37	40	36	L	S
Clinic M	105	137	172	160	147	141	М	L
Clinic N	53	84	107	92	84	71	Ν	L
Clinic O	32	32	39	36	26	29	0	S
Clinic P	68	71	66	70	65	63	Р	٨
Clinic Q	58	78	68	55	59	46	Q	٨
Clinic R	41	41	33	29	29	30	R	S
Clinic S	73	83	79	76	80	84	S	

*Sample sizes presented for each site above include all patients reviewed who were diagnosed on or before December 31, 2005, alive at the end of the year, with at least 2 visits during the review year.

*For certain clinical or outcome indicators presented in this report, a smaller number or a subset of the patient sample were used as the denominator. For example, a subset or only those patients who were on ART at last visit were included in the denominator for the clinical indicator "last viral load ≤ 400 ".

In the report for distribution to individual clinics, site names and site-specific sample sizes are not included to preserve anonymity. Instead, sites are arbitrarily assigned a letter code and are categorized by size of caseload in 2005 and 2006 as follows:

in 2000 und	2000 45 10110 115.
Small	\leq 50/patients
Medium	51-74
Large	>75 patients