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

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11th International Conference on HIV Treatment and Prevention Adherence
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

<table>
<thead>
<tr>
<th>Municipal STI Clinics (RISK PREVALENCE)</th>
<th>San Francisco City Clinic PrEP Demo Project</th>
<th>Miami-Dade County Health Department PrEP Demo Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Care/Self Referral to ID Specialist (CLINICAL EXPERTISE)</td>
<td>Kaiser Permanente (San Francisco)</td>
<td>Froedtert Hospital / Medical College of Wisconsin (Milwaukee)</td>
</tr>
<tr>
<td>Primary Care (CARE INFRASTRUCTURE)</td>
<td>Whitman-Walker Health Center (DC)</td>
<td>Fenway Health (Boston)</td>
</tr>
</tbody>
</table>
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
  o Health navigation
  o HIV and STD screening
  o Risk reduction counseling
  o Linkage to care
  o Life Coaching
ABOUT MASSACHUSETTS

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

fenwayhealth.org
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).

ABOUT MASSACHUSETTS

Massachusetts Health Insurance Enrollment
(Number Insured by Type of Health Insurance in Thousands)

- **2006:**
  - **PRIVATE EMPLOYMENT:** 4,265
  - **MEDICAID:** 583
  - **MEDICARE:** 881
  - **PRIVATE INDIVIDUAL:** -843
  - **DUAL COVERED:** -821
  - **NOT COVERED:** -918
  - **MILITARY:** -1,097
  - **TOTAL:** 3,468

- **2007:**
  - **PRIVATE EMPLOYMENT:** 4,178
  - **MEDICAID:** 657
  - **MEDICARE:** 905
  - **PRIVATE INDIVIDUAL:** -821
  - **DUAL COVERED:** -918
  - **NOT COVERED:** -1,097
  - **MILITARY:** -1,357
  - **TOTAL:** 3,287

- **2008:**
  - **PRIVATE EMPLOYMENT:** 4,231
  - **MEDICAID:** 917
  - **MEDICARE:** 1,148
  - **PRIVATE INDIVIDUAL:** -918
  - **DUAL COVERED:** -1,097
  - **NOT COVERED:** -1,357
  - **MILITARY:** -1,308
  - **TOTAL:** 3,158

- **2009:**
  - **PRIVATE EMPLOYMENT:** 4,498
  - **MEDICAID:** 1,094
  - **MEDICARE:** 1,103
  - **PRIVATE INDIVIDUAL:** -1,097
  - **DUAL COVERED:** -1,232
  - **NOT COVERED:** -1,308
  - **MILITARY:** -1,134
  - **TOTAL:** 2,933

- **2010:**
  - **PRIVATE EMPLOYMENT:** 4,407
  - **MEDICAID:** 1,032
  - **MEDICARE:** 1,346
  - **PRIVATE INDIVIDUAL:** -1,097
  - **DUAL COVERED:** -1,134
  - **NOT COVERED:** -1,067
  - **MILITARY:** -1,134
  - **TOTAL:** 2,853

- **2011:**
  - **PRIVATE EMPLOYMENT:** 4,280
  - **MEDICAID:** 1,024
  - **MEDICARE:** 1,346
  - **PRIVATE INDIVIDUAL:** -1,097
  - **DUAL COVERED:** -1,134
  - **NOT COVERED:** -1,067
  - **MILITARY:** -1,134
  - **TOTAL:** 2,839

- **2012:**
  - **PRIVATE EMPLOYMENT:** 4,386
  - **MEDICAID:** 1,024
  - **MEDICARE:** 1,308
  - **PRIVATE INDIVIDUAL:** -1,097
  - **DUAL COVERED:** -1,134
  - **NOT COVERED:** -1,067
  - **MILITARY:** -1,134
  - **TOTAL:** 2,839

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

ABOUT MASSACHUSETTS

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

Diagnosed HIV Cases

Deaths among People with HIV/AIDS

Diagnosed HIV Cases N=7,649; Deaths among people with HIV/AIDS N=2,785

* 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

- 12/2006: Fenway NPEP protocol
- 12/2010: IPREX study
- 7/2012: TDF/FTC approved by FDA for PrEP
- 8/2012: MMWR interim guidelines
- 9/2013: Fenway PrEP protocol
VI. RISK FACTORS

In the last 12 months, has the patient...

1. Had vaginal or anal sex with male partner(s)?
   - Yes
   - No
   - Doesn't know
   - Didn't ask

4. Had vaginal or anal sex with female partner(s)?
   - Yes
   - No
   - Doesn't know
   - Didn't ask

7. Has the patient had sex with transgender partner(s)?
   - Yes
   - No
   - Doesn't know
   - Didn't ask

10. How many different people has the patient had sex with in the past 12 months?

11. How many different people has the patient had sex with in the past 3 months?
**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?

<table>
<thead>
<tr>
<th>What type of sex does the patient engage in?</th>
<th>What % of the time is barrier used?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Sex (Insertive)</td>
<td>Yes</td>
</tr>
<tr>
<td>Oral Sex (Receptive)</td>
<td>Yes</td>
</tr>
<tr>
<td>Vaginal Sex (Penis, fingers, toys)</td>
<td>Yes</td>
</tr>
<tr>
<td>Anal Sex (Insertive)</td>
<td>Yes</td>
</tr>
<tr>
<td>Anal Sex (Receptive)</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**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/places to stay/something else the client needed
   - Yes
   - No

3. Vaginal or anal sex with a person who exchanges drugs/money/places 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

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Doesn’t know</th>
<th>Didn’t ask</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the patient engaged in the following substance use risk behaviors</td>
<td></td>
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<tr>
<td>before or during sex in the past 12 months</td>
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<tr>
<td>10. Patient reports alcohol use?</td>
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<tr>
<td>11. Patient reports drug use?</td>
<td>Yes</td>
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<tr>
<td>Has the patient engaged in the following injection drug use risk</td>
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<tr>
<td>behaviors?</td>
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<tr>
<td>12. EVER used injection drugs?</td>
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</tbody>
</table>
### VIII. STD Diagnosis History

In the last 12 months, was the patient diagnosed with a STD? (Check all that apply)
- No history of STI testing
- No history of HIV testing
- No history of HCV testing
- 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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Tested?</th>
<th>Site</th>
<th>Date</th>
<th>Outcome</th>
<th>Treated?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. HIV</td>
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<tr>
<td>2. Gonorrhea</td>
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<tr>
<td>3. Chlamydia</td>
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<td>4. Syphilis</td>
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<td>5. Hepatitis A</td>
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<td>6. Hepatitis B</td>
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<td>7. Hepatitis C</td>
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<td>8. NGU/NSU</td>
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<td>9. HSV - Type 1</td>
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<tr>
<td>10. HSV - Type 2</td>
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<td>11. Trichomoniasis</td>
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<tr>
<td>12. Other</td>
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</tbody>
</table>
### 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
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
  o 91% with 1+ post-PrEP HIV test
  o Median time to post-PrEP HIV test = 2.86 months
  o HIV test frequency median = q5.5 months

• STI Testing
  o 35.9% with any STI while on PrEP
  o STD lab frequency median = q4.5 months

• Safety Lab Testing
  o 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 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
  o 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*
  o CPT 90471 linked to
    1. Z23: *Encounter for immunization*
  o 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
  o Start TDF/FTC 1 tab PO daily
  o Continue estradiol + spiro at current dosing; confirm pt OK with this
  o Reassurance re: skin tag
  o Inform pt of support group for cisgender partners of transgender people

• Follow-Up
  o 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

- Dr. Ken Mayer
- Dr. Doug Krakower
- Michelle Bordeu, MPH
- Chris Grasso, MPH
- Fenway Health Data Team
QUESTIONS?

TAKING MY HEALTH INTO MY HANDS