Routine, opt-out HIV and HCV Screening in ABSMC Emergency Departments


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Established in 2010, Gilead’s FOCUS program (Frontlines of Communities in the United States) partners with healthcare providers, government agencies, and community organizations to change the way healthcare institutions approach HIV and HCV testing, and develop replicable model programs that embody best practices in screening and linkage to care. **FOCUS funds only administrative costs of project implementation and not tests/labs.**

**FOCUS aims to:**

- Make routine screening a standard of medical care.
- Reduce the number of undiagnosed individuals, decrease the number of those who are diagnosed late, and ensure strong linkage to care and treatment.
- Expand stakeholder dialogue on increasing diagnosis and access to care.
Financial Disclosures: Research Grant from Gilead Sciences, Inc.
Learning Objectives

- Highlight incidence and prevalence of HIV and HCV
- Identify sub-populations vulnerable to HIV and HCV infection
- Explain key health disparities that drive HIV and HCV infection
- Review evidence-based recommendations for routine HIV/HCV screening
- Discuss available screening assays
- Share screening outcomes from the FOCUS ABSMC ED initiative
- Highlight clinical and public health benefits of rapid ART
- Summarize DAA treatment options for patients with cHCV
HIV is very treatable, but still very much here…
Rates of Persons Living with Diagnosed HIV, by State, 2013

Rates displayed are the number of cases per 100,000 people.

*Data not shown to protect privacy because of a small number of cases and/or a small population.

**State health department, per its HIV data re-release agreement with CDC, requested not to release data to AIDSVu.
Rates of Persons Newly Diagnosed with HIV, by State, 2014

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Rates of Persons Living with Diagnosed HIV & Poverty Rates, by County, 2013

Persons Living with Diagnosed HIV

Poverty Rates

Rates displayed are the number of cases per 100,000 people.
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NOTE: There are no county-level maps for Alaska, District of Columbia, and Puerto Rico because there are no counties in these states.
Estimated annual HIV infections in the U.S. declined **18%**

Between 2008 - 2014 infections fell from 45,700 to 37,600

- **56%** decline among people who inject drugs
- **36%** decline among heterosexuals
- **26%** decline among gay and bisexual men aged 35-44 years
- **18%** decline among gay and bisexual men aged 13-24 years

Gay and bisexual men remain most affected

- **37,600** New HIV Infections in 2014
- **70%** Gay and bisexual men
- **5%** People who inject drugs
- **23%** Heterosexuals
- **3%** Gay and bisexual men who inject drugs

* 23% increase in infections among 25-34 YO MSM *
Why are we screening for HIV at ABSMC?

1 in 7 living with HIV

30.2% of new infections are transmitted by people with undiagnosed HIV

are unaware of their infection

60.3% of new infections are transmitted by patients not engaged in HIV care

(CDC, 2016; Skarbinski et al., 2015)
### HIV

All persons 13-64 years old receive routine voluntary HIV screening as a normal part of medical practice, similar to screening for other treatable conditions.

### Summary of Recommendations and Evidence

<table>
<thead>
<tr>
<th>Population</th>
<th>Recommendation</th>
<th>Grade (What’s This?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adolescents and Adults 15-65 Years Old</td>
<td>The USPSTF recommends that clinicians screen for HIV infection in adolescents and adults aged 15 to 65 years. Younger adolescents and older adults who are at increased risk should also be screened. Go to the Clinical Considerations for more information about screening intervals.</td>
<td>A</td>
</tr>
<tr>
<td>Pregnant Women</td>
<td>The USPSTF recommends that clinicians screen all pregnant women for HIV, including those who present in labor who are untested and whose HIV status is unknown.</td>
<td>A</td>
</tr>
</tbody>
</table>

### HCV

All persons born between 1945 and 1965

### Summary of Recommendations

<table>
<thead>
<tr>
<th>Population</th>
<th>Recommendation</th>
<th>Grade (What’s This?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults at High Risk</td>
<td>The USPSTF recommends screening for hepatitis C virus (HCV) infection in persons at high risk for infection. The USPSTF also recommends offering 1-time screening for HCV infection to adults born between 1945 and 1965.</td>
<td>B</td>
</tr>
</tbody>
</table>
One-time or annual HCV screening is evidence-based (CDC, USPSTF, AASLD/IDSA)

**Age**
- Born between 1945 and 1965 *
- Child born to anti-HCV–positive mother
- History of long-term hemodialysis
- History of transfusion with blood or organ transplantation before July 1992
- Received a tattoo in an unregulated setting

**Risk**
- Was ever in prison
- Healthcare worker with accidental exposure
- Chronic liver disease/hepatitis with unknown cause, elevated liver enzymes *
- History of illicit injection drug use or intranasal illicit drug use
- HIV infection, not MSM
- HIV infection, MSM
- Ongoing illicit injection drug use
HIV At A Glance - Alameda County

• 5,951 people living with HIV (2016)
• 263 new diagnoses (2016)
• 0.4% prevalence (0.6% national prevalence)
• 82.9% of new diagnoses were among men (2016)
• 26.7% of new diagnoses (2013-2015) were late (AIDS)
  (23% nationally, CDC, 2016)
HIV At A Glance - Alameda County

Figure 2.3: New Diagnoses by Race/Ethnicity, Alameda County, 2014-2016

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Number of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>African American</td>
<td>36.5%</td>
</tr>
<tr>
<td>White</td>
<td>24%</td>
</tr>
<tr>
<td>Latino</td>
<td>26.3%</td>
</tr>
<tr>
<td>API</td>
<td>19.2%</td>
</tr>
<tr>
<td>Other/Unknown</td>
<td>10.9%</td>
</tr>
</tbody>
</table>

Figure 3.2: PLHIV by Race/Ethnicity, Alameda County, year-end 2016

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Number of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>African American</td>
<td>39.8%</td>
</tr>
<tr>
<td>White</td>
<td>31.6%</td>
</tr>
<tr>
<td>Latino</td>
<td>19.2%</td>
</tr>
<tr>
<td>API</td>
<td>6.6%</td>
</tr>
<tr>
<td>Other/Unknown</td>
<td>2.8%</td>
</tr>
</tbody>
</table>

Figure 3.1: PLHIV by Sex, Alameda County, year-end 2016

<table>
<thead>
<tr>
<th>Gender</th>
<th>Number of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>17.1%</td>
</tr>
<tr>
<td>Male</td>
<td>82.9%</td>
</tr>
</tbody>
</table>

Alameda County Dept. of Public Health, Feb. 2017
HIV At A Glance - Alameda County

• Age 20-29 highest impacted demographic (225 new infections in 2015; 3.1% increase in diagnosis rate since 2006)

• 25-29 YO Latinos experienced 8.6% increase in diagnosis rate

• New HIV cases and highest HIV prevalence concentrated in metropolitan Oakland (North/West Oakland, Downtown, Chinatown, San Antonio)
HIV Care Cascade

% Diagnosed: 87 ~90
% Linked to care: 75 73.9
% Retained in care: 57 56
% Virally suppressed: 55 67

Why are we screening for HCV at ABSMC?

- Epidemic of acute HCV (2.9x more cases in 2015 vs 2011)
- Increasing incidence outside birth cohort (13% annual increase in PWID <30 YO)
- Leading cause of liver cancer
- Leading cause of liver transplantation
- Responsible for medically-significant and costly morbidity and mortality
Number of US Individuals With Hepatitis C Antibody

* 1.67% seropositivity rate (Rosenburg et al., 2017)

Added populations: incarcerated (n=163,967-961,941), homeless (n=51,892-363,246); hospitalized (19,122-181,660), nursing homes (30,386-121,545), military (6739-11,794), Indian reservations (83,358-173,474).

HCV Incidence Over Time – U.S.

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Figure 1 - Hepatitis C Incidence in United States, 1982-2014.
This graphic represents the estimated number of new hepatitis C infections per year.

Source: Division of Viral Hepatitis, Statistics and Surveillance
Figure 4.1. Reported number of acute hepatitis C cases — United States, 2000–2015

Source: CDC, National Notifiable Diseases Surveillance System (NNDSS)
Incidence of acute hepatitis C by age group — United States, 2000–2015

Source: CDC, National Notifiable Diseases Surveillance System (NNDSS)
HCV Case Rates- Alameda County

Case Rate per 100,000

2011: 74.4
2013: 57.3
2015: 72.9

*HIV rate

CDPH, Office of Viral Hepatitis Prevention, 2015
HCV Cases by Race, 2015

- African American: 35.5%
- White: 60.8%
- 2015 data

- County population is 12 AA and 34% W
HCV Unknowns

• PLHCV in AC – 25,000 to 50,000?
• HCV treatment cascade
• Incidence – especially among high risk groups
• HCV morbidity and mortality
• How much HCV is underreported in ELR era
County Efforts
Chronic Hepatitis C – Rates of Newly Reported Cases by County, Excluding Cases in State Prisons, California, 2011 and 2015

Notes:
* No cases reported or statistically unstable rates for five local health jurisdictions in 2011, including Alpine, Colusa, Inyo, Mono, and Sierra counties; and two local health jurisdictions in 2015, including Alpine and Sierra counties.
- State prisons cases were removed from local health jurisdiction totals and attributed to the state prison system as a whole.
HGH ED HCV Testing Study

• 2581 ED patients over 6 months
  • Birth cohort, IDU or diagnostic testing

• 267 (10.3%) HCV Ab reactive
  • 38.4% IDU
  • 25.5% homeless
  • 67% had RNA done
    • 70% of those were RNA+

White, Ann Emer Med, 2015
BABY BOOMERS (BORN 1945-1965)

1 IN 30 HAS HEPATITIS C AND MOST DON’T EVEN KNOW IT.

75% of all CHCV infections are in the birth cohort!!!
Natural History of HCV

- HCV infection
- 6 months
- Acute Hepatitis C
- Chronic Hepatitis C
- Cirrhosis
- 15-30%
- 55-85%
- 3-17%
- End-stage liver disease
- Hepatocellular carcinoma
- 1-5% of all people infected with hepatitis C
Chronic HCV: An Expensive Disease

Increasing HCV-associated mortality

Annual Age-Adjusted Mortality Rates*

Death Rate (per 100,000 Persons)

Year

99 00 01 02 03 04 05 06 07

HIV

HCV
HCV Care Cascade – United States

- Chronic HCV-Infected*: 100%
- Diagnosed and Aware†: 50%
- Access to Outpatient Care‡: 43%
- HCV RNA Confirmed§: 27%
- Underwent Liver Biopsy¶: 17%
- Prescribed HCV Treatment¶¶: 16%
- Achieved SVR**: 9%

* Chronic HCV Infected: N = 3,500,000
† Diagnosed and Aware
‡ Access to Outpatient Care
§ HCV RNA Confirmed
¶ Underwent Liver Biopsy
¶¶ Prescribed HCV Treatment
** Achieved SVR

Schranz et al., 2014
CDC: Effectiveness of HCV Testing for Persons Born During 1945-1965

- 3 large primary care health systems (2012-2014)
  - Systematic 1-time HCV test versus usual care (likely risk-based or medical indication-based testing)
  - 3 independent HCV testing trials (results available for 2)
    - Trial 1: stratified multi-clinic, individually randomized (9 clinics)
    - Trial 2: cluster randomized (10 clusters)
  - No prior HCV test or infection

- Birth-cohort HCV testing
  - 4 times more effective in identifying persons with HCV infection compared with usual care

### HCV Testing Results

<table>
<thead>
<tr>
<th></th>
<th>HCV Identified (per 1000 eligible)</th>
</tr>
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<tbody>
<tr>
<td><strong>Trial 1</strong></td>
<td></td>
</tr>
<tr>
<td>Birth cohort testing (n=2996)</td>
<td>2.7</td>
</tr>
<tr>
<td>Usual care (n=5996)</td>
<td>0.3</td>
</tr>
<tr>
<td><strong>Trial 2</strong></td>
<td></td>
</tr>
<tr>
<td>Birth cohort testing (n=2996)</td>
<td>3.0</td>
</tr>
<tr>
<td>Usual care (n=5996)</td>
<td>1.1</td>
</tr>
</tbody>
</table>

Relative Probability of Identifying HCV-Positive Patients Using Birth Cohort Versus Usual Care
Risk Ratio: 4.0 (1.9-8.7)

HIV/HCV Screening at ABSMC EDs

- Routinizes screening in ED
- Screening is Integrated into RN workflow
- Only for patients receiving blood draw
- Uses 4th generation HIV Ag/Ab combo assay and HCV Ab (Abbott Architect platform) for initial screen, with reflex to confirmatory testing (Shared Lab)
- Facilitates test-and-treat model for HIV+ Pts

May 9, 2017
Provider-led HIV testing during team triage only

August 31, 2017:
Nurse-led HIV & HCV testing (24/7)
Generations of HIV Screening
• Acute HIV is 26x more infectious
• 40-50% of cases can be asymptomatic
• 8 transmissions averted per 100 persons newly aware of their diagnosis

DHSS, 2001; Kahn, 1998; Hall et al., 2012
ABSMC Screening Hubs

Two, large urban EDs with:

- Diverse patient populations
- Approximately 97,500 annual visits
- 265 daily visits
- Multiple insurance payers
  - 39% MediCal
  - 35% Medicare
  - 20% PPOs/HMOs
  - 2% self-pay
Screening at ABSMC is opt-out…
Monthly HIV Testing Results (2017-2018)

<table>
<thead>
<tr>
<th>Month</th>
<th>Testing Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>May</td>
<td>55</td>
</tr>
<tr>
<td>June</td>
<td>46</td>
</tr>
<tr>
<td>July</td>
<td>55</td>
</tr>
<tr>
<td>August</td>
<td>57</td>
</tr>
<tr>
<td>September</td>
<td>826</td>
</tr>
<tr>
<td>October</td>
<td>912</td>
</tr>
<tr>
<td>November</td>
<td>787</td>
</tr>
<tr>
<td>December</td>
<td>925</td>
</tr>
<tr>
<td>January</td>
<td>956</td>
</tr>
</tbody>
</table>
HIV Screening Results (May 1-Oct 15, 2017)

- Tests performed: 3263
- Ab+: 13
- RNA+: 11
- 0.4% test prevalence rate
- 82% of pts linked to care
Demographics of HIV Ab+ Pts

Race

- Unknown: 1
- Black: 10
- White: 9

Gender

- Male: 1
- Female: 1

Age

- 13-24: 2
- 25-34: 4
- 35-49: 1
- >55: 1
HIV linkage-to-care (May 1 - Oct 15 2017)
Acute HIV And RAPID ART At EBAC

• 14 Pts had acute HIV infection (AHI)
• All 14 Pts with AHI linked to outpatient medical care (13 of 14 at EBAC)
• All 14 Pts started ART within 5 to 96hrs of their diagnosis
• 12 of 14 acute HIV infections were among A. Americans, 1 API, 1 Caucasian
• 10, men, 1 transmale, 1 transwoman, and 2 women had acute HIV
• 10 of 14 (75%) were under age 34 (>34 Applon, King, Murphy)
• 4 hospital admissions among acute HIV + Pts immediately after diagnosis in ED: 2 for colitis, 2 for aseptic meningitis - (from acute HIV) related sxs, including encephalopathy
• At least 50% of Pts with acute HIV also found to have concurrent urethral, pharyngeal or rectal STI or syphilis
Acute HIV And RAPID ART At EBAC

- Median CD4 count at time of diagnosis or first visit at EBAC:
- Median VL at time of diagnosis
- More than 2/3 of Pts with acute HIV infection became virally suppressed within 2-3 months after ART initiation
- 1 Pt (23 YO M, father with 1 YO twins) who initiated RAPID ART on 5/5/17 is now undetectable and well-engaged in care
EBAC received warm hand-offs from ABSMC ED providers for 11/13 Pts with reactive Ab+ tests (1 Pt discharged before result returned from lab; other Pt left ED AMA before results returned)

Majority of linked Pts (6/9; 67%) have started, or re-started ART
HIV

• 14 Pts had acute HIV infection (AHI)
• 8 false positive tests (including 1 young woman admitted for PID and h/o prior FP 1 year ago)
• 3 Pts had concurrent syphilis infection (1 with possible neurosyphilis), and 1 had pharyngeal GC at time of their reactive HIV tests
• 3 Pts had AIDS diagnosis at presentation, 1 of whom also received new HCC diagnosis and another with acute liver failure
• Husband and wife with reactive screen on 6/17/17 remain OOC; referred to DPH PH investigator
HCV Screening Results (Aug 31-Oct 15, 2017)

6.6% test prevalence rate

40.9% of pts have cHCV
Demographics of patients with cHCV

![Pie chart showing demographics of patients with cHCV.]

- 56% Male
- 31% Female
- 6% Asian
- 5% Black or African American
- 5% White
- 8% Bi or multiracial
- 6% Unknown
Birth cohort vs non-birth cohort chronic infections

- Outside birth cohort: n=23 (64%)
- Inside birth cohort: n=13 (36%)
Of 36 patients with cHCV....

- Known positive - already in care, 4
- Linked to care elsewhere, 4
- Linked to care at EBAC, 2
- No phone number, 12
- Linkage in process, 14
Clinical Summaries/Success Stories

HIV

- EBAC received warm hand-offs from ABSMC ED providers for 11/13 Pts with reactive Ab+ tests (1 Pt discharged before result returned from lab; other Pt left ED AMA before results returned)
- Majority of linked Pts (6/9; 67%) have started, or re-started ART
- 1 Pt (23 YO M, father with twins) who initiated RAPID ART on 5/5/17 is now undetectable and well-engaged in care
- 50 YO MSW with reactive test on 10/15/17 initiated ART within 36hrs
Clinical Summaries/Success Stories

HIV

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Clinical Summaries/Success Stories

HCV

• 1 Pt initiated DAA therapy on 10/25/17
• 14 Pts have referrals/insurance navigation in process
• 4-5 inpatient referrals in-process; 3 of these Pts (1 of whom is engaged in advanced liver care, but not tx candidate now) have decompensated cirrhosis and were referred directly to EBAC’s partner hepatologist, Dr. Will Holt
• Active care coordination with county FQHCs and Highland Hospital for Pts who aren’t eligible for treatment at EBAC, or remain out of care
Cases from the ED

23 YO AA male with recent HIV exposure and severe GI sx

Presented at Alta Bates ED on 5/15/17 with nausea + abdominal pain
Labs significant for mild transaminitis, thrombocytopenia, and leukopenia
5/5/17: Reactive 4th gen test; HIV ½ (Multispot) neg; HIV RNA: 6.8 million
Exposure likely 2.5-3 weeks prior to reactive test; Pt had 1-2 male sexual partners
Linked to care at EBAC 4 hours after diagnosis; started F/TAF + DTG same day

28 YO AA male with multiple ED visits for gastritis

Presented at Alta Bates ED on 9/6/17 with gastritis and AMS
8 ED visits between 4/2016 and 9/6/17; never tested for HIV
Labs significant for mild leukopenia and hypokalemia
9/6/17: Reactive 4th gen test; HIV-1 Ab+; HIV RNA: 68k
By history, possible HIV exposure in last 4-6 weeks
Linked to care at EBAC within 24hrs; not on ART yet; RPR+; possible neurosyphilis
HIV/HCV Screening in the ED....

- Cost-effective
- Covers necessary, evidence-based preventive health service for patients without insurance or a medical home
- Creates opportunity for rapid ART, PEP, and maybe even PrEP
- Captures high HIV and HCV seroprevalence rates (0.1-1.7%)
HIV/HCV Screening in the ED:

- Can re-engage out-of-care, HIV+ patients
- Cuts down on stigma of screening
- Conduit to link patients with cHCV to a life-saving cure
History of anti-HCV treatment

- Interferon
- Interferon + ribavirin
- Peginterferon + ribavirin
- Peginterferon + ribavirin + PI
- Interferon-free combination

Sustained virological response rates (%)

- 1990: 7-10%
- 1998: 25%
- 2001: 40-50%
- 2011: 60-70%
- 2014: >90%
HARVONI

Approved by US Food and Drug Administration

Mavyret: $39,600

$94,500
Benefits of SVR

Leads to improved liver histology and some regression in fibrosis
Lowers risk of liver decompensation and esophageal varices
Decreases risk of HCC by ~ 75% (though can still occur s/p SVR)
Decreases overall mortality risk (~50%)
Reduces overall, liver-associated healthcare costs
95-99% remain HCV negative for >10 years


CDC, 2016
EBAC HCV Care Continuum (co-infected Pts)

- Estimated HCV Ab +: 450
- Diagnosed/Linked: 115
- Initiated DAA therapy: 68
- SVR-12: 54

SVR rate 79%
ION4 – SOF/LDV for Pts with HIV/HCV co-infection

No impact on SVR12 rate: gender, HCV genotype, baseline HCV RNA, IL28B genotype, cirrhosis, prior HCV treatment, ART regimens, and baseline CD4 count.
Lower SVR12 rate observed among black patients (90%).

ENDURANCE-1, -2, -4 Studies: Efficacy of GLE/PIB for Treating GT1, 2, 4, 5, 6 HCV

1 case of on-treatment virologic failure at Day 29 in pt with GT1a HCV infection

*ITT-PS analysis: included all pts receiving ≥ 1 dose of study drug; excluded pts with HIV coinfection or SOF experience. †ITT analysis: excluded pts with SOF experience. ‡ITT analysis.

ASTRAL-1: Sofosbuvir/Velpatasvir for GT1, 2, 4, 5, 6 HCV

- Double-blind, placebo-controlled trial (N = 740), tx naive or experienced
  - Pts randomized 5:1 to sofosbuvir/velpatasvir or placebo for 12 wks
  - Key baseline characteristics: cirrhosis 19%, tx exp’d 32%, BL NS5A RAVs 42%
- No impact of cirrhosis, tx experience, BL NS5A RAVs on SVR12 rates

Current Challenges

• Increasing testing rates and RN buy-in
• Optimize BPA functionality
• Continue to improve disclosure and linkage to care process among ED providers
• Linking patients without phone contacts
Future Horizons…

• **Comprehensive STI Testing** *(think HIV, AND syphilis !! )*
  Importance of taking thorough sexual histories; Always get blood drawn for diagnostic HIV and syphilis testing with presentations suspicious for STI

• **nPEP and PEP**
  The critical, 72-hr window *(HIV exposure is a medical emergency !!!)*
  More tolerable regimens *(Descovy+dolutegravir or Genvoya)*

• **Rapid ART**
  Test-and-treat model reduces size of viral reservoir, viral load, and transmission risk

• **Re-engagement in HIV care**
  Linkage to comprehensive medical care and ART = **reduced transmission risk**
  Reduction in morbidity and mortality
Acknowledgements

Annette Shaieb MD
Bebs Navarro RN
Brenda Tiernan RN
Brian Potts MD
Christopher Hall MD
Cristina Perkins RN
Gregory Callison NP
Erica Ivans PA

Erin Bures RN
Emily Rymland NP
Geraldine Rimando RN
Jessica Horwitz NP
Jessica Ruston RN
Janet Lo
Kara Vassily RN
Michael Cheng

Monica Steiner RN
Ronn Berrol MD
Steve Bills
Steve Nesbitt
Steve O’Brien MD

FOCUS PROJECT
Thank you for your time & attention