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Acute Hepatitis B Outbreaks in Two Skilled Nursing Facilities and Possible Sources of Transmission — North Carolina, 2009–2010

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Abstract

Objectives—Acute hepatitis B virus (HBV) infections have been reported in long-term care facilities (LTCFs) primarily associated with infection control breaks during assisted blood glucose monitoring. We investigated HBV outbreaks that occurred in separate skilled nursing facilities (SNFs) to determine factors associated with transmission.

Design—Outbreak investigation with case-control studies.

Setting—Two SNFs (Facility A and B) in Durham, North Carolina during 2009–2010.

Patients—Residents with acute HBV infection and controls randomly selected from HBV-susceptible residents during the outbreak period.

Methods—After initial cases were identified, screening was offered to all residents with repeat testing three months later for HBV-susceptible residents. Molecular testing was performed to assess viral relatedness. Infection control practices were observed. Case-control studies were conducted to evaluate associations between exposures and acute HBV infection in each facility.

Results—Six acute HBV cases were identified in each SNF. Viral phylogenetic analysis revealed a high degree of HBV relatedness within, but not between, facilities. No evaluated exposures were significantly associated with acute HBV infection in Facility A; those associated with infection in

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Ethical Considerations: The investigation followed the guidelines of the U.S. Department of Health and Human Services regarding protection of human subjects.

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Facility B (all odds ratios>20) included injections, hospital or emergency room visits, and daily blood glucose monitoring. Observations revealed absence of trained infection control staff at Facility A, and suboptimal hand hygiene practices during blood glucose monitoring and insulin injections at Facility B.

Conclusions—These outbreaks underscore the vulnerability of LTCF residents to acute HBV infection, the importance of surveillance and prompt investigation of incident cases, and the need for improved infection control education to prevent transmission.

Despite the decline in incidence of acute hepatitis B virus (HBV) infection in the United States since the 1980s,[1] increasing reports of HBV outbreaks among persons residing in assisted living and skilled nursing facilities (SNFs) have generated growing concern and resulted in Advisory Committee on Immunization Practice recommendations for HBV vaccination of diabetics.[2] During 1996–2011, 30 outbreaks of acute HBV infection were reported among residents of US long-term care facilities (LTCFs).[3–4] Of these, 25 (86%) were associated with breaks in infection control practices during assisted blood glucose monitoring, one during podiatry care, and one with behavioral risks.[3] These outbreaks require considerable expenditure of financial and personnel resources at the LTCFs and health departments conducting the investigations. More importantly, they resulted in preventable illnesses and deaths among residents. The risk of progression to chronic infection from acute HBV infection is higher among the elderly than younger adults,[5] and mortality rates as high as 75% have been reported in recent LTCF outbreaks.[6]

During October 2009 – June 2010, we identified two outbreaks of acute HBV infection through investigation of individual cases among residents of separate SNFs in Durham, North Carolina. We conducted epidemiologic investigations of these outbreaks to identify additional cases and potential modes of HBV transmission.

METHODS

Investigations were conducted by the Durham County Department of Public Health (DCoDPH), the North Carolina Department of Health and Human Services (NC DHHS), and the Centers for Disease Control and Prevention (CDC). All aspects of the investigation were considered part of a public health response and determined to be exempt from Institutional Review Board approval.

Case Finding

The first acute HBV case in Facility A was reported to DCoDPH in July 2009. Three additional cases among residents of the same SNF were reported during October – December, 2009. In January 2010, HBV screening was performed on all consenting residents with unknown HBV status. Serologic testing was repeated in April 2010 for HBV susceptible residents to identify new infections that might have been undetectable during initial screening.[7]

The first acute HBV case in Facility B was reported to DCoDPH in April 2010. After additional cases were identified by targeted screening of residents with shared exposures,

HBV screening of all consenting residents with unknown HBV status was performed in June 2010 with repeat testing in September 2010.

Laboratory Methods

All specimens were initially tested for HBsAg (Bio-Rad GS HBsAg EIA 3.0), anti-HBs, and anti-HBc (Bio-Rad MONOLISA™) qualitatively at the NC State Laboratory of Public Health using BioRad Evolis analyzers. Specimens that tested positive for total anti-HBc were tested for IgM anti-HBc (Bio-Rad MONOLISA™). Serum samples from residents identified with acute or chronic HBV infection were sent to CDC's Viral Hepatitis Reference Laboratory for additional qualitative testing for anti-HBc (VITROS® aHBc), IgM anti-HBc (VITROS® HBcM), and HBsAg (VITROS® HBsAg). These specimens were also tested quantitatively for anti-HBs (VITROS® anti-HBs) using automated VITROS® Immunodiagnostic system (Ortho-Clinical Diagnostics, Inc., Rochester, NY).

Serum samples with a positive HBsAg result were sent to the CDC's Molecular Epidemiology and Bioinformatics Laboratory for HBV sequence analysis. HBV DNA was extracted from 100 μL of serum. The entire HBV genome was amplified by nested polymerase chain reaction, and the sequences were compared to determine the genetic relatedness of HBsAg positive samples as previously described.[8] In specimens with viral titers insufficient to obtain full HBV genome, a 425 base-pair fragment of the HBV "S" gene region was sequenced to determine HBV genotype.

Case-Control Studies

Separate case-control studies were performed in each facility to evaluate exposures associated with acute HBV infection. We defined HBV infection and HBV susceptibility status based on laboratory criteria (Table 1). Facility medical records and laboratory data were reviewed for each case to determine the most likely date of disease onset. Disease onset date was defined as either the earliest date on which HBsAg or IgM anti-HBc was detected, or on which jaundice or alanine aminotransferase levels >2 times the upper limit of normal was detected in the absence of another etiology. For each acute HBV case, four controls were randomly selected among residents of the same facility who were HBV-susceptible and had resided in the facility throughout the case's exposure period, defined as six months to six weeks prior to disease onset date.[6] Facility medical records were reviewed for each control to evaluate potential source exposures during the case's exposure period.

Medical record abstractions were performed using the same data collection form in both facilities. This form included demographic information, clinical history, room assignments, and potential healthcare exposures including blood glucose monitoring, podiatry care, hospitalizations or emergency room (ER) visits, outpatient invasive procedures, dental care, wound care, and phlebotomy.

Data Analysis

Basic demographic characteristics and exposures with the potential for HBV transmission were compared among cases and controls using two-tailed Wilcoxon signed rank sum tests for continuous variables and Mantel-Haenzel chi-square tests for dichotomous variables.

Fisher's exact test was used to assess variables with small numbers of observations (< 5). Healthcare exposures were only included in the analyses if they occurred during the exposure period for cases or the corresponding time period for controls. To assess whether the frequency of certain healthcare exposures was associated with acute HBV infection, we collected data on the number of days of blood glucose monitoring, injections, wound care, and phlebotomy for cases and controls. All analyses were performed in SAS version 9.2 (SAS Institute, Cary, NC).

Infection Control Observations

On-site services were observed at each SNF to assess for potential percutaneous exposures, including podiatry, ophthalmology, phlebotomy, dentistry, physical and occupational therapy, and beautician and barber services. Blood glucose monitoring, insulin preparation and administration, and wound care procedures were observed on multiple days and at different times. Information regarding infection control procedures was gathered through staff interviews. Infection control policy manuals, needlestick injury protocols, and staff HBV vaccination status were reviewed.

RESULTS

Case Finding and Clinical Characteristics

Initial and repeat serologic HBV screening results are summarized for each SNF in Figure 1. Six cases with acute HBV infection and one case with previously known chronic hepatitis B infection were identified from each facility, for a total of 12 acute HBV cases (6%) among 209 residents tested for HBV. No additional acute or chronic HBV infections were identified during repeat screening. Serologic testing at CDC confirmed the status of 11 acute HBV-infected cases; one patient died before a specimen could be obtained for CDC testing.

Three cases had jaundice with or without other symptoms at Facility A; the other three cases at Facility A and all six cases at Facility B had no symptoms attributable to acute HBV infection. Three patients from Facility A died within two months of diagnosis; one death was attributed to HBV infection. No deaths attributable to HBV infection were identified among patients from Facility B. One of three surviving patients at Facility A and three of six patients at Facility B developed chronic HBV infection.

Molecular Analysis

Phylogenetic testing of the specimens from Facility A revealed that virus from all acute cases and the resident with chronic infection were HBV genotype A2, with an identical 425bp segment of the 'S' gene. A full HBV genome could be isolated from four acute cases and the patient with chronic infection; all five specimens shared a high degree of nucleotide identity (99.7–100%) (Figure 2). Sequences from two cases who had been roommates had 100% genetic identity across the full genome. Phylogenetic testing of Facility B specimens revealed that HBV from all six acute cases were genotype A2 and shared a high degree of genetic identity (99.9–100%) across the full genome (Figure 2). A comparison of HBV phylogenetic sequences between the two clusters indicated a low degree of genetic identity, suggesting that the clusters were not related.

Case-Control Study, Facility A

There were no significant differences in age, gender, race, or co-morbid conditions between cases and controls in Facility A (Table 2). Five cases and 11 controls had chronic renal insufficiency; however, none were receiving dialysis.

There were no statistically significant differences in healthcare exposures between cases and controls (Table 2). Among three cases who had been exposed to assisted blood glucose monitoring, one received daily fingersticks, another received twice weekly fingersticks, and a third case received blood glucose monitoring only once during the exposure period. A review of hospital and ER visits showed that none of the cases or the resident with chronic infection had visits to the same facility during overlapping time periods.

Cases had more frequent exposure to onsite phlebotomy, with a median of 15 days during the exposure period (range 3–49) compared to 4 days (range 0–42) for controls (Table 3); however, this difference was not statistically significant (p=0.08). There were no significant differences between cases and controls with respect to median days of wound care, blood glucose monitoring, or onsite injections during the exposure period.

Case-Control Study, Facility B

There were no significant differences in age, gender, race, or co-morbid conditions between cases and controls in Facility B (Table 1). Only two of the cases and seven of the controls had been diagnosed with diabetes. One case and four controls had renal insufficiency, but none were on dialysis.

Although there was no exposure shared by all cases, several healthcare exposures were significantly associated with acute HBV infection in Facility B (Table 2). Cases had more frequent exposure to assisted bloodblood glucose monitoring, with four out of six cases receiving daily fingersticks versus only two out of 24 controls. Although having had any exposure to blood glucose monitoring was not significantly associated with acute HBV infection, daily blood glucose monitoring was significantly associated (OR 22.0; 95% CI: 2.4–204.1). Having had a hospital/ER visit also was strongly associated with acute HBV infection (OR 22.0; 95% CI: 2.4–204.1); however, none of the cases or the resident with chronic infection had hospitalizations or ER visits at the same facility during overlapping time periods. In addition to more frequent blood glucose monitoring, cases also had more frequent exposure to phlebotomy and injected medications (including insulin) as compared to controls (P=0.05 and <0.01, respectively) (Table 3).

Assessment of Behavioral Risk Factors

Staff and administrators in both SNFs denied any knowledge of sexual activity, elder abuse or injection drug use among the patients. Case interviews were conducted but were limited in some instances due to dementia. All cases required skilled nursing care and were too debilitated to leave the facility without assistance.

Only two of the cases had resided in the same room at Facility A during the likely exposure period. None of the cases from Facility B had been roommates during their exposure

periods. No other cases shared a room or common bathroom with each other, although sharing of shower rooms was possible.

Infection Control Assessment

Although both facilities had written infection control policies in place, Facility A was not in compliance with a North Carolina administrative code rule requiring that an on-site staff member be designated to direct infection control activities and complete a state-approved infection control course.[9]

Infection control observations revealed that staff members did not consistently perform hand hygiene between patients during blood glucose monitoring and insulin injections at Facility B. Both facilities used single-use, auto-disabling fingerstick devices. Blood glucometers were shared among multiple residents, but were cleaned and disinfected according to manufacturer's instructions after every use. No sharing of insulin or injection supplies was identified.

Staff at Facility A voiced concerns about the infection control practices of the contracted phlebotomy service provider, who was shared by both facilities. Observations and a review of practices by this provider revealed several areas that needed attention including placing used gloves in contact with clean supplies and failing to consistently perform hand hygiene between patients. No lapses in infection control that would have facilitated bloodborne pathogen transmission were witnessed during observations of other services, including wound care, physical therapy, occupational therapy, dentistry, and podiatry.

Hepatitis B Vaccinations

Only twelve residents at each SNF had serologic evidence of previous hepatitis B vaccination (Figure 1). At Facility A, 72% of 104 staff members employed during July 2010 had received hepatitis B vaccination; at Facility B, 65% of 69 staff members who were involved in direct patient care during May 2010 had received hepatitis B vaccination. During the investigation, hepatitis B vaccinations were recommended for previously unvaccinated staff involved in direct patient care, and combined hepatitis A/B vaccinations were provided to susceptible residents at both SNFs after the initial HBV screening.[10]

DISCUSSION

We describe two outbreaks of acute HBV infection in separate SNFs located within the same geographical area during the same time period. In Facility A, we did not find a significant association between acute HBV infection and any healthcare exposures. The second outbreak at Facility B was strongly associated with several exposures including blood glucose monitoring and insulin injections, but there was no single exposure shared by all cases. We found no evidence indicating that the two outbreaks were related and no common modes of transmission were identified between facilities.

Both laboratory and provider reporting of acute HBV cases are essential for viral hepatitis surveillance and early outbreak detection. This outbreak illustrates the challenges in recognizing acute HBV infections among SNF residents, since most cases in the elderly are

asymptomatic[11] and do not meet the national case definition for acute infection requiring signs and symptoms.[12] This report also illustrates an outstanding example of cooperation between local, state, and federal partners, in which prompt recognition and investigation of all incident HBV infections reported among LTCF residents was important for preventing HBV transmission. The CDC has developed recommendations for the investigation of single cases of viral hepatitis infection suspected to be associated with healthcare delivery,[13,14] which may provide a useful framework for health departments in developing an approach to investigations that fits their resources.

Determining whether these two outbreaks were directly linked was a major concern initially, given their close proximity in time and space and the use of shared ancillary service providers. Full-genome viral phylogenetic analysis was important in identifying two distinct clusters likely due to HBV transmission within the facilities, but not between facilities, in contrast to recent outbreaks in other states.[3] HBV genotype A2 is common (about 80% of US isolates)[15] and relatively homogeneous. Genetic homology of < 99.9% may not provide definitive evidence for a direct transmission link in the absence of epidemiologic evidence suggesting such transmission. However, phylogenetic clustering of HBV variants according to facilities, with isolates from two roommate cases at Facility A and five cases at Facility B having 100% genetic identity, suggest that direct transmission within facilities was very likely.

Unlike prior reports of acute HBV outbreaks, which have been primarily observational or retrospective cohort studies, we conducted separate case-control studies in which controls had to have resided in the facility throughout the cases' exposure periods. This method allowed us to conduct chart reviews on a smaller number of residents as compared to a full cohort study, and reduced the possibility for bias introduced by comparing cases and controls who did not share the same healthcare exposures.

While most previous reports have linked HBV outbreaks in LTCFs to one predominant mode of transmission- usually unsafe practices during blood glucose monitoring- our findings suggest that multiple modes of transmission may be involved in these outbreaks. It is also possible that transmission in these facilities occurred through exposures other than those we analyzed. While we did not ascertain HBV status among unvaccinated staff, healthcare worker-to-patient transmission is unlikely as these events have been documented only during certain invasive procedures (e.g. cardiothoracic surgery).[16] No controlled substances for injection administration (e.g. narcotics) were stored at the facilities, so contamination of medication vials or needles/syringes by staff practicing illicit drug use was unlikely. A confidential survey of staff conducted at Facility A and in-person case interviews in both facilities (data not shown) did not identify any behavioral risks for transmission, such as sexual contact between cases and staff members.

Our investigation was subject to several limitations. Interpretation of our data was limited by the small number of acute HBV cases. Also, data were collected primarily from medical records and provider interviews; information obtained from case interviews was limited due to dementia. Our results could have been biased if the assessment of cases' onset dates and exposure periods was incorrect, particularly in Facility B where the majority of cases were

asymptomatic. In absence of symptoms, we defined the disease onset date as the time that testing was performed; therefore, we may have abstracted information on exposures that occurred after the cases had already acquired HBV infection. Finally, it is possible that infection control breaches had been corrected prior to our investigation or were not apparent during our observations. Breaches may be intermittent, particularly if healthcare providers are aware of proper technique but lapse when distracted or busy.[17] Knowledge that an investigation is underway might also lead to immediate changes in unsafe practices.

There have been numerous reports of acute HBV infection outbreaks associated with assisted bloodblood glucose monitoring among residents in assisted living facilities[6,18–22] and SNFs.[18,23] Although the role of blood glucose monitoring in our outbreaks is unclear, hand hygiene was not consistently practiced between residents who had assistedblood glucose monitoring or insulin injections at Facility B, and glucometers were shared between residents at both facilities. Guidance on infection control practices during blood glucose monitoring and insulin administration has been recently updated.[24] The adoption of these preventive measures, along with hepatitis B vaccination of diabetic patients,[2] are critical to reducing the risk of HBV transmission in LTCFs.

These outbreaks underscore the continued vulnerability LTCF residents to HBV and suggest that transmission may occur through multiple modes during a single outbreak. Coordinated efforts between local, state, and federal partners utilizing both traditional and molecular epidemiologic methods may be necessary to fully assess potential healthcare exposures. Improving patient safety in LTCFs will require a multifaceted strategy that incorporates improved recognition and prompt investigation of incident HBV infections among residents, HBV vaccinations for diabetic residents, and improved infection control education for LTCF staff.

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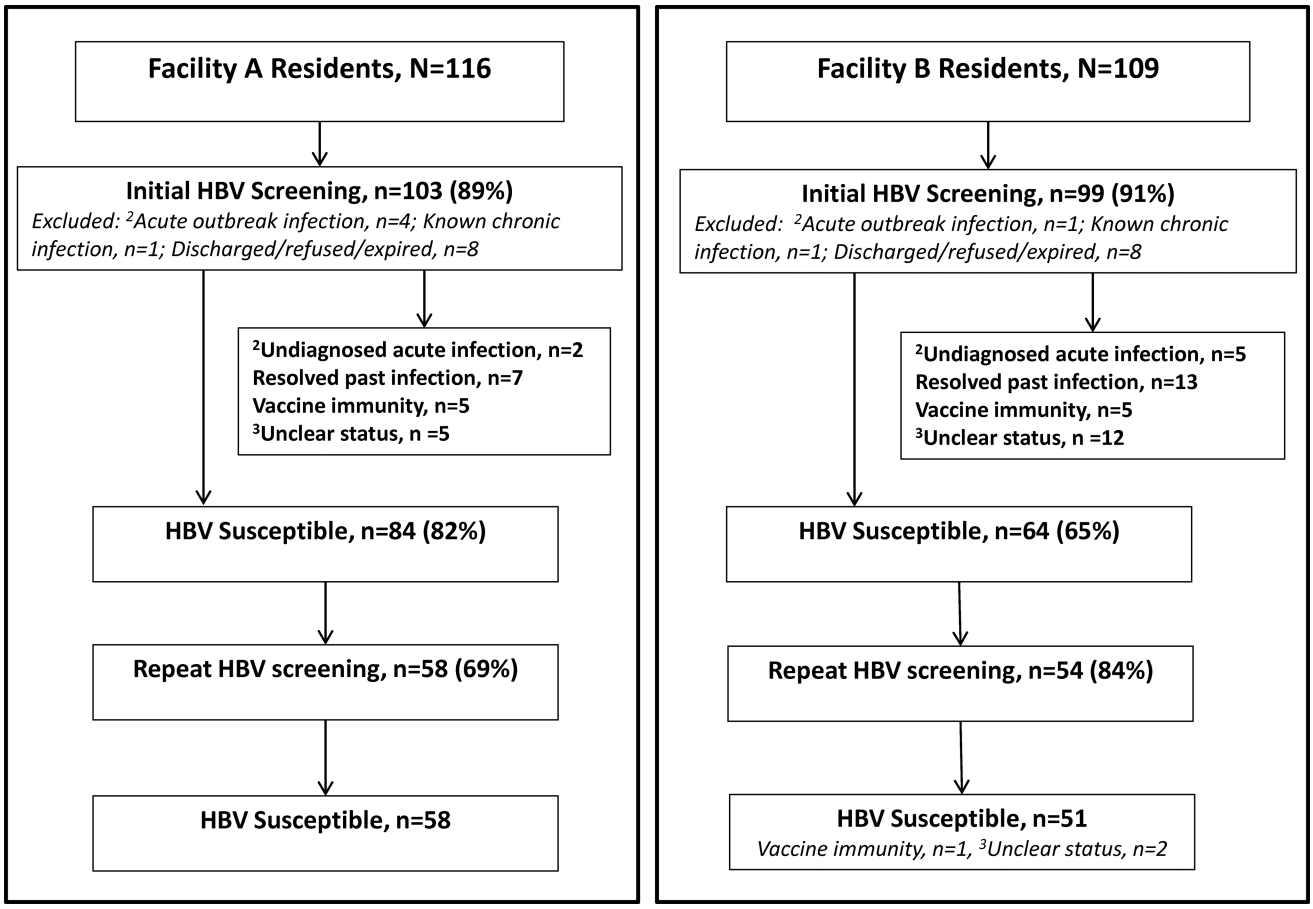

Figure 1. Hepatitis B screening results from Facility A and Facility B.[1]

[1]See Table 1 for definitions,

[2]These patients represented the acute cases of HBV infection detected in each facility during the outbreak investigation.

[3] Seventeen patients from the two facilities had unclear serologic results. Of these, 15 patients had isolated positive anti-HBc with anti-HBs and all other markers negative, 1 had a (+) HBcAb and (+) anti-HBs (without documented vaccination status) and 1 had a (+) anti-HBs only.

Isolated positive core antibody may indicate a false positive result, low-level chronic infection with low level of infectivity, or most commonly in elderly populations past infection with waning immunity.[12]

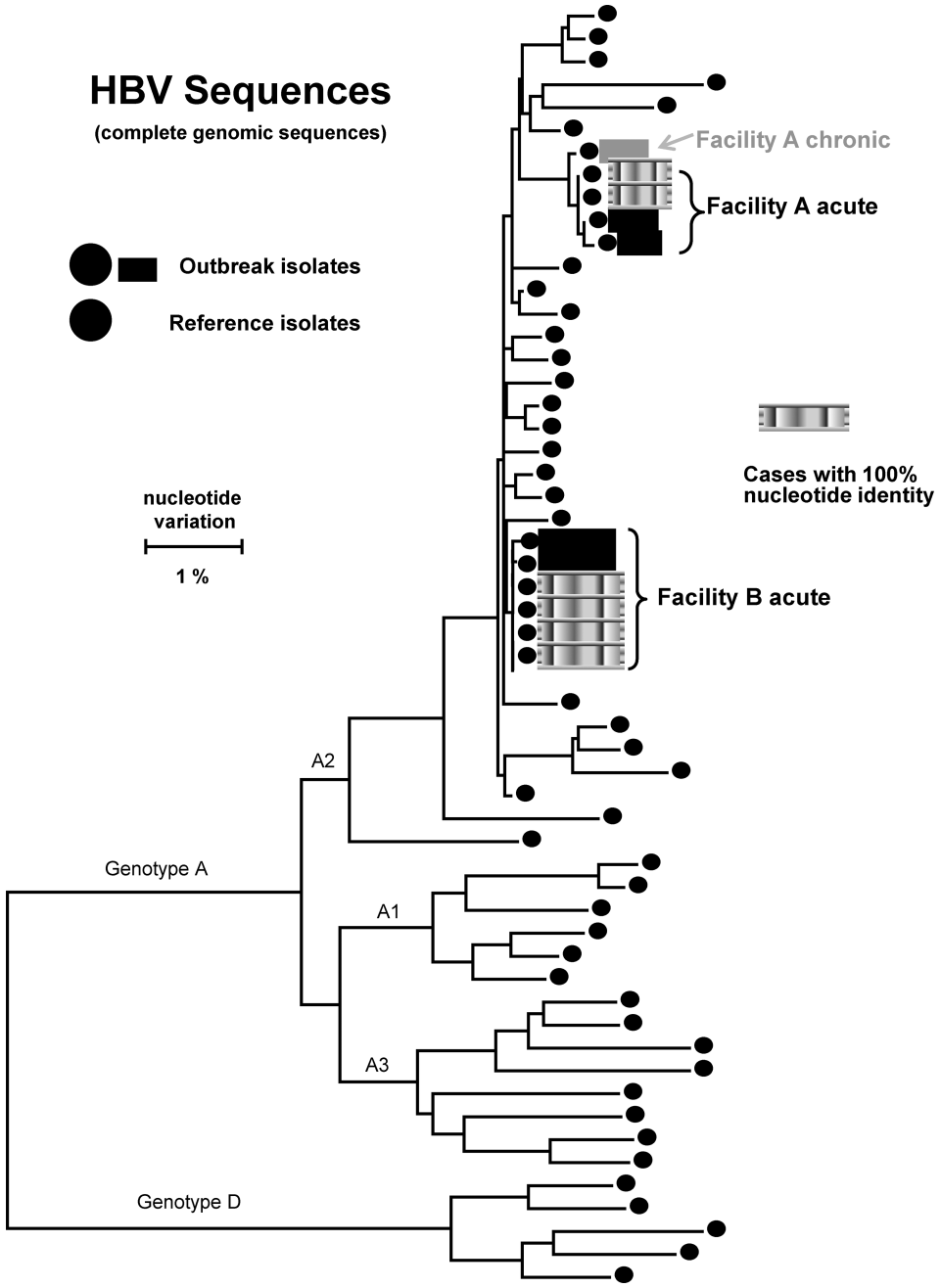

Figure 2. Hepatitis B virus phylogenetic analysis tree

Phylogenetic testing analysis of specimens from Facility A revealed that five acute cases and one resident with chronic infection had HBV genotype A2 with an identical 425bp segment of the 'S' gene. Isolation of the full HBV genome from four of the acute cases and the patient with chronic infection revealed a high degree of nucleotide identity (99.7–100%). From Facility B, phylogenetic testing analysis from all six acute cases also identified HBV genotype A2 and a high degree of genetic identity (99.9–100%) across the full genome.

Table 1

Laboratory criteria for hepatitis B virus case classifications.

Case Classification	Laboratory Criteria			
	HBsAg	Anti-HBc	IgM Anti-HBc	Anti-HBs
Acute hepatitis B infection	(+)	(+)	(+)	(−)
Chronic hepatitis B infection	(+)	(+)	(−)	(−)
Previous hepatitis B infection	(−)	(+)	(−)	(+)
Immunity to hepatitis B infection due to vaccination	(−)	(−)	(−)	(+)
Susceptible to hepatitis B infection	(−)	(−)	(−)	(−)

HBsAg = hepatitis B surface antigen
IgM anti-HBc = IgM antibodies to hepatitis B core antigen
anti-HBc = antibodies to hepatitis B core antigen
anti-HBs = positive hepatitis B antibody

*Very early acute infection may present with positive HBsAg but negative anti-HBc and negative IgM anti-HBc, and subsequent development of anti-HBc.

Table 2

Prevalence of selected exposures among acute hepatitis B cases and control subjects, Facility A and Facility B.

Exposure	Facility A			Facility B		
	Cases (n=6), n (%)	Controls (n=24), n (%)	Odds Ratio** (95% CI)	Cases (n=6), n (%)	Controls (n=24), n (%)	Odds Ratio** (95% CI)
Any assisted blood glucose monitoring	3 (50%)	6 (25%)	2.9 (0.4, 21.1)	4 (67%)	10 (42%)	2.8 (0.4–18.4)
Daily assisted blood glucose monitoring	1 (17%)	5 (21%)	0.8 (0.0, 9.7)	4 (67%)	2 (8%)	22.0 (2.4–204.1)
Any injected medication*	2 (33%)	12 (50%)	0.5 (0.1, 3.4)	6 (100%)	9 (38%)	21.2 (1.1–416.7)
Insulin injection	1 (17%)	4 (17%)	1.0 (0.0, 10.3)	4 (67%)	3 (13%)	14.0 (1.7–112.4)
Dental examination	0	1 (4%)	7.2 (0.1, 377.7)	1 (17%)	11 (46%)	0.2 (0.0–2.3)
Podiatry care	1 (17%)	5 (21%)	0.8 (0.0, 7.4)	1 (17%)	13 (54%)	0.2 (0.0–1.7)
Ophthalmologic care	3 (50%)	7 (29%)	2.4 (0.3, 16.9)	1 (17%)	7 (29%)	0.5 (0.0–4.9)
Phlebotomy	6 (100%)	22 (92%)	2.9 (0.1, 52.1)	6 (100%)	20 (83%)	2.9 (0.1–60.2)
Wound care	4 (67%)	11 (46%)	2.3 (0.3, 20.9)	3 (50%)	4 (17%)	5.0 (0.7–34.4)
Physical or occupational therapy	5 (83%)	17 (71%)	2.0 (0.2, 55.6)	5 (83%)	11 (46%)	5.9 (0.6–58.5)
Outpatient medical visit	2 (33%)	7 (29%)	1.2 (0.1, 8.5)	0 (0%)	4 (17%)	0.4 (0.0–7.4)
Surgical procedure	1 (17%)	0	7.2 (0.1, 377.7)	1 (17%)	2 (8%)	2.2 (0.2–29.3)
Hospital/emergency room visit	3 (50%)	6 (25%)	2.9 (0.4, 21.1)	4 (67%)	2 (8%)	22.0 (2.4–204.1)

* Injected medication included thiamine, vitamin K, lorazepam (not stored at facility), and analgesics (not stored at facility) in addition to insulin injections.

** 0.5 correction added to cells containing zero in order to estimate odds ratios and confidence intervals.

Table 3

Days of exposure to phlebotomy, wound care, assisted blood glucose monitoring and injections among acute hepatitis B cases and control subjects, Facility A and Facility B.

Exposure	Facility A			Facility B		
	Acute HBV cases (n=6)	Control subjects (n=24)	P-value*	Acute HBV cases (n=6)	Control subjects (n=24)	P-value*
Phlebotomy						
Median days exposed (range)	14.5 (3–49)	4 (0–42)	0.08	16 (1–37)	5 (0–40)	0.05
Wound care						
Median days exposed (range)	28 (0–76)	0 (0–142)	0.15	2 (0–140)	0 (0–94)	0.06
Assisted blood glucose monitoring						
Median days exposed (range)	0.5 (0–81)	0 (0–142)	0.39	140 (0–140)	0 (0–140)	0.04
Injections (including insulin)						
Median days exposed (range)	23 (0–31)	54 (0–305)	0.67	140 (0–140)	0 (0–140)	<0.01

*Wilcoxon rank sum exact test (two tailed).