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# **Effectiveness and Outcomes**

## **Research in AIDS**

# **The Prospective Effect of Access to Medical Care on Health-Related Quality of Life Outcomes in Patients with Symptomatic HIV Disease**

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*Medical Care*. Volume 36, Number 3, pp 295-306, 1998

# Objectives

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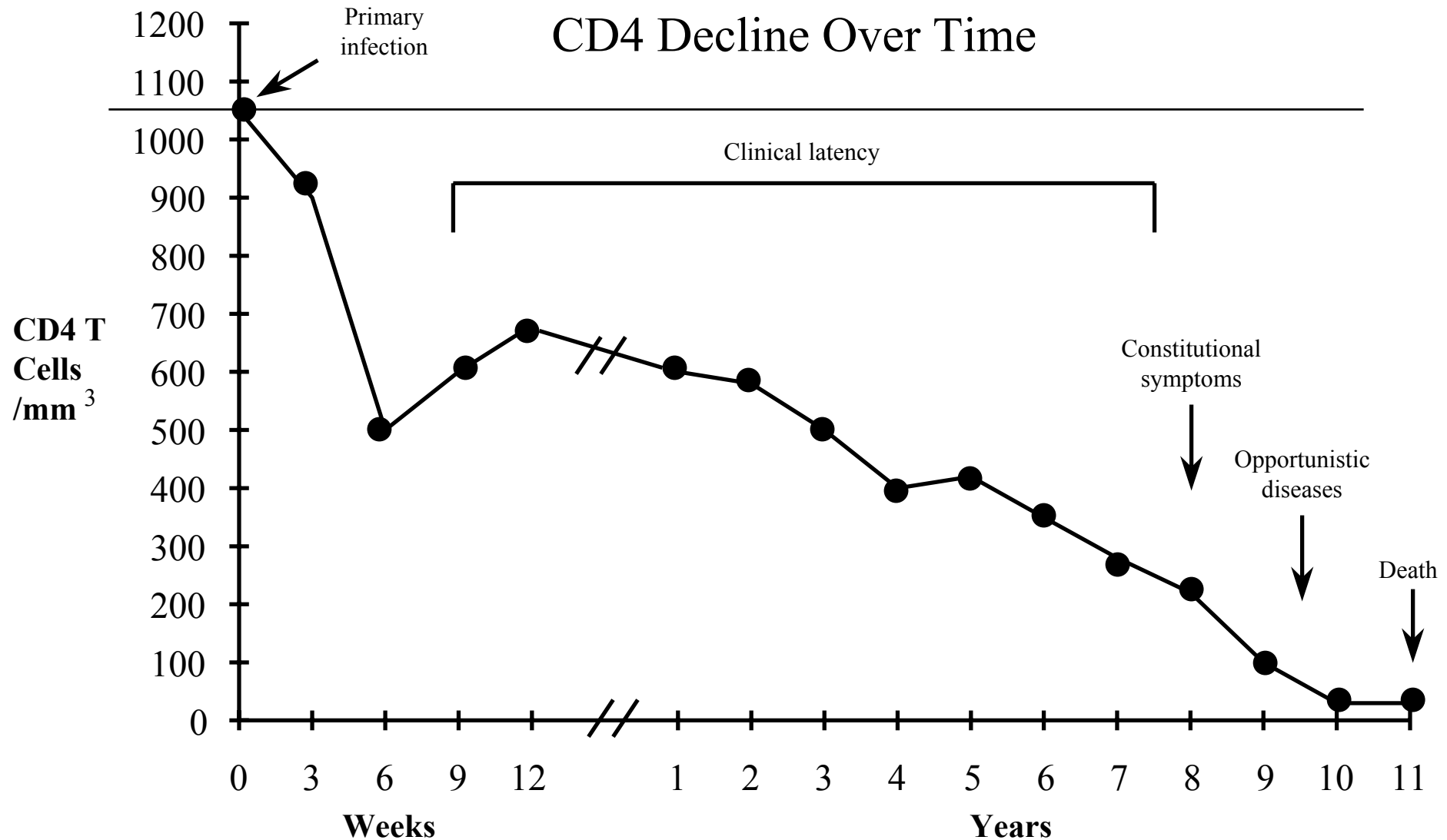
- Assess the prevalence of specific access to care problems in low income, symptomatic, HIV-infected patients.
- Examine the prospective effect of access to care on health-related quality of life (HRQOL) outcomes.

# Significance of Access in HIV Disease

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- Access to early treatment in HIV disease can prevent disease progression and complications
- Specific access measures are needed to evaluate health care delivery
- Access problems are more important if they result in poorer health

# Untreated Course of HIV Infection



# 1992 Revised Classification System for HIV Infection and Expanded AIDS Surveillance Case Definition for Adolescents and Adults

	CLINICAL CATEGORIES		
CD4+ CELL CATEGORIES	(A) Asymptomatic, or PGL**	(B) Symptomatic, not (A) or (C) conditions	(C) AIDS-indicator conditions
(1) $\geq 500/\text{mm}^3$	A1	B1	C1
(2) 200-499/ $\text{mm}^3$	A2	B2	C2
(3) $< 200/\text{mm}^3$ AIDS-indicator cell count	A3	B3	C3

\*\* PGL = persistent generalized lymphadenopathy. Clinical category A includes acute (primary) HIV infection. CDC 1993

# Stages of HIV Disease

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- **CD4 > 500**
  - most patients asymptomatic
  - bacterial infections, TB, shingles
- **CD4 200-500**
  - many patients asymptomatic
  - generalized lymphadenopathy, thrush
- **CD4 < 200**
  - PCP, cryptococcosis, toxoplasmosis
- **CD4 < 50**
  - CMV and MAC infections
  - lymphoma
  - mortality highest

# **Significance of HRQOL Outcomes in HIV**

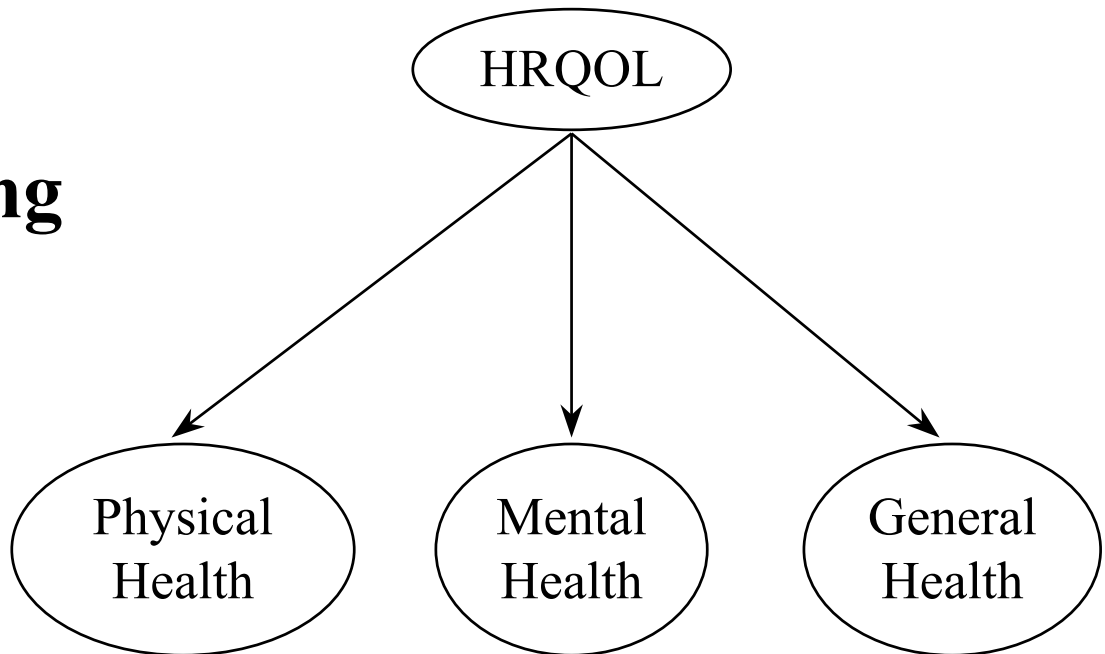
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- **Chronic illness that affects functioning and well-being.**
- **Despite available treatment, HIV is often fatal.**
- **Maintaining quality of life is the treatment goal in chronic disease.**
- **Quality of life outcomes may be sensitive to clinical and policy factors.**

# Definition of Health-Related Quality of Life (HRQOL)

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- **Ability to engage in daily functions:**
  - Physical
  - Role
  - Social
- **Perceived well-being versus distress**
- **Multi-dimensional**



# HRQOL Measures for HIV Research (Number of Items in Each Domain)

Number of items in each sub-scale

Scale	SF-20	MOS-HIV	SF-36	SF-12	SF-38	SF-21	ACTG SF21	SF-56	HCSUS
Physical functioning	6	6	10	2	6	4	4	6	9
Role functioning	2	2	7	4	2	2	2	2	2
Disability days	0	0	0	0	0	3*	0	1*	1*
Pain	1	2	2	1	1	2	2	2	2
Social functioning	1	1	2	1	1	2	2	2	2
Emotional well-being	5	5	5	2	5	3	3	5	7
Energy / fatigue	0	4	4	1	4	2	2	5	2
Cognitive functioning	0	4	0	0	6	3	3	6	0
General health	5	5	5	1	5	3	3	5	3
Health distress	0	4	0	0	0	0	0	0	0
Overall QOL	0	1	0	0	7	0	0	3	1
Overall health	0	0	0	0	0	1*	1*	0	1
Absence of loneliness	0	0	0	0	0	0	0	8	0
Hopefulness	0	0	0	0	0	0	0	11	0
Health transition	0	1*	1*	0	1*	0	0	0	0

\* Scored separately

- Wu, *QLR* 1997

# HCSUS HRQOL Measure

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	<b>No. of Items</b>	<b><math>\alpha</math></b>
<b>Physical Function</b>	<b>9</b>	<b>0.91</b>
<b>Role Function</b>	<b>2</b>	<b>0.85</b>
<b>Pain</b>	<b>2</b>	<b>0.84</b>
<b>General Health Perceptions</b>	<b>3</b>	<b>0.80</b>
<b>Emotional Well-Being</b>	<b>7</b>	<b>0.90</b>
<b>Social Function</b>	<b>2</b>	<b>0.82</b>
<b>Energy</b>	<b>2</b>	<b>0.74</b>

# Example Disease-Targeted (symptom) HRQOL Items From HOS

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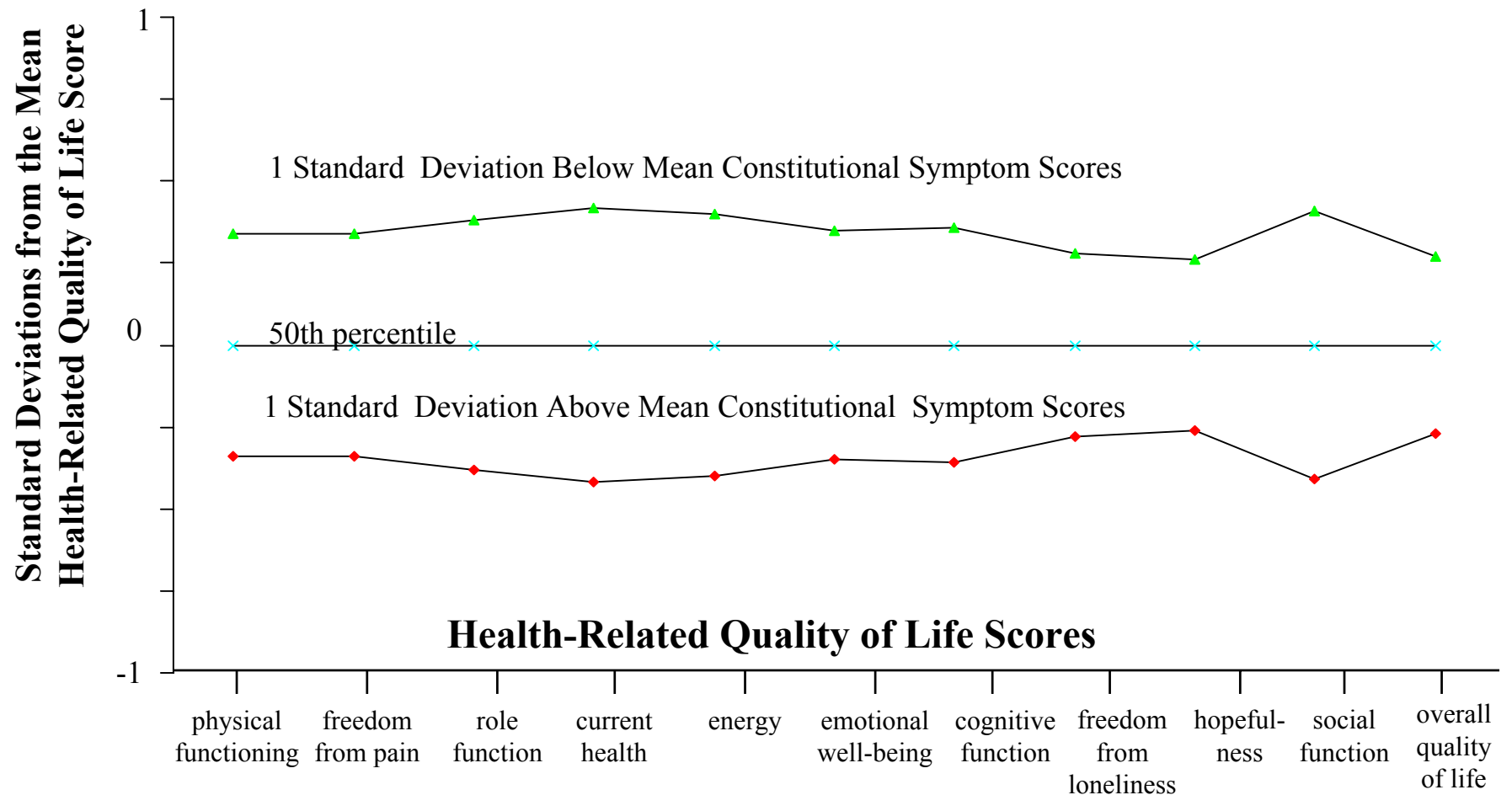
- During the **PAST 7 DAYS**, did you have pain or cramping in your abdomen with your bowel movement?
  1. Never
  2. Less than half my bowel movement
  3. Half or more than half, but not all my bowel movements
  4. Every bowel movement
  
- During the **PAST 7 DAYS**, how often have you had pains or spasm in your rectum without passing stool?
  1. Never
  2. One day
  3. 2-3 days
  4. 4-6 days
  5. Once or twice a day every day
  6. More than twice a day every day

# **Example Disease-Targeted (symptom) HRQOL Items from HCSUS**

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- **In the last 6 months, have you had fever, sweats, or chills?**
- **In the last 6 months, have you had nausea or loss of appetite?**
  - **Yes or No**
  - **If yes, how bothersome is it?**
    - **Extremely, quite a bit, moderately, very little**

# Multivariate Regression Results for the Relationship of Constitutional Symptom Score to Health-Related Quality of Life Score



# Design: Cohort Study

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- **282 adult public hospital patients**
  - VA & HUMC
- **AIDS or HIV positive with: fever, weight loss, and/or diarrhea**
- **2 Face-to-Face Interviews**
  - 1) **Baseline**
  - 2) **Follow-up (median of 100 days later)**
    - **79% completed**
    - **17% dead**
    - **4% lost**

# Measures of HRQOL

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- **Adapted from Medical Outcomes Study**
- **56 items, 11 scales: general health, physical health, mental health**
- **Physical health and mental health factor composites**
- **Scores range from 0-100 with higher values representing better health**
- **Reliabilities (alphas) exceeded 0.70, except for the pain measure (0.64); composites exceed 0.90**

# Measures of Access

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- **9-item scale of perceived access (alpha = 0.74)**
- **Covers affordability, convenience, and availability**
  - **Problems covering the costs of care**
  - **Inconvenience of office location**
  - **Problems obtaining urgent care when needed**

# Measures of Access (Con't)

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- **3 individual items measure temporal access**
  - **Transportation time**
  - **Urgent appointment wait**
  - **Office wait**

# Analysis

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- **Transform Scores:**     **0 = Worst Possible HRQOL**  
                                  **100 = Best Possible HRQOL**
- **Psychometric performance of measures**
  - **Reliability -- internal consistency**
  - **Item discrimination across scales**

# Analysis (Con't)

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- **Compared the HRQOL change scores by high vs. low access at baseline, stratifying on initial HRQOL**
- **Regressed HRQOL change scores (physical and health composites) on access measures.**
- **Controlled for age, sex, race, income, marital status, education, risk group, CD-4 count, and symptoms, stratifying on initial HRQOL**

# Demographic Characteristics

## (N=205)

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<u>Characteristic</u>		N	(%)
Sex:	male	193	93
Race:	black	54	26
	latino	57	28
	white	79	38
Insurance:	uninsured	84	41
	medi-cal	70	34
	VA	35	17
Mean Age ( $\pm$ Sd):		36 $\pm$ 8 Years	
Median Annual Income:		\$5,000-\$10,000	

# Clinical Characteristics

## (N=205)

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	N	(%)
Diarrhea	104	51
Fever	88	43
Weight Loss	13	6
Antiretroviral RX	123	60
PCP Prophylaxis	63	31
In Randomized Trial	5	2
“Alternative” Therapy	29	14

# Access Problems in the HOS vs. MOS

Access Measure	HOS Study Sample (n = 282)	MOS Comparison Sample (n=2471)
Problems with Affordability		
Trouble Covering the Cost of Care	47	70*
Going Without Care Because of Cost	63	76*
Problems of Availability of:		
Emergency Care	59	78*
Hospital Care	72	81*
Urgent Care	77	74
Problems with Convenience		
Office Hours Inconvenient	38	62*
Location Inconvenient	61	75*
Contacting Provider to Ask Questions Inconvenient	79	68*
Problems Accessing Specialists	70	72
Overall	63	73*

<sup>a</sup> p<0.0001

# Temporal Access Problems (N=282)

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Access Measure	% Reporting Problem	National Norm <sup>b</sup>
Typical Transportation Time to Regular Source of Care		
>30 minutes	55	9
>1 hour	17	2
Typical Number of Days to Schedule an Urgent Appointment		
> 1 day	50	----
> 2 hours	23	----
Typical Time Spent Waiting in the Office Before Appointments		
>1 hour	54	13
>2 hours	32	----

<sup>b</sup> Aday and Andersen, 1984

# Multitrait/Multi-Item Matrix for HOS HRQOL Measures

	Physical Function (PF)	Mental Health (MH)	Social Function (SF)
PF #1	.52*	.14	.44
PF #2	.64*	.20	.46
PF #3	.67*	.24	.44
PF #4	.76*	.20	.36
PF #5	.64*	.33	.37
PF #6	.50*	.25	.32
MH #1	.20	.59*	.33
MH #2	.23	.61*	.31
MH #3	.30	.61*	.49
MH #4	.17	.61*	.41
MH #5	.25	.65*	.39
SF #1	.48	.42	.55*
SF #2	.46	.46	.55*

\* Item-Scale Correlation Corrected for Overlap

# Multivariate Relationship of Access to Insurance Status

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<u>Access Measure</u>	Adjusted Access Score		
	<u>Uninsured</u>	<u>VA</u>	<u>Medi-Cal</u>
<u>Costs</u>			
Covering The Costs Of Care	43	67*	70*
No Care Because Of Costs	56	71*	74*

(0-100 with 100 = Highest Access)  
\*P < 0.01, compared to uninsured

# Multivariate Relationship of Access to Insurance Status (Con't)

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Access Measure	Adjusted Access Score		
	Uninsured	VA	Medi-Cal
<u>Convenience</u>			
Convenience Of Office Hours	34	41	39
Convenience Of Office Locations	67	72	68
Calling Provider To Ask Questions	86*	59	87*

(0-100 With 100 = Highest Access)

\* P <001, compared to VA

# Multivariate Relationship of Access to Insurance Status (Con't)

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## Adjusted Access Score

Access Measure	Uninsured	VA	Medi-Cal
<u>Availability of:</u>			
Emergency Care	64	86*	62
Hospital Care	69	86*	76*
Specialty Care	62	64	67
Urgent Care	38	41	39

(0-100 With 100 = Highest Access)

\*P <0.01

# Key Comparisons in Assessing the Effect of Access to Care on HRQOL Outcomes

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H R Q O L C o m p o s i t e M e a s u r e s *	H i g h A c c e s s			L o w A c c e s s			D i f f e r e n c e o f C h a n g e f o r H i g h v s . L o w A c c e s s
	B a s e l i n e	3 m o n t h	C h a n g e	B a s e l i n e	3 m o n t h	C h a n g e	
P h y s i c a l H e a l t h							
M e n t a l H e a l t h							

# Key Comparisons in Assessing the Effect of Access to Care on HRQOL Outcomes

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HRQOL Composite Measures*	High Access (n=142)			Low Access (n=54)			Difference of Change for High vs. Low Access
	Baseline	3 month	Change	Baseline	3 month	Change	
<b>Physical Health</b>	<b>50.4</b>	<b>56.9</b>	<b>6.6†</b>	<b>45.1</b>	<b>47</b>	<b>1.9</b>	<b>4.7</b>
<b>Mental Health</b>	<b>58.9</b>	<b>63.1</b>	<b>4.2†</b>	<b>48.8</b>	<b>49.5</b>	<b>0.6</b>	<b>3.6</b>

† p<0.05

# Mean Changes (over 3 months) in Physical Health, Stratified by Level of Baseline Access and by Tertile of Baseline HRQOL (1)

H R Q L C o m p o s i t e M e a s u r e s *	H i g h A c c e s s (n= 142)			L o w A c c e s s (n= 54)			D i f f e r e n c e o f C h a n g e f o r H i g h v s . L o w A c c e s s
	B a s e l i n e	3 m o n t h	C h a n g e	B a s e l i n e	3 m o n t h	C h a n g e	
P h y s i c a l H e a l t h C o m p o s i t e							
(l o w t e r t i l e < 41 , n= 64 )	26.9	41	14.1†	28.1	39.1	11.0‡	3.1
(m i d d l e t e r t i l e 41-57 , n= 69 )	48.1	54.8	6.7‡	48.3	44.8	-3.5	10.2‡
(h i g h t e r t i l e > 57 , n= 63 )	72.3	72.4	0.1	69.1	64.7	-4.4	4.5
O v e r a l l	50.4	56.9	6.6	45.1	47	1.9	4.7

† p<0.05

‡ p<0.01

§ p<0.001

# Mean Changes (over 3 months) in Mental Health, Stratified by Level of Baseline Access and by Tertile of Baseline HRQL (2)

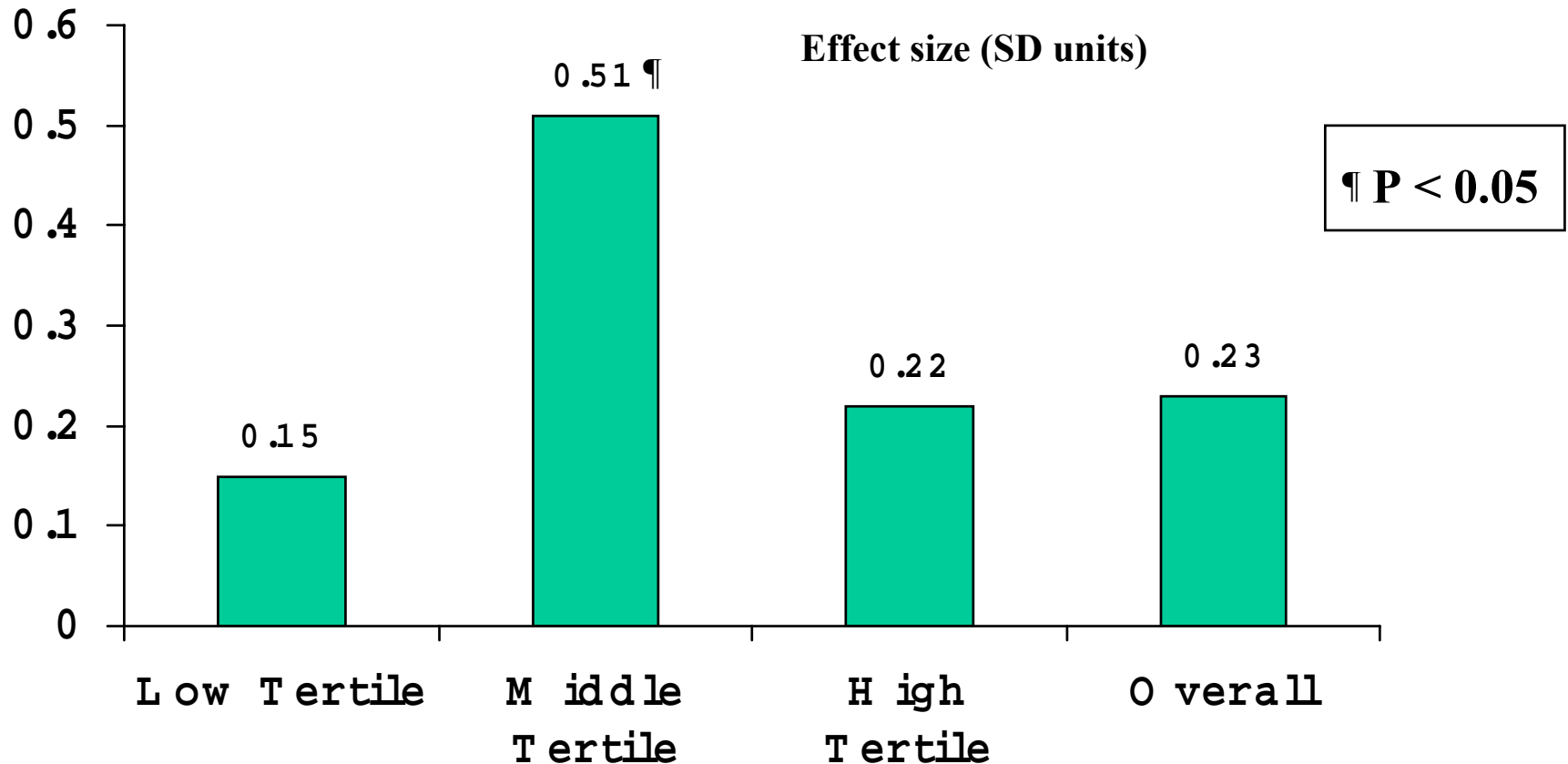
H R Q L C o m p o s i t e M e a s u r e s *	H i g h A c c e s s (n= 142)			L o w A c c e s s (n= 54)			D i f f e r e n c e o f C h a n g e f o r H i g h v s . L o w A c c e s s
	B a s e l i n e	3 m o n t h	C h a n g e	B a s e l i n e	3 m o n t h	C h a n g e	
M e n t a l H e a l t h C o m p o s i t e							
(l o w t e r t i l e < 48 , n= 71 )	39	48.5	9.5†	35.8	38.5	2.7	6.8
(m i d d l e t e r t i l e 48-64 , n= 62 )	55.3	62.1	6.8‡	57.5	57.3	-0.2	7.0§
(h i g h t e r t i l e > 64 , n= 63 )	77.8	75.5	-2.3	73.4	68.8	-4.6	2.3§
O v e r a l l	58.9	63.1	4.2†	48.8	49.5	0.6	3.6

† p<0.05

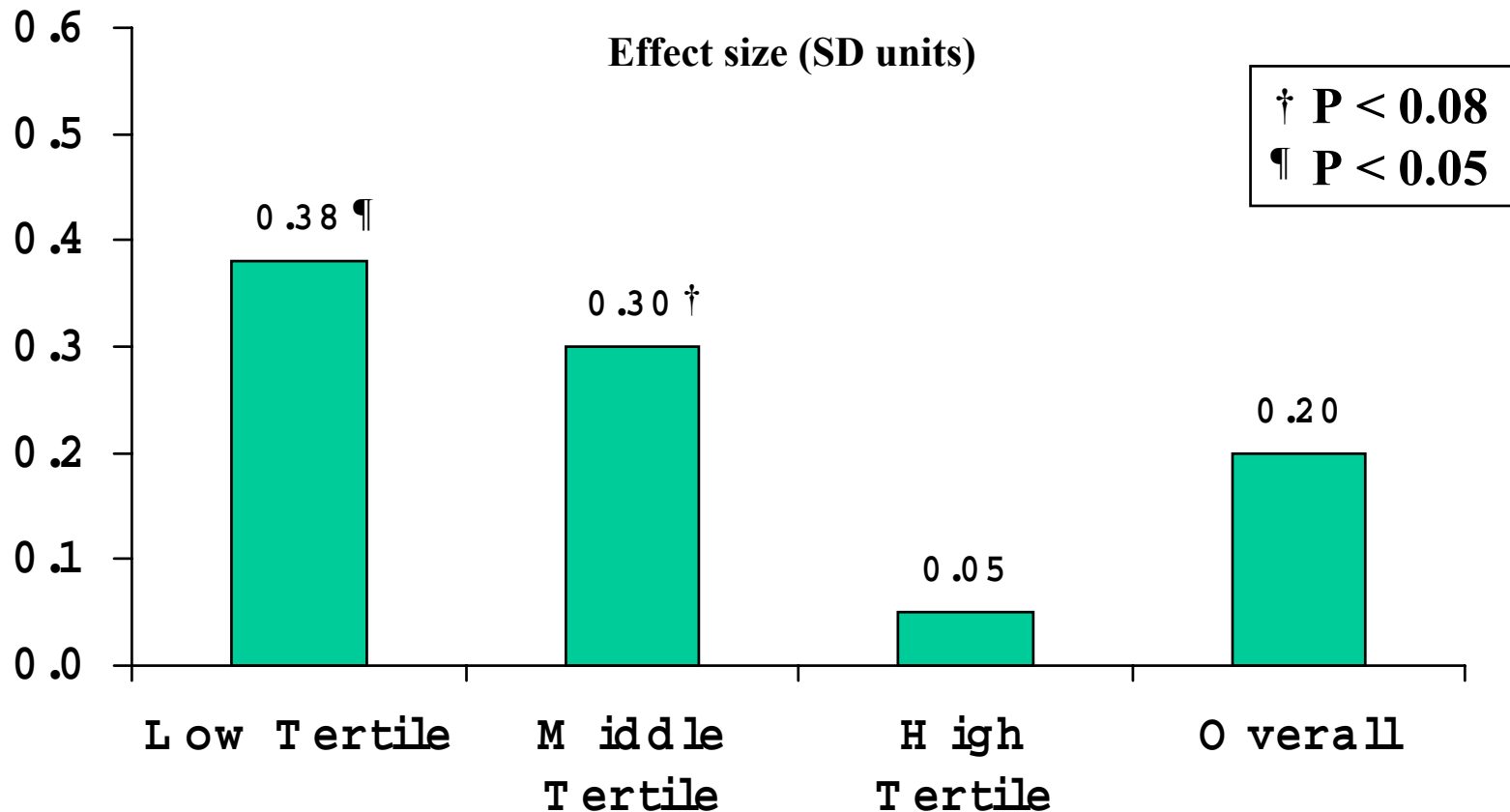
‡ p<0.01

§ p<0.001

# Mean Changes (over 3 months) in Physical Health, Stratified by Level of Baseline Access and by Tertile of Baseline HRQL (3)



# Mean Changes (over 3 months) in Mental Health, Stratified by Level of Baseline Access and by Tertile of Baseline HRQL (3)



# Baseline Perceived Access Equal to Baseline Fever in Predicting Overall Quality of Life

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	High Access (+1 SD)	Low Access (-1 SD)	Difference
Overall Quality of Life	55	47	8*

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	No Fever	Fever	Difference
Overall Quality of Life	65	57	8*

\*P<.01

# Results Summary

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- **Access to care at baseline predicted better physical and mental health outcomes for those with moderate initial PH and for those with moderate or poor initial MH.**

# Results Summary (Con't)

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- **The magnitude of difference in overall quality of life scores between high and low access was 8 out of 100 points. This is similar to the difference in quality of life between patients who had fever at baseline and those who did not.**

# Limitations

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- **Sample includes only patients in the health care system.**
- **Follow-up period short.**
- **Pre-HAART era.**

# Conclusions

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- **Better access predicts better 3-month quality of life, in HIV-infected patients.**
- **The low income, HIV-infected patients studied have extensive problems with access to care.**
- **Increasing access to care for poor public hospital patients, may help to improve HRQOL outcomes among selected persons with HIV disease.**
- **Future studies need to assess the effectiveness of improving access on HRQOL outcomes and on costs.**

# Analytic Model for an Outcomes Study

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