

# Adverse drug events' a worsening problem

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Ronald Marks' heart-bypass surgery went so well he was expected to be quickly moved from the coronary-care unit to a regular room at Pennsylvania Hospital.

Five days later, he was dead, apparently of a potassium overdose.

Marks' case could be a metaphor for a worsening problem in U.S. health care. The number of patients who are victims of medication mistakes or experience serious drug reactions - known collectively as adverse drug events - jumped 41 percent in the eight-county Philadelphia area from 1997 to 2005.



*PETER TOBIA / Inquirer Staff Photographer*  
Vicki Bralow meets with Tom Kline of Kline & Specter.  
Bralow, a doctor, suspects a medication error caused her father's death.

According to an Inquirer analysis of billing records, 31,639 patients had an adverse drug event - nearly four of every 100 hospitalized patients.

That's in line with the national average. Nationwide, 1.2 million hospitalized patients had experienced one or more adverse drug events in 2004, the federal Agency for Healthcare Research and Quality (AHRQ) reported in a study released last week.

While the majority of those incidents were bad reactions to correctly administered medicines, more than 100,000 were mistakes made by hospital staff, other health providers, or the patients themselves.

Marks went into cardiac arrest less than two hours after his bypass operation. Despite his surgeon's efforts - including open heart massage for 45 minutes - the 68-year-old died.

His daughter, Vicki Bralow, a doctor on staff at the hospital, looked at the medical records and thinks a preventable drug error killed her father.

"He received a large amount of potassium in a short period of time, and it stopped his heart," she said. "Now, I wonder how many people are told that their loved one died of a heart attack and never learn that there was a medication error."

Hospitals in Pennsylvania must by law tell patients or their families when a medical mistake causes serious injury or death. The 2003 provision also requires hospitals here to report all medical errors to the state's Patient Safety Authority, even those that don't cause serious harm.

Last year, hospitals reported 44,469 medication errors to the authority. Only a fraction were classified as "serious events" that resulted in patient deaths or permanent injury, while 99 percent were "incidents" that didn't cause long-term harm.

Marks' daughter said officials at Pennsylvania Hospital denied that any error occurred in his care, so she doubted an error report was made.

"If you don't report it, you can't fix it," said Bralow.

Six months after Marks died on March 5, 2005, his family sued the hospital and the nurse who administered the potassium.

Bralow said she decided to sue, in part, to get the hospital to acknowledge its mistake and make changes to prevent other patients from being harmed.

Citing continuing litigation, Pennsylvania Hospital officials declined to comment. But in court filings, the hospital denied that its care was negligent. At all times, the hospital and its personnel acted "in accordance with the accepted standards of medical and/or hospital care," court documents say.

Last summer, the Institute of Medicine, a nonprofit group that advises the federal government, estimated at least 400,000 preventable medication errors occur each year in U.S. hospitals, resulting in about 9,000 deaths and \$3.5 billion added to the cost of care.

Those estimates were based on three published studies of clinical data from the 1990s, while the AHRQ, the federal research agency, examined hospital billing records for diagnoses of adverse drug events.

The problem has long been recognized in the medical community, and efforts have been made, including in this area, to reduce medication errors.

"The work is going much too slowly toward building a medication system that is safe," said Jim Conway, a senior vice president at the Institute for Healthcare Improvement in Cambridge, Mass.

Others say there's been some progress, but advances in the strengths of new drugs as well as sicker patients now in hospitals drive up the number of adverse drug events.

"I think we are safer today from a medication standpoint than we were 10 years ago," said Michael Cohen of the Institute for Safe Medication Practices in Huntingdon Valley. "Still, all of us say, 'My God, we have a long way to go.' "

AHRQ stressed in its report that even properly administered drugs carry significant risks.

"So many of these drugs are so powerful and create adverse events in and of themselves," said Robert I. Field, chair of the department of health policy and public health at the University of the Sciences in Philadelphia.

Hospitals participating in 2000 in a regional medication-safety program led by the Health Care Improvement Foundation reported significant progress three years later.

"The region's hospitals have devoted tremendous resources to prevent medication errors," said Andrew Wigglesworth, president of the foundation.

In 2006, the Patient Safety Authority found that 20 percent of the error reports it received involved "high-alert" drugs such as painkillers, blood thinners and insulin products that can cause significant injuries when used incorrectly.

After getting reports about a syringe problem causing insulin overdoses, the authority issued a statewide hospital alert, resulting in a dramatic decline in reports of the problem, said Mike Doering, interim executive director of the authority.

Researchers at the AHRQ also wanted to identify which medicines cause particular problems, said Anne Elixhauser, senior research scientist at the agency.

She and a colleague found that tranquilizers, antidepressants and painkillers were among the top causes of the 100,000 medical mistakes or "poisonings." Cancer drugs, blood thinners and corticosteroids were leading causes of the bad reactions to medicines.

Tom Kline of Kline & Specter in Philadelphia represents the Marks family. He questioned why the incident did not rise to the level of a serious event since Marks died after getting twice the standard dose of potassium chloride in about one-third the time.

"Medication errors appear to still exist in large numbers," Kline said, "and there are no signs of any downward trend from what we have observed in our practice."