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Tube mix-ups can be deadly

Thirty-five weeks pregnant, Robin Rodgers was vomiting and losing weight, so her doctor hospitalized her and ordered that she be fed through a tube until the birth of her daughter.

But in a mistake that stemmed from years of lax federal oversight of medical devices, the hospital mixed up the tubes. Instead of snaking a tube through Rodgers' nose and into her stomach, the nurse instead coupled the liquid-food bag to a tube that entered a vein.

Putting such food directly into the bloodstream is like pouring concrete down a drain. Rodgers was soon in agony.

"When I walked into her hospital room, she said, 'Mom, I'm so scared,'" her mother, Glenda Rodgers, recalled. They soon learned that the baby had died.

"And she said, 'Oh, Mom, she's dead.' And I said, 'I know, but now we have to take care of you,'" the mother recalled. And then Robin Rodgers -- 24 years old and already the mother of a 3-year-old boy -- died on July 18, 2006, as well. She lived in a small Kansas town, but because of a legal settlement with the hospital, her mother would not identify it.

The deaths were among hundreds of fatalities or serious injuries that researchers have traced to tube mix-ups. But no one knows the real toll, because this kind of mistake, like medication errors in general, is rarely reported. A 2006 survey of hospitals found that 16 percent had experienced a feeding tube mix-up.

Experts and standards groups have advocated since 1996 that tubes for different functions be made incompatible -- just as different nozzles at gas stations prevent drivers from using the wrong fuel.

But action has been delayed by resistance from the medical-device industry and an approval process at the Food and Drug Administration that can discourage safety-related changes.

Hospitals, tube manufacturers, regulators and standards groups all point fingers at one another to explain the delay. Hospitalized patients often have an deliver or extract medicine, nutrition, fluids, gases or blood to veins, arteries, stomachs, skin, lungs or bladders. Much of the tubing is

interchangeable, and with nurses connecting and disconnecting dozens each day, mix-ups happen -- sometimes with deadly consequences.

"Nurses should not have to work in an environment where it is even possible to make that kind of mistake," said Nancy Pratt, a senior vice president at Sharp HealthCare in San Diego who is a vocal advocate for changing the system. "The nuclear power and airline industries would never tolerate a situation where a simple misconnection could lead to a death."

An international standards group is seeking consensus on specific designs on how tubes for different bodily functions should differ, but the group has been laboring for years and its complete recommendations will take years more. Some manufacturers have used color-coding to distinguish tubes for different functions, but with each manufacturer using a different color scheme, the colors have in some cases added to the confusion.

An alarm is raised

Advocates in California got legislation passed in 2008 that would have mandated that feeding tubes no longer be compatible with tubes that go into the skin or veins by 2011. But in 2009, AdvaMed, the manufacturers' trade association, successfully pushed legislation to delay the bill's effects until 2013 and 2014 or until the international standards group reaches a decision.

In the meantime, FDA reviewers have begun to question whether feeding tubes that could mistakenly be connected to intravenous tubes should be declared fundamentally unsafe.

The catalyst for those questions, according to internal documents provided to The New York Times, was an application filed in August 2009 from Alan Reid, president of Multi-Med in West Swanzey, N.H., to produce feeding tubes for newborns that go into the stomach using the same connectors as those that go into veins. The FDA was so concerned about the application that it inspected the Multi-Med plant in September and issued a warning letter for Multi-Med's failure to test or design its pediatric feeding tubes adequately.

The similarity of feeding and intravenous tubes caused the near-death of Johannah Back's premature infant, Chloe Back, in 2006. A nurse mistakenly connected a bag of breast milk to an intravenous tube, leading Chloe to form tiny blood clots throughout her body, bleed profusely and suffer seizures for months.

"These problems have been going on since at least the 1970s. Why?" asked Back, of Las Vegas.

Federal approvals

Because of such problems, an FDA reviewer recommended against the approval of Multi-Med's application, even though the company planned to use a special color and label to distinguish it as a feeding tube, according to internal agency documents provided to The Times. Dr. Kevin McBryde, the FDA reviewer, wrote in an April 20 memorandum that the Multi-Med application "does not adequately address the safety concerns for misconnections."

An FDA manager overruled McBryde, saying Multi-Med's tubing was no more dangerous than tubes already on the market. The manager's reasoning was based on the agency's own rules for an abbreviated device-approval process that requires only that the manufacturer prove that a new product works just like an old one, whether the old one is safe or not.

The result of these rules is that the FDA sometimes approves devices even when officials suspect that they might harm or kill patients. Indeed, the FDA has on occasion approved a new device, mandated that it be recalled and then approved another just like it because the rules are set up to require such approvals.

In 2005, for instance, the French company Gambro was forced to recall its Prisma dialysis machine because patients died or were injured after the patients or caregivers ignored warnings from the machine and, as a result, received too much or too little fluid. In 2007, Edwards Lifesciences of California sought approval for the Aquarius system, a dialysis machine that an agency reviewer noted had the same problem.

The agency had never rescinded its original approval of the Gambro device; such approvals are rarely rescinded, even after a recall, partly because there is some debate about whether it would be legal to do so. So the agency approved the Edwards one as well, documents show.

In February, the Edwards device was recalled because of "reports of clinically significant fluid imbalance," according to the recall alert.

"I raised this issue during the review, but the division director at the time advised that the device should be" approved, wrote Joshua Nipper, an FDA device reviewer, in a Feb. 18 internal e-mail provided to The Times. "We knew that the device could result in serious injury or death, and we allowed it be marketed anyway. Not surprisingly, the device causes serious injury/death and now must be recalled."

John McGrath, a vice president at Edwards, said there had been no patient injuries or deaths in the United States caused by the Aquarius system.

Christy Foreman, acting director for the FDA's office of device evaluation, said that Gambro fixed its dialysis device after the 2005 recall so that its approval did not need to be rescinded. Foreman said that Edwards Lifesciences had asserted that better training and instructions would prevent a repeat of the Gambro problem.

"Unfortunately, those mitigations weren't as effective as the reviewer thought," she said.

The FDA is in the midst of a wide-ranging reassessment of its device approval process and released a report Aug. 4 that highlighted some of its flaws, including approvals of devices modeled on unsafe or obsolete predecessors.

Foreman said the FDA was considering the creation of a list of old products that manufacturers should avoid using as models for new ones.

Calls for safety

Dr. Robert Smith, an FDA device reviewer who left the agency July 31 and was among nine agency employees who in 2009 decried the agency's device approval process as illegal and dangerous, said that the tubing problem, which has gone on for decades, was another example of how the agency failed to protect the public.

"FDA could fix this tubing problem tomorrow, but because the agency is so worried about making industry happy, people continue to die," Smith said.

In the meantime, the FDA has issued three alerts to hospitals and manufacturers warning about tube mix-ups, the most recent of which was sent out last month after The Times began asking about the issue. Pratt said she persuaded one manufacturer, Viasys, to produce neonatal feeding tubes that are incompatible with other tubing. Viasys' tubing is now used in Sharp's neonatal intensive-care units, but they are expensive -- \$13 compared with \$1.50 for regular tubes.

"The regulators have been waiting for the manufacturers to come up with a solution," Pratt said, "and the manufacturers won't spend the money to design and produce something different until the regulators force them to. And now the international standards organization is taking forever to get the whole world onto the same page."

Nancy Foster, vice president for quality and patient safety policy at the American Hospital Association, agreed, "These things are hard to change when you have to get so many different organizations to act in concert."