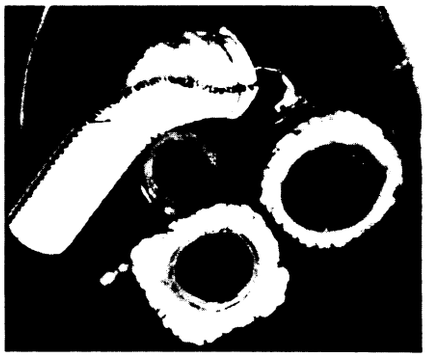
Of hearts and minds in emergencies

Last week's furor concerning the emergency implant of an artificial heart not approved by the Food and Drug Administration (FDA) has raised several ethical and legal questions, including whether or not there should have been a furor at all.

Thomas Creighton, a 33-year-old auto mechanic, died March 8 after being given three consecutive hearts during three days of intense surgery at the University of Arizona hospital in Tucson. A surgical team led by Jack Copeland implanted the unapproved "Phoenix heart," developed by dental surgeon Kevin Cheng of St. Luke's Hospital in Phoenix, after Creighton's body rejected a first heart transplant. The artificial device sustained him for 11 hours until a new donor heart was found. Creighton died after the second donor heart was transplanted.



Wide World

Some medical ethicists question the Arizona team's decision to use the Phoenix heart rather than the Jarvik-7, the FDA-approved permanent artificial heart developed at the University of Utah that has been implanted in three people since 1982. The Arizona team had requested the Jarvik-7, but the Phoenix heart (above) arrived about three hours earlier and was used because "something had to be done as soon as possible," according to a spokesperson for St. Luke's.

But all the facts are not yet in, says Bruce Jennings, associate for policy studies at the Hastings Center, a medical ethics institute in Hastings-on-Hudson, N.Y. "If the Arizona group was motivated to save the patient's life," Jennings says, "there's no justification for using a device that's untested if they can get their hands on a better device." The Arizona group, however, apparently would not have been on better legal ground if they had used the Jarvik-7. The FDA's 1976 Medical Device Act allows for emergency use of artificial hearts only if the doctor or hospital has filed for FDA approval. They had not.

Hershey (Pa.) Medical Center's "Penn State Heart," a temporary artificial heart designed to sustain patients during emergency situations like that in Tucson, is the only other artificial heart up for FDA approval. The FDA is expected to respond to that request this month. Last year, the agency approved clinical trials for Stanford University Medical Center's left-ventricular assist device, which takes over the heart's muscular workhorse, the left ventricle, during heart transplants or open-heart surgery. It will be implanted in about 10 patients before final FDA approval is sought. The Phoenix heart, made of the same material its developer uses to replace jawbones in facial reconstructive surgery, has been tested in calves for about two years. Clinical trials, a spokesperson for St. Luke's says, are "not yet even part of the protocol."

Nevertheless, the group's actions elicited sympathy for the plight of doctors in emergency situations. When it comes to going by the book or saving a life, most doctors would opt for saving a life, says Robert Bartlett of the American Society of Artificial Internal Organs (ASAIO) in Boca Raton, Fla. "If every doctor who improvised something had to go through FDA approval, it would be preposterous," he says. Last month, the ASAIO submitted a petition to the FDA to shorten the approval process for emergency use of experimental devices.

The FDA this week issued a mild reprimand to the University of Arizona hospital, and is conducting an investigation of the Arizona group's actions during the emergency. —*D. D. Bennett*

Breast cancer: Death to the radical?

Breast cancer victims are just as well served by removal of only the tumor and adjacent tissue as by more extensive surgery, according to a five-year study of 1,843 women conducted at 89 institutions. And a 10-year study shows that these results can be expected to hold up over time, good news to the 1 of every 11 women in the United States who will get breast cancer. Reports of the work appear in the March 14 NEW ENGLAND JOURNAL OF MEDICINE (NEJM).

The studies were initiated as a result of increasing numbers of breast cancer victims seeking options other than the radical mastectomy, and medical reports of good results with less drastic surgery (SN: 3/7/81, p. 153; 7/11/81, p. 22). The radical mastectomy, developed in the early 1900s, involves removal of the breast tissue, underlying muscle and all lymph nodes in the armpit. In the two reports, radical mastectomy was compared with segmental mastectomy (lumpectomy), in which the tumor plus a margin of the surrounding normal tissue is removed; and with total mastectomy, in which the breast tissue is removed, along with a few lymph nodes if the cancer has spread, but muscle is allowed to remain.

In the five-year study, women with tumors 4 centimeters or smaller received a total or segmental mastectomy with no radiation or a segmental mastectomy with radiation. All had their underarm lymph nodes removed.

The researchers report that "disease-free survival after segmental mastectomy plus radiation was better than disease-free survival after total mastectomy, and overall survival after segmental mastectomy, with or without radiation, was better than overall survival after total mastectomy." Therapeutic radiation, which an accompanying NEJM editorial notes "has almost been discarded," showed a clear benefit: 92 percent of radiation-treated women were tumor-free after five years, compared with 72 percent of nonirradiated women.

The second trial compared radical mastectomy with total mastectomy in 1,665 women followed for about 10 years, and showed essentially the same outcome for the two procedures. Whether or not lymph nodes were removed, the researchers found no difference in disease progression or survival — "support," they note, "for our concept that regional lymph nodes are indicators rather than instigators of distant disease."

The National Cancer Institute in Bethesda, Md., and the American Cancer Society in New York supported these National Surgical Adjuvant Breast Project studies. —*J. Silberner*

Antibodies in cow's milk

Human milk contains most of the intestinal antibodies needed by newborn infants, providing them a natural protection against many common infections. But a study at Johns Hopkins Medical School in Baltimore shows that cow's milk, like human milk but unlike commercial infant formulas, contains antibodies that protect infants from a common diarrhea virus called rotavirus.

The scientists, who reported their study in the March 7 NEW ENGLAND JOURNAL OF MEDICINE, detected antibodies to rotavirus in both raw and pasteurized cow's milk. Although most infant formulas are made with cow's milk, antibodies are absent, they say, probably because of the high-temperature processing of cow's milk before it is added to formula preparations. Lower temperatures used in simple pasteurization allow many of the antibodies to be retained in pasteurized milk. If rotavirus antibodies could be preserved in infant formula, the researchers say, this food also might protect infants from rotavirus-related diarrhea.

Antibodies to rotavirus in cow's milk probably appear because of naturally occurring rotavirus infection in cow herds or vaccination with rotavirus preparations, according to the researchers. □