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HETA 98-0185
December 2, 1999

Rupali Das, MD, MPH
California Department of Health Services
Occupational Health Branch
1515 Clay St., Suite 1901
Oakland, CA 94612

Dear Dr. Das:

This letter summarizes the health hazard evaluation (HHE) conducted by the National Institute for Occupational Safety and Health (NIOSH) at the Stericycle facility in Loma Linda, CA. The NIOSH investigation was requested by the Occupational Health Branch of the California Department of Health Services (OHBCDH) to investigate the potential for *Mycobacterium tuberculosis* (Mtb) and bloodborne pathogen (hepatitis B, hepatitis C and the human immunodeficiency virus) transmission to employees from their exposure to medical waste.

I. BACKGROUND

In October, 1998, NIOSH investigators reported the potential for occupational transmission of Mtb and bloodborne pathogens to workers at the Stericycle medical waste processing facility in Morton, Washington.[1] (See also Attachments A and B). Because there was a Stericycle facility in Loma Linda, CA, which operated a waste treatment process similar to the one at the Stericycle facility in Morton, WA, OHBCDH representatives requested the help of NIOSH to evaluate similar types of exposures at the Loma Linda facility.

II. METHODS

NIOSH representatives visited the Stericycle facility in Loma Linda on June 8, 1998. An opening meeting was held with Stericycle employee and management representatives, and representatives from the OHBCDH. A walkthrough of the facility was performed to observe worker activities and operational equipment. However, the facility was not operating on the day of our site visit. According to Stericycle management representatives, this inoperational status was for routine maintenance and remodeling of the facility. Therefore, the walkthrough consisted of looking at the types of equipment present at the facility, and reviewing the plans for remodeling of the facility. We also conducted private medical interviews of employees, reviewed the Occupational Safety and Health Administration (OSHA) 200 Log and Summary of Occupational Injuries and Illnesses (form 200) for the years 1992-1998, and reviewed available medical records for employees who reported occupational injuries or illnesses.

A second visit was planned for August, 1999. However, prior to that visit, NIOSH representatives were informed by Stericycle that the Loma Linda facility would be closed in the near future. Since closure of the facility would result in no further occupational exposure to employees, the second visit was canceled.

III. EVALUATION CRITERIA

Bloodborne Pathogens

Hepatitis B

One of the most infectious of all the known bloodborne pathogens is Hepatitis B Virus (HBV). Among susceptible health-care workers who have had needlestick injuries where the patient has had HBV infection, up to 30 % have developed infection with this virus.[2,3,4,5] Persons infected with HBV as adults have a 2% to 10% chance of becoming chronically infected. Persons chronically infected with HBV are at risk for chronic liver disease (i.e., chronic active hepatitis, cirrhosis, and primary hepatocellular carcinoma) and can infect others. An estimated 100-200 health-care personnel have died annually during the past decade because of the chronic consequences of HBV infection (Centers for Disease Control and Prevention (CDC), unpublished data). A vaccine for HBV is available, and the CDC recommends that workers potentially exposed to blood or blood-contaminated body fluids receive this three-dose vaccine series.[6]

Hepatitis C

Hepatitis C virus (HCV) was identified in 1988 as the primary cause of non-A, non-B hepatitis, and as a major cause of acute and chronic hepatitis worldwide. HCV is most efficiently transmitted by large or repeated percutaneous exposures to blood, such as through the transfusion of blood or blood products from infectious donors and sharing of contaminated needles or other supplies among injection drug users. The risk factors for HCV transmission in the occupational setting are not well-defined.[7,8,9,10] The average incidence of anti-HCV seroconversion after unintentional needle sticks or sharps exposures from an HCV-positive source is 1.8% (range 0% to 7%).[11] During the past decade, the annual number of newly acquired HCV infections has ranged from an estimated 28,000 to 180,000.[12] Of these, an estimated 2-4 % occurred among health care personnel who were occupationally exposed to blood.[13]

At least 85 % of persons with HCV infection become chronically infected, while chronic liver disease with persistently elevated liver enzymes develops in about 67 % of those chronically infected.[11] These extraordinarily high rates of chronic disease and persistent viremia in humans indicate the absence of an effective neutralizing immune response.[14,15] Although postexposure prophylaxis after occupational exposure to HCV has been difficult to assess, immune globulin does not appear to be effective in preventing HCV infection.[15]

Even in the absence of available postexposure prophylaxis, individual worksites should establish policies and procedures for follow-up after percutaneous or mucosal exposure to anti-HCV positive blood to address individual worker's concerns about their risk and outcome. CDC recommends the following post-exposure follow-up of health-care, emergency medical, and public safety workers for HCV infection: for the source, baseline testing for anti-HCV; for the person exposed to an HCV-positive source, baseline and follow-up testing including baseline tests for anti-HCV and ALT activity, and follow-up test for anti-HCV and ALF activity in 4-6 months (testing for HCV RNA may be performed earlier if desired - at 4-6 weeks). Confirmation by supplemental anti-HCV testing of all anti-HCV results reported as positive by EIA.[15] Employers should provide education to employees regarding the prevention of HCV in the occupational setting,[15] and such information should be routinely updated to ensure accuracy.

Human Immunodeficiency Virus (HIV)

The human immunodeficiency virus (HIV) is the cause of acquired immuno-deficiency syndrome (AIDS). Exposures to this virus can occur through needlesticks or cuts from other sharp instruments contaminated with an infected person's blood or through contact of the eye, nose, mouth, or skin with contaminated blood. All exposures of this type should be evaluated by a health-care provider.

Most occupational exposures to HIV do not result in infection. The risk of infection varies with the type of exposure and factors such as the amount of blood involved in the exposure, the amount of virus in the blood, and whether treatment was given after the exposure. Among health care workers, the average risk of HIV infection after a needlestick or cut exposure to HIV-infected blood from freshly contaminated sharps is 0.3 % (about one in 300).[16,17] Stated another way, 99.7 % of needlestick/cut exposures do not lead to infection. The risk of HIV infection after exposure of the eye, nose, or mouth to HIV-infected blood is estimated to be 0.1 % (1 in 1000), and the risk after exposure of the skin to HIV-infected blood is estimated to be less than 0.1 %.[18] There have been no documented cases of HIV transmission due to an exposure involving a small amount of blood on intact skin. The risk may be higher if the skin is damaged or if the contact involves a large area of skin or is prolonged. It is important to note that these data are for exposures that occur from contact with sharp objects or needles that are freshly contaminated. Since HIV (unlike HBV) does not survive long in the general environment, the risk of HIV infection from sharp objects that are not freshly contaminated, such as those present at the Stericycle plant, is probably lower than the risk among health care workers.

Treatment is available after an occupational exposure to HIV. Results from a small number of studies suggest that the use of zidovudine (ZDV) and other antiviral drugs after certain occupational exposures may reduce the chance of HIV infection after exposure.[21] However, a health care provider familiar with the risks of HIV infection and the side effects of the drugs should be consulted to determine whether post-exposure treatment is appropriate.

Tuberculosis (TB)

TB is an infectious disease caused by the bacterium *Mycobacterium tuberculosis* (Mtb). Mtb is carried in small airborne particles. These particles are so small (1-5 microns) that normal air currents keep them airborne and can spread them throughout a room or building. Infection occurs when a person inhales aerosolized Mtb and bacteria become established in the lungs and spread throughout the body.[19] Within 2 to 10 weeks after exposure, an infected person will usually have a positive tuberculin skin test (TST).

Most persons infected with Mtb will never have symptoms from this infection. The bacteria will be contained by the immune system and cause no overt illness, and the individual will not be contagious to others. In a small proportion of infected persons, the initial infection develops into "active" TB disease. With active TB disease, a person usually feels sick with cough, fevers, and weight loss and can infect others. To decrease the chance of developing active disease once infected, the CDC recommends that all persons with positive TSTs be evaluated for preventive drug therapy.[20]

Viability of *Mycobacterium Tuberculosis* (Mtb)

Although Mtb can take up to six weeks to grow in culture and requires fastidious conditions, once established, Mtb is quite hardy. Following the acute phase of rapid growth, older Mtb cultures may enter into a dormant state in which they demonstrate increased survival under adverse conditions, including temperature elevation and anaerobic conditions.[21,22] In fact, gradual depletion of the oxygen content of the cultures can produce reproducible stages of quiescence recognized by specific physiologic changes.[23]

Given gradual oxygen depletion, Mtb can survive in culture media containing 0.06 % oxygen in the dormant state.[26] Both young (0-3 days old) and old (15-35 days old) cultures were resistant to 90 minutes of heating in a 50°C (122°F) water bath. Heating to 53°C (127°F) for 120 minutes resulted in significant death in the younger cultures, but not the older cultures.[23] In an experiment to test the viability of Mtb in heat-fixed sputum smears, slides were prepared from patient sputum samples approximately 5 days old.[24] Using the standard flame technique, 99 % of the slides produced subsequent cultures. After hot plate heating for 120 minutes, 63 % of the slides heated to 65°C (149°F) yielded growth, as did 28 % of the slides heated to 85°C (185°F). Slides stained with phenol-auramine produced no growth. In another experiment, cockroaches were fed fresh heat-fixed sputum smears.[25] Fecal pellets were collected after four weeks and half of these were kept in a screw-capped glass jar in the dark for an additional 8 weeks. All were microscopically positive and produced positive cultures. Thus, not only did the bacilli survive the cockroach digestive process, but also the 8 weeks of dry storage in the fecal pellets.

In an older (1912), but very well documented study, the length of survival of Mtb under a variety of conditions was assessed.[26] This was of considerable interest at the time because the mode of TB transmission was still unknown. The methodology involved inoculation of guinea pigs with Mtb culture samples to confirm viability. Positive endpoints were the development of tuberculosis or a localized lesion that caused tuberculosis when inoculated into a second guinea pig. These were confirmed by culture.

In the initial experiment, it was found that Mtb exposed to sunlight for one minute survived, but Mtb exposed for two minutes was killed. Mtb culture suspension that was allowed to dry on sterile paper slips and subsequently cultured showed growth after four days, but not after eight days. In another phase of the study, an emulsion of cultured Mtb was made. Two hundred-fifty cubic centimeters of this emulsion were poured into a moistened, porous, 6-inch high flowerpot. The flowerpot was placed into a gallon sized glass jar which was filled with continually running water kept at a level of about three inches. After varying lengths of time, the flowerpot was scraped, the water spun, and the sediment made into guinea pig inoculum. After 307 days, viable Mtb was found, but not after 441 days. A guinea pig that died with disseminated TB infection was kept in running water in a similar manner. Tissue samples taken up to 321 days later contained viable bacilli. Sputum from a patient infected with Mtb was kept in the same fashion and contained viable Mtb for up to 187 days. In the final experiments, an emulsion of cultured Mtb was mixed into butter. Samples were kept at 20°C, 4°C, and -10°C. Viable Mtb were detected after 274 days of storage in each.

Guidelines for Controlling Occupational Transmission of TB

Criteria for evaluating the risk of TB transmission specifically in medical waste treatment facilities do not exist. However, the following basic approaches have been recommended to reduce the risk of TB transmission in health care settings: (1) prevent infectious particles from entering the air by providing rapid identification, isolation, and treatment of persons with active TB; (2) reduce the number of infectious particles entering the air by containing them at their source and by providing directional airflow and dilution ventilation; (3) use appropriate respiratory protection in areas where there is still a risk of exposure to Mtb; and (4) use TST screening to identify persons with tuberculous infection, and provide preventive treatment (or treatment of active TB) when appropriate.

Screening and Early Identification of Persons Infected with TB

The identification of individuals with Mtb infection is commonly accomplished using the TST. The TST involves injecting a small amount of purified protein from Mtb into the upper layers of the skin. If the person being tested has previously been infected with Mtb, his or her immune system usually reacts against this protein. The reaction causes a reddish swelling at the site of the injection (a "positive" result if this swelling is of a certain size). If the person has not been infected previously, there will be little or no reaction (a "negative" result). There are standardized guidelines for interpreting the TST results.[23,27] The injection does not contain live Mtb bacteria and cannot cause Mtb infection; furthermore, repeated skin testing will not cause a positive test in a person who has not been infected with TB.

If a person with a previously negative skin test reacts positively to a TST, the test should be followed by a chest x-ray to determine whether active TB has developed. Prophylactic (preventive) drug therapy is generally prescribed upon diagnosis to prevent the infection from advancing to active TB disease.[23] Some strains of Mtb are resistant to the most commonly used drugs, necessitating the use of other pharmaceuticals.[28] In addition to identifying individuals for whom treatment is appropriate, routine TST screening can also serve as a surveillance tool to identify areas or occupations for which there may be an increased risk of TB transmission.

It should be noted that even if the drug treatment successfully kills the Mtb and prevents the development of active disease, the patient will continue to test positive on later TB skin testing because his or her immune system will "remember" the TB protein and react to the skin test.

IV. RESULTS

During the walkthrough of the Loma Linda facility, we confirmed that the processing machinery and personal protective equipment were similar to what was used at the Stericycle facility in Morton, Washington.

Eleven (55%) of the 20 current employees participated in the private medical interviews. Those employees whose primary language was Spanish were interviewed with the help of a NIOSH Spanish-speaking translator. Some interviewed employees reported that some needlestick and other sharp object injuries, as well as splashes to eyes, nose, mouth, or skin were not always reported to company representatives. Some employees did not seem to understand the seriousness of the health risks from these exposures and the need for prompt follow-up.

Review of OSHA 200 logs from 1992 through 1998 showed 10 needlestick injuries. There were inconsistencies in follow-up of these needlestick injuries in that not all workers received the 3-dose hepatitis vaccine series that is recommended by the CDC, and not all workers were counseled about the potential for hepatitis or HIV transmission from these injuries.

V. CONCLUSIONS AND RECOMMENDATIONS

Based on the fact that (1) Mtb is known to be a very hardy organism which can survive for long periods of time under a variety of adverse conditions, (2) that the Loma Linda Stericycle facility processed infectious waste (including cultures of Mtb) which is not deactivated until the waste had been shredded and compacted, and (3) that Stericycle uses a process that creates the potential for aerosolization of the products contained in the waste (including Mtb), NIOSH concludes that employees could have been exposed to pathogens potentially present in the medical waste.

The following recommendations should be implemented for Loma Linda facility employees at the time of closure of the facility.

1. Employees should receive education about tuberculosis and bloodborne pathogen risk in both Spanish and English. A qualified health professional should provide them with information about signs and symptoms of tuberculosis and hepatitis, and they should be told to seek medical evaluation if they develop these signs or symptoms.

2. If an employee has sustained a needlestick or other puncture injury, he or she should receive follow-up medical counseling and treatment until this is complete; i.e., the employee should receive (or complete) their full series of hepatitis vaccine and tests for HIV as determined by the employee's medical provider in accordance with current guidelines.[5,6,11]

3. All employees should receive an "exit" tuberculin skin test and should receive adequate follow-up if their test is positive.[19]

This letter constitutes the final report of our investigation. For the purpose of informing affected employees, copies of this report should be posted by the employer in a prominent place accessible to the employees for a period of 30 calendar days. If the facility is closed at the time of receipt of this letter, all employees should be mailed a copy of this letter and its attachments. If Stericycle is unable to provide this letter to all of the Loma Linda employees, the California State Health Department should ensure that employees receive a copy of this letter.

If you have any further questions, please do not hesitate to call either Yvonne Boudreau at 303-236-6032, or Angela Weber at 404-639-0444.

Sincerely,

Yvonne Boudreau, MD, MSPH
NIOSH, Denver Field Office

Angela M. Weber, MS
NIOSH, Atlanta Field Office

cc: Joel Wilson, VP, Domestic Operations, Stericycle, Inc.
Robert McMillan, MD, Stericycle, Inc.

bcc: Chief, HETAB/NIOSH
Rick Hartle, HETAB/NIOSH
Angela Weber, HETAB/NIOSH
File, HETA 98-0185 (closeout)

VI. REFERENCES

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Attachment A: Results, in English, of NIOSH investigation at Stericycle facility in Morton, WA.

Tuberculosis Outbreak at Stericycle, Inc.

What NIOSH Did

Looked at work practices to find ways employees could be exposed to bacteria from the medical waste.

Examined air flow through the whole plant and checked to see if air was leaking out of the containment room.

Checked to see if the bacteria in the medical waste was getting into the air.

Reviewed the medical records of workers who had TB (tuberculosis).

What NIOSH Found

The state health department found that at least one worker had gotten TB from exposure to the medical waste.

Bacteria in the medical waste was getting into the air of the containment room.

When the shredders become clogged, it could cause bacteria to get into the air in the main plant.

When bins were emptied, contaminated air could come out of the in-feed chute.

The airline respirator in the press room was not made up of parts approved by NIOSH.

When process lines become clogged, workers remove needles and other sharp objects with their hands.

When workers were stuck by needles or other sharp objects, they did not always tell their supervisor.

Workers did not get the right training about cleaning up spills and using protective equipment.

Some of the process equipment was not maintained well.

Some of the company policies were not followed.

What Stericycle Can Do

Stericycle should make their laboratory customers decontaminate waste before sending it to Stericycle.

Stericycle should work on ways to stop clogs in the process line. In the meantime, employees should be protected when clogs happen.

Workers should be better trained on how to do their jobs, and how to use protective equipment.

Process equipment should be checked and maintained regularly.

Workers should be instructed to see a doctor quickly if they get stuck by a needle or other sharp object.

Stericycle should arrange and pay for yearly TB tests for workers.

What Stericycle Employees Can Do

Ask about the right way to wear protective clothing and equipment.

Tell your supervisor quickly about any problems with the process.

If you get stuck by a needle or other sharp object, tell your supervisor and quickly see a doctor or nurse.

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

What To Do For More Information:
We encourage you to read the full report. If you would like a copy, either ask your health and safety representative to make you a copy or call 1-513-841-4382 and ask for HETA Report # 98-0027-2709

National Institute for Occupational Safety and Health
NIOSH

Attachment B: Results, in Spanish, of NIOSH investigation at Stericycle facility in Morton, WA.

Brote de Tuberculosis en Stericycle, Inc.

Lo que hizo NIOSH

Examinó las prácticas de trabajo para determinar la forma en que los empleados podrían haber estado expuestos a las bacterias de los desechos médicos.

Examinó el flujo de aire a través de toda la planta e hizo una inspección para ver si había un escape de aire fuera del cuarto de contención.

Realizó una inspección para ver si las bacterias en los desechos médicos estaban contaminando el aire.

Revisó los registros médicos de trabajadores que habían sufrido de TB (tuberculosis).

Lo que encontró NIOSH

El Departamento de Salud del Estado encontró que por lo menos uno de los trabajadores había contraído TB como resultado de la exposición a los desechos médicos.

Las bacterias en los desechos médicos estaban contaminando el aire del cuarto de contención.

Cuando las trituradoras se obstruían, las bacterias contaminaban el aire de la planta principal.

Cuando se vaciaban los recipientes, el aire contaminado podía salir a través del conducto de alimentación.

El respirador de la línea de aire en el cuarto de la prensa no estaba fabricado con piezas aprobadas por NIOSH.

Cuando ocurrían obstrucciones en las líneas de proceso, los trabajadores tenían que retirar agujas y otros objetos afilados con sus propias manos.

Cuando los trabajadores se lesionaban con agujas o con otros objetos afilados, no informaban siempre a sus supervisores.

Los trabajadores no habían recibido el adiestramiento correcto sobre la forma de limpiar derrames y usar los equipos de protección.

Algunos de los equipos de proceso no tenían mantenimiento adecuado.

Algunas de los lineamientos de la compañía no habían sido cumplidos.

Lo que Stericycle puede hacer

Stericycle debe requerir a sus clientes la descontaminación de los desechos de laboratorio antes de que envíen estos a Stericycle.

Stericycle debe hacer todos los esfuerzos posibles para evitar obstrucciones en la línea de proceso. Mientras tanto, los empleados deben ser protegidos adecuadamente cuando ocurra una obstrucción.

Los trabajadores deben recibir un mejor adiestramiento sobre la forma de hacer su trabajo y la forma de usar el equipo de protección.

Los equipos de proceso se deben inspeccionar y mantener a intervalos regulares.

Los trabajadores deben recibir instrucciones para que vayan a ver a un médico rápidamente si sufren una punción con una aguja o se lastiman con algún objeto afilado.

Stericycle debe contratar y pagar la realización de pruebas anuales de TB para sus trabajadores.

Lo que los empleados de Stericycle pueden hacer

Pregunte sobre la forma correcta de usar la ropa y el equipo de protección.

Informe inmediatamente a su supervisor si ocurre algún problema con el proceso.

Si se punza con una aguja a se corta con algún objeto afilado, informe a su supervisor y vaya ràpidamente a ver un doctor o una enfermera.

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CDC
CENTROSPARA EL CONTROL Y PREVENCI Ó N DE ENFERMEDADES

Lo que debe hacer para obtener más información:
Le exhortamos a leer el informe completo. Si desea recibir una copia, pídale a su representante de salud y seguridad que le haga una copia o llame al teléfono 1-513-841-4382 y solicite el informe HETA #98-0027-2709.

National Institute for Occupational Safety and Health
NIOSH