National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention



#### **Background – Hepatitis A Among the Homeless**

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#### Outline

- Epidemiology
- Hepatitis A Vaccines
- Hepatitis A Outbreaks
- Hepatitis A and Homelessness San Diego County, 2016–2018
- Homelessness



## Rates of Reported Acute Hepatitis A Cases United States, 1966-2016



•National Notifiable Diseases Surveillance System (NNDSS); Armstrong GL. Pediatrics 2007;119:e22-9

#### Rates of Reported Acute Hepatitis A United States, 2007-2016



National Notifiable Diseases Surveillance System (NNDSS); http://www.healthypeople.gov/2020/topicsobjectives2020/pdfs/Immunization.pdf

## Prevalence of anti-HAV by age group, NHANES, United States 2009–2010



NHANES, National Health and Nutrition Examination Survey

Murphy TV et al. Progress Toward Eliminating Hepatitis A Disease in the United States. MMWR Suppl. 2016 Feb 12;65(1):29-41.

## **Hepatitis A Vaccines**

## Hepatitis A Vaccines in 1995 and 1996 Efficacy of Hepatitis A Vaccines\*

| Vaccine*  | Site and<br>Age Group  | Number<br>in Trial | Vaccine Efficacy<br>(95 % Cl) |  |  |  |
|---|------------------------|--------------------|-------------------------------|--|--|--|
| VAQTA <sup>®</sup> , Merck,<br>Sharpe, and<br>Dohme<br>(MSD) <sup>1</sup> | New York<br>2-16 years | 1,037              | 100% (85-100%) <sup>§</sup>   |  |  |  |
| HAVRIX <sup>®</sup> ,<br>SmithKline<br>Beecham<br>(SKB) <sup>2</sup>      | Thailand<br>1-16 years | 38,157             | 94% (74-98%)                  |  |  |  |
| *Pediatric formulation<br>§Determined 6–18 months after dose 1            |                        |                    |                               |  |  |  |

(1) Werzberger, A et al. *New Engl J Medicine*. 1992;327:453–7
(2) Innis BL, et al. *JAMA* 1994;271:1328–34

## **Hepatitis A Vaccine Safety**

- In pre-licensure trials, adverse reactions to HAVRIX, VAQTA and TWINRIX were mostly injection site reactions and mild systemic reactions
  - Most frequent side effects are soreness or erythema at injection site, fever, headache, and malaise
  - Multiple studies demonstrate no serious adverse events definitively attributed to inactivated vaccine
- Postmarketing surveillance for adverse events following receipt of HepA vaccines has been performed primarily by two systems in the United States: the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD)
  - No unusual or unexpected safety patterns were observed for any of the HepA vaccines licensed in the United States

## **ACIP Hepatitis A Vaccine Recommendations**

#### Targeted vaccination, 1996-1999

- 1996
  - Children at age 2 years in communities with high rates of disease
  - Children through teen years in outbreaks
- 1999
  - Recommended in 11 states with rates 2x the national average
  - Considered in 6 states with rates above the national average
- 2006
  - Universal childhood vaccination
  - Recommended for use at age 12-23 months in all states
  - Continue existing vaccination programs for ages 2-18 years
  - Consider catch-up vaccination in outbreaks and areas with increasing disease rates
  - Any person wishing to obtain immunity



#### **ACIP Hepatitis A Vaccine Recommendations** Groups at increased risk of HAV or severe HAV disease

- Travelers
- Men who have sex with men
- Users of injection and non-injection drugs
- Persons with clotting-factor disorders
- Persons who work with nonhuman primates
- Persons who anticipate close personal contact with an international adoptee
- Persons with chronic liver disease
- Homelessness

#### **Immunogenicity – Long-term Protection**

- Anti-HAV has been shown to persist in vaccine recipients for at least 20 years in adults administered inactivated vaccine as children with a three dose schedule.<sup>1</sup>
- At least 20 year anti-HAV persistence was demonstrated among adults vaccinated with a two-dose schedule as adults.<sup>2</sup>
- Detectable antibodies are estimated to persist for 40 years or longer based on mathematical modeling and anti-HAV kinetic studies.<sup>2,3</sup>
- Protection following natural infection is lifelong and may also be following vaccination
- Anti-HAV after a single dose of HepA vaccine can persist for almost 11 years<sup>4</sup>
  - A single dose of HepA vaccine was shown to promote HAV-specific cellular immunity similar to that induced by natural infection<sup>5</sup>

Plumb ID, et al. J Viral Hepat. 2017 Jul;24(7):608-612.; 2. Theeten H, et al. Vaccine. 2015 Oct 13;33(42):5723-7.
 Hens N, et al. Vaccine. 2014;32(13):1507-1513. 4. Ott J.J. and Wiersma S. T., Int. J. Infect. Dis., vol. 17, no. 11, pp. e939-44, Nov. 2013.
 Melgaço JG, et al. Vaccine. 2015 Jul 31;33(32):3813-20

#### Hepatitis A Vaccine Coverage, United States, 2016

#### Children<sup>1</sup>

- 60.6% for children age 19-35 months, ≥2 doses (59.7%, 2017)
- 86.1% for children age 19-35 months, ≥1 dose (86%, 2017)

#### Adolescents<sup>2</sup>

- 64.4% for adolescents age 13-17 years, ≥2 doses
- 73.9% for adolescents age 13-17 years, 1 dose

#### Adults<sup>3</sup>

- 9.5% for adults ≥19 years, ≥2 doses
- 13.4% for adults 19-49 years, ≥2 doses; Travelers, 19.3%; CLD, 23.7%
- 5.4% for adults ≥50 years, ≥2 doses
- 1. Hill HA, et al. MMWR 2017;66:1171–1177.
- 2. Nelson NP, et al. *Vaccine* 2018. Mar 14;36(12):1650-1659
- 3. Vaccination Coverage Among Adults in the United States, National Health Interview Survey, 2016. https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/NHIS-2016.html#hepA

Hepatitis A Virus Outbreaks

## Hepatitis A Virus Outbreaks – United States, 2016–2018

- CDC has assisted in multiple HAV outbreaks since July 1, 2016
  - Common Source Transmission
    - Hawaii-Frozen Scallops
    - Multistate- Frozen Strawberries
  - Person-to-Person Transmission
    - Individuals who report drug use and/or homelessness
    - Men who have sex with men
- >7,500 outbreak associated cases reported since July 1, 2016 to present



## **Shifting Hepatitis A Virus Epidemiology**

- Past outbreaks were associated with asymptomatic children
- A large population of adults are not immune to hepatitis A virus
- Older individuals are more likely to experience severe disease and adverse outcomes
- Vaccination uptake among at-risk adults is low

Collier M, et al. *Hepatology* 2015., Ly KN, Klevens RM. *J Infect Dis* 2015. Epson E, et al. *Public Health*, 2015. Murphy TV, et al. *MMWR Suppl* 2016.

#### Division of Viral Hepatitis Outbreak Website Map: https://www.cdc.gov/hepatitis/outbreaks/2017March-HepatitisA.htm



## 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   | 169   | 81 (48%)         | 1      |  |  |  |
| Indiana (10/19/2018)   |       | 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) <sup>a</sup>  | 704   | 461 (65%)        | 21     |  |  |  |
| North Carolina (10/22/2018)  | 31    | 24 (77%)         | 0      |  |  |  |
| Massachusetts (10/18/2018)   | 98    | 83 (85%)         | 1      |  |  |  |
| Total  | 7,520 | 4,386 (58%)      | 74     |  |  |  |
| *Outbreak case definition and criteria for reporting of case totals differs by state<br>https://www.cdc.gov/hepatitis/outbreaks/2017March-HepatitisA.htm |       |                  |        |  |  |  |
| a. California case counts included but case reporting ceased April 2018  |       |                  |        |  |  |  |

#### **Case Counts among Homeless – State Data**

| State         | Dates              | Total HAV Homeless cases       | HAV Homeless cases | HAV Homeless + injection  |
|---------------|--------------------|--------------------------------|--------------------|---------------------------|
|               |                    | (including homeless with other | only               | or non-injection drug use |
|               |                    | risk factors)                  |                    | cases                     |
| Arkansas      | 2/2018-10/23/2018  | 4                              | 1                  | 3                         |
| California    | 11/22/16 - 7/10/18 | 372 (52.5%)                    | 109 (15%)          | 263 (37%)                 |
| San Diego     | - 8/3/2018         | 292 (49%)                      | 91 (15%)           | 201 (34%)                 |
| Indiana       | 12/1/1810/19/18    | 56 (10%)                       | 7 (1.3%)           | 49 (8.8%)                 |
| Kentucky      | 8/1/17 - 10/13/18+ | 246 (11.3%)                    | 40* (1.8%)         | 206 (9.5%)                |
| Michigan      | 8/1/2016-8/23/2018 | 112 (13.8%)                    | 7 (0.9%)           | 99 (12.2%)                |
| Ohio          | -10/16/18          | 49 (~7%)                       | 12 (~1.7%)         | 37 (~5.2%)                |
| Tennessee     | 12/31/17-10/12/18  | 38 (11.4%)                     | 3 (0.9%)           | 35 (10.5%)                |
| Utah          | 5/8/17-10/15/18    | 121 (43%)                      | 21 (7.5%)          | 100 (35.8%)               |
| West Virginia | 1/13/18 - 10/19/18 | 198 (12.3%)                    | 37 (2.3%)          | 161 (10%)                 |

† Total (cumulative) number of outbreak cases for this time frame: 2,168; those missing all risk factor information (lost to follow-up): 389 Drug use only: 1145

\*18 Report "Homeless" as their only risk factor, 22 report "Homeless", but are missing data on "Illicit drug use"

\*\* Those reporting risk factor data: 1779 - Those reporting no known risk factors: 388

## **Increased Morbidity and Mortality during 2016–2018**

- Hepatitis A related hospitalizations were increasing prior to 2016
   7% in 1999 to 46% in 2015
- Hospitalizations for outbreaks during 2016-2018 range from 25-82%
- Case mortality in California and Michigan is around 3%
- Coinfections with hepatitis B and hepatitis C

Ly et al. J Infect Dis. 2015; https://www.cdc.gov/hepatitis/statistics/2015surveillance/pdfs/2015HepSurveillanceRpt.pdf; CDC MMWR pending publication

## **Hepatitis A among Homeless**

- Little is known about hepatitis A immunity among homeless
- High incidence of hepatitis A infections among people who use drugs and among people who are homeless and use drugs
- Transmission related to crowding and poor hygiene



Photo Credit: E. McDonald

Hennessey KA, et al. Public Health Reports. 2009; Villano et al. Clinical Infectious Diseases. 1997; MMWR 1996;45(No. RR-15):1--30

### **Hepatitis A Vaccination for Outbreak Control**

- Vaccination is the cornerstone for control of community outbreaks
- Post-exposure prophylaxis alone may not effectively control outbreaks
- Targeted vaccination to the groups at highest risk are the best way to control disease spread
- Primary prevention with adequate vaccination of atrisk groups is preferable

## Vaccine Supply

- In 2017 the large outbreaks of hepatitis A among adults in several US cities resulted in increased demand for vaccine, resulting in constrained supplies of vaccine.
  - In response, CDC:
    - (1) worked directly with public health officials in affected jurisdictions to provide guidance about targeting vaccine in response to local epidemiology;
    - (2) collaborated with manufacturers to understand options for managing supplies in the private sector and increasing national supply;
    - (3) implemented ordering controls in the public sector; and
    - (4) increased vaccine availability on CDC's adult vaccine contracts.
- As available vaccine supplies have increased and progress has been made regarding ongoing outbreaks, the public sector vaccine supply strategy has evolved.
- Additional vaccine has been made available for unaffected jurisdictions to facilitate routine vaccination activities.
- While manufacturers have supply to meet current demand, CDC and vaccine manufacturers continue to monitor ongoing demand for and usage of adult hepatitis A vaccine closely.
   https://www.cdc.gov/vaccines/hcp/clinical-resources/shortages.html#note1

#### **Outbreak Response – San Diego County**

#### 2,538 total hepatitis A vaccination events

- 833 Points of Dispensing events
- 80 Mobile Van events
- 1,625 Foot Team events
- Total hepatitis A vaccinations administered in San Diego County from (March 6, 2017 -January 23, 2018):
  - 121,921

#### Total at-Risk Population vaccinated (estimated):

- 103,000
- Jail vaccinations through January 23, 2018:
  - 8,335

# Hepatitis A and Homelessness — San Diego County, 2016–2018

Corey Peak and Eric McDonald

Brief Summary Prepared for the ACIP Hepatitis WG



#### Hepatitis A and Homelessness — San Diego County, 2016–2018

#### Analyses of homelessness as a risk factor

- HAV transmission
  - Test-negative case control study
- Elevated disease severity
  - Cohort Study
- Conclusions
  - Vaccine indication unrecognized for >25% of patients reporting homelessness
  - Homelessness was independently associated with:
    - 2-3 times higher odds of infection with HAV
    - 2-4 times higher odds of severe outcomes of HAV infection, specifically hospitalization or death

## **Methods**

- Data Collection
  - Cases reported between November 2016–May 2018 in San Diego County
  - Routine RNA testing of patients partially meeting CSTE case criteria
  - Measured ACIP vaccine indications: Illicit drug use, coinfection with HBV or HCV (surrogate for chronic liver disease), international travel, MSM

#### Analyses of Homelessness as a Risk Factor for...

#### ...HAV transmission

- Test-negative case control study
  - Cases: HAV RNA (+)
  - Controls: HAV RNA (-)
- Backwards selection stepwise regression

#### ...elevated disease severity

Cohort Study Outcomes:

Hospitalization related to Hepatitis A Death related to Hepatitis A

Backwards selection stepwise regression



#### Conclusion

- Vaccine indication unrecognized for >25% of patients reporting homelessness
- Homelessness was independently associated with:
  - 2-3 times higher odds of infection with HAV
  - 2-4 times higher odds of severe outcomes of HAV infection, specifically hospitalization or death

## **Costs of Outbreak Response**

- San Diego County spent about \$12.5 million as of the end of April 2018 on the outbreak response
  - Other states have spent millions of dollars in the response
- Hospitalization expenses
- Diversion of human and financial resources from other activities in many affected jurisdictions
- Homeless involved in propagating the outbreak, even if all of the costs are not associated with the homeless

## Homelessness

#### **Homelessness: Definition**

#### There is more than one "official" definition of homelessness.

- Different agencies use different definitions of homelessness, which affect how various programs determine eligibility for individuals and families at the state and local level.
- Health centers funded by the U.S. Department of Health and Human Services use the HHS definition in providing services.
  - A homeless individual is defined in section 330(h)(5)(A) as "an individual who lacks housing (without regard to whether the individual is a member of a family), including an individual whose primary residence during the night is a supervised public or private facility (e.g., shelters) that provides temporary living accommodations, and an individual who is a resident in transitional housing." A homeless person is an individual without permanent housing who may live on the streets; stay in a shelter, mission, single room occupancy facilities, abandoned building or vehicle; or in any other unstable or non-permanent situation. [Section 330 of the Public Health Service Act (42 U.S.C., 254b)]

National Health Care for the Homeless Council, https://www.nhchc.org/faq/official-definition-homelessness/

## **Estimates of Numbers of Homeless Persons**

- Key Findings of the Housing and Urban Development (HUD) 2017 Annual Homeless Assessment Report:
  - On a single night in January 2017, state and local planning agencies (Continuums of Care) reported:
    - 553,742 people were homeless representing an overall 0.7 percent increase from 2016.
    - Most homeless persons (360,867) were located in emergency shelters or transitional housing programs while 192,875 persons were unsheltered.

#### **Estimates of Homelessness in Outbreak Affected States**

| State             | Individuals | People in Families | Unaccompanied | Veterans | Chronically homeless | Sheltered      | Unsheltered    |
|-------------------|-------------|--------------------|---------------|----------|----------------------|----------------|----------------|
|                   |             |                    |               |          |                      |                |                |
|                   |             |                    |               |          |                      |                |                |
|                   |             |                    |               |          |                      |                |                |
| Arkansas          | 2,068       | 399                | 208           | 239      | 450                  | 1,273 (51.6%)  | 1,194(48.4%)   |
| California        | 112,756     | 21,522             | 15,458        | 11,472   | 35,798               | 42,636 (31.8%) | 91,642 (68.2%) |
| Indiana           | 3,623       | 1,815              | 294           | 615      | 486                  | 4,869 (89.5%   | 569 (10.5%)    |
| Kentucky          | 3,032       | 993                | 253           | 489      | 383                  | 3,298 (81.9%)  | 727 (18.1%     |
| Michigan          | 5,628       | 3.423              | 608           | 773      | 709                  | 8,028 (88.7%)  | 1,023 (11.3%)  |
| Missouri          | 3,768       | 2,269              | 548           | 538      | 883                  | 4,885 (80.95)  | 1,152 (19.1%)  |
| Ohio              | 6,688       | 3,407              | 695           | 862      | 725                  | 8,786 (87.0%)  | 1,309 (13.0%)  |
| Tennessee         | 6,137       | 2,172              | 457           | 757      | 1,295                | 5,544 (66.7%)  | 2,765 (33.3%)  |
| Utah              | 1,882       | 970                | 180           | 220      | 163                  | 2,574 (90.3%)  | 278 (9.7%)     |
| West Virginia     | 1,032       | 277                | 79            | 137      | 188                  | 1,121 (85.6%)  | 188 (14.4%)    |
|                   |             |                    |               |          |                      |                |                |
| 2017 PIT Estimate | 369,081     | 184,661            | 40,799        | 40,056   | 86,962               | 360,867 (65%)  | 92,875 (35%)   |

The U.S. Department of Health and Human Services.

https://www.hudexchange.info/resources/documents/2017-AHAR-Part-1.pdf

## **Homeless and Health**

- People experiencing homelessness experience diseases at higher rates than domiciled persons
  - Higher rates of chronic conditions, acute illnesses and behavioral health issues
- Conditions are more difficult to treat for a person experiencing homelessness
- Problems with health sometimes leads to homelessness, and homelessness leads to and exacerbates health issues
- Persons who are homeless experience greater barriers to accessing care:
  - Lack of a stable address
  - Difficulty with transportation
  - Uninsured or public insurance
  - Need to prioritize basic survival (food, shelter, safety) before health care

#### **National Health Care for the Homeless Council**

- A membership organization that provides training and technical assistance to 300 Health Care for the Homeless (HCH) Federally Qualified Health Centers and 90 Medical Respite Programs
  - Medical Respite Program provides homeless individuals a safe place to recover from acute injury or illness
- Shares best practices among the community, conducts research, and advocates for policies to eliminate homelessness
- At least one HCH program in each state, DC and Puerto Rico
- HCH programs meet all the requirements of FQHCs and, must conduct outreach and provide or have strong linkages to mental health and substance abuse services



## Health Care for the Homeless (HCH)

- In 2018, >300 sites delivered care to over 850,000 individuals
- HCH programs provide primary care, behavioral health and support services to people who are homeless regardless of their insurance status or ability to pay

#### Requirements for outreach

- Shelter based
- Mobile clinics
- Street Clinics in over 30 metropolitan areas
  - Street Medicine Institute (SMI) facilitates and enhances the direct provision of health care to the unsheltered homeless where they live

#### **Health Insurance Coverage – Health Care for the Homeless**

- 90% of HCH clients are <100% Federal Poverty Level; 64% insured</p>
- 2016, 295 HCH programs provided care to 934,174 patients
  - 51%, Medicaid; 4% Medicare and Medicaid; 4% Medicare (other); 5% Private, 36% Uninsured
  - 25% Uninsured in expansion states
- For uninsured, referral to specialty care is limited
  - Decrease in uninsured since Medicaid expansion
- Wide variation in outreach and enrollment activities across states
- Medicaid largest source of insurance for HCH patients overall
- As states continue working to reduce health care disparities and improve health, access to comprehensive health insurance remains a key factor in access to care

National Health Care for the Homeless Council

## **Routine Vaccination of Homeless**

- Integrate vaccination into clinics that serve the homeless
  - FQHCs, CHCs, Shelters, Mobile clinics, Street clinics
  - Familiar setting
  - Providers experienced in caring for persons who are homeless
  - Opportunity for education
  - Access to other preventive and health services

#### **Other Considerations**

## **Herd Immunity**

- Study in Israel of trends in disease incidence after the implementation of universal hepatitis A vaccination among children (Chodick, 2008)
  - <10% of the rest of the Israeli population was immunized during the study period, the overall incidence of hepatitis A declined by nearly 90%
  - Among children aged 5 to 14 years an estimated 81% decline in incidence occurred at a time when vaccination coverage had reached 25%

#### Vaccine demonstration project conducted in Butte County, California, 1995–2000

 Incidence of reported hepatitis A cases dropped by 93% despite immunization coverage of only 60% (Averhoff, 2001)

#### Study in Alaska suggested 80% vaccine coverage is needed to control an outbreak

- Susceptible population was a rural population, not persons from a specific risk group (McMahon, 1996)
- Challenging to determine herd immunity thresholds for routine vaccination among specific risk populations (e.g., Homeless, PWUD, MSM)

## **Costs of Vaccination – Adult vaccination**

| Adult Vaccine Price List                          |   |                   |                             |                   |                              |  |  |
|---|---|-------------------|-----------------------------|-------------------|------------------------------|--|--|
| Vaccine   | Brandname/<br>Tradename                 | NDC               | Packaging                   | CDC Cost/<br>Dose | Private Sector<br>Cost/ Dose |  |  |
| Hepatitis A-<br>Adult [ <mark>5</mark> ]          | Vaqta®<br>Merck                         | 00006-<br>4096-02 | 10 pack – 1<br>dose syringe | \$28.28           | \$66.91                      |  |  |
|   |   | 00006-<br>4841-41 | 10 pack – 1<br>dose vial    | \$26.29           | \$66.91                      |  |  |
| Hepatitis A<br>Adult [ <u>5</u> ]                 | Havrix <sup>®</sup><br>GlaxoSmithKline  | 58160-<br>0826-52 | 10 pack – 1<br>dose syringe | \$28.28           | \$67.55                      |  |  |
| Hepatitis A-<br>Hepatitis B<br>Adult [ <u>3</u> ] | Twinrix <sup>®</sup><br>GlaxoSmithKline | 58160-<br>0815-52 | 10 pack – 1<br>dose syringe | \$56.76           | \$101.00                     |  |  |

#### Footnotes

- 3. Vaccine cost includes \$1.50 per dose Federal Excise Tax
- 5. Vaccine cost includes \$0.75 per dose Federal Excise Tax

https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html



#### Summary - I

- Hepatitis A vaccine is largely responsible for the marked reduction in hepatitis A cases
- Increasing proportion of adults in United States are susceptible to hepatitis A
  - Reduced exposure to HAV early in life
  - Significant decreases in anti-HAV seroprevalence in older adults (≥ 40 years)
  - Low 2-dose vaccination coverage exists in adults, including high risk adults (e.g., travelers, chronic liver disease)

#### **Summary - II**

- Outbreaks Shifting epidemiology, person-person transmission among unvaccinated vulnerable populations (e.g., homeless)
- Community outbreaks of hepatitis A virus are often prolonged and challenging to control
- Vaccination is the cornerstone of outbreak control of community outbreaks
  - Outreach and vaccination of persons at-risk in targeted venues is effective outbreak control
- However, routine vaccination of HAV risk groups is critical for outbreak prevention

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