HEPATITIS A OUTBREAK RESPONSE PLAN

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Scope and Purpose

Although many of the procedures discussed in this plan are applicable to the investigation of other infectious diseases, this plan details the response to a hepatitis A outbreak specifically. It is the intent of this plan to be fully compatible with CDC recommendations for hepatitis A investigation and control while applying those recommendations to procedural response by NDDoH Disease Control Division and the Emergency Preparedness and Response Section. Whenever parts of this plan are dependent on other existing plans, those plans will be referenced.

This plan contains factual data derived from standard reference sources which are referenced in the text where appropriate and listed at the end of the document.

Agent and Illness

Hepatitis A virus, a picornavirus, is one of several causes of acute viral hepatitis in the United States the most important of which are A, B and C. Although often considered together because the predominant manifestation of each is acute inflammation of the liver, the physiology and public health management of hepatitis A, B and C are more different than similar and are dealt with in separate plans. In addition, many other infectious diseases (e.g., viral, fungal, bacterial, protozoan, helminth) also cause acute liver inflammation, usually as one of many manifestations of the illness.

Hepatitis A is distributed worldwide but is no longer common in the US or other developed countries of

Disease Statistics

- <u>Symptoms:</u> fever, malaise, anorexia, nausea, abdominal discomfort, dark urine, jaundice
- <u>Incubation period:</u> 15-50 days (average 28)
- <u>Duration</u>: 2 months for 65%, almost all resolved by 6 months
- Hospitalization: 11% to 22% of cases
- <u>Infectivity:</u> 1-2 weeks before and 1-3 weeks after onset of symptoms, infective during relapses
- <u>Susceptibility</u>: No prior history of hepatitis A and no prior vaccination
- <u>Fecal shedding in children</u>: Up to 10 weeks for children and up to 6 months for infants
- Mode of spread: fecal-oral
- <u>Laboratory detection of IgM:</u> 5-10 days before symptom onset (usually), lasting up to 6 months
- Environmental persistence: up to months
- <u>Environmental inactivation:</u> 185° F, chlorine, formalin
- <u>Treatment:</u> supportive
- <u>Post-exposure prophylaxis window:</u> 2 weeks after last exposure
- <u>Isolation and quarantine:</u> No, but restriction on work for some people
- <u>Sequela:</u> None, but may exacerbate other chronic liver disease
- <u>Risk factor prevalence</u> (Note: A person may have more than one risk factor): International travel: 46% Contact with domestic case: 15% Employee or child in daycare: 7% Common source outbreak: 7% Illicit drugs: 4% MSM: 4% No identified risk factor: 37%

the west. Although still endemic in the US, most of population never comes in contact with the virus. About one-third of the population currently has immunity, but many of those have vaccine-induced immunity rather than immunity due to natural infection. Many of those with natural immunity are older with exposure that occurred during a time when the virus was more common. Importation by international travelers and contact with an international traveler now account for a substantial proportion of new cases.

Currently in the United States, persons 20-29 years old are at highest risk of acquiring the disease and children school age and younger (who are likely to have been vaccinated) are at lowest risk.

The acute illness is characterized by sudden onset of fever, malaise, anorexia, nausea, and abdominal discomfort followed a few days later by jaundice. Diarrhea may be associated with the illness and may

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increase the risk of spread. Illness is typically milder than that seen with Hepatitis B but can be severe, and is frequently disabling during the acute illness. Severity increases with advancing age. Young children (e.g., pre-school) are often asymptomatic and are rarely jaundiced if they become ill, whereas most persons older than 6 years become ill and jaundice is expected to occur among more than 70%. The illness is prolonged, usually lasting 2-6 months, with a prolonged recovery period following the acute illness. Relapsing illness occurs in up to 15% of cases with total duration of up to one year. Persons over 55 are at increased risk of fulminant and potentially fatal hepatitis. (Persons >60 years old may have a case fatality rate, as high as 1.8%.) Hospitalization occurs in 11% to 22% of cases and lost time from work averages 15 days for non-hospitalized and 33 days for hospitalized adults.

Infectivity and Outbreak Origin

Hepatitis A virus is excreted into the bile and is found in the stool with peak infectivity occurring during the two week period before onset of jaundice or elevation of liver enzymes. After the onset of jaundice, virus continues to be present in the stool but at reduced concentrations. Children shed virus for up to 10 weeks post illness onset (longer than adults) and infants can shed virus for up to six months. Chronic shedding does not occur. The virus is found in the blood and can also be transmitted parenterally (e.g., IV drug users); however, fecal-oral transmission accounts for nearly all cases.

The source of hepatitis A is changing since introduction of the vaccine. Based on surveillance data from 2005-2007, the following sources were identified:

International travel: 46% Contact with domestic case: 15% Employee or child in daycare: 7% Common source outbreak: 7% Illicit drugs: 4% MSM: 4% No identified risk factor: 37%

In studies of households in which no source was identified, 25-40% of children less than 6 had evidence of acute infection. Hepatitis A outbreaks have not been associated with natural disasters. Hepatitis A transmission is not increased among sewage workers. Food handlers are not at increased risk due to occupation.

Outbreaks in institutions are increasingly rare due to vaccination. Day care is still considered a potential risk factor, but most children in day care who develop hepatitis A acquired the infection outside the day care. Day cares without diapered children rarely have outbreaks. School-based transmission is rare so multiple cases in a school should prompt an investigation for a common source.

Food Code

The North Dakota food code provides legal authority to exclude or restrict the employment of food handlers infected or exposed to hepatitis A. Food handlers are required to report a diagnosis of hepatitis A or any exposure within the past 30 days. Workers who become infected cannot return to work until they have been symptomatic at least 14 days or seven days after jaundice onset. Persons may also be excluded if they have an asymptomatic infection diagnosed. The precise duration of exclusion in this case is not specified but should be based on last possible exposure. Persons who have

been exposed to hepatitis A are excluded from work until they can present evidence of prior infection, past vaccination history or post-exposure prophylaxis.

Case Definition

A confirmed case of hepatitis A is:

- 1. A case that meets the clinical criteria and is laboratory confirmed; or
- 2. A case that meets the clinical criteria 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).

<u>Clinical Criteria</u>

An acute illness with a) discrete onset of symptoms and b) jaundice or elevated serum aminotransferase levels (ALT or AST)

Laboratory criteria

Immunoglobulin M (IgM) antibody to hepatitis A virus (anti-HAV) positive. False positives can occur¹.

Laboratory

Specimen Collection

Blood should be collected in a clot separator tube. The specimen should include 3 cc of serum, but as little as 0.5 cc may be acceptable. The specimen should be spun down within four hours and the serum transported at refrigerator temperatures (3° - 8°C).

IgM and total anti-HAV are the two serological tests available. Only IgM can be used to confirm acute infection. PCR and viral isolation can be done but is not available in commercial labs.

IgM may be detectable after vaccination in up to 20% of recipients after a single dose of vaccine and IgM may be detectable for two to three weeks; therefore, IgM for disease confirmation should be obtained before vaccination².

Specimen Transport

One of two options is used to transport most specimens to the state lab, as follows:

- 1. FedEx with next day delivery
- 2. Courier The courier service transports specimens to the state lab Monday Friday from 14 major ND hospitals. Specimens arrive at the state lab late at night same day or very early in the morning the next day.

Need for more urgent transport and diagnosis confirmation if needed will require separate arrangements. This can be arranged locally by sending designated staff with the specimen or Disease Control (or DOC if activated) can arrange to make use of NDDoH partners (e.g., Highway Patrol). Need for urgent transport for diagnosis of hepatitis A is extremely unlikely.

¹ Persons with acute illness only should be tested. Elevated liver function tests in the absence of symptoms of acute illness is not an indication for laboratory testing for hepatitis A.

² Passive immunization interferes substantially less with inactivated viral vaccines than with live virus vaccines.

Hepatitis A viral sequencing is available and may be useful in some outbreak settings of multiple cases in which a common source has not been identified to determine if a common source should be suspected.

Surveillance

Hepatitis A is a mandatory reportable condition. During an outbreak period, additional surveillance may be used to find cases including contact tracing, stimulated passive reporting through contact with the medical community in the outbreak area and active surveillance among populations impacted by the outbreak.

In 2012, North Dakota had five confirmed cases of hepatitis A. Over the past decade, two or three confirmed cases would be reported in a typical year. In addition to confirmed cases, NDDoH receives the following types of reports which do not represent a confirmed case based on the information submitted:

- 1) Reports of positive IgM for hepatitis A in the absence of clinical symptoms³
- 2) Reports of total hepatitis A antibody (but not IgM antibody) in a person with compatible illness (Note that these persons may never be brought back in for IgM antibody testing, and thus, never confirmed as a case.)
- 3) Reports of total antibody obtained as part of a "hepatitis panel;" hepatitis A may not be suspected, but the laboratory result is reported.

Response to Hepatitis A Case Surveillance Report

Because hepatitis A cannot be diagnosed solely on clinical grounds, nearly all reports received by NDDoH are expected to be based on a positive serology. The Division of Disease Control will initiate an investigation to confirm that the case meets case definition (in addition to a positive serology, this means a compatible clinical illness). Once a case of hepatitis A is confirmed, priority is on identifying the contacts at risk for illness and identifying the source. This is accomplished through extensive interview of the case and follow-up of contacts.

Response Activation

Department Operations Center (DOC)

It is unlikely that the DOC will be activated unless a sizable sustained outbreak of hepatitis A is detected. In a large or difficult to control outbreak, the state is likely to seek assistance from CDC to obtain specific types of expertise such as experienced field investigators (e.g., and Epi-aid) and advanced laboratory support.

- The test was taken before symptom onset.
- The specimen was taken from an asymptomatic case.
- The test is a false positive. False positives appear to be common particularly among elderly persons.
- The test is an old positive. IgM antibodies usually disappear within 6 months, but duration greater than one year occasionally occurs.

³ A positive test without symptoms would mean that one of the following is true:

In the absence of a known outbreak, there is no indication for testing for Hepatitis A in the absence of clinical symptoms. During an outbreak, persons without symptoms may occasionally be tested (e.g., to investigate whether an asymptomatic child in day care could have been the source).

In the event that the DOC is activated, examples of assistance from the DOC likely of value in an outbreak of hepatitis A include the following:

- 1. Activation of HAN
- 2. Statewide videoconferencing support
- 3. Personnel assistance for tasks in Disease Control (data entry, data management/analysis, vaccine record research)
- 4. Vaccine management and cold chain
- 5. Assistance with mass vaccination
- 6. Resources and logistics
- 7. Media management

Role of LPHU

Specific activities would be the primary responsibility of the local public health agency; however, some local jurisdictions have very little public health capacity, so additional assistance may have to come from the state or from other local jurisdictions. Tasks which would fall to local public health include:

- Case investigation teams In the event that additional investigators are needed, local public health would potentially be called upon to supply personnel to assist with case investigation and contact tracing. LPH may be a ready source of nursing personnel who can obtain laboratory specimens and administer vaccine or immunoglobulin (IG), preferably at the time of initial contact, to persons who were potentially exposed (this would require portable cold chain capability).
- 2. Mass vaccination clinics In difficult to control outbreaks, contacts of food handlers with risk factors for transmitting the infection, or in outbreaks involving schools, mass vaccination clinics may be necessary. This would be a primary responsibility of LPH.

External Communication

Communicating with the Health Care System

It is unlikely that health care systems would need to be involved to any substantial extent unless 1) a sizable outbreak was occurring among older or medically vulnerable populations with high complication rates, or 2) assistance was needed from the private sector in providing vaccination or vaccination records, or 3) evidence was obtained of hepatitis A transmission in a health care facility.

Communicating with the Public

It is unlikely that a hepatitis outbreak would result in a high level of public concern except in the circumstance in which the public became aware that an infected food handler provided meals to a large number of people. In most of these latter circumstances, the state would be prone to withhold post-exposure prophylaxis (due to lack of indication) from many people who thought they needed it, which could cause some friction. In some high risk circumstances in which transmission from the food handler is a substantial risk, the media could be used to identify and bring in persons who needed post-exposure prophylaxis.

In some outbreaks, messages may be targeted to populations potentially impacted by an outbreak such as day care center directors or parents of children in day care; however, this information is likely to disseminated through institutional (e.g., day care) contacts. Unlike day cares, schools are not particularly prone to hepatitis A outbreaks.

Disease Investigation

Evaluation of Cases and Contacts

CDC provides a draft case report form for evaluation of cases of hepatitis which can be found at http://www.cdc.gov/hepatitis/PDFs/vhsp02.pdf. In addition to disease tracking, the evaluation of cases should determine risk factors for acquisition of the infection and identify persons who may be at risk of having been exposed in such a way that fecal-oral transmission is a reasonable likelihood. Because the period of infectivity is long, identification of all persons who may be at risk of developing disease requires careful interviewing.

Sporadic cases may be investigated by a single case investigator. Outbreak investigation of multiple cases may also be done by a single individual, but may benefit from use of a two person team. Contacts can be interviewed by telephone to further assess risk of exposure and vaccination status. Exposed, unvaccinated contacts can be asked to come into a public health vaccination site to receive appropriate post-exposure prophylaxis; however, these individuals need to be tracked to confirm that they have complied with prophylaxis. Further communication and home visit by a health care provider licensed to vaccinate should be used if needed to ensure receipt of prophylaxis.

Defining Exposure to Confirmed Case

Persons considered to be exposed to a laboratory confirmed case of hepatitis A include the following:

- Close personal contact defined as persons in household, sexual contact or person who shared illicit drug.
- (Possible) Persons with substantial household exposure (e.g., regular babysitter)
- Child care center with diapered children: Child care staff and attendees when one or more cases occur in children or employees at the center or two or more cases in families of attendees
- Child care center without diapered children: classroom contacts only
- (Possible) Families of diapered child care attendees when three or more families at child care center affected
- Food handling co-worker or infected food handler
- (Possible) Patrons of food handler when food handler had diarrhea or poor hygiene during period of infectivity
- (Possible) Patrons with recurrent exposure to food handler (e.g., institutional cafeteria)
- Close contacts of case at school or health care facility when 'within institution' transmission has occurred (but not indicated for institutional contacts in which institutional transmission is not documented)

Evaluation of Vaccination Status

At the time of this writing, persons who have been previously vaccinated should be at very low risk of disease (i.e, do not be considered as either contact for prophylaxis or as possible source); however, durable protection requires completing a complete course of vaccination series according to schedule. Vaccination status should be confirmed from the registry prior to interview of contact, or from records of health care providers identified during interview.

Currently, Advisory Committee on Immunization Practices (ACIP) recommends hepatitis A vaccination of all children at age 12–23 months, catch-up vaccination of older children in selected areas, and vaccination of persons at increased risk for hepatitis A (including travelers to endemic areas, users of illicit drugs, or men who have sex with men and contacts of newly arriving adoptees from countries with

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high or intermediate HAV endemicity). During 2007, the overall U.S. vaccination coverage, with at least 1 dose of HAV vaccine, among children 24–35 months was 47.4%.

HAVRIX is available in two formulations: pediatric (720 ELISA units [EL.U.] per 0.5-mL dose) and adult (1,440 EL.U. per 1.0-mL dose) (Table 1). Children 1 through 18 years of age should receive a single primary dose of the pediatric formulation followed by a booster dose 6 to 12 months later. Adults 19 years of age and older receive one dose of the adult formulation followed by a booster 6 to 12 months later. The vaccine should be administered intramuscularly into the deltoid muscle. A needle length appropriate for the vaccinee's age and size (minimum of 1 inch) should be used.

VAQTA is quantified in units (U) of antigen and is available in pediatric and adult formulations (Table 2). Children 1 through 18 years of age should receive one dose of pediatric formulation (25 U per dose) with a booster dose 6 to 18 months later. Adults 19 years of age and older should receive one dose of adult formulation (50 U per dose) with a booster dose 6 to 18 months after the first dose. The vaccine should be administered intramuscularly into the deltoid muscle. A needle length appropriate for the vaccinee's age and size should be used (minimum of 1 inch).

The hepatitis A component of TWINRIX consists of 720 ELISA units in a 1.0 mL dose (Table 3). It is approved for vaccination of persons aged >18 years in 2 schedules: a 3-dose schedule (0, 1, and 6 months) and alternate 4-dose schedule (0, 7, and 21–30 days, followed by a dose at 12 months). The alternative 4-dose schedule can be used where vaccination with TWINRIX or single antigen HAV vaccine has been initiated and travel or other potential exposure is anticipated before the second dose is due. A person 19 years of age or older who receives one dose of TWINRIX may complete the hepatitis A series with two doses of adult formulation hepatitis A vaccine separated by at least 5 months. A person who receives two doses of TWINRIX may complete the hepatitis A series with one dose of adult formulation hepatitis A vaccine may complete the series with two doses of TWINRIX or one dose of adult formulation hepatitis A vaccine may complete the series with two doses of TWINRIX or one dose of adult formulation hepatitis A vaccine may complete the series with two doses of TWINRIX or one dose of adult formulation hepatitis A vaccine may complete the series with two doses of TWINRIX or one dose of adult formulation hepatitis A vaccine. An 18-year-old should follow the same schedule using the pediatric formulation.

TWINRIX should be administered by intramuscular injection in the deltoid muscle. Injections in the gluteus can result in a lower response. When given with other vaccines or IG they should be given with different syringes and in different injection sites.

Documents and Forms

Investigators should have access to the following documents during an outbreak investigation:

- Interview forms These should be standardized for a single outbreak and may include information to be collected specific to the outbreak (e.g., information about a day care or other transmission setting)
- Release of information forms –If complete vaccination history is not available, a release of information may be required to obtain additional vaccination data from the primary provider.
- Educational documents to provide the case or contact (or their caregiver)
- Completed line listings of current cases.

Containment and Prophylaxis

Post-Exposure Prophylaxis

Post-exposure prophylaxis is indicated for all persons defined above as exposed if 1) they have not been previously vaccinated, and 2) they are within two weeks of their <u>last</u> exposure⁴. (Risk of acquiring hepatitis A among non-immune household contacts who do not receive post-exposure prophylaxis may be as high as 30%.) Both immunoglobulin (IG)⁵ and vaccine provide good protection (e.g., 85%-90%); however, recommendations differ by risk of adverse outcome with persons at high risk of adverse outcome preferentially getting IG and others preferentially getting vaccine.

Vaccine (either HAVRIX or VAQTA) is recommended as post-exposure prophylaxis in healthy persons 12 months through 40 years of age as of 2007 because it induces active immunity providing longer protection, has higher acceptability and availability, and is easy to administer. Immune globulin (IG) is typically used for post-exposure prophylaxis of hepatitis A in susceptible persons who are either older than 40 years of age, children younger than 12 months of age, immunocompromised persons, and persons with chronic liver disease.

Persons who are receiving IG, who would ordinarily be candidates for vaccine can be vaccinated simultaneously. Development of protective antibody will be muted for persons who are vaccinated soon after receiving IG; however, all persons will develop protective antibodies. Persons with low CD4 counts typically will not respond to vaccination and some transplant patients will not respond. Infants will respond but their protective antibody level is much lower that is usually achieved. Older persons also respond, but with a somewhat lower level of protective antibody.

Vaccination for post-exposure prophylaxis is indicated for persons ages 12 months to 40 years. Single antigen hepatitis A vaccine should be used, since combined hepatitis A and hepatitis B vaccine has a much smaller antigenic dose of hepatitis A and has not been studied for post-exposure prophylaxis. Children less than 12 months, adults over 40, immunocompromised individuals, persons with chronic liver disease and persons with contraindications to vaccination should receive IG (0.02cc/kg).

It may be possible to provide generalized vaccination to an at-risk group during an outbreak, but such efforts should consider the pros and cons such as time and costs.

Pre-Exposure Prophylaxis

Although beyond the scope of this document, pre-exposure prophylaxis delivered according to recommendations would make it unlikely that an international traveler returning to the US would be the source of a hepatitis outbreak. A vaccination schedule for Hepatitis A can be found in an attachment to this document

Immunoglobulin Precautions

IG is contraindicated in persons with isolated IgA deficiency and intramuscular IG is contraindicated in persons for whom IM injections are contraindicated (e.g., severe bleeding diathesis).

⁴ No data is available for efficacy of post-exposure prophylaxis given greater than two weeks after last exposure.

⁵ Some decline in HAV specific antibody has been noticed with reduced disease incidence, but it does not appear to have affected protection.

Vaccination Precautions

The primary contraindication to vaccination is prior severe reaction to hepatitis A vaccination or any of its components. The vaccine is not live and is safe during pregnancy and for immunocompromised individuals.

Adverse Reaction Reporting

Adverse reactions to vaccination should continue to be collected. Reports of adverse reactions can be reported to NDDoH, where they will be entered them into VAERS, or they can be entered directly into VAERS by the clinical provider. Even if entered directly into VAERS by the provider, NDDoH should be notified of any unusually severe or unusual type of adverse reaction.

Vaccine Management

Except for some Vaccines For Children (American Indian, Medicaid-eligible, uninsured, or underinsured) vaccine, NDDoH does not maintain supplies of hepatitis A vaccine in the state for use in outbreak management. However, substantial amounts of vaccine exist in the state at the local public health and private provider level. Should additional vaccine be needed, it can be ordered and will arrive quickly. When possible, vaccine shipments should go directly to the local public health agency that will be using it. If vaccine needs to come to NDDoH, it will be managed by cold chain procedures developed by the NDDoH warehouse and transported or shipped to its point of use. (See Cold Chain plan). NDDoH can supply VFC vaccine for eligible recipients when needed. Funding to purchase substantial quantities of vaccine are not pre-identified in Disease Control. NDDoH may receive permission from CDC to use VFC funds for outbreak control, or NDDoH may need to tap other sources in the agency to purchase vaccine (e.g., emergency response or state general funds).

Isolation and Quarantine

Isolation of cases and quarantine of contacts is not indicated for control of hepatitis A. However, even if household contacts have received prophylaxis, ill persons in a household will be asked to limit certain activities to decrease the risk of disease transmission (e.g., handling food).

Preventing Transmission in Health care Settings

Transmission in a health care facility is relatively uncommon and nearly all cases should be manageable by enforcement of standard and contact precautions. Employees with hepatitis A may work as long as they follow personal hygiene and usual precautions; however, institutions may choose to restrict their activity to minimize any risk of disease transmission during their period of infectivity. Health care providers are restricted from patient care areas until one week after onset of jaundice.

Data Management

During an outbreak, cases and contacts would be tracked within the MAVEN outbreak module. Cases and contacts should be entered in the system ASAP after data collection so that data is not dropped and individuals not lost to follow-up. Basic information for the line listing should be entered into a log book at the time of data collection rather than on a random piece of paper. The log book should include space to document that specific actions have been completed for each person in the line listing (e.g., specimen collection, vaccination of contacts). Data should be entered from the log book into MAVEN on return to the base office. An aggregate line listing should be published on paper, updated daily and provided to each investigator; the aggregate listing should provide basic information about each identified case and contacts. Old line listings from previous days should be shredded. In addition to a log book, a filing system needs to be maintained for all records. Each interviewed individual may have several documents or forms including clinical summaries, interview forms, vaccination forms, release of information forms and laboratory results. Records for cases and contacts should be separated and each folder clearly label as case or contact. If two or more linked cases (outbreak) are identified, the outbreak will be reported through NORS.

CDC surveillance data collection instruments are already loaded into MAVEN; however, data collection instruments may have to be modified to include outbreak specific risk factors. If a substantial amount of data needs to entered, managed and analyzed due to a large outbreak, Disease Control might need additional assistance from other NDDoH personnel (e.g., DOC) or temporary contract personnel. Persons without advanced data skills could be used to enter information and NDDoH non-infectious disease epidemiologists or analysts from other parts of the agency may be used to assist with data management, analysis and result production. These persons could either be assigned to Disease Control or work under some other part of the incident command system in support of Disease Control.

Vaccination Data

NDIIS would be used to identify vaccination completeness. If a person is not in NDIIS or records appear incomplete, vaccination history would be obtained through provider offices. Which provider offices to contact would need to be determined from the case or contact interview. Vaccination status determination requiring calls to provider offices would likely be done in Disease Control. Additional personnel assistance may be needed for this activity.

In the setting of a mass vaccination clinic, direct entry into NDIIS would be preferable, but may not be logistically possible in all situations. An alternative paper data collection form would be provided by Disease Control. These forms would need to be entered into NDIIS after the mass clinic either by local public health or by NDDoH.

Data Analysis and Report Production

Multiple types of data and multiple targets for data results will likely need to be managed during an outbreak. Source of data may include the following:

- Case information data collected on investigation forms, complications, actions taken, lab results, case definition classification
- Control information data collected on investigation form, immunity status, actions taken
- Surveillance data
- Intervention data (e.g., data from mass vaccination clinics)
- Vaccine management data

Targets for data would primarily be the following:

- Incident command system Case and control line listing, epi curve, geographic mapping of outbreak, related out-of-state contacts, vaccine availability, surveillance report, at-risk population susceptibility/vaccine coverage, supply transport
- Agency administration outbreak summary information and progress reports
- Public information officer Number of cases, populations at risk, hospitalizations or deaths, new cases/epi curve, geographic extent, progress toward disease containment
- Teams in the field case specific information, line listings

Worker Protection

Investigation of a hepatitis A case should pose no risk to an investigator and investigators do not need to have prophylaxis or a history of vaccination for Hepatitis A prior to participating in an investigation. Should an investigator be involved in collecting specimens, the investigator should use standard precautions.

Education and Training

Patient and Contact Education

Each person with hepatitis A and each contact will need to receive education. Generally the education will be performed by the investigator at the time the history is taken. Content of the education may include:

- Information about the disease such as manifestations and prognosis
- Incubation period post exposure
- Communicability
- Protecting family members
- Contact information to reach local public health
- Post-exposure prophylaxis including safety/risks of vaccine or Ig

Responder Training

Some of those called upon to respond to a hepatitis A outbreak will need just-in-time training related to roles that they will fill. This may include:

- Disease information
- Role assignments
- Phlebotomy
- Provision of post-exposure prophylaxis
- Adverse reactions to post exposure prophylaxis
- Monitoring for illness and potential for illness post prophylaxis
- Obtaining specimens for laboratory evaluation
- Interviewing
- Contact tracing

Analyst/Assistant Training

Persons recruited to assist with data management will require some training as to specific tasks and products for which they will be responsible. Because the training requirements for some systems

are high, staff in Disease Control may manage aggregation of raw data from and provide it to a single person responsible for allocating tasks among analysts and receiving back results.

Recovery and After Action

Several tasks will need to be completed as the outbreak winds down. These include:

 Identification of source introduction – This process may be simple or complex depending on how the outbreak occurred and whether there is concern that a commercial product may be responsible. More extensive interviewing may be needed and coordination with CDC to track viral signature and match it up with potential sources may be necessary.

- 2. Missed opportunities for interdiction As part of the after action, specific focus should be placed on opportunities missed to prevent or control the outbreak. This may lead to procedural or policy changes. Examples might include:
 - a. Missed contacts not found until they had become ill
 - b. Vaccination gaps that contributed to the outbreak spread
 - c. Effectiveness or lack of effectiveness of post-exposure prophylaxis
 - d. Adequacy of protection of vulnerables who could not be vaccinated or who were at high risk of complications
 - e. Failures of notification particularly across state lines of possible contacts which could lead to outbreaks
 - f. Evidence of vaccine or cold chain problems (e.g., private offices or LPHU)
 - g. Unique factors or populations (e.g., oil country, hard to reach populations)
- 3. Opportunities for increasing vaccination coverage long term
- 4. Training gaps e.g., vaccine storage, case investigation and contact tracing, resources for phlebotomy or vaccination of small children

<u>References</u>

Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP)(May 19, 2006) found at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm

Manual for the Surveillance of Vaccine-Preventable Diseases5th Edition, 2012 & 6th Edition, 2013 (updated August, 2011) found at <u>http://www.cdc.gov/vaccines/pubs/surv-manual/index.html</u>

Update: Prevention of Hepatitis A After Exposure to Hepatitis A Virus and in International Travelers. Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP) (Oct 19, 2007) found at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5641a3.htm

North Dakota Food Code found at <u>http://www.ndhealth.gov/FoodLodging/PDF/Food_Code_2012_Final.pdf</u>

Attachment 1: Vaccination Schedule

Table 1. The dose of HAVRIX is quantified in enzyme-linked immunosorbent assay (ELISA) units (EL.U.). HAVRIX is currently licensed in a two-dose schedule of 720 EL.U. per dose (0.5 mL) for children and adolescents (12 months through 18 years of age), and 1440 EL.U. per dose (1.0 mL) for adults (older than 18 years of age).

Group	Age	Dose (EL.U.)†	Volume	No. doses	Schedule§
Children and adolescents	12 months–18 years	720	0.5 mL	2	0, 6–12
Adults	>18 years	1,440	1.0 mL	2	0, 6–12

Table 1. Recommended doses of HAVRIX® (hepatitis A vaccine, inactivated)*

* GlaxoSmithKline

[†]Enzyme-linked immunosorbent assay units

§Months; o months represents timing of the initial dose; subsequent number(s) represent months after the initial dose.

Table 2. The dose of VAQTA is quantified in units (U). The dose and schedule for children and adolescents (12 months through 18 years of age) is 25 U per dose in a two-dose schedule, and for adults (older than 18 years of age), 50 U per dose in a two-dose schedule.

Table 2. Recommended doses of VAQTA® (hepatitis A vaccine, inactivated)*

Group	Age	Dose (U)†	Volume	No. doses	Schedule§
Children and adolescents	12 months–18 years	25	0.5 mL	2	0, 6–18
Adults	>18 years	50	1.0 mL	2	6–18

* Merck & Co., Inc.

† Units

§ Months; o months represents timing of the initial dose; subsequent number(s) represent months after the initial dose.

Table 3. The dose of Twinrix is quantified in ELISA units (EL.U.) and micrograms. Each dose of Twinrix contains at least 720 EL.U. of inactivated hepatitis A virus and 20 μ g of recombinant hepatitis B surface antigen (HBsAg) protein. There is a three dose schedule, given at 0, 1, and 6 months (the same schedule as that used for single-antigen hepatitis B vaccine), and a four dose schedule to accommodate travelers with short notice.

Table 3. Recommended doses of TWINRIX® * (combined hepatitis A and B vaccine for persons >18 years of age)

Group	Age	Dose†	Volume	No. doses	Schedule§
Adults	>18 years	720 EL.U. and 20mcg of HBsAg	1.0 mL	3	0, 1, 6
Adults	>18 years	720 EL.U. and 20mcg of HBsAg	1.0 mL	4	0,7, 21-30 days, 12 months

* GlaxoSmithKline

† Enzyme-linked immunosorbent assay units

§ Months; 0 months represents timing of the initial dose; subsequent number(s) represent months after the initial dose.

<u>Attachment 2: Elements of Data Collection for</u> <u>Hepatitis A Investigation</u>

- A. Background (Cases and Contacts)
 - a. Interviewer name
 - b. County of interview
 - c. Date of interview
 - d. Case or contact interview
- B. Source of report
 - a. Reason for testing
 - b. Sporadic or outbreak associated
 - c. If outbreak suspected common source
- C. Demographics (Cases and Contacts)
 - a. Name
 - b. Address and county of residence
 - c. Date of birth
 - d. Age
 - e. Sex
 - f. Ethnicity
 - g. Race
- D. Clinical (Cases)
 - a. Date of symptom onset
 - b. Dates for any relapses
 - c. Symptoms
 - i. Initial
 - ii. At time of interview
 - d. Liver functions tests
 - e. Hospitalization
 - f. Complications
 - g. Outcome (live or dead)
- E. Laboratory (Cases and Contacts)
 - a. Date serology drawn
 - b. Number of days before or after symptom onset
 - c. Serological test results
- F. Status of Case or Contact
 - a. Confirmed Case
 - b. Contact
- G. Presumptive period of infectivity (dates)

- G. Risk factors for acquiring illness
 - a. Household contact of case
 - b. International travel
 - c. Day care contact (employee, child, family)
 - d. Contact of high risk food handler
 - e. Illicit drug sharing
 - f. MSM
 - g. Exposure to food handler (specify risk)
 - h. Other (e.g., playmate, babysitter)
- H. Risk factors for transmission
 - a. Food handler during transmissible period
 - b. Diarrhea
 - c. Poor hygiene
 - d. Diapered
- I. List of potential contacts
- J. Vaccination status
 - a. Number of doses of vaccine received
 - b. Dates of hepatitis A vaccination
 - c. Manufacturer name
 - d. Vaccine lot number
 - e. Location of vaccination if not US
- K. Epidemiological
 - a. Earliest possible date of exposure
 - b. Last possible date of exposure
 - c. Linked or unlinked case
- L. Outbreak Specific Information
- M. Food History