Lancet Device Incident
Investigation Report - 2012

Summary

On May 16, 2012 the Winnipeg Regional Health Authority (WRHA) received notification from the University of Manitoba (U of M) of an incident at a Winnipeg high school (Grades 9 to 12) where up to 80 staff and students had received blood sugar testing on May 4, 2012 using a lancet device that is designed for single-person use only. A public health investigation team was established and a letter was sent to all students, parents, guardians, and school staff informing them of the incident and recommending voluntary testing for specific blood-borne pathogens. A total of 72 members of the school self-identified as having participated in the testing and were offered opportunities to be tested for blood-borne pathogens. Of those, 62 students and staff were tested for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV). Results revealed that over 70% of students were already immune to HBV (through prior vaccination), and no students or staff were currently infected with any of these viruses at baseline testing. Retesting 6 months after baseline testing has been recommended. Other recommendations made as a result of this investigation are outlined at the end of this report. This investigation provided a very good example of the importance of HBV immunization and the need to continue to strive to improve immunization rates in the Winnipeg Health Region (WHR). In addition, efforts to increase awareness of the proper use of lancet devices should continue.

Description of Incident

On May 4, 2012, blood sugar testing was carried out at a Health Fair celebrating Diabetes Awareness Day at a boarding school for Grade 9 to 12 students in the WHR. This testing was performed by a U of M professor appointed in the Department of Pediatrics and Child Health of the Faculty of Medicine. Although the school notified parents and guardians in writing on April 30th of the Health Fair, there was no mention in the notification that blood testing might take place. The blood sugar testing was performed using one of two single patient use lancet devices (OneTouch Ultra 2) on all students and school staff who volunteered to be tested. The lancet devices were purchased for the Health Fair event by the professor at a local pharmacy. The lancets were changed between persons tested and skin was prepped with alcohol for each test. It was reported that there was no visible blood contamination of the devices at any time, and the plastic end cap of the devices was nevertheless wiped with alcohol between each use. It was initially estimated that approximately 70 to 80 children and staff were tested based on 80 lancets missing from the package of 100.

On May 16, 2012, the WRHA Population and Public Health Program (PPH Program) was notified by the U of M of this incident.

Public Health Response

Given that there was no ongoing risk of transmission (as the lancet devices were no longer in use) and given that there was no necessary immediate public health preventive intervention (such as vaccination or preventive medications) to reduce the transmission of a communicable disease, establishment of the PPH investigation team was deferred until after the May long weekend, in order to ensure that once the affected students and staff were notified there would be someone available to answer any questions they might have.

On May 22, 2012 a WRHA PPH investigation team composed of the Medical Officer of Health, the Communicable Diseases Coordinator, and public health nurses (PHNs) from the Healthy Sexuality and Harm Reduction Team was established. The incident and initial response by the U of M was discussed with the Head of the Department of Pediatrics and Child Health at the U of M with agreement that the PPH Program would lead the public health investigation of the incident. The MOH also contacted the school principal to arrange a meeting.

On May 23, 2012, the MOH met with the school principal to discuss the plan for a public health investigation including the need for a notification letter to parents/guardians/staff and the planning of a testing clinic at the school to facilitate access to HBV, HCV, and HIV voluntary testing for anyone wishing to be tested. Mandatory testing was not indicated given the anticipated good HBV immunization rate among students in this school and given the extremely low risk of HCV or HIV transmission.

On May 25, 2012, an emergency meeting of the board of directors of the school was organized by the principal and attended by the MOH and PHN leading the public health response. At this meeting, agreement was obtained to proceed with the planned public health response.

On May 28, 2012, a meeting between the MOH/PHN and all school staff was held to inform them of the incident and outline the public health response summarized in a letter that was to be sent to all staff/students/parents/guardians later that day. A general school assembly followed with the same messages delivered to the student body including time for discussion and questions. Letters to parents/guardians, staff, and students 18 years and over were distributed on May 28th requesting verbal consent to voluntary testing for HBV, HCV, and HIV. During that week, 72 individuals (staff and students combined) came forward to say that the lancet device had been used on them. Of these, 62 (86%) provided informed consent to be tested.

On June 4, 2012, the PPH Program Healthy Sexuality and Harm Reduction team of PHNs held a testing clinic at the school, testing 46 students and 7 staff. A further 3 students and 1 staff revealed that they had already been tested by their family physician during the previous week.

On June 11, 2012, the PHNs returned to the school to provide results to all those who were tested. Four more students and 1 staff came forward and provided consent for

testing during that week. This resulted in a total of 53 students and 9 staff who were tested, with 8 students and/or parents/guardians and 2 staff declining testing.

Results of Baseline Testing

A total of 62 individuals were tested for hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (anti-HBs), hepatitis C antibody (anti-HCV), and HIV antibody. All baseline testing results for these viruses were negative for any evidence of acute or chronic infection. Of the 61 students who were interviewed (53 tested and 8 who declined testing), 43 were fully immunized against hepatitis B (according to the Manitoba Immunization Monitoring System database) or demonstrated protective antibody levels to HBV and were considered immune, with a further 10 having received at least 2 doses of HBV vaccine (8 students had either no record of HBV immunization or had only received one dose). In total, 70.5% of the students were deemed fully immunized and/or immune to HBV. The students who were not fully immunized against HBV were recommended to receive their required doses of HBV vaccine from their Nursing Stations upon return to their home communities.

All staff and students who were tested were also reminded that follow up testing for HCV and HIV is required in 6 months, and HBV testing is required in 6 months only for those who were not deemed immune to HBV at baseline testing.

Six-month Follow-Up Testing

Follow-up testing in November of 2012 was offered to students and staff 6 months after the initial baseline testing. Testing was undertaken for anti-HCV and HIV antibody. In addition, HBsAg and anti-HBs was tested in those individuals who were deemed not to be immune to hepatitis B virus on baseline testing.

A total of 32 individuals (26 students, 6 staff) were tested at the school at the six month follow–up testing period. Five students chose to have follow-up testing elsewhere and an additional 18 students who were no longer enrolled at the school were located and reminded of the need for testing. Several students and staff declined follow-up testing when offered. All those who were tested at the six-month follow up period were negative for acute or chronic HBV, HCV or HIV. In addition, all those with evidence of incomplete immunization for HBV were encouraged to complete an immunization series.

Discussion and Conclusions

Lancet devices are small pen-like tools that hold a spring-loaded disposable lancet, which is a small needle used to pierce the skin to obtain a small drop of blood for blood sugar testing. The devices are simple to use and with minimal training are used by many patients with diabetes who test their own blood sugars on a daily basis. One does not need to be a licensed health care professional to use such a device, but training and certification to use lancet devices is recommended. Most lancet devices are designed for single-person use only, even when the lancet (needle) is disposed after each use. This is because there is a small risk that blood could contaminate the

plastic end cap of the device where the lancet (needle) goes through on its way to piercing the skin. Such blood contamination could result in the transmission of blood-borne infections (such as HBV) as has been recently reported in the USA (*Multiple Outbreaks of Hepatitis B Virus Infection Related to Assisted Monitoring of Blood Glucose Among Residents of Assisted Living Facilities – Virginia, 2009-2011*, published in Morbidity and Mortality Weekly Report (MMWR) 2012;61(19):339-343). There are other types of lancet devices that are designed to be used between different individuals where both the lancet (needle) and the end piece/cap that contains the lancet are disposed after each use.

Although not conclusively proven, the published associations of HBV transmission with the sharing of single-person use lancet devices among individuals suggests that HBV may be spread in this manner. The estimated risk of spreading HBV through the sharing of single-person use lancet devices between individuals (assuming one of them is infected with HBV) is less than 1 in 10,000.

There has never been any published association of HCV or HIV with the sharing of single-person use lancet devices. This is likely due to the fact that both HCV and HIV blood-borne transmission rates are much lower than for HBV. It is therefore estimated that the risk of spreading HCV or HIV through the sharing of single-person use lancet devices between individuals (assuming one of them is infected with HCV or HIV) is extremely low, in the range of less than 1 in a million.

It is therefore reassuring that HBV vaccination rates and confirmation of immunity via the presence of anti-HBs antibodies were very good in this cohort of students, which differs somewhat from other schools where HBV vaccination rates are below 60%. The fact that all those tested showed no evidence of active HBV infection also reduces the probability of HBV transmission to virtually zero. This logic also holds true for HCV and HIV for which no evidence of infection was found at baseline testing of 86% of the cohort exposed to the lancet device.

This is not the first such inadvertent misuse of lancet devices in the WHR. In 2004, 2 primary care clinics discovered the misuse by health care professionals of single-person lancet devices between patients. This similarly led to large investigations requiring the testing of many patients for HBV, HCV and HIV. Although no transmission of blood-borne viruses was documented at that time, significant resources went into completing those investigations. In addition, at that time Manitoba Health sent out informative fact sheets and warnings for healthcare providers to be on the lookout for misuse of single-person use lancet devices. It is disconcerting that such incidents continue to be reported from several jurisdictions as recently reported in the MMWR. Although the instructions found in the Blood Glucose Monitoring System User Guide state “never to share a lancet or a lancet device with anyone”, this message is only found in the fine print on page 8 of a 28-page document and the device itself has no visible warning labels identifying them as “single-person use only”.

Thankfully, this cohort of students had good HBV immunization rates of over 70%, in comparison to inner city schools that have immunization rates as low as less than 60%. Given such good immunization rates and the fact that most of the remaining not fully

immunized students had received 2 doses of HBV vaccine and were partially protected, the risk of HBV transmission was likely rendered to virtually zero. This investigation provided a very good example of the importance of HBV immunization and the need to maintain good immunization rates in Winnipeg Health Region (WHR) schools that are performing well and to improve immunization rates in schools that are not doing so well.

Recommendations

1. It is recommended that the U of M independently investigate and report on this incident, and ensure that policies and procedures are established and/or followed to prevent future recurrences of unauthorized use of lancet devices.

2. It is recommended that the school independently investigate and report on its policies and procedures for notification of students and parents/guardians when hosting or facilitating healthcare activities at school Health Fairs.

3. Manitoba Health will be requested to inform Health Canada and the Public Health Agency of Canada of this incident (as such incidents have repeatedly been reported throughout North America), expressing a concern over the poor visibility of warning messages in the instructions and the absence of such messages on lancet devices that are clearly meant to be single-person use only, and requesting notification of lancet device manufacturers.

4. The WRHA will notify the Institute for Safe Medication Practices (ISMP) to raise awareness among the ISMP network of partners in the province.

5. The WRHA PPH Program will continue with strategies to improve HBV immunization rates in WHR school youth.