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Protect Patients from Improper Use of Single-dose/Single-use Vials

Dawn Terashita, MD, MPH

In May, the Centers for Disease Control and Prevention (CDC) restated its position on the use of single-dose/single-use vials and addressed inaccuracies being disseminated to health care providers.

The guidelines require that medications labeled as “single dose” or “single use” be used for only one patient. This practice protects patients from life-threatening infections that occur when medications become contaminated from unsafe use. The priority is protecting patients from harm.

The Los Angeles County Department of Public Health routinely investigates infectious disease outbreaks involving single-dose/single-use vials being used for multiple patients. These outbreaks cause extensive harm to patients, and they are associated with significant health care and legal expenses. Therefore, the CDC and the LA County

Department of Public Health continue to strongly support current policies regarding single-dose/single-use vials.

Concerns have been raised about whether single-use medications contribute to drug shortages and increased medical costs to health care providers. There may be drug shortages; however, such shortages are a result of manufacturing, shipping, and other issues (www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm275051.htm). It is imperative that drug shortages and drug waste concerns are dealt with appropriately and do not lead to unsafe medical practices that impose increased disease risk on patients.

Dedicating a single-dose/single-use vial to one patient is a critical element of proper infection control. The CDC continues to see outbreaks in health care settings associated with single-use/single-use medications where providers

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Basic Safe Injection Practice Messages

Vials labeled by the manufacturer as “single dose” or “single use” should only be used for a single patient. These medications typically lack antimicrobial preservatives and can become contaminated and serve as a source of infection when they are used inappropriately.

- Safe injection practices include one-time use of needles and syringes and limiting sharing of medication vials.
- Vials labeled as “single dose” or “single use” should not be used on multiple patients.
- Use aseptic technique when preparing and administering injections.
- Injection safety is every provider’s responsibility.
- The CDC is aware of at least 19 outbreaks associated with single-dose/single-use medications.
- Health care providers should consult with pharmacy professionals and USP 797 standards when there is a need to subdivide contents of single-dose/single-use vials.



Frequently Asked Questions Single-Dose/Single-Use Vials in Clinical Settings

What is a single-dose or single-use vial?

A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that is meant for use in a single patient for a single case/procedure/injection. Single-dose or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative.

Can single-dose or single-use vials be used for more than one patient?

No. Vials that are labeled as single-dose or single-use should be used for a single patient and single case/procedure/injection. There have been multiple outbreaks resulting from health care personnel using single-dose or single-use vials for multiple patients.

Even if a single-dose or single-use vial appears to contain multiple doses or contains more medication than is needed for a single patient, that vial should not be used for more than one patient nor stored for future use on the same patient.

To prevent unnecessary waste or the temptation to use contents from single-dose or single-use vials for more than one patient, clinicians and purchasing personnel should select the smallest vial necessary for their needs when making treatment and purchasing decisions.

Is it acceptable to combine (pool) leftover medication from single-dose or single-use vials?

No. Do not combine (pool) leftover contents of single-dose or single-use vials or store single-dose or single-use vials for later use. Single-dose or single-use vials are intended for use on a single patient for a single case/procedure. There have been outbreaks resulting from pooling of contents of single-dose or single-use vials and/or storage of contents for future use.

When should single-dose or single-use vials be discarded?

Medication vials should always be discarded whenever sterility is compromised or questionable. In addition, the following recommendations are made for handling of single-dose or single-use vials:

- If a single-dose or single-use vial has been opened or accessed (e.g., needle-punctured), the vial should be discarded according to the time the manufacturer specifies for the opened vial or at the end of the case/procedure for which it is being used, whichever comes first. It should not be stored for future use.
- If a single-dose or single-use vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date.



incorrectly thought they were preparing and administering injections safely.

In the last 5 years there have been at least 26 outbreaks due to unsafe injection practices. These outbreaks resulted in more than 95,000 patients being referred for testing after potential exposure to infectious diseases; 73% (n=19) of these outbreaks involved the use of single-dose/single-use medications for more than one patient. All of the outbreaks associated with improper use of single-dose/single-use medications occurred in outpatient settings, with pain remediation clinics (n=8, 42%) representing the most common type of facility

Poor infection control practices are common; in one study published in the *Journal of the American Medical Association*, the CDC and Centers for Medicare and Medicaid Services colleagues reported that two-thirds of the outpatient facilities inspected had lapses in basic infection control practices. 

Note: This article is adapted from the CDC's Position Statement: "Protect Patients Against Preventable Harm from Improper Use of Single-dose/Single-use Vials."

Dawn Terashita, MD, MPH, is a medical epidemiologist, Acute Communicable Disease Control, Los Angeles County Department of Public Health.

Resources

CDC Statement

Protect Patients Against Preventable Harm from Improper Use of Single-dose/Single-use Vials
<http://www.cdc.gov/injectionsafety/CDCposition-SingleUseVial.html>

CDC Injection Safety

www.cdc.gov/injectionsafety

CDC Outbreaks and Patient Notifications in Outpatient Settings

<http://www.cdc.gov/HAI/settings/outpatient/outbreaks-patient-notifications.html>

LA County Department of Public Health

Identifying Unknown Risks of Bloodborne Pathogen Transmission to Patients

<https://admin.publichealth.lacounty.gov/wwwfiles/ph/media/media/rx2011apr.pdf>

LA County Department of Public Health

Lessons of Recent Healthcare-Associated Infections in Outpatient Settings

<https://admin.publichealth.lacounty.gov/wwwfiles/ph/media/media/rxmar10.pdf>

UPCOMING TRAININGS

Immunization Training Resources for Clinicians

The Los Angeles County Department of Public Health Immunization Program, the California Department of Public Health, the CDC and other entities offer a variety of web-based and in-person immunization training programs for clinicians and staff. Some programs offer CMEs.

Visit www.publichealth.lacounty.gov/ip/trainconf.htm

Immunization Skills Training for Medical Assistants

The Immunization Skills Institute is a 4-hour course that trains medical assistants on safe, effective, and caring immunization skills.

UPCOMING COURSES

- June 27, 2012: Pacoima Family Source Center, Noon-4 pm
- July 18, 2012: Torrance Health Center, Noon-4 pm
- August 23, 2012: Los Angeles County Department of Public Health, Commerce, Noon-4 pm
- September 19, 2012: Palmdale Primary Care, 10 am-2 pm
- October 24, 2012: Curtis Tucker Health Center, Inglewood, Noon-4 pm
- November 21, 2012: Citrus Valley Medical Center, West Covina, Noon-4 pm
- December 19, 2012: Pacoima Family Source Center, Noon-4 pm

To register, visit www.publichealth.lacounty.gov/ip, or call (213) 351-7800

Lithium Button Batteries Pose Increasing Health Risk to Children

By James M. DeCarli, MPH, MPA, MCHES

As battery-operated devices increasingly permeate daily life, so does the risk of injury among children swallowing the coin-sized lithium batteries used to run them. Common items such as children's talking books, watches, car key fobs, remote controls, bathroom scales, hearing aids, flameless candles, and greeting cards are a growing health threat to infants and toddlers who can open the battery compartments, pull out the batteries, and ingest them.

When a battery is ingested, the saliva triggers an electrical current that can result in a chemical burn. This can severely injure the esophagus or trachea in as little as 2 hours. Once the burn begins, damage can continue even after the battery is removed. These injuries may result in multiple surgeries and feeding and breathing tubes, or in fatalities.

In many cases, parents are unaware that the child has swallowed a battery. Children can still breathe and may not be choking. Because the symptoms, such as coughing and discomfort, are similar to those of other childhood illnesses, such as a cold or the flu, the problem can be difficult to identify. In an X-ray, for example, the battery can be mistaken for a coin.

When a battery is ingested, the saliva triggers an electrical current that can result in a chemical burn.

Incidence

More than 4 times as many cases where children have been seriously hurt or have died have been reported to U.S. poison control centers during 2006-2010 compared to 2001-2005. In 2010 alone, there were more than 3,500 swallowing cases (an average of 10 per day) of all sizes

and types of button batteries. The most serious cases are associated with 20-mm diameter batteries, about the size of a nickel, because they can easily become lodged in a small child's throat (Figure 1).

What Physicians Can Do

Physicians, especially those working in urgent or emergency care situations, need to be suspicious of battery ingestion when children present with coughing and discomfort.

To reduce the risk of button battery ingestion by infants and toddlers, physicians can share basic safety tips with parents and caregivers (see Box).

Additional educational and awareness information from the "The Battery Controlled" campaign can be downloaded at www.publichealth.lacounty.gov/ivpp.

Prevention through Education

Because of the growing frequency of severe swallowing incidents, SAFE KIDS USA has partnered with "The Battery Controlled"—a new, nationwide effort to raise awareness. The national partnership also works directly with electronics designers and manufacturers to discuss ways they can help address this problem. 

James M. DeCarli, MPH, MPA, MCHES, is a research analyst, Injury and Violence Prevention Program, Los Angeles County Department of Public Health.



Figure 1. Lithium coin-sized battery lodged in a child's throat.

Safety Tips for Parents and Caregivers

- Keep button batteries and devices that use them out of the reach of children if the battery compartments are not secure. (Note: Some parents have secured devices with strong tape.)
- If a child swallows a battery, go to the emergency room immediately. Do not let the child eat or drink until an X-ray determines if a battery has been ingested. Do not induce vomiting.
- Talk to older children and others living in the home about the dangers of button-sized batteries and the importance of not leaving devices that use them within reach of infants and toddlers.

Cat Scratch Disease

By Tamerin Scott, DVM

In 2009, a 19-year-old woman presented to a hospital in Los Angeles County with a history of a large (6 cm x 3 cm), tender left inguinal lymph node with surrounding skin erythema, swelling, and fever. The patient owned several pets, including a squirrel, dog, rabbit, and two cats. She was admitted to the hospital. Two weeks prior, the woman had been bitten on the finger by a squirrel, but she denied a history of a recent cat bite or scratch.

Purulent material was drained from the lymph node. Gram stain and cultures of the exudate were both negative. However, serology demonstrated a positive ELISA for the bacterium *Bartonella henselae* (IgG ≥1:1024, IgM=1:20), the agent of cat scratch disease (CSD). The patient was treated with oral ciprofloxacin (500 mg PO BID) for two weeks, with resolution of the fever and groin swelling.

Although this patient denied being injured by a cat, most people with CSD have been bitten or scratched by a cat.

Background

CSD is a feline-associated zoonotic disease. It is not a reportable disease; however, estimates of its incidence range from 0.77-9.3 cases per 100,000 per year, or approximately 24,000 cases of CSD annually in the United States.^{1,3-5} These numbers suggest there are 100-900 cases per year in Los Angeles County.

Domestic cats are the natural reservoir for *Bartonella henselae*, the cause of CSD in humans. The genus *Bartonella* is a group of aerobic, small, intracellular Gram-negative bacilli-shaped bacteria. Ten other species of *Bartonella* are either known or suspected to cause disease in humans, and each has a distinct reservoir species. Knowledge on *Bartonella* species continues to evolve.^{1,2}

The cat flea (*Ctenocephalides felis*) is the major vector for CSD.² Transmission to humans is primarily through contact with flea feces, which can be present on a domestic cat's skin, claws, or mouth.² Most commonly, infection occurs from inoculation of the bacterium into the skin, such as from a cat scratch, bite, or lick.^{1,2,3-5} There are also a few reports of dog-associated disease.^{3,4} While it has not been proven, some suggest that cat fleas may also be able to directly transmit *Bartonella* to humans.³ Although cats are considered the reservoir for CSD, cases have occurred following exposure to squirrels, dogs, goats, crab claws, and barbed wire.³

Roughly 30% of households in the U.S. have a pet cat,⁵ and approximately half of the domestic cats are seropositive for *B. henselae*.^{1,2,5} Most cats are asymptomatic carriers. Cats are believed to become infected with *Bartonella* via exposure to infected fleas.² Young, outdoor, flea-infested cats are most likely to be infected.^{1,2}

Signs and Symptoms

The most common clinical signs of CSD include skin rash, especially near the inoculation site, localized lymphadenopathy, and fever.^{1,3} The cutaneous lesions consist of small, erythematous papules, pustules, macules, vesicles, or ulcers.³ More unusual presentations include hepatosplenic microabscesses and granulomas, osteomyelitis, endocarditis, glomerulonephritis, pneumonia, encephalopathy, or hemolytic anemia.¹ Bacteremia and bacillary angiomatosis may appear in immunocompromised people.³

On average, the incubation period is 3-10 days and, regardless of treatment, symptoms may last for weeks to months.^{1,3}

Diagnosis

Diagnosis of CSD is commonly based on compatible clinical signs, cat and/or flea exposure history, and a positive IgM titer and/or a rising IgG antibody titer. Antibody elevations may last several months. Although most people have no baseline immunity against *Bartonella* spp., some cat owners may have longstanding elevations in antibody levels. Because culturing the organism is often difficult, it is of limited clinical value. PCR testing of aspirates or biopsies from lymph nodes (or other tissues) is the most sensitive diagnostic test, if available.^{1,3,6}

Treatment

The disease is often self-limiting in immunocompetent people and may resolve in 2-4 months.⁶ Treatment is primarily supportive and may include drainage or excision of severely affected lymph nodes.^{1,3} Response to antibiotics is variable. This may be due to the intracellular nature of the organism. Bacillary angiomatosis is the one condition that consistently responds to antibiotics.^{1,3} Azithromycin, rifampin, doxycycline, ciprofloxacin, gentamicin, or trimethoprim-sulfamethoxazole may be effective in humans; however, no treatment regimen is considered standard.^{1,3} Since cats rarely exhibit clinical signs from *B. henselae* infection, they are seldom treated and antibiotics are of limited use. No antibiotic regimen has been proven effective to completely eliminate the infection in cats.²

Clinical Considerations

Zoonotic diseases sometimes present with nonspecific clinical signs. Asking a patient about exposure to animals and vectors, such as fleas, ticks, mosquitoes, and rodents, can provide valuable clues for diagnosis. If a zoonotic disease is diagnosed in a pet owner, in addition to treatment, clinicians should recommend that the patient consult with a veterinarian for treatment and special care of the animal to reduce further infection risk to humans.

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Safe Pet Handling Tips

To help prevent CSD, physicians may share these tips with patients who own or are in the vicinity of cats.

- Avoid “rough play” with cats, especially kittens. This includes any activity that may lead to cat scratches and bites.
- Wash cat bites and scratches immediately and thoroughly with running water and soap.
- Do not allow cats to lick open wounds.
- Control fleas.
- Trim pets’ nails regularly.
- If an infection develops (with pus and pronounced swelling) in the area of a cat scratch or bite, or if there are other symptoms, such as fever, headache, swollen lymph nodes, and fatigue, patients should contact their physician.

More information is available at www.cdc.gov/healthypets/diseases/catscratch.htm.

Special thanks to Glenn E. Mathisen, MD, and Christine Yeramian-Balekian, MD, for the case study and their contributions to this article. 

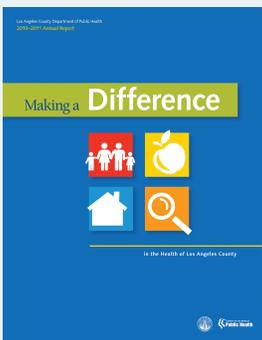
Tamerin Scott, DVM, is a California epidemiologic investigation service fellow, Veterinary Public Health, Los Angeles County Department of Public Health.

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VITAL SIGNS

Health-related news from Los Angeles County departments



Department of Public Health Releases 2010-2011 Annual Report

The Los Angeles County Department of Public Health has just published its 2010-2011 annual report, which features the major achievements of the department’s many programs. The theme of this latest publication is “Making a Difference in the Health of Los Angeles County.”

Through bold, crisp graphics and concise text, this 42-page annual

report tells the story of how the department’s many programs have made a difference in the health of the community. Features include the opening of the Martin Luther King Jr. Center for Public Health, the staging of numerous vaccination clinics and outreach as a result of the pertussis epidemic and a new California law, the creation of the bed bug toolkit, the response to the

Japan radiation release, the operation of the women’s health hotline, the development of the public school food safety inspection program, the launch of the mobile food facilities grading program, and participation on the Rave Task Force.

Additionally, it provides updates on Project RENEW—which seeks to implement policy, systems, and environmental changes to improve nutrition, increase physical activity, and reduce obesity—and Project TRUST—which focuses on reducing smoking prevalence and decreasing exposure to secondhand smoke.

Also highlighted is a bulleted list of additional accomplishments, the department’s priorities, a colorful map of the Area Health Offices, photos and addresses for the department’s 14 health centers, and listings of reports published and awards won during the fiscal year.

The annual report may be viewed and downloaded from the department’s website at www.publichealth.lacounty.gov/docs/annualrpt2011L.pdf. 

Barriers and Unmet Needs for Supportive Services for HIV Patients

By Amy Rock Wohl, MPH, PhD

Persons infected with HIV face many challenges related to mental health, substance abuse, housing, transportation, and employment.¹ Such situations commonly result in missed HIV primary care visits, suboptimal adherence to complex medication regimens, and poor quality of life. A variety of supportive or ancillary services can help HIV-infected patients manage these challenges, leading to better management of their disease. These services include case management, drug and alcohol treatment, housing support, and transportation assistance.

While supportive services for low-income persons with HIV are available through the Ryan White (RW) Care Act and other sources, patients often do not actually receive these services.² Barriers to receiving these services include language difficulties, active drug use, health beliefs, lack of case management, diminished mental status, inadequate housing, stigma, and lack of disclosure of HIV status to members of their social network. Additionally, patients may not be aware that they are eligible for services or may be unable to navigate the care delivery system.

Since there is limited information on the barriers and unmet service needs of HIV-infected patients in Los Angeles County, the Department of Public Health's Division of HIV and STD Programs analyzed data collected in 2007-2009 during face-to-face interviews with 333 adult patients as part of the Medical Monitoring Project (MMP). This project is a national supplemental surveillance system for HIV-infected persons in care, funded by the U.S. Centers for Disease Control and Prevention.

Findings from the Data Analysis

Based on the data collected in 2007-2009, overall, 71% (n=236) of HIV-infected patients reported a need for at least one supportive service. Further, 35% (n=83) of those who needed services reported at least one unmet need. ("Unmet need" was defined as a need for the service in the previous 12 months that was not received.)

Unmet Need for Services

- Gay or bisexual orientation men had greater unmet service needs.
- Unmet needs were greatest for assistance in finding shelter/housing (42%), assistance in finding dental services (30%), social services (23%), homemaker services (21%), and mental health counseling (19%).

Barriers

The main reasons patients did not receive services included lack of information (47%; e.g., do not know where to go or who to call), agency barriers (33%; e.g., system too confusing, wait list too long), and financial/practical barriers (18%; e.g., too expensive, transportation problems).

Need for Services

- After controlling for other socio-demographic factors, African American race/ethnicity and low annual income (<\$10,000) were predictors of at least one service need.

- Services most commonly needed were assistance finding dental services (39%), HIV case management (34%), and mental health counseling (30%).

While the MMP has under-representation of African Americans and young persons aged 18-29 and an over-representation of Latinos and persons with an AIDS diagnosis, the data suggest that HIV-infected patients in LA County have many competing needs and that current service offerings may not be sufficient to address those demands. The 35% of HIV-infected patients in LA County with unmet needs in the past year is similar to a national estimate (27% over 6 months; Katz 2000).

Better dissemination of information on the availability and location, as well as more streamlined delivery of support services for persons with HIV in LA County could improve care. In particular, improving access and reducing barriers for African American, low income, uninsured, and gay and bisexual men is needed.

How Can Physicians Help?

There are several actions primary care physicians and other health care providers can take to help reduce the barriers to support services:

- Recognize the substantial need for supportive services.
- Assess HIV-infected patients' needs for assistance in finding dental services, case management, and mental health counseling.
- Refer patients to available HIV support services. A searchable online database of HIV resources in Los Angeles County by topic area and geographic location is available at www.HIVLA.org.

For more information on services for persons with HIV in LA County, go to www.HIVLA.org. For more information on the MMP project, go to www.cdc.gov/hiv/topics/treatment/mmp/index.htm. 

Amy Rock Wohl, MPH, PhD, is chief epidemiologist, Division of HIV and STD Programs, Los Angeles County Department of Public Health.

Note: This article is adapted from Wohl AR, Carlos J, Tejero J, Dierst-Davies R, Daar E, Khanlou H, Cadden J, Towner W, Frye D. Barriers and Unmet Need for Supportive Services for HIV Patients in Care in Los Angeles County, California. *AIDS Patient Care STDs*. 2011;25(9):525-532.

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Rx for Prevention is published 10 times a year by the Los Angeles County Department of Public Health. If you would like to receive this newsletter by e-mail, go to www.publichealth.lacounty.gov and subscribe to the ListServ for *Rx for Prevention*.

Rx for Prevention

Promoting health through prevention in Los Angeles County

Save the Date

Prevention Symposium: How the New Health Care Paradigm Supports Healthy Aging

June 5, 2012 • 1 pm-5 pm

The Los Angeles County Department of Public Health hosts this symposium, which is designed to engage local medical providers in active discussions with a variety of experts on healthy aging. The session will also highlight evidence-based strategies that protect health and promote positive health outcomes through the integration of clinical and community-based care for elderly patients.

For details, contact
medicalaffairs@ph.lacounty.gov

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Index of Disease Reporting Forms

All case reporting forms from the LA County Department of Public Health are available by telephone or Internet.

Reportable Diseases & Conditions

Confidential Morbidity Report
Morbidity Unit (888) 397-3993
Acute Communicable Disease Control
(213) 240-7941
www.publichealth.lacounty.gov/acd/reports/CMR-H-794.pdf

Sexually Transmitted Disease
Confidential Morbidity Report
(213) 744-3070

www.publichealth.lacounty.gov/std/providers.htm (web page)
www.publichealth.lacounty.gov/std/docs/STD_CMR.pdf (form)

Adult HIV/AIDS Case Report Form

For patients over 13 years of age at time of diagnosis
HIV Epidemiology Program
(213) 351-8196
www.publichealth.lacounty.gov/HIV/hivreporting.htm

Pediatric HIV/AIDS Case Report Form

For patients less than 13 years of age at time of diagnosis

Pediatric AIDS Surveillance Program
(213) 351-8153

Must first call program before reporting
www.publichealth.lacounty.gov/HIV/hivreporting.htm

Tuberculosis Suspects & Cases

Confidential Morbidity Report
Tuberculosis Control (213) 744-6160
www.publichealth.lacounty.gov/tb/forms/cmr.pdf

Lead Reporting

No reporting form. Reports are taken over the phone.
Lead Program (323) 869-7195

Animal Bite Report Form

Veterinary Public Health (877) 747-2243
www.publichealth.lacounty.gov/vet/biteintro.htm

Animal Diseases and Syndrome Report Form

Veterinary Public Health (877) 747-2243
www.publichealth.lacounty.gov/vet/disintro.htm

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