GUIDELINES FOR
VIRAL HEPATITIS SURVEILLANCE
AND CASE MANAGEMENT

January 2005

Guidelines for Viral Hepatitis Surveillance and Case Management

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Suggested citation

Centers for Disease Control and Prevention. Guidelines for Viral Hepatitis Surveillance and Case Management. Atlanta, GA 2005

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Summary

Surveillance for viral hepatitis is needed to direct and evaluate prevention and control activities. CDC recommends that all states and territories conduct surveillance for acute viral hepatitis, including hepatitis A, B, C, and non-ABC hepatitis. In addition, states and territories should consider establishing computerized databases of persons who test positive for hepatitis B surface antigen (HBsAg) or antibody to hepatitis C virus (anti-HCV) to facilitate the notification, counseling and management of persons with chronic hepatitis B virus (HBV) or hepatitis C virus (HCV) infections. The purpose of this document is to 1) provide guidance to clinicians, state and local health departments, and other health agencies regarding case ascertainment, reporting, investigation, and follow-up of persons with acute viral hepatitis; and 2) provide a framework for the development of systems for identifying and following up persons who may have chronic HBV or HCV infections. These guidelines describe the essential elements and best practices for conducting surveillance for viral hepatitis, and were developed based on consultation with representatives from state and local health departments who met in Atlanta in January 1999.

BACKGROUND

The primary goals of conducting surveillance for viral hepatitis are to direct prevention and control activities for these diseases and to evaluate the impact of these activities. In 2000, there were approximately 25,000 cases of acute viral hepatitis reported nationwide, including 14,000 cases of hepatitis A and 8,000 cases of hepatitis B. In addition, 1.25 million persons are chronically infected with HBV and 2.7 million are chronically infected with HCV. Any person with a hepatitis virus infection is a potential source of infection to others. The investigation of infected persons can prevent further transmission by identifying contacts who require vaccination or other preventive interventions and by detecting outbreaks, determining the cause, and implementing appropriate control and prevention measures. Aspects of the epidemiology and prevention specific for each type of viral hepatitis need to be considered in developing surveillance systems for these diseases. Surveillance overall helps to accomplish these goals by providing information to:

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- *Monitor trends in incidence of and risk factors for disease*
- *Assess burden of disease*
- *Identify infected persons requiring counseling and medical follow-up*
- *Identify contacts of infected persons requiring counseling and/or post exposure prophylaxis*
- *Identify and control outbreaks*

Information on cases of viral hepatitis reported nationally has been maintained at CDC in two surveillance systems. Information collected by the National Notifiable Disease Surveillance System (NNDSS) includes diagnosis, event dates (e.g., illness onset), and basic demographic data (e.g., state, county, age, race, ethnicity). Additional information collected by the Viral Hepatitis Surveillance Program (VHSP) includes clinical features, serologic test results, and risk factors for infection. This information is needed to confirm the diagnosis, determine a source of infection, and identify others at risk of infection that would benefit from preventive intervention.

In 1989, a consolidation of VHSP and NNDSS was initiated with efforts to have all acute viral hepatitis surveillance data reported electronically to a single system, the National Electronic Telecommunications System for Surveillance (NETSS). Data entry screens are available in NETSS that include all of the information requested for both NNDSS and the VHSP.

Not all states have participated in VHSP, and among states that have participated in VHSP, the proportion of cases reported to both NNDSS and VHSP has been variable. In addition, several participating states have continued to report data only on the paper copy of the VHSP form, rather than electronically. Paper reporting via VHSP was discontinued as of January 2002. Thus, all information on reported cases of acute viral

hepatitis are now received and maintained through a single unified electronic reporting system. Improving the completeness of case reports made through this system will require further efforts by CDC and state health departments.

As an element of the planned National Electronic Data Surveillance Systems (NEDSS), substantial changes in the structure and function of NETSS are expected. The development of a person-based system that collects and stores public health information according to widely used, standardized definitions and formats and that uses unique identifiers to link information from different disease reports and other health data sources will significantly enhance the capacity to conduct surveillance for viral hepatitis.

To date, nationwide surveillance efforts for viral hepatitis have focused on cases of newly acquired clinically apparent disease, and historically, most cases of acute viral hepatitis have been identified on the basis of a clinician's report of a patient with an illness compatible with acute hepatitis. With the implementation of laboratory reporting requirements in many states, laboratory-based reporting of serologic markers for viral hepatitis is an increasingly common route by which suspected cases are identified to state and local health departments. Although laboratory-based reporting can increase the completeness and timeliness of case identification, it also identifies asymptomatic individuals with newly acquired infections, individuals with chronic infection, and individuals for whom there is insufficient information to verify the diagnosis based on laboratory testing alone.

Although asymptomatic individuals with newly acquired infections represent incident infections, they have not been included as reportable conditions. However, as the incidence of all types of acute viral hepatitis declines, the ascertainment and reporting of all persons testing positive for serologic markers of recent infection with hepatitis viruses will be necessary to monitor their incidences. When the definitions and categories for reporting cases of acute viral hepatitis are expanded to include those identified by laboratory test results alone, it will be important to distinguish symptomatic from asymptomatic individuals. This is because the numbers of asymptomatic persons identified can be highly variable depending on testing practices, and result in artificial differences in incidence both temporally and geographically. In addition, the ability to identify such individuals is primarily limited to HAV and HBV infections, for which IgM antibody assays specific for acute infection are available. No serologic marker is available for acute HCV infection, thus, the incidence of HAV or HBV infections relative to HCV infection would not accurately reflect their true relationships. The full implications of expanding surveillance case definitions to include asymptomatic individuals will not be known until these strategies are implemented.

Laboratory-based reporting also identifies HBV or HCV infected

persons with chronic infection. Although previously not included among nationally notifiable conditions, the public health importance of chronic viral hepatitis infections dictates that they be added. Several states and counties have established viral hepatitis infection databases for persons testing positive for HBsAg or anti-HCV, but their experience indicates that managing large numbers of HBsAg positive and anti-HCV positive laboratory reports has the potential to overwhelm a surveillance system and divert scarce resources into data management rather than disease prevention. The expected integration of functions and standards in NEDSS that facilitate the implementation of such databases will enhance capacity to manage and monitor these reports. Further assessment at the state and local level is needed to determine the most feasible and useful approaches for establishing these types of systems and linking them to prevention activities.

Hepatitis A

Rates of hepatitis A are now the lowest ever recorded. Nevertheless, hepatitis A remains one of the most frequently reported vaccine preventable diseases in the United States

Epidemiologic characteristics

Periodic epidemics of hepatitis A have occurred in the United States approximately every decade; the last nationwide epidemic occurred in 1995 [1]. Since then, rates of hepatitis A have declined precipitously and are now the lowest ever recorded. Nevertheless, hepatitis A remains one of the most frequently reported vaccine preventable diseases in the United States. In 2000, a total of 13,397 cases of hepatitis A were reported to CDC[1], which, when corrected for underreporting and asymptomatic infections, represents an estimated 57,000 cases and 143,000 infections.

Historically, incidence of hepatitis A has varied by race/ethnicity with the highest rates among American Indians/Alaska Natives and rates among Hispanics that were higher than among non-Hispanics. However, rates among American Indians/Alaska Natives have dropped dramatically since the implementation of widespread routine hepatitis A vaccination in high rate Native American communities and are now the same as for other races. Rates among Hispanics remain higher than among non-Hispanics. The highest rates of reported disease have been among children 5-14 years of age, and although disease rates in this group have decreased substantially in recent years and are similar to those among adults, $\geq$25 percent of reported cases are in persons <20 years of age. Asymptomatic or unrecognized infections occurring in young children are often a source of infection to others. Most cases of hepatitis A result from person-to-person transmission during community-wide epidemics in which children play a critical role in sustaining hepatitis A virus (HAV) transmission.

Prevention strategies

Hepatitis A vaccine has been licensed in the United States since 1995, and in 1996 routine childhood hepatitis A vaccination was recommended in communities with the highest hepatitis A rates, which

included American Indian, Alaskan Native and selected Hispanic, migrant and religious communities. Coincident with the implementation of hepatitis A vaccination of children in those communities, there have been dramatic reductions in hepatitis A rates in those areas.

In 1999, the recommendations for routine vaccination of children were extended to include children living in states or counties with rates at least twice the 1987-1997 national average (i.e. ≤20 cases per 100,000 population) [2]. It was suggested that vaccination also be considered for children living in states or counties with average rates that exceeded the 1987-1987 national average (i.e., ≥10-≤20 cases per 100,000). Reductions in hepatitis A rates in these areas since 1999 suggest that routine vaccination is having an impact but further monitoring is needed to determine whether these decreased rates are sustained and attributable to vaccination. Pre-exposure vaccination is also recommended for persons at high risk for hepatitis A including illegal drug users, men who have sex with men, persons traveling to countries where HAV is endemic, and persons with occupational risk of infection (i.e., persons who work with HAV-infected primates or with HAV in a research laboratory), as well as for persons with chronic liver disease. However, since as many as 50% of reported cases do not belong to one of these identified risk groups, vaccination of persons in these groups has little effect on national disease rates and does not prevent the majority of cases.

Surveillance

Because no chronic infection develops after hepatitis A, reported cases of acute disease provide a valid measure of ongoing transmission and the overall burden of disease due to HAV. Investigation of reported cases to determine their characteristics and source for infection provides the best information for monitoring trends in transmission patterns. Monitoring changes in overall and age-specific disease rates is the only means available to assess the effectiveness of hepatitis A vaccination programs.

Demographic and risk factor information collected through surveillance can be used to direct ongoing prevention efforts by identifying new target groups or areas in which vaccination programs should be initiated. Missed opportunities for vaccination can be assessed by investigating cases occurring in persons belonging to a group for which vaccination is recommended to determine where they have received health care and other recommended vaccinations. Intensive investigation of cases occurring in persons who received hepatitis A vaccine may be used to evaluate the frequency and causes of vaccine failure.

Timely identification of persons with acute hepatitis A allows exposed contacts to receive effective prophylaxis to prevent secondary spread of HAV. This is important in preventing outbreaks associated with day care centers or infected food handlers and to prevent person-to-person transmission in households and extended family settings and

among sexual contacts.

Hepatitis A often occurs in the context of community wide epidemics, but outbreaks also occur among persons reporting certain behaviors (e.g., men having sex with men, illicit drug use) or exposures (e.g., food contaminated with HAV). By investigating reported cases for risk factors and recent exposures, groups at increased risk for infection can be identified for targeted prevention activities or a potential common source can be identified that might have placed additional persons at risk.

Hepatitis B

Epidemiologic characteristics

Acute and chronic HBV infections are a major cause of morbidity and mortality in the United States. Acute hepatitis B is one of the most commonly reported vaccine preventable diseases; in 2000, 8036 cases were reported [1]. However, because most newly infected persons are asymptomatic [3], and because even symptomatic persons are underreported [4], reported hepatitis B cases markedly underestimate the incidence of HBV infection. Based on catalytic modeling of data from the second and third National Health and Nutrition Examination Surveys, the estimated number of new infections in 2000 was 81,000, a decrease of 70% from a peak of approximately 280,000 in the mid-1980's. In addition to acute disease, approximately 1.25 million persons in the United States have chronic HBV infection. These persons are at increased risk for chronic liver disease, including cirrhosis and hepatocellular carcinoma, and they are the major reservoir of ongoing HBV transmission.

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The incidence of HBV infection differs significantly by race and ethnicity with the highest rates among blacks; rates are higher among Hispanics than non-Hispanics. Incidence also varies by age with the highest rates reported among persons 20-39 years of age. Less than 5% of the HBV infections that occur among children are reported as cases of acute hepatitis B to CDC because HBV infections that occur in infants and children rarely produce signs or symptoms of disease. Furthermore, chronic HBV infection develops in approximately 90% of children infected at birth and 30%-60% of children infected between 1 to 5 years of age compared with 2%-6% of older children and adults; thus, prior to routine immunoprophylaxis of infants and children, cases occurring in children accounted for a disproportionate amount of the disease burden due to chronic infection.

In addition to infections occurring in childhood, CDC estimates that 20,000 (95% confidence interval, 15,000 to 32,000) infants are born to HBsAg positive mothers each year [5]. Post-exposure prophylaxis is highly effective in preventing transmission of HBV from mother to infant. However, an estimated 1000 of these infants become chronically infected with HBV each year because not all infected mothers are identified and not all infants receive appropriate post-exposure prophylaxis. Although perinatal HBV infections have been nationally notifiable since 1995,

reported cases have not been reliable for monitoring the number of perinatal infections that are occurring in the United States because of a lack of follow-up serologic testing of infants born to infected mothers.

Prevention strategies/recommendations

Hepatitis B vaccine has been available in the United States since 1982. A comprehensive immunization strategy to eliminate HBV transmission in the United States includes 1) preventing perinatal HBV transmission by screening all pregnant women for HBsAg and providing immunoprophylaxis to infants of HBV-infected women; 2) routine immunization of all infants; 3) catch-up vaccination of all previously unvaccinated children aged <19 years, with priority for vaccination at 11 to 12 years of age; and 4) vaccination of adolescents and adults at high risk for infection including persons with a history of multiple sex partners (>1 partner/6 months) or a sexually-transmitted disease; men who have sex with men; injecting drug users; incarcerated persons; household and sex contacts of persons with chronic HBV infection; health care and public safety workers who have exposure to blood in the workplace; and hemodialysis patients.

Enhanced surveillance for cases occurring in age groups for which routine vaccination is recommended (i.e., children <18 years of age) to determine their characteristics and vaccination history provides information to monitor and evaluate the operation of childhood vaccination programs.

Surveillance

To accomplish the goals of conducting surveillance for hepatitis B, multiple types of surveillance activities are needed, including surveillance for acute hepatitis B, surveillance for perinatal HBV infection, and surveillance for persons who test positive for HBsAg to identify those with chronic HBV infections.

Surveillance for acute hepatitis B—newly acquired symptomatic infections – is needed to monitor ongoing transmission of HBV, and investigation of these cases to determine their characteristics and risk factors provides the information needed for monitoring trends in transmission patterns and targeting prevention activities. Enhanced surveillance for cases occurring in age groups for which routine vaccination is recommended (i.e., children <18 years of age) to determine their characteristics and vaccination history provides information to monitor and evaluate the operation of childhood vaccination programs. Additional information on reported cases of acute hepatitis B is useful to identify settings in which hepatitis B vaccine could have been offered. Analysis of cases of acute hepatitis B reported during 1996-1998 indicated that more than half had previously received care in settings where hepatitis B vaccine is recommended (i.e. STD clinics, correctional facilities) [6]. Furthermore, 40% of persons who report no recognized risk factor for infection during their exposure period reported high-risk characteristics or behaviors that place them in groups for which hepatitis B vaccine is recommended (past history of MSM activity, IDU or treatment for a STD). Monitoring changes in the incidence of acute disease provides data to assess the impact of hepatitis B vaccination programs. National hepatitis B disease reduction objectives for the year 2010 include reducing the incidence of acute hepatitis B among persons <19

Surveillance for perinatal HBV infection depends upon the identification of HBV-infected mothers by screening pregnant women for HBsAg and the post-vaccination testing of infants born to HBV-infected mothers. including their mothers.

Many states currently have regulations requiring laboratories to report all HBsAg positive results to local health departments. These results can be used to identify persons with chronic HBV infection who need counseling and referral for medical follow-up and whose contacts require immunization.

years of age by >99% and reducing hepatitis B incidence in adult high risk groups by >75% [7]. The effect of routine infant and adolescent vaccination can already be seen in the declining rate of disease in persons <19 years of age. Similarly, the impact of a 1992 OSHA rule requiring employers to offer hepatitis B vaccine to at risk employees is demonstrated by vaccine coverage levels of >65% and a decrease of >70% in the number of cases occurring among health care workers since 1993. In contrast, the continued high incidence among persons in other risk groups for which vaccination is recommended such as injection drug users and persons engaging in high risk sexual behaviors indicates that programs for reaching these populations with vaccine need to be developed or strengthened.

The timely identification of persons recently infected with HBV provides the opportunity not only to counsel the infected individual but also to identify susceptible contacts requiring post-exposure prophylaxis early enough to prevent further transmission. Fifteen to 20% of acute hepatitis B cases are acquired from a known infected contact and could have been prevented by timely pre- or post-exposure prophylaxis (JID, submitted). By monitoring the exposures of recently infected persons, surveillance for acute disease also provides the information critical for identifying outbreaks of hepatitis B that, while uncommon, do occur. Nosocomial outbreaks involving patient-to-patient transmission have occurred in association with a variety of transmission vehicles including multidose medication vials, reusable fingerstick devices, and other contaminated medical equipment [8, 9, 10, 11, 12]. Although cases of provider-to-patient transmission of HBV are rare in the United States continued vigilance is needed to detect these cases should they occur.

Surveillance for perinatal HBV infection is needed to evaluate the effectiveness of the perinatal HBV prevention program by monitoring the incidence of these infections and to identify HBV-infected infants for referral for medical management and treatment if appropriate. Surveillance for perinatal HBV infection depends upon the identification of HBV-infected mothers by screening pregnant women for HBsAg and the post-vaccination testing of infants born to HBV-infected mothers. Post-vaccination testing also identifies uninfected infants who did not respond to vaccination and require re-vaccination because of ongoing exposure to infected household contacts including their mothers.

Intensive investigation of infected infants is needed to assess and reduce missed opportunities for providing post-exposure immunoprophylaxis and to assess the frequency and risk factors for failure of immunoprophylaxis. Although rare, possible reasons for failure of immunoprophylaxis include incomplete vaccination, *in utero* infections, delayed vaccination doses, and infection with an HBV variant [13, 14, 15, 16, 17]

Surveillance for chronic HBV infection: HBsAg can be detected in virtually all persons with chronic HBV infection. Many states currently have

regulations requiring laboratories to report all HBsAg positive results to local health departments. These results can be used to identify persons with chronic HBV infection who need counseling and referral for medical follow-up and whose contacts require immunization.

Determining the frequency and characteristics of persons reported as HBsAg-positive also describes who and where infected persons are being identified. Although dependent upon testing practices, this information can help in developing minimum estimates of infection burden and is useful for identifying gaps in current testing practices. Further investigation of chronically infected persons (or a sample of them) to determine why they were identified and what actions (e.g. medical evaluation, vaccination of contacts) resulted from being identified provides information to direct and evaluate prevention activities.

Hepatitis C

There are an estimated 3.9 million Americans who have been infected with HCV. Approximately 75% of these persons are chronically infected and may not be aware of their infection because they are not clinically ill

Epidemiologic characteristics

Hepatitis C virus (HCV) infection is the most common chronic bloodborne infection in the United States. Although the annual number of new infections has declined since 1989 by more than 80% to 36,000 in 2000, data from the Third National Health and Nutrition Examination Survey [18] conducted during 1988-1994 indicate that there are an estimated 3.9 million Americans who have been infected with HCV. Approximately 75% of these persons are chronically infected and may not be aware of their infection because they are not clinically ill. These persons serve as a source of transmission to others and are at risk for chronic liver disease or other HCV-related chronic diseases.

HCV infection occurs among persons of all ages, but the highest incidence of acute hepatitis C is found among persons 20-39 years. African Americans and whites have similar incidence rates of acute disease with higher rates in persons of Hispanic ethnicity.

Prevention strategies

With no effective vaccine or post-exposure prophylaxis, reducing the burden of HCV infection and HCV-related disease in the United States requires implementation of primary prevention activities to reduce the risk of contracting the infection and secondary prevention activities to reduce the risk of liver disease and other HCV-related chronic diseases among HCV-infected persons [19].

Surveillance

Hepatitis C surveillance is a critical component of a comprehensive strategy to prevent and control HCV infection and HCV-related chronic

liver disease. To accomplish the goals of hepatitis C surveillance, activities are needed to identify persons with acute hepatitis C, as well as persons with chronic HCV infection.

Surveillance for acute hepatitis C –newly acquired symptomatic infection- is needed to monitor ongoing transmission of HCV, and investigation of these cases to determine their characteristics and risk factors provides the best information for monitoring trends in transmission patterns. The collection of this information for reported cases is useful for characterizing groups at risk of infection and targeting prevention activities. Monitoring changes in acute disease incidence and in the risk factors for infection can be used to assess the effectiveness of prevention programs.

Surveillance for newly acquired symptomatic hepatitis C is needed to monitor ongoing transmission of HCV, and investigation of these cases to determine their characteristics and risk factors provides the best information for monitoring trends in transmission patterns

By monitoring the exposures of recently infected persons, surveillance for acute hepatitis C also provides the information needed to detect outbreaks that, while uncommon, do occur. Although rarely reported in the United States except in the chronic hemodialysis setting, nosocomial outbreaks of HCV involving patient-to-patient transmission can occur if infection control techniques or disinfection procedures are inadequate and contaminated equipment is shared among patients. The risk of HCV transmission from an infected health care worker to patients appears to be very low but vigilance is needed to detect these cases should they occur.

Conducting surveillance for acute hepatitis C on a nationwide basis has been difficult because a) no serologic marker for acute infection is available; b) cases are usually reported on the basis of a positive laboratory report and most health departments do not have the resources to conduct investigations to determine if these reports represent acute infection, chronic infection, repeated testing of a person who was previously reported, or a false-positive result; and c) it can be difficult to differentiate acute infection from exacerbation of chronic infection based on clinical features of disease. Thus, the cases reported as acute hepatitis C to the National Notifiable Disease Surveillance System have been unreliable to date. Instead acute disease incidence and transmission patterns have been monitored using reported cases from CDC's Sentinel Counties Study of Acute Viral Hepatitis, in which all patients with signs and symptoms of viral hepatitis are investigated to ascertain cases of acute hepatitis C.

However, reliable state-specific data are needed to direct and evaluate hepatitis C prevention and control programs. In addition to expanding the use of strategies such as sentinel surveillance or serial serologic surveys to address local needs for hepatitis C surveillance data, the implementation of methods that facilitate the management and evaluation of case reports of suspected hepatitis C can enhance the capacity of state or local health departments to conduct surveillance for acute hepatitis C. For example, the revision of the case definition for acute hepatitis C to include a higher ALT threshold provided a more

efficient and specific criterion to determine which reports require further investigation to distinguish anti-HCV positive individuals with acute disease from those with remote or chronic infection.

Surveillance for HCV-Infection. Many states currently have regulations requiring laboratories to report all anti-HCV positive results to local health departments. Although limitations exist to the use of anti-HCV positive laboratory reports to conduct surveillance for HCV infection, these reports can be an important source from which state and local health departments can identify HCV-infected persons who need counseling and medical follow-up.

Although limitations exist to the use of anti-HCV positive laboratory reports to conduct surveillance for HCV infection, these reports can be an important source from which state and local health departments can identify HCV-infected persons who need counseling and medical follow-up.

Determining the frequency and characteristics of persons reported as anti-HCV-positive also describes who and where infected persons are being identified. Although dependent upon testing practices, this information can help in developing minimum estimates of infection burden and is useful for identifying gaps in current testing practices. Further investigation of chronically infected persons (or a sample of them) to determine why they were identified and what actions (e.g. medical evaluation) resulted from being identified provides information to direct and evaluate prevention activities.

Non-ABC Hepatitis

HAV, HBV and HCV are the etiologic agents of >95 % of acute viral hepatitis in the United States. However, a small percentage of persons with signs and symptoms typical of acute viral hepatitis do not have serologic markers of infection with these viruses, and may be infected with other viruses. Hepatitis D (delta) virus (HDV) is an incomplete virus that requires the helper function of HBV to replicate. HDV can be acquired either as a coinfection with HBV or as a superinfection in persons with chronic HBV infection. The incidence of delta hepatitis cannot be directly calculated from national surveillance data because this disease is not reportable in the United States; however, in prevalence studies among patients with acute hepatitis B, 1.5-7.2% had serologic evidence of HBV-HDV coinfection [20].

Hepatitis E is rare in the United States and most reported cases have been associated with travel to HEV-endemic countries [21, 22]. However, several cases of acute hepatitis E have been reported in persons with no recent history of travel outside the United States [23, 24] and HEV infection should be considered in patients with non-ABC hepatitis. Additional candidate hepatitis viruses that have been isolated from patients with posttransfusion hepatitis include hepatitis G virus (also called GB virus C), TTV, and SENV [25, 26, 27, 28]; however, none of these viruses has been demonstrated to be a cause of acute or chronic hepatitis [27, 29].

GENERAL SURVEILLANCE GUIDELINES

Case Ascertainment

Methods to improve the timeliness and completeness of reporting include a) implementing laboratory reporting laws, b) ensuring that all patients who have signs and symptoms of acute viral hepatitis are appropriately tested and reported; and c) ensuring that all patients with chronic hepatitis, or who have risk factors for HBV or HCV infection are appropriately tested and reported if positive.

Laboratory reporting rules. All states should implement rules or regulations requiring laboratories to promptly report test results positive for any of the following serologic markers of acute or chronic hepatitis:

- IgM antibody to HAV (IgM anti-HAV);
- Hepatitis B surface antigen (HBsAg);
- IgM antibody to hepatitis B core antigen (IgM anti-HBc); and
- Antibody to HCV (anti-HCV).

The clinical features of acute disease caused by hepatitis viruses are similar. Thus, serologic testing is necessary to establish a diagnosis in persons with jaundice or other signs and/or symptoms of acute hepatitis.

Computerized data systems are maintained by many clinical laboratories. The establishment of information management systems for receiving data electronically from laboratories can facilitate surveillance for viral hepatitis by increasing timeliness and completeness of case identification. State regulations for laboratory reporting of serologic markers of viral hepatitis should include requirements to report available information which could facilitate case identification and investigation, including contact information for the patient and for the patient's physician. Reports of positive test results should also include the results for other serologic markers of viral hepatitis that were evaluated on the same individual, and serum aminotransferase (e.g. ALT) levels, if available. In addition, pregnancy status should be reported if testing was done as part of a prenatal test panel.

Testing of patients with signs and/or symptoms of acute viral hepatitis. The clinical features of acute disease caused by hepatitis viruses are similar. Thus, serologic testing is necessary to establish a diagnosis in persons with jaundice or other signs and/or symptoms of acute hepatitis (e.g., anorexia, nausea, malaise, vomiting, dark urine, clay colored or light stools, and abdominal pain). Appropriate diagnostic testing of such patients is crucial to ensure complete case ascertainment. To facilitate accurate testing, laboratories, managed care organizations and payors should encourage implementation and use of standardized diagnostic panels for testing patients with signs and symptoms of acute hepatitis which should include all of the serologic markers that are included in state laboratory reporting requirements (e.g., IgM anti-HAV, HBsAg, IgM anti-HBc, and anti-HCV). In addition, educational efforts should be developed and promoted in conjunction with professional

organizations to increase awareness of appropriate testing algorithms and reporting laws among clinicians.

Testing of patients with chronic hepatitis, or risk factors for chronic HBV or HCV infection. Most persons with chronic HBV or HCV infection are asymptomatic. Thus, testing programs for persons with risk factors for infection and/or elevated liver enzymes (e.g., ALT, AST) are required to identify chronically infected persons. Routine screening of pregnant women for HBsAg is done to identify infants of infected women who require post-exposure prophylaxis. High risk populations for chronic HBV infection (e.g., STD and drug treatment patients, inmates of correctional facilities, immigrants from countries with a HBsAg prevalence >2%) might benefit from routine HBsAg testing, but the feasibility and cost effectiveness of such testing in various clinical settings has not been determined. Recommendations have been developed for routine anti-HCV testing for persons at high risk of HCV infection (i.e., persons who have ever injected illegal drugs, persons who received a blood transfusion or organ transplant before July 1992, persons ever on chronic hemodialysis, persons who received clotting factor concentrates made before 1987, persons with abnormal liver enzyme levels) [30].

Most persons with chronic HBV or HCV infection are asymptomatic. Thus, testing programs for persons with risk factors for infection and/or elevated liver enzymes (e.g., ALT, AST) are required to identify chronically infected persons.

The specificity of HBsAg or anti-HCV testing is high when used to evaluate persons with signs or symptoms of hepatitis. However, as with any test, the positive predictive value of these tests when used to screen asymptomatic persons depends on the prevalence of the condition among the persons being tested, and the likelihood of a false-positive test result increases when the tests are used in low-risk populations. Confirmation of a positive test result for HBsAg or anti-HCV by an additional more specific assay is needed to rule out a false-positive result, especially in persons with no identified risk factor for infection. The presence of other serologic markers of HBV infection (i.e. total anti-HBc or IgM anti-HBc) can be used to evaluate the likelihood that an HBsAg positive test result is a true positive but isolated HBsAg positive test results should be verified by a confirmatory assay (e.g. neutralization assay). Anti-HCV positive results by enzyme immunoassay (EIA) should be verified by a supplemental antibody assay (e.g., RIBA™). If supplemental test results are not available, a positive EIA test can also be confirmed by calculating the signal to cutoff ratio (S/CO) for the specimen. If the S/CO is $\geq$3.8, the likelihood that the specimen would be positive by supplemental assay is >95%. Detection of HCV RNA by RT-PCR verifies HCV infection, but the absence of detectable RNA in a single serum specimen does not exclude the possibility of HCV infection.

Case Reporting

Data elements

The collection of a minimum set of standardized data elements

(Table I) on all reported cases of viral hepatitis ensures that information collected can be effectively used at the local, state and national level. These minimum data elements should conform wherever possible to the definitions and formats specified for NEDSS. In addition to locators (e.g., state, county of report) and demographic descriptors (e.g., age, race, ethnicity, sex), the following information, required for classifying the case as acute or chronic and for determining appropriate follow-up should be reported for every case:

- Presence of symptoms consistent with acute hepatitis and the date of onset for those symptoms
- Presence of jaundice
- Results and date of serum aminotransferase testing, if available.
- Serologic test results for any markers of viral hepatitis (see Case Ascertainment)

Confirmation of a positive test result for HBsAg or anti-HCV by an additional more specific assay is needed to rule out a false-positive result, especially in persons with no identified risk factor for infection

Unique Identifiers. Patient name and other identifying information (e.g. birthdate/social security number) are typically maintained as part of state surveillance databases. A unique identifier is essential for appropriate patient follow-up, distinguishes newly identified cases from previously reported individuals and allows linkage to related health-care data. Efforts are underway by CDC and its' public health partners to develop a unique identifier composed of standardized data elements that are used throughout the health-care and public health sectors. Policies for ensuring patient privacy and security of data should be in place for any system maintaining unique patient identifiers.

In addition to these core elements, information including recent exposures should be collected and reported as part of the recommended case investigation of cases of acute viral hepatitis or perinatal HBV infection. The information to be collected and reported for investigations of different types of viral hepatitis are described in the virus specific guidelines below. Recommendations regarding the types of information that might be collected in a chronic infection database also are included in the disease specific sections below; however, further evaluation is needed to determine the types of information that will be most useful.

Table I: Information elements to be collected for case reports of viral hepatitis

Information Collected	Comments
Locator Information	
• State, county, ZIP code	Core variables (NEDSS standards)
Demographic Information	
• Date of birth, age, sex, race, ethnicity	Core variables (NEDSS standards)
Clinical Data	
• Date of illness onset	First sign or symptom of hepatitis
• Presence of symptoms of acute hepatitis	Verifies case definition
• Presence of jaundice	Verifies case definition
• ALT level	Verifies case definition
• Hospitalization for hepatitis	If yes, verify dates of hospitalization
• Death from hepatitis	If yes, review death certificate and medical records to rule out other potential causes of death and to confirm acute liver failure as cause of death
Diagnostic Testing Results	
• IgM anti-HAV, HBsAg, IgM anti-HBc, anti-HCV, anti-HDV	Verifies case definition. Determine all results (positive and negative). HBsAg and anti-HCV positive test results require confirmation by an additional more specific assay or for anti-HCV, a S/CO ratio $\geq$ 3.8.
• Date of diagnosis	Date of test result confirming infection
Other	
• Pregnancy Status	If pregnant, infants of HBV or HCV infected women should be tested for infection (see disease specific guidelines)
• Origin of report	Site requesting viral hepatitis testing

Reporting cases to CDC

With the implementation of NEDSS, which will include standards for electronic transfer of data, all reporting of viral hepatitis case data, including risk factor information, will occur electronically. States that currently transmit VHSP data electronically via NETSS should discontinue paper-based reporting. CDC is committed to working with those states that rely on paper-based reporting to overcome barriers to electronic reporting of hepatitis surveillance data.

Databases of persons chronically infected with HBV or HCV

Computerized databases of HBsAg positive and anti-HCV positive persons can facilitate the notification, counseling and medical management of persons chronically infected with HBV or HCV. These databases can be used to:

- distinguish newly reported cases of infection from previously identified cases;
- facilitate and track the follow-up of chronically infected persons; and
- provide local, state, and national estimates of the proportion of persons with chronic HBV or HCV infection who have been identified.

Computerized databases of HBsAg positive and anti-HCV positive persons can facilitate the notification, counseling and medical management of persons chronically infected with HBV or HCV.

The specific information elements to be maintained in a database of chronically infected persons will depend upon the objectives of establishing the database and the feasibility of collecting that information. At a minimum, sufficient information should be collected to distinguish newly identified persons from previously reported individuals including information to establish a unique identifier (e.g. name, race, date of birth) and serologic test results to confirm chronic infection with HBV or HCV. Information about the clinical characteristics of the individual (e.g. presence of symptoms consistent with acute viral hepatitis, date of symptom onset, results of liver enzyme testing) and why they were identified can help to distinguish persons with chronic infection from those with acute disease. The collection of the minimum demographic information that is required for reporting of acute cases is also recommended for cases of chronic infection as these data can be used to describe the population of infected persons that has been identified, information useful for allocating public health resources and directing and evaluating prevention programs. The collection of additional information for a sample of persons in these databases can be useful to further characterize the infected population (e.g. past exposures or risk factors) or to assess the impact of public health follow-up of these persons (e.g. did they receive medical evaluation, did their susceptible contacts receive appropriate follow-up). The recommended information to be collected in databases of persons with chronic HBV or HCV infection is included in the disease specific sections below.

When any type of database is established, the confidentiality of individual identifying information should be ensured according to applicable laws and regulations. Guidelines that clarify how and when line-listed data with or without personal identifiers are transmitted and used can facilitate the protection of confidential data.

Methods for accomplishing the follow-up of persons identified in chronic infection databases include contacting health care practitioners and/or patients individually by telephone, mail or in person. Mechanisms such as automated systems for the mailing of follow-up educational materials might be useful. Such systems require relatively few health department resources and involve little or no interaction with patients or

their health care practitioner; however, the effectiveness of such systems should be evaluated. Effective mechanisms for delivering follow-up to mobile and hard-to-reach individuals such as injection drug users need to be identified.

Monitoring the Quality of Surveillance Data

Periodic, regular evaluations of surveillance data for quality, completeness, and timeliness are essential to identify specific aspects of surveillance and case investigation that need improvement. The completeness of surveillance data is assessed by determining the frequency with which individual data elements are reported with non-missing data. The quality or validity of the data is measured by the proportion of each data element that is reported with a correct or valid answer. Timeliness of surveillance data can be measured by determining the average length of time in days required for each of the steps in the surveillance process.

The use of standardized indicators to assess the completeness (e.g. proportion of cases that are reported with risk factor information) or timeliness (e.g. time between date of diagnostic testing and date reported to health department) of surveillance data will allow more accurate interpretation and comparison of data reported at different times or by different sources. The development of data quality indicators to measure the completeness of case-investigation and follow-up activities (e.g., proportion of at-risk contacts immunized) also might be useful.

Data Analysis and Dissemination

Periodic summaries of analyzed surveillance data that are accompanied by a concise interpretation can be useful to a variety of audiences including public health decision makers, clinical case reporters, and other health professionals. Health department should consider developing specialized communications for dissemination of annual reports of case rates analyzed by person, place and time to different audiences. These communications might also include: reports to data providers identifying providers' specific contribution to surveillance efforts, newsletters or bulletins providing concise data interpretation and advice to clinicians and laboratory directors, and press release/reports for general public releases. In addition to dissemination via printed media, other dissemination mechanisms such as the internet should be explored

In addition to summarized data, line listed data should be provided to local health departments to ensure complete and accurate description of identified cases and to highlight those cases that require further follow-up. The regular (at least quarterly) provision of summarized state specific surveillance data by CDC can be useful to state and local health departments in monitoring the reporting of cases to CDC and in providing feedback to local health departments and other public health partners.

DISEASE-SPECIFIC SURVEILLANCE GUIDELINES

Acute Hepatitis A

Case Definition (*)

Clinical criteria

An acute illness with

- discrete onset of symptoms (e.g. fatigue, abdominal pain, loss of appetite, intermittent nausea, vomiting), and
- jaundice or elevated serum aminotransferase levels

Laboratory criteria

- IgM antibody to hepatitis A virus (anti-HAV) positive

Case Classification

- Confirmed. A case that meets the clinical case definition and is laboratory confirmed or a case that meets the clinical case definition and occurs in a person who has an epidemiologic link with a person who has laboratory-confirmed hepatitis A (i.e., household or sexual contact with an infected person during the 15-50 days before the onset of symptoms).

*This case definition was approved by CSTE in September, 1996. [31]

To date, asymptomatic individuals who are IgM anti-HAV positive have not been included as reportable cases. However, these cases do represent incident infections and it is expected that as rates of acute disease continue to decline, the case definition will be expanded to include newly infected individuals identified on the basis of laboratory results alone. When the case definition is expanded to include asymptomatic HAV infections, these cases will need to be distinguished from symptomatic cases to ensure accurate interpretation of surveillance data.

Case Ascertainment

The primary methods to ascertain suspected acute hepatitis A cases are

- Laboratory reporting of all persons who test IgM anti-HAV positive to state and/or local health departments; and
- Reporting by health care practitioners of persons with symptoms of acute hepatitis who are IgM anti-HAV positive. Persons reported as suspected cases of viral hepatitis on the basis of clinical criteria alone should be followed up to ensure that appropriate diagnostic testing for acute viral hepatitis is done.

Case Investigation

Confirmed or suspected cases of acute hepatitis A should be reported and investigated as soon as possible after the case is identified to ensure adequate time to implement preventive measures, including the provision of post-exposure prophylaxis to contacts. To report a case as confirmed, it should be verified that the case meets both the serologic and clinical criteria of the case definition. The components of a case investigation should include:

- ***Clinical features.*** Determine date of illness onset, whether jaundice was present and results of testing for aminotransferase levels.
- ***Serologic test results***. For suspected cases, confirmation by IgM anti-HAV testing is ideal but if not done, a potential case of acute hepatitis A can be reported as confirmed if the person has an epidemiologic link.
- ***Risk factors for infection.*** (Table II) All confirmed cases of acute hepatitis A should be interviewed to identify a potential source or risk factor for infection during the 2-6 weeks prior to illness onset. Because IgM antibodies persist for up to 6 months after infection, it is not possible to define the appropriate exposure period for asymptomatic IgM anti-HAV positive persons. Therefore, risk histories for these persons may be unreliable for determining a source of infection.
- ***Identification of contacts requiring post exposure prophylaxis*.** Immunoprophylaxis with immune globulin (IG) should be provided to persons recently exposed to a person with acute hepatitis A including close personal contacts and others in selected settings according to existing recommendations of the Advisory Committee on Immunization Practices[32]. IG should be given as soon as possible but not >2 weeks after the last exposure. Post-exposure prophylaxis is not recommended for contacts of persons with asymptomatic HAV infection because the period of exposure is unknown.

Reporting to CDC

Case reports of acute hepatitis A should be transmitted weekly by state health departments to CDC via NETSS. Symptomatic cases need to be distinguished from asymptomatic cases to accurately assess changes in incidence. *See Appendix X for CDC hepatitis A case report form.*

Table II. Components of Acute Hepatitis A Case Investigations

Information Collected	Comments/Action
Risk factors (2-6 weeks prior to illness onset)	
• Close contact with a person w/confirmed or suspected acute hepatitis A	If yes, type of contact (sexual/household). Evaluate missed opportunities to receive immunoprophylaxis
• Employment or attendance of nursery, day care center or preschool	If yes, notify and investigate facility to determine if others are at risk for transmission
• Household contact of a child or employee in a nursery, day care center or preschool	
• Travel outside of the United States or Canada	If yes, where and how long?
• Illicit drug use	If yes, notify contacts of need for post-exposure prophylaxis
• No. of male sex partners • No. of female sex partners	If yes, notify contacts of need for post-exposure prophylaxis
Detection and prevention of common source outbreaks	
• Employment as a foodhandler	If yes, notify and investigate food handler and establishment Enhance case finding among persons eating at establishment
• Part of recognized common-source foodborne outbreak	If yes, determine if other cases linked to same source and report to CDC foodborne outbreak surveillance system
Vaccination history	
• Hepatitis A vaccination status	If vaccinated, number of vaccine doses, date(s) of vaccination
Results of case investigation and follow-up	
• Date reported to health department responsible for case investigation	
• Date case investigation initiated	Date of first contact with patient and/or health care practitioner
• At-risk contacts identified	Specify type of contact and whether post-exposure prophylaxis was received
Missed Opportunities for Prevention/Vaccination	
• Household or sex contact of person with acute hepatitis A	If yes, notify health care practitioner and assess barrier(s) to timely administration of IG
• Sought medical care prior to foreign travel	If yes, notify health care practitioner and assess barrier(s) to timely administration of pre-exposure prophylaxis (hepA vaccine and/or IG)
• Ever in treatment for illicit drug use	If yes, determine date of most recent treatment, notify facility, and assess barrier(s) to receiving HepA vaccine
• Child living in area/state where routine childhood vaccination is recommended	If yes, identify child's source of health care and assess reason(s) for failure to receive HepA vaccine.

Uses of Surveillance Data

Monitoring trends in disease incidence and determining risk factors for infection. Hepatitis A surveillance data should be analyzed at weekly intervals by time, place and person to monitor disease incidence. Cases reported in adults provide a valid measure of trends in incidence and the overall burden of disease in those age groups. Because most children with HAV infection are asymptomatic, reported cases represent only a small proportion of the overall burden of HAV infection in young age groups. Nevertheless, trends in the incidence of cases reported in children do reflect changes in the frequency of HAV transmission among children and can be used to estimate the impact of prevention strategies. The proportion of cases reporting specific risk factors should be determined to monitor disease transmission patterns.

Identifying community-wide epidemics. Significant increases in hepatitis A incidence can indicate that a community-wide epidemic is developing and requires further investigation. Surveillance data should be analyzed to determine the areas (e.g., rates by county or zipcode) and groups (e.g., age-specific incidence rates and frequencies of reported risk factors) affected.

Identifying common-source outbreaks. The identification of clustering of hepatitis A cases should prompt an investigation to determine if a common-source outbreak is occurring. This investigation should include collection of additional information from reported cases regarding potential common exposures (e.g., restaurants, community gatherings, child day care centers) and enhancement of prospective surveillance to identify additional cases that might be associated with a common source of transmission.

Amplification and sequencing of viral isolates using nucleic acid based methods can help to identify cases that might share a common source. Therefore, when investigating a possible common source outbreak, efforts should be made to collect sera from cases for possible sequence analysis. Public health professionals who need information regarding use of nucleic acid based methods for the investigation of hepatitis A outbreaks can contact CDC's Division of Viral Hepatitis, National Center for Infectious Diseases at (404) 371-5910.

Assessing missed opportunities for prevention. Case-patients whose source for infection was reported as household or sexual contact with a suspected or confirmed hepatitis A case should be investigated to determine if the case-patient received post-exposure prophylaxis when the source case was identified. The health care practitioners for these persons should be contacted to determine why the patient did not receive timely post-exposure prophylaxis (e.g., late identification of the source case or of the contact) so potential barriers to administering post-exposure prophylaxis to patients at risk of hepatitis A can be identified and resolved.

Missed opportunities for vaccination should be assessed among cases occurring in persons for whom hepatitis A vaccination is recommended (e.g., adults in high risk groups such as MSM, and illicit drug users, or children in selected high rate states/communities) by inquiring about their history of previous contact with health care practitioners or other settings in which vaccination could have been given (e.g., drug treatment centers, STD clinics). These facilities and health care practitioners should be contacted to determine why the case-patient did not receive hepatitis A vaccine so potential barriers to vaccinating patients at risk of hepatitis A can be identified and resolved.

Assessing the impact of vaccination programs. Age-specific hepatitis A rates for the target groups and the community as a whole can be compared to historical rates for the same age groups to assess the impact of routine vaccination programs.

Acute Hepatitis B

Case Definition (*)

Clinical criteria

An acute illness with:

- discrete onset of symptoms (e.g. fatigue, abdominal pain, loss of appetite, intermittent nausea, vomiting), and
- jaundice or elevated serum aminotransferase levels

Laboratory criteria

- IgM antibody to hepatitis B core antigen (anti-HBc) positive or Hepatitis B surface antigen (HBsAg) positive
- IgM anti-HAV negative (if done)

Case classification

- Confirmed. A case that meets the clinical criteria and is laboratory confirmed

To date, asymptomatic individuals who are IgM anti-HBc positive have not been included as reportable cases. However, it is expected that as rates of acute disease continue to decline, the case definition will be expanded to include newly infected individuals identified on the basis of laboratory results alone. In expanding surveillance to include asymptomatic HBV infections, these cases will need to be distinguished from symptomatic cases to ensure accurate interpretation of surveillance data.

Case Ascertainment

The primary methods to ascertain suspected acute hepatitis B cases are:

- Laboratory reporting of all IgM anti-HBc positive and HBsAg positive test results to state and/or local health departments;
- Reporting by health care practitioners of persons with confirmed acute hepatitis B. Follow-up with providers reporting persons testing HBsAg-positive who have signs and/or symptoms of acute viral hepatitis to ensure testing for IgM anti-HBc;
- Follow-up with providers reporting persons as suspected cases of acute viral hepatitis on the basis of clinical criteria alone to ensure appropriate diagnostic testing for acute viral hepatitis.

Case Investigation

Confirmed and suspected cases of acute hepatitis B should be reported and investigated as soon as possible after the case is identified to ensure adequate time to implement preventive measures including post-exposure prophylaxis of contacts. To report a case as confirmed, it should be verified that the case meets both the serologic and clinical criteria of the case definition. The components of a case investigation should include:

- ***Clinical features.*** Determine date of illness onset, whether jaundice was present and results of testing for elevated aminotransferase levels.
- ***Serologic test results***. Serologic confirmation of acute hepatitis B requires a positive IgM anti-HBc test result. Individuals meeting the clinical criteria who test positive for HBsAg but who were not tested for IgM anti-HBc should be classified as suspected cases.
- ***Risk factors for infection.*** (Table III) All confirmed or suspected cases of acute hepatitis B should be interviewed to identify a source or risk factor(s) for infection during the 6 weeks to 6 months prior to illness onset. Because IgM antibodies persist for up to 6 months after infection, it is not possible to define the appropriate exposure period for asymptomatic IgM anti-HAV positive persons. Therefore, risk histories for these persons may be likely to be unreliable for determining a source of infection.
- ***Vaccination history*****.** Obtain a complete history of all doses of hepatitis B vaccine received including dates of vaccination and the results and dates of post-vaccination testing if such testing was performed.

- ***Identification of contacts who require post exposure prophylaxis*.** Immunoprophylaxis following exposure to a person with acute hepatitis B (HBsAg positive) should be provided according to existing recommendations of the Advisory Committee on Immunization Practices [33]. At-risk contacts requiring post-exposure prophylaxis include infants whose primary caretaker has acute hepatitis B, sexual partners, and other contacts who have had a blood exposure to the index patient (e.g., needle sharing contacts of injection drug users, non-sexual household contacts who may have had inapparent exposure to the blood of the index patient through exposures such as sharing toothbrushes or razors). The vaccination status of children and adolescents in the household of a person with acute hepatitis B should be assessed to ensure that they receive vaccine if not previously vaccinated.
- ***Referral for medical evaluation*.** Persons with acute hepatitis B should be evaluated for the development of chronic infection. The detection of HBsAg >6 months after illness onset indicates the presence of chronic infection.

Reporting to CDC

Case reports of acute hepatitis B should be transmitted weekly by state health departments to CDC via NETSS. In reporting, symptomatic cases need to be distinguished from asymptomatic cases to accurately assess changes in incidence. *See Appendix X for CDC Hepatitis B case report form.*

Table III. Components of Acute Hepatitis B Case Investigations

Information Collected	Comments/Action
Risk factors (6 wks-6 mo prior to illness onset)	
• Contact with a person w/confirmed or suspected HBV infection	Type of contact (sexual, household, casual)
• Employment involving contact with human blood	Degree of blood contact (several times weekly/infrequent)
• Receipt of blood transfusion or blood products	Product(s) administered, date(s) received
• Dialysis or kidney transplant patient	Notify and investigate facility; assess barriers to vaccination
• Injecting drug use • Number of different male sex partners • Number of different female sex partners	Notify at risk contacts of need for hepatitis B vaccination -- (and HBIG, if it can be administered within 14 days of last contact)
• Hospitalization and/or surgery • Intravenous infusions or injections received in outpatient settings • Residence in a long term care facility (e.g. nursing home) • Dental work/oral surgery • Acupuncture/tattooing/body piercing	Determine if additional cases are linked to same facility; assess need for investigation for a nosocomial source of infection
• Puncture with a needle or other object contaminated w/blood	Determine post-exposure prophylaxis history: date(s) of HBIG administration, date(s) of vaccination
Vaccination History	
• Hepatitis B vaccination status	If vaccinated, number of vaccine doses, date(s) of vaccination, and post-vaccination test results (if available)
Results of Case Investigation and Follow-up	
• Date reported to health department responsible for case investigation	
• Date case investigation initiated	Date of first contact with patient and/or health care practitioner
• At risk contacts identified	Sexual contacts, household contacts, and needle-sharing contacts
• At risk contacts initiating prophylaxis	Need to assure completion of 3-dose HepB vaccine series
• Date referred for medical evaluation	Evaluate for development of chronic infection including testing for HBsAg >6 months after illness onset
Missed Opportunities for Hepatitis B Vaccination	
• Household or sex contact of HBV-infected person	Notify health care practitioner and assess barrier(s) to providing HepB vaccine
• Ever in correctional facility	Determine date of most recent incarceration, notify facility and assess barrier(s) to providing HepB vaccine
• Ever treated for a sexually-transmitted disease • Ever in treatment for injecting drug use	If yes, determine date of most recent treatment, notify facility, and assess barrier(s) to providing HepB vaccine

Uses of Surveillance Data

Identifying outbreaks. Identification of any of the following risk factors among persons with acute hepatitis B should prompt an investigation to determine if additional cases are associated with a common source of transmission:

*Receipt of blood or blood product*s. When cases are identified in persons who received a blood transfusion during the incubation period, the transfusion service and the blood collection establishment should be notified. For patients who have no other recognized risk factors for infection, the blood collection establishment should identify and retest the donor(s) for evidence of HBV infection (HBsAg, anti-HBc). For persons who received plasma-derived products during the incubation period, the specific product name and lot number should be obtained.

Hemodialysis. The patient's dialysis unit should be contacted to determine if additional cases have been detected. Current policies of the unit should be determined regarding vaccination and routine serologic testing of patients as well as infection control practices. The unit should be provided with appropriate recommendations to prevent transmission of HBV and other bloodborne pathogens in the facility[34].

Hospitalization, surgery, other medical or dental procedures. Additional information should be obtained regarding the specific medical care provider(s) and setting (e.g., hospital, clinic) involved. The occurrence of at least two cases associated with the same medical care provider or setting or one case with no other recognized risk factors for infection should prompt an investigation to determine if there is a nosocomial source of infection.

Monitoring trends in disease incidence and determining risk factors for infection. Acute hepatitis B surveillance data should be analyzed at regular intervals (e.g., weekly) by time, place, and person to monitor disease incidence. The proportion of cases with specific risk factors should be determined to monitor disease transmission patterns and to identify high risk groups that need to be targeted by vaccination programs.

Assessing missed opportunities for prevention. Case-patients whose source for infection was reported as household or sexual contact with a person with acute or chronic HBV infection should be investigated to determine if the case-patient should have been immunized when the source case was identified. The health care practitioners for these persons should be contacted to determine why the case-patient did not receive hepatitis B vaccine so barriers to vaccinating at-risk contacts of identified cases can be identified and resolved.

Missed opportunities for pre-exposure vaccination should be assessed among cases of acute hepatitis B occurring in persons for

whom hepatitis B vaccination is recommended (e.g.,MSM, injecting drug users) by inquiring about their history of previous contact with health care practitioners or other settings in which vaccination could have been given (e.g., STD clinics, correctional facilities, drug treatment centers). These facilities/health care practitioners should be contacted to determine why the case-patient did not receive hepatitis B vaccine so barriers to vaccinating persons belonging to groups at increased risk of HBV infection can be identified and resolved. Missed opportunities for vaccination should also be assessed among cases occurring in children less than 18 years of age to determine the frequency and characteristics of these cases so that the effectiveness of routine childhood vaccination programs can be monitored and any barriers to vaccinating children can be identified and resolved.

Assessing the frequency and causes of immunization failure. The frequency of cases occurring in vaccinated persons should be determined to monitor the efficacy of vaccination and to detect possible cases of vaccine failure. Additional investigation is needed to identify causes for these potential breakthrough infections (e.g., waning of vaccine induced immunity, infection with viral variants). Health care professionals who need information regarding investigation of these cases can contact CDC's Division of Viral Hepatitis, National Center for Infectious Diseases at (404) 371 5910.

Perinatal HBV Infection

Case Definition (*)

Clinical description

Perinatal HBV infection in the newborn can range from asymptomatic to fulminant hepatitis.

Laboratory criteria

Hepatitis B surface antigen (HBsAg) positive

Case classification

HBsAg positivity in any infant >1-24 months old who was born in the United States or in U.S. territories to an HBsAg-positive mother.

Comment: Infants born to HBsAg-positive mothers should receive hepatitis B immune globulin (HBIG) and the first dose of hepatitis B vaccine within 12 hours of birth, followed by the second and third doses of vaccine at 1 and 6 months of age, respectively. Postvaccination testing for HBsAg and anti-HBs (antibody to HBsAg) is recommended from 3 to 6 months following completion of the vaccine series. If HBIG and the initial dose of vaccine are delayed for >1 month after birth, testing for HBsAg may determine if the infant is already infected.

*This case definition was adopted by CSTE in March 1995 [31].

Case Ascertainment

Virtually all infants who are infected with HBV are asymptomatic. The primary method for identifying such infants is to test pregnant women for HBsAg and test the infants born to infected women for HBsAg at 9-15 months of age.

To facilitate identification of HBV-infected infants:

- consider laws or regulations to require prenatal HBsAg screening of all pregnant women;
- ensure that all birthing hospitals have appropriate written standing orders and/or administrative procedures for determining the HBsAg status of all pregnant women during each pregnancy and prior to delivery;
- ensure that all birthing hospitals have appropriate written standing orders and/or procedures to test mothers with an unknown HBsAg status at the time of delivery;
- make HBsAg-positive test results in pregnant women a reportable condition;
- establish links with hospitals and infection control practitioners for reporting of all births to HBsAg-positive women;
- consider requirements to document maternal HBsAg status on the newborn metabolic screening card or birth certificate;
- assure that health care practitioners, health care organizations, and perinatal HBV prevention programs have appropriate policies and procedures for active tracking and/or case-management of infants born to HBsAg-positive mothers;
- assure testing of all infants born to HBV-infected women for HBsAg and anti-HBs at 9 to 15 months of age; and
- establish routine reporting as part of health department case-management of all HBsAg and anti-HBs test results (positive and negative) from infants born to HBsAg-positive women.

Case Investigation

Case investigations of suspected cases of perinatal HBV infection should be conducted promptly. Information to be collected includes (Table IV):

- ***Serologic test results:*** Obtain documentation of positive HBsAg test results for both the mother and the infant, the age of the child, and the child's country of birth.
- ***Post-exposure prophylaxis history.*** Ascertain the date and dosage of HBIG and the date and dosage of all doses of hepatitis B vaccine given to the child.

- ***Referral for medical evaluation.*** Children with HBsAg positive test results should be evaluated (by referral or consultation, if appropriate) to:
  - verify the presence of chronic HBV infection;
  - assess for biochemical evidence of chronic liver disease; and
  - assess for severity of disease and possible treatment according to current practice guidelines in consultation with, or by referral to, a specialist knowledgeable in this area.
- ***Revaccination of susceptible infants:*** Ensure that children who test negative for HBsAg and anti-HBs at 9-15 months of age are revaccinated.

Table IV. Components of Perinatal HBV Infection Case Investigations

Information Collected for Infant	**Comments/Action**
Demographic Information	
• Sex, date and place of birth, age, race/ethnicity	
Diagnostic Test Results	
• HBsAg, anti-HBs	Testing should be done at 9-15 months of age If HBsAg positive , refer for medical evaluation If HBsAg negative and anti-HBs negative, revaccinate
• Date of diagnosis	
Immunization History	
• Date and dosage of HBIG administered	
• Date(s) and dosage of hepatitis B vaccine administered	
Information Collected for Mother	
Demographic information	
• Age, date of birth, race/ethnicity, country of birth	
Diagnostic Test Results	
• HBsAg	
• Date of diagnosis	Date of positive HBsAg test
Results of Case Investigation and Follow-up	
• Date reported to health department responsible for case investigation	
• Date case investigation initiated	Date of first contact with patient and/or health care practitioner
• At risk contacts identified	Sexual and household contacts, and needle-sharing contacts of injecting drug users
• At risk contacts initiating hepatitis B vaccination	Need to assure completion of 3-dose HepB vaccine series
• Date referred for medical evaluation	Evaluate for chronic liver disease, eligibility for treatment

Reporting to CDC

Confirmed cases of perinatal HBV infection should be reported to health departments as specified by local regulations. Case reports should be transmitted weekly by state health departments to CDC using the separate NETSS category established for reporting cases of perinatal HBV infection. *See Appendix for CDC perinatal HBV case report form.*

Uses of Surveillance Data

Monitoring the operation and effectiveness of perinatal HBV prevention programs:

The following indicators can be used to monitor the operation and effectiveness of perinatal HBV prevention programs and should be determined for all infants born to HBV-infected women:

- The proportion of cases that received the first hepatitis B vaccine dose <12 hours after birth;
- The proportion of cases that received the third hepatitis B vaccine dose <8 months after birth;
- The proportion of cases that received HBIG <12 hours after birth; and
- The proportion of cases that received $\geq$ 3 hepatitis B vaccine doses.

Assessing the frequency and causes of immunization failure.

The frequency of cases occurring in infants who received post exposure prophylaxis should be determined to monitor its efficacy. Investigation of cases of perinatal HBV infection should be done to evaluate causes of possible breakthrough infections and should include obtaining sera from the infant and mother to test for the presence of HBV variants. Health care professionals who need information regarding testing infants with perinatal HBV infection for HBV variants can contact the Perinatal Hepatitis B Prevention Program in their state health department or CDC's Division of Viral Hepatitis, National Center for Infectious Diseases at 404-371-5910.

Chronic HBV Infection

The objectives and activities of existing state-based databases of persons who test positive for HBsAg vary considerably and have not been standardized. The following case definition, case ascertainment methods, and case investigation and follow-up methods are provided as a guide for management of persons who test HBsAg positive. Further assessment is needed to determine the most feasible and useful approaches to establish these types of systems.

Case Definition (*)

Clinical description

Persons with chronic hepatitis B virus (HBV) infection may be asymptomatic. They 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

- Hepatitis B surface antigen (HBsAg) positive, total anti-HBc positive (if done) and IgM anti-HBc negative, OR
- HBsAg positive two times at least 6 months apart

Case classification

- Confirmed. A case that is laboratory confirmed

*Note: This case definition was approved by CSTE in June 2002. This is the first published case definition for chronic HBV infection.

Comment:

HBsAg positive test results by enzyme immunoassay (EIA) that are not supported by positive test results for total anti-HBc or IgM anti-HBc should be confirmed by an additional more specific assay (e.g. neutralization assay)

Case Ascertainment

The primary methods to ascertain cases of chronic HBV infection are:

- Laboratory reporting of all HBsAg-positive results to state and/or local health departments
- Make HBsAg-positive test results a reportable condition. All positive HBsAg test results should be followed-up to determine if the person has chronic HBV infection (see case definition above). Particular efforts should be made to follow-up women of reproductive age.

Case Investigation and Follow-up

Case investigation and follow-up should be conducted for persons with HBsAg-positive laboratory results and should include (Table V.):

- ***Serologic test results***. A single HBsAg positive and total anti-HBc positive test result in an asymptomatic person that is simultaneously negative for IgM anti-HBc confirms chronic infection. Chronic HBV infection can also be verified by two or more HBsAg positive test results separated by at least 6 months. The results of prior hepatitis test results should be reviewed if available.
- ***Pregnancy status for women of childbearing age.*** All HBsAg-positive pregnant women should be reported to the Perinatal Hepatitis B Prevention Program Manager to ensure that infants born

to these women receive appropriate postexposure management according to existing ACIP recommendations [33].

- ***Immunoprophylaxis and counseling to prevent transmission.*** HBsAg-positive persons should be advised regarding how to reduce their risk of transmitting HBV to others, including notifying their sexual, household, and other (e.g., needle-sharing contacts of IDUs) contacts at risk of the need to get vaccinated against hepatitis B. [35]
- ***Counseling and referral.*** HBsAg-positive persons should be advised regarding how to reduce their risk of liver injury and referred for medical evaluation and management [35].

Table V. Components of case investigations of persons testing HBsAg-positive

Information Collected	Comments/Action
Clinical data	
• Pregnancy status (if female)	If yes, report to State Perinatal Hepatitis B Prevention Program
Risk factors (lifetime history)*	
• Hemodialysis	
• Injection drug use	
• Number of sex partners	
• Contact with a person who had hepatitis	If yes, type of contact (sexual, household, casual)
• Employment involving contact with human blood	If yes, degree of blood contact (several time weekly/infrequent)
• Incarceration	
Results of Case Investigation and Follow-up	
• Date reported to health department responsible for case investigation	
• Date case investigation initiated	Date of first contact with patient and/or health care practitioner
• At risk contacts identified	Sexual contacts, household contacts, and needle-sharing contacts of injecting drug users
• At risk contacts initiating hepatitis B vaccination	Need to assure completion of 3-dose HepB vaccine series
• Date referred for medical evaluation	Evaluate for chronic liver disease, eligibility for treatment

*The collection of risk factor information is not recommended for individuals belonging to groups in which most chronic HBV infections are attributable to perinatal or early childhood infection with HBV (e.g. emigrants from countries endemic for HBV). The routine collection of risk factor information for other individuals is not required but may provide useful information for the development and evaluation of programs to identify and counsel HBV-infected persons.

Reporting to CDC

Cases of chronic HBV infection should be reported to CDC through the NNDSS. Inclusion of chronic HBV infection in the list of nationally reportable conditions is pending CSTE approval.

Uses of Surveillance Data.

Databases of HBsAg-positive persons should be established to distinguish newly reported cases of chronic HBV infection from previously identified cases. Periodic analyses of the cumulative number of persons with HBV infection included in these databases could be used to provide local, state and national estimates of the proportion of persons with HBV infection who have been identified.

Acute Hepatitis C

Case Definition(*)

Clinical criteria

An acute illness with

- discrete onset of symptoms consistent with acute viral hepatitis, and
- jaundice or elevated serum aminotransferase levels

Laboratory criteria

- Serum alanine aminotransferase levels >7 times the upper limit of normal, and
- IgM anti-HAV negative (if done), and
- IgM anti-HBc negative , or if not done, HBsAg negative and
- Antibody to hepatitis C virus (anti-HCV) positive (repeat reactive) by EIA, verified by an additional more specific assay (e.g. RIBA™ for anti-HCV or nucleic acid testing for HCV RNA)
  O*R*
  Anti-HCV positive (repeat reactive) by screening immunoassay with a signal to cut-off ratio predictive of a true positive as determined for the particular assay (e.g., ≥3.8 for enzyme immunoassay).

Case classification

Confirmed: A case that meets the clinical case definition and is laboratory confirmed.

Comment

1) Up to 10% of cases of acute hepatitis C will be anti-HCV negative when tested initially because some have not yet seroconverted and others (<3%) remain negative even with prolonged follow-up.
2) Available serologic tests for anti-HCV do not distinguish between acute and chronic or past infection. Thus, other causes of acute hepatitis should be excluded for anti-HCV positive patients who have an acute illness compatible with hepatitis.
3) The diagnosis of HCV infection can be made by detecting HCV RNA using gene amplification techniques (e.g. RT-PCR). However, a negative HCV RNA test result does not exclude the possibility of HCV infection.

*This case definition was approved by CSTE in June, 2003. It has been updated from the previously published case definition.

Case Ascertainment

The primary method to ascertain suspected cases of acute hepatitis C is by follow-up of reported clinical cases of hepatitis C and non-A, non-B hepatitis. This includes:

- Serologic testing of patients with signs/symptoms of acute viral hepatitis, according to an appropriate algorithm (see section on case ascertainment).
- Repeat anti-HCV testing, or testing for HCV RNA by RT-PCR, of persons with suspected acute viral hepatitis who test negative for IgM anti-HAV, IgM anti-HBc, and anti-HCV at the time the case is reported.

Laboratory reporting of anti-HCV positive results is encouraged as a method to identify persons with HCV infection. However, most HCV-infected persons who are identified on the basis of anti-HCV positive laboratory reports have chronic, rather than acute, infections. Thus, the investigation of these reports is not likely to be an efficient mechanism to identify acute hepatitis C cases unless additional clinical information is obtained with the serologic result. Routine reporting of ALT levels with anti-HCV positive laboratory results might be useful to identify persons who are most likely to have acute disease, and would enhance the usefulness of laboratory reporting in conducting surveillance for acute hepatitis C.

Case Investigation

Case investigations should be conducted of suspected cases of acute hepatitis C and should include (Table VI):

- **Clinical features**. Determine the date of illness onset, whether jaundice or other symptoms consistent with acute viral hepatitis were present and the results of testing for aminotransferase levels. If possible, evaluate previous medical history for evidence of past infection to assess likelihood that current symptoms are due to a newly acquired infection.
- **Diagnostic test results:** Serologic confirmation of acute hepatitis C requires negative test results for IgM anti-HAV and IgM anti-HBc and a positive test result for anti-HCV by EIA verified by a positive test result from an additional more specific assay (e.g., RIBA™ for anti-HCV or RT-PCR for HCV RNA), or by an average EIA signal to cutoff ratio of $\geq$3.8.
- **Risk factors for infection**. (Table VI) All confirmed cases of acute hepatitis C should be interviewed to identify a risk factor(s) for infection during the 2 weeks to 6 months prior to illness onset.
- **Pregnancy status of HCV-infected women of childbearing age.** No post-exposure prophylaxis is available to prevent perinatal transmission of HCV. Children born to anti-HCV positive women should be tested for infection.[19]

- **Counseling and referral for follow-up** Persons with acute hepatitis C should be advised regarding how to reduce their risk of transmitting HCV to others and the need for follow-up to determine the outcome of their infection [19].

Table VI. Components of Acute Hepatitis C Case Investigations

Risk factors (in 2 wks-6 mo prior to illness onset)	
• Contact with a person w/ confirmed or suspected HCV infection	Type of contact (sexual, household, casual)
• Employment involving contact with human blood	Assess degree of blood contact (frequent/infrequent)
• Receipt of blood transfusion or blood products	Determine product(s) received, date(s) of administration, notify transfusion service
• Dialysis or kidney transplant	Notify and investigate facility
• Injecting drug use	Refer injecting drug use contacts for counseling and testing
• Number of different male sex partners	Refer all sex contacts for counseling and testing
• Number of different female sex partners	
• Hospitalization and/or surgery	Determine if additional cases are linked to same facility; assess need for investigation for a nosocomial source of infection
• Intravenous infusions or injections received in an outpatient setting	
• Residence in long-term care facility (e.g. nursing home)	
• Dental work/oral surgery	
• Acupuncture/tattooing/body piercing	
• Puncture with a needle or other object contaminated w/ blood	
Case Investigation and Follow-up	
• Date reported to health department responsible for case investigation	
• Date case investigation initiated	Date of first contact with patient and/or health care practitioner
• At-risk contacts identified and referred for counseling and testing	Sex partners, injecting drug use contacts

Reporting to CDC

Case reports of acute hepatitis C are transmitted weekly by state health departments to CDC via NETSS. *See Appendix X for CDC case report form.*

Uses of Surveillance Data

Identifying outbreaks Identification of any of the following risk factors in persons with acute hepatitis C should prompt an investigation to determine if additional cases are associated with a common source of transmission:

- *Receipt of blood or blood products.* When cases are identified in persons who received a blood transfusion during the incubation period, the transfusion service and the blood collection establishment should be notified. For those patients who have no other recognized risk factors for infection, the blood collection establishment should identify and retest the donor(s) for evidence of HCV infection. For persons who received plasma-derived products during the incubation period, the specific product name and lot number should be obtained.
- *Hemodialysis***.** The patient's dialysis unit should be contacted to determine if additional cases have been detected. Current policies of the unit should be determined regarding routine testing of patients for ALT and anti-HCV as well as infection control practices. The unit should be provided with appropriate recommendations to prevent transmission of HCV and other bloodborne pathogens in the facility[34] .
- *Hospitalization, surgery, other medical or dental procedures.* For persons who report a history of hospitalization, surgery, and/or dental procedures, and who have no other recognized risk factors for infection, additional information should be obtained regarding the specific medical care provider(s) and setting (e.g., hospital, clinic) involved. The occurrence of at least two cases associated with the same medical care provider or setting or one case with no other risk factors should prompt an investigation to determine if there is a nosocomial source of infection.

Monitoring trends in disease incidence and determining risk factors for infection Acute hepatitis C surveillance data should be analyzed at regular intervals by time, place and person to monitor disease incidence. The proportion of cases with specific risk factors should be determined to monitor disease transmission patterns.

Hepatitis C Virus Infection, (Past or present)

The objectives and activities of existing state-based databases of persons reported as anti-HCV positive vary considerably and have not been standardized. The following case definition, case ascertainment methods, and case investigation and follow-up methods are provided as a guide for management of persons who test anti-HCV positive. However, further evaluation is needed to determine the most feasible and useful approaches to establish these types of systems.

Case Definition (*)

Clinical description

Most HCV-infected persons are asymptomatic. However, many have chronic liver disease, which can range from mild to severe including cirrhosis, and liver cancer.

Laboratory criteria

- Anti-HCV positive (repeat reactive) by EIA, verified by an additional more specific assay (e.g. RIBA for anti-HCV or nucleic acid testing for HCV RNA)
  Or
- Anti-HCV positive (repeat reactive) by EIA with a signal to cut-off ratio predictive of a true positive as determined for the particular assay (e.g., ≥3.8 for the enzyme immunoassays).

Case Classification

Confirmed. A case that is laboratory confirmed.

Probable. A case that is anti-HCV positive (repeat reactive) by EIA and has alanine aminotranferase (ALT or SGPT) values above the upper limit of normal, but the anti-HCV EIA result has not been verified by an additional more specific assay or the signal to cut-off ratio is unknown.

*Note: This case definition was approved by CSTE in June 2002 and is the first published for HCV infection.

Case Ascertainment

The primary method to ascertain cases of HCV infection is by reporting of all anti-HCV positive laboratory results to state and/or local health departments.

Case Investigation and Follow-up

Case investigation and follow-up should be conducted for persons with anti-HCV positive laboratory results and should include (Table VII.)

- ***Serologic test results.*** The diagnosis of HCV infection in a person testing positive for anti-HCV by EIA should be confirmed by an additional more specific assay (e.g., RIBA for anti-HCV or RT-PCR for HCV RNA). However, if test results by an additional more specific assay are not available, a person who tests positive for anti-HCV by EIA with an average signal to cut-off ratio $\geq$3.8 can also be reported as confirmed. An anti-HCV positive person who has elevated liver enzyme levels but for whom additional confirmatory data are unavailable should be reported as a probable case.
- ***Counseling and referral for medical management.*** HCV-infected persons should be advised regarding how to reduce their risk of transmitting HCV to others and how to reduce further liver injury. They should also be referred for medical evaluation and management[19].

Reporting to CDC

Cases of Hepatitis C virus infection should be reported to CDC through the NNDSS. Inclusion of HCV infection, chronic or resolved in the list of nationally reportable conditions is pending CSTE approval.

Uses of Surveillance Data

Periodic analyses of the cumulative number of persons enrolled in HCV infection databases could be used to provide local, state and national estimates of the proportion of persons with HCV infection who have been identified. Recommended information elements to be maintained in such databases are described in Appendix.

Table VII. Components of HCV Infection Case Investigations

Information Collected	Comments/Action
Clinical data	
• Pregnancy status (if female)	If yes, provide counseling regarding risks of transmission from mother to infant. Arrange follow-up of infant to test for infection. Consider testing other children for infection
• Reason for testing	
Diagnostic Test Results	
• Anti-HCV (EIA) • Anti-HCV (RIBA™) • HCV RNA	Obtain most recent and prior diagnostic test results for HCV infection (if available), including dates of testing
• Date of diagnosis	Date of first positive anti-HCV test
Risk factors (lifetime history)*	
• Blood transfusion prior to 1992	
• Organ transplant prior to 1992	
• Receipt of clotting factor concentrates made prior to 1987	
• Hemodialysis	
• Injection drug use	
• Number of sex partners	
• Contact with a person who had hepatitis	If yes, type of contact (sexual, household, casual)
• Employment involving contact with human blood	If yes, degree of blood contact (several times weekly/infrequent)
Case Investigation and Follow-up	
• Date reported to health department responsible for case investigation	
• Date case investigation initiated	First contact with patient and/or health care practitioner
• Date referred for medical evaluation	Evaluate for chronic liver disease, eligibility for treatment

*Routine collection of risk factor information for persons who test HCV positive is not required. However, collection of risk factor information for such persons may provide useful information for the development and evaluation of programs to identify and counsel HCV-infected persons

Acute non-ABC hepatitis

Surveillance for non-ABC hepatitis is needed to identify and monitor the frequency of disease that may be associated with other known agents of viral hepatitis (HDV and HEV) and to detect new etiologic agents. Individuals with signs and symptoms of acute viral hepatitis who are negative for serologic markers of acute hepatitis A (IgM anti-HAV), acute hepatitis B (IgM anti-HBc) and hepatitis C (anti-HCV) should be reported via the state health department to CDC and further investigation to describe the characteristics of the case and to identify a causal agent may be considered. Health-care professionals who need information on additional testing of persons with acute non-ABC hepatitis may contact CDC's Division of Viral Hepatitis, National Center for Infectious Diseases at (404) 371-5910.

OTHER SURVEILLANCE METHODS

Serologic Surveys

Many persons with new HAV, HBV, and HCV infections, particularly young children, are asymptomatic and many cases of symptomatic disease are not reported to the Nationally Notifiable Disease Surveillance System. Thus, serosurveys are needed to assess the extent of the disease burden associated with viral hepatitis and to monitor the impact of prevention and control programs. National seroprevalence data for HAV, HBV, and HCV infections are provided by the CDC National Health and Nutrition Examination Survey (NHANES), a periodic survey of a sample of the civilian, non-institutionalized U.S. population. However, NHANES can provide only regional seroprevalence estimates and the survey does not have an adequate sample size for some population groups that are at high risk of viral hepatitis. Thus, selected serosurveys conducted at the state and local level and of specific population groups are needed to measure the effectiveness of prevention and control programs.

Chronic Liver Disease Surveillance

Surveillance for HBV and HCV-related chronic liver disease can provide information to measure the burden of disease, determine natural history and risk factors, and develop and evaluate the effect of therapeutic and prevention measures on incidence and severity of disease. Recently, a sentinel surveillance pilot program for physician-diagnosed chronic liver disease was established which will provide baseline data and a template for a broader surveillance system for chronic liver disease. As the primary source of data regarding the incidence and natural history of chronic liver disease, this network will be pivotal for monitoring the effects of education, counseling, other prevention programs, and newly developed therapies on the burden of the disease.

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U.S. DEPARTMENT OF
HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE

VIRAL HEPATITIS CASE REPORT

CDC
Centers for Disease Control and Prevention
Hepatitis Branch, (G37)
Atlanta, Georgia 30333

The following questions should be asked for every case of viral hepatitis

Was this record submitted to CDC through the NETSS system? Yes ☐ No ☐

If yes, please enter **NETSS ID NO.** ☐☐☐☐☐☐☐☐☐☐ If no, please enter **STATE CASE NO.** _____

DEMOGRAPHIC INFORMATION

RACE (check all that apply):

☐ Amer Indian or Alaska Native ☐ Black or African American ☐ White
☐ Asian ☐ Native Hawaiian or Pacific Islander ☐ Other Race, specify: _____

ETHNICITY:
Hispanic ..... ☐
Non-hispanic ..... ☐
Other/Unknown ..... ☐

SEX: Male ☐ Female ☐ Unk ☐ **PLACE OF BIRTH:** ☐ USA ☐ Other:_____

DATE OF BIRTH: M M / D D / Y Y Y Y **AGE:** ___ ___ **(years)** **(00= <1yr , 99= Unk)**

CLINICAL & DIAGNOSTIC DATA

REASON FOR TESTING: (Check all that apply)
☐ Symptoms of acute hepatitis ☐ Evaluation of elevated liver enzymes
☐ Screening of asymptomatic patient with reported risk factors ☐ Blood / organ donor screening
☐ Screening of asymptomatic patient with no risk factors (e.g., patient requested) ☐ Follow-up testing for previous marker of viral hepatitis
☐ Prenatal screening ☐ Unknown ☐ Other: specify: _____

CLINICAL DATA:

Diagnosis date: M M / D D / Y Y Y Y

	Yes	No	Unk
Is patient symptomatic?	☐	☐	☐
if yes, onset date: M M / D D / Y Y Y Y			
Was the patient			
• Jaundiced?	☐	☐	☐
• Hospitalized for hepatitis?	☐	☐	☐
Was the patient pregnant ?	☐	☐	☐
due date : M M / D D / Y Y Y Y			
Did the patient die from hepatitis?	☐	☐	☐
• Date of death: M M / D D / Y Y Y Y			

DIAGNOSTIC TESTS: CHECK ALL THAT APPLY

	Pos	Neg	Unk
• Total antibody to hepatitis A virus [total anti-HAV]	☐	☐	☐
• IgM antibody to hepatitis A virus [IgM anti-HAV]	☐	☐	☐
• Hepatitis B surface antigen [HBsAg]	☐	☐	☐
• Total antibody to hepatitis B core antigen [total anti-HBc]	☐	☐	☐
• IgM antibody to hepatitis B core antigen [IgM anti-HBc]	☐	☐	☐
• Antibody to hepatitis C virus [anti-HCV]	☐	☐	☐
- anti-HCV signal to cut-off ratio _____			
• Supplemental anti-HCV assay [e.g., RIBA]	☐	☐	☐
• HCV RNA [e.g., PCR]	☐	☐	☐
• Antibody to hepatitis D virus [anti-HDV]	☐	☐	☐
• Antibody to hepatitis E virus [anti-HEV]	☐	☐	☐

LIVER ENZYME LEVELS AT TIME OF DIAGNOSIS

- ALT [SGPT] Result _____ Upper limit normal_____
- AST [SGOT] Result _____ Upper limit normal_____
- Date of ALT result M M / D D / Y Y Y Y
- Date of AST result M M / D D / Y Y Y Y

• If this case has a diagnosis of hepatitis A that has not been serologically confirmed, is there an epidemiologic link between this patient and a laboratory-confirmed hepatitis A case?	Yes	No	Unk
	☐	☐	☐

DIAGNOSIS: (Check all that apply)

☐ Acute hepatitis A
☐ Acute hepatitis B ☐ Chronic HBV infection ☐ Perinatal HBV infection ☐ Hepatitis Delta (co- or super-infection)
☐ Acute hepatitis C ☐ HCV infection (chronic or resolved)
☐ Acute hepatitis E ☐ Acute non-ABCD hepatitis

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Patient History- Acute Hepatitis A **NETSS ID NO.** ☐☐☐☐☐☐☐☐☐☐

STATE CASE NO. _____

During the **2-6 weeks** prior to onset of symptoms-	Yes	No	Unk
Was the patient a contact of a person with confirmed or suspected hepatitis A virus infection?	☐	☐	☐
If yes, was the contact (check one)			
• household member (non-sexual)	☐	☐	☐
• sex partner	☐	☐	☐
• child cared for by this patient	☐	☐	☐
• babysitter of this patient	☐	☐	☐
• playmate	☐	☐	☐
• other _____	☐	☐	☐
Was the patient			
• a child or employee in a day care center, nursery, or preschool ?	☐	☐	☐
• a household contact of a child or employee in a day care center, nursery or preschool ?	☐	☐	☐
If yes for either of these, was there an identified hepatitis A case in the child care facility?	☐	☐	☐

Please ask both of the following questions regardless of the patient's gender.

In the **2- 6 weeks** before symptom onset how many	0	1	2-5	>5	Unk
• male sex partners did the patient have?	☐	☐	☐	☐	☐
• female sex partners did the patient have?	☐	☐	☐	☐	☐

In the **2- 6 weeks** before symptom onset	Yes	No	Unk
Did the patient inject drugs not prescribed by a doctor?	☐	☐	☐
Did the patient use street drugs but not inject?	☐	☐	☐
Did the patient **travel** outside of the U.S.A. or Canada	☐	☐	☐
• If yes, where? 1) _____ 2) _____ (Country) 3) _____			
In the **3 months** prior to symptom onset Did anyone in the patient's household travel outside of the U.S. A. or Canada?	☐	☐	☐
• If yes, where? 1) _____ 2) _____ (Country) 3) _____			
Is the patient suspected as being part of a common-source outbreak?	☐	☐	☐
If yes, was the outbreak			
Foodborne- associated with an infected food handler	☐	☐	☐
Foodborne - **NOT** associated with an infected food handler	☐	☐	☐
• specify food item _____			
Waterborne	☐	☐	☐
Source not identified	☐	☐	☐
Was the patient employed as a food handler during the **TWO WEEKS** prior to onset of symptoms or while ill?	☐	☐	☐

VACCINATION HISTORY

	Yes	No	Unk
Has the patient ever received the hepatitis A vaccine ?	☐	☐	☐
• If yes, how many doses?	1 ☐	≥2 ☐	
• In what year was the last dose received?	Y Y Y Y		
	Yes	**No**	**Unk**
Has the patient ever received immune globulin ?	☐	☐	☐
• If yes, when was the last dose received? _____ / _____	**mo**	**yr**	

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STATE CASE NO. _____

Patient History- Acute Hepatitis B

NETSS ID NO. | | | | | | | | | | |

During the **6 weeks- 6 months** prior to onset of symptoms was the patient a contact of a person with confirmed or suspected acute or chronic hepatitis B virus infection? **Yes** **No** **Unk**

If yes, type of contact

- Sexual ☐ ☐ ☐
- Household [Non-sexual] ☐ ☐ ☐
- Other: _____ ☐ ☐ ☐

Ask both of the following questions regardless of the patient's gender.

In the **6 months** before symptom onset how many **0** **1** **2-5** **>5** **Unk**

- male sex partners did the patient have? ☐ ☐ ☐ ☐ ☐
- female sex partners did the patient have? ☐ ☐ ☐ ☐ ☐

Was the patient ***EVER*** treated for a sexually-transmitted disease? **Yes** ☐ **No** ☐ **Unk** ☐

- If yes, in what year was the most recent treatment ? Y Y Y Y

During the **6 weeks- 6 months** prior to onset of symptoms

- inject drugs not prescribed by a doctor? ☐ ☐ ☐
- use street drugs but not inject? ☐ ☐ ☐

During the **6 weeks- 6 months** prior to onset of symptoms

Did the patient- **Yes** **No** **Unk**

- undergo hemodialysis? ☐ ☐ ☐
- have an accidental stick or puncture with a needle or other object contaminated with blood? ☐ ☐ ☐
- receive blood or blood products [transfusion] ☐ ☐ ☐
  - if yes, when? M M / D D / Y Y Y Y
- receive any IV infusions and/or injections in the outpatient setting... ☐ ☐ ☐
- have other exposure to someone else's blood ☐ ☐ ☐

specify: _____

During the **6 weeks - 6 months** prior to onset of symptoms

- Was the patient employed in a medical or dental field involving direct contact with human blood ? ☐ ☐ ☐
  If yes, frequency of direct blood contact?
  Frequent (several times weekly) ☐ Infrequent ☐
- Was the patient employed as a public safety worker (fire fighter, law enforcement or correctional officer) having direct contact with human blood? ☐ ☐ ☐
  If yes, frequency of direct blood contact?
  Frequent (several times weekly) ☐ Infrequent ☐
- Did the patient receive a tattoo? ☐ ☐ ☐
  where was the tattooing performed? (select all that apply)
  ☐ commercial parlor / shop ☐ correctional facility ☐ other _____

During the **6 weeks- 6 months** prior to onset of symptoms

- Did the patient have any part of their body pierced (other than ear)?
  where was the piercing performed? (select all that apply)
  ☐ commercial parlor / shop ☐ correctional facility ☐ other _____

Yes **No** **Unk**

- Did the patient have dental work or oral surgery? ☐ ☐ ☐
- Did the patient have surgery ? (other than oral surgery) ☐ ☐ ☐
- Was the patient- ***Check all that apply***
  - hospitalized ? ☐ ☐ ☐
  - a resident of a long term care facility ? ☐ ☐ ☐
  - incarcerated for longer than 24 hours ? ☐ ☐ ☐
    if yes, what type of facility (check all that apply)
    prison ☐ ☐
    jail ☐ ☐
    juvenile facility ☐ ☐

During his/her lifetime, was the patient ***EVER***

- incarcerated for longer than 6 months ? ☐ ☐ ☐
  - If yes,
    what year was the most recent incarceration ? __ Y Y Y Y
    for how long ? __ __ __ **mos**

Did the patient ever receive hepatitis B vaccine? **Yes** ☐ **No** ☐ **Unk** ☐

If yes, how many shots? **1** ☐ **2** ☐ **3+** ☐

- In what year was the last shot received? Y Y Y Y

Was the patient tested for antibody to HBsAg (anti-HBs) within 1-2 months after the last dose? **Yes** ☐ **No** ☐ **Unk** ☐

- If yes, was the serum anti-HBs ≥10mIU/ml? ☐ ☐ ☐
  (answer 'yes' if the laboratory result was reported as 'positive' or 'reactive')

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Perinatal Hepatitis B Virus Infection

NETSS ID NO. | | | | | | | | | | |

STATE CASE NO. _____

RACE OF MOTHER:

☐ Amer Ind or Alaska Native ☐ Black or African American ☐ White ☐ Unknown
☐ Asian ☐ Native Hawaiian or Pacific Islander ☐ Other Race, specify: _____

ETHNICITY OF MOTHER:

Hispanic ..... ☐
Non-hispanic ..... ☐
Other/Unknown ..... ☐

	Yes	No	Unk
Was **Mother** born outside of United States?	☐	☐	☐
If yes, what country? _____			
Was the **Mother** confirmed HBsAg positive prior to or at time of delivery ? ...	☐	☐	☐
• If no, was the mother confirmed HBsAg positive after delivery?	☐	☐	☐

Date of HBsAg positive test result ..... M M / D D / Y Y Y Y

How many doses of hepatitis B vaccine did the child receive ? ..... 0 ☐ 1 ☐ 2 ☐ 3 ☐

- When?
- Dose 1- M M / D D / Y Y Y Y
- Dose 2- M M / D D / Y Y Y Y
- Dose 3- M M / D D / Y Y Y Y

	Yes	No	Unk
Did the child receive hepatitis B immune globulin (HBIG)?	☐	☐	☐

- If yes, on what date did the child receive HBIG? ..... M M / D D / Y Y Y Y

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Patient History- Acute Hepatitis C

STATE CASE NO. _____

During the **2 weeks- 6 months** prior to onset of symptoms was the patient a contact of a person with confirmed or suspected acute or chronic hepatitis C virus infection?

	Yes	No	Unk
If yes, type of contact			
• Sexual	☐	☐	☐
• Household [Non-sexual]	☐	☐	☐
• Other: _____	☐	☐	☐

Ask both of the following questions regardless of the patient's gender.

In the **6 months** before symptom onset how many

	0	1	2-5	>5	Unk
• male sex partners did the patient have?	☐	☐	☐	☐	☐
• female sex partners did the patient have?	☐	☐	☐	☐	☐

	Yes	No	Unk
Was the patient ***EVER*** treated for a sexually transmitted disease?	☐	☐	☐

• If yes, in what year was the most recent treatment ? Y Y Y Y

During the **2 weeks- 6 months** prior to onset of symptoms

• inject drugs not prescribed by a doctor?	☐	☐	☐
• use street drugs but not inject?	☐	☐	☐

During the **2 weeks- 6 months** prior to onset of symptoms

Did the patient-

	Yes	No	Unk
• undergo hemodialysis?	☐	☐	☐
• have an accidental stick or puncture with a needle or other object contaminated with blood?	☐	☐	☐
• receive blood or blood products [transfusion]	☐	☐	☐
• if yes, when? M M / D D / Y Y Y Y			
• receive any IV infusions and/or injections in the outpatient setting...	☐	☐	☐
• have other exposure to someone else's blood	☐	☐	☐

specify: _____

During the **2 weeks - 6 months** prior to onset of symptoms

• Was the patient employed in a medical or dental field involving direct contact with human blood ?	☐	☐	☐

If yes, frequency of direct blood contact?

Frequent (several times weekly) ☐ Infrequent ☐

• Was the patient employed as a public safety worker (fire fighter, law enforcement or correctional officer) having direct contact with human blood?	☐	☐	☐

If yes, frequency of direct blood contact?

Frequent (several times weekly) ☐ Infrequent ☐

• Did the patient receive a tattoo?	☐	☐	☐

where was the tattooing performed? (select all that apply)

☐ commercial parlor / shop ☐ correctional facility ☐ other _____

During the **2 weeks- 6 months** prior to onset of symptoms

• Did the patient have any part of their body pierced (other than ear)?

where was the piercing performed? (select all that apply)

☐ commercial parlor / shop ☐ correctional facility ☐ other _____

	Yes	No	Unk
• Did the patient have dental work or oral surgery?	☐	☐	☐
• Did the patient have surgery ? (other than oral surgery)	☐	☐	☐
• Was the patient- ***Check all that apply***			
• hospitalized ?	☐	☐	☐
• a resident of a long term care facility ?	☐	☐	☐
• incarcerated for longer than 24 hours ?	☐	☐	☐
if yes, what type of facility (check all that apply)			
prison	☐	☐	
jail	☐	☐	
juvenile facility	☐	☐	

During his/her lifetime, was the patient ***EVER***			
• incarcerated for longer than 6 months ?	☐	☐	☐

• If yes,

what year was the most recent incarceration ? __ __ __ __

for how long ? __ __ __ **mos**

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Patient History- Hepatitis C Virus Infection (chronic or resolved)

STATE CASE NO. _____

The following questions are provided as a guide for the investigation of lifetime risk factors for HCV infection. Routine collection of risk factor information for persons who test HCV positive is not required. However, collection of risk factor information for such persons may provide useful information for the development and evaluation of programs to identify and counsel HCV-infected persons.

	Yes	No	Unk
• Did the patient receive a blood transfusion prior to 1992?	☐	☐	☐
• Did the patient receive an organ transplant prior to 1992?	☐	☐	☐
• Did the patient receive clotting factor concentrates produced prior to 1987?	☐	☐	☐
• Was the patient ever on long-term hemodialysis?	☐	☐	☐
• Has the patient ever injected drugs not prescribed by a doctor even if only once or a few times?	☐	☐	☐
• How many sex partners has the patient had (approximate lifetime) ? _____			
• Was the patient ever incarcerated?	☐	☐	☐
• Was the patient ever treated for a sexually transmitted disease?	☐	☐	☐
• Was the patient ever a contact of a person who had hepatitis ?	☐	☐	☐
If yes, type of contact			
• Sexual	☐	☐	☐
• Household [Non-sexual]	☐	☐	☐
• Other: _____	☐	☐	☐

	Yes	No	Unk
• Was the patient ever employed in a medical or dental field involving direct contact with human blood?	☐	☐	☐