FOCUS: (On the) Frontline of Communities in the U.S.

A program for routine HIV and HCV screening and linkage-to-care

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FOCUS Program
Gilead Sciences

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FOCUS: a Public Health Program

*Developing a model for large scale HIV and HCV screening*

**FOCUS program initiated in 3 counties** to develop a systems change approach that embodies best practices in HIV screening and linkage to care.

- **2006:** CDC releases HIV testing guidelines recommending routine screening for everyone aged 13-64 years old.
- **2010:** 300k HIV tests in 10 counties encompassing the regions most impacted by HIV.
- **2012:** 900k HIV tests in 11 counties FOCUS begins integration of HCV testing into expansion of program.
- **2013:** 2.2M HIV tests & 300k HCV tests in 21 counties with routine screening program.
- **2014:** Projected: 3M HIV tests & 1M HCV tests in 45 counties with routine screening program.
- **2015:**
- **2016:**
- **2017:**
TEST: FOUR PILLARS OF ROUTINE SCREENING

**Testing Integrated into Normal Clinical Flow**
To promote the normalization and sustainability of testing.

**Electronic Medical Record Modification**
To prompt testing, automate processes, populate lab orders and track performance.

**Systemic Policy Change**
A multi-level, organization-wide commitment to implement routine testing and linkage to care.

**Training, Feedback & Quality Improvement**
To identify best practices and motivate staff.
FOCUS: using CDC data to identify areas of need
FOCUS Partnership Requirements

Establish and meet testing and linkage-to-care targets
  • Total number of tests over grant term (12 months)
  • Linkage-to-care rate

Submit data reports on testing, diagnoses, and linkage-to-care
  • Monthly
  • Quarterly
  • Interim at 6-month anniversary
  • Year-end after 12-month anniversary

Regularly scheduled meetings
  • Monthly calls with FOCUS Regional Lead
  • Quarterly regional meetings
  • Annual regional meetings
  • Biannual national Partner Summit
Dissemination: Telling the FOCUS Story

Examples

FOCUS | Q1 2017

3.4M HIV Tests since 2010, 1M HCV Tests since 2014

- 0.8% HIV Seropositivity
- 6.0% HCV Ab Seropositivity

2010: 27,380
2011: 163,041
2012: 402,427
2013: 908,184
2014: 1,601,264
2015: 2,292,780
2016: 3,395,123

26K HIV+, 32K HCV RNA+ Identified Through Testing

- 61K HCV Ab+
- 52K HCV RNA tests
- 32K HCV RNA+
- 26K HIV+

81% HIV Median LTC
67% HCV Median LTC

HCV/HBV: 8%
HIV Only: 4%
HCV Only: 24%
HIV/HCV Screening: 62%
HCV/Other: 2%

159 Current Partnerships in 68 Cities/Counties*

- Hospital (43%)
- Community Health Center (32%)
- Community/Other* (25%)

FOCUS Partners Screen in Over 1,000 Locations

Current: 1,048 Screening Locations
Since 2010: 1,500+ Screening Locations

HIV/HCV/HBV (8%)
HIV Only: 4%
Blood Borne Virus: HIV/HCV/HBV (8%)

FOCUS Partners Adapt Model to Local Need*

376 Abstracts accepted at major conferences
45 Journal Articles published in peer-reviewed journals

Dissemination by FOCUS Partners

*Partner screening models are determined based on local disease epidemiology and unmet public health need.

*Other includes health departments, substance use, training, and corrections.

As of July 2017
Questions?

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Thank you!
Integrating HCV treatment by primary care providers at community health centers

Megan Crowley, MPH
HIV Project Manager
Alameda Health Consortium
Our community health centers

Over 200,000 collective patients:
- 48% Latino/Hispanic
- 23% Asian/Pacific Islander
- 19% Black/African-American
- 14% Non-Hispanic white
- 95% at or below 200% FPL
- 41% best served in a language other than English
- 62% with Medicaid
- 25% uninsured

Source: 2015 UDS
HIV ACCESS Primary Care Network

- Ryan White Part C network in Alameda County
- Serving ~1,300 PLWHA in Alameda County across 5 agencies and 7 clinic locations:
  - 5 federally qualified health center sites
  - 2 ambulatory care sites operated by County hospital system
HIV ACCESS Primary Care Network

- 92% HIV linkage to care rate (2014-2016)
- 96% prescription of ART (Q2 2017)
- 89% viral load suppression (Q2 2017)
- Robust quality management program
- 2017 network priorities:
  - Retention in care and re-engagement
  - Rapid ART initiation
  - Treatment adherence
Need for hepatitis C treatment capacity

Cumulative HCV tests and RNA+ results
January 2015 - December 2016

1007 RNA+

Cumulative total tested
Cumulative total RNA+
Where the hepatologists are
Hepatitis C treatment capacity building: essential ingredients

1. Trainings
2. Clinical champion
3. Direct mentorship
4. Protocols, work flows, EHR tools
5. Linkage navigator
6. Active leadership support
Cross-pollination from HIV program

Clinical champion

Protocols, work flows, EHR tools

Linkage navigator

Active leadership support
Half-day intensive workshops
Quarterly update meetings
Clinical champions and direct mentorship with teams
Clinical champions and direct mentorship with teams
Hepatitis C protocol

Hepatitis C screening, referral and treatment protocol
[Updated AASLD guidelines: www.hcvguidelines.org; this document updated 9/14/2016]

For all primary care provider teams

Who should be screened?

- All US adults born 1945-1965, regardless of risk [CDC 2012, USPSTF grade B 2013]
- All others at high risk: IDU, HIV, dialysis, ↑ALT, transfusion or transplant <1992, clotting factors <1987, needle-stick, incarceration, intranasal drugs, unregulated tattoos, mother with HCV; consider those from endemic countries: Egypt, Pakistan, Mongolia, Russia, Middle East, Taiwan, many countries in Africa.

If the hepatitis C (HCV) antibody is positive, within 1 month, order (if not already reflexed):

- HCV quantitative RNA PCR to evaluate if patient is chronically infected vs. cleared/cured
  - if Ab+ and RNA undetected, retest for Ab and RNA in 1+ months (6 mo if recent exposure) to confirm

If the HCV RNA PCR is positive (patient is chronically infected) evaluate staging¹ within 6 months:

- HCV genotype
- CBC with platelets
Hepatitis C treatment updates

TREATMENT

Who is eligible for treatment?

1) **California State Medi-Cal Guidelines** covers tx for pts with any of the following:
   - APRI score > 0.7
   - Diabetic
   - Women of Childbearing Age who wish to get pregnant
   - Co-infected with HIV OR Hep B
   - Other coexistent liver disease, such as NAFLD
   - Porphyria Cutanea Tarda
   - MSM with high risk practices
   - Active injection drug users
   - Pts on dialysis
   - HC worker with exposure prone procedures
   - “Evidence of extra-hepatic manifestation: such as type 2 or 3 cryoglobulinemia”

2) **Medicare**: Part D plans usually, but not always, cover all Hep C pts, regardless of stage, but may require other regiments such as PrOD (ie Viekira pak) or Grazoprevir-Elbasvir (Zepatier). Medicare Advantage programs may be more restrictive.
Hepatitis C treatment capacity building

January 2015 – December 2016:

• 6 half-day workshops (~60 PCPs trained)
• 4 quarterly provider update meetings
• 4-6 updates/month via e-mail list
• Ongoing clinical mentoring for providers
• Ongoing coaching and technical assistance for clinics
Where the hepatologists are
Where our clinics with hepatitis C treatment are
Results: # of PCPs treating

Providers treating HCV and patients initiating HCV treatment
January 2015 – December 2016

30 PCPs
320 patients
↑525%
Results: 2015-2016

• 291 clients completed treatment
• 197 completed 12-week post-treatment labs
• 189 achieved a sustained viral response at 12 weeks (SVR12)

96% cured!
HCV-HIV Co-Infection

As of 12/31/2016:

• 42 co-infected with HIV and HCV
• All engaged in HIV primary care
• 31 started HCV treatment
• 29 completed treatment
• 23 returned for 12-week follow-up labs
• 22 achieved SVR12 → 96% cured!
Hepatitis C Care Cascade:
Alameda Health Consortium 2015-2016

- 35,219 tested
- 3% seropositivity
- 30 PCPs treating
- 96% SVR12

<table>
<thead>
<tr>
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<th>Percentage</th>
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<tr>
<td>Diagnosed</td>
<td>77%</td>
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<tr>
<td>% Linked to HCV care</td>
<td>32%</td>
</tr>
<tr>
<td>% Prescribed HCV tx</td>
<td>29%</td>
</tr>
<tr>
<td>% SVR12 w/labs</td>
<td>19%</td>
</tr>
<tr>
<td>% SVR12 (all)</td>
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2016-2018 Expansion

**July 2016:** Alameda County Health Care Services Agency (HCSA) added hepatitis C testing and treatment required deliverables for health centers

- Expansion from 5 to 8 health centers, plus primary care clinics in the County hospital system (AHS)
- AHC support for hepatitis C activities will continue through June 2018 with additional focus on patient navigation and quality management
Where our clinics with hepatitis C treatment are
UPDATE!

Cumulative Progress:

• 1,061 initiated treatment
• 758 completed treatment
• 563 cured!

Source: Alameda County Health Care Services Agency
Primary care providers can be trained rapidly and effectively to provide hepatitis C treatment, increasing access to hepatitis C care for underserved and vulnerable populations.
• Jan Diamond, MD, MPH – Hepatitis C Clinical Advisor
• Sophy Wong, MD – Clinical Quality Advisor
• Chela Zitani – Hepatitis C Coordinator, LifeLong Medical Care
• FOCUS Coordinators and patient navigators at the following agencies:
  – Asian Health Services
  – La Clinica
  – LifeLong Medical Care
  – Tiburcio Vasquez Health Center
  – Tri-City Health Center
• Myra Ozaeta and Gilead FOCUS Program
HCV TEST AND CURE PROGRAM

Development of a Community-based Testing, Linkage, and Hepatitis C Treatment Program

Christian B. Ramers¹, Robert Lewis¹, Letty Reyes¹, Danelle Wallace¹, Shannon Hansen
1. Family Health Centers of San Diego
Disclosures

• Ramers: consultant, advisor, speaker: Gilead, BMS, AbbVie, Merck, Janssen, Project ECHO, HealthHIV, Clinical Care Options, Pacific AETC
• Lewis, Reyes, Wallace: none
• The following slides contain information on treatment. FOCUS funds are used to support testing and linkage to care services at Family Health Centers of San Diego and do not support medical services
Background

- Chronic HCV is a major public health concern and the leading viral cause of death in the United States.
- Recent reports suggest nearly 20,000 HCV-associated deaths/yr and a surge in new HCV cases to 30,500 in 2014.
- CDC, USPSTF, AASLD and IDSA guidelines promote risk-based and birth cohort screening to identify asymptomatic HCV infection.
- The 3/17 NAS National HBV/HCV Elimination Strategy emphasizes testing, referral, and support systems and increasing HCV treatment in primary care settings.
- Community-based, and health-systems testing strategies are needed to identify undiagnosed infections, and new models of care may increase overall treatment capacity.
Specific Aims

• To implement targeted, community-based HCV testing using rapid, point-of-care diagnostics followed by immediate on site confirmatory HCV RNA PCR
• To rapidly and reliably link HCV-infected individuals to care with an HCV-treating provider
• To minimize barriers to HCV treatment by providing intensive patient navigation, insurance application assistance, and complete diagnostic evaluation and treatment within the Primary Care Medical Home model
• To reproduce high SVR rates of DAA therapy in an urban underserved, community clinic setting
Methods – Testing Protocol

- HIV test/counselors trained on HCV counseling/testing methods
- Test/counselors, phlebotomists (CPT), care coordinators deployed within several urban FQHC’s, two Syringe Exchange programs, and >60 SD County Drug/Alcohol rehab sites
- POC testing w/ OraQuick HCV test; positive results prompt phlebotomy for HCV RNA testing
- HCV Navigator/Care Coordinator links HCV+ patients to care
Methods – Testing/Treatment Sites
Community-based Testing at all SD County ADS sites

69 sites
(14 N. County)
Linkage to Care – Best Practices

**Staffing of testing teams**
- Cross-training of CPT’s as certified test-counselors (CTC’s)
- Annual training in MI, Trauma-informed care, Cultural Competence
- Dedicated ‘eligibility worker’ (a.k.a care coordinator/navigator)

**Optimized testing flow**
- Active, engaged education/conversation re: linkage during wait times
- Rapid turnaround (3-7 days) with in-house HCV RNA

**Collaboration across the testing/care continuum**
- Weekly ‘huddles’ to discuss testing/linkage issues, debrief re: no-shows
- MD, NP, PA, CPT, CTC, Navigators

**Expanded HCV Care Capacity**
- Dramatically decreased wait time for initial visit: 3 months → 1-2 weeks
- 3 sites offering care (8AM-8:20 PM); on-site scheduling of first visit
Methods – HCV Evaluation/Treatment flowchart

Providers
- E-HR

FHCSD Clinics

Community

Test/Counselor

CPT

Care Coordinator

HCV Navigator

Providers
- ID
- NP
- NP
- IM
- NP
- IM
- FP

Rx

‘Medical criteria’

- H&P
- Labs
- Imaging
- Elastography

Linkage to Care

Internal Referral

Linkage to Care
Multidisciplinary co-management via telehealth

FOCUS HCV Testing (N = 1412)

- 1247 (88%) HCV Ab -
- 165 (12%) HCV Ab +

HCV Ab + (N = 165)

- 105 (64%) HCV RNA +
- 42 (25%) HCV RNA -
- 18 (11%) HCV RNA ND

Total HCV Ab+/HCV RNA + = 105
Results – HCV Ab + Age Distribution (N = 165)
Fig. 2 HCV-Infected Patients Starting Treatment, by Provider Type, 2013-2016 (N=473)

- ID MD
- NP
- PCP MD
- Total Pts Treated

Total Treated per Interval

Number of Patients Starting Treatment

- Jan-June 2013: 0
- July-Dec 2013: 0
- Jan-June 2014: 20
- July-Dec 2014: 31
- Jan-June 2015: 0
- July-Dec 2015: 53
- Jan-June 2016: 0
- July-Dec 2016: 67
- Jan-June 2017: 12
- July-Dec 2017: 88
- Jan-June 2018: 11
- July-Dec 2018: 37
- Jan-June 2019: 22
- July-Dec 2019: 85


Medical services not supported by FOCUS funding
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</tr>
<tr>
<td>HCV RNA drawn</td>
<td>147</td>
</tr>
<tr>
<td>HCV RNA positive</td>
<td>105</td>
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<tr>
<td>Linked</td>
<td>68</td>
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<tr>
<td>Completed Tx</td>
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Medical services not supported by FOCUS funding
Conclusions

- Rapid, point-of-care testing conducted at EtOH/Drug rehabilitation programs in San Diego yielded high prevalence of HCV exposure (12%) and chronic HCV (7%)
- Less than half of HCV Ab+ patients had insurance coverage at the time of testing, necessitating ACA enrollment
- A team composed of a test/counselor, a phlebotomist, and a care coordinator were effective at linkage to care
- Per Protocol SVR12 rates were comparable to large ‘real world cohorts’
- High administrative burden, ‘eligibility criteria’ and limited treatment capacity remain major barriers to expanding access to HCV cure
Lessons Learned

• **Successes**
  - Patients *strongly* favor treatment within Medical Home
  - HCV testing most effective in high-prevalence environments; however, linkage more effective from rehabilitation sites
  - Patient navigator role essential; advocacy groups absent
  - Insurance application assistance should occur at point of testing

• **Gaps/Areas for Improvement**
  - ‘Wrap around’ services needed for vulnerable patients
    - Mental Health, insurance assistance, undocumented, substance abuse
  - Must be sensitive to the ‘bottom line’
    - Enlisting 340B pharmacies, clinical efficiencies
  - Need to expand pool of treaters; inspiring and training local champions to acquire HCV knowledge

Medical services not supported by FOCUS funding
Acknowledgements

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