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Houston Area HIV Services Ryan White Planning Council

Comprehensive HIV Planning Committee Meeting

12:00 p.m., Monday, July 30, 2018
Meeting Location: 2223 W. Loop South, Room 532
Houston, Texas 77027

AGENDA

I. Call to Order
   - A. Welcome
   - B. Moment of Reflection
   - C. Adoption of the Agenda
   - D. Approval of the Minutes

Ted Artiaga and
Steven Vargas, Co-Chairs

II. Public Comment and Announcements

(NOTE: If you wish to speak during the Public Comment portion of the meeting, please sign up on the clipboard at the front of the room. No one is required to give his or her name or HIV status. All meetings are audio taped by the Office of Support for use in creating the meeting minutes. The audiotape and the minutes are public record. If you state your name or HIV status it will be on public record. If you would like your health status known, but do not wish to state your name, you can simply say: "I am a person living with HIV", before stating your opinion. If you represent an organization, please state that you are representing an agency and give the name of the organization. If you work for an organization, but are representing yourself, please state that you are attending as an individual and not as an agency representative. Individuals can also submit written comments to a member of the staff who would be happy to read the comments on behalf of the individual at this point in the meeting. All information from the public must be provided in this portion of the meeting.)

III. FY 2019 EIIHA Target Populations

Amber Harbolt, Health Planner
Office of Support

   - A. Review FY 2019 EIIHA Plan Motions from EIIHA Workgroup
   - B. Review Council and Community Input on Target Populations
   - C. Approve FY 2019 EIIHA Target Populations

IV. Committee Quarterly Report

V. Announcements

Ted Artiaga and
Steven Vargas, Co-Chairs

VI. Adjourn

Houston Area HIV Services Ryan White Planning Council

Comprehensive HIV Planning Committee
1:00 p.m., Thursday, June 28, 2018
Meeting Location: 2223 West Loop South, Room 416; Houston, Texas 77027

Minutes

MEMBERS PRESENT	MEMBERS ABSENT	OTHERS PRESENT
Ted Artiaga, Co-Chair	Dawn Jenkins	Sha'Terra Johnson-Fairley, TRG
Steven Vargas, Co-Chair	Osaro Mgbere, excused	Crystal Townsend, TRG
Herman Finley	Faye Robinson	Amber Harbolt, Office of Support
Denis Kelly	Isis Torrente	Diane Beck, Office of Support
Rodney Mills	Cristina Martinez	
Robert Noble	Oluseyi Orija	
Shital Patel	Crystal Starr, excused	
Ryan Clark		
Cynthia Deverson		
Nancy Miertschin		
Esther Ogunjimi		
Amana Turner		
Larry Woods		

Call to Order: Ted Artiaga, Co-Chair, called the meeting to order at 1:04 p.m. and asked for a moment of reflection.

Adoption of Agenda: ***Motion #1:*** *it was moved and seconded (Vargas, Turner) to adopt the agenda.* **Motion carried.**

Approval of the Minutes: ***Motion #2:*** *it was moved and seconded (Vargas, Mills) to approve the May 10, 2018 minutes.* **Motion carried.** Abstentions: Finley, Kelly, Noble, Patel, Woods.

Public Comment: None.

FY19 EIIHA Plan: Harbolt reviewed the EIIHA planning process and requirements, development timeline and FY19 EIIHA Approval Motion, see attached. ***Motion #3:*** *it was moved and seconded (Kelly, Turner) to approve the following motion: In order to meet HRSA grant application deadlines, request the Planning Council to allow the Comprehensive HIV Planning Committee to have final approval of the FY 2019 EIIHA Plan, provided that:*

- *The FY 2019 EIIHA Plan is developed through a collaborative process that includes stakeholders from prevention and care, community members, and consumers; and*
- *The recommended FY 2019 EIIHA Plan is distributed to Planning Council members for input prior to final approval from the Comprehensive HIV Planning Committee.*

Motion carried.

2018 Epidemiological Profile

Update on Collaboration with Houston Health Department: Harbolt said she met with Luna and they organized who will handle what. They are changing the way we look at Youth ages 13-24 by dividing the population into adolescents 13-17 and young adults 18-24. We will also have transgender data that we haven't had before.

Steering Committee Feedback on Chapter 1: Harbolt reviewed the recommended changes, see attached. ***Motion #4:*** *it was moved and seconded (Vargas, Woods) to make the following changes to Chapter 1 of the 2018 Epidemiological Profile: add the denominator to the charts, bold and italicize household income to differentiate from individual measures of poverty, consider working with the Sharing Science Symposium to present the epi data to the public and create a factsheet that in simple language that is graphically and visually accessible for download on the website.* **Motion carried.**

Announcements: The FY19 EIIHA Plan Workgroup will meet on July 23rd at 2:00 p.m.; let Beck know if you want to be on the workgroup. The draft EIIHA plan will be sent out for comment and the Comprehensive HIV Planning Committee will meet on July 30th at 12:00 p.m. for final approval of the EIIHA plan.

Townsend said that it is National Testing Week, if you post an event online please use the hashtag #endHIVhou and she will repost it.

Adjournment: The meeting was adjourned at 1:50 p.m.

Submitted by: Approved by:

_____ _____

Amber Harbolt, Office of Support Date Chair of Committee Date

JA = Just arrived at meeting
LR = Left room temporarily
LM = Left the meeting
C = Chaired the meeting

2018 Voting Record for Meeting Date June 28, 2018

MEMBERS	**Motion #1:** Agenda **Motion Carried**				**Motion #2:** Minutes **Motion Carried**				**Motion #3:** FY19 EIIHA Approval Motion **Motion Carried**				**Motion #4:** Changes to Epi Report Chapter 1 **Motion Carried**			
	ABSENT	**YES**	**NO**	**ABSTAIN**	**ABSENT**	**YES**	**NO**	**ABSTAIN**	**ABSENT**	**YES**	**NO**	**ABSTAIN**	**ABSENT**	**YES**	**NO**	**ABSTAIN**
Ted Artiaga, Co-Chair				**C**				**C**				**C**				**C**
Steven Vargas, Co-Chair		**X**				**X**				**X**				**X**		
Herman Finley		**X**						**X**		**X**				**X**		
Dawn Jenkins	**X**				**X**				**X**				**X**			
Denis Kelly		**X**						**X**		**X**				**X**		
Osaro Mgbere	**X**				**X**				**X**				**X**			
Rodney Mills		**X**				**X**				**X**				**X**		
Robert Noble		**X**						**X**		**X**				**X**		
Shital Patel		**X**						**X**		**X**				**X**		
Faye Robinson	**X**				**X**				**X**				**X**			
Isis Torrente	**X**				**X**				**X**				**X**			
Ryan Clark		**X**				**X**				**X**				**X**		
Cynthia Deverson		**X**				**X**				**X**				**X**		
Cristina Martinez	**X**				**X**				**X**				**X**			
Nancy Miertschin	**X**				**X**					**X**				**X**		
Esther Ogunjimi		**X**				**X**				**X**				**X**		
Oluseyi Orija	**X**				**X**				**X**				**X**			
Crystal Starr	**X**				**X**				**X**				**X**			
Amana Turner		**X**				**X**				**X**				**X**		
Larry Woods		**X**						**X**		**X**				**X**		

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Fiscal Year 2019
Early Identification of Individuals with HIV/AIDS (EIIHA)
Target Populations Criteria Worksheet

Type of Data	Possible Criterion	Definition	Suggested Thresholds	Selected
Epidemiological	**1. HIV diagnosis rate***	Number of new diagnoses of HIV disease within the population after accounting for population size (per 100,000)	Rate > EMA rate	✓
	2. HIV prevalence rate	Number of HIV diagnosed people within the population after accounting for population size (per 100,000)	Rate > EMA rate	
	3. Unaware estimates*	Number of people in each population group estimated to be HIV+ and unaware of their status using the CDC estimate (17.3%)	Comprises largest # of status-unaware within demographic category	✓
Care Continuum	**4. Linked proportion***	Percent of population that was linked to HIV medical care within **3 months**** of diagnosis	% < EMA %	✓
	5. Unmet need/out of care proportion*	Percent of diagnosed persons in the population with no evidence of HIV medical care in the previous 12 months per HRSA definition	% > EMA %	✓
Planning	**6. Special populations**	Population is designated as a "special population" in the Comprehensive HIV Plan	Yes/No	✓
	7. FY18 EIIHA Target Group*	Population was included in the FY18 EIIHA Matrix as a Target Group	Yes/No	✓
Other	**8. Late diagnosis***	Percent of persons within each group who are diagnosed with HIV stage 3 within 3 months of initial HIV diagnosis	% > EMA %	✓

*Criteria used in selection of FY 2018 EIIHA target populations

**Linkage within 1 month not available by population

Fiscal Year 2019
Early Identification of Individuals with HIV/AIDS (EIIHA)
Target Populations Selection Matrix

DRAFT – ALL CRITERIA

■ = meets criteria

	1. HIV Diagnosis Rate	2. HIV Prevalence Rate	3. Undiagnosed Estimate	4. Linked Proportion	5. Unmet Need / Out of Care Proportion	6. Special Populations	7. FY18 EIIHA Target Group	8. Late Diagnosis	Total # Criteria
Houston EMA	20.0	457.8	6,625	80%	25%	--	--	22%	8
Sex									
Male	32.6	692.0	4,971	80%	25%	Y	Y	22%	5
Female	7.6	227.0	1,654	81%	23%	Y	Y	23%	3
Race/Ethnicity									
White	6.7	245.8	1,249	84%	22%	N	N	21%	0
Black / African American	53.1	1,265.1	3,246	77%	26%	Y	Y	19%	7
Hispanic	19.4	334.6	1,860	83%	25%	Y	Y	27%	3
Other	4.8	72.2	91	69%	28%	N	N	22%	2
Multi-race	--	--	178	91%	15%	Y	N	16%	1
Age									
0 - 1	0.0	1.1	0	--	---	N	N	--	0
2 - 12	0.1	5.7	14	100%	9%	N	N	--	0
13 - 24	27.3	120.7	289	79%	22%	Y	N	9%	3
25 - 34	49.3	611.5	1,347	78%	24%	N	Y	20%	4
35 - 44	27.3	754.3	1,557	82%	26%	N	Y	30%	5
45 - 54	20.4	966.9	1,795	84%	24%	Y	Y	34%	6
55-64 (55-64 in 2017)	11.1	758.9	1,217	86%	24%	Y	Y	34%	4
65+ (new in 2017)	2.3	797.6	406	76%	31%	Y	Y	30%	6
Risk Category									
Male-Male Sexual Contact	[d]	[d]	3787	79%	24%	Y	Y	19%	4
Injection Drug Use	[d]	[d]	556	72%	28%	Y	N	33%	4
MSM/IDU	[d]	[d]	258	83%	24%	Y	N	23%	1
Sex with Female/Sex with Male	[d]	[d]	1,940	83%	25%	Y	N	28%	2
Perinatal	[d]	[d]	81	100%	28%	N	N	--	1
Adult other risk	[d]	[d]	4	--	28%	N	N	--	1

Notes	1. **HIV Diagnosis Rate**	**2. HIV Prevalence Rate**	**3. Undiagnosed Estimate**	**4. Linked Proportion**	**5. Unmet Need / Out of Care Proportion**	**6. Special Populations**	**7. FY18 EIIHA Target Group**	**8. Late Diagnosis**
Definition of selection criterion	Number of new diagnoses of HIV within a population while accounting for population size (rate is the number of new HIV cases per 100,000 population)	Number of HIV diagnosed people within the population after accounting for population size (rate is the number of HIV + HIV stage 3 cases per 100,000 population)	Number of people in each population group estimated to be living with HIV and unaware of their status using the CDC estimate (19.0%)	Percent of newly diagnosed individuals linked to HIV medical care within 3 months of diagnosis	Percent of diagnosed people living with HIV with no evidence of HIV medical care in the previous 12 months per HRSA definition	Population is designated as a "special population" in the Comprehensive HIV Plan	Population was included in the FY18 EIIHA Matrix	Percent of persons within each group who are diagnosed with HIV stage 3 within 3 months of HIV diagnosis. **Denominator is new diagnoses ONLY.**
Threshold for prioritization	Rate > EMA rate	Rate > EMA rate	Comprises largest # of status-unaware within demographic category	% < EMA %	% > EMA %	Yes/No	Yes/No	% > EMA %
Data source	DSHS, New diagnoses 2017. Released 7/23/18	DSHS, Prevalence 2017. Released 7/23/18	DSHS, HIV Undiagnosed 2017. Released 7/20/18	DSHS, Linkage to care 2017. Released 7/20/18	DSHS, Unmet need 2017. Released 7/20/18	2017 Comprehensive Plan Special Populations	FY18 Houston EMA EIIHA Target Populations, approved by the Comprehensive HIV Planning Committee on 9/28/17	DSHS, Late Diagnosis by population 2016. Released 7/20/18
Explanations and additional background	Population data are not available for risk groups; therefore, it is not possible to calculate rate by risk	HIV+HIV stage 3 (total HIV disease prevalence) Population data are not available for risk groups; therefore, it is not possible to calculate rate by risk	Estimates have been extrapolated using a national approximation of status unaware. No local estimates are available.	Linked proportion not available for risk category Adult other	Unmet need proportion numerator for age range 0-1 was 1 individual	--	Target Groups for FY18 EIIHA Plan were: • African Americans • Hispanics/Latinos age 25 and over • Men who have Sex with Men (MSM)	Late diagnosis proportion not available for age range 0-1; risk category Adult Other There were no late diagnoses observed among age range 2 – 12.

Fiscal Year 2019
Early Identification of Individuals with HIV/AIDS (EIIHA)
Target Populations Selection Matrix

DRAFT – Selected Criteria

■ = meets criteria

	1. HIV Diagnosis Rate	3. Undiagnosed Estimate	4. Linked Proportion	5. Unmet Need / Out of Care Proportion	6. Special Populations	7. FY18 EIIHA Target Group	8. Late Diagnosis	Total # Criteria
Houston EMA	20.0	6,625	80%	25%	--	--	22%	7
Sex								
Male	32.6	4,971	80%	25%	Y	Y	22%	4/7
Female	7.6	1,654	81%	23%	Y	Y	23%	3/7
Race/Ethnicity								
White	6.7	1,249	84%	22%	N	N	21%	0/7
Black / African American	53.1	3,246	77%	26%	Y	Y	19%	6/7
Hispanic	19.4	1,860	83%	25%	Y	Y	27%	3/7
Other	4.8	91	69%	28%	N	N	22%	2/7
Multi-race	--	178	91%	15%	Y	N	16%	1/7
Age								
0 - 1	0.0	0	--	---	N	N	--	0/7
2 - 12	0.1	14	100%	9%	N	N	--	0/7
13 - 24	27.3	289	79%	22%	Y	N	9%	3/7
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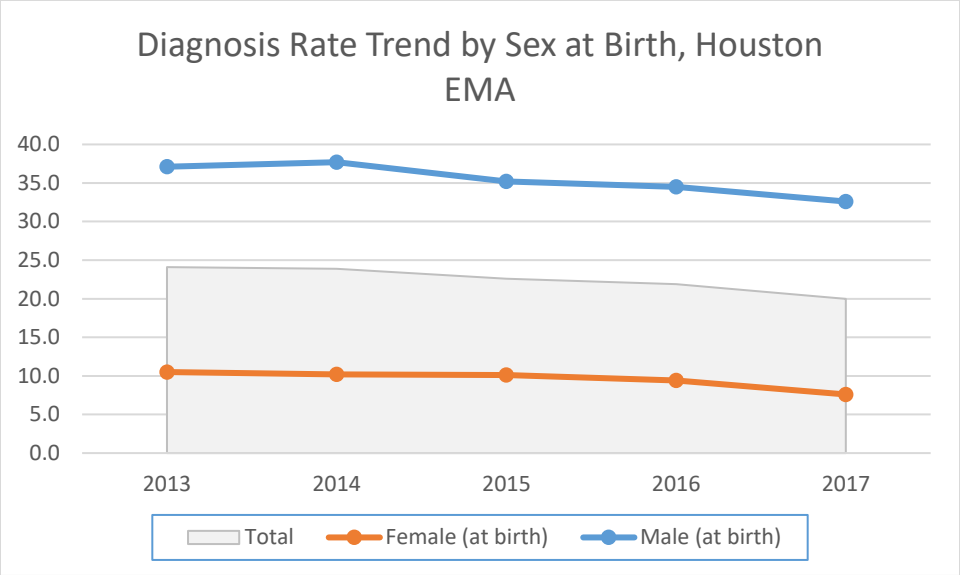
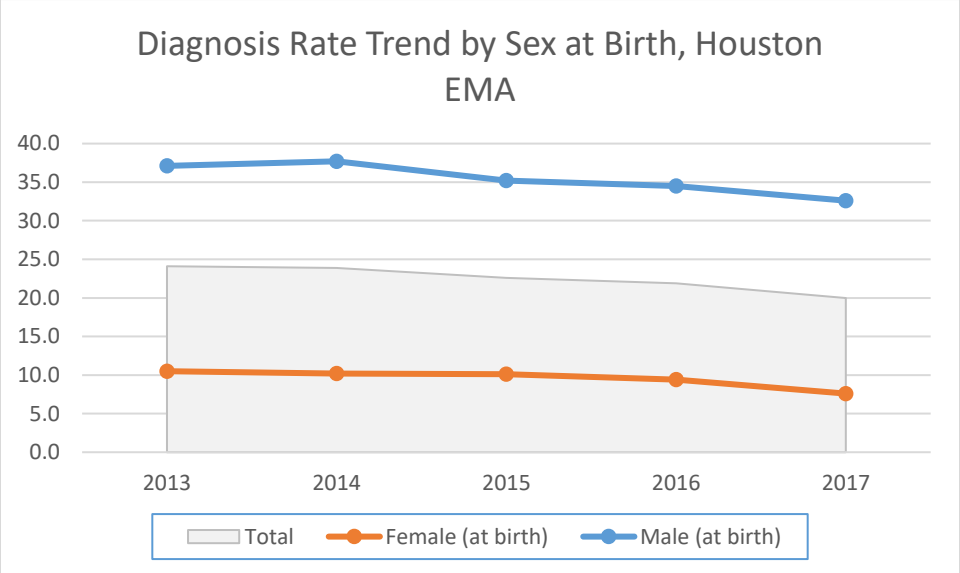
65+ (new in 2017)	2.3	406	76%	31%	Y	Y	30%	5/7
Risk Category								
Male-Male Sexual Contact	[d]	3787	79%	24%	Y	Y	19%	4/6
Injection Drug Use	[d]	556	72%	28%	Y	N	33%	4/6
MSM/IDU	[d]	258	83%	24%	Y	N	23%	1/6
Sex with Female/Sex with Male	[d]	1,940	83%	25%	Y	N	28%	2/6
Perinatal	[d]	81	100%	28%	N	N	--	1/6
Adult other risk	[d]	4	--	28%	N	N	--	1/6

Notes	1. HIV Diagnosis Rate	3. Undiagnosed Estimate	4. Linked Proportion	5. Unmet Need / Out of Care Proportion	6. Special Populations	7. FY18 EIIHA Target Group	8. Late Diagnosis
Definition of selection criterion	Number of new diagnoses of HIV within a population while accounting for population size (rate is the number of new HIV cases per 100,000 population)	Number of people in each population group estimated to be living with HIV and unaware of their status using the CDC estimate (19.0%)	Percent of newly diagnosed individuals linked to HIV medical care within 3 months of diagnosis	Percent of diagnosed people living with HIV with no evidence of HIV medical care in the previous 12 months per HRSA definition	Population is designated as a "special population" in the Comprehensive HIV Plan	Population was included in the FY18 EIIHA Matrix	Percent of persons within each group who are diagnosed with HIV stage 3 within 3 months of HIV diagnosis. **Denominator is new diagnoses ONLY.**
Threshold for prioritization	Rate > EMA rate	Comprises largest # of status-unaware within demographic category	% < EMA %	% > EMA %	Yes/No	Yes/No	% > EMA %
Data source	DSHS, New diagnoses 2017. Released 7/23/18	DSHS, HIV Undiagnosed 2017. Released 7/20/18	DSHS, Linkage to care 2017. Released 7/20/18	DSHS, Unmet need 2017. Released 7/20/18	2017 Comprehensive Plan Special Populations	FY18 Houston EMA EIIHA Target Populations, approved by the Comprehensive HIV Planning Committee on 9/28/17	DSHS, Late Diagnosis by population 2016. Released 7/20/18
Explanations and additional background	Population data are not available for risk groups; therefore, it is not possible to calculate rate by risk	Estimates have been extrapolated using a national approximation of status unaware. No local estimates are available.	Linked proportion not available for risk category Adult other	Unmet need proportion numerator for age range 0-1 was 1 individual	--	Target Groups for FY18 EIIHA Plan were: • African Americans • Hispanics/Latinos age 25 and over • Men who have Sex with Men (MSM)	Late diagnosis proportion not available for age range 0-1; risk category Adult Other There were no late diagnoses observed among age range 2 – 12.

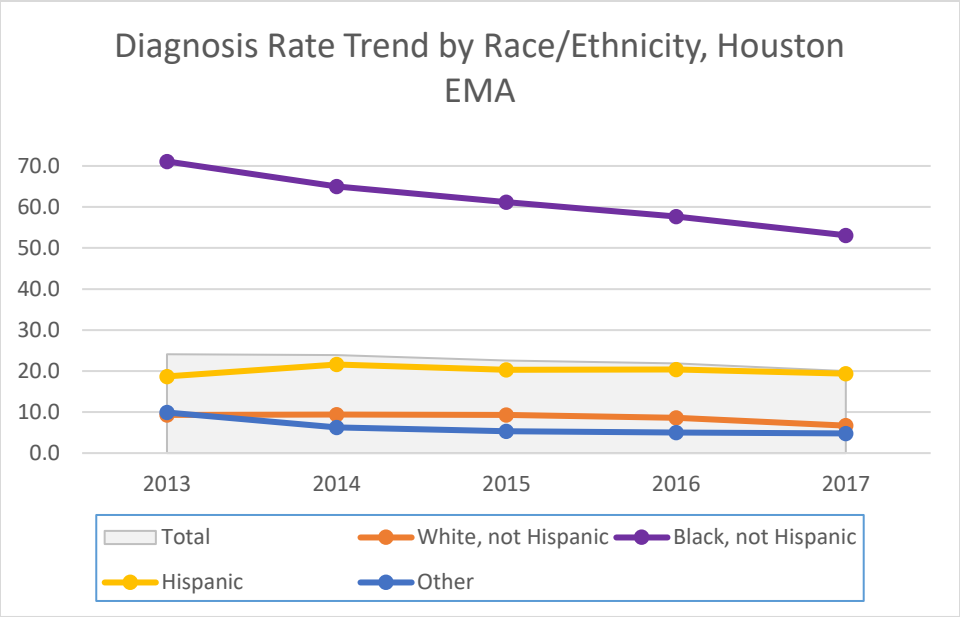
EIIHA Trends Data:

HIV Diagnosis Rate:

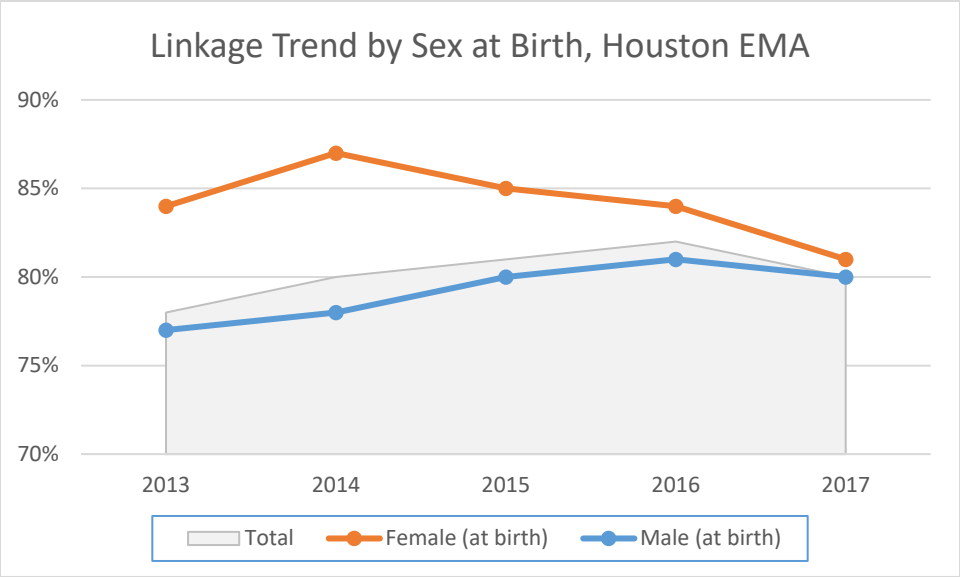


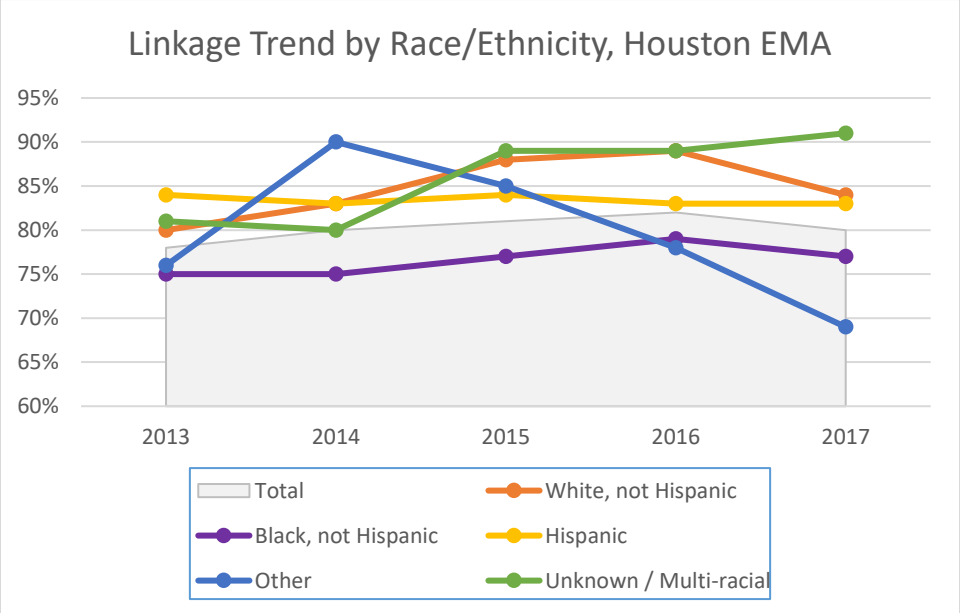


HIV Diagnosis Rate (Continued):

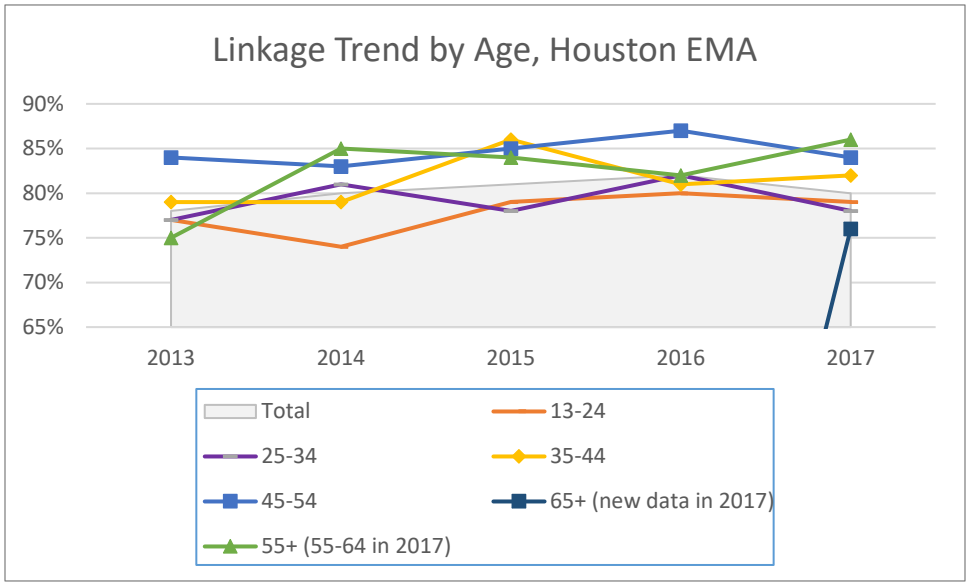


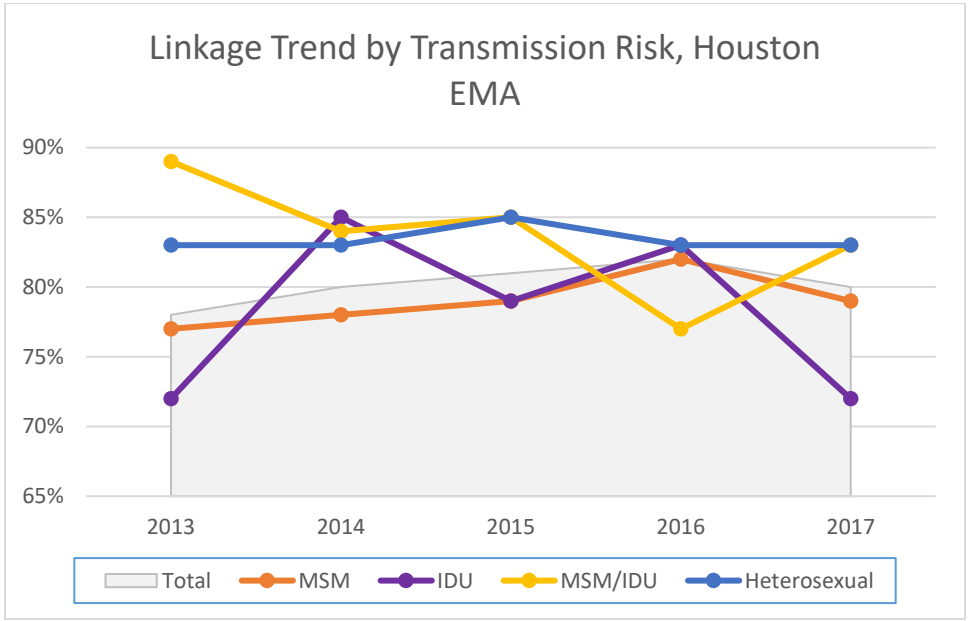
Linked Proportion:



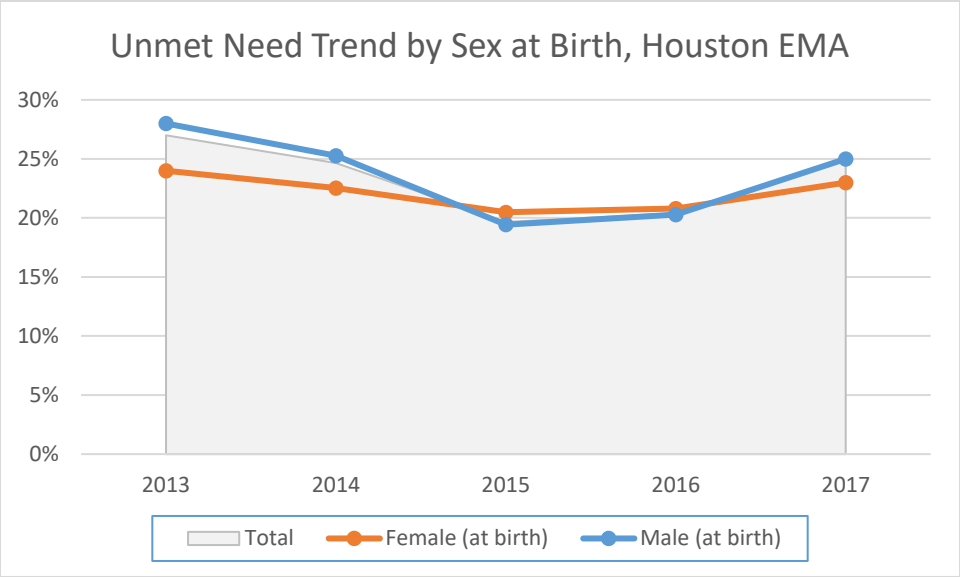


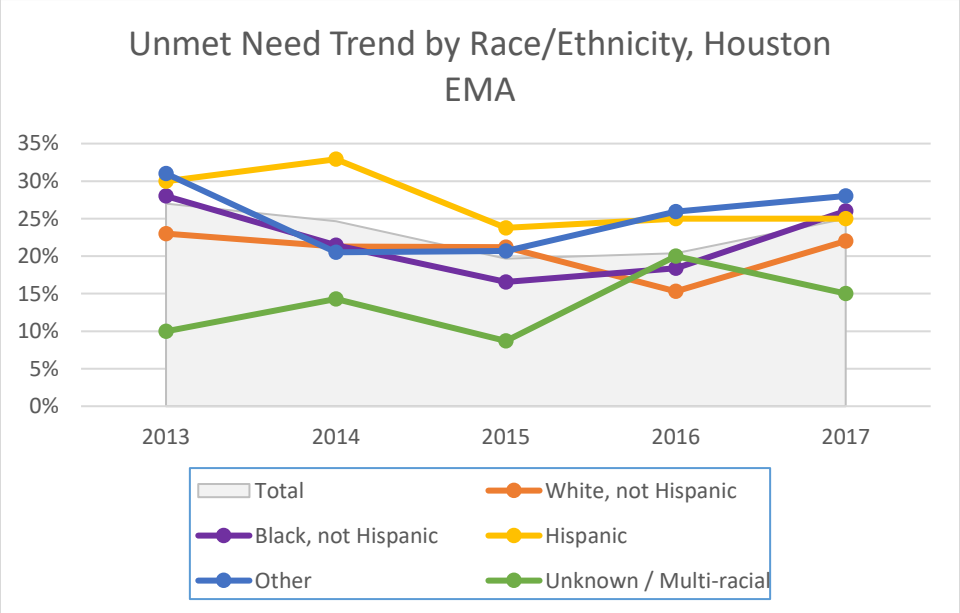
Linked Proportion (Continued):



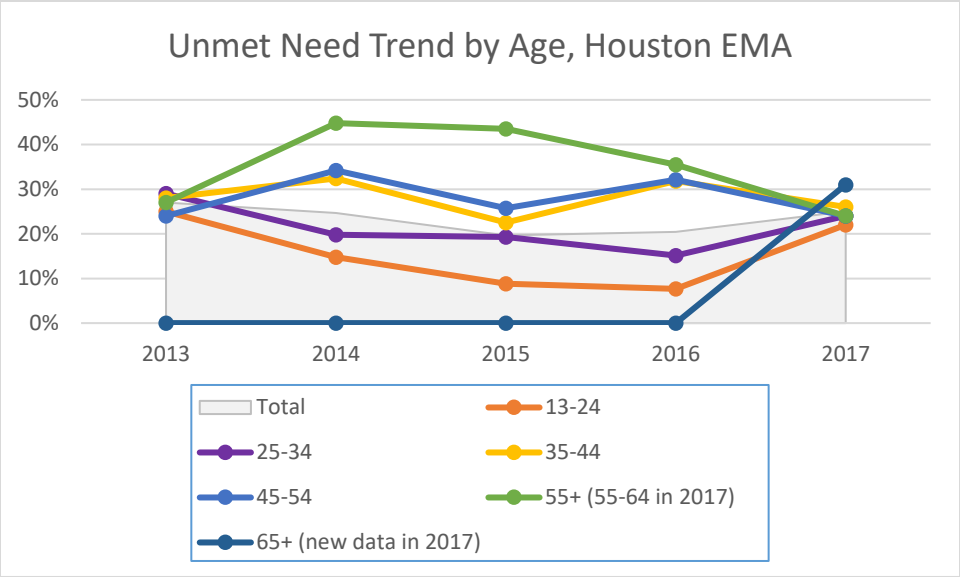


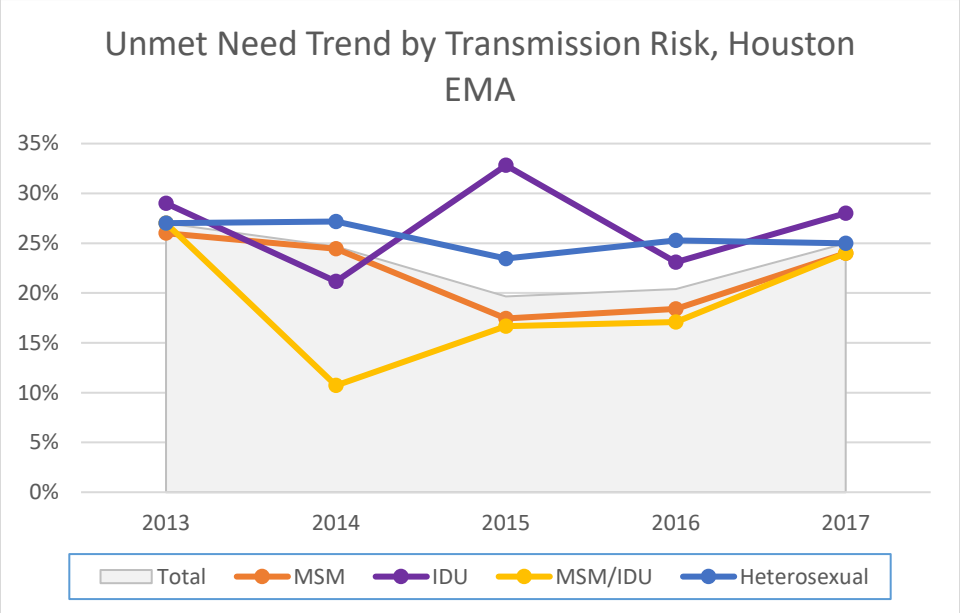
Out of Care / Unmet Need:



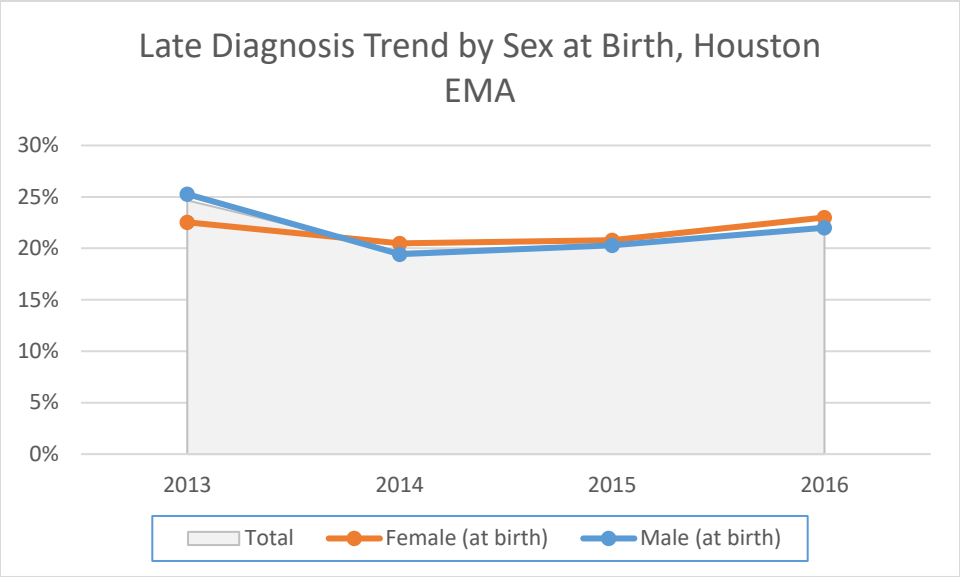


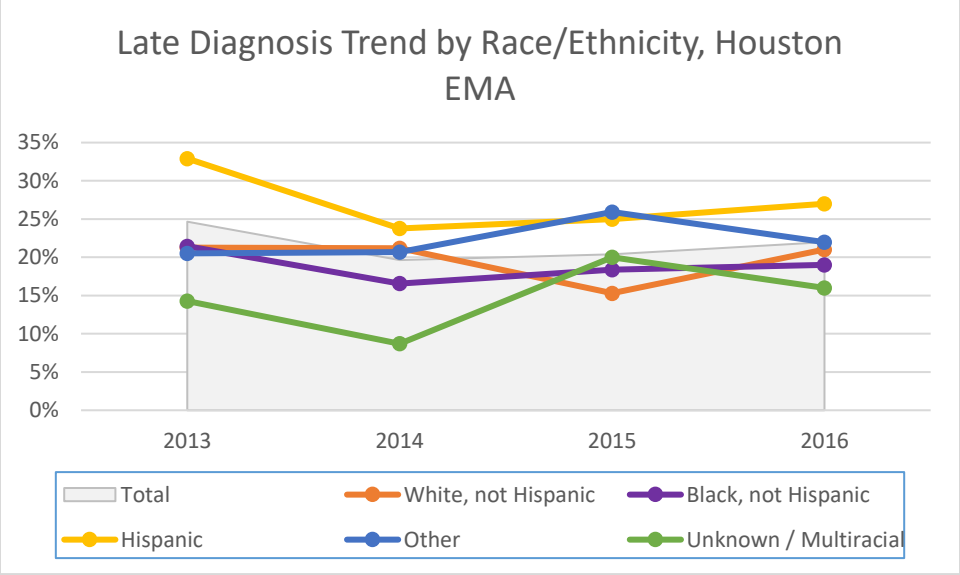
Out of Care / Unmet Need (Continued):



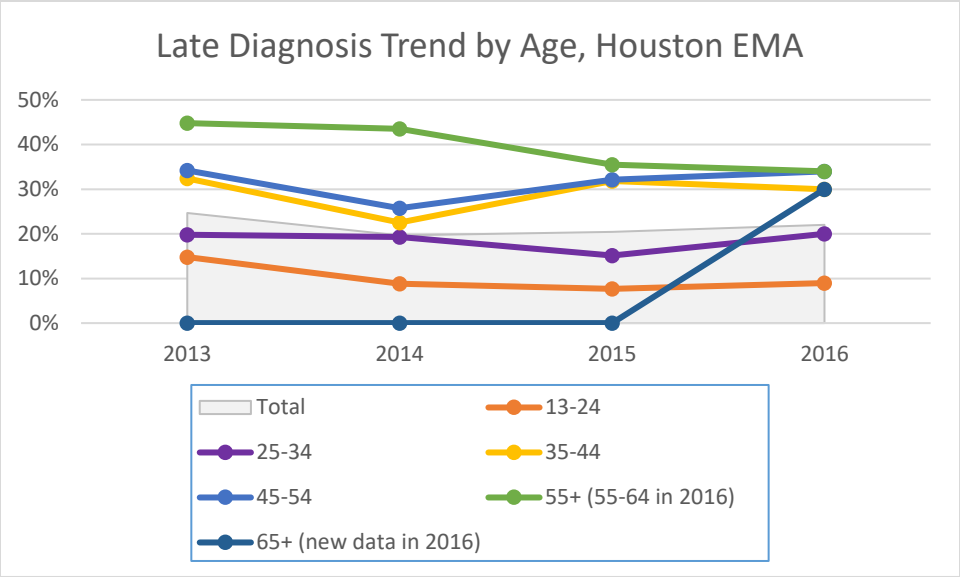


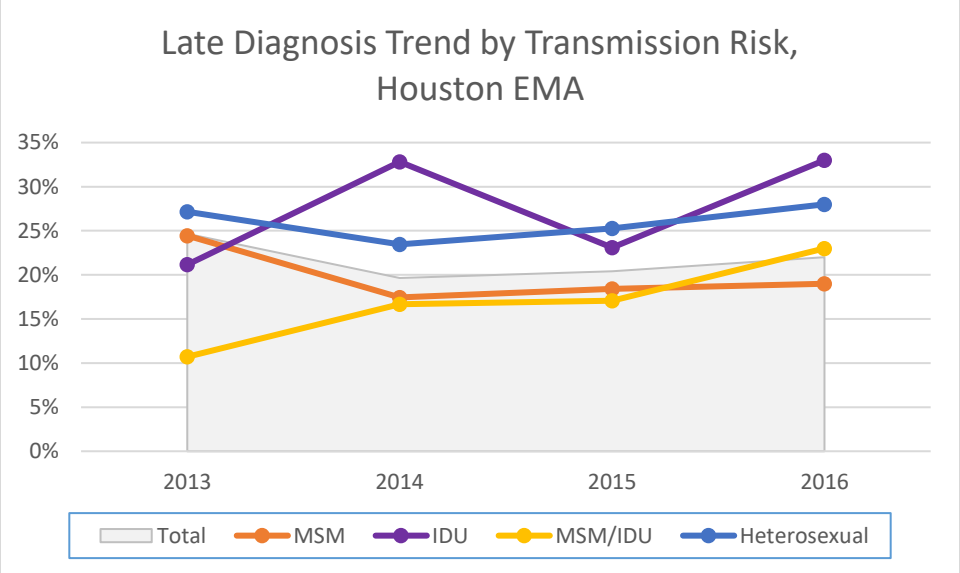
Late Diagnosis:





Late Diagnosis (Continued):





EIIHA Workgroup Motions
FY 2018 EIIHA Target Populations – 07/23/2018

The EIIHA Workgroup met on July 23, 2018. Participants included representatives from prevention and care, community members, and consumers. The Workgroup reviewed the FY 2019 guidance from HRSA, adopted selection criteria, and selected the FY 2019 target populations.

Item: FY 2019 EIIHA Plan Target Populations

Recommended Action: **FYI: (Committee provided final approval):** Approve the following target populations for the FY 2019 EIIHA Plan:

1. African Americans
2. Hispanics/Latinos age 25 and over
3. Men who have Sex with Men (MSM)

Office of Support is to include information on late diagnoses, along with HIV and aging, in the EIIHA section of the HRSA application.

Recommended Action: **FYI: (Committee provided final approval):** Office of Support is to include a statement in the EIIHA section of the HRSA application recognizing that currently available epidemiologic data is not sufficient to assess the need for testing, referral, and linkage in at-risk populations such as among those who are transgender, intersex, homeless, those released from incarceration, adolescents ages 13 to 17, and young adults ages 18 to 24.

The only change from the FY 2018 EIIHA Plan is the inclusion of information regarding late diagnoses observed for the Houston EMA in 2016. Data from the Texas Department of State Health Services indicate a slight increase in the percentage of late/concurrent HIV diagnoses among several populations reviewed at the July 23rd EIIHA Workgroup meeting.

The Comprehensive HIV Planning Committee will meet on Monday, July 30, 2018 at 10:30 a.m., located at 2223 West Loop South, Room 532, Houston, TX 77027, to review and approve the FY 2019 EIIHA Plan target populations.

All are welcome to provide public comment at the July 30th Comprehensive HIV Planning Committee meeting at 10:30 a.m. Those unable to attend are encouraged to provide input via phone, email or fax to Amber Harbolt no later than Monday, July 30, 2018 at 9:00 a.m. Those submitting input via email or fax are encouraged to call to confirm receipt.

Input can be submitted via:

Phone:	(713) 572-3724
Email:	amber.harbolt@cjo.hctx.net
Fax:	(713) 572-3740

2018 QUARTERLY REPORT
COMPREHENSIVE HIV PLANNING COMMITTEE

Status of Committee Goals and Responsibilities (*means mandated by HRSA):

1. *Assess, evaluate, and make ongoing recommendations for the Comprehensive HIV Plan.

   Recommended **revision** from 2017 Committee: "Assess, evaluate, and make ongoing recommendations for the Comprehensive HIV Prevention and Care Services Plan **and corresponding areas of the End HIV Plan."**

2. *Determine the size and demographics of the estimated population of individuals who are unaware of their HIV status.

3. *Work with the community and other committees to develop a strategy for identifying those with HIV who do not know their status, make them aware of their status, and link and refer them into care.

4. *Explore and develop on-going needs assessment and comprehensive planning activities including the identification and prioritization of special studies.

5. *Review and disseminate the most current Joint Epidemiological Profile.

_____ _____

Committee Chairperson **Date**

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 021752/S-055

SUPPLEMENT APPROVAL

Gilead Sciences, Inc.
Attention: Kim Lindstrom, PhD
Associate Director, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Dr. Lindstrom:

Please refer to your Supplemental New Drug Application (sNDA) dated November 15, 2017, and received November 16, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TRUVADA® (emtricitabine and tenofovir disoproxil fumarate) tablets, 200/300 mg, 167/250 mg, 133/200 mg, and 100/150 mg.

We acknowledge receipt of your Risk Evaluation and Mitigation Strategy (REMS) assessment, received on November 16, 2017, and your amendments.

This efficacy supplement provides the following revisions to the labeling for Truvada® and proposes a Major Modification to the approved REMS:

- Expansion of the Pre-Exposure Prophylaxis (PrEP) indication to include adolescents weighing at least 35 kg who are at risk of HIV-1 acquisition.
- Updates to Section 8 of the U.S. Prescribing Information (PI) to align with the Pregnancy and Lactation Labeling Rule (PLLR).
- Revised REMS materials to reflect expansion of the patient population based on the proposed revision to the PrEP indication. The proposed REMS Major Modification includes the Single Shared System (SSS) REMS.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

WAIVER OF HIGHLIGHTS SECTION

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

3401-1 Collect prospective real-world data (e.g., registry, observational cohorts) from primary data sources to document new HIV-1 infections and the development of

any resistance to Truvada or generic emtricitabine/tenofovir disoproxil (gFTC/TDx) among adults and adolescents prescribed Truvada or gFTC/TDx for pre-exposure prophylaxis (PrEP). In addition, provide information on adherence, risk factors for non-adherence and HIV-1 acquisition, and monitoring practices in clinical practice for adults and adolescents prescribed Truvada or gFTC/TDx for PrEP.

The timetable you submitted on April 30, 2018, states that you will conduct this study according to the following schedule:

Draft Protocol Submission:	12/2018
Final Protocol Submission:	06/2019
Study/Trial Completion:	12/2022
Final Report Submission:	06/2023

Submit clinical protocols to your IND 108930 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to this postmarketing commitment should be prominently labeled **"Postmarketing Commitment Protocol," "Postmarketing Commitment Final Report," or "Postmarketing Commitment Correspondence."**

We remind you that there are postmarketing requirements and a postmarketing commitment listed in the July 16, 2012 approval letter that are still open.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for TRUVADA® (emtricitabine/tenofovir disoproxil fumarate) for a PrEP indication was originally approved on July 16, 2012, and the SSS REMS for emtricitabine/tenofovir disoproxil fumarate was approved on June 8, 2017. The REMS consists of elements to assure safe use (ETASU) and a timetable for submission of assessments of the REMS. Your proposed modification to the REMS consists of modifications to the SSS REMS materials to reflect expansion of the PrEP indication to include the adolescent patient population based on the revisions to the indication.

Your proposed modified REMS, submitted on November 16, 2017, amended and appended to this letter, is approved.

The timetable for submission of assessments of the REMS remains the same as that approved on June 8, 2017.

There are no changes to the REMS assessment plan described in our June 8, 2017 letter.

We remind you that in addition to the REMS assessments submitted according to the timetable in the approved REMS, you must include an adequate rationale to support a proposed REMS modification for the addition, modification, or removal of any goal or element of the REMS, as described in section 505-1(g)(4) of the FDCA.

We also remind you that you must submit a REMS assessment when you submit a supplemental application for a new indication for use, as described in section 505-1(g)(2)(A) of the FDCA. This assessment should include:

a) An evaluation of how the benefit-risk profile will or will not change with the new indication;
b) A determination of the implications of a change in the benefit-risk profile for the current REMS;
c) *If the new indication for use introduces unexpected risks*: A description of those risks and an evaluation of whether those risks can be appropriately managed with the currently approved REMS.
d) *If a REMS assessment was submitted in the 18 months prior to submission of the supplemental application for a new indication for use*: A statement about whether the REMS was meeting its goals at the time of that last assessment and if any modifications of the REMS have been proposed since that assessment.
e) *If a REMS assessment has not been submitted in the 18 months prior to submission of the supplemental application for a new indication for use:* Provision of as many of the currently listed assessment plan items as is feasible.
f) *If you propose a REMS modification based on a change in the benefit-risk profile or because of the new indication of use, submit an adequate rationale to support the modification, including*: Provision of the reason(s) why the proposed REMS modification is necessary, the potential effect on the serious risk(s) for which the REMS was required, on patient access to the drug, and/or on the burden on the health care delivery system; and other appropriate evidence or data to support the proposed change. Additionally, include any changes to the assessment plan necessary to assess the proposed modified REMS. *If you are not proposing REMS modifications*, provide a rationale for why the REMS does not need to be modified.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 021752 REMS ASSESSMENT METHODOLOGY

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

We remind you that section 505-1(f)(8) of FDCA prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval of an application under section 505(b)(2) or (j). A violation of this provision in 505-1(f) could result in enforcement action.

Prominently identify any submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 021752 REMS ASSESSMENT

or

NEW SUPPLEMENT FOR NDA 021752/S-000
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR NDA 021752/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR NDA 021752/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABEL CHANGES
SUBMITTED IN SUPPLEMENT XXX

or

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 021752/S-000
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

Should you choose to submit a REMS revision, prominently identify the submission containing the REMS revisions with the following wording in bold capital letters at the top of the first page of the submission:

REMS REVISIONS FOR NDA 021752

To facilitate review of your submission, we request that you submit your proposed modified REMS and other REMS-related materials in Microsoft Word format. If certain documents, such as enrollment forms, or website screenshots are only in PDF format, they may be submitted as such, but Word format is preferred.

SUBMISSION OF REMS DOCUMENT IN SPL FORMAT

FDA can accept the REMS document in Structured Product Labeling (SPL) format. If you intend to submit the REMS document in SPL format, as soon as possible, but no later than 14 days from the date of this letter, submit the REMS document in SPL format using the FDA automated drug registration and listing system (eLIST).

For more information on submitting REMS in SPL format, please email REMS_Website@fda.hhs.gov.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Alicia Moruf, PharmD, MPH, Regulatory Project Manager, at (301) 796-3953.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director
Division of Antiviral Products
Office of Drug Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
REMS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DEBRA B BIRNKRANT
05/15/2018

Understanding the HIV Care Continuum

Overview

Recent scientific advances have shown that antiretroviral therapy (ART) not only preserves the health, quality of life, and life expectancy of people living with HIV, but people living with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load have effectively no risk of transmitting HIV to their HIV-negative sexual partners.

These developments have transformed the nation's approach to HIV prevention. By ensuring that everyone with HIV is aware of their infection, receives the treatment they need, and achieves sustained viral suppression, we can sharply reduce new infections in the United States.

This vision is a core focus of CDC's high-impact HIV prevention strategy, which aims to achieve the greatest possible reductions in HIV infections by making sure that resources go to the regions, populations, and prevention strategies where they will have the greatest impact.

To help gauge progress towards national goals (see sidebar) and direct HIV prevention resources most effectively, CDC tracks the "HIV care continuum." The continuum is the series of steps from the time a person receives a diagnosis of HIV through the successful treatment of their infection with HIV medications. This fact sheet explains the various approaches and data used to develop the HIV care continuum, how it is used to improve outcomes for people living with HIV in the United States, and how it helps guide the nation's response to HIV.

National HIV Prevention Objectives on HIV Diagnosis and Care

At the national level several specific goals related to early HIV diagnosis and effective care include:

- 90% — Increasing the proportion of HIV-positive **individuals aware of their status** to 90%.
- 85% — Increasing the proportion of **persons with newly diagnosed HIV who are linked to care** within one month to 85%.
- 80% — Increasing the proportion **of HIV-diagnosed individuals whose virus is effectively suppressed to 80%,** with an emphasis youth and persons who inject drugs.

What is the HIV Care Continuum?

The ultimate goal of HIV treatment is to achieve viral suppression, which means the amount of HIV in the body is very low or undetectable. This is important for people with HIV to stay healthy, have improved quality of life, and live longer. People living with HIV who maintain viral suppression have effectively no risk of passing HIV to others.

The HIV care continuum consists of several steps required to achieve viral suppression. Specifically, CDC tracks:

Diagnosed

receives a diagnosis of HIV

Linked to care*

visited a heath care provider within 30 days after HIV diagnosis

Received or were retained in care*

received medical care for HIV infection once or continuously

Viral suppression

amount of HIV in the blood was at a very low level.

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Division of HIV/AIDS Prevention

*Linked to care is calculated differently from other steps in the continuum, and cannot be directly compared to other steps. See Table 1 on page 5 for details.** Note. Receipt of medical care was defined as ≥1 test (CD4 or VL) in 2015. Retained in continuous medical care was defined as ≥2 tests (CD4 or VL) ≥3 months apart in 2015. Viral suppression was defined as <200 copies/mL on the most recent VL test in 2015. See Table 1 on page 5 for details.

Two Ways to Monitor the Continuum

CDC currently uses two different approaches to monitor the HIV care continuum. The two approaches are used for different purposes, and both are essential to monitor the nation's progress and identify key HIV prevention and care needs.

The major difference between the two approaches is that they have **different denominators.** That is, they measure progress among different groups of people living with HIV:

The prevalence-based HIV care continuum describes the number of people who are at each step of the continuum as a percentage of the ***total* number of people living with HIV** (known as HIV prevalence). Prevalence includes both people whose infection has been diagnosed and those who are infected but don't know it.

This approach allows us to monitor elements of the care continuum by measuring the care outcomes among all Americans living with HIV. It can also monitor outcomes for broad populations, such as African Americans or men who have sex with men (MSM). However, because of certain statistical limitations, this approach does not allow more segmented analyses within those populations, such as young black MSM. See Figure 1 for the 2015 Prevalence-based HIV Care Continuum.

The diagnosis-based HIV care continuum shows each step as a percentage of **the number of people living with diagnosed HIV.**

This approach gives us more detailed information about persons who are living with diagnosed HIV and provides a way to look at the continuum within subgroups of affected populations, for example young black MSM. For the 2015 diagnosis-based continuum, see Figure 2.

The difference is in the denominators • All people living with HIV (includes persons with diagnosed and undiagnosed infection) is used as the denominator for the prevalence-based continuum. People living with ***diagnosed*** HIV is the denominator used for the diagnosis-based continuum.

Figure 1: Prevalence-based HIV Care Continuum, 2015

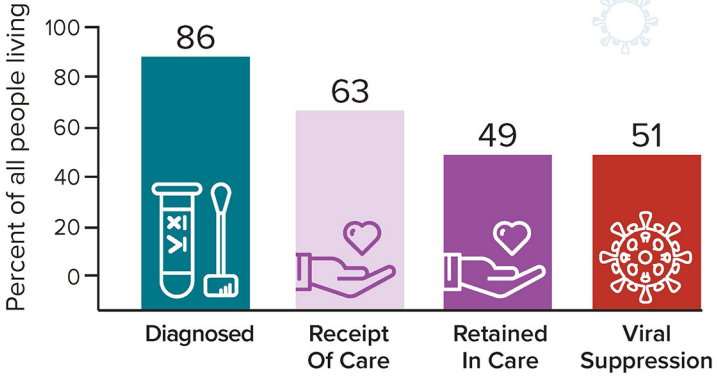
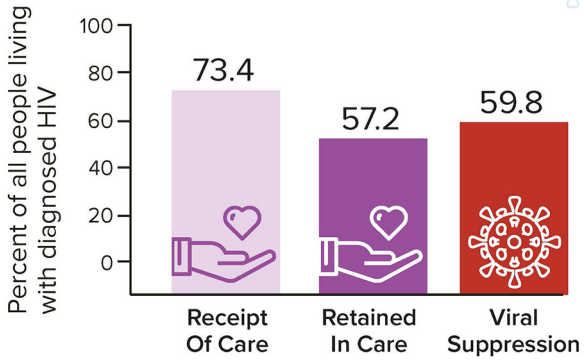
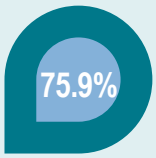


Figure 2: Diagnosis-based HIV Care Continuum, 2015



Linked to Care

- In 2016, 75.9% of persons receiving a diagnosis of HIV were linked to care within 1 month.
- Defined as linked to care within 1 month of HIV diagnosis.



- Denominator is persons receiving a diagnosis of HIV in a measurement year; numerator is the number of persons who were linked to care within 1 month of HIV diagnosis.
- Because it has a different denominator, it cannot be directly compared to other steps.

See Table 1 on page 4 for additional details

Different Approaches for Different Needs

CDC's current approaches draw on the best data available.

It is **important to know how the continuum will be used.** Some uses of the **prevalence-based continuum** include:

- Monitoring testing efforts in the U.S. and demonstrating the importance of diagnosing HIV infections to achieve viral suppression.
- Monitoring how the U.S. is doing among **all** persons living with HIV
- Comparing U.S. data to other countries who monitor the continuum among all persons living with HIV

Some uses of the **diagnosis-based continuum** include:

- Monitoring U.S. progress in comparison to national level 2020 goals
- Monitoring U.S. progress in comparison to the UNAIDS 90-90-90 goals
- Monitoring disparities by examining data among sub-groups of the population
- Monitoring data at a local level to understand local progress and identify additional action steps to meet national level goals

Ways of presenting the continuum will also continue to evolve over time, as better and more complete data become available.

How CDC Develops the Continuum

The data for both the prevalence- and diagnosis-based continua of care approaches come from **The National HIV Surveillance System (NHSS),** which provides a range of information on people who have diagnosed HIV or have died with HIV. Data are from every U.S. state and territory and the District of Columbia and include race/ethnicity, route of transmission, and age. The data are reported to CDC by state and local health departments. This is the source of data for both the prevalence and diagnosis denominators. Data from the states and D.C. that have complete laboratory reporting are used to calculate some measures of the continuum.

For more information, details on the two continuum approaches are found in Table 1 below. Some of these indicators are also used to monitor progress toward the national goals. For more information on national indicators, please see [insert link to Fact Sheet on Selected National HIV Prevention and Care Outcomes].

What is CDC doing to improve the outcomes at every step of the HIV Care Continuum?

CDC is undertaking many initiatives including:

- **Directly funding health departments to implement a comprehensive HIV surveillance and prevention program** – to prevent new HIV infections and achieve viral suppression among persons living with HIV. The integrated approach promotes and supports improving health outcomes for persons living with HIV through achieving and sustaining viral suppression, and reducing health-related disparities by using quality, timely, and complete surveillance and program data to guide HIV prevention efforts. Priority activities include HIV testing; linkage to, re-engagement in, and retention in care and support for achieving viral suppression; support for pre-exposure prophylaxis (PrEP); community-level HIV prevention activities; and HIV transmission cluster investigations and outbreak response efforts.
- **Directly funding community-based organizations (CBOs)** – to increase HIV testing, improve linkages to care and support improvement of viral suppression for persons living with HIV, and improve linkages to PrEP and other prevention services for persons who are at risk for HIV.
- **Providing technical assistance** – to help health departments and CBOs develop the tools and skills to successfully implement effective HIV prevention activities for people living with HIV in their communities.
- **Improving surveillance capability and technology –** to assist states in outbreak response and improving completeness of laboratory data that are needed to assess many of the steps in the HIV care continuum and the selected national HIV care outcomes.
- **Researching new approaches** – to include studies of clinical, behavioral and structural interventions to help people with HIV stay in care, get back in care if they fall out of care, and adhere to their medications.
- **Developing guidelines** – to assist health care providers with HIV testing, care, treatment, and prevention.
- **Launching educational campaigns and a HIV Risk Reduction Tool** – to help health care providers integrate simple prevention approaches into routine care for people living with HIV and to help all audiences understand risks for HIV and the benefits of HIV testing.

Table 1: Calculating the Continuum: Step by Step

Continuum Step	
Diagnosed	Measures the percentage of the total number of people living with HIV whose infection has been diagnosed. The denominator for this continuum step is HIV prevalence, which is the total number of people living with HIV (includes both those with diagnosed infection and those with undiagnosed infection). HIV prevalence is estimated through statistical modeling using NHSS data from all U.S. states and the District of Columbia.
Receipt of Care	NHSS data from states and DC with complete reporting of CD4 and viral load test results are used to estimate "receipt of care" and "retained in care." Receipt of care is measured as the percentage of persons with diagnosed HIV who had at least 1 CD4+ or viral load test. The denominator for the prevalence-based continuum is all persons living with HIV (HIV prevalence) The denominator for the diagnosis-based continuum is all persons living with diagnosed HIV (diagnosed prevalence*).
Retained in Care	NHSS data from states and DC with complete reporting of CD4 and viral load test results are used to estimate "receipt of care" and "retained in care." Retained in care is measured as the percentage of persons with diagnosed HIV who had two or more viral load or CD4+ tests, performed at least three months apart. The denominator for the prevalence-based continuum is all persons living with HIV (HIV prevalence). The denominator for the diagnosis-based continuum is all persons living with diagnosed HIV (diagnosed prevalence*).
Viral Suppression	NHSS data from states and D.C. that have complete laboratory reporting are used to determine viral suppression. Viral suppression is measured as a viral load test result of <200 copies/mL at the most recent viral load test during measurement year.
Linked to Care	NHSS data from states and DC with complete reporting of CD4 and viral load test results are used to determine "linked to care." Linked to care measures the percentage of people receiving a diagnosis of HIV in a given calendar year who had one or more documented viral load or CD4+ test within 30 days (1 month) of diagnosis. Because this measure is limited to people with HIV diagnosed in a single year only, it cannot be directly compared to other steps in the continuum. This means that the denominator for linkage to care is different from the denominators used to calculate the other steps in the continuum. It is also important to note that an individual who enters care more than 30 days after diagnosis may still be included in subsequent steps of the continuum, but would not be counted as "linked to care."

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*Diagnosed prevalence is defined as the number of persons with HIV diagnosed through the end of 1 year and are living through the end of the next year (e.g. diagnosed prevalence for 2015 is defined as persons receiving a diagnosis of HIV by end of 2014 and living through the end of 2015).