Officially, artist Andy Warhol died from cardiac arrhythmia, a complication after “routine” gallbladder surgery in 1987. But his family won millions in a lawsuit against the New York City hospital where he underwent his surgery by successfully arguing that the arrhythmia was a result of water intoxication caused by faulty administration of an infusion pump.

Other infusion errors and pump failures—from opioid overdoses, to battery malfunctions, to software errors, to dosage miscalculations—may not make the headlines, but they seriously threaten the health and well-being of patients. The particularly bad news for patients is that these are far from being isolated cases. After receiving 56,000 reports of infusion pump incidents—including 710 deaths—and issuing 87 infusion pump recalls between 2005 and 2009, the U.S. Food and Drug Administration (FDA) has initiated a sweeping program aimed at preventing infusion pump problems and improving patient safety.

The goal, according to an FDA white paper on the initiative, is “to support the benefits infusion pumps can provide while reducing associated risks.” While manufacturers have already introduced some design changes to cut down on errors, all parties agree that more needs to be done.

An estimated 90 percent of hospital patients receive an infusion as part of their treatment. The pumps deliver nutrients and medications like pain killers, antibiotics, and chemotherapy drugs that can mean the difference between life and death. But the powerful medications can cause serious harm, even death, if improperly delivered.

Healthcare providers, clinical engineers, and manufacturers have long been aware of a disturbing trend in errors and faulty performance associated with infusion pumps. Seven years ago, a Massachusetts General Hospital infusion pump task force reported that “compelling incidents and near-misses motivated the formation of our team, and led to the devotion of significant energy to preventing IV drug administration errors.” Twelve years before that, a Harvard Medical Practice Study reported that infusion errors and drug complications were the most common type of preventable adverse events reported in hospitals.

Until recently, end users—nurses and doctors backed by pharmacists—bore the burden of performing complex mathematical conversions of dose rate units into fluid-flow units. And if a busy floor nurse programming an IV
device at a patient’s bedside missed a decimal point or accidentally double-pressed a key, the resulting dosage error could be fatal.

“Smart pumps,” complete with onboard drug libraries and dose-monitoring capabilities, were seen by many as the best hope to address the problem. By 2005, almost one-third of hospitals had begun using smart pumps; four years later, more than half of the nation’s hospitals reported adopting the technology. But, as current FDA statistics point out, nascent “smart pump” technology hasn’t proven a panacea for infusion pump problems.

“You can still hang the wrong bag on a device and the machine would never know,” says Marla Husch, a patient safety expert and project manager at Central Dupage Hospital in Illinois. Previously, Husch was the project manager responsible for implementing the conversion to smart pumps at Northwestern Memorial Hospital. “Infusion pumps that perform as stand-alone devices—no matter how ‘smart’ they are—simply leave too many gaps,” Husch explains.

A 2005 Northwestern Memorial study led by Husch reported that more than two-thirds of the infusions observed by investigators had one or more errors associated with their administration. Only one of the 389 errors could have been prevented by smart pump technology. At its July 2008 Safety Summit, the American Society of Health-System Pharmacists (ASHP) recommended that manufacturers redesign intelligent pumps to focus on user-defined, rather than vendor-defined, features.

“They recommended such functionality as teaching prompts embedded in pump controls; standardized field names and dose expressions that match infusion order-writing conventions; a pump programming sequence that matches the medication order sequence; and the ability to back out of a wrong action,” explains Bona Benjamin, director of medication-use quality improvement at the ASHP. “It’s puzzling that such features are not available now—or why users do not perceive them to be available. Apparently many infusion devices are not as ‘usable’ as they need to be. Why not?”

So what’s the answer to this complicated problem? Well, not surprisingly, it’s complicated.

What Went Wrong?
For starters, experts believe that infusion pump problems are compounded by inaccurate reporting of root causes. “We do not have a valid analysis of the 56,000 reports of problems with infusion pumps,” says Nat Sims, MD, a physician advisor to Massachusetts General Hospital’s Biomedical Engineering Department. Raw data submitted by hospitals, manufacturers and others has proven “difficult to analyze—even by FDA analysts—to categorize primary and secondary causes,” Sims explains.

FDA experts agree with Sims that discerning the cause
of pump failures and use errors is the first step to improving the safety of the devices. At a public meeting convened by the agency in May, Division of Electrical and Software Engineering Director Al Taylor explained that “many failure investigations reported by pump manufacturers have misidentified the root cause of adverse events as ‘use error’ or ‘random component failure.’”

FDA-run investigations have reached a different conclusion. “Many adverse events are caused by design deficiencies that were foreseeable and preventable. Pump deficiencies place an undue burden on users, caregivers, and support staff, adding to an already stressful environment,” said Taylor.

Pat Baird, a principal project engineer at Baxter International Inc. and co-chair of the AAMI Infusion Device Committee, says infusion pumps shouldn’t be looked at in isolation. “The industry must look at infusion systems holistically, as part of this ecosystem of patient care, to effectively tackle the potential safety issues we all face,” said Taylor. (Read more of Baird’s comments in the Final Word on page 440.)

At the Duke University Health System, patient safety specialist Glenn Scales and his colleagues have seen infusion pump incidents that range from inadequately validated software errors, to defects in the manufacturing of IV administration sets due to environmental issues in the manufacturing facility, to improper manufacturing of the devices themselves. “More common problems,” says Scales, include entering dose values in the ml/hr field, entering incorrect numeric values in the correct field, transposing digits when entering values, and substituting decimal points for zeros when entering values because they are next to each other on the keypad.

“Our clinical staff work in a very demanding environment that is rife with distractions and simultaneous demands on the caregiver for multiple interactions with the surrounding technology,” says Scales. And with increasingly complex technology that requires more interaction on the part of a clinician, errors become more likely. “We well know that no one wants to make errors, but the environment we place our caregivers in frequently predisposes them to become distracted, take shortcuts, or utilize work-arounds that lead to error-prone behavior.”

Many of these errors are flagged by an alert message, but that doesn’t necessarily mean that the problem will be fixed. “During high stress, these messages are sometimes cleared without correcting the error,” says Scales. “Post-event analysis and user interviews frequently reveal that users were completely unaware of having passed by the alert.”

Clinicians override some 90 percent of alerts, according to Husch. Some of the alerts get ignored because clinicians are overtaxed, but others just “don’t make sense,” she says. In some dosage situations, alerts are automatic. “They know that they’re going to get an alert every time in that situation and that they’re going to override it every time, so they become completely desensitized to all alerts.”

“When a system is designed in a way where there is a potential for errors, there will be,” says Tony Easty, senior scientist with the Centre for Global eHealth Innovation in Toronto. “Training someone not to make mistakes isn’t effective. You can’t do it. We’re humans, not machines. We’re not programmed to do the right thing every time.”

In a recent study looking at the impact of traditional and smart pump infusion technology on medication administration, Easty’s group observed a trend: Problems most often occurred when multiple drugs and therapies were being administered. When nurses were asked to “piggyback” a drug, they repeatedly made errors. Easty has been talking to manufacturers about the problem, and a follow-up study has been planned to focus on the issue of multiple lines.

“The theory is that greater complexity causes greater error,” Easty says. “Not much work has been done in the area of multiple infusions, so none of our current technologies really address this issue.”

As infusion pump use rises with an aging population, these issues will only multiply, says Frank Overdyk, MS, MD, a professor of anesthesiology at the Medical University of South Carolina. In Overdyk’s research,
he sees an alarming rate of opioid infusion overdoses on general-care floors. “Usually, it involves a knowledge deficit about patient-controlled analgesia (PCA) devices on the part of the family and the nurses and providers,” says Overdyk. “The lockout and hourly limit constraints are interpreted as a foolproof safety mechanism. They are obviously not.”

Working to keep existing pumps performing safely doesn’t come cheaply. Michael Fraai, director of Biomedical Engineering at Brigham and Women’s Hospital in Boston, told attendees at the FDA’s Infusion Pump Workshop that his hospital spends about $500,000 a year to service infusion pumps. That translates into spending 45 percent of his department’s service costs on just 16 percent of its inventory.

Early Answers
On April 30, 2010, the FDA sent a letter to Baxter Healthcare Corporation ordering the company to recall and destroy all models of its Colleague Volumetric Infusion Pumps. As many as 200,000 of the pumps were estimated to be in use in the United States at the time. While the Colleague pump recall may have garnered more attention than other recalls, it’s just one of 87 recalls initiated by the agency in the past five years.

In addition to the strain on operations during the time it takes a vendor to address such a problem, responding to recalls places a considerable “burden on hospitals to do a lot of the logistics work themselves,” reported Fraai.

In an open letter to patient and healthcare professional organizations this spring, Anthony Watson of the FDA Office of Device Evaluation wrote: “Problems with infusion pumps encompass multiple manufacturers and models. They include poor design, structural problems, and software defects. Although the overall benefits of using infusion pumps still outweigh the risks, this is an unacceptable situation.”

Since that time, the FDA has set up an infusion pump website, drafted guidance for premarket reviews, convened a stakeholder teleconference, hosted a public workshop and planned an October summit, co-hosted by the Association for the Advancement of Medical Instrumentation. (See box on page 376.) The agency has demonstrated a “commitment to fixing this problem,” according to ASHP’s Benjamin.

“We are only at the beginning of what will be a lengthy process of focusing on infusion pumps and on patient safety when patients are receiving IV infusions,” says Sims. “Since infusion pumps are used in so many settings and in almost every hospital bed, many changes will no doubt be forthcoming in the next few months and years.”

Sims and his colleagues at MGH have long been leaders in patient safety initiatives, including one on infusion pump safety. Changes have included preparing standardized syringes and drug bags of IV medications in the hospital pharmacy or an outsourced compounding agent to eliminate “ad hoc compounding at the bedside.” MGH also has computerized provider order entry (CPOE) systems for use by caregivers when writing prescriptions, with clinical decision support to make sure IV medications are ordered correctly.

“And we have a ‘bedside barcoding’ system to ensure the ‘five rights’ of medication administration are always correct,” adds Sims. The five rights are: right patient, right route, right dose, right time, and right medication. An early adopter of smart pumps, MGH has had the devices in their intensive care units, operating rooms, pediatric, and general-care areas since the mid-1990s. “We believe very strongly in standardization of drugs, clinical protocols, and drug libraries.”
At the Duke University Health System, several different kinds of smart pumps are in use and, says Scales, “each was selected, configured, and implemented by a team with experts selected for their expertise in the new modality.” Pumps were selected for neonatal air transport, epidural and regional pain management, IV pain management, and magnetic resonance imaging cardiac stress testing. In addition, a multidisciplinary group that includes pharmacists, nursing practice experts, nurse educators, and clinical engineers routinely reviews data extracted from the smart pumps to look for failure modes and improvements to drug libraries. “Part of this review,” explains Scales, “includes an analysis of how ‘smart pump’ libraries work in conjunction with our CPOE system.”

When errors occur, the organization has a system in place to respond. “All device-related medication errors and adverse drug events are reviewed by a clinical pharmacist and a clinical engineer who collaborate on causes and recommendations for improvement,” explains Scales.

In addition to hospital initiatives, manufacturers have responded to reported problems with technology enhancements and design improvements. Overdyk cites enhancements in PCA devices. “The number of cases I have reviewed involving errors in pump programming or pump malfunction has decreased markedly as a result of redesigned user interfaces, Guardrails,® and other ergonomic features that have been implemented as a result of sentinel events with PCA pumps,” he says.

But real progress, according to Overdyk and others, is only going to be made when people stop looking at infusion pumps as “stand-alone” devices.

Making the Connection

“Stand-alone devices won’t work,” states Husch, who sees the solution to infusion pump problems as being part of a larger issue of connectivity: enabling interaction between electronic medical records, infusion pumps, monitoring devices, and other technology. A tall order—but possible,
she believes.

“There are all sorts of legal and proprietary barriers to achieving connectivity, but I believe it’s achievable. It’s just going to require more regulatory oversight so that we can create the universal, ubiquitous standards we need,” says Husch. For example, existing medical record frameworks like HL7—standards for the exchange, integration, sharing, and retrieval of electronic health information—exist in “so many versions that they’re essentially meaningless,” she explains.

Experts agree that integration of electronic medical records with infusion pump functionality will prove a vital step in reducing dosage errors. “We would like to have better ‘wireless connectivity’ between pumps and clinical information systems, so we can know with certainty that every drug infusion is being given in accordance with the original order for that specific patient,” says Sims. Going one step further, Scales says healthcare providers need “the ability to import data from infusion pumps into medical records.”

“Our challenge is getting the pumps to talk to other interfaces,” concurs Easty.

In the case of multiple drug infusions, this might take the form of technology that links particular bags of medication to particular channels of an infusion pump so that, for example, a drug that needs to drip intravenously couldn’t accidentally be piggybacked below the drip, allowing free flow of the drug into the patient.

Integrating emerging barcoding technology with smart pump technology offers promise here. Sims says that he would like every IV drug container to have a barcode that can be recognized by a drug infusion pump to ensure 100 percent accuracy. In addition, pumps with barcoding technology have already proven useful in reducing “wrong patient” errors, according to a recent study—though the same study concluded that “until bar- code pumps are integrated with other systems within the medication administration process, their role in enhancing patient safety will be limited.”

“I feel that barcode medication administration will, if implemented correctly, dramatically reduce errors,” Scales agrees. “However, this is expensive and the implementation must incorporate many areas beyond the pump design—including information systems, pharmacy, materials, and the institution’s supply chain. The implementation of this kind of system requires much long-term planning from many diverse stakeholders to ensure success.”

Another key connectivity issue Sims sees is the need for integration between PCA pumps and monitors for early detection of respiratory depression, or failure to breathe adequately. Overdyk, too, believes that an essential component of improving infusion pump safety is to integrate infusion pumps with monitoring equipment. “Since infusion pumps may administer a potentially toxic substance—like morphine, potassium, or heparin—an intuitive safety feature to me is to ‘close the loop’ by measuring the drug’s effect on things such as respiratory rate, oxygen saturation, and carbon dioxide levels.”

Some work is already being in done in this direction. Overdyk points to PCA pumps that offer oximetry

“...In many cases, industry has responded to adverse events by enhancing pump safety features.”
—Bona Benjamin, the American Society of Health-System Pharmacists

Want More Information?
To get more details on infusion pump safety, check out these sites:

AAMI Hot Topics
http://www.aami.org/hottopics/

ASHP IV Safety Summit
http://www.ashp.org/iv-summit

FDA Infusion Pump Improvement Initiative
www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps

Centre for Global e-Health Innovation
www.ehealthinnovation.org/?q=node/365

Institute for Safe Medication Practices
http://www.ismp.org/

San Diego Patient Safety Consortium

Intravenous Medication Safety and Smart Infusion Systems

ECRI Institute
https://www.ecri.org/Pages/default.aspx
First, Do No Harm: Making Infusion Pumps Safer

(SpO₂) and capnography (EtCO₂) monitoring modules. One early adopter, St. Joseph’s/Candler Health System in Savannah, GA, reported preventing 328 potentially serious overdoses in six months with the monitoring modules in place.10

Recent developments with electronic medication administration record (eMAR) systems that have demonstrated “success data” for non-intravenous medications show promise for infusion pumps, as well. “As soon as real-time data from infusion pumps connected to a particular patient are auto-documented into eMAR records for that patient, it will be possible to ‘close the loop’ and prove safe care,” says Sims, who points to systems successfully implemented at hospitals such as Intermountain Health Care in Salt Lake City and Lancaster General Hospital in Pennsylvania.

Put simply, the “development of interoperability interfaces” is critical to helping prevent dosing errors, says Scales.

Next Steps

Even before issues of connectivity and interoperability are worked out, experts see a host of shorter-term actions that should be taken.

According to ASHP’s Benjamin, a critical challenge is determining “how to ‘road test’ devices, so that the design flaws can be exposed and corrected.” While Benjamin doesn’t assert that it’s possible to predict everything that could go wrong with a pump, she believes that “a rigorous testing process in realistic conditions needs to be developed.”

Peter Doyle, a human factors engineer, also sees the need for more rigorous design-phase testing of infusion pumps. “I strongly support the need to involve human factors expertise during design and to conduct usability testing during various phases of design development to ensure that representative users will be able to use the pumps reliably in the environments of use,” says Doyle of Johns Hopkins Hospital’s Clinical Engineering Services.

FDA has begun work in this area. “Particularly encouraging is the Infusion Pump Initiative and its focus on testing pumps in a real-world environment,” Benjamin says. Sims agrees: “We applaud the FDA’s efforts to add more rigor to the design development and premarket submission [510(k)] process.”

As part of its initiative, FDA is requesting additional validation for infusion pump submissions, specifically simulation testing prior to a clinical evaluation. “Simulated use testing is necessary to ensure sufficient safety and effectiveness prior to the clinical evaluation,” Ron Kaye of FDA told attendees at the agency’s May workshop on infusion pumps.

Design improvements are needed for both hardware and software, say experts. “Software designs need to better address how and why errors are made and why the device operator is seemingly unaware of how and why the error occurred until the patient’s physiological condition makes it known,” says Scales. Potential hardware refinements include enhancing battery life, preventing fluid infiltration, and designing “more robust” pump accessories that can “stand up under typical use,” he adds.

Manufacturers are already responding to these challenges, says Benjamin. “In many cases, industry has responded to adverse events by enhancing pump safety features,” she says. Overdyk concurs: “Certainly the user...
interface has been improved in infusion pumps, making programming errors less common. Pump malfunction incidence has also been reduced.”

In addition to improving patient outcomes, reducing infusion pump incidents means savings for hospitals. Each preventable adverse drug event (ADE) has been reported to cost $8,750. At St. Joseph’s/Candler Health System, the purchase of a $1.5-million IV safety system resulted in an estimated reduction of 471 ADEs over a five-year period that, if not averted, would have resulted in potential costs to the hospital of almost $4 million, yielding an estimated 5-year return on investment of $1.8 million.11

Sims sees additional potential in further opening the door to foreign device companies. “I think it would be useful to have more competition in the infusion device industry. Competition leads to higher quality in device design and lower prices, when hospitals have more choices,” he says. Sims looks to European manufacturers of drug infusion pumps, who make more than 100,000 pumps per year for many countries throughout the world—just not the United States. “We need to ensure that vigorous healthy competition is maintained in the industry.”

Even with better pump designs, healthcare institutions must take responsibility for patient safety, says Scales: “The key to these issues is having an established safety culture and a relationship between clinical engineering and the front-line caregivers that ensures that when incidents occur, they are reported promptly—within minutes, not days—that evidence is preserved and documented, and that all the interested parties actively participate in finding long-term solutions.”

In addition, institutions may need to re-examine staffing and monitoring standards on general-care floors in order to reduce infusion pump sentinel events. In a recent editorial, Overdyk wrote: “Infrequent patient monitoring, with intervals as far apart as every four hours on the first postoperative night, is a major reason for the persistence of these events. ‘Failure to rescue’ is a misnomer, since it is not a failure of the code team to resuscitate, but a ‘failure to recognize’ respiratory decompensation in a timely fashion.”12

As long-term solutions are developed, the FDA is asking clinicians to take general precautionary steps:
Establish a plan to prevent known pump problems and to respond in the event of pump failure, label infusion pump channels and tubing to reduce errors, monitor patients closely for signs of over- or under-infusion, and report adverse events promptly to the agency.

With more infusion pumps in hospitals today than any other device, their safety record—despite some improvements over the years—remains a call to action. On the horizon are more robust FDA oversight, new safety standards to reflect current technology and practices, human factors-driven design improvements, and universal standards for interoperability of devices.

References
8. CareFusion’s Guardrails® Suite MX Safety software.
Eight Titles That Every Medical Device Technology Professional Should Own.

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