



## Toxic shock studies conducted yet exact cause still unknown

By Beth Headrick

There have been 408 cases of toxic shock syndrome reported to the Center for Disease Control in Atlanta, Ga. Forty deaths have been attributed to the disease, all of them women. Two of those women were from Lincoln.

Dr. Marguerite Neill of the Special Pathogens Branch at CDC, said before January 1980, less than 100 toxic shock syndrome cases had been reported.

Of the cases reported since January, 1980, 95 percent have been women.

In May, the CDC correlated menstruation with the syndrome when findings showed that 95 percent of those cases occurred when women were having their menstrual periods, Neill said. It became apparent that the syndrome affects previously healthy women less than 30 years old during their menstrual periods.

In June, the CDC studies showed that, in some way, tampons contribute to the syndrome.

Although statistics show Rely to be the greatest risk to women, cases of the syndrome have occurred in women using all five of the major brands of tampons.

### Symptoms identified

In tests of 42 women who had the syndrome, 71 percent used Rely, 19 percent used Playtex, 5 percent used Tampax, 2 percent used Kotex and 2 percent used OB.

Now that the symptoms are identified, the earliest reports of cases can be found in 1975, Neill said.

The original study recognizing the syndrome was in 1978 by Dr. James Todd in a British medical journal. The article focused on the syndrome's effects on children.

Since then, the reported cases of the syndrome have increased sharply, with the disease now predominantly occurring in women.

Neill said that it isn't known why there has been a sudden increase of the disease. She said because Rely tampons were introduced on the market in different parts of the country at different times, it could have created a problem in establishing significant statistics earlier. The other factor is that the public's and physician's awareness of the symptoms has increased recently.

The Food and Drug Administration's Bulletin said "the syndrome is characterized in its most severe form by sudden onset of high fever, vomiting, and diarrhea with rapid progression to hypotension and shock. Patients require large volumes of fluid and frequently require intensive care. Urine output is often decreased, and patients may be disoriented or combative. The case-fatality ratio is between 3 percent and 10 percent."

### Still unknown

A bacterial organism called staphylococcus aureus produces the toxin that can develop into the syndrome. Just how tampon use contributes to the bacteria growth is still unknown.

Currently, studies are being done by the FDA, the Center for Disease Control and state health departments to try and answer these questions.

Procter and Gamble, makers of Rely, also is investigating causes of the syndrome, said Marjorie Bradford, public relations spokesperson for the corporation.

Rely announced on Sept. 22 that sales of their product would be suspended. By Oct. 13, virtually all Rely tampons were removed from the market, she said.

On Oct. 6, Procter and Gamble started a four-week series of announcements involving 600 television stations, 350 radio stations and 1,200 newspapers warning women to stop using Rely and to get a refund for any unused Rely tampons they have.

Both product lines of Rely, super and regular tampons, have been called off the market. One theory suggests that the super absorbency Rely tampon increased the risk because it is often left in the body longer, allowing the growth of the toxin. Another theory is that the synthetic materials used in the super absorbency tampons are adding to the problem.

Bradford said the tampon is made of polyester sponges with cellulose material for absorbency. The whole tampon is enclosed in a polyester overwrap and the string is made from polyester.

### Theories suggested

The cellulose has been used for years in other products, such as surgical sutures, she said.

Other theories suggest that the tampons' bacterial organism is carried by the fingers when the tampon is inserted. Another suggestion is that the tampon provides a favorable environment for the toxin regardless of how it is introduced into the system, or that the use of tampons may traumatize the vaginal mucosa, causing an imbalance and allowing the bacteria to grow.

Neill said the Surgeon General generally has been misquoted. She said he does not recommend women stop using tampons.

Women should be aware of the symptoms, she said. If a woman is concerned, she could alternate between the use of tampons and pads or change the tampon more often.

Dr. Harlan Papenfuss, the coroner's physician to Lancaster County who performed an autopsy on the two Lincoln women who died said the majority of fatal cases die within 24 hours of diagnosis.

Papenfuss said he agrees that the super absorbency tampons left inside the body all day provide a way for the toxin to grow if the bacteria already has colonized. He also recommended changing tampons every three or four hours.

The FDA is developing a Federal Register proposal to require warnings of the connection between toxic shock syndrome and tampon use be put on all packages.

Women who wish to get a refund on Rely should send the unused tampons and the package to: Rely, P.O. Box 85519, Cincinnati, Ohio 45202.

## Doctor discusses theories on toxic shock syndrome

By Mary Kempkes

It hasn't been easy studying toxic shock cases in Nebraska. The first two studies were performed from autopsy results.

A UNL case was the first live case Nebraska doctors have had to go on said Dr. Monte Scott, an internal medicine specialist. Scott spoke Tuesday night to about 75 women at Bryan Memorial Hospital who came to ask questions about tampon use and their health.

The disease is caused by a vaginal staph bacteria (*staphylococcus aureus*), Scott said, and while the staph itself is not harmful, the toxin it releases can cause severe repercussions.

In milder cases, the woman may not even know she had the illness, Scott said. But when shock occurs, there is damage to the central nervous system (coma can occur), liver, heart and lungs. Recovery is slow in these cases, he said. Some patients cannot lift their head off the pillow after two weeks and organ damage may be permanent.

The symptoms include chills, fever, severe muscle aches, nausea, vomiting and diarrhea. In advanced cases, the woman develops a sunburn-like rash which peels in the second week of recovery, he said. And in serious cases, the patient collapses and goes into shock. The onset of the disease varies, Scott said, but one Nebraska woman died within 48 hours of diagnosis.

The typical victim is female, young, menstruating and using tampons. Rely is the tampon most often associated with toxic shock, he said, but all major tampons have been cited in statistics.

Toxic shock caused by staph infection is not new, Scott said. There are recorded cases in men and children as early as 1927

but cases related to tampon use were first recorded in 1975. Statistics indicate that three out of every 100,000 menstruating women a year will develop the disease, Scott said, less than the chances of being killed in a car accident. The figures are probably underestimated, he said, since mild cases are not reported.

The Center for Disease Control has not determined the cause for a recent surge in toxic shock cases but has several theories, Scott said.

Tampons have been used for more than 20 years but at first they were little more than pieces of compressed cotton. Now they contain synthetics and chemicals including nylon, polyester and deodorants which may increase staph growth, he said. But direct contamination by tampons has "been pretty much ruled out," he said.

A second theory suggests tampons impede menstrual flow, creating a favorable environment for staph. Also, plastic applicators may irritate or scratch the vaginal wall allowing toxins into the bloodstream.

But CDC is investigating a fourth theory that this strain of staph may be unique and stronger. By using an abundance of antibodies to combat other illnesses and acne, Scott said, women may have created a "super staph" such as this one which is resistant to common types of penicillin.

To reduce the chances of contracting toxic shock syndrome, Scott suggests women either not use tampons or use them only intermittently with napkins. And don't use Rely tampons, he said.

If a woman suspects she has contracted toxic shock syndrome, she should remove the tampon and call a doctor. The tampon should not be discarded, Scott said, because it must be used in testing to determine if the woman actually has the disease.

## Legal aspects of shock syndrome are investigated

By Mary Kempkes

The mother of a UNL student who contracted toxic shock syndrome—the disease associated with tampon use—said she suspected the disease caused a heart murmur.

Barbara Hungerford, whose daughter dropped out of school and off the track team last month because of illness, said Gina did not have a heart murmur in August when she had a physical examination, but one was found after she contracted toxic shock syndrome.

The heart murmur and other conditions have not cleared up, Mrs. Hungerford said, but Gina is steadily recuperating and gaining back her strength.

Gina, a 20-year-old junior, was admitted to Bryan Memorial Hospital Sept. 4. Mrs. Hungerford said Gina thought she had the flu, but the night of her hospital admission, her temperature peaked between 106 and 107 degrees before going into shock.

Hungerford said she and her husband had not decided whether or not to sue Procter and Gamble, makers of the Rely tampons Gina had used for about two years. She said she is skeptical of other women who were suing the company.

"You hear all of these cases, but you don't know if they had the actual disease," she said.

No one from Nebraska has filed suit, but the husband of Lori A. Crawford, 17, who died Aug. 17, from toxic shock, said he is considering legal action. Max Crawford said his wife was using Kotex tampons at the time of her death.

Area lawyers also are skeptical as to whether women will be able to collect on the suits. They say the proof of liability is shaky.

"One of the elements the plaintiff would have to demonstrate is that the product was the cause of a damaging condition or injury," said John Strong, Dean of UNL Law College.

The cause of toxic shock syndrome is unknown, even though the Center for Disease Control in Atlanta has speculated the disease is caused by a staphylococcus infection.

Other doctors said the construction of tampons in the last 20 years has changed and they may now contain some element that supports an overgrowth of staphylococcus. Studies now are being conducted to determine which, if any, element is the cause.

Suing Procter and Gamble would involve technical

jargon difficult for a jury to understand, Strong said, and experts would have to be called for testimony, which, at this point, would be based on opinion.

Law Professor John Heidt said the case for the plaintiff's against the company looks better than most product liability suits. But it's definitely not open and shut, he said.

By removing Rely from the market, "There seems to be an admission of guilt," Heidt said.

But the court may not allow that action as evidence, he said, not wishing to discourage other companies from removing suspected faulty products from consumer use.

"I would think they (the plaintiff's) have adequate evidence," Strong said.

Studies being conducted about Rely's connection to toxic shock syndrome may save the plaintiff from gathering his own evidence, Heidt said. An August study found that 70 percent of toxic shock syndrome victims in one group had used Rely tampons.

The first few cases will be important to Procter and Gamble, Strong said. If they lose, it may bring other suits and set a precedent for their success. If they win, they will fight subsequent suits harder.