

# Hepatitis B Business Rules for Investigation and Reporting in NC EDSS

## 1) Required investigation and documentation in NC EDSS for:

- a. Persons with no prior events in NC EDSS and have positive hep b lab results (HBsAg, HBV DNA, HBeAg and IgM anti-HBc) must be reported as a **NEW EVENT**.
  - i. Whether the labs are manually entered (as Hepatitis B Acute or Hepatitis B Chronic Carrier) or directly feed by ELR which would create a lab condition report (LCR) the Local Health Department (LHD) needs to determine if the event is best entered as an acute or chronic carrier event.
  - ii. Once the event is changed to either acute or chronic carrier all packages (clinical, risk, administrative, vaccine) must be completed and an investigation and medical record reviewed. Assign to the State Disease Registrar once event is completed.
  - iii. Household, sexual and needle sharing contacts to Hepatitis B-positive women who are currently pregnant or women that have given birth in last 24 months (these contacts must be entered as linked contacts to the woman's event). The events should contain vaccination and testing data and be assigned to state Prenatal Case Management (PCM). If one of these contacts is found through testing to be HBsAg, HBV DNA, HBeAg (+), the case must be reported to the State Disease Registrar as a new event.
  - iv. Household, sexual and needle sharing contacts need only be added for all other events if they are tested and found to be either HBsAg, HBeAg or HBV DNA positive and must be linked to their contacts events.
    1. For guidance on how to link events in NC EDSS please see:
      - a. Linking Events in NC EDSS under NC EDSS Guidance of the Hepatitis B Manual
- b. Persons previously reported as Acute or Perinatally Acquired with additional lab work. **EXISTING EVENT**
  - i. When lab results indicate a disease progression from Acute Hepatitis B or Perinatally Acquired to Chronic Confirmed Carrier a new event must be reported (usually 6 months after previous labs)
    1. Whether the labs are manually entered or directly feed by ELR (which would create an LCR) LHD's will either create a Hepatitis B Chronic

Carrier event (in the case of paper copy labs) or change an LCR to a Hepatitis B Chronic Carrier event and complete all necessary packages.

- a. If investigation was completed in prior event (Acute or Perinatal) LHD's will only need to complete the subsequent report package in the new event,
- b. If an investigation was not completed and/or control measures were not issued an investigation will now need to be completed and documented in the new chronic event.

2. Event will then be assigned to the State Disease Registrar.

c. Persons previously reported as Chronic Carrier Probable and are now Chronic Carrier Confirmed. **CLASSIFICATION CHANGE**

i. Received lab results confirm a previously reported chronic carrier classified as probable. An LCR will be sent to the State Disease Registrar to update the classification status of the existing event (chronic probable carrier).

1. Whether the additional labs are manually entered (LHD created LCR) or directly feed by ELR (system generated LCR) LHD's need to leave the event as an LCR and complete the subsequent report package (SRP) (linking previous event in SRP). The disease classification will be changed to confirmed in the administrative trail and assigned to the State Disease Registrar. Only the State Disease Registrar will then merge the LCR into the existing Hepatitis Chronic Carrier event.

ii. When a paper report or ELR is received by the state as confirming a Chronic Probable Carrier, the State Disease Registrar will automatically update existing events for male patients and female patients outside the child bearing years >50 unless the new labs indicate a control measure violation (i.e. lab connected to blood/tissue donation, new dialysis testing not previously identified).

1. LHD's will still be required to mark the events containing the ELR as reviewed in the Lab Results-Hep B-Lab result review required (local) workflow.

d. Updating a previously reported event with new lab work. **NEW LABS FOR PREVIOUSLY REPORTED EVENT**

i. If the labs are feed in by ELR (system generated LCR) LHD's need to leave the event as an LCR and complete the subsequent report package (SRP) (linking previous event in SRP). Once the SRP is completed, the event will need to be reassigned to the State Disease Registrar with a note in the admin trail "please

merge with previous reported event". Only the State Disease Registrar will then merge the LCR into the existing event.

- ii. If paper labs are received and the persons existing event is a chronic confirmed male or a chronic confirmed female over 50 those labs do not need to be entered in NCEDSS.
  - 1. Exception to this rule:
    - a. Control measure violations
    - b. Recent/new dialysis
- e. Females 14-50 regardless of prior events must be investigated to determine pregnancy status. (Note: There may be occasions in which newly identified cases of hepatitis B will be reported in females younger than 14. Consult with the provider to determine why testing was done. If the exposure was through sexual intercourse and the female is sexually active, then pregnancy status should be determined through conversations with the provider).
  - i. With reports of Acute or an initial Chronic Carrier, LHDs will document pregnancy status. If pregnant the estimated date of delivery (EDD) and pregnancy information will need to be documented in the clinical package. Once all question packages are complete assign to the State Disease Registrar for initial reporting to CDC and reassignment to PCM for follow-up.
  - ii. For previously reported women the LHD will need to create an LCR or edit the ELR generated LCR with the patient's current pregnancy status, EDD and insurance information in the subsequent report package. These events will be left as LCR's and assigned to Perinatal Case Management for follow-up (ensure that the admin trail has the correct classification each time it's re-assigned).
    - 1. LHD's will initiate PCM for all pregnant females that are HBsAg, HBeAg, HBV DNA and IgM anti-HBc (+) as well as HBsAg (unknown) lab results.
      - a. LHD's will follow pregnancies until infant is delivered. Once delivered LHD's will update events with delivery information and re-assign event to PCM for follow-up.
      - b. LHD's will create a linked Hepatitis B Perinatally Acquired event to the mother event and assign event to PCM for follow-up.
      - c. If the pregnancy is terminated or the mother leaves NC to reside in another state or country, both the date and reason for termination along with new address will need to be documented and re-assigned to PCM.

- iii. For pregnant women with HBsAg unknown results and/or testing cannot be performed by LHD or by patient's provider the LHD will follow persons until delivery and continue tracking the infant once delivered.
- f. Infants born to Hepatitis B-infected mothers will be followed post-delivery (usually for 9-12 months) to ensure:
  - i. Post exposure prophylaxis (PEP) with HBIG & hep b vaccine were administered within 12 hours of delivery.
    - 1. HBIG is documented in the Clinical package under –Treatment
    - 2. Hep B vaccines are documented in the Vaccine Information package.
    - 3. Once vaccine series is complete Post Vaccine Serologic Testing (PVST) is to be done but no earlier than 9 months of age. (1-2 months post vaccine series completion)
  - ii. When a ELR generates a LCR documenting PVST the SRP should be marked to indicate that the event is currently being followed and re-assigned to the State Disease Registrar for merging.
  - iii. When a paper lab is received the labs should manually be added the existing perinatal event.
  - iv. LHD will reassign event to PCM for follow-up once vaccine series is complete and PVST is completed (HBsAg & anti-HBs only)

2) Investigation not required for:

- a. Non-reportable Hepatitis B lab results (Anti-HBC, Anti-HBe) do not require investigation.
  - i. If IgM anti-HBC is reported alone and no signs/symptoms are present investigation is not required to occur
  - ii. IF IgM anti-HBC is reported with signs/symptoms it is expected that LHD CD Nurse will call testing provider to obtain additional HBV serology. Patients should not be contacted until the following is done.
    - 1. If additional testing is obtained and found to be negative no further action is required.
    - 2. If additional testing is positive investigation will continue as normal.
- b. If a non-reportable lab result is received as an ELR, NC EDSS will not create a new event.
- c. If a Hepatitis B event already exists for the person, the ELR will update the event. The update will cause previously reported events that are closed to appear in the Hepatitis B – Lab Result Review Required Workflow. These events can be marked as reviewed

without further action. If the ELR updates a currently open event, the event should continue through the reporting process.

3) Investigation of Hepatitis B positive dialysis patients:

a. Dialysis patients that test positive for HBsAg:

i. Determine if the HBsAg is a false positive. This is a common occurrence when hepatitis testing occurs within 30 days of a recent vaccine.

1. Obtain records from the dialysis center regarding vaccinations (date of vaccine administration) and hepatitis testing 3 months prior to the positive if available.

a. Retesting of the patient should occur 60 days after the date of the last vaccine.

ii. If testing is found to be a true positive, please use the Management of exposure to HBsAG located in the HBV manual under investigation steps and case management.

4) Investigation of Life Insurance Companies:

a. Contacting the ordering provider, life insurance company and/or laboratory will not provide any additional information. The person must be contacted directly by the LHD. Often this will be the first time the person is made aware of their HBV status. Provide explanations of how/why the LHD received their lab results and information about the disease process. Recommend the person see their own provider for additional confirmation testing and evaluation. If the person and/or their contacts do not have a provider or are uninsured, the LHD may offer follow up confirmation testing through the NC SLPH.

i. If no other testing is done, this person should be reported as a probable chronic hepatitis B case.

ii. If additional testing is done, the case should be evaluated based on prior and current serology results.

b. For persons being reported as a probable or confirmed hepatitis B case, their sexual partners, household contacts and persons who may have shared needles or drug paraphernalia should be tested and vaccinated in accordance with 10A NCAC 41A .0203.

c. Control measures should be issued to anyone that meets case definition.

5) Responsibility for Investigation:

- a. Reported cases of communicable disease are to be investigated and reported by the county health department in which the patient currently resides.
- b. For previously reported chronic carrier cases, the original county of residence shall be maintained in the original reported event. The current county of residence will create a LCR to update classification, pregnancy status, conduct perinatal/contact tracking and/or reinforce control measures. The event should then be assigned to the State Disease Registrar as an LCR.

6) Deduplication of Hepatitis B Events:

- a. **Deduplication/merging of Hepatitis B events is to be done at the state level only.** LHDs with events that need deduplication/merging should contact the Viral Hepatitis Surveillance Nurse.
- b. The State Disease Registrar will routinely merge LCRs into the previously reported event at the time the event is assigned to the state for closure. This will result in one complete event with a chronological listing of labs and subsequent events, such as pregnancies.

7) Person Deduplication:

Person deduplication helps to ensure that persons are not saved in the system more than once. A person might be referenced more than once because he or she might have more than one event over time, but events should always reference back to the same specific person

- a. Potential person deduplications can be sent to the state disease registrar or by email to the NC EDSS Helpdesk: [ncedsshelppdesk@dhhs.nc.gov](mailto:ncedsshelppdesk@dhhs.nc.gov)
  - i. The email needs to include all applicable event ID numbers
    - 1. This is in part because once person deduplication is completed, events may be identified that require deduplication.
  - ii. Ensure that the most recent event has updated and correct demographics. Please not in the administrative trail that all information is correct.

8) Data Correction in Previously Reported Events:

- a. LHDs can provide updates to a previously reported case by creating an LCR and entering the additional information into the Subsequent Report package and assigning the event to the State Disease Registrar. The State Disease Registrar will then merge the LCR into the original event.

- b. Other requests for corrections to closed events should be made to the Hepatitis Surveillance Nurse.

9) State Functions:

- a. The State Disease Registrar for Hepatitis B with the Communicable Disease Branch is tasked with:
  - i. Review all Hepatitis B events assigned to the State Disease Registrar for classification, mark the event for reporting to CDC if appropriate, merge the event into an original event if needed, and close the event.
  - ii. Review all Hepatitis B events assigned to the State Disease Registrar for an indicated pregnancy and process as follows:
    - 1. Hepatitis B events received by the State Disease Registrar missing required information will be returned to the LHD for completion.
    - 2. Hepatitis B events for women in which a birth is indicated in the last 24 months but have no link to an event(s) re: the treatment of the child or children, will be assigned to Perinatal Hep B Case Management.
  - iii. Paper laboratory test results for positive, reportable Hepatitis B labs received by the state by mail or fax will be reviewed and entered by the State Disease Registrar as LCRs.

10) State Case Management Functions for Prevention of Perinatal Transmission:

- a. The Immunization Branch will perform case management activities to prevent perinatal transmission of Hepatitis B.
  - i. Events for Perinatal Hepatitis B contacts will be assigned to the State Disease Registrar for reporting and closure when complete. State Disease Registrar will close the event using the final case classification indicated by PCM.
  - ii. All case management activities will be recorded in the event assigned to PCM. The event will remain open until reassigned to the State Disease Registrar for merging, reporting, and closure as appropriate.
- b. Events requiring assignment to a LHD during case management will be assigned by PCM with directions for the LHD to reassign the event to PCM when the event is complete.

- c. Interstate referrals of currently pregnant Hepatitis B positive females or infants being followed for perinatal exposure to Hepatitis B will be entered into NC EDSS and assigned to LHDs for case management.

11) Hepatitis B Events – Best Practice Guidelines:

- a. Complete information must be provided in the designated packages.
  - i. Demographic package
    - 1. First and last name of patient
    - 2. Date of birth
    - 3. Address
    - 4. County of residence for the event & Zip code
    - 5. Race & Ethnicity
    - 6. Gender
  - ii. Clinical package...complete all sections, with emphasis on the following:
    - 1. Is/was patient symptomatic for this disease? If YES, check all symptoms that apply.
    - 2. Pregnancy status for all females aged 14-50. If currently pregnant, provide EDD, OB information and insurance information.
    - 3. Reason for testing
    - 4. Document that control measures were given, if applicable. For additional guidance, see “Documenting Hepatitis B Control Measures” in the Hepatitis B Manual.
  - iii. Risk History package...Please list all known possible exposures.
    - 1. Risk information that was not asked should be left blank/missing.
  - iv. Vaccine Information package...provide complete documentation of all vaccinations received, if applicable.
    - 1. Patients assumed to have false positive HBsAg due to recent vaccination must have vaccines entered.
  - v. Administrative package
    - 1. Initial source of report to public health
    - 2. Date of initial report to public health
    - 3. NC county of residence for the event
    - 4. Correct assignment of the event, as follows:
      - a. Assign all hepatitis B events to the State Disease Registrar once case investigation is complete.
      - b. Assign all Perinatally-Acquired Hepatitis B events to state Perinatal Hep B Case Management.



- c. If an event has been assigned to you by the State Disease Registrar, please provide the requested information, and return the event to the State Disease Registrar.
- d. If an event has been assigned to you by PCM, please provide the requested information, and return the event to PCM.

**NOTE:**

- All Hepatitis B events with pregnancies resulting in live births must have a linked Hepatitis B Perinatally Acquired event for each infant.
- **NEVER** merge Hepatitis B events (this is also known as deduplication).
- **NEVER** transmit sensitive client information through unsecured email.