August 2018

Hepatitis B

Surveillance and Investigation Protocol

Disease Summary

Hepatitis B is a serious liver infection caused by the hepatitis B virus. The virus is spread by exposure to hepatitis B infected blood or body fluid. In the United States, the most common methods of transmission include: intravenous drug use and sexual intercourse. Hepatitis B can take 30 to 180 days to show physical symptoms in someone who is infected.

The hepatitis B virus can cause both acute and chronic infections. Many experience no signs or symptoms. Others may develop a rapid onset of sickness including: nausea, vomiting, jaundice (yellow skin and/or eyes), fatigue, dark urine, or abdominal pain. Often, the body can fight off the infection, and develop immunity to the hepatitis B virus. Although, those who do not recover from the infection develop what is known as chronic hepatitis B. Chronic hepatitis B is a lifelong infection that can progress to conditions such as hardening of the liver, scarring, and even liver cancer.

Provider Responsibilities

1. Report cases of acute, chronic, or perinatal hepatitis B to the local health department within 24 hours of diagnosis
2. Evaluate and test patients who present with signs and symptoms of acute hepatitis
3. Conduct appropriate screening of pregnant women
4. Consider screening patients who are asymptomatic but who have risk factors for viral hepatitis infection
5. Receive disease reporting education from Local Health Departments
6. Anticipate the need to work with Local Health Departments to:
    a. Supply appropriate clinical information
    b. Supply additional demographic information
    c. Supply additional laboratory results

Laboratory Responsibilities

1. For paper copies of positive laboratory results for hepatitis B (HBsAg, anti-HBc IgM, HBeAg, hepatitis B DNA) forward a copy to the Local Health Department within 24 hours of report. For electronic lab reporting facilities the positive laboratory results must be reported to the State Health Department within 24 hours of report.
2. Please include:
    a. Patient's full name, date of birth, address and phone number.
    b. Patient's demographic information including age, sex, race, and ethnicity
    c. Full ordering physician name, address, and phone number

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d. Laboratory results, normal values, and interpretation including:
    i. IgM antibody to HAV (IgM anti-HAV)
    ii. Hepatitis B surface antigen (HBsAg)
    iii. IgM antibody to Hepatitis B core antigen (IgM anti-HBc)
    iv. hepatitis B DNA
    v. hepatitis B Genotype
    vi. Antibody to HCV (anti-HCV)
    vii. HCV RNA
    viii. Bilirubin levels
    ix. Transaminase levels

Local Health Responsibilities

1. Education and Outreach

a. Educate providers about the importance and the appropriate use of hepatitis B vaccine, especially in newborns, adolescents, and those with reported risk factors.
b. Educate providers about the importance of screening and identifying pregnant women who are hepatitis B positive, and the importance of notifying public health.
c. Educate the general public about hepatitis B risk factors, hepatitis B vaccine, and prevention of hepatitis B transmission.
d. Per the Reportable Disease Rule (WV Code 16-3-1; 64CSR7) Local Health Departments will:
    i. Educate healthcare providers about the requirement to report hepatitis B, acute, chronic or perinatal to the Local Health Department within 24 hours of diagnosis
    ii. Educate laboratories about the requirement to report hepatitis B surface antigen (HBsAg) positive, IgM antibody to hepatitis B core antigen (HBcAb-IgM), hepatitis B "e" antigen (HBeAg), and hepatitis B DNA (hepatitis B DNA) laboratory serology to the Local Health Department within 24 hours of report

2. Investigations Note: Completion of the West Virginia Electronic Disease Surveillance System (WVEDSS) hepatitis case report will ensure a complete and appropriate hepatitis B case investigation.
http://www.dhhr.wv.gov/oeps/disease/WVEDSS/Documents/HBV_HCV.pdf

a. Within 24 hours of receiving a report of a HBsAg, HBeAg or hepatitis B DNA positive laboratory result, the Local Health Department will perform the following actions:

i. Report all positive hepatitis B lab results to the Division of Infectious Disease Epidemiology (DIDE) by fax at (304)558-8736
ii. Conduct a record search to determine if the patient was previously investigated for hepatitis B by:
    1. Searching WVEDSS for previous investigations
    2. Reviewing local health department case records of previously reported cases
    3. Contacting the State Health Department to search database records and to determine if the patient was reported outside of the Local Health Departments jurisdiction
iii. Contact the physician to gather the additional information including:
    1. Demographic information
    2. Clinical information
    3. **Patient's pregnancy status** (If pregnant, please notify DIDE immediately)
    4. Other related laboratory results (hepatitis A, hepatitis C, or liver enzymes)
    5. History of drug abuse or alcohol abuse
    6. Hepatitis B vaccination history
    7. Determine if the patient is aware of their hepatitis B positive diagnosis
    8. Inform the provider that you will be contacting the patient to complete the public health investigation
iv. Interview the patient to collect the following information:
    1. Any missing demographic or clinical information
    2. Exposure and risk factor information
    3. Evaluate for potential healthcare associated exposure including:
        No risk factor identified other than a healthcare procedure that occurred within 180 days of the date of onset of symptoms (See Page 10)
    4. Hepatitis B vaccination records
    5. Information about disease contacts
        a. Name of contact and date of birth
        b. Type of contact (sexual, drug, or household)
        c. Contact's address and phone number
v. Public Health Action

1. Provide education on hepatitis B prevention and transmission to the patient
2. Refer the patient to a physician for further testing and disease management if needed
3. Notify, and investigate potential contacts of the index case (See Page 4, Section 5)
    a. Provide education on hepatitis B prevention and transmission to contacts
    b. Provide testing, vaccine, and post exposure prophylaxis (PEP) (See table 1) to contacts.
    Note: On the West Virginia Office of Laboratory Services lab specimen submission form, patient type is "investigation" for contacts identified during a hepatitis B case investigation.

b. Document public health actions taken, and date in the WVEDSS
c. **WVEDSS -**
    i. Complete the hepatitis B case investigation in WVEDSS
    ii. Submit the case investigation to the regional epidemiologist for regional review

3. The local health department should assure that all patients who are positive for hepatitis B receive education on hepatitis B prevention and transmission.

4. If the patient has had an invasive medical procedure within 180 days prior to the date of onset of symptoms and reports no other risk factors for hepatitis B infection, local health should report the case to the DIDE at (304)558-5358, extension 1 immediately. A suspect case of healthcare associated hepatitis B infection warrants an investigation. Steps for investigation a single case of hepatitis B infection suspected of being related to healthcare delivery can be found at:
http://www.cdc.gov/hepatitis/outbreaks/pdfs/healthcareinvestigationguide.pdf

5. Managing contacts of acute and chronic cases

a. Provide partner notification to:
    i. Sexual partners
    ii. Household contacts
    iii. Needle/drug paraphernalia sharing contacts
b. Complete the contact tracing section in the WVEDSS investigation
c. Testing Contacts
    i. Submit a blood sample from the contact(s) to the West Virginia Office of Laboratory Services for a hepatitis B screen and enter the results into WVEDSS

d. Vaccinating Contacts
    i. Administer hepatitis B immunoglobulin (HBIG) when appropriate (see Table 1) and the first dose of hepatitis B vaccine to the contact(s) prior to testing for hepatitis B.
    ii. If the hepatitis serologies are positive, stop the vaccination series and refer the patient for medical care. If serologies are negative, complete the full immunization series.
    iii. If a patient receives HBIG and/or hepatitis B vaccine, the Local Health Department should document vaccines administered into the WVEDSS investigation and into the West Virginia Statewide Immunization Information System (WVSIIS)
    iv. If the source patient has chronic hepatitis B or develops a chronic infection, all household contacts should receive the hepatitis B vaccine series, unless there is proof of vaccination or immunity to hepatitis B.
e. Provide education to contacts about hepatitis B prevention and transmission
f. Document public health actions and date taken in the WVEDSS investigation

6. Lost to Follow Up/Disease Intervention Specialists

a. Each health department should maintain a policy on how to manage patients who are lost to follow up.
b. A case may be considered lost to follow up at the local level if the case is unable to be located two weeks after initial assignment, and after the Local Health Department has documented three good faith attempts in the WVEDDS to contact the patient which includes, but is not limited to:
    i. Three phone call attempts on separate days.
    ii. Two letters (at least one certified)
c. If the Local Health Department determines that the case is lost to follow up, it may be submitted to the state as lost to follow up.
d. The Hepatitis B epidemiologist will then submit the case as lost to follow up to the Disease intervention specialist supervisor, who will assign the case within one week to the Viral hepatitis disease intervention specialist.
e. The Viral hepatitis disease intervention specialist will perform the following duties:
    i. If the patient is located, interview the patient for all contacts including: sexual, household, and needle/drug paraphernalia sharing contacts
    ii. Provide partner notification services when applicable
    iii. Refer the patient back to the Local Health Department for follow-up

iv. Update the WVEDSS with any additional information obtained through interview
v. Complete and submit a field record to the Disease intervention specialist supervisor.

f. The Viral hepatitis disease intervention specialist will attempt to locate the patient for up to four weeks after receiving the lost to follow up case. If the patient is unable to be located within four weeks, it will be closed as lost to follow up.

Table 1. Testing, Immunization and Post-exposure Prophylaxis Recommendations for Contacts of Cases of Acute and Chronic Hepatitis B

	Testing Recommended	Immunization Recommended	HBIG Recommended
Contacts – Hepatitis B Acute Case			
Sexual contact of acute case of hepatitis B within last 14 days	Yes	Yes	Yes
Household contact of acute case, no known blood/body fluid exposure	Yes	Yes	No
Household contacts of acute case, known exposure within last 14 days (e.g. shared toothbrush, razor, blood contact)	Yes	Yes	Yes
Needle sharing contact within last 7 days	Yes	Yes	Yes
Contacts – Hepatitis B Chronic Case			
Sexual contact of chronic case of hepatitis B	Yes	Yes	No
Household contact (any) of chronic case of hepatitis B	Yes	Yes	No
Needle sharing contact	Yes	Yes	No

State Health Responsibilities

1. Prompt and complete reporting of hepatitis B cases to the Center for Disease Control (CDC) through WVEDSS.
2. Report cases of hepatitis B to the CDC within 7 days of notification of complete case investigation by local health.

3. Provide technical expertise and consultation regarding surveillance, investigation, control measures and prevention of hepatitis B.
4. Notify the CDC of suspected outbreaks identified in West Virginia and assist local health jurisdictions in obtaining the knowledge and resources necessary for investigations of a hepatitis B outbreak.
5. Summarize surveillance data for hepatitis B on an annual basis.
6. Provide Hepatitis B Immunoglobulin for contacts of cases to local health departments.
7. Offer laboratory testing of hepatitis B through the Office of Laboratory Services at no cost for the contacts of acute and chronic hepatitis B cases.
8. Assist with difficult investigations including:
    a. Interface with providers on behalf of Local Health Departments as necessary
    b. Provide assistance via the Viral hepatitis disease intervention specialists to Local Health Departments for investigating cases that are lost to follow up
    c. Investigation of possible exposures in unusual settings
    d. Investigation of healthcare associated hepatitis B infections

Disease Control Objectives

1. Identify and investigate community-based and healthcare associated outbreaks of hepatitis B in a timely fashion so that appropriate control measures can be applied.
2. Reduce transmission from persons with hepatitis B infection including:
    a. Perinatal transmission; and
    b. Transmission to household, sexual, and drug-using partners

Disease Prevention Objectives

1. Reduce the incidence of hepatitis B by:
    a. Assuring full hepatitis B immunization of all infants.
    b. Assuring “catch-up” hepatitis B immunization of all adolescents at the adolescent visit**.**
    c. Assuring full hepatitis B immunization of high-risk individuals to include:
        i. Sexually active adolescents and adults (including adolescents in STD clinics)
        ii. Household contacts and sexual partners of hepatitis B carriers
        iii. Healthcare personnel and those who have occupational exposure to blood
        iv. Residents and staff of institutions for the developmentally disabled
        v. Hemodialysis patients
        vi. Recipients of certain blood products
        vii. International travelers

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viii. Injection drug users and
ix. Inmates in correctional facilities

d. Reduce the incidence of hepatitis B through community education and programs to prevent drug use and sharing of needles during IDU.
e. Prevent nosocomial transmission of hepatitis B through effective infection control measures.
f. Prevent transmission of hepatitis B through screening of blood and organ donors.
g. Prevent perinatal transmission of hepatitis B by screening pregnant women and administering HBIG and hepatitis B vaccine to babies born to HBsAg positive mothers, within 12 hours of delivery.

Disease Surveillance Objectives

1. Determine the incidence of acute hepatitis B in West Virginia.
2. Determine the risk factors associated with acute hepatitis B in West Virginia.
3. Determine the demographic characteristics of persons with acute and chronic hepatitis B.
4. Distinguish between failure to immunize (preventable cases) versus failure of vaccine (non-preventable cases) among the reason(s) for continued occurrence of hepatitis B.
5. Detect outbreaks, clusters, or unusual patterns of transmission of hepatitis B.
6. Estimate the annual number of newly diagnosed chronic cases of hepatitis B.

Occupational Health

Hepatitis B is highly infectious, can be transmitted in the absence of visible blood, and can continue to be infectious on environmental surfaces for at least 7 days. Hepatitis B is transmitted through percutaneous (needle sticks), mucosal (contact with mucous membranes), or non-intact skin and exposure to infectious blood or body fluids. Percutaneous exposures are among the most efficient modes of hepatitis B transmission, but these exposures account for only a minority of hepatitis B infections among healthcare personnel. In several investigations of hepatitis B outbreaks, most infected healthcare personnel could not recall an obvious percutaneous exposure.

Education and Infrastructure

At the time of hire, healthcare providers and healthcare institutions should provide training to improve recognition and encourage timely reporting of blood and body fluid exposures. Institutions should ensure that healthcare personnel have rapid access to post exposure testing and prophylaxis, including HBIG and hepatitis B vaccine.

Vaccination

All healthcare personnel whose work, training, and volunteer activities involve anticipated exposure to blood or body fluids should be vaccinated with a complete, 3-dose hepatitis B vaccine series. The Occupational Safety and Health Administration (OSHA) mandates that vaccination be available for employees within 10 days of initial work assignment. Healthcare personnel should complete the hepatitis B vaccine series before the possibility of exposure to blood or body fluids.

Public Health Significance

Hepatitis B is a vaccine preventable disease. When the vaccine was introduced in 1982, it was recommended for high-risk groups (e.g. men who have sex with men, persons with multiple sexual partners or a history of a sexually transmitted disease, injection drug users, healthcare workers or persons with occupational exposure to blood, etc.). However, the epidemiology of hepatitis B infection has evolved since introduction of the vaccine shifting from urban areas to also include rural areas, and fewer cases identified among men who have sex with men to more cases identified among those who inject drugs and share drug paraphernalia.

In 1991, the Advisory Committee on Immunization Practices (ACIP) recommended universal infant immunization for hepatitis B, followed by a recommendation for catch-up vaccination of adolescents in 1996 as a national strategy to eliminate hepatitis B. At this time, the incidence of hepatitis B is stable in the US (1 per 100,000 persons), although the incidence of new infections is increasing in the Appalachian region of the US (West Virginia reported 14.7 per 100,000 persons in 2015.

Chronic hepatitis B virus infection is associated with the development of liver disease, including hepatocellular carcinoma. According to the CDC, one of 20 persons in the U.S. has been infected with hepatitis B virus during their lifetime (about 12.5 million); one of 200 persons has chronic (lifelong) infection with hepatitis B virus (about 1.25 million); and 4,000 to 5,000 persons die each year from hepatitis B-related chronic liver disease (cirrhosis, liver cancer).

In the United States, children can become infected with hepatitis B through a variety of means. The risk of perinatal hepatitis B infection among infants born to hepatitis B -infected mothers ranges from 10% to 85% depending on each mother's hepatitis B *e* antigen (HBeAg) status. Infants who become infected by perinatal transmission have a 90% risk of chronic infection, and up to 25% will die of chronic liver disease as adults. Even when not infected during the perinatal period, children of hepatitis B -infected mothers remain at high risk of

acquiring chronic hepatitis B infection by person-to-person horizontal transmission during the first five years of life. More than 90% of these infections can be prevented if HBsAg positive mothers are identified so that their infants can receive hepatitis B vaccine and hepatitis B immune globulin (HBIG) soon after birth.

The Significance of Healthcare Associated Infections

Healthcare exposures should be considered when investigating a case of acute hepatitis B infection that has no other risk factors than a healthcare procedure that occurred within 180 days prior to the date of onset of symptoms. Any single case of suspected healthcare associated hepatitis B infection warrants an investigation. Investigation of these suspected cases is a vital public health response, as it can result in the identification of an outbreak and/or unsafe clinical practices that can place additional patients at risk. Steps for investigating a single case of hepatitis B infection suspected of being related to healthcare delivery can be found at: http://www.cdc.gov/hepatitis/outbreaks/pdfs/healthcareinvestigationguide.pdf

Clinical Description

Signs and Symptoms of Acute Disease

Those who are acutely infected with hepatitis B virus may be asymptomatic or symptomatic. Typical symptoms include tiredness, headache, loss of appetite, nausea, vomiting, fever, and chills with onset three to 10 days prior to jaundice. Right upper quadrant pain is common. Urine may become dark, and stools may become clay-colored. The hallmark of the disease is jaundice (yellow color of the skin and sclera). Infants and children are usually asymptomatic, and an estimated 50% of adults with acute hepatitis B are asymptomatic.
Fulminant hepatitis occurs in very few patients and is usually fatal. Duration of illness is usually several weeks, with symptoms occasionally persisting beyond three to four months.

Signs and Symptoms of Chronic Infection

Most adults with acute hepatitis B will develop protective antibodies within six months of the infection. A small proportion (6-10%) of adult patients with acute hepatitis B will develop chronic hepatitis B. Most persons with chronic hepatitis B will not display symptoms but will continue to be infectious. Complications of chronic hepatitis B infection may include cirrhosis and/or hepatocellular carcinoma.

Hepatitis B

Surveillance and Investigation Protocol

Etiologic Agent

hepatitis B is a small double-stranded DNA virus. The outer protein coat contains the hepatitis B surface antigen.

Reservoir

Humans are the only known host.

Mode of Transmission

The virus is transmitted by parenteral or mucosal exposure to HBsAg positive bodily fluids from an infected person. The virus can be found in blood, body fluids (e.g. wound exudates), semen, cervical fluid, and saliva of persons who are HBsAg positive. Blood and serous fluids have the highest concentration of virus, and saliva the lowest. There appears to be no transmission of hepatitis B via tears, sweat, urine, stool, or droplet nuclei.

In the United States, the most common risk factor for transmission of hepatitis B is sexual contact with an infected person; however, the greatest risk for development of chronic infection is through perinatal transmission**.** Perinatal transmission from mother to infant at birth is very efficient. Transmission of perinatal hepatitis B infection can be prevented in approximately 95% of infants born to HBsAg-positive mothers when immunization and HBIG is administered to the infant within 12 hours of birth.

Person-to-person transmission of hepatitis B can occur in settings involving interpersonal contact over extended periods of time, such as in a household with a person with chronic hepatitis B infection. Transmission from sharing inanimate objects may also occur because hepatitis B can survive at room temperature for up to seven days but is inactivated by commonly used disinfectants, such as a 1:10 bleach solution. Hepatitis B is not transmitted by the fecal oral route.

Incubation Period

The incubation period is usually 45 to 180 days, with an average of 60 to 90 days. Time to detection of HBsAg can be as short as two weeks or as long as six months, depending on inoculum, host factors, and other variables.

Period of Communicability

All persons who are HBsAg positive are potentially infectious. The presence of HBeAg is associated with a very high level of infectivity.

Outbreak Recognition

Outbreak-associated hepatitis B and hepatitis C infections are defined as those with epidemiologic evidence supporting health care related transmission and include patients/residents identified with acute infection, or previously undiagnosed chronic infections with epidemiologic evidence indicating that these were likely outbreak-related incident cases that progressed from acute to chronic. Patients/residents identified as likely (previously infected) sources for transmission are not included. In the outbreak investigation setting case definitions are based on laboratory profile and clinical evidence rather than CDC surveillance case definitions which may omit asymptomatic cases.

Acute hepatitis B is typically defined as having a positive hepatitis B surface antigen and positive IgM core antibody, or positive surface antigen and negative total core antibody (early infection). Chronic hepatitis B is typically defined as having a positive hepatitis B surface antigen, positive total core antibody and negative IgM core antibody.

Case Definition

Hepatitis B, Acute (2012 Case Definition)

Clinical Description

An acute illness with a discrete onset of any sign or symptom* consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain), and either a) jaundice, or b) elevated serum alanine aminotransferase (ALT) levels >100 IU/L.

*A documented negative hepatitis B surface antigen (HBsAg) laboratory test result within 6 months prior to a positive test (either HBsAg, hepatitis B "e" antigen (HBeAg), or hepatitis B virus nucleic acid testing (hepatitis B NAT) including genotype) result does not require an acute clinical presentation to meet the surveillance case definition.

Laboratory Criteria for Diagnosis

HBsAg positive, AND Immunoglobulin M (IgM) antibody to hepatitis B core antigen (IgM anti-HBc) positive (if done)

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Case Classification

Confirmed - A case that meets the clinical case definition, is laboratory confirmed, and is not known to have chronic hepatitis B.

Not a case – Any case that does not meet ALL of the requirements listed above for a confirmed case.

Hepatitis B, Chronic (2012 Case Definition)

Clinical Description

No symptoms are required. Persons with chronic hepatitis B virus (hepatitis B) infection may have no evidence of liver disease or may have a spectrum of disease ranging from chronic hepatitis to cirrhosis or liver cancer.

Laboratory Criteria for Diagnosis

Immunoglobulin M (IgM) antibodies to hepatitis B core antigen (IgM anti-HBc) negative AND a positive result on one of the following tests: hepatitis B surface antigen (HBsAg), hepatitis B e antigen (HBeAg), or nucleic acid test for hepatitis B virus DNA (including qualitative, quantitative and genotype testing), OR

HBsAg positive or nucleic acid test for hepatitis B DNA positive (including qualitative, quantitative and genotype testing) or HBeAg positive two times at least 6 months apart (Any combination of these tests performed 6 months apart is acceptable)

Case Classification

Probable - A person with a single HBsAg positive or hepatitis B DNA positive (including qualitative, quantitative and genotype testing) or HBeAg positive lab result and does not meet the case definition for acute hepatitis B.

Confirmed - A person who meets either of the above laboratory criteria for diagnosis.

Comments:

Multiple laboratory tests indicative of chronic hepatitis B infection may be performed simultaneously on the same patient specimen as part of a "hepatitis panel." Testing performed in this manner may lead to seemingly discordant results, e.g., HBsAg-negative AND hepatitis B DNA-positive. For the purposes of this case definition, any positive result among the three laboratory tests mentioned above is acceptable, regardless of other testing results. Negative

HBeAg results and hepatitis B DNA levels below positive cutoff level do not confirm the absence of hepatitis B infection.

Preventive Interventions

Hepatitis B vaccine is a very safe and effective vaccine for prevention of hepatitis B, and it is recommended for all infants, adolescents who have not already had the vaccine, those with high risk behavior, and anyone who may be at risk for hepatitis B infection:

1. Babies who are born to a mother who is HBsAg positive
2. Those who have a job that involves contact with blood and blood products
3. Injection drug users
4. Sexually active persons who have had more than one partner in the last six months or who have a sexually transmitted disease previously
5. Sexually active men who have sex with men
6. Household contacts and sexual partners of persons who are chronically infected and HBsAg-positive
7. Residents and staff of institutions for developmentally disabled persons
8. Staff of nonresidential child care and school programs for developmentally disabled persons if the program is attended by a known HBsAg-positive person
9. Patients undergoing hemodialysis
10. Patients with bleeding disorders who receive clotting factor concentrates
11. Members of households with adoptees who are HBsAg-positive
12. International travelers to areas in which hepatitis B infection is of high or intermediate endemicity
13. Inmates of juvenile detention centers and other correctional facilities

Treatment

No specific therapy for *acute* hepatitis B infection is available other than supportive therapy for symptoms of acute hepatitis B. Patients should check with their physician about treatment for chronic hepatitis B. The goal of treatment in patients with chronic hepatitis B infection is to prevent progression to cirrhosis, hepatic failure, and hepatocellular carcinoma.

Surveillance Indicators

1. Proportion of acute cases with complete demographic information.
2. Proportion of acute cases with complete clinical information.
3. Proportion of acute cases with complete risk factor/exposure information.

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4. Proportion of acute cases with complete vaccination history.
5. Proportion of acute cases that have received education and the date they were educated.
6. Proportion of acute cases reported to public health within the required timeframe.

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