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Wayne County Hepatitis B Outbreak Summary

Background

On Tuesday, October 12, 2010, the North Carolina Division of Public Health was notified by the Wayne County Health Department of four cases of Hepatitis B among residents of an assisted living facility (ALF) in Mt. Olive. The census of this ALF is usually near 58, consisting of elderly persons and others with dementia and mental illness requiring varying degrees of assistance with activities of daily living.

Because acute Hepatitis B infections in the elderly are uncommon and often associated with healthcare exposures, the Wayne County Health Department and the North Carolina Division of Public Health (NC DPH) investigated to characterize the extent of the outbreak and to identify how residents were being exposed to infection in order to control the outbreak. NC DPH informed the North Carolina Division of Health Service Regulation of the outbreak.

Methods

Infection control observations

We observed blood glucose monitoring, insulin injection, and medication administration practices within the facility on multiple occasions beginning on October 13. We also interviewed facility employees about infection control policies and practices and other potential sources of exposure among residents.

Case finding

We reviewed hospital records of all identified cases. Wayne Memorial Hospital, where all of the initially-identified patients had been hospitalized, reviewed their records for additional cases of Hepatitis B infection among residents of the ALF.

On October 15, we requested serologic testing for Hepatitis B infection for all persons who had resided in the facility at any time since January 1, 2010. The facility obtained blood samples and arranged for serologic testing for Hepatitis B surface antigen, Hepatitis B surface antibody, and Hepatitis B total core antibody beginning on October 18. For those with detectable Hepatitis B surface antigen, testing for Hepatitis B core IgM was also performed. When possible, persons who had detectable Hepatitis B core IgM were checked for antibodies to Hepatitis D virus (HDV).

Analysis of potential exposures

In order to identify risk factors associated with acute Hepatitis B infection, we performed a retrospective cohort study by reviewing ALF records using a chart abstraction tool adapted from previous Hepatitis B outbreaks in long-term care facilities. We gathered information on potential health care exposures (occurring within and outside of the ALF), past medical history, and risk behaviors (when available).

For this investigation, we used the following case definitions:

- Acute Hepatitis B infection:



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- Positive Hepatitis B surface antigen **and** Hepatitis B core IgM results from serum obtained at least 6 weeks after admission to the ALF from a person who resided in the ALF on or after January 1, 2010
- OR--
- Clinical evidence of acute hepatitis (defined as jaundice, dark urine or serum transaminase levels greater than two times the upper limit of normal) identified at least six weeks after admission to the ALF in a person who resided in the ALF on or after January 1, 2010 **and** no negative Hepatitis B surface antigen results during the same timeframe.
- Hepatitis B susceptible:
 - Negative Hepatitis B surface antigen, surface antibody, and core antibody results in a person who resided in the ALF on or after January 1, 2010.
- Hepatitis B immune:
 - Positive Hepatitis B surface antibody or Hepatitis B core antibody results and negative Hepatitis B surface antigen results in a person who resided in the ALF on or after January 1, 2010.
- Chronic Hepatitis B infection:
 - Positive Hepatitis B surface antigen and Hepatitis B core antibody results and negative Hepatitis surface antibody and core IgM results in a person who resided in the ALF on or after January 1, 2010.

We performed chart abstractions for all persons who met our acute or chronic Hepatitis B infection or Hepatitis B susceptible case definitions. In cases where residents were unavailable for testing, we reviewed charts for clinical evidence of acute hepatitis (as defined above). If this was not present, we excluded them from the analysis as we were unable to classify their status. Only those meeting the acute Hepatitis B infection and Hepatitis B susceptible case definitions were included in our analyses of potential risk factors. For acute cases, health care exposure information was included for the period 6 months–6 weeks before the onset/diagnosis date. For susceptible residents, health care exposure information was collected for the period beginning January 1, 2010 or the date of admission (whichever was later) through the date of testing.

Data were entered manually into an Access database. Relative risks (RR) and 95% confidence intervals (95% CI) were calculated. Analyses were performed using SAS 9.1 (Cary, NC).

Results

Infection control observations

During observations performed October 13, we observed that glucometers were stored together in a single compartment in a drawer of the medication cart and were not obviously labeled with resident names. Multiple-use adjustable lancing devices were kept in a drawer on the medication cart in boxes labeled with resident names. A spray bottle labeled “Bleach” was on top on the medication cart; date of preparation and concentration were not clearly indicated. Multi-dose insulin vials were in use and were labeled with resident names and dates opened. During observations on October 15, glucometers were clearly labeled with resident names but were still stored together in a single drawer on the medication cart. Adjustable lancing devices were still in boxes labeled with resident names; however, an unlabelled adjustable lancing device was also present in the same drawer. During observations on October 15, neither the blood glucose monitors nor the adjustable lancing devices (both labeled with individual resident names) were cleaned or disinfected after use. During observations on October 15, the bleach bottle was noted to be labeled “bleach and water” still with no concentration or date of preparation indicated. On repeat observations on October 26, glucometers were housed within a locked compartment on the medication cart in individual pouches, which were labeled with resident names, with unlabeled reusable lancing devices and labeled glucometers in each pouch. The medication tech was observed to clean the lancing device and glucometer with an alcohol swab after use. The nursing consultant indicated that the facility was planning to discontinue use of adjustable lancing devices in favor of single-use, auto-retracting lancing devices in response to DPH recommendations. This practice was reported to have been implemented on October 30

The facility reported that medications are prepared on a medication cart in the hallway just prior to entering the patient's room. There are three medication carts, one for each hallway in the facility.

During interviews, one medication tech indicated that adjustable lancing devices had been used on more than one patient prior to the initiation of our investigation. The medication tech we interviewed indicated that glucometers and adjustable lancing devices were not routinely cleaned and disinfected between uses. Other facility employees reported to Wayne County Health Department that they were allowed only one box of gloves per shift and, as a result, were purchasing their own additional gloves for use within the facility.

Prior to the initiation of the investigation, approximately 5 staff members had requested vaccination against Hepatitis B once the outbreak had been identified.

We reviewed the facility's infection control policy, which addresses blood-borne pathogens and blood glucose monitoring, including a specific statement that each patient shall have their own lancet device and own glucometer. At the time of this investigation, no one employed within the facility had completed a state-approved infection control course, and an infection control coordinator had not been designated. Since that time, an infection control coordinator has been named, and several employees attended an infection control course on November 3.

Case finding and case description

Upon review of the hospital charts, discussion with Wayne Memorial Hospital, and a serologic survey of the facility, four additional cases of acute Hepatitis B infection were identified, bringing the total number of cases to eight (see Figure 1). Seven (88%) had detectable Hepatitis B surface antigen, and five (63%) had detectable Hepatitis B core IgM. All eight were hospitalized during August 22–October 24, 2010, although two were hospitalized for reasons not related to Hepatitis B infection. As of November 9, 2010, five (63%) have died from their hepatitis infection. Because of the high mortality rate, HDV antibody testing was performed on three of the acute cases, including two of the deceased, but was negative for all.

Of the eight persons with acute Hepatitis B infection, six (75%) were male. Five (63%) were black, and 3 (37%) were white. The mean age of these persons was 70.6 years (range: 57–84 years). Illness onset dates (or dates of serologic diagnoses if illness onset was unknown) ranged from June 20, 2010–October 19, 2010. Seven (88%) were diabetic, and all eight had undergone fingerstick blood glucose testing. All of them had elevated transaminases and four (50%) had jaundice. One person died before Hepatitis B testing could be performed.

As of November 9, 2010, the facility has performed serologic testing on 54 persons, and testing is ongoing. Through the serologic survey, we identified one additional acute case of Hepatitis B infection and one chronically-infected resident in the facility. (Of note, the chronically-infected person is not diabetic and does not undergo any fingerstick procedures.) Of the other 52 persons tested, 20 (38%) were found to be immune to Hepatitis B infection. Of these 20, three (15%) show evidence of past vaccination, while the remaining 17 (85%) show evidence of immunity secondary to past infection.

Analysis of potential exposures

Eighty-seven persons were identified as having resided in the facility since January 1, 2010. Twenty persons were excluded from our analysis due to immunity to Hepatitis B. Twenty-six persons were excluded because we were unable to determine their Hepatitis B status either because they refused testing, died before being tested, or were discharged from the facility and unable to be reached for testing.

Our cohort analysis included 42 (48%) of the 87 current and former residents identified. This included eight persons who met our definition of acute Hepatitis B infection and 34 persons who were susceptible to infection.

Among the 42 persons whose charts we reviewed, 55% were male, 69% were white non-Hispanic, and 69% were diabetic. Median age was 75.5 years (interquartile range: 57–83). Thirty-eight percent of the residents whose charts we reviewed had undergone some type of fingerstick diagnostic procedure.

Among the eight residents with acute infection, two pairs were roommates. Residents of three adjacent rooms became ill during the outbreak. At least two residents on each of the three hallways in the facility became ill.

All eight persons with acute Hepatitis B had undergone fingerstick blood glucose monitoring (FSBGM) in the ALF. The relative risk of contracting acute Hepatitis B among those exposed to FSBGM was therefore undefined (50% attack rate among those exposed to FSBGM vs. 0% among those unexposed). Persons with diabetes had 15 times the risk of contracting acute Hepatitis B as compared to non-diabetics (54% vs. 15%, 95% CI: 2.1–110.2). Having visited a primary care physician during the exposure period was also associated with acute infection, although the cases had different primary care providers. Our analysis did not reveal any other significant risk factors for illness; additional risk factor and underlying condition data are listed in Table I.

To further evaluate the association between diabetes and acute Hepatitis B infection, we conducted an additional analysis which accounted for differences in the number of months spent in the facility by diabetic and nondiabetic residents during the likely exposure period. In this analysis, there were approximately 0.1 acute infections per month spent in the facility among diabetic residents and approximately 0.005 acute infections per month among nondiabetic residents, for a relative risk of 26 (95% CI: 3.2–213.1).

Conclusions

Our investigation suggests that person-to-person transmission of Hepatitis B occurred in the ALF, most likely as a result of unsafe blood glucose monitoring practices. The risk of becoming ill with acute Hepatitis B was 15 times higher among persons who were diabetic than among those who were not, and all of those who became ill underwent blood glucose monitoring. Other risk factors associated with diabetes, such as wound care and podiatry, were not statistically significant during our analysis. These findings, in addition to our observations of blood glucose monitoring practices, strongly implicate blood glucose monitoring as the most likely method of transmission during this outbreak.

Based on our investigation, it is not possible to determine how illness entered the facility in the first place. All of the residents with acute Hepatitis B in this outbreak were ambulatory to some degree, and the facility is open to family members and other outside visitors. Because high-risk behaviors such as sexual activity or injection drug use were not well-documented in the facility records, we are unable to evaluate these potential exposures for most residents. It is also possible that the virus was first introduced by a resident who was a chronic carrier of Hepatitis B but was deceased or discharged before this investigation began. Although transmission from staff to residents was considered, this appeared unlikely based on finding that drugs of abuse were not present in the facility and the types of medical supplies used for resident care presented limited opportunities for intentional misuse.

Also of note, we were unable to classify several current and former residents. If a large number of these residents had hepatitis and differed significantly from those included in our analysis, it could affect our analysis of potential risk factors. However, this appears unlikely since none of the residents who could not be classified had clinical evidence of acute hepatitis.

Interestingly, a large proportion of persons in the facility (38%) were noted to be immune to Hepatitis B secondary to past infection. Because we are unable to determine when these persons were infected, we cannot determine whether their infections were related to this outbreak. The attack rate could therefore be much higher and our risk ratios could differ significantly from what is calculated here.

Recommendations

The recommendations below were made to the facility during the course of the investigation:

Hepatitis identification and management

1. All current residents and former residents who have lived in the GlenCare Mount Olive facility since January 1, 2010 should be notified of the potential exposure and encouraged to seek testing for Hepatitis B virus (HBV) infection.
2. All current residents should be tested for HBV infection with the following tests:
 - a. Hepatitis B surface antigen (HBsAg). This is a marker of active infection.
 - i. Those who have a positive HBsAg test should also be tested for Hepatitis B core IgM antibody (HBcIgM), a marker of acute/recent infection.
 - b. Hepatitis B surface antibody (HBsAb). This is a marker of immunity/protection.
 - c. Hepatitis B total core antibody (HBcAb). This is a marker of exposure to HBV.
3. All residents who have been tested should be notified of their infection status. Those with acute or chronic infection should be referred to a physician for evaluation and monitoring. Please notify any former residents that if they are tested, they should notify the Wayne County Health Department with the results.
4. All residents who are found to be HBV susceptible at the time of the initial screening should be offered vaccination with a combined Hepatitis A/Hepatitis B vaccine (three dose series with dose at 0, 1, and 6 months). Hepatitis B single antigen vaccine is acceptable if the combined vaccine is not available.
5. All residents who are found to be HBV susceptible at the time of the initial screening should be retested in 2–4 months (testing again for HBsAg, HBsAb, and HBcAb as outlined above with testing of HBcIgM if HBsAg is positive) to identify those who might have been infected but not detectable by serologic tests at the time of the initial screening.
6. All residents who are found to be HBV susceptible at the time of the initial screening should be monitored for clinical evidence of acute Hepatitis for the next six months.
7. Instruct facilities accepting discharged residents in the next six months to monitor for clinical evidence of acute Hepatitis.

Blood Glucose Monitoring

1. Assign separate glucometers to individual residents. Do not use a glucometer for more than one resident.
2. If at all possible, consider storing glucometers in a secure area within the resident's room to avoid accidental use on other residents.
3. Glucometers should be cleaned and disinfected after each use, even if there is no visible blood, following the manufacturer's directions. Use an EPA-registered disinfectant effective against HBV, HCV and HIV.
4. Never reuse needles, syringes, or lancets.
5. Strongly consider using single-use lancets that permanently retract upon puncture. Reusable lancing devices have been associated with transmission of blood-borne pathogens.
6. Dispose of single-use fingerstick devices at the point of use in an approved sharps container.
7. If reusable lancing devices must be used, restrict use to individual patients. Clean and disinfect them after each use, even if there is no visible blood, following the manufacturer's directions. Use an EPA-registered disinfectant effective against HBV, HCV and HIV.
8. Wear gloves during blood glucose monitoring procedures. Change gloves between patient contacts. Change gloves that have touched potentially blood-contaminated objects or finger-stick wounds before touching clean surfaces. Perform hand hygiene each time after removing gloves.
9. Review indications for finger-stick glucose measurements with staff, especially for patients who are not diabetic, to identify any potentially unnecessary procedures.

Hand Hygiene

1. Wear gloves during any procedure that involves potential exposure to blood or body fluids. Change gloves between patient contacts. Change gloves that have touched potentially blood-contaminated objects or wounds before touching clean surfaces.

2. Remove and discard gloves in appropriate receptacles after every procedure that involves potential exposure to blood or body fluids.
3. Perform hand hygiene (i.e., hand washing with soap and water or use of an alcohol-based hand rub) immediately after removal of gloves and before touching other medical supplies intended for use on other residents.

Medications and Vials

1. Use single-use or single-dose vials whenever possible.
2. If multi-dose vials must be used (e.g. insulin), they should be assigned to individual patients and labeled appropriately with the patient's name and the date the vial was opened. Storing insulin vials in individual bags clearly labeled with the patient's name may reduce the possibility of medication errors or cross-contamination.

General infection control and education

1. One on-site staff member should be designated to coordinate all infection control activities. These activities include: ensuring that all staff members are trained in the principles of infection control and the practices required by the facility's infection control policy; requiring and monitoring compliance with the policy; and updating the policy as needed to prevent transmission of HIV, Hepatitis B, Hepatitis C and other bloodborne pathogens. This designated staff member must complete a course in infection control approved by the North Carolina Department of Health and Human Services, in accordance with NC Administrative Code 10A NCAC 41A .0206.
2. The above-mentioned infection control policy should include:
 - A procedure for employees to follow in the case of a needlestick or other exposure to blood or body fluids
 - Manufacturer's guidelines for how to clean and disinfect multiple use lancing devices and glucometers, how to store them, and how often to clean and disinfect these items
 - Instructions on where to discard items contaminated with blood or body fluids and how they should otherwise be handled; and
 - Directions to notify the local health department and to perform an internal investigation if a resident develops a new infection with a blood-borne pathogen (Hepatitis B virus, Hepatitis C virus, or HIV) during their stay at the facility to ensure that all infection control practices are being followed.
3. Health care workers who have exudative lesions or weeping dermatitis shall refrain from handling patient care equipment and devices used in performing invasive procedures and from all direct patient care that involves the potential for contact of the patient, equipment, or devices with the lesion or dermatitis until the condition resolves.
4. All equipment used to puncture skin, mucous membranes, or other tissues must be disposed in an appropriate manner after use or sterilized prior to reuse. Needles, syringes, and other equipment intended for single use should not be reused.
5. Sharps disposal containers should be available in all locations where sharps use is anticipated.

Vaccination of staff

1. All staff with direct patient care responsibilities should receive a full Hepatitis B vaccination series if previously unvaccinated. Post vaccination titers should be checked one or two months after vaccination, and documented.

Follow-Up

As a result of the serologic screening, we recommended that 27 persons be vaccinated. All were vaccinated during October 26, 2010–October 30, 2010. We also recommended retesting five persons during the week of November 8, 2010 who appeared to be in the window period of an infection and recommended retesting 30 persons 3 months from the time of initial testing to ensure that they are not currently in their incubation period. As of November 12, approximately five facility employees have started the vaccination series.

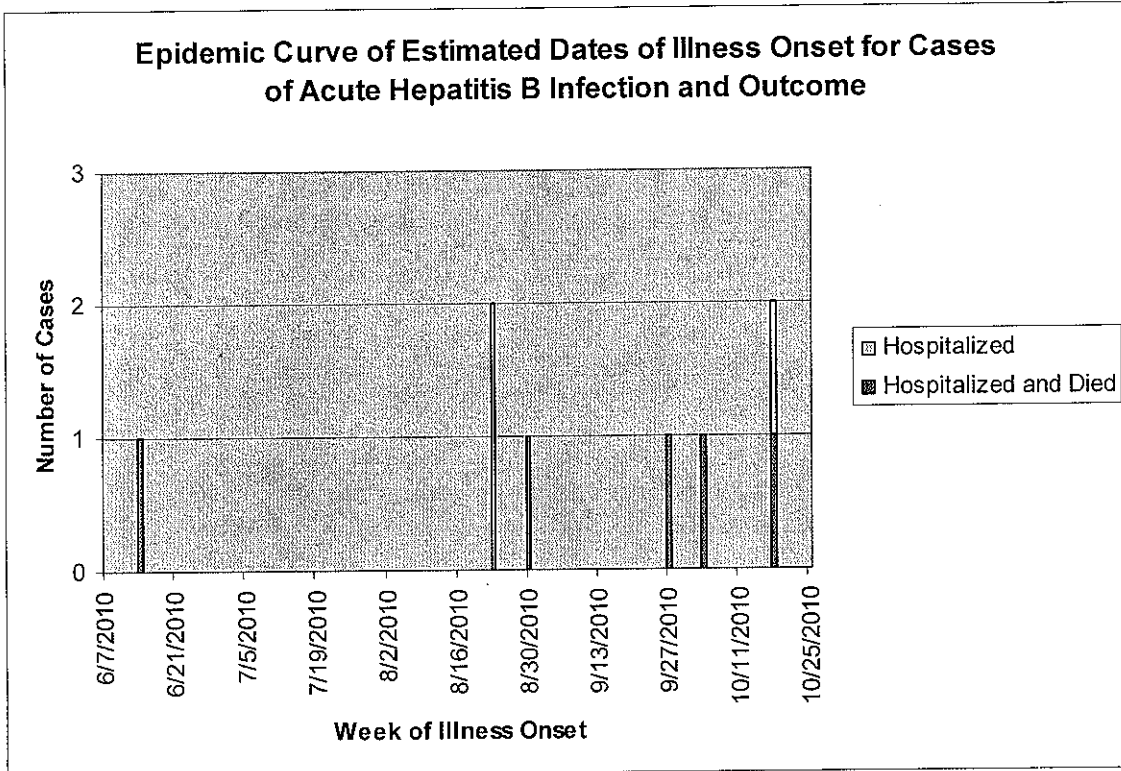


Figure 1. Epidemic Curve of Facility Residents Meeting Definition of Acute Illness

Table I. Relative risks for Exposures among All Facility Residents (n=42)

Exposure	Exposed			Not Exposed			Attack Rate	III	Attack Rate	Total	Not III	Total	Attack Rate	Relative risk	95 % CI
	III	Not III	Total	III	Not III	Total									
Chronic medical conditions															
Diabetes mellitus	7	6	13	1	27	28	53.9		3.6	15.1	2.1-110.2				
Hypertension	8	21	29	0	13	13	27.6		0	undef	undef				
Renal insufficiency	2	5	7	4	24	28	28.6		14.3	2.0	0.5-8.8				
Depression	4	11	15	2	20	22	26.7		9.1	2.9	0.6-14				
CHF	2	3	5	4	27	31	40		12.9	3.1	0.8-12.7				
Hyperlipidemia	3	12	15	3	17	20	20		15	1.3	0.3-5.7				
OA	3	10	13	3	21	24	23.1		12.5	1.8	0.4-7.9				
CAD	4	5	9	3	24	27	44.4		11.1	4.0	1.1-14.6				
Other	7	33	40	0	1	1	17.5		0	undef	undef				
Ambulatory	8	29	37	0	5	5	21.6		0	undef	undef				
Any fingerstick	8	8	16	0	26	26	50		0	undef	undef				
Blood transfusion	0	1	1	8	32	40	0		20	0	0				
Phlebotomy	4	22	26	4	12	16	15.4		25	0.6	0.2-2.1				
Devices															
Peripheral catheter	0	2	2	8	30	38	0		21.1	0	0				
Central catheter	0	2	2	8	30	38	0		21.1	0	0				
PCP visit	7	14	21	0	5	5	33.3		0	undef	undef				
Podiatry	2	7	9	5	16	21	22.2		23.8	0.9	0.2-3.9				
Wound care	1	7	8	6	24	30	12.5		20	0.6	0.1-4.5				
Dental care	2	5	7	5	22	27	28.6		18.5	1.5	0.4-6.3				
PT/OT	2	5	7	5	24	29	28.6		17.2	1.7	0.4-6.8				
Ophthalmology	3	5	8	5	23	28	37.5		17.9	2.1	0.6-2.9				
Home health	4	9	13	4	20	24	30.8		16.7	1.8	0.6-6.2				
Hospitalization/ED visit	6	16	22	2	16	18	27.3		11.1	2.5	0.6-10.7				
Surgery/Invasive procedure	2	4	6	6	27	33	33.3		18.2	1.8	0.5-7.0				
Injectable medications	4	13	17	4	19	23	23.5		17.5	1.4	0.4-4.7				

No one in the cohort underwent hemodialysis, had a PICC line or ostomy. Sexual activity and other social history and vaccine history were unreliable.