THE TASK FORCE FOR GLOBAL HEALTH

# Optimization of Screening Strategies

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### Agenda

**Screening Criteria** 

**Screening Roles** 

**Essential Components of Screening Programs** 

Technical and Operational Research



## Public Health Screening Criteria

- 1. The condition sought should be an important health problem.
- 2. There should be an accepted treatment
- 3. Facilities for diagnosis and treatment should be available.
- 4. There should be a recognizable latent or early symptomatic stage.
- 5. There should be a suitable test or examination.
- 6. The test should be acceptable to the population.
- 7. The natural history of the condition should be adequately understood.
- 8. There should be an agreed policy on whom to treat as patients.
- 9. The cost of case-finding should be economically balanced in relation to possible expenditure on medical care as a whole.
- 10. Case-finding should be a continuing process



Wilson Junger, WHO 1968. www.who.int

### **Role of Screening**

Prevention of transmission

• Prevention of disease and mortality

Policy and planning

• Public health surveillance and program evaluation



### **HCV** Testing

- HCV: Antibody + PCR testing
- Lab based and Point of Care

#### Test Patients Born from 1945 through 1965 for Hepatitis C Ask to be tested **Test patients Blood test** for hepatitis C antibody Baby boomers Doctore nurse Born from 1945 and other health through 1965 care providers - Negative -+ Positive + Follow-up RNA blood test No hepatitis C virus infection for hepatitis C virus infection No further + Positive + - Negative action needed Hepatitis C No hepatitis C virus infection virus infection Refer for Connect to medical care further ev Justion No further action needed

### Role of HBV and HCV Screening in Prevention of Transmission

Blood Bank Screening (HBsAg, anti-HCV, PCR testing) 99% reduction in transmission since 1980s 7-14% risk to 1/488,000 (HBV) and 1 /1,200,000 (HCV

Maternal HBsAg testing improves perinatal HBV prevention HBIG/HepB superior to vaccine alone (RR 0.08 vs. 0.28) Maternal anti-viral prophylaxis (i.e., > 6 log<sub>10</sub> HBV copies/mL)

#### Other

Vaccination of household and other susceptible persons Enhance infection control (e.g., HBsAg testing of patients on dialysis, occupational exposures) Enhance harm reduction– (behavior change)

Dodd R, Transfusion 2002. C Lee, BMJ 2006; H Zhang Hepatology 2014; CDC.gov/Hepatitis



### Antiviral Therapy Can Reduce HCV Prevalence Among Injecting Drug Users

5 per 1000 IDUs annually Relative prevalence reduction (%) at 10 years 100 -10 per 1000 IDUs annually 20 per 1000 IDUs annually 90 40 per 1000 IDUs annually 80 -70 -60 -50 -40 -30 -20 -10 -20% 40% 60%

Baseline chronic prevalence

Annually treating 10 HCV infections per 1000 IDU and achieve SVR of 62.5%

Projected to result in a relative decrease in HCV prevalence over 10 years of 31%, 13%, or 7% for prevalence of 20%, 40%, or 60%, respectively

HCV Cure as Prevention

Benefits of HBV and HCV Screening: Linkage to Care and Treatment

- HBV treatment- long term viral suppressive therapy
  - Reduced risk of liver cancer- 50%
  - Reduced risk of all cause mortality- 40%
  - Generic tenofovir \$32 per year.
- HCV treatment- >90% cure with 8-12 weeks of therapy
  - Reduced risk of liver cancer- 80%
  - Reduced risk of all cause mortality- 75%
  - Licensed generics per course ~ \$200
  - Less for others –e.g., \$68 Ukraine; \$75 Pakistan
- Cost- effective or cost-saving







### **Greatest Challenge to Elimination of Pre-mature Mortality Testing and Early Treatment of HBV and HCV Infection**

HBV 257 million Global: Diagnosed 9%; on treatment 1% HCV 71 million Global: Diagnosed: 20%; Treated 4%

HBV 740,000-2.2M US- Diagnosed 60% on treatment 15% HCV 3.5 M US : Diagnosed 50%; Treated 25%



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## **Components of Effective Screening Programs**

- Strategic information to assess disease burden and health system capacity
- Testing policies and plan for implementation
- Civic and political support for implementing partners and target populations
- Capacity to deliver interventions to target populations
- Strategic data to monitor program performance
- Technical and operational research



### WHO Recommendations for HBV and HCV Testing and Treatment

- Testing
  - Risk populations- exposures, clinical illness
    - Exposures- blood, and sexual and household (HBV)
  - All blood donors
  - General population- > 2% or > 5%
     prevalence including HBsAg for pregnant women;
  - Sub-population
    - Birth cohorts
- Treat all persons with HCV



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### HBV Screening in the United States

### >850,000–2.2 million persons with chronic HBV

- 50% are Asian/Pacific Islanders (API); 6-fold mortality risk for API
- HBV testing recommended for persons from countries with >2% prevalence (i.e., Asia, Africa)
- Others at risks- e.g, injection drug use
- Strategies
  - Culturally approach outreach
  - Peer support and navigation
  - □ Need new strategies to keep persons in care

### HBV Linkage to Care Cascade, Three Programs, United States, 2014–2016



L Schillie S, Vellozzi C, Reingold AR. MMWR January 12, 2018 / 67(1);1–31. ee KN, Clin Infect Dis. 2014 Jan;58(1):40-9; MMWR, January 12, 2018, Vol 67,(1);1-31; Abara WE, Qaseem A, Schillie S. Ann Intern Med. 2017;167(11):794-804; Harris AM Public Health Rep. 2016 May-Jun;131 Suppl 2:20-8. . Lok A, McMahon BJ, Brown RS. Hepatology 2016;63:284-306 Harris AM, Chandrasekar E, Wang S. abstract 1773 Hepatology 2017 https://aasldpubs.onlinelibrary.wiley.com/doi/full/10.1002/hep.28800

### HBV Testing and Linkage to Care-The Gambia

Community screening

- Engaged community leaders
- Door-to door solicitation
- Point-of-care HBsAg testing
- Participants
  - Low HBV knowledge
  - No prior testing

Blood bank screening - 90% men

Most inactive chronic carriers- need ongoing monitoring

Of 47 recommended for treatment

- All accepted
- 12 month adherence- 81%
- Loss of HBV DNA- 91%





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### One HCV Testing for Persons Born 1945-1965 United States





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### **Proportion of HCV infected Persons** by Year of Birth- 16 Countries



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## HCV Burden of Disease, HCV Testing and Treatment Cost- Thailand

Total HCV infected 356,670 > 30 yrs of age 343,698 (96%)

52% have advanced liver disease

Focus testing on persons > 30 yrs, born before 1983

HCV treatment cost \$250 per course

HCV diagnosis \$79 (anti-HCV, PCR)

HCV monitoring \$90-180 (PCR)



#### Age range (years)

Wasitthankasem R, Vichaiwattana P, Siripon N, Posuwan N, Auphimai C, et al. (2018) Birth-cohort HCV screening target in Thailand to expand and optimize the national HCV screening for public health policy. PLOS ONE 13(8): e0202991. https://doi.org/10.1371/journal.pone.0202991 https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0202991

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## Strategies that Expand Access to HCV Testing, Care and Cure- United States



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## **Educating Providers and Communities**



### **Reflex HCV Testing**

### **Public-Private Partnerships**

RNA follow-up testing within 30 days of Ab+ result



Total tested: Quest 415,000; LabCorps 319,000

CDC, unpublished data

### **Eliminating Hepatitis C Among US Military Veterans- VA**

- Implementing strategies
  - Standing testing orders/reminders
  - Care algorithms
  - Program evaluation and staff accountability
  - Resources for HCV treatment
- Status
  - -78.8% of Veterans born 1945-1965 screened for HCV
  - ->90% diagnosed; ~15,500 undiagnosed
  - -87,000 treated with all-oral DAAs; 90-95% cure
  - 58,000 remain eligible for treatment; most difficult to engage in care

#### VA is curing Hepatitis C



Tim Morgan viralhepatitisaction.org/summit-presentations

## As Native People and as Cherokee Nation **Citizens, We Must Keep Striving to Eliminate** Hepatitis C." American Indians have highest HCV incidence and mortality



- Cherokee Nation launched elimination program in 2015 Universal HCV testing for patients 20-69 yrs.
  - Training and electronic tools to prompt testing
  - □ Care managed by mid-level providers (e.g., pharmacists)
  - □ Health system strategies to pay for testing and treatment
  - Contact tracing to identify new HCV infections
  - □ Partnerships with CDC, state/local health, NGOs



Mera J, personal communication MMWR Morb Mortal Wkly Rep 2016 May 13:65(18):461-6

#### "Chief Bill John Baker

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### Elimination Programs Improve Access Country of Georgia Example

- ~150,000 HCV RNA+ persons; 5.4% prevalence
- Goal: 90% diagnosed; 95% treated; 95% cured by 2020
- 40,000 HCV RNA+ persons treated (5/15-10/2017)
- Key tools
  - National planning
  - Data to guide and evaluate program
  - Health system strengthening
  - Political support
  - Partnerships Gilead, Abbott, CDC, State, WHO,





### **Evaluate Quality of Hepatitis Laboratory Testing WHO Assessment Tool Hep-LAT (10 Quality System Elements)**



DVH WIP | June 13, 2017

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### Increase Priority for Neglected Populations: The Incarcerated

Incidence 16.4 per 100py

Prevalence -26% ; 2.2M

- > Testing/treatment cost-effective \$20-29K/QALY
- Only 6 studies to guide HCV testing
- Fewer studies of care and treatment



Any National Campaign to Eliminate Hepatitis C Would Almost Certainly Involve Prisons." —

#### The New York Times

March 18, 2018

Canary L, APHA 2016; CDC unpublished data He T, Ann Intern Med. 2016 Jan 19;164(2):84-92 Hochstatter KR, Health Justice. 2017 Oct 30;5(1):10.

### New Target Populations: HCV Infected Mothers

- Increased HCV among pregnant women
   In 2014, 1 of 308 U.S. births were to HCV+ mothers
  - 1 of 63 in Kentucky (high incidence state)
- > 6-12% transmission risk for infants
- > ~1700 HCV+ infants born in 2015
- Consider routine testing of pregnant women
- > New strategies for implementation
- One clinical trial of anti-viral treatment of pregnant women NCT02683005

Rates of Infants Born to HCV-Infected Mothers, Kentucky, 2011–2014



Adapted from: Koneru A, Nelson N, Hariri S, MMWR 2016 Jul 22;65(28):705-10.

## **Consider Screening All Adults for HCV infection**

- Response to large increases in HCV incidence (United States)
- Increase opportunities for treatment as prevention
- Recognized benefits of early treatment
- Integrate with other strategies- i.e., HIV
- Cost-effective
  - United States
    - \$28,000/QALY with 280,000 additional cures
    - \$11,378/QALY gained when HCV prevalence > 0.07%
  - France €31,100/QALY.

Eckman M, Clin Gastroenterol Hepatol. 2018; Deuffic-Burban S ; J Hepatol. 2018 Barocas JA Clin Infect Dis. THE TASK FORCE 2018

### **Improve Tests for Current HCV infection**

- HCV core antigen testing: low sample volume, less pristine sampling; rapid turn around (1 hour), CE marked
- High correlation with HCV RNA
- High sensitivity/ specificity; in 33 studies 93% /99%
- Reduced sensitivity at <3000 HCV RNA</li>
- · Not widely commercially available
- Point of care PCR: rapid turn around (105 minutes vs 5 hours for lab-based) limit of detection (10 to 10 8) similar to lab based PCR no biosafety handling, CE marked
- Sensitivity/ specificity 100%/94%
- Need POC



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## Task Force for Global Health Program for Viral Hepatitis Elimination



Making Hepatitis B History

www.hepb.org



