2012 Houston Area Comprehensive HIV Services Plan
PREVENTION AND EARLY IDENTIFICATION WORKGROUP

KEY QUESTIONS FOR EXPLORATION

DATA COLLECTION PACKET

October 12, 2011

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GIS Mapping	5. HIV/AIDS Mortality by Super Neighborhood, Age-Adjusted, Annual Average Rate (1999-2003) 6. Years of Potential Life Lost (Premature Death) by Super Neighborhood, Age-Adjusted, Annual Average Rate due to HIV/AIDS (1999-2003) 7. Rate of New HIV By Census Tract in Houston/Harris County (2009) 8. Spatial Clustering of HIV Diagnoses in Houston/Harris County (2008-2010)
HIV Testing Recommendations and Data	9. HRSA Program Assistance Letter: HIV Testing in Health-Care Settings (September 2010) 10. *U.S. Preventive Services Task Force*: Recommendation Statement on Screening for HIV 11. HIV Testing, Positivity, and Status-Awareness, By Type, Houston EMA, 2010
Affordable Care Act (ACA) and HIV Testing	12. Preventive Services Covered by Private Health Plans under the Affordable Care Act, Kaiser Family Foundation Fact Sheet
ARTP, PrEP and nPEP	13. CDC Dear Colleague Letter: ART for Preventing Secondary Transmission of HIV (May 2011) 14. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents: Preventing Secondary Transmission of HIV (January 2011) 15. CDC Press Release: Results of Preexposure Prophylaxis (PrEP) Clinical Trials among Heterosexuals (July 2011) 16. Interim Guidance: PrEP for the Prevention of HIV Infection in MSM (January 2011) 17. HRSA Guide for HIV/AIDS Clinical Care: Nonoccupational Postexposure Prophylaxis (nPEP) (January 2011) 18. Ben Taub General Hospital Emergency Center HIV nPEP Risk Assessment - Sexual Assault Patients

HIV Testing Promotion Campaigns and Model Programs
References

1. HIV/STD testing community norm change: **GYT**
   www.gytnow.org
2. Provider behavior change: **HIV Screening. Standard Care**
   www.actagainstaids.org/provider/hssc/index.html
3. Prevention with positives: **Prevention is Care**
   www.actagainstaids.org/provider/pic/index.html
4. Prevention with positives/retention in care: **in+care**
   incarecampaign.org/
5. Effective Behavioral Interventions (EBIs) with a focus on testing
   Counseling, Testing, and Referral (CTR)
   Safe in the City
   www.effectiveinterventions.org/en/home.aspx

2012 Houston Area Comprehensive HIV Services Plan
INVENTORY OF SPECIAL POPULATIONS – NATIONAL & LOCAL GUIDANCE

2012 Comprehensive Plan - HRSA Guidance

- Adolescents
- IDU
- Homeless
- Transgender

2011 Integrated Epi Profile

- MSMOC/WMSM
- Women of childbearing age
- Youth
- African Americans
- Hispanics
- Rural

2009 Comprehensive Plan

- Recently released
- Youth (18+)
- Women
- Substance users
- *Mentally ill*
- *Homeless*
- *African American MSM*
- *African American men*
- *Spanish speakers*

RW/A Emerging Populations & EIIHA*

- African Americans
- Hispanics
- MSM
- Women
- Youth (13-24)
- Rural

RW/B-D

- Rural
- Women, infants, and children
- Youth
- MSM
- African American

Texas HIV Services Plan

- Mental health
- Substance users
- Hispanics

CPG HIV Prevention Plan*

- MSM
- FSM
- MSF
- M/IDU
- MSM/IDU
- F/IDU
- *Transgender*
- *Incacerated*
- *Recently released*

CDC HIV Prevention - "Persons at greatest risk"

- All gay and bisexual men
- African Americans
- Hispanics
- IDU
- Transgender

National HIV Strategy - "High risk populations"

- Gay and bisexual men and transgender
- African Americans
- Hispanics
- Substance users
- Asian Americans, American Indians, Alaska Natives

Healthy People 2020

- Adolescents
- Adolescent MSM
- Heterosexuals
- MSM
- IDU
- Perinatal/pregnant women
- Substance users

Undiagnosed HIV Infections By Sex, Race, Age, and Exposure Category, All Texas v. Houston EMA, 2009[1]

	All Texas				Houston EMA			
	# Aware	%Aware	#Unaware	Total (Aware + Unaware)	# Aware	%Aware	#Unaware	Total (Aware + Unaware)
Total	61,948	100.0	16,467	78,415	19,959	100.0	5,306	25,265
Sex								
Male	48,231	77.9	12,821	61,052	14,688	73.6	3,904	18,592
Female	13,717	22.1	3,646	17,363	5,271	26.4	1,401	6,672
Race/Ethnicity[2]								
White	21,158	34.2	5,624	26,782	5,444	27.3	1,447	6,891
Black	23,627	38.1	6,281	29,908	9,758	48.9	2,594	12,352
Hispanic	16,230	26.2	4,314	20,544	4,436	22.2	1,179	5,615
Other	621	1.0	165	786	237	1.2	63	300
Age								
Under 2	16	0.0	4	20	6	0.0	2	8
2 - 12	227	0.4	60	287	83	0.4	22	105
13 - 24	2,983	4.8	793	3,776	1,013	5.1	269	1,282
25 - 34	11,158	18.0	2,966	14,124	3,723	18.7	990	4,713
35 - 44	19,402	31.3	5,157	24,559	6,159	30.9	1,637	7,796
45 - 54	19,822	32.0	5,269	25,091	6,110	30.6	1,624	7,734
55+	8,340	13.5	2,217	10,557	2,865	14.4	762	3,627
Exposure Category[3]						-		
MSM	33,672	54.4	8,951	42,623	10,045	50.3	2,670	12,715
IDU	8,696	14.0	2,312	11,008	2,288	11.5	608	2,896
MSM/IDU	4,144	6.7	1,102	5,246	1,085	5.4	288	1,373
Heterosexual	14,653	23.7	3,895	18,548	6,257	31.3	1,663	7,920
Perinatal	636	1.0	169	805	257	1.3	68	325
Other	147	0.2	39	186	27	0.1	7	34

[1] Data Source: Texas HARS data as of July, 2011

[2] Combined Asian/Pacific Islander, Native American, and Multi-Racial cases

[3] Cases with unknown risk have been redistributed based on historical patterns of risk ascertainment and reclassification

Table 1. Percentage of 2010 Newly Diagnosed Individuals Linked into Care within Three Months of Diagnosis

	Total		Austin TGA		Dallas EMA		Fort Worth TGA		Houston EMA		San Antonio TGA		Other Texas		TDCJ	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Total	**2180**	**68.6**	**138**	**79.8**	**627**	**76**	**132**	**71.7**	**650**	**65.1**	**139**	**69.2**	**431**	**65.6**	**63**	**45**
Sex																
Female	534	72.3	27	87.1	139	78.1	39	75	162	66.1	28	80	130	75.6	9	34.6
Male	1646	67.5	111	78.2	488	75.4	93	70.5	488	64.7	111	66.9	301	62.1	54	47.4
Race/Ethniciy																
White	569	72.6	60	77.9	187	82	51	79.7	117	66.9	30	65.2	115	69.3	9	32.1
Black	889	64.5	31	81.6	293	73.1	56	64.4	329	61	22	62.9	124	60.2	34	46.6
Hispanic	677	70.7	44	81.5	133	73.5	21	75	192	71.1	81	71.1	187	68.5	19	50
Other	33	80.5	2	100	8	88.9	4	100	10	83.3	6	100	3	37.5	.	.
Unknown	12	70.6	1	50	6	100	.	.	2	66.7	.	.	2	50	1	100
Age																
0-1	4	80	.	.	1	100	1	100	2	66.7	.	.	.	.	.	.
02-12	2	66.7	.	.	.	.	.	.	1	50	.	.	1	100	.	.
13-24	456	63.7	28	75.7	138	69	26	70.3	123	57.5	36	69.2	95	61.3	10	47.6
25-34	668	69.1	39	78	191	75.2	38	74.5	200	67.6	42	63.6	132	67	26	49.1
35-44	543	70.8	38	82.6	169	81.3	34	65.4	172	67.2	28	70	85	66.9	17	44.7
45-54	382	70.9	27	84.4	99	79.2	22	73.3	111	67.3	22	78.6	91	68.4	10	38.5
55+	125	68.7	6	75	29	78.4	11	84.6	41	65.1	11	73.3	27	61.4	.	.
Mode of Transmission																
MSM	1331	69.1	93	79.3	438	76.7	75.9	70.8	378	65.2	90	69.5	229	63.3	27	46
IDU	165	59.9	14	86.7	23.4	69.4	11.3	78.5	32.9	51.1	20	74.8	44.4	61.2	20	41
MSM/IDU	60.1	63.9	4.6	59	11.1	73.5	3.5	61.4	11.9	58.1	5.9	46.8	17.8	78.8	5.3	54.6
Heterosexual	618	70.6	27	83	153	75.1	40.3	72.4	224	68.1	24	71.7	139	69.7	10	46.8
Pediatric	6	75	.	.	1	100	1	100	3	60	.	.	1	100	.	.
Late Diagnosis (<1 year between HIV and AIDS)																
Not a Late DX	1422	61.9	103	77.4	406	70	87	68.5	402	57.3	88	62.4	282	58	54	42.2
Late DX	758	85.9	35	87.5	221	90.2	45	79	248	83.5	51	85	149	87.1	9	75
HIV/2010 STI Coinfection																
No HIV/STD coinfection	1936	68.5	114	79.2	554	76.9	120	74.1	578	64.2	116	69.1	393	65.9	61	44.9
HIV/STD coinfection	244	69.3	24	82.8	73	69.5	12	54.6	72	73.5	23	69.7	38	62.3	2	50

Table 2. Percentage of 2010 Newly Diagnosed Individuals Linked into Care within Three Months of Diagnosis by Race/Ethnicity and Sex

	Total				Austin TGA				Dallas EMA				Fort Worth TGA				Houston EMA				San Antonio TGA				Other Texas				TDCJ			
	Female		**Male**		**Female**		**Male**		**Female**		**Male**		**Female**		**Male**		**Female**		**Male**		**Female**		**Male**		**Female**		**Male**		**Female**		**Male**	
	#	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**
Total	**534**	**72.3**	**1646**	**67.5**	**27**	**87.1**	**111**	**78.2**	**139**	**78.1**	**488**	**75.4**	**39**	**75**	**93**	**70.5**	**162**	**66.1**	**488**	**64.7**	**28**	**80**	**111**	**66.9**	**130**	**75.6**	**301**	**62.1**	**9**	**34.6**	**54**	**47.4**
Race/Ethniciy																																
White	88	73.3	481	72.4	9	81.8	51	77.3	15	93.8	172	81.1	14	77.8	37	80.4	15	51.7	102	69.9	6	100	24	60	27	81.8	88	66.2	2	28.6	7	33.3
Black	320	69.7	569	61.9	11	100	20	74.1	106	76.8	187	71.1	18	69.2	38	62.3	115	64.6	214	59.3	9	75	13	56.5	56	68.3	68	54.8	5	41.7	29	47.5
Hispanic	113	78.5	564	69.3	7	77.8	37	82.2	16	76.2	117	73.1	3	75	18	75	31	83.8	161	69.1	12	75	69	70.4	42	84	145	65	2	28.6	17	54.8
Other	10	76.9	23	82.1	.	.	2	100	1	50	7	100	4	100	.	.	1	100	9	81.8	1	100	5	100	3	60	.	.	.	.	.	.
Unknown	3	100	9	64.3	.	.	1	50	1	100	5	100	.	.	.	.	.	.	2	66.7	.	.	.	.	2	100	.	.	.	.	1	100

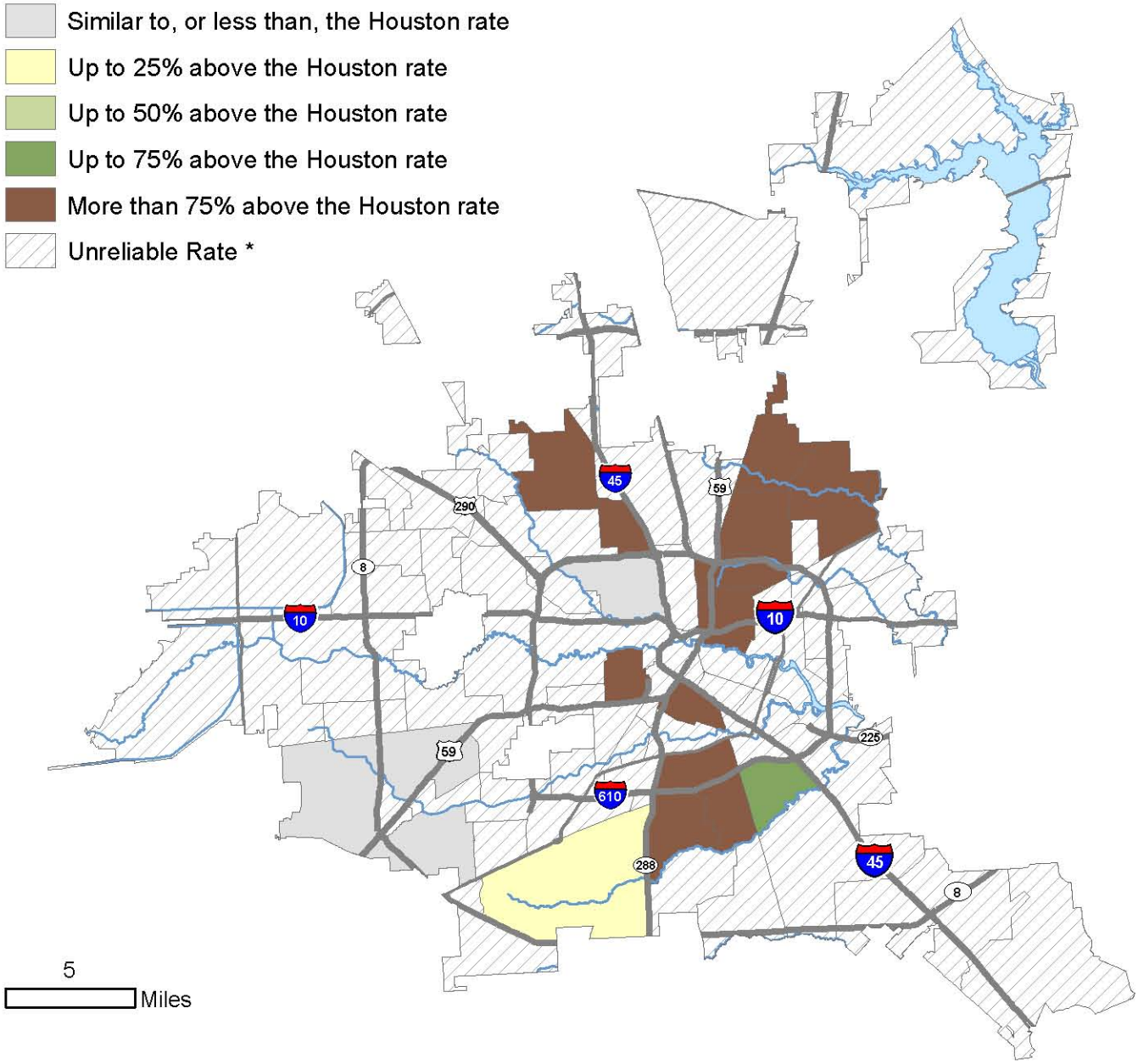
Table 3. Percentage of 2010 Newly Diagnosed Individuals Linked into Care within 3 Months of Diagnosis by Race/Ethnicity & Mode of Transmission

		Total		Austin TGA		Dallas EMA		Fort Worth TGA		Houston EMA		San Antonio TGA		Other Texas		TDCJ	
		#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Total		**2180**	**68.6**	**138**	**79.8**	**627**	**76**	**132**	**71.7**	**650**	**65.1**	**139**	**69.2**	**431**	**65.6**	**63**	**45**
MSM	White	417	73.5	45.1	78.4	161	81.1	31.3	80.3	91.6	71.6	19.6	60.5	65.8	66.3	2.4	18.8
	Black	413	62.5	14.8	78.3	158	71.6	27.9	62.7	144	57.3	9.1	61.9	45.2	53.6	14.8	52.9
	Hispanic	473	71.6	29.9	81.5	109	76.8	16.7	73.6	133	70.2	57.2	73.2	118	67.8	9.4	52.8
	Other	19	84.1	2	100	5.6	100	.	.	7.4	86.1	4	100	.	.	.	.
	Unknown	8.4	64.1	1	52.6	4.7	100	.	.	2	66.7	.	.	.	.	0.7	100
	Total	1331	69.1	92.8	79.3	438	76.7	75.9	70.8	378	65.2	89.9	69.5	229	63.3	27.3	46
IDU	White	45.3	65.8	3	90.9	6.3	85.1	5.1	91.1	7.6	47.8	4.8	82.8	14.2	68.3	4.3	43
	Black	78.1	56.5	5.6	76.7	14.2	71	3.2	56.1	20.9	50.7	4.9	60.5	18.2	64.3	11.1	40.2
	Hispanic	38.8	59.5	5.1	98.1	1.7	33.3	2.4	96	4.4	62	9.9	80.5	10.7	49.3	4.6	40.7
	Other	1.1	68.8	.	.	0.2	100	0.6	100	.	.	.	.	0.3	50	.	.
	Unknown	2.1	95.5	.	.	1	100	.	.	.	.	.	.	1	90.9	0.1	100
	Total	165	59.9	13.7	86.7	23.4	69.4	11.3	78.5	32.9	51.1	19.6	74.8	44.4	61.2	20.1	41
MSM/IDU	White	26.5	65.9	4.3	67.2	6.2	82.7	0.7	35	3.6	51.4	2	48.8	8.5	80.2	1.2	46.2
	Black	20.4	70.3	.	.	3.4	85	2.5	73.5	6.8	69.4	0.4	50	5.5	85.9	1.8	50
	Hispanic	12	51.1	0.3	75	1.4	40	0.3	100	1.5	40.5	2.5	37.3	3.8	69.1	2.2	64.7
	Other	1	90.9	.	.	.	.	.	.	.	.	1	100	.	.	.	.
	Unknown	0.2	100	.	.	0.1	100	.	.	.	.	.	.	.	.	0.1	100
	Total	60.1	63.9	4.6	59	11.1	73.5	3.5	61.4	11.9	58.1	5.9	46.8	17.8	78.8	5.3	54.6
Hetero	White	79.2	74.4	7.6	77.6	13.3	92.4	12.9	78.7	14.2	58.9	3.6	97.3	26.5	74.9	1.1	42.3
	Black	373	68.6	10.6	98.2	118	75.1	22.4	67.1	155	66.5	7.6	66.7	54.1	63	6.3	45.7
	Hispanic	152	73.2	8.7	74.4	19.9	67.7	1.6	64	53.1	76.1	11.4	67.9	54.7	75.9	2.8	50.9
	Other	11.9	75.8	.	.	2.2	68.8	3.4	100	2.6	81.3	1	100	2.7	55.1	.	.
	Unknown	1.3	86.7	.	.	0.2	100	.	.	.	.	.	.	1	90.9	0.1	100
	Total	618	70.6	26.9	83	153	75.1	40.3	72.4	224	68.1	23.6	71.7	139	69.7	10.3	46.8
Pediatric	White	1	100	.	.	.	.	1	100	.	.	.	.	.	.	.	.
	Black	4	66.7	.	.	.	.	.	.	3	60	.	.	1	100	.	.
	Hispanic	1	100	.	.	1	100	.	.	.	.	.	.	.	.	.	.
	Total	6	75	.	.	1	100	1	100	3	60	.	.	1	100	.	.

Table 4. Percentage of 2010 Newly Diagnosed Individuals Linked into Care within Three Months of Diagnosis by Mode of Transmission, Race/Ethnicity and Sex

		Total				Austin TGA				Dallas EMA				Fort Worth TGA				Houston EMA				San Antonio TGA				Other Texas				TDCJ			
		Female		Male		Female		Male		Female		Male		Female		Male		Female		Male		Female		Male		Female		Male		Female		Male	
		#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Total		**534**	**72.3**	**1646**	**67.5**	**27**	**87.1**	**111**	**78.2**	**139**	**78.1**	**488**	**75.4**	**39**	**75**	**93**	**70.5**	**162**	**66.1**	**488**	**64.7**	**28**	**80**	**111**	**66.9**	**130**	**75.6**	**301**	**62.1**	**9**	**34.6**	**54**	**47.4**
MSM	White	.	.	417	73.5	.	.	45	78.4	.	.	161	81.1	.	.	31	80.3	.	.	91.6	71.6	.	.	20	60.5	.	.	65.8	66.3	.	.	2.4	18.8
	Black	.	.	413	62.5	.	.	15	78.3	.	.	158	71.6	.	.	28	62.7	.	.	144	57.3	.	.	9.1	61.9	.	.	45.2	53.6	.	.	15	52.9
	Hispanic	.	.	473	71.6	.	.	30	81.5	.	.	109	76.8	.	.	17	73.6	.	.	133	70.2	.	.	57	73.2	.	.	118	67.8	.	.	9.4	52.8
	Other	.	.	19	84.1	.	.	2	100	.	.	5.6	100	.	.	.	.	.	.	7.4	86.1	.	.	4	100	.	.	.	.	.	.	.	.
	Unknown	.	.	8.4	64.1	.	.	1	52.6	.	.	4.7	100	.	.	.	.	.	.	2	66.7	.	.	.	.	.	.	.	.	.	.	0.7	100
	Total	.	.	1331	69.1	.	.	93	79.3	.	.	438	76.7	.	.	76	70.8	.	.	378	65.2	.	.	90	69.5	.	.	229	63.3	.	.	27	46
IDU	White	26.4	66.7	18.9	64.7	2.9	96.7	0.1	33.3	3.6	92.3	2.7	77.1	2.2	81.5	2.9	100	4.8	45.7	2.8	51.9	4	100	1.2	54.6	8.2	72.6	6	63.2	1	23.9	3.2	59.3
	Black	33.4	62.7	44.7	52.7	2.5	100	3.1	64.6	7.8	72.9	6.4	68.8	1.5	60	1.7	53.1	5.7	41.3	15.2	55.5	3	73	2.2	50	11	70.1	7.2	57.1	2	50	8.9	38.4
	Hispanic	12.2	72.2	26.6	55.1	1.3	100	3.8	97.4	0.1	8.33	1.6	41	2	95.2	0.4	100	0.4	57.1	4	62.5	5	100	5.2	68.4	3.3	86.8	7.4	41.3	0	12.9	4.2	51.2
	Other	1	100	0.1	16.7	.	.	.	.	0.1	100	0.1	100	0.6	100	.	.	.	.	.	.	.	.	.	.	0.3	100	.	.	.	.	.	.
	Unknown	2	100	0.1	50	.	.	.	.	1	100	.	.	.	.	.	.	.	.	.	.	.	.	.	.	1	100	.	.	.	.	0.1	100
	Total	75	66.5	90.4	55.4	6.7	98.5	7	77.8	12.6	74.6	10.8	64.3	6.3	79.8	5	76.9	10.9	43.6	22	55.8	11	91.7	8.6	60.6	23.8	74.1	20.6	51	4	30.6	16	44.4
MSM/IDU	White	.	.	26.5	65.9	.	.	4.3	67.2	.	.	6.2	82.7	.	.	0.7	35	.	.	3.6	51.4	.	.	2	48.8	.	.	8.5	80.2	.	.	1.2	46.2
	Black	.	.	20.4	70.3	.	.	.	.	.	.	3.4	85	.	.	2.5	73.5	.	.	6.8	69.4	.	.	0.4	50	.	.	5.5	85.9	.	.	1.8	50
	Hispanic	.	.	12	51.1	.	.	0.3	75	.	.	1.4	40	.	.	0.3	100	.	.	1.5	40.5	.	.	2.5	37.3	.	.	3.8	69.1	.	.	2.2	64.7
	Other	.	.	1	90.9	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	1	100	.	.	.	.	.	.	.	.
	Unknown	.	.	0.2	100	.	.	.	.	.	.	0.1	100	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	0.1	100
	Total	.	.	60.1	63.9	.	.	4.6	59	.	.	11.1	73.5	.	.	3.5	61.4	.	.	11.9	58.1	.	.	5.9	46.8	.	.	17.8	78.8	.	.	5.3	54.6
Hetero	White	60.6	76.3	18.6	68.9	6.1	76.3	1.5	83.3	11.4	94.2	1.9	82.6	11	75.5	2.1	100	10.2	55.1	4	71.4	2	100	1.2	92.3	18.8	86.6	7.7	56.2	1	37.5	0.2	100
	Black	285	70.9	88.5	62.1	8.5	100	2.1	91.3	98.2	77.1	19.4	66	17	70.2	5.9	59.6	108	67.2	46.2	65.1	6	75.9	1.3	41.9	44	67.4	10.1	49	3	36.8	3.5	56.5
	Hispanic	101	79.3	51.4	63.7	5.7	74	3	75	15.9	80.3	4	41.7	1	52.6	0.6	100	30.6	84.3	22.5	67.2	7	64.6	4.1	74.6	38.7	83.8	16	61.8	2	41	1.2	75
	Other	9	75	2.9	78.4	.	.	.	.	0.9	47.4	1.3	100	3.4	100	.	.	1	100	1.6	72.7	1	100	.	.	2.7	57.5	.	.	.	.	.	.
	Unknown	1	100	0.3	60	.	.	.	.	0	.	0.2	100	.	.	.	.	.	.	.	.	.	.	.	.	1	100	.	.	.	.	0.1	100
	Total	456	73.4	162	63.6	20	83.9	6.6	80.5	126	78.5	26.8	62.6	32	73.6	8.6	68.3	150	69.2	74.3	66.2	17	73.9	6.6	66.7	105	75.7	33.8	55.9	5	38.1	5	61.7
Pediatric	White	1	100	.	.	.	.	.	.	.	.	.	.	1	100	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Black	2	50	2	100	.	.	.	.	.	.	.	.	.	.	.	.	1	33.3	2	100	.	.	.	.	1	100	.	.	.	.	.	.
	Hispanic	.	.	1	100	.	.	.	.	.	.	1	100	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	Total	3	60	3	100	.	.	.	.	.	.	1	100	1	100	.	.	1	33.3	2	100	.	.	.	.	1	100	.	.	.	.	.	.

HIV/AIDS Mortality by Super Neighborhood
Age-Adjusted, Annual Average Rate (1999-2003)



* Age-adjusted rates are not presented where fewer than 25 deaths occurred.

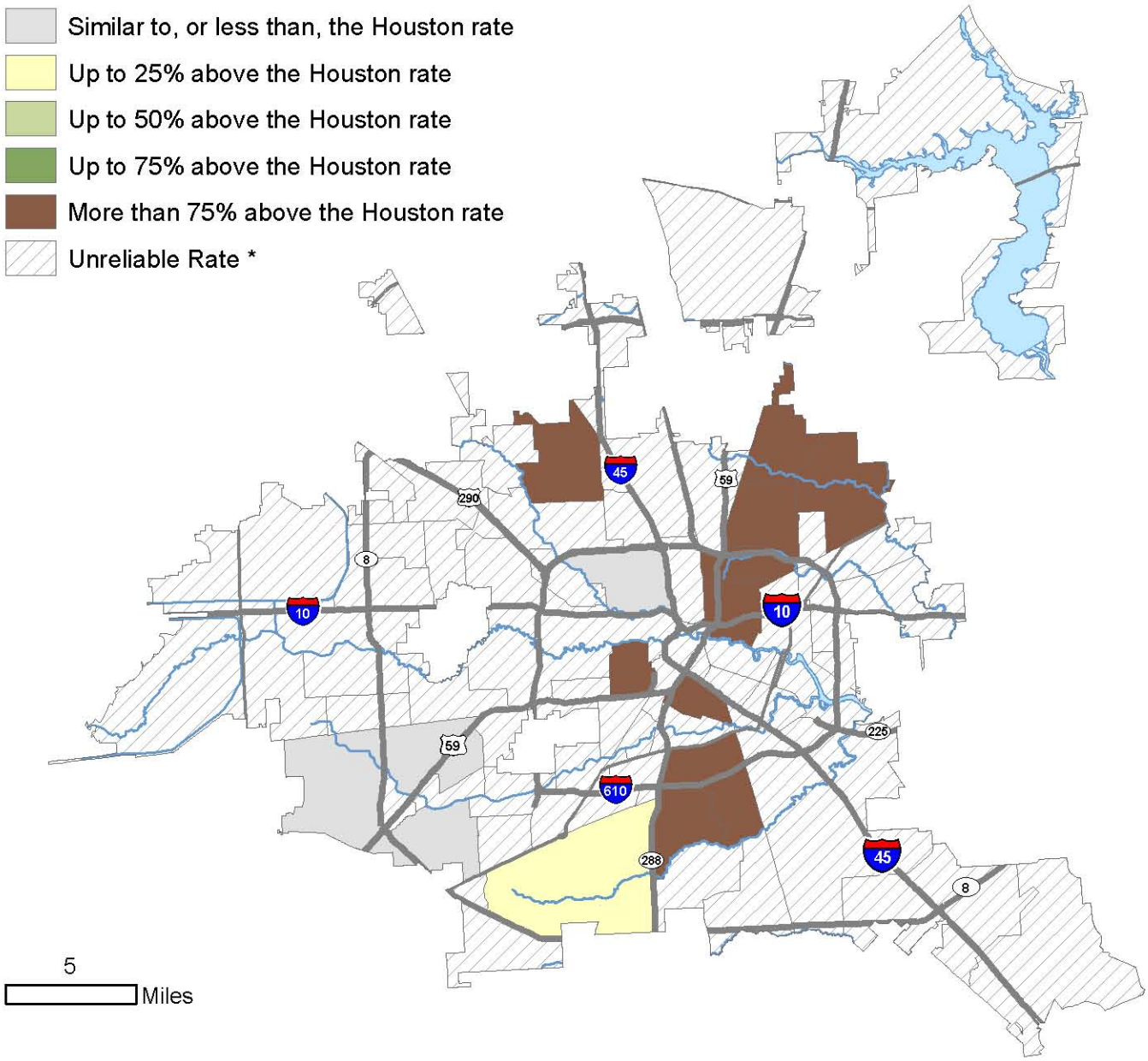
Rates represent age-adjusted annual average deaths per 100,000 population, standardized using the 2000 U.S. Standard Million.

GIS HOUSTON DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Surveillance & Public Health Preparedness
Community Health Statistics Program

Data Sources: Texas Department of State Health Services, Vital Statistics; US Census, 2000

Years of Potential Life Lost (YPLL) by Super Neighborhood Age-Adjusted, Annual Average Rate due to HIV/AIDS, 1999-2003



* Age-adjusted rates are not presented where fewer than 25 deaths occurred.

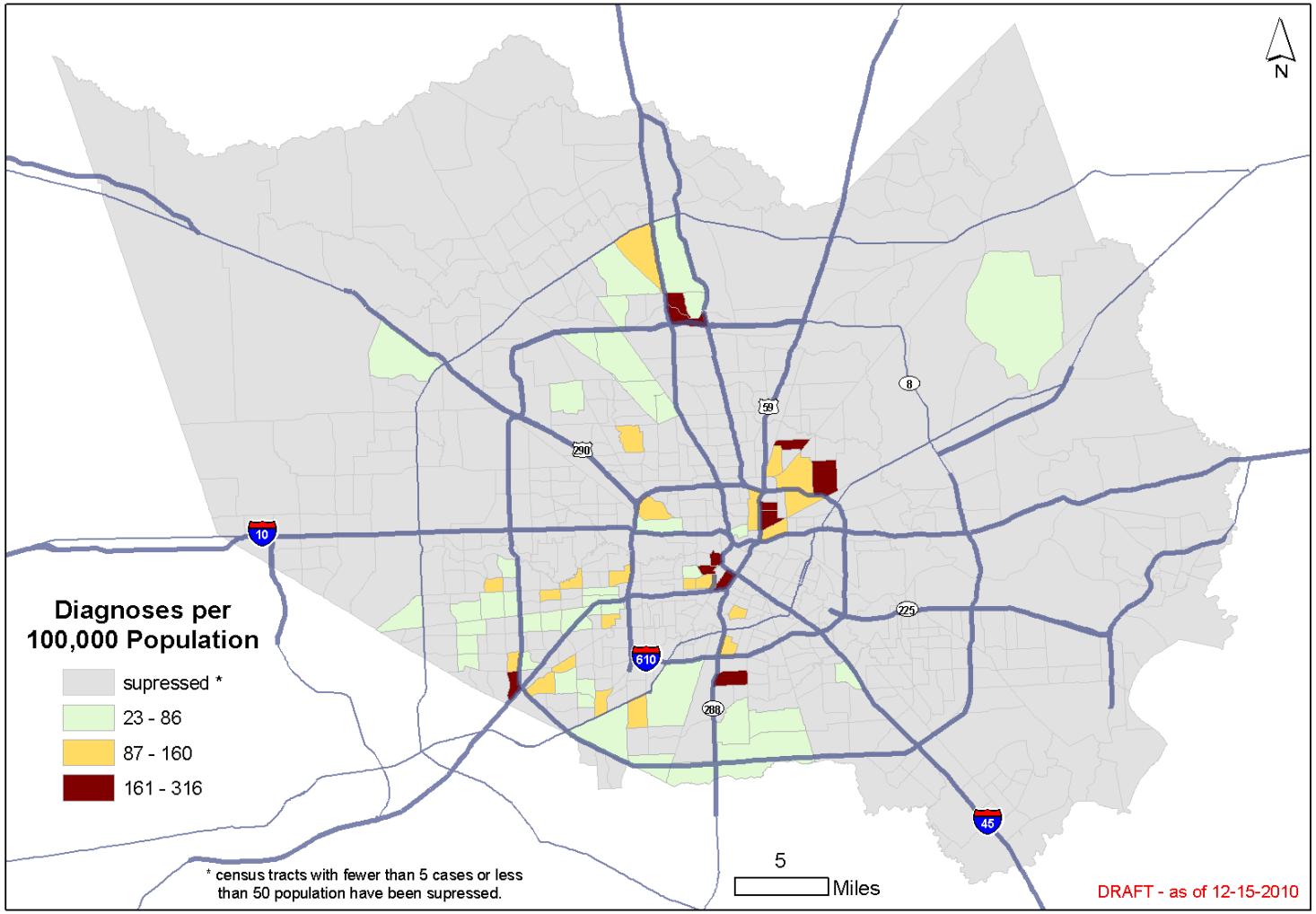
Rates represent age-adjusted annual average YPLL per 100,000 population under 65, standardized using the 2000 U.S. Standard Million.

GIS HOUSTON DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Surveillance & Public Health Preparedness
Community Health Statistics Program

Data Sources: Texas Department of State Health Services, Vital Statistics; US Census, 2000

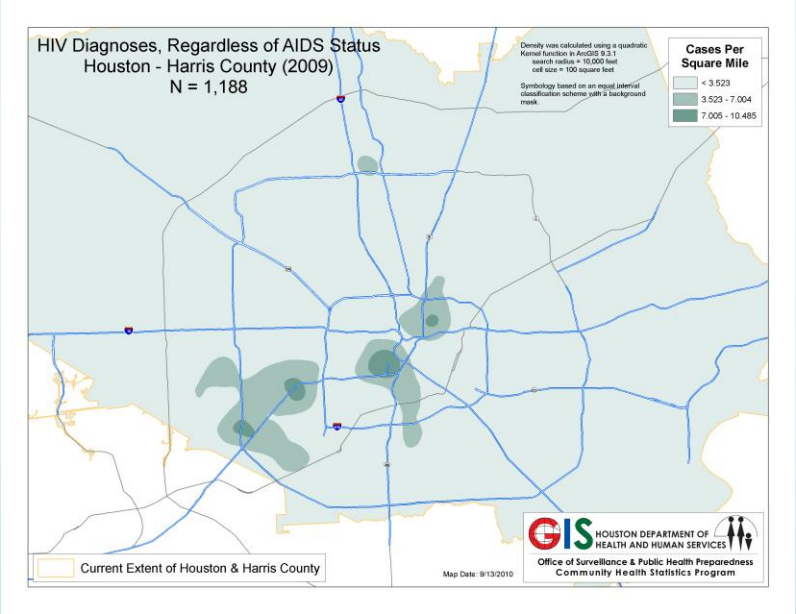
Rate of New HIV Diagnosis by Census Tract in Houston / Harris County (2009)

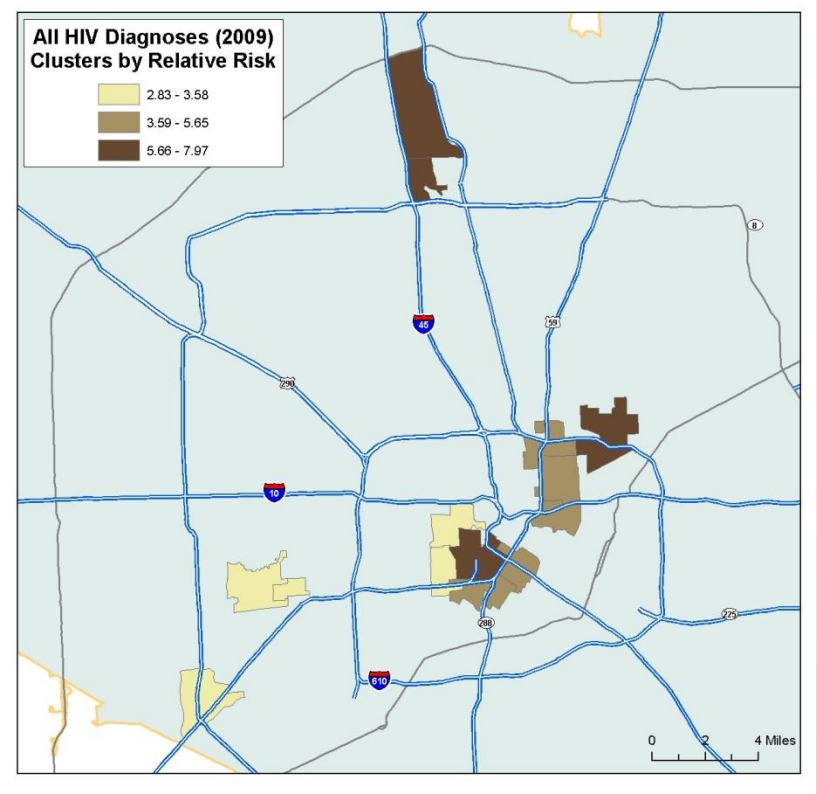


Houston Department of Health and Human Services

Manuscript – Spatial Clustering of HIV Diagnoses in Houston/Harris County, Texas 2008-2010

- Comparison of results from multiple cluster identification techniques to locate areas of excess burden & risk across the 3 years of data
- May submit to Health & Place





Houston Department of Health and Human Services

U.S. Department of Health and Human Services
HRSA
Health Resources and Services Administration

Program Assistance Letter

DOCUMENT NUMBER: 2010-13

DATE: September 29, 2010

DOCUMENT TITLE: HIV Testing in Health-Care Settings

TO: Health Center Program Grantees
Primary Care Associations
Primary Care Offices
National Cooperative Agreements

I. Purpose

The purpose of this Program Assistance Letter (PAL) is to provide grantees information regarding the Centers for Disease Control and Prevention's (CDC) "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings." The Health Resources and Services Administration (HRSA) and Bureau of Primary Health Care continue to support reducing the number of people who become infected with HIV, increasing access to care and optimizing health outcomes for people living with HIV, and reducing HIV-related health disparities. This PAL also identifies resources for training and technical assistance to help Health Centers follow the Revised Recommendations.

II. Background

Approximately 25 percent of people living with HIV/AIDS (PLWHA) in the United States do not know their HIV status,[1] partly because many underestimate their risk and do not seek testing.[2] Unaware of their HIV status, PLWHA forego needed care and risk poor health outcomes and increased morbidity and mortality.[3]

The National HIV/AIDS Strategy[4] (NHAS) released on July 13, 2010, outlines the commitment to reduce HIV incidence in the United States by 25% by 2015. The NHAS calls for refocused and intensified activities towards reducing HIV incidence; increasing access to high quality care; reducing health disparities; and improving federal coordination and collaboration.

Health Centers are a critical partner in meeting the Strategy's goals. For more than 40 years, health centers have delivered comprehensive, high-quality preventive and primary health care to patients regardless of their insurance status or ability to pay. During that time health centers have become the essential primary care medical home for America's most vulnerable populations: the poor, uninsured, and homeless; minorities; migrant and seasonal farmworkers;

public housing residents; geographically isolated communities and inner cities; and people with limited English proficiency. Today, more than 1,100 health centers operate 7,900 service delivery sites that provide care to nearly 19 million patients in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. About half of all health center grantees serve a critical need in rural America; the remainder are found in urban areas.

The HIV/AIDS epidemic has profoundly and disproportionately affected these communities and the populations served by health centers. With appropriate care, HIV/AIDS can be managed as a chronic condition in primary care and outpatient specialty settings. Early detection and care is essential however, to reduce HIV/AIDS-related morbidity and mortality and improve quality of life.

Many PLWHA who are unaware of their disease status seek health care services at a variety of clinical settings including health centers, providing opportunities for conventional or rapid HIV testing. Routinely providing rapid HIV testing at these points of entry can increase the number of people who learn their HIV status,[5] although conventional testing remains appropriate in many circumstances.

III. Summary of Revised Testing Recommendations

In September 2006, the CDC updated its recommendations for HIV testing in health care settings and for HIV screening of pregnant women. The objectives of the updated recommendations were as follows: 1) to increase the number of individuals receiving HIV screening in health care settings, including pregnant women; 2) to facilitate earlier detection of HIV infection; 3) to identify individuals with unrecognized HIV infection, provide them with counseling services and referrals to clinical and prevention HIV services; and 4) to further reduce perinatal transmission of HIV in the United States.

Excerpts of major revisions from previously published guidelines include the following:

For Adults and Adolescents

- Screening after notifying the patient that an HIV test will be performed unless the patient declines (opt-out screening) is recommended in all health-care settings. Specific signed consent for HIV testing should not be required. General informed consent for medical care should be considered sufficient to encompass informed consent for HIV testing.
- Persons at high risk for HIV should be screened for HIV at least annually.
- HIV test results should be provided in the same manner as results of other diagnostic or screening tests.
- Prevention counseling should not be required as a part of HIV screening programs in health-care settings. Prevention counseling is strongly encouraged for persons at high risk for HIV in settings in which risk behaviors are assessed routinely (e.g., STD clinics) but should not have to be linked to HIV testing.

- HIV diagnostic testing or screening to detect HIV infection earlier should be considered distinct from HIV counseling and testing conducted primarily as a prevention intervention for uninfected persons at high risk.

For Pregnant Women

- HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women. Patients should be informed that HIV screening is recommended for all pregnant women and that it will be performed unless they decline (opt-out screening).
- Repeat HIV testing in the third trimester is recommended for all women in jurisdictions with elevated HIV or AIDS incidence and for women receiving health care in facilities with at least one diagnosed HIV case per 1,000 pregnant women per year.
- Rapid HIV testing should be performed for all women in labor who do not have documentation of results from an HIV test during pregnancy. Patients should be informed that HIV testing is recommended for all pregnant women and will be performed unless they decline (opt-out screening). Immediate initiation of appropriate antiretroviral prophylaxis should be recommended on the basis of a reactive rapid HIV test result, without awaiting the result of confirmatory testing.

The full text of the Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings were published in Morbidity and Mortality Weekly Report (MMWR), September 22, 2006, Volume 55, Number RR-14; available online at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm.

IV. Additional Resources

There are numerous technical assistance and training resources to assist Health Centers in following the CDC HIV testing recommendations.

The HRSA's HIV/AIDS Bureau (HAB) administers the **AIDS Education and Training Centers (AETCs) Program**. The AETC Program is a network of regional and national centers that provide multidisciplinary training for health care providers treating PLWHA, including Health Centers and other safety net providers. The AETC National Resource Center maintains a central repository of training materials developed by regional and national AETCs and can provide technical assistance and training addressing HIV testing. Additional resources are available through the National Minority AETC and the National HIV/AIDS Clinicians' Consultation Center. For more information, see http://www.aids-ed.org/, http://www.nmaetc.org/, and http://www.nccc.ucsf.edu/.

The CDC's **National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)** supports HIV programs across the country and funds a variety of entities, include state and local health departments, that can provide technical assistance and other resources to

providers, administrative staff, and PLWHA. The NCHHSTP is responsible for public health surveillance, prevention research, and programs to prevent and control human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS), other sexually transmitted diseases (STDs), viral hepatitis, and tuberculosis (TB). Center staff work in collaboration with governmental and nongovernmental partners at community, State, national, and international levels, applying well-integrated multidisciplinary programs of research, surveillance, technical assistance, and evaluation. For more information, see http://www.cdc.gov/nchhstp/ or http://www/cdc.gov/hiv/topics/testing/healthcare/.

The **National Association of Community Health Centers (NACHC)** (see http://www.nachc.com/) has a standing committee on HIV/Substance Abuse Prevention and Treatment. The committee engages in the following: 1) encourages and supports Health Centers in the provision of primary HIV and substance abuse care: 2) tracks funding and develops partnerships with Federal Agencies (i.e., SAMSHA, CDC, HRSA); and 3) develops and provides relevant training and technical assistance to Federally Qualified Health Center (FQHCs). In addition, NACHC provides technical assistance to individual Health Centers on-site regarding the development of programmatic, administrative, and clinical policies and protocols addressing HIV testing and HIV/AIDS care and treatment. For more information, see http://www.nachc.com/.

Finally, many **State and Local Health Departments** help providers navigate testing barriers through the provision of rapid test kits, laboratory services, and training on how to administer tests.[6] Health Departments also can help providers establish screening algorithms for confirmatory HIV testing, which is required when rapid HIV testing produces a reactive, or HIV-positive, result.[7]

Early detection and treatment of HIV/AIDS increases longevity and quality of life for PLWHA and reduces the likelihood of new HIV infections. As the HIV/AIDS epidemic in the United States moves toward a 30 year history, Health Centers continue to play a vital role in caring for PLWHA and in eliminating new infections. HRSA remains a committed partner in your efforts to help PLWHA, their families, and communities live longer, healthier, and more fulfilling lives.

Sincerely,

James Macrae
Associate Administrator

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[3] Peck P. HIV testing often comes late in course of infection. *Medpage Today.* June 25, 2009. Available at: http://www.medpagetoday.com/HIVAIDS/HIVAIDS/14863.
[4] The *National HIV/AIDS Strategy for the United States* and the accompanying *Federal Implementation Plan* may be accessed at: http://www.whitehouse.gov/ONAP.
[5] Branson B, Handsfield H, Lampe M, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR*. 2006;55(RR14):1-17.
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[7] CDC. Notice to readers: protocols for confirmation of rapid reactive HIVtest. *MMWR.*2004;53(10):221-222.

Screening for HIV: Recommendation Statement

U.S. Preventive Services Task Force

Summary of Recommendations

The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen for human immunodeficiency virus (HIV) all adolescents and adults at increased risk for HIV infection (see Clinical Considerations for discussion of risk factors). **A recommendation.**

The USPSTF found good evidence that both standard and U.S. Food and Drug Administration (FDA)-approved rapid screening tests accurately detect HIV infection. The USPSTF also found good evidence that appropriately timed interventions, particularly highly active antiretroviral therapy (HAART), lead to improved health outcomes for many of those screened, including reduced risk for clinical progression and reduced mortality. Since false-positive test results are rare, harms associated with HIV screening are minimal. Potential harms of true-positive test results include increased anxiety, labeling, and effects on close relationships. Most adverse events associated with HAART, including metabolic disturbances associated with an increased risk for cardiovascular events, may be ameliorated by changes in regimen or appropriate treatment. The USPSTF concluded that the benefits of screening individuals at increased risk substantially outweigh potential harms.

The USPSTF makes no recommendation for or against routinely screening for HIV adolescents and adults who are not at increased risk for HIV infection (see Clinical Considerations for discussion of risk factors). **C recommendation.**

The USPSTF found fair evidence that screening adolescents and adults not known to be at increased risk for HIV can detect additional individuals with HIV, and good evidence that appropriately timed interventions, especially HAART, lead to improved health outcomes for some of these individuals. However, the yield of screening persons without risk factors would be low, and potential harms associated with screening have been noted (see above). The USPSTF concluded that the benefit of screening adolescents and adults without risk factors for HIV is too small relative to potential harms to justify a general recommendation.

The USPSTF recommends that clinicians screen all pregnant women for HIV. **A recommendation.**

The USPSTF found good evidence that both standard and FDA-approved rapid screening tests accurately detect HIV infection in pregnant women and fair evidence that introduction of universal prenatal counseling and voluntary testing increases the proportion of HIV-infected women who are diagnosed and are treated before delivery. There is good evidence that recommended regimens of HAART are acceptable to pregnant women and lead to significantly reduced rates of mother-to-child transmission. Early detection of maternal HIV infection also allows for discussion of elective cesarean section and avoidance of breastfeeding, both of which are associated with lower HIV transmission rates. There is no evidence of an increase in fetal anomalies or other fetal harm associated with currently recommended antiretroviral regimens (with the exception of efavirenz; see below). Serious or fatal maternal events are rare using currently recommended combination therapies. The USPSTF concluded that the benefits of screening all pregnant women substantially outweigh potential harms.

Background

In 1996, the USPSTF recommended routine counseling and screening for all persons at increased risk for HIV infection (an "A" recommendation) and routine counseling and screening for high-risk pregnant women, as well as those residing in communities where the prevalence of seropositive newborns is increased (an "A" recommendation) (1). At that time, the USPSTF found insufficient evidence to recommend for or against routine HIV screening for persons without identified risk factors (a "C" recommendation) and insufficient evidence to recommend for or against universal prenatal screening in low-prevalence communities (a "C" recommendation). Testing infants born to high risk mothers was recommended when the antibody status of the mother is unknown (a "B" recommendation). Since then, the USPSTF approach to making recommendations has changed (2) and significant new evidence on screening for and treating HIV infection has been published in the medical literature. Therefore, this recommendation statement has been updated and revised based on a new review of the literature, using the current USPSTF methodology.

Clinical Considerations

- A person is considered at increased risk for HIV infection (and thus should be offered HIV testing) if he or she reports 1 or more individual risk factors or receives health care in a high-prevalence or high-risk clinical setting.

- Individual risk for HIV infection is assessed through a careful patient history. Those at increased risk (as determined by prevalence rates) include: men who have had sex with men after 1975; men and women having unprotected sex with multiple partners; past or present injection drug users; men and women who exchange sex for money or drugs or have sex partners who do; individuals whose past or present sex partners were HIV-infected, bisexual, or injection drug users;

persons being treated for sexually transmitted diseases (STDs); and persons with a history of blood transfusion between 1978 and 1985. Persons who request an HIV test despite reporting no individual risk factors may also be considered at increased risk, since this group is likely to include individuals not willing to disclose high risk behaviors.

- There is good evidence of increased yield from routine HIV screening of persons who report no individual risk factors but are seen in high-risk or high-prevalence clinical settings. High-risk settings include STD clinics, correctional facilities, homeless shelters, tuberculosis clinics, clinics serving men who have sex with men, and adolescent health clinics with a high prevalence of STDs. High-prevalence settings are defined by the Centers for Disease Control and Prevention (CDC) as those known to have a 1% or greater prevalence of infection among the patient population being served. Where possible, clinicians should consider the prevalence of HIV infection or the risk characteristics of the population they serve in determining an appropriate screening strategy. Data are currently lacking to guide clinical decisions about the optimal frequency of HIV screening.

- Current evidence supports the benefit of identifying and treating asymptomatic individuals in immunologically advanced stages of HIV disease (CD4 cell counts < 200 cells/mm^3) with HAART. Appropriate prophylaxis and immunization against certain opportunistic infections have also been shown to be effective interventions for these individuals. Use of HAART can be considered for asymptomatic individuals who are in an earlier stage of disease but at high risk for disease progression (CD4 cell count < 350 cells/mm^3 or viral load >100,000 copies/mL), although definitive evidence of a significant benefit of starting HAART at these counts is currently lacking.

- The standard test for diagnosing HIV infection, the repeatedly reactive enzyme immunoassay followed by confirmatory western blot or immunofluorescent assay, is highly accurate (sensitivity and specificity ≥ 99%). Rapid HIV antibody testing is also highly accurate; can be performed in 10 to 30 minutes; and, when offered at the point of care, is useful for screening high risk patients who do not receive regular medical care (eg, those seen in emergency departments), as well as women with unknown HIV status who present in active labor.

- Early identification of maternal HIV seropositivity allows early antiretroviral treatment to prevent mother-to-child transmission, allows providers to avoid obstetric practices that may increase the risk for transmission, and allows an opportunity to counsel the mother against breastfeeding (also known to increase the risk for transmission). There is evidence that the adoption of "opt-out" strategies to screen pregnant women (who are informed that an HIV test will be conducted as a standard part of prenatal care unless they decline it) has resulted in higher testing rates. However, ethical and legal concerns of not obtaining specific informed consent for an HIV test using the "opt-out" strategy have been raised. While dramatic reductions in HIV transmission to neonates have been noted as a

result of early prenatal detection and treatment, the extent to which detection of HIV infection and intervention during pregnancy may improve long-term maternal outcomes is unclear.

Discussion

Of the estimated 850,000 to 950,000 persons in the United States infected with HIV-1, 25% are thought to be unaware of their status (3, 4). If untreated, almost all infected individuals will eventually develop acquired immunodeficiency syndrome (AIDS), defined by opportunistic infection or severe immune dysfunction. Despite significant recent advances in treatment, AIDS is the seventh leading cause of death in persons aged 15 to 24 years, and the fifth leading cause of death in persons aged 25 to 44 years in the United States (5).

HIV incidence rates (an estimated 40,000 new infections annually) have remained steady in the United States over the last decade (6). This figure includes infection via mother-to-child (vertical) transmission, with approximately 300 infants infected each year. Women are the fastest-growing group of persons with new HIV diagnoses, and an estimated 6,000 to 7,000 HIV-positive women give birth each year in the United States (7, 8). Effective interventions are available to reduce rates of vertical transmission for women diagnosed with HIV infection. However, in 2000, 40% of infected infants were born to mothers not known to have HIV infection before delivery (9).

To update its 1996 recommendations on HIV screening, the USPSTF examined the evidence from 1983 through June 2004 on the benefits and harms of screening and of currently available interventions for HIV infection in adults, adolescents, and pregnant women. Relevant studies on risk factor assessment and the accuracy and acceptability of testing were also reviewed.

The USPSTF review found that standard testing for HIV infection has a sensitivity and specificity greater than 99% and that false-positive test results are rare, even in low risk settings (10, 11). While indeterminate results may occur a little more frequently among parous and pregnant women, the diagnostic accuracy of standard HIV testing is thought to be similar for pregnant women and non-pregnant women and men (12). Alternative FDA-approved screening technologies are also highly accurate and may increase testing acceptability. Compared with standard HIV testing, the reported sensitivities of rapid tests on blood specimens range from 96% to 100%, with specificities greater than 99.9% (13-15). Reported sensitivities and specificities of oral fluid HIV tests are also high (> 99%), although the diagnostic accuracy of urine tests appears lower than that of standard testing (16, 17). One good-quality study of the only FDA-approved home collection kit, using finger-stick blood spot samples, found it to be highly accurate compared with standard testing (18).

A large, good-quality U.S. study found that risk factor assessment can identify individuals at substantially higher risk for HIV, but still misses a significant proportion (20% to 26%) of HIV-positive clients who report no risk factors (19) (since some patients

may choose not to disclose high risk behaviors and others, especially women, may be unknowingly at risk from an infected sex partner) (20). There is fair evidence to indicate that a broader strategy targeted to individuals who report risk factors, combined with routine (voluntary) testing of those being seen in high-prevalence clinical settings, would result in substantially fewer missed diagnoses (21-23). In 2 good-quality studies, HIV screening of populations with a 1% prevalence rate was found to be cost-effective (in terms of acceptable cost per quality-adjusted life-year) compared with no screening (24, 25). One study (25) found that screening populations with even lower prevalence rates is also cost-effective if one assumes secondary transmission benefits. Neither study, however, reported on the incremental cost-effectiveness of screening lower-risk versus higher-risk patients.

The wide adoption in 1995 to1997 of the use of HAART regimens with 3 or more antiretroviral agents has been associated with a marked decline in morbidity and mortality of HIV-infected patients in the United States (3). Good quality evidence has shown HAART regimens to be consistently effective in reducing clinical progression and mortality in persons with CD4 cell counts less than 200 cells/mm^3 (26, 27); the percentage of patients found in studies to be candidates for HAART regimens at the time of HIV diagnosis has ranged from 12% to 43% (20, 28). In addition, 2 good-quality systematic reviews found that the use of antibiotic medication to prevent opportunistic infections (eg, *Pneumocystis carinii* pneumonia and disseminated *Mycobacterium avium-intracellulare* complex) is effective in persons with advanced disease (29, 30). Theoretically, asymptomatic patients in an earlier stage of disease at the time of diagnosis (CD4 cell counts between 200-350 cells/mm^3 or viral load >100,000 copies/mL) may also benefit from HAART regimens. However, there are no completed trials showing clinical benefit from treatment versus no treatment in such patients. Data from the Strategies for Management of Anti-Retroviral Therapy (SMART) trial, which focuses on this group, will not be available for a few more years.

The standard of care in the United States for preventing vertical HIV transmission in seropositive pregnant women has evolved from monotherapy (zidovudine) to combination antiretroviral regimens, including HAART regimens, starting at 14 to 34 weeks' gestation through labor and augmented with 6 weeks of neonatal prophylaxis with zidovudine (31). Avoidance of breastfeeding is recommended for seropositive women since observational studies have shown that breastfeeding increases transmission rates even when adjusted for other factors, including antiretroviral use. A good-quality randomized clinical trial has demonstrated that elective cesarean section also reduces vertical transmission, compared with other modes of delivery, by minimizing contact between the fetus and infected maternal bodily fluids (32), although the benefit appears small in women with undetectable viral loads. There is fair to good evidence that the newer regimens, in combination with formula feeding and elective cesarean delivery, are associated with a reduction in perinatal transmission of 14% to 25% without interventions to 1% to 2% with interventions.

Information about the consequences of false-positive HIV test results (ie, anxiety, labeling) is mostly anecdotal, although true-positive HIV test results have been shown to

result in anxiety, depression, social stigmatization, changes in relationships with sexual partners, and discrimination (33). Evidence suggests that persons testing positive for HIV (especially heterosexual serodiscordant couples) are more likely than others to avoid risky sexual behavior. On the other hand, optimistic beliefs about the effectiveness of HAART regimens have been shown to be associated with increased risky behaviors in individuals known to be seropositive (34, 35). All antiretroviral drugs and drug combinations are associated with specific harm profiles, although most harms are short term or self limited and effective alternatives can often be found (36). Metabolic disturbances (hyperlipidemia and diabetes) related to HAART regimens have been associated with an increased incidence of cardiovascular events, especially with longer exposure (37). The estimated 3-year benefits of HAART regimens appear, however, to greatly outweigh the cardiovascular complications.

No significant increases in the rates of congenital anomalies, neonatal conditions, or other fetal harm have been associated with in utero exposure to FDA-approved regimens of antiretroviral drugs (38), with the exception of those including efavirenz. Efavirenz has recently been re-classified as Class D in pregnancy (positive evidence of human fetal risk). Although studies have demonstrated no ill effects of limited exposure to zidovudine monotherapy in women followed postpartum for as long as 6 years, no studies have evaluated the effects of limited exposure to combination antiretroviral drugs during pregnancy on the long-term clinical outcomes of HIV-infected women.

Recommendations of Other Groups

Counseling and HIV testing of high risk individuals (as defined in the Clinical Considerations section) are recommended by the CDC (39), the Canadian Task Force on the Periodic Health Examination (now the Canadian Task Force on Preventive Health Care) (40), and numerous professional organizations, including the American Medical Association (AMA) (41), the American Academy of Family Physicians (AAFP) (42), the American College of Obstetricians and Gynecologists (ACOG) (43), the American College of Physicians (ACP) (44), and the Infectious Diseases Society of America (IDSA) (45). Also, the American Academy of Pediatrics (AAP) (46) considers all sexually active adolescents to be a high risk group and recommends they be counseled and offered HIV testing. In addition, the CDC recommends that routine, voluntary testing be offered to all patients seen either in health care facilities where the prevalence of HIV infection is 1% or greater or in settings serving client populations at increased behavioral or clinical HIV risk.

The CDC, AMA, AAFP, ACOG, IDSA, AAP (47) and the American College of Nurse-Midwives (48) recommend that all pregnant women be routinely counseled and encouraged to have HIV testing. ACOG, AAP, and the CDC go further in recommending that HIV testing be part of a routine battery of prenatal blood tests unless declined (ie, an “opt-out” approach). The CDC and ACOG also recommend retesting women in their third trimester of pregnancy who are known to be at high risk for

acquiring HIV, as well as rapid HIV testing in labor for women with undocumented HIV status.

Members of the USPSTF

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This statement summarizes the USPSTF recommendations on screening for HIV and the supporting scientific evidence, and updates the 1996 recommendations contained in the *Guide to Clinical Preventive Services,* second edition (1). Explanations of the ratings and of the strength of overall evidence are given in Appendix A and Appendix B, respectively. The complete information on which this statement is based, including evidence tables and references, is included in the summaries of evidence (49, 50) and evidence syntheses (51, 52) on this topic, available through the USPSTF Web site (http://www.preventiveservices.ahrq.gov). The recommendation is also posted on the Web site of the National Guideline Clearinghouse™ (http://www.guideline.gov).

Recommendations made by the USPSTF are independent of the U.S. Government. They should not be construed as an official position of AHRQ or the U.S. Department of Health and Human Services.

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Appendix A

U.S. Preventive Services Task Force Recommendations and Ratings

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The Task Force grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

A. The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. *The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.*

B. The USPSTF recommends that clinicians provide [the service] to eligible patients. *The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.*

C. The USPSTF makes no recommendation for or against routine provision of [the service]. *The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.*

D. The USPSTF recommends against routinely providing [the service] to asymptomatic patients. *The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.*

I. The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. *Evidence that [the service] is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.*

Appendix B

U.S. Preventive Services Task Force
Strength of Overall Evidence

The USPSTF grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

AHRQ Publication No. 05-0580-A
July 2005

HIV Testing, Positivity, and Status-Awareness, By Type, Houston EMA, 2010

	Targeted Testing[1]		**Non-Targeted Testing[2]**		**Total**	
	Number	Percent	Number	Percent	Number	Percent
Number of HIV tests conducted	18107		146969		165076	
Number informed of status	16114	89.0%	15002	10.2%	31116	18.8%
Number NOT informed of status	1993	11.0%	131967	89.8%	133960	81.2%
Number of positive tests	311	1.7%	1726	1.2%	2037	1.2%
Number of positives informed of status	289	92.9%	308	17.8%	597	29.3%
Number of positives referred to care	236	75.9%	245	14.2%	481	23.6%
Number of positives linked to care	198	63.7%	204	11.8%	402	19.7%
Number of positives NOT informed of status	22	7.1%	1418	82.2%	1440	70.7%
Number of negative tests	17794	98.3%	64734	44.0%	82528	50.0%
Number of negatives informed of status	15823	88.9%	24601	38.0%	40424	49.0%
Number of negatives referred to services	1472	8.3%	187	0.3%	1659	2.0%
Number of negatives NOT informed of status	1971	11.1%	20796	32.1%	22767	27.6%

Data Source: Texas Department of State Health Services

[1]Targeted testing includes all traditional publically-funded testing

[2]Non-targeted testing includes publically funded testing by systems that do not collect all data requested by HRSA such as informed of results and referred to care. Non-targeted testing includes expanded testing and testing funded by MHSA.

FOCUS on Health Reform

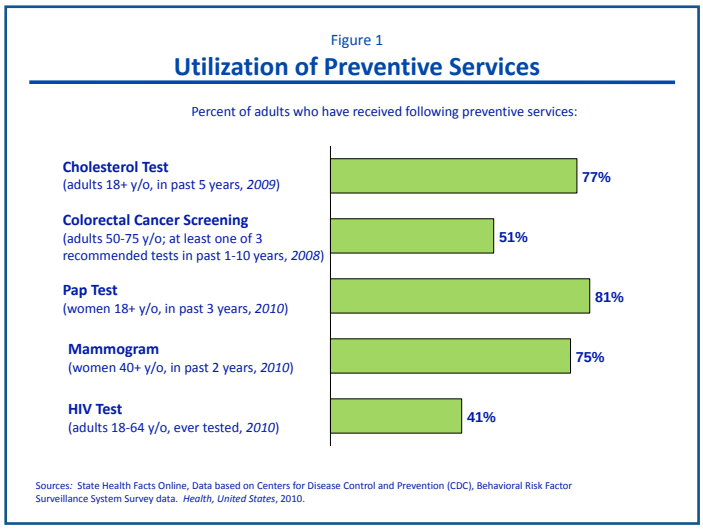
THE HENRY J. KAISER FAMILY FOUNDATION

September 2011

Preventive Services Covered by Private Health Plans under the Affordable Care Act

The Affordable Care Act (ACA) requires private insurers (including self-funded employers) – with the exception of so-called "grandfathered" plans – to cover certain preventive services without any patient cost-sharing. With proper preventive care, health problems can often be identified earlier, managed more effectively, and treated before they develop into more complicated, debilitating illness. Research has shown that evidence-based preventive services can in many cases save lives, and that some services are also cost-effective.[i]

Despite long-standing recommendations for use of evidence-based preventive services for a wide range of health conditions, actual utilization varies substantially (Figure 1). While a number of factors contribute to use of preventive services, out of-pocket costs in the form of copayments and deductibles can act as a barrier, keeping even the insured from seeking recommended screenings, counseling, and immunizations.[ii]



New Prevention Requirements

Under the ACA, private health plans[1] must provide coverage for a range of preventive services and may not impose cost-sharing (such as copayments, deductibles, or co-insurance) on patients receiving these services. The ACA requires private plans to provide coverage for services under four broad categories: evidence-based screenings and counseling, routine immunizations, childhood preventive services, and preventive services for women. A summary of these preventive services is presented in Table 1.

I. Evidence-Based Screenings and Counseling

Insurers will provide coverage for evidence-based items or services that have a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF), an independent panel of clinicians and scientists. An "A" or "B" letter grade indicates that the panel finds there is high certainty that the services have a substantial or moderate net benefit. The services required to be covered without cost-sharing include screening for depression, diabetes, cholesterol, obesity, various cancers, HIV and sexually transmitted infections, as well as counseling for drug and tobacco use, healthy eating, and other common health concerns.

II. Routine Immunizations

Health plans must also provide coverage without cost-sharing for immunizations that are recommended and determined to be for routine use by the Advisory Committee on Immunization Practices, a federal entity comprised of immunization experts. These guidelines require coverage of immunizations for influenza, meningitis, tetanus, HPV, hepatitis A and B, measles, mumps, rubella, and varicella.

III. Preventive Services for Children and Youth

The ACA provides specifically for the preventive health needs of children, requiring private insurers to cover without cost-sharing the preventive services recommended by the Health Resources and Services Administration's (HRSA's) Bright Futures Project, which provides evidence-informed recommendations to improve the health and wellbeing of infants, children, and adolescents. The preventive services to be covered for children and adolescents include the immunization and screening services described in the previous two categories, behavioral and developmental assessments, iron and fluoride supplements, and screening for autism, vision impairment, lipid disorders, tuberculosis, and certain genetic diseases.

IV. Preventive Services for Women

In addition to the evidence-based screening, counseling, and routine immunizations services described above, the ACA authorizes the federal Health Resources and Services Administration (HRSA) to make additional coverage requirements for preventive services for women. Based on recommendations from a committee of the Institute of Medicine (IOM),[iii] federal regulations will require insurers to cover a range of women's preventive services without cost-sharing, including annual well-woman visits, testing for STIs and HIV, support for breast feeding, and screening and counseling for domestic violence. The requirements also include all FDA-approved contraception methods (including sterilization procedures) as prescribed by a clinician, as well as patient education and counseling on contraception. The regulations

[1] Note that the rules described in this fact sheet apply to private insurers, self-insured employer plans, and are separate from preventive requirements for public programs like Medicare or Medicaid.

propose that plans sponsored by certain religious employers be exempt from the contraception coverage requirements.

Cost-Sharing

So long as the preventive service is performed by an in-network provider, is not billed separately from the office visit, and is the main reason for the office visit, then the visit and the preventive service will be covered by the insurer without cost-sharing. The circumstances under which insurers may charge copayments and use other forms of cost-sharing include:

- If the office visit and the preventive service are billed separately, the insurer may still impose cost-sharing for the office visit itself.
- If the primary reason for the visit is not the preventive screening, patients may have to pay for the office visit.
- If the service is performed by an out-of-network provider, insurers may charge patients for the office visit and the preventive service.

If the frequency with which plans should provide coverage for a given preventive service is not specified in the guidelines, insurers can use reasonable judgment based on established medical practices to make coverage decisions.[iv]

Applicability

These requirements will apply to all private plans – including individual, small group, large group, and self-insured plans in which employers contract administrative services to a third party payer – with the exception of those plans that maintain "grandfathered" status. In order to have been classified as "grandfathered," plans must have been in existence prior to March 23, 2010 and cannot make significant changes to their coverage (for example, increasing patient cost-sharing, cutting benefits, or reducing employer contributions). Plans that lose their grandfather status must then abide by the preventive service requirements of the ACA. HHS expects 45% of large employer plans and 60% of small employer plans to relinquish their grandfathered status by 2013.[v]

The federal government is developing guidelines that will apply to value-based insurance designs (plans that include incentives for patients to use more high value, evidence-based services). When finalized, these additional guidelines will provide direction on how value-based plans should cover preventive services.

The requirement that insurers must provide coverage for preventive services in the first three categories of recommendations above (i.e. USPSTF recommended services with grades "A" or "B," immunizations recommended by the ACIP, and childhood preventive services supported by the Bright Futures program) went into effect for non-grandfathered plans with plan-years beginning on or after September 23, 2010. Beginning August 1, 2012, non-grandfathered insurers will also be required to cover the additional services recommended for women's preventive health care.

As state-based insurance Exchanges begin operations, leading up to 2014, individual and small group plans in these new marketplaces will also be required to cover an essential health benefit package – in addition to the full range of preventive requirements described in this fact sheet.

Economic Impact

The exact effect that these new requirements will have on premiums is likely to vary greatly from state to state and plan to plan, as some plans already cover many preventive services and several states already have laws mandating coverage for insured plans. Of the 29 states with immunization coverage mandates, for example, 18 require coverage without a deductible and 12 require coverage without copayment.[vi]

The effect of required preventive coverage on health insurance premiums will also vary from service to service based on the cost of the added utilization of preventive services and the effectiveness at reducing future costly illnesses. Reducing out-of-pocket costs could in some cases be cost-saving by encouraging broader use of preventive services, therefore improving worker productivity and preventing the development of costly illnesses over time. For example, HHS estimates that obesity prevention services could decrease premiums by 0.05 to 0.1 percent by reducing the rate of obesity amongst enrollees. Conversely, by eliminating cost-sharing and reducing barriers to access, the new rules may in some cases result in higher premiums due to increased utilization of preventive services that is not fully offset by future cost savings from the prevention of illness. Taking all these factors into account, HHS estimates that premiums will increase by approximately 1.5 percent on average in non-grandfathered plans due to required coverage of prevention services (other than additional recommendations related to women's health).[vii]

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[i] Maciosek, Michael V. "Greater Use Of Preventive Services In U.S. Health Care Could Save Lives At Little Or No Cost." *Health Affairs* 29.9 (2010): 1656-660.
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[iv] Department of Health and Human Services. "Preventive Regulations." http://www.healthcare.gov/center/regulations/prevention/regs.html
[v] Ibid.
[vi] Ibid.
[vii] Ibid.

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Table 1: Summary of Selected Preventive Services that will be Covered by Non-Grandfathered Private Plans without Cost Sharing Requirements

Cancer	Chronic Conditions	Immunizations	Health Promotion	Pregnancy-Related**	Reproductive Health
• Breast cancer - Mammography (women 40+*) - Genetic (BRCA) screening and counseling (women at high risk) - Preventive medication counseling (women at high risk) • Cervical cancer - Pap testing (risk assessment for adolescents; women 18+, sexually active with cervix) - High-risk HPV DNA testing♀ (women 30+ with normal pap results) • Colorectal cancer - One of following: fecal occult blood testing, colonoscopy, sigmoidoscopy (adults 50-75)	• Cardiovascular health - Hypertension screening (risk assessment in infants, measurement children 3+; adults 18+) - Lipid disorders screenings (children risk assessment 2+: men 35+; women 45+; younger adults at high risk) - Aspirin (men 45-79; women 55-79) • Obesity - Screening (children 6+, all adults) - Counseling and behavioral interventions (obese children, adults) - Body mass index (BMI) (children 2+) • Type 2 Diabetes screening (adults w/ elevated blood pressure) • Depression screening (adults and adolescents, when follow up supports available) • Osteoporosis screening (all women 65+, women 60+ at high risk)	• DTaP (children 15-18 months, 4-6 years) • *Haemophilus influenzae* type b (children 12-18 months) • Hepatitis A (children 12-23 months, 2-18 years w/risk factors; adults 19+ w/ risk factors) • Hepatitis B (children newborn-18 months, 7-18 years; adults 19+ w/ risk factors) • HPV (women 11-26) • Inactivated Poliovirus (children 6-18 months, 4 years+) • Influenza (yearly) (children 6+ months and adults) • Meningococcal (children 11-12 , 2-18 w/risk factors; adults 19+ w/ risk factors) • MMR (children 1-18 years; adults 19-49; 50+ w/risk factors) • Pneumococcal (children 12-18 months, 2 years+ w/risk factors; adults 19-64 w/risk factors) • Td booster, Tdap (children 11-18 years; adults 19-64) • Varicella (children 12-18 months, 2 years+ w/risk factors; adults 19+) • Rotavirus (children 2-8 months) • Zoster (adults 60+)	• History and physical exams (children newborn-adolescents 21 years) • Measurements: Length/height, weight, head circumference, weight for length (children newborn+) • Vision and hearing screenings/assessment (children newborn+) • Metabolic/hemoglobin, phenylketonuria, sickle cell, congenital hypothyroidism screenings (newborn) • Gonorrhea prophylaxis (newborn) • Anemia screening, supplements (children 6 months+) • Lead screening (children risk assessment and/or test 6 mo.- 6 years) • Tuberculin screening (children risk assessment 1 month+) • Oral health – risk assessment, referral to dental home, (children 6 months - 6 years) • Developmental screenings and surveillance (children newborn-adolescence) • Alcohol misuse screening and counseling (risk assessment adolescents 11+; all adults) • Tobacco counseling and cessation interventions (all adults) • Intensive healthy diet counseling (adults w/high cholesterol, CVD risk factors, diet-related chronic disease) • Interpersonal and domestic violence screening, counseling♀ (women) • Well-woman visits♀ (women 18-64)	• Prenatal visit • Alcohol misuse screening and counseling • Tobacco counseling and cessation interventions • Rh incompatibility screening • Gestational diabetes screenings♀ - 24-28 weeks gestation - First prenatal visit (women at high risk for diabetes) • Screenings for pregnant women - Hepatitis B - Chlamydia (<24, high risk) - Gonorrhea - Syphilis - Bacteriurea • Folic acid supplements (women w/ reproductive capacity) • Iron deficiency anemia screening • Breastfeeding supports - Counseling - Consultations with trained provider♀ - Equipment rental♀	• STI and HIV counseling (sexually-active adolescents, adults at high risk; all sexually-active women♀) • Screenings - Chlamydia (sexually active women <24 years old, older women at high risk) - Gonorrhea (sexually active women at high risk) - Syphilis (adults at high risk) - HIV (adolescents and adults at high risk; all sexually active women♀) - STIs (risk assessment for adolescents) • Contraception (all women w/ reproductive capacity) ♀ *** - All FDA-approved contraceptive methods as prescribed - Sterilization procedures - Patient education and counseling

Notes: Age ranges are meant to encompass the broadest range possible. Each service may only be covered for certain age groups or based on risk factors. For specific details on recommendations, please consult the websites listed below.
*The ACA defines the recommendations of the USPSTF regarding breast cancer services to "the most current other than those issued in or around November 2009." Thus, coverage for mammography is guided by the 2002 USPSTF guideline.
** Services in this column apply to all pregnant or lactating women, unless otherwise specified. ***Certain religious employers exempt from this requirement.
♀ Recommendation from HRSA Women's Preventive Services. Coverage without cost sharing in "non-grandfathered" plans begins August 1, 2012. Coverage without cost sharing for all other services went into effect Sep. 23, 2010.
Sources: U.S. DHHS, "Recommended Preventive Services." Available at http://www.healthcare.gov/center/regulations/prevention/recommendations.html . More information about each of the items in this table, including details on periodicity, age, risk factors, and specific tests and procedures are available at the following websites:

USPSTF: http://www.uspreventiveservicestaskforce.org/recommendations.htm; Bright Futures: http://brightfutures.aap.org/pdfs/AAP%20Bright%20Futures%20Periodicity%20Sched%20101107.pdf:
ACIP: http://www.cdc.gov/vaccines/pubs/ACIP-list.htm#comp; http://www.cdc.gov/vaccines/recs/schedules/downloads/child/0-18yrs-11x17-fold-pr.pdf; HRSA Women's Preventive Services: http://www.hrsa.gov/womensguidelines/

May 13, 2011

Dear Colleague:

This week the National Institutes of Health (NIH) released findings from a large-scale clinical study which concluded that men and women with HIV reduced their risk of transmitting the virus to their heterosexual partners by 96% when taking oral antiretroviral therapy (ART). The study also found that treatment earlier in the course of HIV reduced the incidence of HIV-associated diseases, especially tuberculosis. These results represent the strongest evidence to date that early HIV treatment dramatically reduces the chance that an HIV positive individual will transmit the virus to a sexual partner.

The clinical trial, known as HPTN 052, began in April 2005 and enrolled 1,763 couples, 97 % of whom were heterosexual. The study was conducted at 13 sites in Botswana, Brazil, India, Malawi, South Africa, Thailand, the United States, Zimbabwe and CDC's research center in Kenya. At the time of enrollment, the HIV-infected partners (890 men, 873 women) had CD4+ T-cell levels—a key measure of immune system health—between 350 and 550 cells per cubic millimeter (mm^3). Throughout the study, both groups received HIV-related care that included counseling on safe sex practices, free condoms, treatment for sexually transmitted infections, regular HIV testing, and frequent evaluation and treatment for any complications related to HIV infection. Each group received the same amount of care and counseling.

The trial was scheduled to end in 2015 but was stopped early after an interim review of the study data by an independent data and safety monitoring board (DSMB) concluded that use of ART by HIV-infected individuals reduced the chance that they would transmit to their partners and was associated with reduced incidence of tuberculosis in the partner with HIV. The results in this trial indicate both clinical and prevention benefits for ART and these accrue, even for people with relatively high CD4 cell counts. The results support the Department of Health and Human Services guidelines for the use of ART (http://www.aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf) that recommend ART for people with CD4 counts less than 500 cells/ml and are permissive for treatment above this level for potential clinical and prevention benefits.

While today's announcement provides cause for optimism that this approach may help reduce new HIV infections overall in the United States and around the world, the degree of impact at a population level will depend on many factors, including the real-world feasibility of scaling up intensive testing and care services in a broad range of settings, as well as the ability for individuals to maintain high levels of drug adherence over time. CDC is working with NIH and local health departments to assess the feasibility of expanded testing, improving HIV treatment, and linking to care in the United States in HPTN 065, which examines the feasibility of events necessary for "test and treat" programs to succeed. Key components of this study include expanded testing, linkage to care, the initiation of ART, adherence to ART with viral suppression, and prevention with positives. The study will also look at the use of financial incentives to improve linkage and adherence. CDC's surveillance system will be used to measure the study outcomes.

The results of HPTN 052 confirm the importance of the nation's increasing focus on expanded testing, treatment and prevention strategies for HIV-infected persons, but

diagnosis and treatment alone will likely not end the HIV epidemic in the United States. In addition, the majority of the U.S. epidemic occurs among men who have sex with men (MSM) and the transmission dynamics may differ in this population, so the prevention benefits identified in this study may not be directly extrapolated to this population. Despite all of these challenges, the HPTN 052 findings add to an existing strong mix of effective prevention interventions that can make a significant difference in this country's HIV epidemic. CDC is working to identify the combination of high-impact prevention strategies that are likely to yield the greatest impact on the U.S. epidemic. For example, we are currently conducting demonstration projects in 12 of the hardest hit cities in the United States with the goal of identifying the most effective combination of prevention interventions in each area to reduce infections. CDC is also working to improve surveillance systems to better capture CD4 and viral load levels that will help monitor the national epidemic. Furthermore, at a national level, we are pursuing a tiered, combination approach to HIV prevention that will prioritize intensive interventions for HIV positive individuals and very high risk individuals; community level and structural interventions in highly impacted areas; and fundamental knowledge among all Americans to create an enabling and supportive environment necessary for success.

The HPTN 052 trial results represent a significant advance in HIV prevention research, but because no prevention strategy is one hundred percent effective, including ART, it is important that individuals at risk for acquiring or transmitting HIV continue to use condoms and other proven risk reduction strategies. Individuals infected with HIV should not simply assume that they are not infectious to their partners, if they are on treatment.

This is an exciting development in HIV prevention, and we look forward to working together to implement these findings in practice as part of high-impact prevention and care strategies.

Sincerely,

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Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents

January 10, 2011

Developed by the DHHS Panel on
Antiretroviral Guidelines for Adults
and Adolescents – A Working Group of the
Office of AIDS Research Advisory Council (OARAC)

How to Cite the Adult and Adolescent Guidelines:
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It is emphasized that concepts relevant to HIV management evolve rapidly. The Panel has a mechanism to update recommendations on a regular basis, and the most recent information is available on the **AIDS*info* Web site** (**http://aidsinfo.nih.gov**).

Preventing Secondary Transmission of HIV

(Updated December 1, 2009)

PREVENTION COUNSELING

Interventions to prevent transmission of HIV are key components of the management of HIV infection, yet multiple studies show that prevention is frequently neglected in clinical practice. Each patient encounter provides opportunities to reinforce HIV prevention messages—messages that patients often look to their providers to deliver but may fail to receive *[1-2]*. Despite the challenges to providing effective prevention interventions in a busy practice setting, multiple approaches are available, including formal guidance from the Centers for Disease Control and Prevention (CDC) for incorporating HIV prevention into medical care settings *[3]*. Such interventions have been demonstrated to be effective in changing sexual risk behavior *[4-6]*and can reinforce self-directed behavior change early in diagnosis *[7]*.

The CDC has identified prevention interventions for HIV-infected people that meet stringent criteria for efficacy and scientific rigor *[8]* and three that demonstrated efficacy in treatment settings (Options, Partnership for Health, and Positive Choices). The interventions are available through CDC trainings and materials, delivered as brief messages by providers or via laptop computer, and are readily implemented into busy clinics (**http://www.cdc.gov/hiv/topics/research/prs/index.htm**).

Evidence also exists regarding the efficacy of interventions to reduce injection drug use risk behavior. These include both behavioral interventions *[9-11]* and opiate substitution treatment with methadone *[12-13]*.

There is evidence of increases in HIV risk behaviors among infected persons coinciding with the availability of potent combination antiretroviral therapy (ART). In some cohorts the rate of reported risk behaviors almost doubled compared with rates in the era prior to such therapies *[7]*. A meta-analysis of studies of HIV risk behaviors demonstrates that the prevalence of unprotected sex acts increased in those who believed that receiving ART or having a suppressed viral load protects against transmitting HIV *[14]*. Attitudinal shifts away from safer sexual practices since the availability of potent ART underscore the role for provider-initiated HIV prevention counseling. With wider recognition of the concept that effective treatment may decrease the probability of transmission, it is particularly important for providers to help patients understand that a sustained viral load below the limits of detection will dramatically reduce but does not absolutely assure the absence of virus in the genital and blood compartments, and hence the inability to transmit virus to others *[14-15]*.

Additionally, given the role of sexually transmitted infections (STIs) as facilitators of HIV transmission, an essential adjunct to prevention counseling is the routine screening and symptom-directed testing for STIs, as recommended by CDC *[3]*.

ANTIRETROVIRAL THERAPY AS PREVENTION

ART does have a role in preventing HIV transmission. Lower levels of plasma RNA have been associated with decreases in the concentration of virus in genital secretions *[16-17]*. Observational studies have demonstrated a decreased rate of HIV transmission among serodiscordant heterosexual couples following antiretroviral (ARV)-induced viral suppression in the absence of concomitant STIs. Multiple studies have demonstrated a direct correlation between HIV inoculum size (i.e., viral load) and probability of transmission *[18-19]*. Although some data suggest that the risk of heterosexual HIV transmission is low when an individual's viral load is <40 copies/mL, these data are contingent upon several assumptions, including: (1) completely suppressed viremia; (2) complete adherence to an effective ARV regimen; and (3) the absence of a concomitant STI. Detection of HIV RNA in the genital secretions has been documented in individuals with controlled plasma HIV RNA *[20-21]*. Moreover, it is critical that any biological reduction in infectivity not be offset by increases in risk behavior (i.e., risk compensation).

SUMMARY

In summary, consistent and effective use of ART resulting in a sustained reduction in viral load, in conjunction with consistent condom usage, safer sexual and drug use practices, and detection and treatment of STIs are essential tools for prevention of sexual and blood-borne transmission of HIV. Given these important considerations, medical visits provide a vital opportunity to reinforce HIV prevention messages, discuss sexual- and drug-related risk behaviors, diagnose and treat intercurrent STIs, and develop open communication between provider and patient.

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Press Release

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CDC Trial and Another Major Study Find PrEP Can Reduce Risk of HIV Infection among Heterosexuals

CDC Assessing Data from All Heterosexual Trials to Develop Interim Guidance for Use

A new CDC study called the TDF2 study, along with a separate trial released today, provide the first evidence that a daily oral dose of antiretroviral drugs used to treat HIV infection can reduce HIV acquisition among uninfected individuals exposed to the virus through heterosexual sex.

The CDC TDF2 study, conducted in partnership with the Botswana Ministry of Health, found that a once-daily tablet containing tenofovir disoproxil fumarate and emtricitabine (TDF/FTC, known by the brand name Truvada) reduced the risk of acquiring HIV infection by roughly 63 percent overall in the study population of uninfected heterosexual men and women. The strategy of providing daily oral antiretroviral drugs to uninfected individuals prior to HIV exposure is called pre-exposure prophylaxis, or PrEP.

In a separate announcement, the University of Washington (UW) released preliminary results of the Partners PrEP study, which also found that daily PrEP reduced HIV transmission among heterosexual couples in Kenya and Uganda. CDC co-managed two of the nine sites for this study. The Partners PrEP study found that two separate antiretroviral regimens – tenofovir (known by the brand name Viread) and TDF/FTC – significantly reduced HIV transmission among serodiscordant couples, in which one partner is infected with HIV and the other is not. The findings were released after the trial's independent data safety monitoring board conducted an interim review of the trial data and recommended that the placebo arm of the study be discontinued early due to strong evidence of effectiveness, so that all participants could be offered PrEP. For more information on this study, visit http://www.uwicrc.org/.

The CDC study findings were scheduled to be released next week at the International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention (http://www.ias2011.org/) in Rome by the CDC principal investigator Michael C. Thigpen, M.D. However, due to the unexpected release of the Partners PrEP data today, CDC is releasing the TDF2 results now, to

ensure that all emerging trial data are concurrently available to fully inform public health and policy discussions moving forward. The results will still be presented and discussed at the IAS 2011 conference on Monday, July 18.

"These are exciting results for global HIV prevention. We now have findings from two studies showing that PrEP can work for heterosexuals, the population hardest hit by HIV worldwide," said Kevin Fenton, M.D., director of CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. "Taken together, these studies provide strong evidence of the power of this prevention strategy."

A previous study (iPrEx) had already shown PrEP reduced HIV transmission among men who have sex with men (MSM) last fall, but it was not previously known if the strategy could prevent HIV infection among heterosexuals.

The CDC and UW study results follow preliminary findings from another PrEP study earlier this year, the FEM-PrEP trial, which did not demonstrate a protective effect of PrEP among heterosexual women. Researchers from that study are conducting additional analyses, including a close examination of adherence among women in the trial, to better understand the potential reasons for the interim outcome of that study.

More Information on CDC TDF2 Study and Results

In addition to finding PrEP reduced the risk of HIV infection by roughly 63 percent in the study population overall, researchers from CDC's TDF2 study also conducted a separate analysis to better understand the level of effectiveness among trial participants believed to be taking study medications. This analysis excludes any HIV infections that occurred more than 30 days after a participant's last reported drug dose, because those individuals could not have been taking study pills at the time of infection. These results indicate that TDF/FTC reduced the risk of HIV infection by 78 percent.

Overall, a total of 1,219 HIV-uninfected heterosexual male and female participants (aged 18-39) in Botswana were enrolled in the TDF2 trial and randomly assigned to take a daily TDF/FTC pill or a placebo pill. All participants in the study were provided comprehensive HIV prevention services, including male and female condoms, intensive risk-reduction behavioral counseling, and testing and treatment for sexually transmitted infections. Three participants were determined to be HIV-infected at the time of enrollment, and 16 of the participants randomized never began study medication. Those individuals were excluded from these analyses, which include data on the remaining 1,200 participants who were HIV-negative at the time of enrollment and began study medication (54.7 percent male, 45.3 percent female).

In the primary analysis, among the 601 participants who received TDF/FTC, there were nine who became infected with HIV during the study. Among the 599 individuals who received a placebo, 24 became infected with HIV during the study. This translates into a statistically significant overall reduction in risk of 62.6 percent.

Among participants known to have a supply of study drugs (the separate analysis described above), protection was even greater, with a statistically significant risk reduction of 77.9 percent. Additional analyses of the level of effectiveness based on the level of adherence to the study regimen, as well as an examination of the level of protection provided by detectable drugs in the blood, are under way but are not yet complete.

Consistent with other PrEP studies, preliminary analyses did not identify any significant safety concerns associated with daily use of TDF/FTC. Participants assigned to receive the study drug were more likely than those assigned to the placebo arm to report nausea, vomiting, and dizziness.

All participants infected during the study were immediately referred to medical care. All uninfected participants will be offered the study drug for a year as part of a CDC follow-up study.

CDC officials note that the trial would not have been possible without the dedication of the more than 1,200 participants and the strong collaboration between the Botswana Ministry of Health and CDC. Additional study funding was also provided by the National Institutes of Health, and Gilead Sciences, based in Foster City, Calif., donated the study drug.

"Given the severity of the HIV epidemic among heterosexual men and women globally – and the critical need for female-controlled prevention methods – this study provides exciting and welcome news," said Jonathan Mermin, M.D., director of CDC's Division of HIV/AIDS Prevention. "The next important step is to fully review the data and assess when and how PrEP should best be used for HIV prevention among heterosexuals."

TDF/FTC is FDA-approved and marketed for use in the United States under the name Truvada, for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older. It is not FDA-approved for PrEP.

Next steps

In the wake of today's announcements, CDC will fully review the data from all of the heterosexual trials and will begin working with a range of stakeholders and with established guidelines development working groups to develop guidance specific to the use of PrEP among heterosexual men and women in the United States.

CDC urges heterosexual men and women and their health care providers in the United States to await that guidance before considering PrEP. However, if providers have patients for whom they believe the initiation of PrEP is urgent, CDC recommends following the cautions and procedures previously published for PrEP use in MSM (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a1.htm?s_cid=mm6003a1_w). The Partners PrEP finding that TDF alone was as effective as TDF/FTC in studies for prevention of heterosexual transmission suggests that providers may consider daily doses of either regimen in this population. However, for MSM, the interim guidance remains that only TDF/FTC should be

prescribed, because there are no data on effectiveness for TDF alone to prevent HIV acquisition by MSM.

It will also be critical for providers to consider factors unique to heterosexuals, including concerns related to the use of PrEP among women who may become pregnant.

Importantly, anyone considering using PrEP should know:

- PrEP should only be used among individuals who have been confirmed to be HIV-negative. Initial and regular HIV testing is critical for anyone considering using PrEP. All individuals considering PrEP must also be evaluated for other health conditions that may impact PrEP use.
- PrEP should never be seen as the first line of defense against HIV. It was only shown to be effective in clinical trials when provided in combination with regular HIV testing, condoms, and other proven prevention methods.
- Taking PrEP daily is critical. No other dosing regimen was evaluated in these studies.
- PrEP must be obtained and used in close collaboration with health care providers to ensure regular HIV testing, risk reduction and adherence counseling, and careful safety monitoring. Anyone considering using PrEP should speak with his or her doctor.
- PrEP has only been shown in clinical trials to reduce HIV infection among heterosexual men and women and among men who have sex with men. At this time, there are no data on its benefits or risks among injection drug users.
- Because pregnant and breastfeeding women were excluded from participation in PrEP trials, further evaluation of available data will be needed before any recommendations can be made regarding the use of PrEP for women during conception, pregnancy, or breastfeeding.

For more information on efforts to evaluate and plan for PrEP implementation in the United States, visit www.cdc.gov/hiv/prep.

For a complete list of PrEP trials being conducted, see http://www.avac.org/ht/a/GetDocumentAction/i/3113.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

MMWR

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Interim Guidance: Preexposure Prophylaxis for the Prevention of HIV Infection in Men Who Have Sex with Men

An estimated 56,000 human immunodeficiency virus (HIV) infections occur each year in the United States (*1*). Men who have sex with men (MSM) account for 53% of the estimated incident infections, and surveillance data suggest that the annual number of new HIV infections among MSM has been rising since the mid-1990s (*1*). Strategies for reducing acquisition of HIV infection by MSM have included 1) expanded HIV testing so that infected persons can be treated and their risk for transmitting infection minimized; 2) individual, small-group, and community-level behavioral interventions to reduce risk behaviors (*2*); 3) promotion of condom use; 4) detection and treatment of sexually transmitted infections (*3*); and 5) mental health and substance abuse counseling when needed. On November 23, 2010, investigators for the Pre-Exposure Prophylaxis Initiative (iPrEX) study announced results from a multinational, randomized, double-blind, placebo-controlled, phase III clinical trial of daily oral antiretrovirals (tenofovir disoproxil fumarate [TDF] and emtricitabine [FTC]) to prevent acquisition of HIV infection among uninfected but exposed MSM (*4*). This report provides interim guidance to health-care providers based on the reported results of that trial, which indicated that TDF plus FTC taken orally once a day as preexposure prophylaxis (PrEP) is safe and partially effective in reducing HIV acquisition among MSM when provided with regular monitoring of HIV status and ongoing risk-reduction and PrEP medication adherence counseling.

The iPrEx study was conducted in Peru, Ecuador, Brazil, Thailand, South Africa, and the United States. Eligible participants were consenting HIV-uninfected men and male-to-female transgender adults (aged ≥18 years) who reported sex with a man and reported engaging in high-risk sexual behaviors during the preceding 6 months, and had no clinical contraindication to taking a combined formulation of 300 mg TDF and 200 mg FTC (TDF/FTC).*

Enrolled participants were randomized to receive either daily doses of TDF/FTC or a placebo pill. Participants were seen every 4 weeks for an interview, HIV testing, risk-reduction and PrEP medication adherence counseling, pill count, and dispensing of pills and condoms. Every 3 months, participants received physical examinations with collection of blood and urine samples for evaluation of renal and liver function, and were tested for sexually transmitted infections and treated as needed. Positive HIV rapid tests were confirmed by Western blot. The cohort was followed for an average 1.2 years with a maximum of 2.8 years. Participants were tested for hepatitis B infection at enrollment, and those found to be susceptible to hepatitis B infection were offered vaccination; 94% accepted.

Based on analysis of data from visits through May 1, 2010, for 2,499 enrolled participants (including 29 male-to-female transgender persons) in the modified "intent to treat" analysis (excluding 10 participants found to be HIV-infected at enrollment and 48 who did not have an HIV test after enrollment), 36 of 1,224 participants in the PrEP arm and 64 of 1,217 participants in the placebo arm who were followed for acquisition of HIV infection. Enrollment in the PrEP arm was associated with a 44% reduction in HIV acquisition (95% confidence interval [CI] = 15%–63%). The reduction was greater in the "as treated" analysis; participants at visits with ≥50% adherence by

* Marketed under the brand name Truvada (Gilead Sciences, Inc., Foster City, California).

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U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

self-report and pill count/dispensing had a 50% reduction in HIV acquisition (CI = 18%–70%). Reduction in risk for HIV acquisition was 21% among participants at visits with <90% adherence (CI = -31%–52%) and 73% at visits with ≥90% adherence (CI = 41%–88%). Among those randomly assigned to the TDF/FTC arm, drug level testing was performed for all HIV seroconverters and a matched subset of participants who remained uninfected; a 92% reduction in risk for HIV acquisition (CI = 40%–99%) was found in participants with detectable levels of TDF/FTC versus those with no drug detected. TDF/FTC generally was well tolerated, although nausea in the first month was more common among those taking medication than among those on placebo (9% versus 5%). No differences in severe (grade 3) or life-threatening (grade 4) laboratory abnormalities were observed between the active and placebo arms, and no drug-resistant virus was found in the 100 participants infected after enrollment. Among 10 participants who were seronegative at enrollment but later found to have been infected before enrollment, two cases of FTC resistance occurred in the active arm, and one occurred in the placebo arm. Participants in both arms reported lower total numbers of sex partners with whom the participants had receptive anal intercourse and higher percentages of partners who used condoms than reported at baseline.

What is already known on this topic?

HIV infections are increasing among men who have sex with men (MSM) in the United States despite awareness of HIV/AIDS and the protective effect of consistent condom use. A recent international study indicated that HIV infection among MSM can be reduced by daily preexposure prophylaxis (PrEP) with a well-tolerated combination of specific antiviral medications.

What is added by this report?

This report provides interim guidance for health-care providers in the United States based on results of the only large clinical trial testing the efficacy and safety of PrEP for reducing HIV acquisition by MSM.

What are the implications for public health practice?

For MSM whose behaviors place them at high risk for HIV infection and who do not use other effective prevention methods consistently, PrEP might reduce their risk for HIV infection. Until comprehensive U.S. Public Health Service guidelines are available, CDC is providing interim guidance to help guide clinical practice.

Reported by

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Editorial Note

This clinical trial demonstrated the safety and efficacy of daily TDF/FTC, in conjunction with behavioral interventions, in reducing sexual HIV acquisition in a multinational population of MSM exposed to HIV through high-risk sex (*4*). A recent safety study of PrEP with TDF among 400 MSM in the United States also revealed few safety concerns (*5*). As a component of a comprehensive HIV prevention intervention, PrEP showed a significant added benefit, although effectiveness was highly dependent on medication adherence.

The findings in this report are subject to at least five limitations. First, the trial was not large enough to evaluate efficacy in each of the sites, and the majority of the participants were in South America; only 10% were in the United States, making it impossible to determine effects on incidence in the United States trial sites specifically. Second, the assessment of adherence by drug-level testing was not performed for all trial participants and was performed for seroconverters at the first clinical visit in which infection was diagnosed; therefore, the findings might not reflect drug levels at the time of infection. Third, the study does not provide information about long-term health effects of TDF/FTC in HIV-uninfected men or men who became HIV-infected while on PrEP medications. Fourth, results of drug-level testing showed that adherence measures in the trial might overstate levels of actual adherence; many of those with high levels of adherence to the daily regimen by self-report, pill count, and bottles dispensed had low levels or no drug measured in their blood (*4*). Finally, sexual risk behavior and adherence to PrEP medications among MSM taking TDF/FTC for PrEP outside of a trial setting, and with awareness of trial results, might be different from what was observed for men in the iPrEx trial.

Based on the results of this study, CDC and other U.S. Public Health Service (PHS) agencies have begun to develop PHS guidelines on the use of PrEP for MSM at high risk for HIV acquisition in the United States as part of a comprehensive set of HIV prevention services. Completing the guidelines and obtaining expert input and public comment will take several months before they can be published. Concerns exist that without early guidance, various unsafe and potentially less effective PrEP-related practices could develop among health-care providers and MSM beginning to use PrEP in the coming weeks and months. These concerns include 1) use of other antiretrovirals than those so far proven safe for uninfected persons (e.g., more than two drugs or protease inhibitors); 2) use of dosing schedules of unproven efficacy (e.g., "intermittent" dosing just before and/or after sex); 3) not screening for acute infection before beginning PrEP or long intervals without retesting for HIV infection; and 4) providing prescriptions without other HIV prevention support (e.g., condom access and risk-reduction counseling). Until the more detailed PHS guidelines are available, CDC is providing interim recommendations to help guide clinical practice (*3,6–9*) (Box).

Until the safety and efficacy of PrEP is determined in trials now under way with populations at high risk for HIV acquisition by other routes of transmission (*10*), PrEP should be considered only for MSM. The iPrEX trial results provide strong evidence that support for adherence to the prescribed medication regimen must be a routine component of any PrEP program. To minimize the risk for drug resistance, PrEP should not be started in persons with signs or symptoms of acute viral infection unless HIV-uninfected status is confirmed by HIV RNA testing or a repeat antibody test performed after the viral syndrome resolves (*6*). When evaluating MSM for the prescription of PrEP medications, it is important to establish whether other effective risk-reduction measures (e.g., condom use) are not being used consistently and to ascertain that the risk for HIV acquisition is high (e.g., frequent partner change or concurrent partners in a geographic setting with high HIV prevalence) because these patients might benefit most from the addition of PrEP to their HIV prevention regimen. Health-care providers and patients should be aware that HIV prevention is not a labeled indication for the use of Truvada[†] and that its long-term safety in HIV-uninfected persons is not yet known. Health-care providers should report any serious adverse events resulting from prescribed TDF/FTC for PrEP to the Food and Drug Administration's MedWatch.[§] In addition, because the medication is costly, ensuring that patients understand the financial implications of starting PrEP is critical.

PrEP has the potential to contribute to effective and safe HIV prevention for MSM if 1) it is targeted to MSM at high risk for HIV acquisition; 2) it is delivered as part of a comprehensive set of prevention services, including risk-reduction and PrEP medication adherence counseling, ready access to condoms, and diagnosis and treatment of sexually transmitted infections; and 3) it is accompanied by monitoring of HIV status, side effects, adherence, and risk behaviors at regular intervals.

[†] These recommendations do not reflect current Food and Drug Administration–approved labeling for TDF/FTC.
[§] Available at http://www.fda.gov/safety/medwatch.

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BOX. CDC interim guidance for health-care providers electing to provide preexposure prophylaxis (PrEP) for the prevention of HIV infection in adult men who have sex with men and who are at high risk for sexual acquisition of HIV

Before initiating PrEP

Determine eligibility

- Document negative HIV antibody test(s) immediately before starting PrEP medication.
- Test for acute HIV infection if patient has symptoms consistent with acute HIV infection.
- Confirm that patient is at substantial, ongoing, high risk for acquiring HIV infection.
- Confirm that calculated creatinine clearance is ≥60 mL per minute (via Cockcroft-Gault formula).

Other recommended actions

- Screen for hepatitis B infection; vaccinate against hepatitis B if susceptible, or treat if active infection exists, regardless of decision about prescribing PrEP.
- Screen and treat as needed for STIs.

Beginning PrEP medication regimen

- Prescribe 1 tablet of Truvada* (TDF [300 mg] plus FTC [200 mg]) daily.
- In general, prescribe no more than a 90-day supply, renewable only after HIV testing confirms that patient remains HIV-uninfected.
- If active hepatitis B infection is diagnosed, consider using TDF/FTC for both treatment of active hepatitis B infection and HIV prevention.
- Provide risk-reduction and PrEP medication adherence counseling and condoms.

Follow-up while PrEP medication is being taken

- Every 2–3 months, perform an HIV antibody test; document negative result.
- Evaluate and support PrEP medication adherence at each follow-up visit, more often if inconsistent adherence is identified.
- Every 2–3 months, assess risk behaviors and provide risk-reduction counseling and condoms. Assess STI symptoms and, if present, test and treat for STI as needed.
- Every 6 months, test for STI even if patient is asymptomatic, and treat as needed.
- 3 months after initiation, then yearly while on PrEP medication, check blood urea nitrogen and serum creatinine.

On discontinuing PrEP (at patient request, for safety concerns, or if HIV infection is acquired)

- Perform HIV test(s) to confirm whether HIV infection has occurred.
- If HIV positive, order and document results of resistance testing and establish linkage to HIV care.
- If HIV negative, establish linkage to risk-reduction support services as indicated.
- If active hepatitis B is diagnosed at initiation of PrEP, consider appropriate medication for continued treatment of hepatitis B.

Abbreviations: HIV = human immunodeficiency virus; STI = sexually transmitted infection; TDF = tenofovir disoproxil fumarate; FTC = emtricitabine.

Sources: CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR 2010;59(No. RR-12).

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*These recommendations do not reflect current Food and Drug Administration–approved labeling for TDF/FTC.

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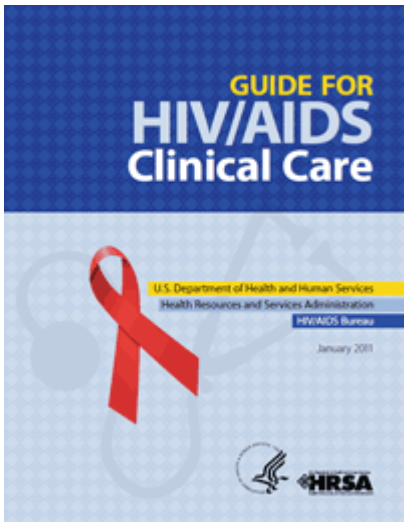

http://hab.hrsa.gov/deliverhivaidscare/clinicalguide11/

Nonoccupational Postexposure Prophylaxis

January 2011

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Background

Although avoiding exposure to HIV is the only reliable way of preventing HIV infection, postexposure prophylaxis (PEP) can decrease the risk of infection after exposure to HIV. Antiretroviral (ARV) therapy is an important prophylactic intervention for appropriate persons with nonoccupational exposures (e.g., sexual contact; sharing of injection drug needles or other equipment) as well as those with occupational exposures (e.g., needlesticks). The U.S. Department of Health and Human Services (DHHS) has developed recommendations for nonoccupational PEP (nPEP) based on data from animal models, perinatal clinical trials, and observational studies. Efficacy of nPEP remains hypothetical, and randomized clinical trials are not possible, but nPEP appears to be safe.

Overall, nPEP is more likely to be effective when the exposure is a single episode and nPEP is initiated in a timely manner. It is not appropriate for cases of multiple sexual exposures or injection drug use (IDU) exposures over time or for exposures that occurred >72 hours before starting nPEP treatment (see Figure 1).

The model for nPEP is derived in part from protocols for occupational PEP (e.g., in terms of risk stratification, pretreatment testing, timing of treatment, treatment regimens, and duration of treatment). However, the recommendations for PEP and nPEP are distinct and should not be confused. (For information on occupational PEP, see chapter *Occupational Postexposure Prophylaxis*.) One significant difference between the protocols is that nPEP protocols should include interventions to reduce the risk of HIV transmission. Although exposed individuals usually seek care because they are interested specifically in antiretroviral prophylaxis, the nPEP model takes advantage of a critical opportunity to provide risk-reduction counseling and education.

See chapter *Occupational Postexposure Prophylaxis* for further discussion of evaluating possible benefits and risks of PEP.

S: Subjective

The patient reports potential exposure to HIV through a sexual encounter or the sharing of needles or other equipment for IDU.

Take a thorough history of the specific sexual or drug-use activities, the time the exposure occurred, the HIV status of the source person (if known), and HIV risk factors of the source person (if HIV status is not known). In cases of sexual assault, evidence collection and specific paperwork may be required as well.

O: Objective

Examine for trauma and for signs or symptoms of sexually transmitted infections (STIs), which may increase the risk of HIV transmission. In injection drug users, examine for abscesses and signs or symptoms of infection. For women who may be pregnant, perform a pregnancy test.

A: Assessment

Assess for potential exposures to HIV and other bloodborne pathogens and for the presence of other STIs. The risk of HIV infection depends on the HIV status of the source and on the characteristics of the source (e.g., HIV viral load) and of the exposure (see Figure 1). The estimated risk of HIV exposure will determine whether nPEP should be offered. An algorithm for risk evaluation and treatment decisions is presented in Figure 1.

P: Plan

Laboratory Testing

- Perform a baseline HIV antibody test.
- Evaluate and test for other infections transmitted through sexual or IDU exposures, including chlamydia, gonorrhea, syphilis, herpes simplex virus infection, hepatitis B (HBV surface antigen, surface antibody, and core antibody), and hepatitis C (HCV antibody).
- Obtain complete blood count (CBC), liver function tests (LFTs), and creatinine and estimated glomerular filtration rate (GFR) at baseline before treatment with ARV medications.

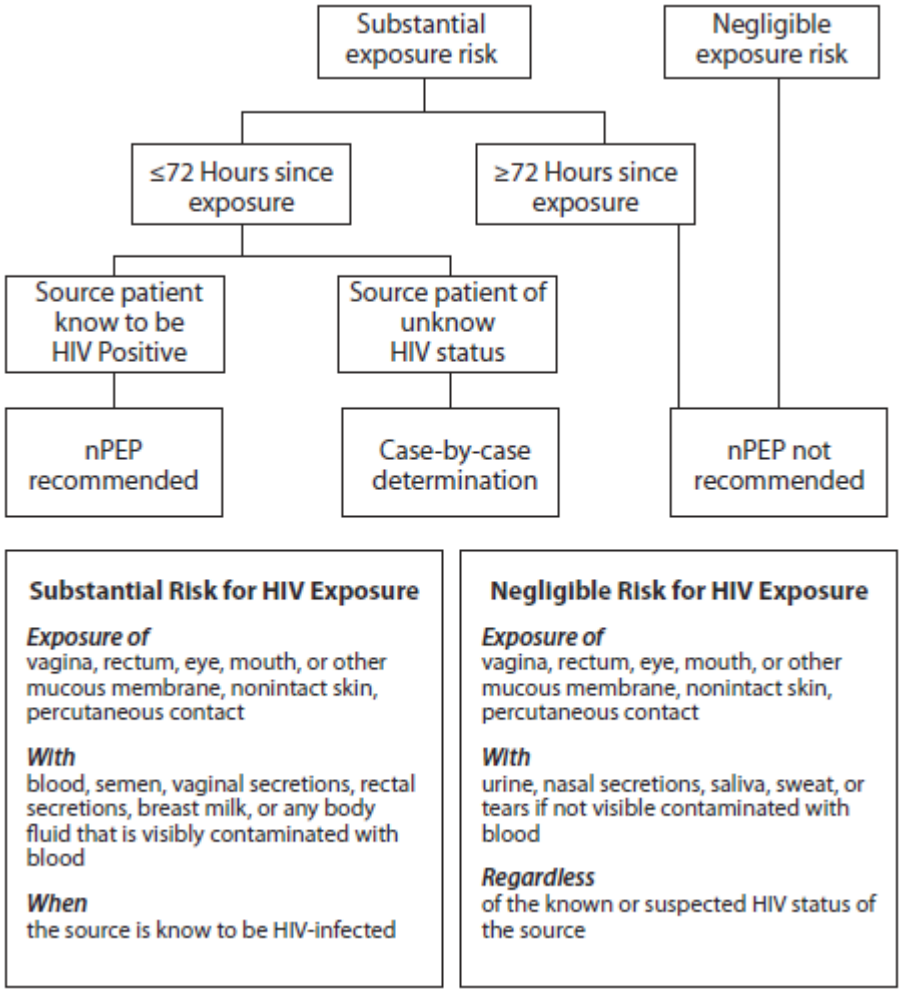
Treatment

Follow the algorithm in Figure 1 to determine whether the patient should be offered nPEP medications. If the patient is a candidate for treatment, provide counseling about the potential risks and benefits of nPEP. Note that the current DHHS nPEP guidelines were last updated in 2005 and do not reflect current practice. **The recommendations presented here are drawn from the 2005 nPEP guidelines but have been adapted to reflect more recent nPEP strategies, the availability of newer ARVs, and current DHHS adult treatment guidelines** (see Table 1). A number of alternatives are available; consult with an expert. Note that, although these regimens are effective in treating HIV infection, their efficacy as prophylaxis has not been demonstrated.

If the source person is known or suspected to have infection with HIV that is resistant to ARV medications, seek expert consultation in selecting an appropriate nPEP regimen.

In general, the recommendations for nPEP involve three-drug combination therapy and are more aggressive than the occupational PEP recommendations. However, if the HIV status of the source person is unknown and the exposure is thought to be of relatively low risk, consider two-drug nPEP (e.g., tenofovir + emtricitabine) to minimize toxicity.

Figure 1. Exposure Risk Algorithm



U.S. Department of Health and Human Services. *Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States*. MMWR Recomm Rep. 2005 Jan 21;54(RR02);1-20.

Select a regimen that is likely to be effective but tolerable; consider the potential adverse effects of ARV agents. Certain ARVs are not recommended for PEP, including abacavir, delavirdine, nevirapine, and the combination of didanosine + stavudine. The 2005 DHHS guidelines list lopinavir/ritonavir as the preferred third agent for the expanded PEP regimen, and it still is commonly used. Newer protease inhibitors (i.e., atazanavir, darunavir) or the integrase inhibitor raltegravir may be appropriate for certain individuals, and should particularly be considered if exposure factors (e.g., comorbidities or interacting drugs) or source patient factors (e.g., concern for resistance) make therapy with lopinavir/ritonavir problematic. Although the 2005 guidelines designate it as a preferred agent, efavirenz may have a higher rate of significant adverse effects than other listed agents. Additionally, efavirenz should not be used with pregnant women, because of possible teratogenicity. Refer to the appendix in the updated DHHS adult treatment guidelines for more complete information on the dosing, advantages, and disadvantages of the various ARV agents. Consider consultation with experts (see "Expert Consultation," below).

Table 1. Antiretroviral Regimens for Nonoccupational Postexposure Prophylaxis of HIV Infection

* Unboosted atazanavir cannot be coadministered with tenofovir (use atazanavir + ritonavir)

Abbreviations: NNRTI = nonnucleoside reverse transcriptase inhibitor; NRTI = nucleoside analogue reverse transcriptase inhibitor; PI = protease inhibitor

Adapted from U.S. Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*. January 10, 2011. and U.S. Department of Health and Human Services. *Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States--January 21, 2005*.

Preferred Regimens	
PI based	Lopinavir/ritonavir (Kaletra) 400/100 mg BID + 2-NRTI combination (see below)
Alternative Regimens	
PI based	Atazanavir 300 mg once daily + ritonavir 100 mg once daily + 2-NRTI combination (see below) Darunavir 800 mg once daily + ritonavir 100 mg once daily + 2-NRTI combination (see below) Atazanavir 400 mg once daily*
Integrase inhibitor based	Raltegravir 400 mg BID + tenofovir/emtricitabine 1 tablet once daily
NRTI combinations (to be used with Preferred or Alternative third agents listed above)	
	Tenofovir 300 mg once daily + emtricitabine 200 mg once daily (available as Truvada, 1 tablet once daily) Zidovudine 300 mg BID + lamivudine 150 mg BID (available as Combivir, 1 tablet BID)

Once the decision is made to institute nPEP, do the following:

- Begin ARV prophylaxis as soon as possible after the exposure, but always within 72 hours. Treatment should be continued for 28 days, unless the source person is determined to be HIV negative.

- Provide counseling about the efficacy of nPEP, including the importance of protection against future HIV exposures, timely initiation of nPEP medications, and adherence to these medications for 28 days.
- Counsel exposed patients to use latex barriers with their sexual partners until transmission of HIV infection has been ruled out.
- Counsel patients, as appropriate, about ways to reduce risks of future exposure to HIV.
- In cases of sexual assault, refer the patient to a rape counselor.

Follow-Up

Patients should be evaluated at 1 week for review of all test results and further risk-reduction counseling. For patients taking nPEP, this follow-up should include adherence assessment and evaluation of any adverse effects. A 2-week blood screening (CBC, LFTs, and creatinine) should be checked for patients on the 28-day nPEP regimen to monitor for nPEP toxicity. Follow-up testing for HIV antibody in patients with a negative baseline HIV antibody test should be done at 6 weeks, 3 months, and 6 months after the exposure.

Patients need health education and risk-reduction counseling and emotional support during their follow-up visits. Nonoccupational PEP programs should focus efforts on risk-reduction counseling rather than the continued use of medicines for prevention. To this end, many programs have case managers, social workers and health educators as the key providers of follow-up and counseling after an exposure, with referral to clinicians as needed.

If patients develop acute HIV infection or are discovered to be HIV seropositive at follow-up testing, refer to an HIV specialist for evaluation and care (see chapter *Primary HIV Infection*).

Expert Consultation

For consultation on the treatment of exposures to HIV (and HBV and HCV), the clinician managing the exposed person can call the National HIV/AIDS Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) at 888-HIV-4911 (888-448-4911). This service is available 24 hours a day at no charge. (However, 24-hour availability may be temporarily interrupted. Additional information on the Internet is available at the PEPline website.) PEPline support may be especially useful in challenging situations, such as when drug-resistant HIV strains are suspected to be involved in the exposure or when the exposed person is pregnant.

Prophylaxis Against HBV and HCV

Prophylaxis against HBV is recommended for patients with potential exposure to HBV who do not have not have immunity against HBV. Give HBV immune globulin (HBIG) as a 0.06 mL/kg IM injection and initiate the vaccination series. For patients who received the vaccine series but did not develop protective antibody (HBV sAb+), give HBIG at the time of the postexposure workup and initiate revaccination; consider repeat of HBIG in 1 month. For patients with immunity to HBV (HBV sAb+), no treatment is indicated.

For HCV, no prophylactic treatments are recommended. After potential exposure, conduct a baseline HCV antibody test. If the source is known to have HCV infection, consider alanine aminotransferase (ALT) and HCV viral load testing at 4-6 weeks. HCV antibody testing should be repeated at 4-6

months. If HCV seroconversion occurs (indicated by ALT elevation, detectable HCV viral load, or confirmed positive HCV antibody test result), refer the patient to a hepatologist because early treatment of acute HCV may be indicated.

Note on Preexposure Prophylaxis

A number of investigations have been undertaken to evaluate the efficacy of ARV medications as preexposure prophylaxis (PrEP)--that is, oral ARVs taken by at-risk HIV-uninfected individuals with the goal of preventing HIV infection. Other studies are examining ARV-based microbicides, topical preparations applied before HIV exposure, with the same goal. Two recent studies have shown that these approaches can reduce the risk of sexual acquisition of HIV. In one, oral tenofovir + emtricitabine (Truvada), taken daily, reduced the risk of HIV acquisition in high-risk MSM and transgender women who have sex with men. In another, tenofovir vaginal gel (available only through research studies), used before and after vaginal intercourse, reduced the rate of HIV infection in high-risk heterosexual women in South Africa. In both studies, the ARV prophylaxis was given *in conjunction with* other risk-reduction interventions, including counseling, condom provision, and STI testing and treatment. This and other studies will explore the efficacy and safety, and possible effects on risk of various types of PrEP and microbicides in different populations. The CDC has issued interim guidelines on the use of oral tenofovir-emtricitabine as PrEP in MSM (see "References," below); until more data are available, alternative approaches to PrEP should not be undertaken.

Patient Education

- Persons who have possible exposures to HIV should contact a medical provider or go to an emergency room as soon as possible after the potential exposure has occurred. PEP may be effective if it is started within 72 hours of exposure, but the sooner medications are initiated, the better the chance for preventing HIV transmission.
- PEP medications should be taken as directed for a full 28-day course. Adherence to PEP medications is essential for successful treatment.
- If patients are experiencing uncomfortable adverse effects, they should contact their care provider. Providers may prescribe medications to alleviate the adverse effects or select other PEP medications.
- Until HIV infection has been ruled out, exposed persons should be advised to use latex barriers to prevent transmission of HIV to their sex partners.
- Exposed persons should be counseled about the symptoms of primary HIV infection and instructed to contact their care provider immediately if symptoms develop.
- The most effective way to prevent HIV infection is to prevent exposure to HIV by practicing safer sex and safer IDU techniques. Using condoms and avoidance of needle sharing are successful preventive measures. If patients have questions about access to condoms or clean needles, they should contact their care provider for assistance.

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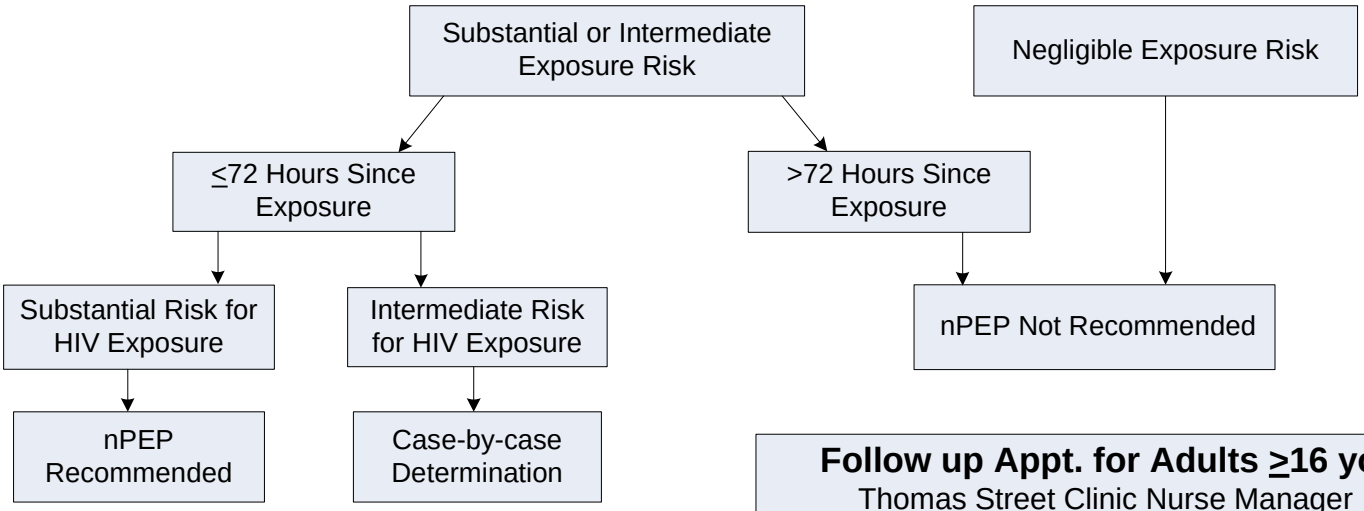
Ben Taub General Hospital Emergency Center

HIV nPEP Risk Assessment
Sexual Assault Patients



Substantial Risk for HIV Exposure:

Exposure of
vagina, rectum, eye, mouth, or other mucous membrane, non-intact skin, or percutaneous contact
With
blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid that is visibly contaminated with blood
When
the source is **known** to be HIV-infected

Intermediate Risk for HIV Exposure:

Exposure of
vagina, rectum, eye, mouth, or other mucous membrane, non-intact skin, or percutaneous contact
With
blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid that is visibly contaminated with blood
When
the sources HIV status is **unknown**

Negligible Risk for HIV Exposure:

Exposure of
vagina, rectum, eye, mouth, or other mucous membrane, intact or non-intact skin, or percutaneous contact
With
urine, nasal secretions, saliva, sweat, or tears if not visibly contaminated with blood
Regardless
of the HIV status of the source

Follow up Appt. for Adults ≥16 yo:
Thomas Street Clinic Nurse Manager
Kimberlynn Luke
713-873-4042

Pediatrics <16 yo:
Call Baylor Pediatric Retrovirology to discuss and arrange f/u for **all** patients:
TCH (832)824-7243 pager# 4719

National PEP Hotline (888)448-4911

nPEP 28 Day Recommended Regimens:
(Write Sexual Assault on Rx)

Adults:
Kaletra (lopinavir & ritonavir) 2 tabs PO BID **with food**
PLUS/EITHER
Truvada (emtricitabine & tenofovir) 1 tab PO QD
(if **NO** renal insufficiency present)
OR
Combivir (lamivudine & zidovudine) 1 tab PO BID
(if renal insufficiency present)
Also
Consider Ondansetron or Promethazine

Pediatrics ≥ 30kg:
Kaletra (lopinavir & ritonavir) 2 tabs PO BID
PLUS
Combivir (lamivudine & zidovudine) 1 tab PO BID
Also
Ondansetron 4 mg tab:
4-11 yo: 1 tab PO 30 min before meds
≥12 yo: 1-2 tabs PO 30 min before meds

< 30kg, Call Baylor Retrovirology for Recommendations