ADVOCACY TO ENSURE THE PRIORITIZATION OF HEPATITIS C IN PEPFAR COPS

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TREATMENT ACTION GROUP

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TAKEAWAY MESSAGES

• Treating HIV/HCV coinfection can be a “win”
• We have a cure and affordable generics!
• We have a global strategy & guidance, with African regional plan on the way
• We don’t have dedicated global viral hepatitis funding & PEPFAR needs to step up!
• There is some viral hepatitis language in COP guidance & we can influence country plans
WHY HEPATITIS? WHY NOW?

2.3M HIV/HCV Coinfected

Global burden among people who inject drugs:

15.6M people (3.2M women) who inject drugs (CI 2-23.7M)

8.2M HCV Ab+ (52.3%)

2.8M HIV+ (17.8%)

+400K HCV; +720K HBV annual deaths

Source: WHO 2017; Fajardo E. 2018 June; Degenhardt L et al. 2017
WHY HEPATITIS? WHY NOW?

Number of people living with:

Number of people in millions

<table>
<thead>
<tr>
<th>Disease</th>
<th>Number of People (in millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV</td>
<td>257</td>
</tr>
<tr>
<td>HCV</td>
<td>71</td>
</tr>
<tr>
<td>HIV</td>
<td>34</td>
</tr>
<tr>
<td>HBV / HIV</td>
<td>2.7</td>
</tr>
<tr>
<td>HCV / HIV</td>
<td>2.3</td>
</tr>
</tbody>
</table>

Source: WHO 2017; amfAR/TREAT Asia 2019
WHY HEPATITIS? WHY NOW?

We have a cure and affordable generics!

**HBV**
Birth dose & preventative vaccine
95% effective

**HCV**
No vaccine; Direct-acting Antivirals
Pangenotypics = 95% SVR 12/24

List prices of SOF/DAC to cure Hepatitis C, by country

<table>
<thead>
<tr>
<th>Country</th>
<th>Price of a 12-week course in USD</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA (NADAC)</td>
<td>$142,710</td>
</tr>
<tr>
<td>Denmark</td>
<td>$104,723</td>
</tr>
<tr>
<td>Norway</td>
<td>$96,404</td>
</tr>
<tr>
<td>Germany</td>
<td>$87,632</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>$84,281</td>
</tr>
<tr>
<td>Sweden</td>
<td>$76,757</td>
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<tr>
<td>France</td>
<td>$78,280</td>
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<tr>
<td>Argentina</td>
<td>$50,059</td>
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<tr>
<td>Saudi Arabia</td>
<td>$47,972</td>
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<tr>
<td>Spain</td>
<td>$37,729</td>
</tr>
<tr>
<td>Brazil</td>
<td>$33,800</td>
</tr>
<tr>
<td>Australia</td>
<td>$29,361</td>
</tr>
<tr>
<td>Thailand</td>
<td>$10,500</td>
</tr>
<tr>
<td>Egypt</td>
<td>$9,906</td>
</tr>
<tr>
<td>India</td>
<td>Estimated $48</td>
</tr>
</tbody>
</table>

Source: amfAR/TREAT Asia 2019 June; Hill A. 2018 Oct; Fajardo E. 2018 June

CHAI: $80/person
Test & Treat
WHY HEPATITIS? WHY NOW?

GLOBAL HEALTH SECTOR STRATEGY ON
VIRAL HEPATITIS
2016–2021
TOWARDS ENDING VIRAL HEPATITIS

- 90 percent reduction in incidence;
- 65 percent reduction in mortality;
- 90 percent of people infected with hepatitis C to be diagnosed; and
- 80 percent of people diagnosed to be treated.³
“...testing and treatment for viral hepatitis...would increase resource use by about 1%, while decreasing deaths by 5% and improve healthy life years by 10% leading to direct and indirect economic benefits...

...investing in viral hepatitis elimination requires strengthening health systems; as well as ensuring the availability of adequate, sustained financial resources and trained and motivated human resources to conduct hepatitis specific activities...”

Cairo Declaration on Viral Hepatitis in Africa
Ratified by African Union member states 1-2 August 2019
COUNTRIES WITH NATIONAL VIRAL HEPATITIS PLANS

- Of 189 countries with info, 111 (58%)* have national hep plans
- 32 plans (or 29%) mention key populations & have specific treatment inclusion strategies
- In Africa, 14 of 55 countries completed plans; 10 are now developing plans; African Union plan in 2020
- PEPFAR countries w/high hep burdens: 21 have plans/4 in development
  Angola, Brazil, Burkina Faso, Burma, Cambodia, Cameroon, Cote d’Ivoire, Democratic Republic of Congo, Ethiopia, Ghana, India, Indonesia, Kazakhstan, Kenya, Kyrgyzstan, Lao PDR, Liberia, Mali, Nigeria, Philippines, Rwanda, Senegal, Sierra Leone, South Africa, Tajikistan, Tanzania, Thailand, Uganda, Ukraine, and Vietnam
- Hepatitis/Harm Reduction in PEPFAR COPs: Angola, Asia/Asia, Barbados, Brazil, Botswana, Burkina Faso, Burma, Burundi, Cambodia, Caribbean, Central America, Cameroon, Cote d’Ivoire, Dominican Republic, Democratic Republic of Congo, El Salvador, Eswatini, Ethiopia, Ghana, Guatemala, Guyana, Haiti, Honduras, India, Indonesia, Jamaica, Kazakhstan, Kenya/Kenya, Kyrgyz Republic, Lao PDR, Lesotho, Liberia, Malawi, Mali, Mozambique, Namibia, Nepal, Nicaragua, Nigeria, Panama, Papua New Guinea, Philippines, Republic of Tajikistan, Rwanda, Senegal, Sierra Leone, South Africa, South Sudan, Surinam, Tanzania, Thailand, Togo, Trinidad & Tobago, Uganda, Ukraine/Ukraine, Vietnam/Vietnam, Zambia, Zimbabwe

Source: WHO Policy Brief 2019; MSF Analysis 2019; mapCrowd 2019
WHAT WE HAVE

$19B
For 2020-2022

- HIV global funding
  - $14B raised for Global Fund (2020-2022) = 15%
  - PEPFAR flat funded since 2010
  - US: $6.8B (FY19) = $5.4B for bilateral programs & $1.35B for Global Fund

$500M
per year

- Viral hepatitis funding
  - < 1/10th of what we need
  - Missing big donor for viral hep & harm reduction

$188M
Allocated in 2016

- Harm reduction
  - Allocated by Global Fund
  - Includes NSP, OST & naloxone
  - “Lost decade”: flat funded (2007-2016)
  - Equivalent to 4¢ per person who injects drugs per day

WHAT WE NEED

$26.2B
By 2020

- Estimated Total

$23.9B
By 2030

- Estimated Total

$51B
To eliminate viral hepatitis by 2030

$2.3B
Estimated global need

Source: UNAIDS; Global Fund; WISH Report; Health GAP; KFF; HRI; INPUD; Bridge J et al. 2015
WHAT DOES PEPFAR 2020 COP GUIDANCE ALREADY SAY ABOUT HEP C?

- **Screening:** “In low-prevalence and concentrated epidemics, HIV testing and counselling is only recommended for adults, adolescents, and children who are: People with sexually transmitted infections, TB, or *viral hepatitis*” (6.3.1.7)

- **Community-based testing:** “Studies show that HIV testing uptake among key populations are highest when combined with testing for TB, STIs, and/or *hepatitis* but somewhat lower when combined with screening for chronic conditions” (6.3.1.8)

- **Diagnosis:** “diagnose and monitor multiple diseases, including HIV and TB but also *hepatitis C*…” References GeneXpert platforms (6.6.1.3)
WHAT DO WE WANT INCLUDED?

• Similar to Global Fund, UNITAID we want PEPFAR to invest in co-infection programs, which can catalyze broader viral hepatitis programs

• Standalone section on HIV/HCV coinfection

• PEPFAR should increase funding for harm reduction and comprehensive package of viral hepatitis services (including HBV vaccination, NSP, OST, naloxone) for people living with or at risk for HIV

• Prevention and education activities
  • 2.3.3 Client-Centered Prevention \( \rightarrow \) include people who use drugs
  • 6.2 Prevention \( \rightarrow \) Align with WHO hepatitis guidelines \( \rightarrow \) “…Prevention services should promote health and treatment literacy about viral hepatitis transmission and prevention, should offer linkage to viral hepatitis testing, DAA treatment, and HBV vaccination for people at highest risk, including people who use and inject drugs. In addition, prevention services should advocate and implement a comprehensive package of harm reduction interventions…”
WHAT DO WE WANT INCLUDED?

- **6.3 Case Finding** → PEPFAR can cover the purchase of GeneXpert HCV cartridges, ABBOTT RealTime, and Roche Cobas Taqman HCV assays, sample transport, and laboratory network strengthening to integrate viral hepatitis testing using existing HIV infrastructure. PEPFAR can cover training and support for the National AIDS Program and National Viral Hepatitis Program to update national guidance on diagnostics to move towards simpler, decentralized diagnostics algorithms that include point-of-care testing.

- **6.3.1.7 Optimized Provider Initiated Testing and Counseling (PITC)** → “subpopulations of increased risk...should be tested for HIV and viral hepatitis in Antenatal Care Clinics, TB clinics, STI, MAT, clinics, harm reduction sites, malnutrition clinics (for children), and for hospitalized patients...”

- **6.3.1.8 Community-Based Testing** → “…Programs should consider incorporating HIV and HCV antibody self-testing into community-based testing strategies where appropriate…”

- **6.4 Linkage to Treatment** → “…with highly effective and safe pangenotypic direct-acting antivirals, people with HCV can effectively be cured and not transmit the virus if accurate, appropriate prevention education and access to harm reduction materials are in place. Linkage to early HCV treatment for people who are HIV/HCV can prevent further liver damage and improve HIV and health outcomes…”

- **6.5 Optimizing HIV treatment and care** → include integration of viral hepatitis into HIV diagnostics algorithm
WE NEED A COMPREHENSIVE HEPATITIS C PACKAGE OF SERVICES FOR PEOPLE WHO USE AND INJECT DRUGS!

Achieving hepatitis C virus (HCV) elimination by 2030 depends on how countries fund prevention, testing, treatment, and care and how they include HCV in efforts for universal health coverage. Investing in elimination requires national programs to provide services for key populations, particularly people who use and inject drugs who are disproportionately affected by the virus. Harm reduction, based on unconditional access to health and human rights, is a prerequisite for reaching people who use and inject drugs and connecting them to care.

This fact sheet helps advocates to demand from their governments a comprehensive hepatitis C package of services for people who use and inject drugs. Noting the political realities that certain provisions may not be available in some countries, we strive to see all these services, based on decades of public health evidence, implemented together.

**Stronger health systems**
- Fair living wage of community health workers with lived experience
- Decriminalize drug use, possession, and low-level drug sales and end mass incarceration of people who use drugs
- Integrated services for other infectious diseases
- HCV/harm reduction sites provide referral services
- High quality services
- Fully fund hepatitis C and harm reduction services in national budgets

**Testing**
- Decentralised, simple, high quality and affordable hepatitis C testing for people who use drugs

**Treatment**
- Affordable, universally accessible treatment for people who use drugs

**Prevention**
- Sufficient number of syringes and access to opioid substitution therapy (OST)
- Overdose and prevention management
- Destigmatising, accurate information about HCV tailored for PWUD
- Comprehensive prevention and sexual health services as part of a general health package for people who use drugs

**Post-treatment monitoring**
- Liver damage and liver cancer screening
- Testing and treating for reinfection

“It’s been more than 5 years since we cured hepatitis C... where’s my package?”

hepCoalition
INFLUENCING COUNTRY PLANS

INDIA
- COP18 “…PEPFAR India’s program in the North East will strengthen existing and implement new demonstration projects to reach highly vulnerable unreached male and female PWID with the core package of harm reduction services. The demonstration projects include a community mentoring program focused on this group, including young PWID, and linking this unreached population to Test and Start…”

KENYA
- PEPFAR linked people to test/treat, HBV vaccination, and harm reduction services, targeting key populations (PWID, incarcerated people). Doesn’t cover NSP, but MAT, counseling, human resources.
- COP17 “The PEPFAR-supported KP program provides a comprehensive package of biomedical and behavioral package of services for prevention, diagnosis and treatment of HIV, sexually transmitted diseases and viral hepatitis…”

TANZANIA
- PEPFAR in partnership with Global Fund and Government supporting harm reduction services (commodities based in historical consumption).
- “PEPFAR/T contributes with GFATM and the GOT to the total country needs for ART, rapid test kits, EID, and viral load commodities by providing them to the central medical stores for distribution…Harm reduction supplies will be supported by PEPFAR/T through IPs who provide harm reduction services…”

UKRAINE
- PEPFAR in partnership with Global Fund & other donors, included HCV testing/treatment, to address high incidence and transmission among MSM & PWID & their sexual partners. Includes access to generic DAAs. Harm reduction as part of cost-effective public health strategy with MoH.
EXCUSES & COUNTER-ARGUMENTS

• Not part of PEPFAR’s mission/priorities
  • Viral hepatitis *is* part of “meeting patients where they are with what they need”

• Asked to do more with less $

• DAAs are too expensive

• Won’t fund needles/syringes (federal ban)
  • HCV diagnosis & treatment and optimized harm reduction improve health outcomes for PWID
TAKEAWAY MESSAGES

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WHY HEPATITIS? WHY NOW?

• HBV/HCV = silent diseases

• Causes liver disease & liver cancer

• Liver damage from HCV happens slowly, progresses more quickly in people living with HIV

• HIV/HCV coinfection makes treating HIV more complicated (need to check drug-drug interactions) & can increase liver toxicity

• Check liver health. Liver function tests = opportunities for coinfection testing

• 4% risk of mother-to-child transmission of HCV, yet no clear protocols for screening/testing pregnant womxn or safety of DAAs during pregnancy

• People living with HIV, taking ARVs, can reduce risk of HIV & HCV transmission
Figure 2
U.S. Funding for the President’s Emergency Plan for AIDS Relief (PEPFAR), FY 2004 - FY 2020 Request

In Millions

- Global Fund
- Bilateral HIV

2020 Request

$4,889

$958

$3,931

2020

NOTES: PEPFAR was created in 2003 and funding began in FY04. While PEPFAR technically includes funding for bilateral HIV, TB, and the Global Fund to Fight AIDS, Tuberculosis and Malaria, this analysis focuses on funding for bilateral HIV and the Global Fund. HIV includes funding through State/OGAC, USAID, CDC, NIH, and DoD. Global Fund includes contributions provided through the State Department, USAID, and NIH. FY13 includes the effects of sequestration. FY19 is based on funding provided in the “Consolidated Appropriations Act, 2019” (P.L. 116-6) and is a preliminary estimate. Some funding for HIV programs through the Economic Support Fund (ESF) account at USAID is not yet known for FY18, FY19, and the FY20 Request and is assumed to remain at prior year levels.


Source: KFF
ADDITIONAL RESOURCES

- TAG 2019 letter & public comments to PEPFAR
- Advocacy materials: hepcoalition.org
- Training curriculum, treatment & diagnostics literacy materials: treatmentactiongroup.org