ACIP Evidence to Recommendations Framework

Use of HepA Vaccines among Persons Living with HIV

Advisory Committee on Immunization Practices

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ACIP Evidence to Recommendations (EtR) Framework

- Policy question
- Background
- Criteria

1. Is the problem a public health priority?
2. How substantial are the desirable anticipated effects?
3. How substantial are the undesirable anticipated effects?
4. Do the desirable effects outweigh the undesirable effects?
5. What is the overall certainty of the evidence for critical outcomes? GRADE
6. Does the target population feel that the desirable effects are large relative to the undesirable effects ?
7. Is there important uncertainty about or variability in how much people value the main outcomes?
8. Is the option acceptable to stakeholders?
9. Is the option a reasonable and efficient allocation of resources?
10. Is the option feasible to implement?

- Other considerations
- Balance of consequences
- ACIP recommendation

Policy question

Should routine two-dose* vaccination vs. no routine vaccination to prevent hepatitis A be given to adult HIV-positive persons regardless of another indication for vaccination?

Population	Adult HIV-positive persons regardless of another indication for vaccination
Intervention	Routine two-dose hepatitis A vaccination
Comparison	No routine two-dose hepatitis A vaccination
Outcomes of interest	▪ Hepatitis A Infection ▪ Mild Adverse Events ▪ Serious Adverse Events

***Note: Though the question refers to two-doses, routine vaccination can also consist of a 3-dose schedule when combined hepatitis A and B vaccine (Twinrix®) is administered**

Background

- Data suggest up to 87% PWHIV are susceptible (anti-HAV negative) to HAV infection[1-6]
  - Of newly diagnosed PWHIV, 75% are at risk for HAV infection[2]
- Medical Monitoring Project (MMP) shows 40.1% PWHIV had no indication for HepA vaccination[7]
- Of HAV cases that reported risk factors*, 56.2% indicated no risk exposures/behaviors for HAV[8]

*45.7% HAV case reports were missing risk data

1. 1. DeGroote 2018; 2. Moon 2018; 3. Adejumo 2010; 4. Sun 2009; 5. Overton 2007; 6. Sheth 2006; 7. CDC MMP 2016; 8. CDC Viral Hepatitis Surveillance 2016

Criteria 1: Is the problem a public health priority?

JUDGEMENTS:

☐ No ☐ Probably No ☐ Uncertain ☐ Probably Yes ☒ **Yes** ☐ Varies

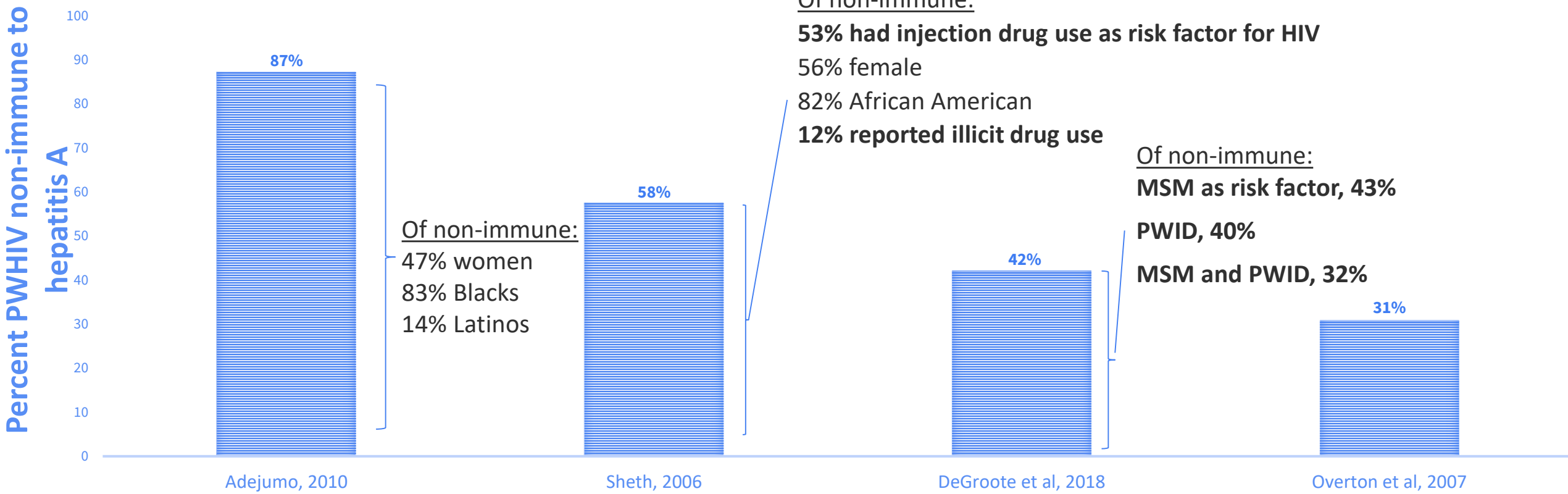
RESEARCH EVIDENCE:

- **PWHIV are at increased risk of HAV infection.[1,2]**
  - **Immunocompromised state**
  - **Missed opportunities for vaccination**
- **Outbreaks that include PWHIV can have prolonged HAV transmission.[3, 4]**
  - **HAV viremia in PWHIV tends to be higher and more durable.[3]**
- **IDSA[5] and 11 other review articles recommend vaccinating all PWHIV. [1, 6-15]**
- **Spain, Italy, and Australia report routinely vaccinating all PWHIV. [16-20]**

1. Koziel 2007; 2. Lin 2017; 3. Puoti 2012; 4. Yotsuyanagi et al, 1996; 5. Aberg 2013; 6. Crum-Cianflone 2014; 7. Pham 2011; 8. Crane 2009;
9. Kresina 2007; 10. Schiff 2007; 11. Brook 2006; 12. Gleeson 2006; 13. Sidiq 2006; 14. Laurence 2005; 15. Kwong 1999
16. Mena 2015; 17. Lugoboni 2012; 18. Turnbull 2011; 19. Rivas 2007; 20. Van Damme 2003

Criteria 1: Public Health Priority

A substantial portion of PWHIV remain non-immune to HAV infection



N=244, New York HIV clinic 2007-2008

N=222, Baltimore HIV clinic 1999-2002

N=8695, Medical Monitoring Project PWHIV who are MSM and/ or PWID 2009-2012

N=906, Wash U Active HIV clinic patients, 2007

Criteria 2: How substantial are the desirable anticipated effects? (Beneficial effects of vaccination)

JUDGEMENTS:

☐ Minimal ☐ Small ☐ Moderate ☒ **Large** ☐ Don't know ☐ Varies

RESEARCH EVIDENCE:

- **HAV infection may increase HIV replication (potentially increasing HIV transmission).[1]**
- **HAV infection in PWHIV is prolonged and can lead to longer transmission period.[1-9]**
- **HepA vaccine is a highly effective vaccine in the general population.[10]**
  - **Seroconversion rates in PWHIV are 49.6–94%.[11]**

1. Gallego 2011; 2. Lee 2018; 3. Ciccullo 2018; 4. Comelli 2018; 5. Lin 2017; 6. Ida 2005; 7. Laurence 2005; 8. Fonquernie 2001; 9. Lombardi 2019; 10. Fiore 2006; 11. Mena 2015

Criteria 3: How substantial are the undesirable anticipated effects? (serious adverse events)

JUDGEMENTS:

☒ **Minimal** ☐ Small ☐ Moderate ☐ Large ☐ Don't know ☐ Varies

RESEARCH EVIDENCE:

- **HepA vaccine is safe.[1-3]**
- **Similar rates of serious adverse events in PWHIV vs. HIV-negative.[4]**
  - **No unexpected vaccine adverse events reported among PWHIV, 1990-2016.[5]**
- **HepA vaccine does not increase HIV viral load, CD4 cell count, or progression to AIDS.[3,4,6-9]**

1. WHO 2013; 2. Fiore 2006; 3. André 2002; 4. Dlamini 2018; 5. Su 2018; 6. Phung 2012; 7. Shire 2006; 8.Kemper 2004; 9. Wallace 2003

Criteria 4: Do the desirable effects outweigh the undesirable effects?

JUDGEMENTS:

☐ No ☐ Probably No ☐ Uncertain ☐ Probably Yes ☒ **Yes** ☐ Varies

RESEARCH EVIDENCE:

- **Protection against HAV in PWHIV can be achieved, despite lower seroconversion rates compared with HIV-negative population.[1-3]**

- **Out of 130 PWHIV, 85% maintained seropositivity 6-10 years after a two-dose vaccine series.[4]**
  - **Vaccination at higher CD4+ counts is associated with better vaccine-induced immune response.[1,4-7]**

1. Mena 2015; 2. Crum-Cianflone 2014; 3. van Damme 2003; 4. Crum-Cianflone 2011; 5. Huang 2019; 6. Armstrong 2010; 7. Kemper 2003

Criteria 5: What is the overall certainty of the evidence for critical outcomes? GRADE

RESEARCH EVIDENCE: Outcome measures included in evidence profile

OUTCOME	IMPORTANCE
Benefits	
(1) Hepatitis A infection	Critical
Harms	
(2) Mild adverse events (any)	Important
(3) Serious adverse events (any)	Critical

Criteria 6: Does the target population feel that the desirable effects are large relative to the undesirable effects?

JUDGEMENTS:

☐ No ☐ Probably No ☐ Uncertain ☒ **Probably Yes** ☐ Yes ☐ Varies

RESEARCH EVIDENCE:

- **Few have studied PWHIV preferences regarding HAV.**

- **Reasons for non-vaccination:[1]**
  - **Not recommended by providers**
  - **Lack of expected effectiveness**
  - **Fear of vaccine adverse effect**

1. Zadeh 2010

Criteria 7: Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENTS:

☐ No ☒ **Probably No** ☐ Uncertain ☐ Probably Yes ☐ Yes ☐ Varies

RESEARCH EVIDENCE:

- **Few studies specific to the PWHIV on valuing protection against HAV.**

- **Among people who use injection drugs (PWID) from five U.S. cities (24.2% PLWH), convenience was the important determining factor for initiating HepA/HepB vaccination.[1]**

1. Campbell 2007

Criteria 8: Is the option acceptable to stakeholders?

JUDGEMENTS:

☐ No ☐ Probably No ☐ Uncertain ☐ Probably Yes ☒ **Yes** ☐ Varies

RESEARCH EVIDENCE:

- **Parallels to recommendations for HepB vaccination in PWHIV.[1]**
  - **Similarly, lower seroresponse to HepB vaccine for people with low CD4.**
  - **Recommended that all HIV patients receive their first dose of HepB during their first HIV care visit after having their HBV serologies drawn.**

- **This option is safe and effective for PWHIV and less confusing for providers.[1]**

1. J. Weiser 2019, communication. CDC Division of HIV/AIDS Prevention.

Criteria 9: Is the option a reasonable and efficient allocation of resources?

JUDGEMENTS:

☐ No ☐ Probably No ☐ Uncertain ☒ Probably Yes ☐ Yes ☐ Varies

RESEARCH EVIDENCE:

- **Adult hepA vaccines are licensed only for certain high-risk groups, and cost effectiveness data on its use for these indications are limited.[1,2]**

- **Outbreak response incur medical cost, productivity losses, disruption of other public health services, and diversion of public health resources and extensive human resources.[3,4]**
  - **Cost of PWID outbreak[1] (n=590, Washington): $3.3 million**
  - **Cost of MSM outbreak[1] (n=136, Ohio): $520,039**

- **Cost of routine immunization through HIV & primary care clinics may be lower per capita than cost of large, rapid vaccination campaigns for outbreak response.[1-4]**

1. Luyten 2009; 2. O'Connor 1999; 3. Epson 2016; 4. Van der Hilst 2009

Criteria 10: Is the option feasible to implement?

JUDGEMENTS:

☐ No ☐ Probably No ☐ Uncertain ☒ Probably Yes ☐ Yes ☐ Varies

RESEARCH EVIDENCE:

- **Simplifying provider guidance may improve protection of at-risk PWHIV.[1,2]**
- **Vaccine response improves if vaccinated earlier in the course of HIV infection[3], when patients have higher initial CD4 counts[4-9] and lower HIV RNA viral load.[6, 10, 11]**
- **Despite recommendations to vaccinate based on specific risk factors, there is inadequate screening & vaccination for HAV among PWHIV, even in HIV clinics.[1, 5, 12]**
  - **In a US study, 23.3% eligible outpatient PWHIV received 1 dose.[1]**
  - **In a British study, HepA vaccine was indicated in 75% of PWHIV and had been delivered to 36% of eligible individuals.[12]**

1. Tedaldi 2004; 2. Mena 2015. Medicina Clínica.; 3. Crum-Cianflone 2014; 4. Kemper 2013; 5. Kourkounti 2013; 6.Sell 2013; 7. Mena 2012; 8. Rimland 2005; 9. Wallace 2004; 10. Tseng 2013; 11. Overton 2007; 12. Quinn 2012

Other considerations

PWHIV may experience milder clinical course of hepatitis A virus infection because of less immune response and liver injury, but infection is prolonged and can lead to longer transmission period.

- **In early small studies, PWHIV infected with hepatitis A virus developed increased HIV load, increased liver enzyme levels, or significant declines in CD4 after pausing ART[1-3].**
  - **HIV viral load increased in 38% of PWHIV with HAV[4]**
  - **ALT > 5x normal limits for >2 weeks after HAV diagnosis, indicating prolonged hepatitis A illness.[1]**
- **Larger recent studies showed less severe, but prolonged HAV course[5-13]**
  - Host immune injury is believed to be the main pathogenic mechanism of liver injury in HAV. Lower levels of ALT in HIV+, supports this hypothesis.

1. Costa-Mattioli 2002; 2. Ridolfo 2000; 3. Wallace 1998; 4. Gallego 2011; 5. Lee 2018; 6. Ciccullo 2018; 7. Comelli 2018; 8. Lin 2017
9. Gallego 2011 10. Ida 2005; 11. Laurence 2005; 12. Fonquernie 2001; 13. Lombardi 2019

Work Group Considerations:

PWHIV is a risk group for HepA vaccination vs. PWHIV is not a risk group for HepA vaccination

- **Factors favoring vaccination of PWHIV:**
  - **HAV infection may increase HIV replication (potentially increasing HIV transmission)**
  - **Resolution of HAV infection may be delayed (potentially prolonging infectious period)**
  - **Up to 40% of PWHIV do not have a risk factor for which HepA vaccination is otherwise recommended**
    - **For PWHIV with an existing risk factor for HepA vaccination, another opportunity for vaccination would be provided for PWHIV who are missed or who do not seek services for other risk factors**
  - **Vaccine is safe and efficacious in PWHIV**
- **Factors not favoring vaccination of PWHIV:**
  - **Illness from HAV infection may be less severe**
  - **Seroconversion may be lower or take longer among PWHIV vaccinated with low CD4 counts**
  - **Immunity may wane in PWHIV with low CD4 counts**
  - **HIV infection alone is not a risk for HAV infection**

Balance of consequences

- ☐ Undesirable consequences clearly outweigh desirable consequences in most settings
- ☐ Undesirable consequences probably outweigh desirable consequences in most settings
- ☐ The balance between desirable and undesirable consequences is closely balanced or uncertain
- ☒ Desirable consequences probably outweigh undesirable consequences in most settings
- ☐ Desirable consequences clearly outweigh undesirable consequences in most settings
- ☐ There is insufficient evidence to determine the balance of consequences

Should routine two-dose vaccination vs. no routine vaccination to prevent hepatitis A be given to adult PWHIV, regardless of another indication for vaccination?

Type of recommendation

☐ We recommend against the intervention

☐ We recommend that the intervention not be routinely recommended for all persons but be available for individual clinical decision-making

☒ We recommend the intervention

☐ We do not recommend the intervention at this time

Future Considerations

- **If hepatitis A vaccination is recommended for PWHIV:**
  - Consider additional protection with immunoglobulin and/or additional vaccine following a known high risk exposure (e.g., household), regardless of vaccination history
  - Consider periodic anti-HAV testing and/or booster doses for persons with an ongoing risk for exposure, as with hepatitis B
  - Evaluate data on vaccine effectiveness among persons living with HIV:
    - Proximity of vaccination to HIV diagnosis
    - CD4 count at vaccination and at exposure to hepatitis A virus

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