



Setting up a PrEP Clinic: the ABC's of Integrating PrEP into Clinical and Other Settings

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CONFLICT OF INTEREST DISCLOSURE

Alex Gonzalez, MD MPH has no real or apparent conflicts of interest to report.

OBJECTIVES

- Present varying models of PrEP integration
- Describe the Fenway Health Model of Care
- Summarize Fenway Health's PrEP experience thus far
- Review some interesting cases

MODELS OF PREP INTEGRATION

Examples		
Municipal STI Clinics (RISK PREVALENCE)	San Francisco City Clinic PrEP Demo Project	Miami-Dade County Health Department PrEP Demo Project
Primary Care/Self Referral to ID Specialist (CLINICAL EXPERTISE)	Kaiser Permanente (San Francisco)	Froedtert Hospital / Medical College of Wisconsin (Milwaukee)
Primary Care (CARE INFRASTRUCTURE)	Whitman-Walker Health Center (DC)	Fenway Health (Boston)

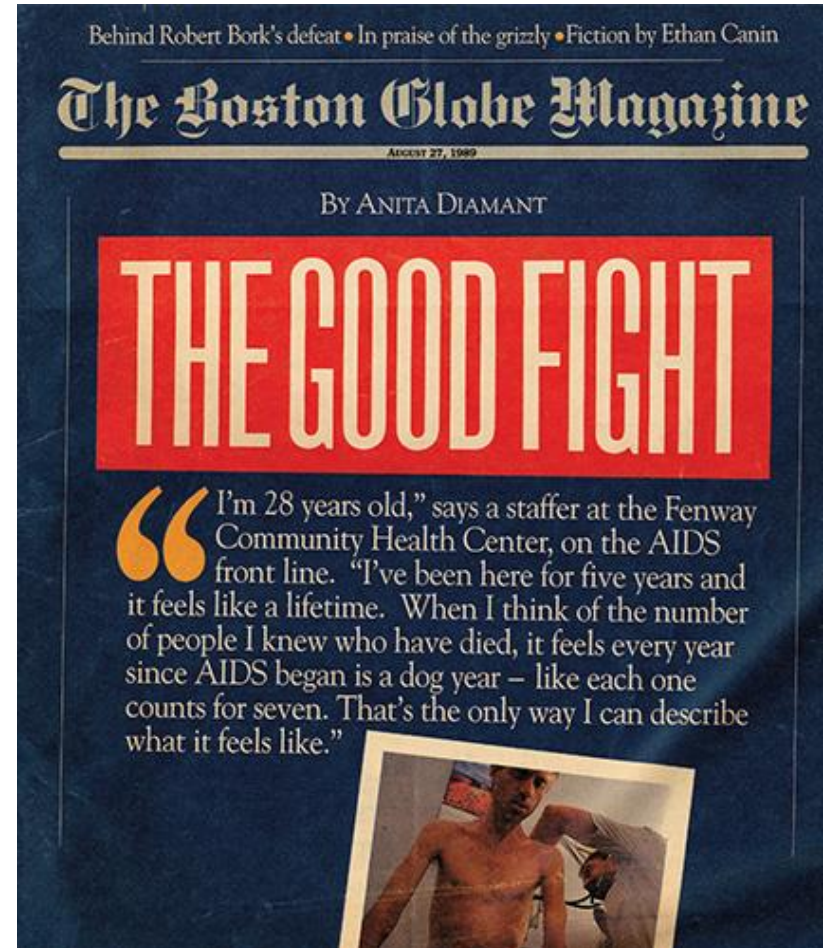
ABOUT FENWAY HEALTH

- Federally qualified health center
- Established 1971
- 3 clinic sites in Boston
- 25,000 patients
 - 12,500 (50%) LGBT
 - 2200 (9%) PLWHA
 - 1800 (7%) Trans*
 - 1477 (6%) PrEP



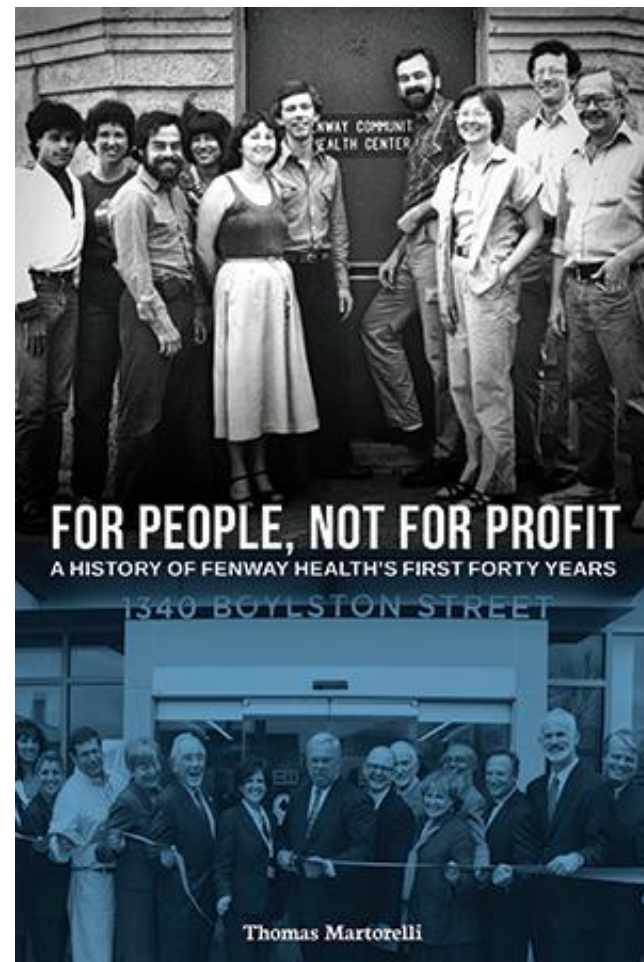
ABOUT FENWAY HEALTH

- NCQA Level 3 Patient Centered Medical Home since 2013
- 35 Primary Care Providers (MD/DO, NP/PA)



ABOUT FENWAY HEALTH

- Medical
- Behavioral Health
- Optometry
- Dentistry
- Radiology
- Lab
- Pharmacy
- The Fenway Institute
- AIDS Action Committee



ABOUT FENWAY HEALTH

Team Based Care

- PCP: physician, NP, PA
- Team Nurse (RN)
- Team Medical Assistant (MA)
- Team Behavioral Health Specialist (LICSW)
- Team Case Manager (BSW)
- Team Patient Services Representative



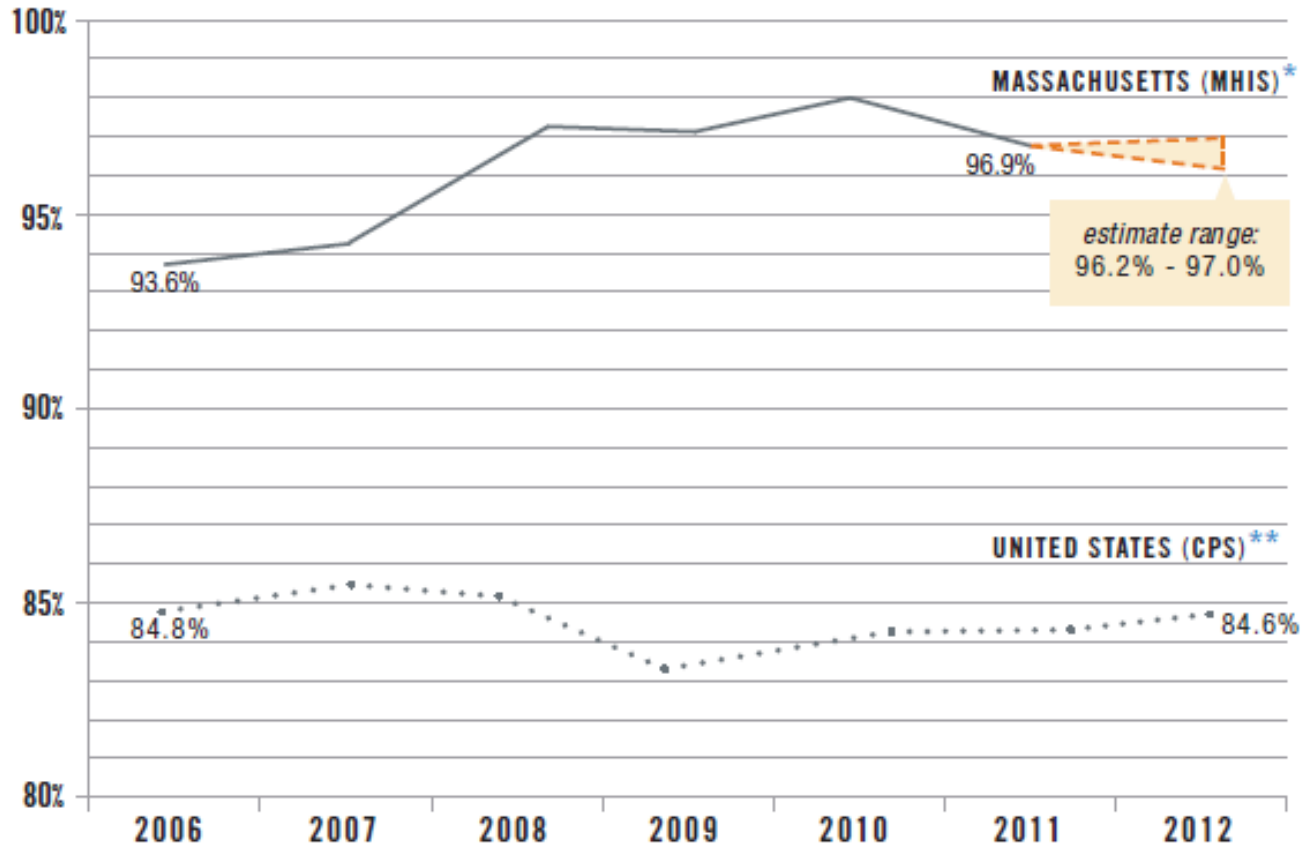
ABOUT FENWAY HEALTH

Fenway Institute Prevention Team

- DPH funded
- 15 people across three agencies (Fenway Health, AIDS Action, Multicultural AIDS Coalition) help expand our clinic's footprint
 - Health navigation
 - HIV and STD screening
 - Risk reduction counseling
 - Linkage to care
 - Life Coaching



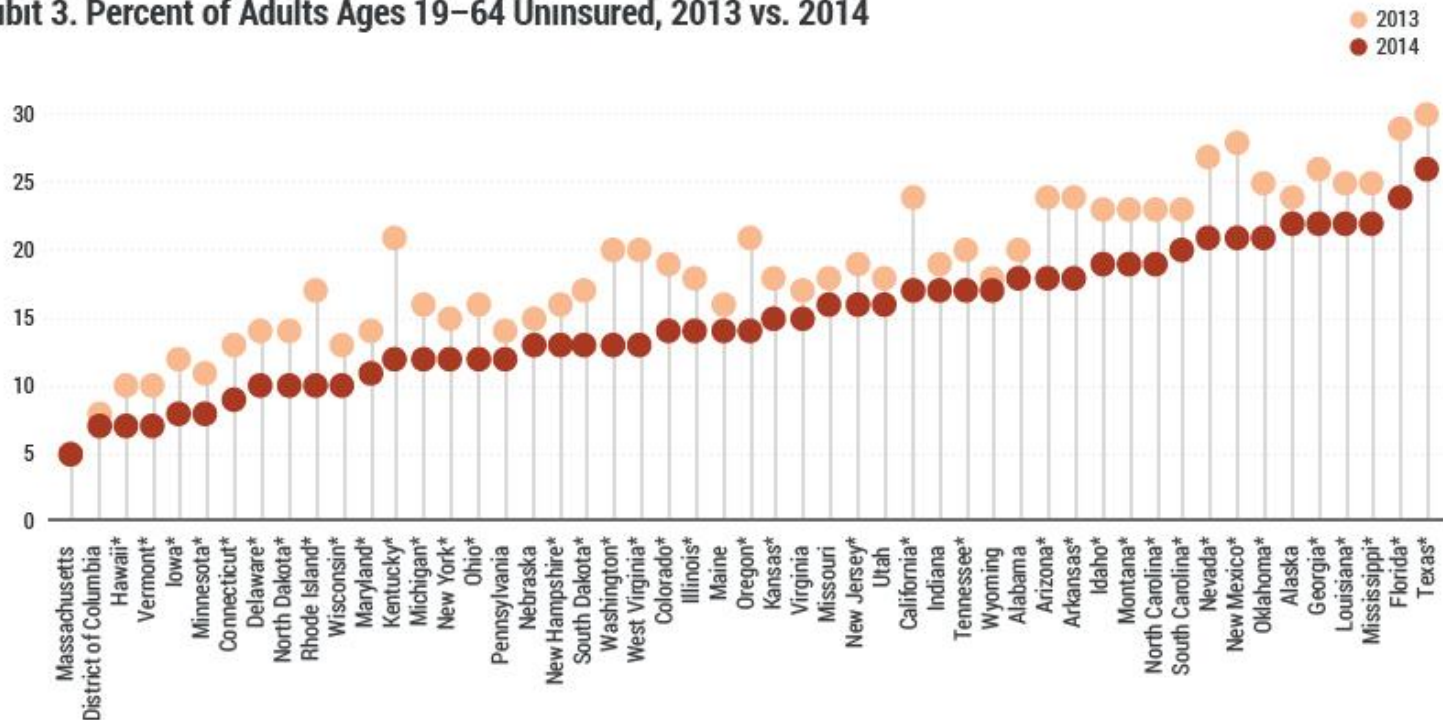
ABOUT MASSACHUSETTS



Source: Center for Health Information and Analysis, Massachusetts Health Insurance Coverage, 2012 Estimate (Dec. 2, 2013)

ABOUT MASSACHUSETTS

Exhibit 3. Percent of Adults Ages 19–64 Uninsured, 2013 vs. 2014



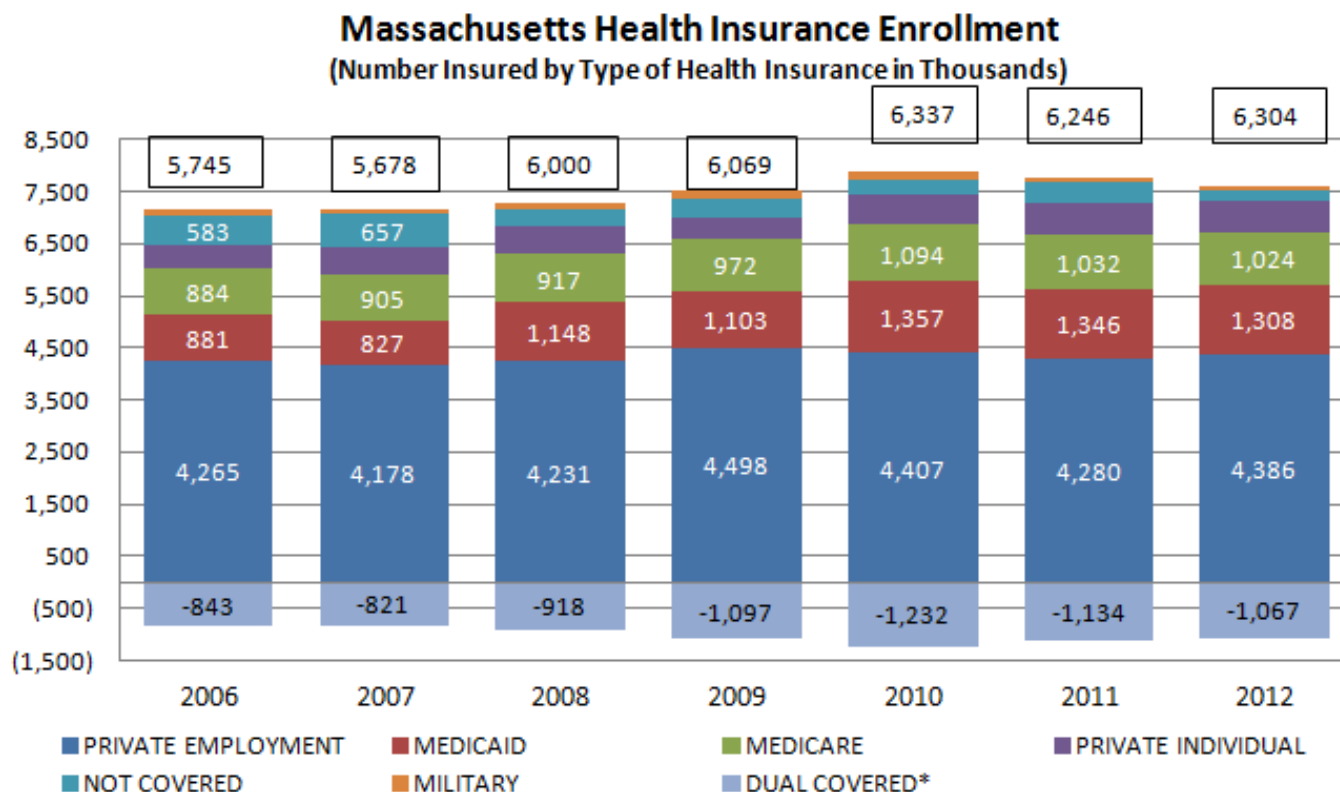
Note: States are arranged in rank order based on their current data year (2014) value.

* Denotes states with at least -.5 standard deviation change (3 percentage point decline) between 2013 and 2014.

Data source: U.S. Census Bureau, 2013 and 2014 1-Year American Community Surveys, Public Use Microdata Sample (PUMS).

Source: Commonwealth Fund, The Changing Landscape of Health Care Coverage and Access: Comparing States' Progress in the ACA's First Year (Dec. 9, 2015)

ABOUT MASSACHUSETTS

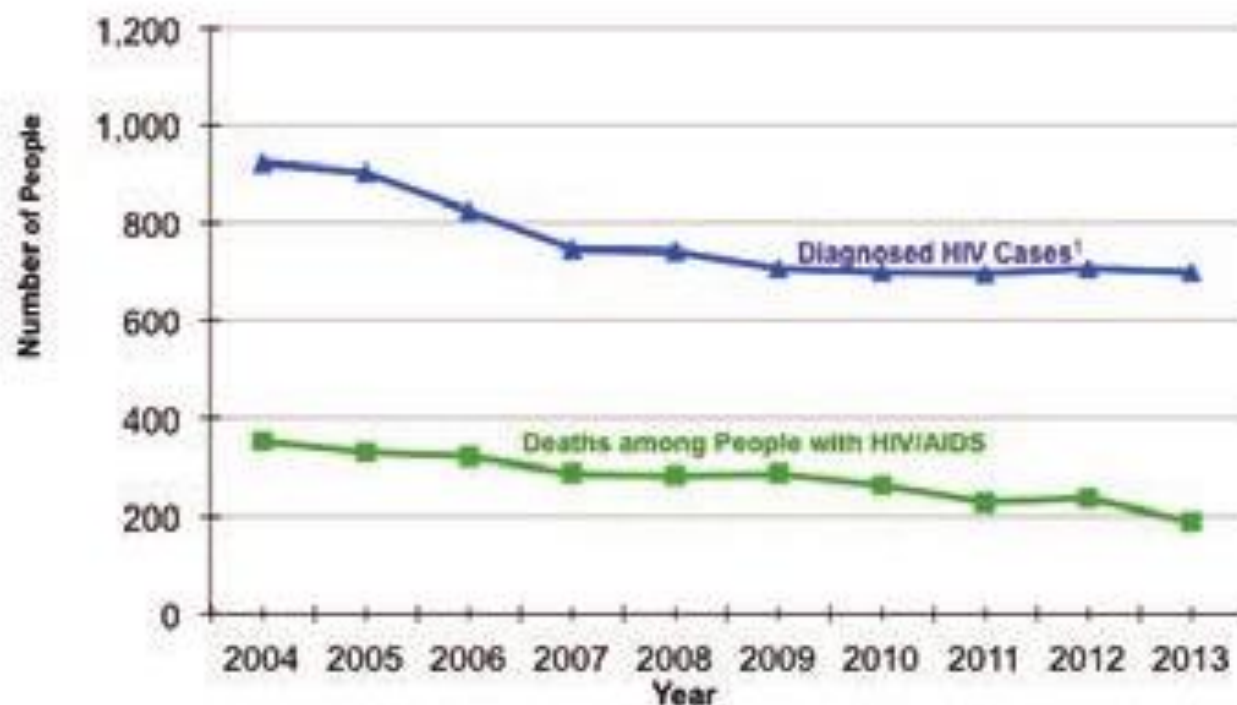


*Dual Covered means enrollee is double counted in other categories, i.e. Medicare/Medicaid; Medicare/Private; Medicaid/Private; Military/Private

Source: U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplement, Data available in MFA's Health Coverage Portal™

ABOUT MASSACHUSETTS

Trends in the Number of HIV Infection Diagnoses and Deaths among People with HIV/AIDS, Massachusetts, 2004–2013

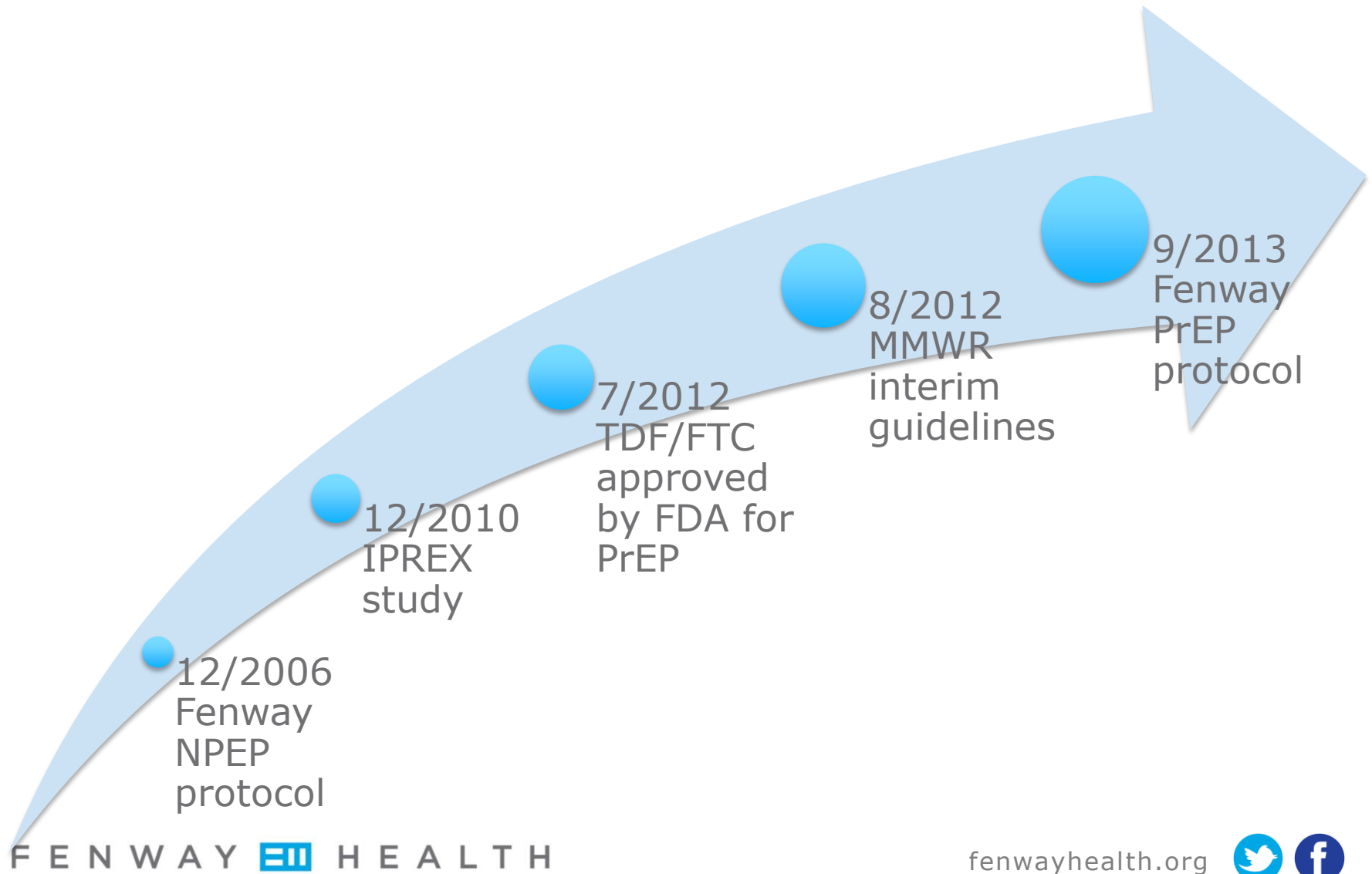


Diagnosed HIV Cases N=7,646; Deaths among people with HIV/AIDS N=2,785

¹ Includes people concurrently or subsequently diagnosed with AIDS

Data Source: MDPH, Bureau of Infectious Disease, data are current as of 1/1/15 and subject to change

FENWAY TIMELINE



FENWAY PREP PROTOCOL – RISK ASSESSMENT

Visit Information	Behaviors	STD & Testing History	Tests Ordered	Education & Referrals
VI. RISK FACTORS				
In the last 12 months, has the patient...				
1. Had vaginal or anal sex with male partner(s)?		<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Doesn't know <input type="radio"/> Didn't ask
<hr/>				
4. Had vaginal or anal sex with female partner(s)?		<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Doesn't know <input type="radio"/> Didn't ask
<hr/>				
7. Has the patient had sex with transgender partner(s)?		<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Doesn't know <input type="radio"/> Didn't ask
<hr/>				
10. How many different people has the patient had sex with in the past 12 months?		<input type="text"/>		
11. How many different people has the patient had sex with in the past 3 months?		<input type="text"/>		

FENWAY PREP PROTOCOL – RISK ASSESSMENT

FEMALE ONLY

12. Has the patient had vaginal or anal sex with male partner(s) who has sex with other men? ☐ Yes ☐ No ☐ Doesn't know ☐ Didn't ask
13. Has the patient had vaginal or anal sex with transgender partner(s) who has sex with other men? ☐ Yes ☐ No ☐ Doesn't know ☐ Didn't ask

14. If no risk factors noted below, why not?

15. Was a risk reduction plan developed during this visit?

What type of sex does the patient engage in?

What % of the time is barrier used?

16. Oral Sex (Insertive) ☐ Yes ☐ No
17. Oral Sex (Receptive) ☐ Yes ☐ No
18. Vaginal Sex (Penis, fingers, toys) ☐ Yes ☐ No
19. Anal Sex (Insertive) ☐ Yes ☐ No
20. Anal Sex (Receptive) ☐ Yes ☐ No

VII. ADDITIONAL RISK FACTORS (FROM DPH CTR FORM)

In the past 12 months, has the patient engaged in the following risk behaviors?

1. Vaginal or anal sex with multiple partners ☐ Yes ☐ No
2. Vaginal or anal sex in exchange for drugs/money/a place to stay/something else the client needed ☐ Yes ☐ No
3. Vaginal or anal sex with a person who exchanges drugs/money/a place to stay/something else the sex partner needed ☐ Yes ☐ No
4. Vaginal or anal sex while intoxicated and/or high on drugs ☐ Yes ☐ No
5. Vaginal or anal sex with a person of unknown HIV status ☐ Yes ☐ No
6. Vaginal or anal sex with an anonymous partner ☐ Yes ☐ No

7. Has the patient ever had sex in another country? ☐ Yes ☐ No
8. Has the patient traveled out of state in the LAST 2 MONTHS? ☐ Yes ☐ No
9. Has the patient been incarcerated in the LAST 6 MONTHS? ☐ Yes ☐ No

FENWAY PREP PROTOCOL – RISK ASSESSMENT

Has the patient engaged in the following substance use risk behaviors before or during sex in the past 12 months

10. Patient reports alcohol use?

☐ Yes

☐ No

11. Patient reports drug use?

☐ Yes

☐ No

Has the patient engaged in the following injection drug use risk behaviors?

12. EVER used injection drugs?

☐ Yes

☐ No

☐ Doesn't know

☐ Didn't ask

FENWAY PREP PROTOCOL – RISK ASSESSMENT

VIII. STD DIAGNOSIS HISTORY

☐ No history of STI testing

☐ No history of HIV testing

☐ No history of HCV testing

In the last 12 months, was the patient diagnosed with a STD? (Check all that apply)

☐ Chlamydia

☐ Gonorrhea

☐ Syphilis

☐ Not applicable-not diagnosed

IX. VACCINATION HISTORY

1. Patient reports vaccination for Hepatitis A

2. Patient reports vaccination for Hepatitis B

3. Patient reports vaccination for HPV? ☐ Yes ☐ No ☐ Doesn't know ☐ Didn't ask

X. STD TESTING HISTORY

Patient reported the following tests on date completed below:

Test Type	Tested?	Site	Date	Outcome	Treated?
1. HIV	<input type="checkbox"/>				
2. Gonorrhea	<input type="checkbox"/>				
3. Chlamydia	<input type="checkbox"/>				
4. Syphilis	<input type="checkbox"/>				
5. Hepatitis A	<input type="checkbox"/>				
6. Hepatitis B	<input type="checkbox"/>				
7. Hepatitis C	<input type="checkbox"/>				
8. NGU/NSU	<input type="checkbox"/>				
9. HSV - Type 1	<input type="checkbox"/>				
10. HSV - Type 2	<input type="checkbox"/>				
11. Trichomoniasis	<input type="checkbox"/>				
12. Other	<input type="checkbox"/>				

FENWAY PREP PROTOCOL – RISK ASSESSMENT

XIII. EDUCATION

1. Education:

- ☐ PEP education
- ☐ PrEP education
- ☐ Counseled client on reducing number of partners

2. Supported Referrals:

- ☐ Drug/alcohol treatment
- ☐ Overdose Education and Naloxone distribution
- ☐ Needle exchange/syringe services programming
- ☐ Pre-exposure prophylaxis (PrEP)
- ☐ Post-exposure prophylaxis (PEP)
- ☐ Peer support (individual)
- ☐ Peer support (group)
- ☐ Health insurance enrollment
- ☐ Mental health treatment program
- ☐ Housing search and advocacy
- ☐ Legal services
- ☐ Partner services (DIS)
- ☐ Group-level evidence-based intervention (e.g. 3mv; WILLOW; Healthy Relationships)
- ☐ Couples HIV/STI testing and counseling provided
- ☐ Personal Cognitive Counseling (PCC)
- ☐ ARTAS intervention provided
- ☐ Vein and wound care
- ☐ Navigated PrEP initiation or adherence
- ☐ Two-session risk reduction counseling
- ☐ Oriented to Every Dose Every Day app

Additional referral/recommendation notes:

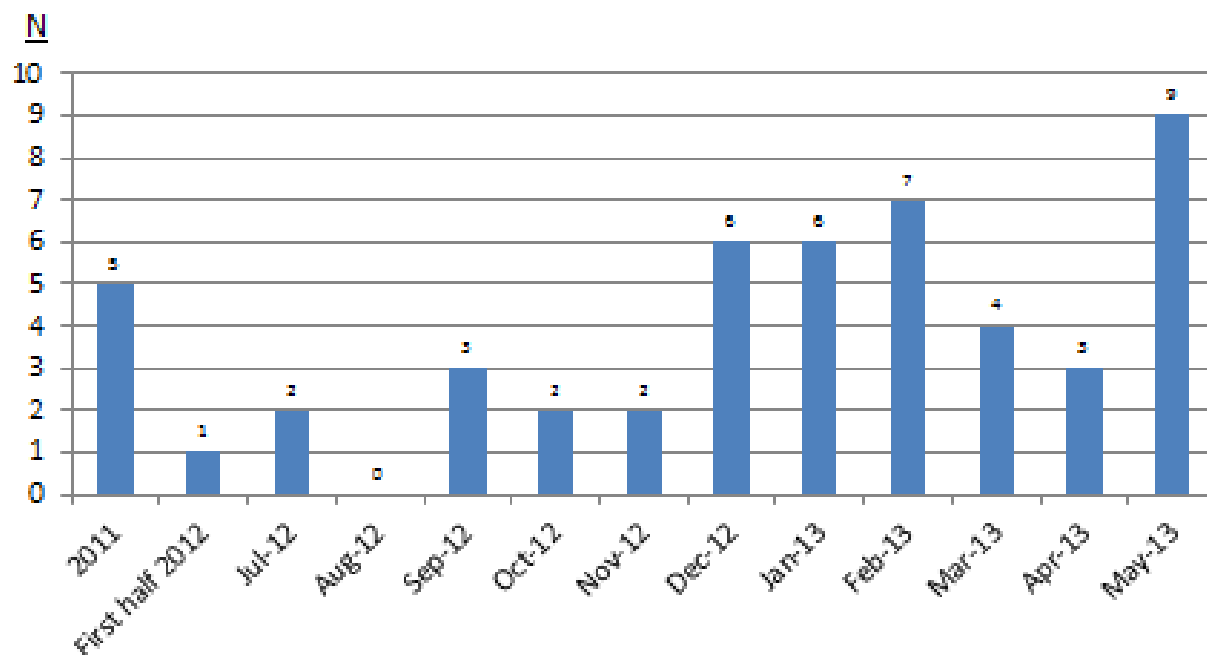
FENWAY PREP PROTOCOL – INITIATION AND MONITORING

1. HIV Testing: at onset and q2-3 months; (VL vs. 4th Gen)
2. STI Testing: including HBV screen with vaccination if needed
3. Safety Labs: at onset and q3 months; include uHCG testing
4. Informed Verbal Consent
 - a) Common vs. serious side effects
 - b) Risk of HIV, STI, pregnancy
 - c) Potential interactions: drug-drug, drug-disease
 - d) Risk of acute seroconversion reaction
5. Counseling
 - a) Drug and alcohol use
 - b) Adherence
 - c) HIV prevention: counseling/testing, risk reduction, condom education, STI counseling
6. Reassessment: discontinue upon abatement of risk

THE FENWAY EXPERIENCE 2012-2013

Non Trial PrEP Use at Fenway Health

Dates of Initiation (N=50)



Source: Dr. Ken Mayer, The Fenway Institute

THE FENWAY EXPERIENCE 2012-2015

- Approximately 600 different patients were prescribed PrEP
- Demographic characteristics
 - 95% cis male
 - 3% trans* female
 - 78% white
 - 12% nonwhite (7% black)
 - 12% Hispanic

Source: Dr. Ken Mayer and Dr. Doug Krakower, The Fenway Institute

THE FENWAY EXPERIENCE 2012-2015

Behavioral characteristics

- >95% MSM
- 87% single or in nonmonogamous relationship at initiation of PrEP
- 77% none or inconsistent condom use with casual partner
- 24% had used NPEP prior to PrEP initiation

Source: Dr. Ken Mayer and Dr. Doug Krakower, The Fenway Institute

THE FENWAY EXPERIENCE 2012-2015

Persistence vs. Discontinuation

- 58% had 0 discontinuation episodes
- 42% discontinued PrEP at least once
 - Main reason for discontinuation was decrease in risk
- 8% delayed PrEP initiation
- 3% never initiated PrEP

Source: Dr. Ken Mayer and Dr. Doug Krakower, The Fenway Institute

THE FENWAY EXPERIENCE 2012-2015

Monitoring

- HIV Testing
 - 91% with 1+ post-PrEP HIV test
 - Median time to post-PrEP HIV test = 2.86 months
 - HIV test frequency median = q5.5 months
- STI Testing
 - 35.9% with any STI while on PrEP
 - STD lab frequency median = q4.5 months
- Safety Lab Testing
 - Safety lab frequency (Cr) median = q4.74 months

Source: Dr. Ken Mayer and Dr. Doug Krakower, The Fenway Institute

THE FENWAY EXPERIENCE 2016

- New PrEP starts 3/2016: 117
- New PrEP starts 4/2016: 123
- Total Patients on PrEP since 1/2016:
>1000
- Number of seroconversions among PrEP initiates:

CASE 1: DONALD T.

DONALD T.

- 24M - Initial visit to clinic
- Linkage: from Fenway Institute study
- CC: "I want to start PrEP" + Annual Physical
- Risk Assessment:
 - MSM
 - intermittent condom use for anal sex
 - AUDIT-C positive

DONALD T.

- Exam: no abnormal findings
- Labs: WNL except for negative HBV and HAV serologies
- Plan:
 - Start TDF/FTC 1 tab PO daily
 - HAV/HBV#1
 - Handoff to BHS for S-**BIRT** re:ETOH
 - Referral to Team Case Manager for help with Copay Assistance Application

DONALD T.

- Follow-Up
 - with provider in 3 months for 20 min.
 - with nurse in 1 month for HAV/HBV#2
- Coding
 - Insurance: Commercial
 - New or Established patient?
 - Preventive or Problem Based Visit or Both?
 - Significant/Separate Evals?
 - Anything else you did today?

DONALD T.

- Coding
 - CPT 99385 linked to
 1. ICD10 Z00.00: *Encounter for general adult medical examination without abnormal findings*
 2. ICD10 Z72.52: *High risk homosexual behavior*
 - CPT 90471 linked to
 1. Z23: *Encounter for immunization*
 - CPT 99420-25 linked to
 1. F10.10: *Alcohol abuse, uncomplicated*

CASE 2: HILLARY C.

HILLARY C.

- 38 trans* F - Subsequent visit to clinic
- Linkage: DPH funded Vaccination Clinic, Established Primary Care x 9 years
- CC: hormone f/u + penile lesion + interest in PrEP since she is restarting escorting
- Risk Assessment:
 - MtFSM
 - Primary partner – Inconsistent condom use
 - Sex work- Always uses condoms

HILLARY C.

- Exam: WNL except for skin tag on base of penis
- Labs: WNL except for...
 - Total testosterone = 369ng/dL (15-70)
 - Note: 4th Gen HIV test had been negative 3 weeks prior and pt has had no sexual activity since >2 weeks before that

HILLARY C.

- Plan
 - Start TDF/FTC 1 tab PO daily
 - Continue estradiol + spiro at current dosing; confirm pt OK with this
 - Reassurance re: skin tag
 - Inform pt of support group for cisgender partners of transgender people
- Follow-Up
 - With provider in 3 months for 20 min.

HILLARY C.

- Coding
 - Insurance: Medicaid MCO
 - New or Established patient?
 - Preventive or Problem Based Visit or Both?
 - Significant/Separate Evals?
 - Anything else you did today?

HILLARY C.

- Coding
 - CPT 99214 linked to
 1. E34.9: *Endocrine disorder, unspecified*
 2. N50.9: *Disorder of male genital organs, unspecified*
 3. Z72.51: *High risk heterosexual behavior*

PREVENTIVE COUNSELING CPT CODES

- 99401: 15 minutes
- 99402: 30 minutes
- 99403: 45 minutes
- 99404: 60 minutes

ACKNOWLEDGEMENTS

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QUESTIONS?

