

ACIP Evidence to Recommendations Framework

Homelessness as a risk group

Advisory Committee on Immunization Practices

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ACIP Evidence to Recommendations Framework

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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?

- Balance of consequences
- ACIP recommendation

Policy question

Policy question: Should routine inactivated two dose hepatitis A vaccination be recommended for protection against hepatitis A among persons experiencing homelessness?

Population	Homeless (all ages)
Intervention	Inactivated Hepatitis A (HepA) vaccine administered as a two dose series
Control	Unvaccinated homeless individuals
Outcomes	Benefits: <ul style="list-style-type: none">• Reduction in disease burden (Hepatitis A virus [HAV]-related disease and fulminant hepatitis A)• Protection against HAV related disease (efficacy, immunogenicity) Harms: <ul style="list-style-type: none">• Local reactions: injection site pain/tenderness, erythema, fever, malaise, headache, loss of appetite drowsiness, irritability• Systemic adverse events: anaphylaxis, transient purpura, interference with other vaccines

Background

Background

- In the U.S., approximately 3 million persons, 1% of the population, are homeless in a given year.
- Rates of homelessness have been increasing for the last decade. Men, women and children of all ages and ethnicities are affected.
- In 2017, in a single night more than 553,742 people experienced homelessness in the United States (HUD, 2017).
- Individuals experiencing homelessness have an increased risk of mortality ranging from 1.5 to 11.5 times the risk in the general population (Gambatese et al, 2013).

Background

- Community health centers provide preventive and primary health services to meet the specific needs of persons experiencing homelessness.
- Thirty four states expanded Medicaid, leading to an increase in coverage and access to care among homeless (National Healthcare for the Homeless Council, 2018).
- Congregate living conditions increase the risk of disease transmission, which can result in outbreaks (Tjon et al, 2005).

Background

Vaccinations are critical to the prevention of disease in such individuals.

- Due to limited access to healthcare, and low rates of insurance coverage, majority of homeless adults have no protection from vaccine preventable diseases.
- Vaccine induced antibodies persist for 20 years in adults and detectable antibodies were estimated to persist for 40 years or longer based on mathematical modeling and anti-HAV kinetic studies (Theeten et al, 2015).
- Appropriate street/shelter based interventions for targeted populations are the most efficient methods for mass vaccination of the homeless.
- Systematic vaccination against HAV along with hepatitis B virus (HBV), influenza, streptococcus pneumonia and diphtheria is strongly recommended. National public health programs specific to the homeless population are required (Badiaga et al, 2008).
- Vaccines are a cornerstone in preventing spread of infectious diseases and in the prevention of future disease in the homeless population (Smith, 2016).

Background: Sero-prevalance studies

Characteristics of included studies

Little is known about HAV sero-prevalence among homeless populations in the U.S. Below are a few studies:

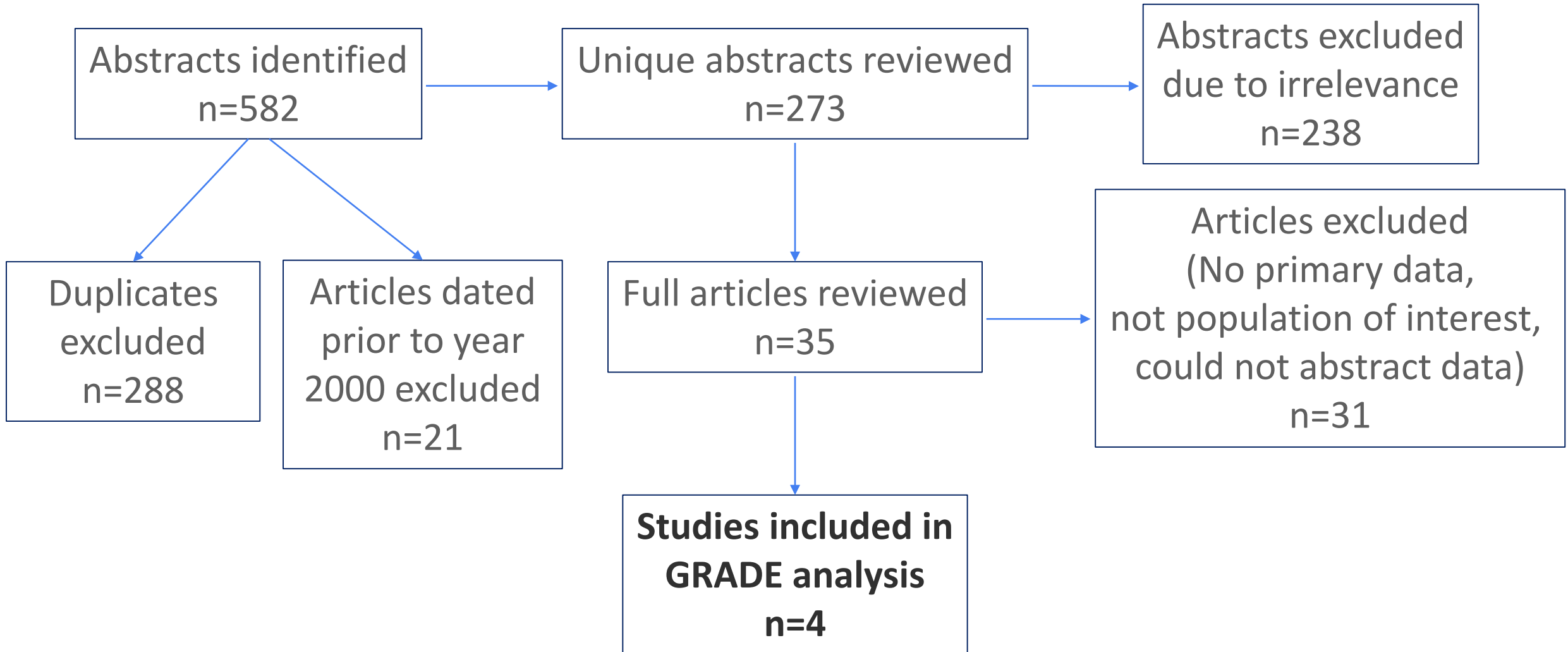
Author, year, location	No of subjects	Population	Seroprevalence
Hennessey, 2009 San Francisco	N=1138 6% aged < 35 years 67% aged 35-45 years 23% aged >45 years	Homeless	Anti-HAV positivity associated with years of homelessness <=1 year: 46% ; 2-4 years: 50% and >=5 years: 61%
Poulos, 2007 Sydney	N=189 Mean age: 42 years	Homeless at Haymarket Foundation Clinic (FQHC)	48% positive for anti-HAV
Ochnio, 2001 Vancouver	N=111 Mean age: 19.6 years Inclusion criteria: • Age=<25 years • Spending at least 8 hours on the street	4 locations: 2 street outreach clinics, needle exchange facility and STD clinic • Street youth (all) • Street youth who are IDU's • Street youth who are not MSM or IDU	6.3% positive for anti-HAV 9.5% positive for anti-HAV 3.1% positive for anti-HAV
Villar, 2013 Brazil	N=160 Mean age:18-25 years	Crack users	78.8% positive for anti-HAV
Kose, 2017 Turkey	N=187 Age range: 6-18 years	Street urchins	34% positive for anti-HAV
Roy, 2002 Montreal, Canada	N=427 Age range 14-25 years	Street youth	4.7 % positive for anti-HAV

Evidence retrieval

Evidence retrieval

- Systematic review of data for Hepatitis A vaccine and homelessness including a search of PubMed, Medline and EMBASE from January 1, 2000 through April 25, 2018
- Search terms included: ((Hepatitis OR HepA OR hepatovirus) AND vaccin*) OR HAV OR vaqta OR avaxim OR epaxal OR havpur OR havrix OR nothav AND Homeless* OR street people OR (living ADJ2 street*)
- Excluded articles in animals
- No language restrictions on initial searches and included articles from any country

Evidence retrieval



Evidence retrieval

- *Exclusion criteria:*
 - Articles dated earlier than year 2000
 - Vaccines not licensed in U.S.
 - Articles not addressing the population of interest
 - Articles where data could not be abstracted

Criteria

Criteria 1: Is the problem a public health priority?

JUDGEMENTS:

No Probably No Uncertain Probably Yes **Yes** Varies

RESEARCH EVIDENCE:

- Homeless people face many barriers to accessing healthcare systems; these factors contribute to increasing the spread of infections.
- Implementing efficient strategies to prevent the spread of communicable infections among the homeless is a public health priority (Hwang , 2001).
- Homelessness is associated with enormous health inequalities, including shorter life expectancy, higher morbidity, and greater usage of acute hospital services (Kushel et al, 2002).
- Compared with the general U.S. population, homeless persons are three to six times more likely to become ill. Hospitalization rates are four times higher, and they are three to four times more likely to die at a younger age (National Health Care for the Homeless Council).

Criteria 1: Is the problem a public health priority? cont'd

- Overuse of emergency department (ED) services leads to higher costs for treatment among the homeless.
 - A quarter to one third of homeless individuals are hospitalized during a given year and 3 times more likely to utilize the ED than the general population (Bhareel, 2013; CDC-NHIS ED visits, 2010).
- Vaccinations are important public health measures for infectious disease control, yet are often not accessible to some of the most vulnerable adults.
- Insurance coverage varies by states, however Medicaid expansion in thirty four states may provide an opportunity to make available routine vaccination coverage and access to care among persons experiencing homelessness.

Criteria 1: Is the problem a public health priority? cont'd

Outbreak investigations among persons who report drug use and/or homelessness in the U.S.

- Homeless people are often at high risk for hepatitis A due to overcrowded and unsanitary living conditions, and should receive active immunization against hepatitis A.
- San Diego outbreak (Peak et al, 2018: unpublished).
 - Homeless were at higher risk of infection, higher risk of severe outcomes from infection, and more than one-fourth were not covered by current indications for vaccination.
 - Of the ~600 reported cases, homelessness was identified as an independent risk factor for HAV transmission in 163 cases.
- Among persons experiencing homelessness in Maricopa county, Arizona, Iverson mentions that expeditious vaccination slowed the spread of a hepatitis A outbreak (Iverson et al, 2017).
- Hepatitis A outbreak in Bristol (UK), there were a total of 123 cases among the homeless [4 patients died and 39 were hospitalized] (Syed et al, 2003).

Criteria 1: Is the problem a public health priority? cont'd

Case counts-Hepatitis A Virus Outbreak among Persons Who Report Drug Use and/or Homelessness—Multiple States, 10/19/2018 - publically available

State	Cases	Hospitalizations	Deaths
Arkansas	168	Not reported	Not reported
Indiana (10/19/2018)	559	251 (45%)	1
Kentucky (10/15/18)	2,050	1,126 (55%)	14
Michigan (10/17/2018)	899	723 (80%)	28
Missouri (10/15/2018)	206	81 (39%)	0
Ohio (10/15/2018)	666	419 (63%)	0
Tennessee (10/12/2018)	332	195 (59%)	1
Utah (10/15/2018)	279	151 (54%)	2
West Virginia (10/12/2018)	1,527	791 (52%)	5
California (4/11/18) ^a	704	461 (65%)	21
Total	7,390	4,198 (57%)	72

*Outbreak case definition and criteria for reporting of case totals differs by state

<https://www.cdc.gov/hepatitis/outbreaks/2017March-HepatitisA.htm>

a. California case counts included but case reporting ceased April 2018

Criteria 1: Is the problem a public health priority? cont'd

Kushel et al, 2018

- Study in California addresses the root cause of hepatitis A outbreak in the homeless.
- Discusses the importance of vaccinating and educating the homeless in order to contain the outbreak.
- Determines more needs to be done to address the underlying cause.

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

JUDGEMENTS:

Minimal Small Moderate Large Don't know Varies

RESEARCH EVIDENCE:

Vaccination programs are an important component of public health initiatives and preventive medicine.

- HepA vaccine is highly effective and a well-understood vaccine.
- 2 doses of inactivated HepA vaccine induce protective efficacies of >90%.
- Effectiveness of inactivated HepA vaccines in large-scale immunization programs in North American populations, resulted in 94%–97% reduction in the incidence of acute HAV within 6–10 years (WHO position statement, July 2012).

Hepatitis A vaccination is effective in ending outbreaks in the homeless population:

- Nelson, R, 2018
 - a vaccination program with more than 90,000 doses distributed was the key to ending an outbreak of hepatitis A in southern California among homeless.

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

- Poulos et al, 2010
 - Completion rates were reasonable in a vaccination program among homeless in Sydney, Australia.
 - Study concluded that if vaccination was part of standard care, as opposed to part of a research project, uptake rates would have been higher among the clinic population.
- Tjon et al, 2005
 - Outbreak of hepatitis A among homeless and drug users in Rotterdam, the Netherlands.
 - Contact tracing was difficult so a mass immunization campaign over a 2 week period was performed.
 - A mass campaign vaccinating 83% (1515/1800) of the homeless people was effective in stopping the outbreak.
- Weatherill et al, 2004
 - During the 5-week hepatitis A and B vaccination blitz in the year 2000, 3,542 persons were immunized, 58% received both vaccines, resulting in reduction of reported cases of hepatitis A.
 - Demonstrated that immunizations can be successfully delivered to high risk inner city population in non-traditional settings.

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

JUDGEMENTS:

Minimal Small Moderate Large Don't know Varies

RESEARCH EVIDENCE:

Most studies reported no serious adverse events

- James et al, 2009: No reported vaccination reactions.
- Tjon et al, 2005
 - During the 2004 hepatitis A outbreak in Rotterdam, Netherland, four homeless people became jaundiced despite vaccination but were thought to be infected at the time of vaccination.

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

JUDGEMENTS:

No Probably No Uncertain Probably Yes **Yes** Varies

RESEARCH EVIDENCE:

- Hepatitis A vaccine is highly immunogenic, provides lasting protection in healthy individuals, and generates protective levels of antibodies in patients with chronic liver disease or impaired immunity.
- Analysis of data accrued for over 2 years from the U.S. Vaccine Adverse Event Reporting System (VAERS) from 1995–1996, 428 adverse events seen following administration of at least 6 million doses. 93 cases of serious events were reported, reaffirming the safety of HepA vaccine (Niu et al, 1998).
- Post-licensure evaluation of safety of VAQTA in children and adults. > 49,000 doses of HepA vaccines (Black et al, 2004).
 - showed no health problems linked to vaccination
- 104 clinical studies-27 countries, 50,000 subjects, 120,000 doses of HepA vaccine (Andre et al, 2002)
 - ~50% who received the vaccines reported no symptoms.
 - among those who reported side effects, the main side effect was a mild and transient local soreness at the site of injection, which resolved spontaneously.

Policy question: Should routine inactivated two dose hepatitis A vaccination be recommended for protection against hepatitis A among persons experiencing homelessness?

Population	Homeless (all ages)
Intervention	Inactivated Hepatitis A (HepA) vaccine administered as a two dose series
Control	Unvaccinated homeless individuals
Outcomes	Benefits: <ul style="list-style-type: none">• Reduction in disease burden (Hepatitis A virus [HAV]-related disease and fulminant hepatitis A)• Protection against HAV related disease (efficacy, immunogenicity) Harms: <ul style="list-style-type: none">• Local reactions: injection site pain/tenderness, erythema, fever, malaise, headache, loss of appetite drowsiness, irritability• Systemic adverse events: anaphylaxis, transient purpura, interference with other vaccines

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

RESEARCH EVIDENCE: Outcome measures included in evidence profile

Outcomes	Importance
Benefits <ul style="list-style-type: none"><li data-bbox="254 671 1057 721">■ Reduction in disease burden	Critical
Harms <ul style="list-style-type: none"><li data-bbox="254 856 1057 906">■ Serious adverse events (any)	Critical

Outcomes #1: Benefits (Reduction in disease burden)

Characteristics of included studies

Study	Type	Population	Intervention	Comparison	Main Outcomes*	Site
Poulos, 2010	Clinical trial	N=201 Homeless Mean age- 42 years	HAVRIX 1440 IU administered at federally funded clinic (Haymark Foundation Clinic)	No comparison group	The outbreak was controlled. No mention on the reduction of cases or percent of hepatitis A cases after vaccination.	Sydney, Australia

Outcomes #2: Harms: serious adverse events

Characteristics of included studies

Study	Type	Population	Intervention	Comparison	Main Outcomes	Site
Poulos, 2010	Clinical trial	N=201 Homeless Mean age: 42 years	HAVRIX 1440 IU administered at federally funded clinic (Haymark Foundation Clinic)	No comparison group	No mention of adverse events	Sydney, Australia
James, 2009	Observational	N=122 Homeless, substance users and incarcerated persons Age > 21 years	Hepatitis A vaccine given at emergency department. Vaccine name and dose unknown	No comparison group	No reported adverse reactions/events	Boston, USA
Tjon, 2005	Observational	N=1,515 Homeless Mean age: 42 years	Hepatitis A vaccine administered. Vaccine name and dose unknown	No comparison group	4 jaundice cases reported after vaccination. Probably a case of vaccine failure where person was already infected at time of vaccination.	Rotterdam, Netherland
Weatherill, 2004	Observational	N=3,542 Vulnerable population Median age: 46 yrs Males: 76%	Mass immunization HAVRIX Vaccine dose unknown	No comparison group	Early 2000 - No adverse events reported. Fall 2000- Multiple vaccines (influenza and pneumococcal and Hepatitis A) administered together. 3 cases of anaphylaxis and 8 cases oculo-respiratory syndrome reported.	Vancouver, Canada

Evidence types for GRADE

Initial evidence type	Study design
1	Randomized controlled trials (RCTs), or overwhelming evidence from observational studies
2	RCTs with important limitations, or exceptionally strong evidence from observational studies
3	Observational studies, or RCTs with notable limitations
4	Clinical experience and observations, observational studies with important limitations, or RCTs with several major limitations

Evidence type for benefits and harms

Outcome	Design (# studies)	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	Evidence type	Overall quality of evidence
Reduction in disease burden	1 clinical trial	Serious	Serious	Serious	Serious	*	4	**
Adverse events	1 clinical trial 3 observational studies	Serious	Serious	Serious	Serious	*	4	⊕⊖⊖⊖ VERY LOW

*Limitations in determining the estimates of the effect as no study had a comparison group available.

**Unable to determine the overall quality of evidence as only one was study available for GRADE.

Limitations/gaps

- Clinical trial study had limitations in detailed design and execution and no comparison/control groups were present.
- Observational studies had severe limitations, and some studies did not report any quantitative data.
- Only one study on immunogenicity of the vaccine in the homeless population, but it included a non-U.S. population.
- Studies did not look at homelessness as a risk factor in isolation.

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:

Limited evidence is available among the homeless population, about their perceptions on comparative health benefits and risks of vaccination.

- Routine ongoing vaccination by providers with established relationships will be better accepted than vaccination by unfamiliar public health professionals during a crisis.
- Barriers to seeking preventive care (Metcalfe & Sexton, 2014)
 - mistrust of healthcare provider
 - fear of needles
 - belief that illness may result from immunizations
- Vaccination efforts during an outbreak (Duncan et al, 2018)
 - homeless expressed distrust of vaccines and the vaccinators
 - believed they could keep themselves clean and therefore were not at risk
- Survey on opinions and behaviors related to vaccine providers (Grabenstein et al, 2002)
 - demonstrated individuals vaccinated at traditional sites (physician offices, public health clinics) felt vaccine provider had more experience and they trusted them
- Identified the clinic chosen had a well-established history of acceptance and utilization by the homeless group (Poulos et al, 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:

- Not many studies specific to the homeless on valuing the protection of disease are available.
- Persons experiencing homelessness have high rates of hospitalizations and deaths. Making necessary vaccines both available and accessible to highly vulnerable homeless is a critical public health issue.
- Completion rates were reasonable, and the identified clinic chosen had a well-established history of acceptance and utilization by the homeless group (Poulos et al, 2010).

Criteria 8: Is the option acceptable to stakeholders?

JUDGEMENTS:

No Probably No Uncertain Probably Yes **Yes** Varies

RESEARCH EVIDENCE:

- Recent hepatitis A outbreak investigations among persons who report drug use and/or homelessness in all 10 states were supported by stakeholders and raised awareness of homelessness among local officials.
- Duncan et al, 2018
 - Hepatitis A outbreak in San Diego county disproportionately affected homeless individuals (53%) and illicit drug users (68%). Community clinics vaccinated 7,521 adults in 7 months.
 - Strong support from executive leaders and public health officials resulted in partnerships with public health nurses who took hepatitis A vaccine to homeless encampments.
- Nelson R, 2018
 - Budget passed in Seattle, increased homelessness spending to \$67 million, a 60% increase over the past four years.
- James et al, 2009
 - Emergency department (ED) made a significant contribution in stemming a hepatitis A outbreak in Boston.
 - Strong leadership and buy-in from ED personnel and hospital stakeholders were credited for the program's success.
- Thorburn et al, 2001
 - Washington state legislature appropriated \$300,000 for vaccination campaign in jurisdictions experiencing a hepatitis A epidemic due to drug user and food handlers.

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

JUDGEMENTS:

No Probably No Uncertain Probably Yes Yes Varies

RESEARCH EVIDENCE:

- Outbreak campaigns entails medical cost, productivity losses, disruption of other public health services and diversion of public health resources and extensive human resources.
 - Cost of responding to HAV outbreak was approximately \$12.5 million in San Diego County (as of the end of April 2018).
 - Costs of routine immunization through clinics serving the homeless are likely to be lower per capita than the costs of large, rapid outbreak response vaccination campaigns.
- Multi-state hepatitis A outbreak in 2013
 - Outbreak-related hospitalizations associated with chronic medical conditions resulted in substantial healthcare usage and lost productivity (Epson et al, 2016 - not specific to homeless).
- Routine childhood and catch-up vaccination was a cost-saving measure from a societal perspective in communities experiencing period outbreaks such as American Indian reservations and Alaskan villages (Bialek et al, 2004).

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

- National study of ED use showed among individuals experiencing homelessness, overuse of emergency services, leads to higher treatment costs. Homeless individuals were more likely to be transported to the hospital via an ambulance, further increasing treatment costs (Ku et al, 2010).
- Systematic review and meta analysis stated the cost of liver transplantation could rise to \$163, 438 (Van der Hilst et al, 2009).
- Vaccination based on housing status may be simpler than vaccination based on disclosure of behavioral risk factors.
 - Adult immunization coverage assessment shows that <10% of adults aged ≥ 19 years with an indication of HepA vaccination had been vaccinated (Walter et al, 2016).
- HepA vaccine is licensed in United States (U.S.) only for certain high-risk groups, and cost effectiveness data on its use for these indications are limited (O'Conner et al, 1999).

Criteria 10: Is the option feasible to implement?

JUDGEMENTS:

No Probably No Uncertain Probably Yes **Yes** Varies

RESEARCH EVIDENCE:

Health departments, emergency departments and clinics are examples of effective venues for conducting immunization campaigns against vaccine-preventable disease.

- Providers demonstrate ingenuity and perseverance in ensuring that uninsured adults have access to vaccine and vaccination services.
- Health departments identified that integrating immunization assessment, screening, and vaccination into the routine clinic flow is important for program success (ASTHO report, 2016).
- Organizations like the National Health Care for the Homeless Council, work to make healthcare for the homeless more accessible. Thirty-four states have expanded Medicaid, leading to increase in coverage and access to care among persons experiencing homelessness.

Criteria 10: Is the option feasible to implement? cont'd

- Nyamathi et al, 2009
 - Study investigated the feasibility of a HAV/HBV vaccination program among homeless adults in Los Angeles. The effectiveness of a nurse-case-managed intervention compared with two standard programs on completion of HAV/HBV vaccine series was evaluated.
 - Study concluded that use of vaccination programs incorporating nurse case management and tracking is critical in supporting adherence to completion of a 6-month HAV/HBV vaccine.
- James et al, 2009
 - Targeted vaccination of homeless, substance users and incarcerated persons aged > 21 years at the emergency department following an HAV outbreak is feasible.
- Poulos et al, 2010
 - This study in Sydney, suggested that a successful vaccination program can be mounted in the homeless population.
 - Completion rates were reasonable, and stated that if vaccination was part of standard care, as opposed to part of a research project, uptake rates would have been higher among the clinic population.

Feasibility: Has vaccine uptake among homeless been demonstrated by other vaccines ?

Vaccine	Uptake among homeless	Author, Location
Influenza (2011-2012 season)	<p>Cross sectional survey at 27 homeless hostels, (2011-2012) N=190 homeless Age 16-64 yrs: clinical risk 24% vs. National 53% Age >=65 years: clinical risk 43% vs National 74%</p> <p>Influenza vaccine uptake was lower than national levels for all clinical risk groups * * Respiratory disease, Heart disease, Diabetes, Liver disease, Degenerative neurological disease</p>	Story et al, 2014 London, U.K.
<p>Zoster</p> <p>Tetanus (Td) and pneumococcal vaccination</p>	<p>Observational study at federally funded clinic, (2015-2017) N=103 aged ≥ 60 years 38% received vaccine at routine primary care visits. Higher than national average (31%) HP2020 goal (30%).</p> <p>Reported rates higher (Td: 81% ; Pneumococcal: 76%) vs. general U.S. population Comprehensive primary care located in a homeless shelter with an on-site refrigerator to store vaccines can effectively achieve high levels of routine immunization among homeless adults.</p> <p>Homeless interested in zoster and other routine vaccination</p>	Weisman et al, 2018 New York City, U.S.

Summary

Should routine inactivated two dose hepatitis A vaccination be recommended for protection against hepatitis A among persons experiencing homelessness?

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 inactivated two dose hepatitis A vaccination be recommended for protection against hepatitis A among persons experiencing homelessness?

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

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