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From the Centers for Disease Control and Prevention

Leads From the Morbidity and Mortality Weekly Report
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Boat-Propeller-Related Injuries—Texas, 1997

MMWR. 1998;47:354-356

Approximately 78 million persons engage in recreational boating annually in the United States.¹ Several types of injury can occur during boating recreation, including drowning, falls, burns, and propeller-related injuries. Injuries from the propeller are typically multiple, deep, parallel lacerations that can result in permanent scarring, substantial blood loss, traumatic or surgical amputation, or death.² Persons sustaining injuries from boat propellers can require long periods of hospitalization, recovery, and rehabilitation. In Texas, the extent of boat-propeller-related injuries is unknown; however, the existence of approximately 600,000 motorboats in the state exposes many Texans to the potential risk for propeller-related injury. To characterize the occurrence of boat-propeller-related injuries in Texas, the Texas Department of Health (TDH) and the Texas Parks and Wildlife Department (TPWD) investigated boat-propeller-related injuries that occurred in four lakes in Texas during May 24–September 1, 1997, the time of year when boating activities are most common. This report summarizes the results of the investigation.

The investigation established active and hospital-based surveillance near four inland lakes in northern, central, and eastern Texas. Thirteen hospitals near the lakes reported to TDH data about patients treated in the emergency department (ED) or admitted to the hospital for a boat-propeller-related injury. The report form included data about age, sex, injury date, types of injuries, and injury circumstances. Bimonthly contact with sentinel hospitals was maintained by telephone. Additional data were reviewed from TPWD's Boating Accident Reports, TDH's Texas Trauma Registry, and newspaper clippings from across the state.

During the study period, TDH identified 13 persons who sustained boat-propeller-related injuries; three of these persons died.

Case Reports

Case 1. In August 1997, a 36-year-old man was operating a motorboat when it turned sharply and ejected him. The boat ran over him, and the propeller cut his head and back. He surfaced and called for help before submerging again. He was not

wearing a personal flotation device. The cause of death was open skull fracture.

Cases 2 and 3. In August 1997, a 12-year-old boy and an 11-year-old girl were passengers on a pontoon boat during a family outing. The two children were dangling their feet over the front end of the boat when the front gate gave way and they fell in the water. The boat ran over the children, and the propeller struck the children. Both children drowned. They were not wearing personal flotation devices.

Summary of Cases

By month, most cases occurred in August (six), followed by June (three), July (three), and May (one). Of the 13 persons identified, nine were males. The mean age was 26 years (range: 6–44 years). Of the 10 nonfatal cases, seven persons sustained lacerations, and four sustained broken bones. The most common circumstances surrounding boat-propeller-related injuries were (1) getting into or out of the boat (five persons), (2) participating in a water activity (e.g., personal watercraft use or skiing) (four), and (3) falling or being thrown from the boat (four).

Five of the injured persons were admitted to the hospital. Hospital information was available for four of these five. The length of hospital stay ranged from 4 to 8 days. Three persons were discharged in good condition, with full recovery expected, and one patient was discharged in a wheelchair and referred for physical therapy and orthopedic surgery follow-up.

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CDC Editorial Note: In 1996, the U.S. Coast Guard reported that 4442 persons were injured and 709 persons died in boating-related incidents in the United States; five (0.7%) of these deaths in-

involved propeller injuries.³ A total of 171 persons were injured in incidents involving a propeller strike.⁴ In previous case reports, fatality rates ranged from 15% in a series of 77 cases to 23% in 223 cases.^{5,6}

In an analytic study of boat-propeller-related injuries that used national, medically verified data, boat propellers were responsible for an estimated 1155 injuries during September 1991–August 1992.² Of these, only 11.5% of injuries required hospitalization. In this report, 50% of the nonfatally injured persons were admitted to the hospital. Because the survey did not include all lakes and waterfronts in Texas, this report probably underestimates the number of boat-propeller-related injuries and deaths.

Most boat-propeller-related injuries result from operator error, and many of them are preventable.³ To prevent injuries that occur through contact with boat propellers, the U.S. Coast Guard recommends that boat operators

- ensure that every passenger is wearing a personal flotation device.
- never operate a boat while under the influence of alcohol or drugs.
- keep the boat clear of marked swimming and diving areas and become familiar with the red and white or blue and white diagonally striped flags signaling that divers are in the area.
- ensure that passengers are properly seated before getting underway.
- never start a boat with the engine in gear.
- designate a passenger who will keep water skier(s) in sight at all times.
- never allow passengers to ride on a seat back, gunwale, or on the transom or bow.

The findings in this report indicate that severe boat-propeller-related injuries may be more common than previously reported, underscoring the need to continue efforts to increase public awareness of safety measures and to improve surveillance for such injuries. Additional recommendations and information about boating safety is available from the Office of Boating Safety, U.S. Coast Guard Infoline; telephone (800) 368-5647, 8 a.m.–4:30 p.m., or the Office of Boating Safety's World Wide Web site, www.uscgboating.org.

References 6 available.

Nosocomial *Ralstonia pickettii* Colonization Associated With Intrinsically Contaminated Saline Solution—Los Angeles, California, 1998

MMWR. 1998;47:285-286

From FEBRUARY 24 through March 15, 1998, a total of 22 respiratory tract cultures from 13 patients at Childrens Hospital Los Angeles (CHLA), California, were culture-positive for *Ralstonia pickettii*. Because of this unusual cluster of colonization, on March 16 the Los Angeles County Department of Health Services initiated an investigation. This report summarizes the findings of the investigation, which resulted in a recall of sterile sodium chloride solution that was contaminated with *R. pickettii*.

A case of *R. pickettii* colonization was defined as isolation of *R. pickettii* from any clinical site in a CHLA patient during February 1-March 27, 1998 (epidemic period). To determine the background rate, CHLA microbiology records were reviewed, and all cultures positive for *R. pickettii* from July 1, 1997, through February 1, 1998 (pre-epidemic period), were identified. Colonized patients' medical records, hospital laboratory culture methods, and respiratory therapy procedures were reviewed. Selected opened and unopened vials of solutions used in respiratory therapy were cultured.

R. pickettii was isolated significantly more frequently from respiratory specimens submitted to the microbiology laboratory during the epidemic than during the pre-epidemic period (36 [7.2%] of 498 compared with three [0.1%] of 2200; relative risk = 53, 95% confidence interval = 16-171). Seventeen patients had isolates meeting the case definition. Colonized patients ranged in age from 4 days to 17 years (median: 2 months), nine (53%) were female, all had been hospitalized in an intensive-care unit, and all had received respiratory therapy.

Of the 17 patients, 16 (94%) were mechanically ventilated, and one had a tracheostomy. The endotracheal suctioning

protocol in this hospital included the pre-suctioning instillation of sterile saline. All colonized patients received endotracheal suctioning after instillation of 0.9% sterile sodium chloride solution (Modudose®, manufactured by Kendall Corporation, Mansfield, Massachusetts*); no infections or deaths were attributed to *R. pickettii*.

Cultures of pooled unopened 3-mL vials of Modudose®, lot number 718315, by the Los Angeles County Public Health Laboratory and the Food and Drug Administration (FDA) grew *R. pickettii*. Patient and product *R. pickettii* isolates had closely related pulsed-field gel electrophoresis patterns. Since March 30, 1998, when the use of this product was discontinued at CHLA, no further *R. pickettii* colonization has been detected.

Modudose® is a sterile 0.9% sodium chloride solution for use in respiratory therapy distributed by Kendall Corporation; Umeco Corporation, San Juan, Puerto Rico; and Westmed Corporation, Tucson, Arizona. On confirmation of Modudose® contamination with *R. pickettii*, the manufacturer voluntarily issued a recall that FDA designated as Class I (defined as having a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death). All lots of the following Modudose® labels and product codes were recalled: Kendall product codes 5251 (3 mL) and 5257 (5 mL), Umeco product code PR5251 (3 mL), and Westmed product code 0454 (1.5 mL).

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CDC Editorial Note: *R. pickettii* is a nonfermentative gram-negative bacillus formerly known as *Pseudomonas pickettii* and *Burkholderia pickettii*.¹ In 1995, a new genus, *Ralstonia*, was proposed on the basis of phenotypic characterization, cellular lipid and fatty acid analyses, phylogenetic analysis of 16S rDNA nucleotide sequences, and rRNA-DNA hybridization. The type species of the new genus is *R. pickettii*.

Since 1972, *R. pickettii* has been detected as a contaminate of several solutions (e.g., saline, deionized water, "sterile" water, and intravenous ranitidine).²⁻⁷ These intrinsically contaminated solutions have been associated with outbreaks of respiratory colonization, bloodstream infections, or catheter-related infections.

Modudose® is filter sterilized. Previous laboratory studies have shown that low numbers (1-10 colony-forming units) of *R. pickettii* inoculated into 0.9% sodium chloride solution can proliferate over a wide range of temperatures (59 F-108 F [15 C-42 C]).⁸ Although the filter size used to terminally sterilize this product is not known (proprietary information), previous studies have shown that *R. pickettii* can pass through a 0.2 µ filter.⁸

Clinicians detecting patients with *R. pickettii* colonization or infection associated with use of Modudose® are encouraged to report these episodes through local and state health departments to CDC's Hospital Infections Program, National Center for Infectious Diseases (telephone [404] 639-6413; fax [404] 639-6459) and to MedWatch, the FDA Medical Products Reporting Program, telephone (800) 332-1088.

References 8 available.

*Use of trade names and commercial sources is for identification only and does not imply endorsement by CDC or the Department of Health and Human Services.

Corneal Decompensation After Intraocular Ophthalmic Surgery—Missouri, 1998

MMWR. 1998;47:306-309

During JANUARY 8-14, 1998, six of eight patients undergoing elective intraocular surgery at a Veterans Affairs medical center (VAMC) in St. Louis, Missouri, developed corneal endothelial decompensation

(corneal edema and opacification) ≤24 hours after surgery. All had been operated on with instruments sterilized by the Abtox Plazlyte system (Abtox, Inc., Chicago, Illinois).¹ This report summarizes the results of the investigation of

these cases and indicates that using the Abtox Plazlyte system to sterilize ophthalmologic surgical equipment led to corneal decompensation.

A case was defined as corneal endothelial decompensation within 24 hours after

surgery in any patient undergoing intraocular ophthalmic surgery during January 5-14, 1998. To ascertain cases and to determine the background rate of corneal decompensation, medical records of patients undergoing ophthalmic surgery during September 1997-January 1998 were reviewed. Six cases were identified. All patients had post-operative findings of persistent low visual acuity, cloudy corneas with corneal endothelial decompensation, and iris paralysis with dilated pupils. All were male, ranged in age from 43 to 85 years (median: 67 years), and had chronic systemic diseases such as coronary artery disease and hypertension. Four patients had cataract extraction and a posterior chamber intraocular lens implant, one had repositioning of a previously implanted anterior chamber intraocular lens that had become dislocated, and one had a trabeculectomy filtering procedure for glaucoma. All had surgery performed in the same operating room. The duration of surgery ranged from 17 minutes to 3.5 hours (median: 1.5 hours). Post-operative vision (range: 20/400 to Hand Motion) was significantly worse than pre-operative vision (range: 20/40-20/200).

When case-patients were compared with six randomly selected controls who underwent surgery during January 5-14 and did not have corneal decompensation, there were no differences in type of ophthalmic surgery performed; medications used before, during, or after surgery; type of local or general anesthesia; surgeons or anesthesiologists; or scrub and circulating nurses.

All instruments used in procedures on the case-patients and controls had undergone Abtox Plazlyte sterilization.¹ In November 1997, the hospital discontinued using ethylene oxide to sterilize instruments used in ophthalmic surgery and began using the Abtox Plazlyte sterilization method.^{1,2} From November 5, 1997, through January 14, 1998, a total of 49 patients had ophthalmic surgery that involved instruments sterilized in the Ab-

tox Plazlyte machine. This method uses a vaporized mixture of peracetic acid, acetic acid, and hydrogen peroxide in combination with low temperature.^{1,2} The vapor is removed with argon, oxygen, and hydrogen gas.^{1,2} The Abtox Plazlyte system has not been cleared by the Food and Drug Administration (FDA) for either safety or performance. An earlier design was cleared by FDA for use only on stainless steel instruments without small hinges are small lumens, but it was never distributed by Abtox. Instruments routinely used in ophthalmic surgery often have small hinges and small lumens. In addition, ophthalmic cannulas (small-lumen instruments) may have nickel- and chrome-plated brass hubs. Brass can be oxidized to yield copper and zinc compounds. Preliminary results using inductively coupled plasma atomic emission spectrometer analyses performed at CDC revealed copper and zinc in water rinsed through cannulas sterilized in the Abtox Plazlyte system. When this rinsate was infused into human and rabbit corneas, corneal decompensation occurred. Further laboratory testing is under way.

On January 14, 1998, the use of the Abtox system was discontinued at the St. Louis VAMC, and ophthalmic instruments were sterilized by steam autoclave. No additional cases have occurred. Abtox is conducting a field correction of the device that includes revised labeling that contraindicates use for ophthalmic instruments.

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CDC Editorial Note: Corneal endothelial decompensation is manifested by opacity of the cornea; it can be a nonspecific response to mechanical or chemical injury.³ Mechanical trauma can result from inci-

dental corneal contact by intraocular instruments during surgery; chemical injury can result from the improper use of intraocular drugs, drugs containing preservatives, or from residues from inadequate rinsing of detergents or other residues from surgical instruments.^{3,4} When severe, corneal endothelial decompensation requires corneal transplantation. Of the estimated 1.4 million cataract surgeries performed in the United States each year,⁵ <0.05% are complicated by corneal endothelial decompensation (A. Lubniewski, Veterans Affairs Medical Center, St. Louis, Missouri; and H. Edelhauser, Emory University, Atlanta, Georgia, personal communication, 1998).

Steam autoclaving is the preferred method for sterilizing surgical instruments. Ethylene oxide sterilization can be used for heat-sensitive items. However, because of the environmentally harmful effects of ethylene oxide, the Environmental Protection Agency encourages health-care providers to reduce the use of this form of sterilization. CDC's National Institute for Occupational Safety and Health considers ethylene oxide to be an occupational carcinogen and reproductive toxin.^{6,7} Since the early 1990s, new types of sterilization using plasma gas technology, such as the Abtox Plazlyte system, have been introduced.^{1,2} The inductively coupled plasma atomic emission data obtained from the CDC laboratory analyses, in part, prompted the FDA to issue a safety alert about the use of the Abtox Plazlyte Sterilization system to sterilize ophthalmic instruments.⁸

To ascertain the extent of this problem, all episodes of corneal decompensation following ophthalmic surgery and information about type of sterilization method used should be reported through state health departments to CDC's Hospital Infections Program, National Center for Infectious Diseases, telephone (404) 639-6413, and to FDA's MedWatch, telephone (800) 332-1088.

References 8 available.

Pregnancy-Related Death Associated With Heparin and Aspirin Treatment for Infertility, 1996

MMWR. 1998;47:368-371

In 1996, a 38-year-old nulliparous woman died from complications of a cerebral hemorrhage. She was approximately 9 weeks' pregnant with triplets at the time of her death. The patient had undergone in vitro fertilization (IVF) and was being treated with anticoagulants (heparin and aspirin) and intravenous immuno-

globulin at the time of her death. This report summarizes the investigation of this case by state and county health departments with assistance from CDC.

The patient had undergone 3 years of infertility therapy, including the use of clomiphene citrate with intrauterine insemination, before beginning IVF in 1995. She had no history of recurrent

pregnancy loss at initiation of IVF. Her infertility workup included a normal hysterosalpingogram; her husband had a normal semen analysis. An autoantibody screen revealed positive antithyroid antibodies (antimicrosomal [76.0 µg/mL] and antithyroglobulin [19.9 µg/mL]; normal: <0.5 µg/mL for both assays). Antiphospholipid antibodies were negative.

In 1985, she had a transphenoidal resection of a pituitary adenoma, with normal prolactin levels thereafter.

She underwent three IVF cycles (ovulation induction, IVF, and embryo transfer). The first ended with a spontaneous abortion at 8 weeks in 1995; the second IVF cycle did not result in a pregnancy; and the third cycle resulted in a pregnancy with triplets in 1996. The patient was treated with estrogen and progesterone during each pregnancy. In addition, with each IVF cycle she received 5000 units heparin subcutaneously twice a day, 81 mg aspirin daily, and intravenous gamma globulin each month. Platelets and prothrombin time (PT) and partial thromboplastin time (PTT) were normal throughout her treatment.

During her ninth week of pregnancy, the patient experienced an acute headache, anxiety, and nausea while visiting a clinic. She was transferred to a general hospital and lost consciousness en route. On admission to the hospital, she underwent immediate radiologic and neurosurgical evaluation. Her platelets and PT and PTT were normal. Neurosurgery identified a hemorrhagic arteriovenous malformation, which was surgically clipped. A postoperative computerized axial tomography (CAT) scan revealed no rebleeding, but her condition worsened. Massive cerebral swelling could not be controlled, and her condition became critical. On her third day of hospitalization, she was pronounced brain-dead, and life support was discontinued the following day.

Reported by: The Executive Council of the Society for Assisted Reproductive Technology, Birmingham, Alabama. Women's Health and Fertility Br and Pregnancy and Infant Health Br, Div of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion; and an EIS officer, CDC.

CDC Editorial Note: CDC, in collaboration with state health departments, maintains a pregnancy-related mortality surveillance system. In 1990, CDC received reports of 417 pregnancy-related deaths in the United States. A pregnancy-related death is one that occurs during or within 1 year of pregnancy and was caused by the pregnancy or its complications. No national surveillance system exists for morbidity associated with infertility therapy.

Treatment of IVF patients with immunotherapy (anticoagulation or immunoglobulin) is aimed at preventing early pregnancy loss. Heparin and aspirin therapy substantially reduces the risk for recurrent spontaneous abortion (more than two pregnancy losses) for women with elevated antiphospholipid antibodies (APA)¹ by modifying the effect of APA on platelet activity, which can cause placental thrombosis and lead to fetal loss.² Heparin and aspirin are widely used in the United States to treat women with recurrent spontaneous

abortion and APA. However, the woman described in this report had no antiphospholipid antibodies and no history of recurrent spontaneous abortion at the initiation of her infertility therapy.

Two recent studies have investigated the role of treating IVF patients with heparin and aspirin to prevent early pregnancy loss. One study documented higher pregnancy rates among women with APA following IVF cycles treated with heparin and aspirin.³ A prospective nonrandomized study did not demonstrate substantially higher pregnancy rates among women with APA undergoing IVF when treated with heparin and aspirin.⁴ A randomized prospective study investigating the efficacy of heparin and aspirin in women undergoing IVF is under way.⁴

Anticoagulation therapy can increase the risk for fatal hemorrhagic stroke.^{5,6} The inhibition of platelet activity with aspirin doses lower than 81 mg daily are well documented.⁷ Although heparin decreases the risk for death from pulmonary embolism in surgical patients, it has been associated with increased postoperative bleeding.⁸ A meta-analysis of randomized clinical trials of low-dose heparin (5000 units/twice daily) to prevent thromboembolism demonstrated an increase in wound hematoma formation associated with heparin treatment.⁹ In surgical patients receiving heparin, the concomitant use of aspirin has been associated with increased risk for serious bleeding.¹⁰

Although data about the risks and benefits of anticoagulation and immunoglobulin therapy in IVF patients are limited, use of this therapy is becoming more common in the United States. Neither aspirin or heparin, alone or in combination, are approved by the Food and Drug Administration (FDA) for this use. In July 1997, a survey of medical practices that provide assisted reproductive technology services indicated that combination therapies of heparin and aspirin for infertility treatment were used at least once by 74% of respondents (Society for Assisted Reproductive Technology, unpublished data, 1997). Of those providing immunotherapy treatment, 94% reported that they considered women who had had recurrent spontaneous abortions as potential candidates for anticoagulation treatment. In addition, 49% considered women who previously had an unsuccessful IVF attempt as potential candidates for immunologic treatment, and 19% considered new IVF patients as potential candidates for therapy.

This case is the first reported pregnancy-related death associated with the use of heparin and aspirin for infertility. The patient died from a cerebral hemorrhage associated with a congenital arteriovenous malformation. Although a causal

relation between anticoagulation and hemorrhage from an arteriovenous malformation cannot be established, pregnant women have the risks for bleeding associated with anti-coagulation therapy found in the general population (cerebrovascular accidents, gastric ulcers, and trauma) in addition to unique hemorrhagic risks such as ectopic pregnancy. Both heparin and aspirin therapy have been associated with increased risks for and severity of bleeding. The patient in this report did not have recurrent spontaneous abortions or a history of antiphospholipid antibodies, widely accepted as indications for heparin and aspirin therapy. Because the potential for bleeding exists with heparin and aspirin, the risks for and benefits of anticoagulation therapy to improve success rates in IVF patients require vigorous scientific investigation before being accepted as routine practice.

The regular monitoring of all pregnancy-related deaths is essential to the reproductive health of women. To further assess the potential health threat of anticoagulation therapy in the treatment of infertility, CDC requests that deaths or severe morbidity associated with the use of heparin and aspirin for the prevention of pregnancy loss be reported to CDC, telephone (770) 488-5372, or to FDA's MEDWATCH, telephone (800) 332-1088. Until the results of further studies are available, women undergoing IVF and their health-care providers should carefully review all information about the risks and benefits of heparin and aspirin therapy.

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