Integrating Hepatitis C Treatment into Primary Care: Innovative Approaches

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Center for Excellence in Primary Care

Webinar sponsored by:
The Center for Excellence in Primary Care and the Center for Care Innovations
Facilitating Care Integration

Nearly half of adults with health issues report problems with the coordination of their care in the United States. As Community Health Centers (CHCs) and other safety net settings transform into Patient-Centered Medical Homes, their role in the larger medical neighborhood will become pronounced. However, challenges with care coordination are magnified in the safety net setting and continue to be increasingly complex.

In 2014, the UCSF Center for Excellence in Primary Care with funding from the Blue Shield of California Foundation, completed a comprehensive literature review outlining strategies CHCs use to integrate into the medical neighborhood in the domains of primary care-specialty care, primary care-diagnostic imaging, primary care-oral health and primary care-hospital care. A conceptual model which was used to classify innovations and strategies for integration can be found in the full report here.

The UCSF Center for Excellence in Primary Care has partnered with the Center for Care Innovations to develop this online resource center. The purpose of this Care Integration site is to disseminate
The Grady Liver Clinic

Integrating Hepatitis C Care and Treatment into a Safety Net Primary Care Center
Objectives

• Understand the Grady Liver Clinic model, focusing on population served and operations
• Learn outcomes from Grady Liver Clinic programs including success rates of antiviral therapy and screening and linkage to care initiatives
• Discuss barriers encountered and explore facilitators for creating similar models of care
Hepatitis C in 2015

- Worldwide: 130-170 million persons infected (2-3%)
- US: 2.7 million chronically infected (1%)
- Leading cause of death from liver disease
- Leading cause of liver transplant

Hepatitis C: Looking Forward

- Incidence down, prevalence peaked in 2001 (3.6M)
- Deaths increasing
- Multicohort natural history model projections
  - Proportion of chronic hepatitis C with cirrhosis
    - 25% in 2010
    - 45% in 2030
  - Total cirrhosis will peak at 1M in 2020 (30% higher)

Davis et al Gastroenterology 2010;138:513–521
From: The Changing Burden of Hepatitis C Virus Infection in the United States: Model-Based Predictions

Grady Liver Clinic

- Grady Memorial Hospital (Atlanta, GA)
  - 1,000 bed, urban, safety net hospital
  - Largely un-and underinsured, African American population
  - Teaching site for Emory and Morehouse SOM

- Grady Liver Clinic
  - Founded in 2002 in Primary Care Center
  - High prevalence hepatitis C
  - Few patients treated for hepatitis C
  - Started multi-disciplinary: hepatology, psych, gen med, PharmD
Grady Liver Clinic: Goals

- Provide access to comprehensive care for underserved patients with hepatitis C
- Evaluate co-morbidities and assess readiness for hepatitis C treatment
- Initiate and monitor patients on treatment
Main site at Grady treating hepatitis C
Every Tuesday and Thursday AM, 80 new referrals per month
Start with group education session

Services provided:
- Education and counseling
- Support group
- HCV RNA testing
- Liver fibrosis assessment (lab and radiology)
- Hepatitis A and B testing and vaccination
- Liver biopsy referral
- Cirrhosis management (HCC screening and referral for varices screening)
- Antiviral medication
  - Counseling
  - Patient assistance
  - Treatment
Model

Staffing:

- 2 attendings per clinic, 6 faculty in pool
- PharmD
- Residents
  - Ambulatory
  - Elective
- Fellows
  - GI 3rd year
  - ID elective
- Volunteers
  - CDC
  - Rollins School of Public Health
Model

• No funding
  – Use PCC’s existing infrastructure
    • Clinic space
    • Nursing staff
  – Grady provides PharmD time
  – Emory Gen Med provides faculty time
  – Use pharmaceutical company patient assistance programs for medications for uninsured patients
Grady Liver Clinic

OUTCOMES
TILT-C: Internal Medicine Trainees Identifying and Linking to Treatment for Hepatitis C

• Teach residents to implement birth cohort screening
• Identify previously undiagnosed hepatitis C infections
• Link HCV positive patients to care at the Grady Liver Clinic
TILT-C: Design

- **TILT-C Screen**
  Residents educated
  Residents screen

- **TILT-C Link**
  TILT-C staff follow up HCV tests
  Perform outreach and linkage to care

- **TILT-C Care**
  Group Education and Physician visit
  Tailored education and counseling
  Risk assessment
  Vaccination assessment
  HCV RNA testing and genotyping
TILT-C: Results

- **TILT-C Screen**
  - 137 (100%) residents educated one-on-one

- **TILT-C Link**
  - N=4,902
  - 10/2012-8/2014

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>HCV Ab Pos</th>
<th>HCV Ab Neg</th>
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<tbody>
<tr>
<td>Mean age</td>
<td>59</td>
<td>59</td>
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</tr>
<tr>
<td>Female (%)</td>
<td>60</td>
<td>40</td>
<td>60</td>
</tr>
<tr>
<td>Race (%)</td>
<td></td>
<td></td>
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<tr>
<td>AA</td>
<td>92</td>
<td>93</td>
<td>92</td>
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<tr>
<td>White</td>
<td>5.0</td>
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<td>5.0</td>
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<tr>
<td>Insurance (%)</td>
<td></td>
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<tr>
<td>Uninsured</td>
<td>53</td>
<td>49</td>
<td>53</td>
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<tr>
<td>Public</td>
<td>40</td>
<td>49</td>
<td>39</td>
</tr>
<tr>
<td>Private</td>
<td>6.7</td>
<td>1.6</td>
<td>7</td>
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</tbody>
</table>
TILT-C: Testing and Linkage Cascade

- 4902 tested
- 380 HCV Ab positive: 7.8% prevalence
- 290 HCV RNA tested: 76% tested
- 201 HCV RNA positive: 76% prevalence viremia
- 167 attended linkage: 83% linked
Improving Access to Hepatitis C Care for Urban, Underserved Patients Using a Primary Care–Based Hepatitis C Clinic

Lesley Miller, MD; Shelly-Ann Fluker, MD; Melissa Osborn, MD; Xiaoxia Liu, MS; Akillah Strawder, PharmD, CDE

Objective: Chronic hepatitis C affects 200 million people worldwide and is a leading cause of death from liver disease. Effective treatment is available but can be difficult to access for uninsured, urban patients. National organizations have called for improving access to hepatitis C care in these groups. We present an innovative model for expanded...
Outcomes: HCV Treatment

- Pegylated IFN/Ribavirin
- Demographics (n=870)
  - 76% AA
  - 59% uninsured
  - 90% genotype 1
  - 28% advanced fibrosis
  - 67% medical comorbid.
  - 14% treated

<table>
<thead>
<tr>
<th></th>
<th>SVR</th>
<th>Grady Liver Clinic</th>
<th>Atlantic Coast Hepatitis Group</th>
<th>Virahep-C Study Group</th>
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</thead>
<tbody>
<tr>
<td>AA, Genotype 1</td>
<td>19%</td>
<td>19%</td>
<td>28%</td>
<td></td>
</tr>
<tr>
<td>White, Genotype 1</td>
<td>22%</td>
<td>52%</td>
<td>52%</td>
<td></td>
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</tbody>
</table>
Outcomes: First Generation DAAs

- 42 geno 1 patients initiated triple therapy (BOC or TVR) from July 2011 to May 2013
- 48% SVR (Cured)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (%)</th>
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<tbody>
<tr>
<td>Age (mean)</td>
<td>56</td>
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<tr>
<td>Race</td>
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<tr>
<td>AA</td>
<td>38 (90)</td>
</tr>
<tr>
<td>White</td>
<td>4 (10)</td>
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<tr>
<td>Fibrosis stage (N=39)</td>
<td></td>
</tr>
<tr>
<td>0-1</td>
<td>7 (18)</td>
</tr>
<tr>
<td>2</td>
<td>18 (46)</td>
</tr>
<tr>
<td>3 or 4</td>
<td>14 (36)</td>
</tr>
<tr>
<td>Prior Treatment</td>
<td></td>
</tr>
<tr>
<td>Naive</td>
<td>28 (67)</td>
</tr>
<tr>
<td>Experienced</td>
<td>14 (33)</td>
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</tbody>
</table>
Outcomes: New DAAs

- 91 patients initiated SOF based tx from Feb 2014-Feb 2015
- 84% SVR12 (Cured)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (%)</th>
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<tbody>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>AA</td>
<td>74 (81)</td>
</tr>
<tr>
<td>White</td>
<td>16 (18)</td>
</tr>
<tr>
<td>Fibrosis stage (N=68)</td>
<td></td>
</tr>
<tr>
<td>0-1</td>
<td>10 (15)</td>
</tr>
<tr>
<td>2</td>
<td>6 (9)</td>
</tr>
<tr>
<td>3 or 4</td>
<td>52 (76)</td>
</tr>
<tr>
<td>Prior Treatment</td>
<td></td>
</tr>
<tr>
<td>Naive</td>
<td>68 (75)</td>
</tr>
<tr>
<td>Experienced</td>
<td>23 (25)</td>
</tr>
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Barriers

• Lack of Funding
  – Wish list: Patient navigator, social worker, nurse educator, fibroscan, additional PharmD

• Patient population with significant social challenges
  – Financial, housing, social support

• High patient volume
  – 4 month wait for new and follow-up appts
  – Limiting treatment to highest priority (cirrhosis)
Recommendations

• Have confidence that primary care physicians can treat and cure hepatitis C
  – Partner with specialists early on
  – Seasoned faculty can train new faculty
  – Use champions

• Share patient and provider educational material
  – hcvguidelines.org
  – hepatitisc.uw.edu
  – telemedicine
Recommendations

• Partner with established programs to share successes and lessons learned
• Use multidisciplinary teams to maximize treatment success and enhance patient experience
  – Clinical pharmacy
  – Social work
  – Nursing
Summary

- Grady Liver Clinic is a successful model for primary care-based hepatitis C care for urban, underserved patients
  - Provides access to care for uninsured
  - Success with antiviral treatment in a real world setting
  - Provides linkage to care for large scale screening program
- Challenges include funding and capacity
- Future directions include expanding clinic hours and staffing and spreading model beyond Grady
Integrating Hepatitis C Treatment into Primary Care: The CHC Experience

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Middletown, Connecticut
September 16, 2015
Financial Disclosures

Marwan Haddad MD has no financial disclosures to declare.
Outline

- CHC Background
- Rationale for HCV Integration
- Role of Health Centers
- Key Clinical Challenges
- CHC Strategies
- CHC Outcomes
Our Vision: Since 1972, Community Health Center, Inc. has been building a world-class primary health care system committed to caring for underserved and uninsured populations and focused on improving health outcomes, as well as building healthy communities.

CHC Inc. Profile:
- Founding Year - 1972
- Primary Care Hubs – 12
- No. of Service Locations - 251
- Licensed /Total SBHC locations –
  - 21 comprehensive
  - 28 behavioral health only
  - 189 mobile dental
- Organization Staff - 605

Innovations
- Integrated primary care disciplines
- Fully integrated EHR
- Patient portal and HIE
- Extensive school-based care system
- “Wherever You Are” Health Care
- Centering Pregnancy model
- Residency training for nurse practitioners
- New residency training for psychologists

Three Foundational Pillars
Clinical Excellence
Research & Development
Training the Next Generation
Buildings in transformation

- Middletown, CT
- New Britain, CT
- New London, CT
- Danbury, CT
- Waterbury, CT
- Groton, CT
- Old Saybrook, CT
- Bristol, CT
- Clinton, CT
- Enfield, CT
- Stamford, CT
CHC Patient Profile

- Patients who consider CHC their health care home: 130,000
- Health care visits: more than 429,000

### Patient Care Model
- PCMH (NCQA Level 3)
- Advanced access scheduling
- “Planned Care” and the Chronic Care Model
- Integrated behavioral health services
- Comprehensive dentistry/oral health
- Clinical dashboards
- Expanded hours and 24/7 coverage
- Comprehensive HIV/AIDS & Hep C care
- Formal research program
- Residency training for nurse practitioners
- Neighborhood outreach, screening, enrollment

### Top Chronic Diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>Diagnosis</th>
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<tbody>
<tr>
<td>Cardiovascular Disease</td>
<td>Obesity/Overweight</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Chronic Pain</td>
</tr>
<tr>
<td>Asthma</td>
<td>Depression</td>
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</tbody>
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### Care Delivery

- Medical Care & Ancillary Services
- Dental Care
- Behavioral Health Care
- Prenatal Services

### CHC Patient Profile

- Patients who consider CHC their health care home: 130,000
- Health care visits: more than 429,000
Rationale for HCV Integration in 2015

- All oral regimens available for all HCV genotypes.
  - Some as simple as one pill once a day
- Pegylated interferon seldom needed.
- Highly effective
- Very well tolerated
- Short duration of treatment
- Consideration of HCV management in primary care essential to ensure every HCV patient has the opportunity to access curative therapy.
Role of Health Centers

- HCV screening
  - Risk-based and one-time birth cohort screening with HCV Ab.
- Confirmation of HCV infection
  - HCV RNA testing required to confirm infection.
- Counseling
  - HCV transmission/prevention
  - Risks of alcohol use
- Screening in HCV-infected individuals
  - HIV/HAV/HBV
  - Alcohol and substance use disorders
Role of Health Centers

- Vaccination
  - Hep A and B
- Baseline liver assessment
  - CBC, INR, albumin, AST/ALT, bilirubin, alkaline phosphatase, GFR

- Treatment and Referral
  - Patients need to be informed of current effective, well tolerated treatments and referred to provider with HCV treatment expertise.
Key Challenges with Integration in Primary Care

- HCV expertise

- Potential costs /burden to health center
  - HCV medications
    - Coverage restrictions
    - Prior authorizations
    - Patient assistance programs
  - Lab tests, imaging, biopsies
    - Uninsured
    - Imaging/biopsies may not be needed
  - Medical visits
    - On average, about 3 visits during 12 week treatment
Key Challenges with Integration in Primary Care

- Liver fibrosis assessment
  - Interventional radiology
  - Non-invasive alternatives
    - serum markers, transient elastography

- Medication-related issues
  - Adherence
  - Drug-drug interactions
  - Side effects

- Ongoing alcohol and drug use

- Cirrhosis
  - Hepatocellular carcinoma screening
  - Referral to GI/transplant team
CHC Strategies
**CHC Strategies**

- **Identification:**
  - Birth cohort screening part of performance appraisals and planned care dashboard

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Screening Recommendations</th>
</tr>
</thead>
</table>
| Colon Cancer (USPST) | - Begin screening for average risk patients at age 50.  
                      | - Adults 50+: FOBT or FIT every year, sigmoidoscopy every 5 years with                 |
|                      |    high-sensitivity FOBT every 3 years, or colonoscopy every 10 years. Standard           |
|                      |    guaiac tests are not recommended.  
                      |    Discontinue screening at age 75 for patients with history of CRC screening.          |
|                      |    Discontinue screening at age 80 for patients with no history of CRC screening.         |
| Lung Cancer (USPST)  | Asymptomatic adults aged 55 to 80 years who have a 30 pack year smoking history and       |
|                      |    current smoke or have quit with in the past 15 years: Screen annually with low dose   |
|                      |    Computed Tomography until the patient has not smoked for 15 years.                     |
| HCV Screening (CDC)  | HCV screening for individuals born between 1945-1965, at least once.                     |
| HIV Screening (CDC)  | HIV screening been done/offered to patients ages 13-64 at least once.                    |
| Depression Screening | Annual depression screening for adolescents ages 12 and above.                          |
| – adolescents (AAP/USPSTF) |                                               |
| Depression Screening | Annual depression screening for adults ages 18 and above.                                |
| – adults (USPSTF)    |                                               |
| Developmental Screening | See Pediatric section.                                                                  |

**Vaccinations**

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV Vaccine (ACIP)</td>
<td>Female patients: offered/given to patients ages 11-26 years.</td>
</tr>
<tr>
<td></td>
<td>Male patients: offered/given to ages 11-21.</td>
</tr>
<tr>
<td></td>
<td>Male patients with risk factors: offered/given until age 26.</td>
</tr>
<tr>
<td>Tetanus booster (ACIP)</td>
<td>Adult patients: Tdap given at least once; Td every 10 years thereafter.</td>
</tr>
<tr>
<td></td>
<td>Pregnant women: Tdap given during each pregnancy.</td>
</tr>
<tr>
<td>Influenza (ACIP)</td>
<td>Offered/given during the last flu season for indicated patients (chronic</td>
</tr>
</tbody>
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CHC Strategies

- Identification:
  - HCV Ab reflexed to HCV RNA
CHC Strategies

- Expertise:
  - The RW-funded HIV team attended a National Association of Community Health Centers (NACHC) training in HCV care in 2007.
  - Treatment of HCV patients began over the next few years at 3 CHC sites only.
  - Project ECHO replication visit to University of New Mexico (UNM) occurred in 2011. Internal CHC faculty joined UNM’s Project ECHO in 2011 for 6 months.
Project ECHO Origins

“The mission of Project ECHO is to develop the capacity to safely and effectively treat chronic, common and complex diseases in rural and underserved areas and to monitor outcomes.”

Dr. Sanjeev Arora, University of New Mexico

**NEJM 6/2011**

- Prospective cohort study comparing HCV Rx at UNM with Rx by primary care clinicians at 21 ECHO sites in rural areas and prisons in NM.
- 407 patients with no previous treatment
- Primary endpoint was SVR.
- 57.5% at UNM and 58.2% at ECHO sites achieved SVR.
- Serious adverse events occurred in 13.7% at UNM and 6.9% at ECHO sites
The Project ECHO® Model

**Benefits**

- Increased knowledge and confidence to manage complex chronic conditions in primary care
- Increased patient access to evidence-based treatments
- Increased provider satisfaction and retention
- Reduction in unnecessary imaging and other laboratory services
- Reduction in overuse/misuse of specialty, surgical, and procedural services
- Reduction in inappropriate medication usage
What Does Project ECHO Do?

- Builds communities of practice
- Connects primary care providers and their teams with a panel of expert multidisciplinary faculty
- Improves retention of primary care providers
- Provides brief didactic and case-based learning and management
- Improves health care outcomes with evidence-based care plans
- Improves access to specialty care
- Creates a force multiplier
Project ECHO at CHCI – Timeline

- Hepatitis C
- Buprenorphine
- HIV
- Pain Management
- Coaches International

Timeline:
- 2012 JAN
- 2013 JAN
- 2013 FEB
- 2013 MAR
- 2013 APR
- 2013 MAY
- 2013 JUNE
In January 2012, CHC Project ECHO launched to increase access to HCV and HIV care to all CHC sites.

- Combined HCV/HIV sessions held every Friday 12:30 to 2:30 EST
- Referrals made via EHR
- Expert recommendations documented by provider within EHR
- CHC ECHO Faculty consisted of:
  - 2 FP specialists, Psych APRN, PharmD, Nurse, Medical Assistant, Case Manager
- ECHOist participants:
  - 8 sites throughout CT + Homeless program (WYA)
  - Primary care clinics in PA, MA, NJ, and IN.
  - Substance use facility in MA.
<table>
<thead>
<tr>
<th><strong>CHC ECHO HCV/HIV Statistics</strong></th>
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<tbody>
<tr>
<td><strong># ECHO HCV/HIV sessions</strong></td>
</tr>
<tr>
<td><strong># HCV/HIV ECHOist providers</strong></td>
</tr>
<tr>
<td><strong># HCV patients presented</strong></td>
</tr>
<tr>
<td><strong># HCV case presentations</strong></td>
</tr>
</tbody>
</table>
CHC Strategies

- Costs
  - ECHO Provider Time: 1 ½ hours a week blocked.
  - ECHO Faculty Time: 1 ½ hours a week blocked with extra time for preparation/meetings as needed.
  - CHC has sliding fees for medical visits for uninsured.
  - Lab services provided to uninsured at no cost through CHC agreement with Quest.
  - Imaging/biopsies, if needed, for uninsured may be available on payment plans through hospitals.

- Medication coverage
  - Advocating against CT Medicaid coverage restrictions.
  - Prior authorizations handled by medical assistant.
  - Patient assistance programs through companies handled by nurse for uninsured.
  - Specialty pharmacies used.
CHC Strategies

- Ongoing alcohol and drug use
  - Integrated Buprenorphine program at CHC for opioid dependence (grant-funding).
  - Behavioral health integration with medical at CHC.
  - SBIRT being adapted at CHC sites (grant-funding).
  - Application for substance use treatment licensure in progress.
  - Coordination with local mental health and substance use services.
CHC STATISTICS
BIRTH COHORT SCREENING AT CHC

Individuals born between 1945 and 1965 with at least one medical visit in last year
N=14,609

n=7,175 (49%)
n=7,434 (51%)
HCV-infected Individuals at CHC

- HCV Ab+ with RNA done: 91% confirmed (N=221)
- HCV Ab+ with RNA+: 67% infected (N=202)
- HCV RNA+ only: (N=135)
- TOTAL HCV RNA+: 2520 HCV infected patients
16% of 2520 HCV-infected patients have been prescribed treatment.
55% prescribed in the last year alone.
Preliminary CHC HCV Treatment Outcomes

N = 92

- Genotype 1: n = 55
- Genotype 2: n = 17
- Genotype 3: n = 16
- Genotype 4: n = 4

Community Health Center, Inc. Where health care is a right, not a privilege, since 1972.
Preliminary SVR Outcomes

Overall SVR Rate: 55/92 (60%)
Genotype 1/4: 32/59 (54%)
Genotype 2/3: 23/33 (70%)
Conclusions

- HCV integration into primary care is essential to be able to manage the HCV epidemic in the U.S.
- Primary care centers can play an integral role in HCV management and treatment.
- Most management recommendations fall within the purview of primary care and can be easily adopted by health centers.
  - Screening (birth cohort and risk-based)
  - Prevention and transmission counseling.
  - Lab tests
  - Vaccination
  - Drug and alcohol counseling
- Treatment of HCV has now become easier and can be managed in primary care with expert guidance, e.g. Project ECHO models of care delivery.
Thank you!

Marwan Haddad MD, MPH, AAHIVS
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