How Mass General’s Medical Technology Breakthroughs Are Improving Patient Safety Standards Across the U.S.

In the rapidly evolving field of medical technology, breakthrough therapies and surgical techniques make headlines. Medical devices such as artificial heart valves and magnetic resonance imaging (MRI) equipment are marvels of the modern era, making it possible for clinicians to diagnose and treat disease or injury more effectively than ever before. But it's the Smart Drug Infusion Pump, a portable, bedside device little known to those who work outside the medical profession, which lies at the heart of the last decade’s revolution in patient safety. Born of a basic premise — that physicians should dispense the correct drug to each patient at the correct time and in the correct dose — the Smart Pump is one homegrown invention that’s saving lives.

The man behind the Smart Pump revolution is Nathaniel Sims, MD, of the Department of Anesthesia, Critical Care and Pain Medicine at Massachusetts General Hospital and innovation advisor to the Center for Integration of Medicine and Innovative Technology (CIMIT). Surrounded in his Mass General lab by dozens of half-assembled prototypes and outdated simple machines, the cardiac anesthesiologist recalls first recognizing the potential hazards of drug-dosing errors in the early days of his career.

“Medication and dosing errors were, and still are, among the leading causes of injury to patients in the medical setting,” says Dr. Sims. Drug infusion pumps, the standard tool for delivering fluids, medication or nutrients into a patient’s circulatory system, are the site of many such errors. In the last five years, the U.S. Federal Drug Administration (FDA) has received approximately 56,000 reports of infusion pump-related errors, many resulting in patient injury or death. “We take an oath to do no harm, so even though I’m not a trained engineer, I felt an obligation to make the drug infusion pumps used on a daily basis in hospitals safer, smaller and more reliable,” he says.

In 1985, Dr. Sims and a small team of engineers from the MGH Department of Biomedical Engineering began work on the first in a series of improved infusion pumps — the calculator pump — developed to prevent errors commonly made in complex dosage calculations. By the late 1980s, calculator pumps had evolved into small, portable devices that could travel alongside patients throughout the hospital safely dispensing standardized, pharmacy-prepared drug mixtures. Encouraged by the efficacy of the calculator pump and hoping to make use of newly available microchip technology in the next iteration of his device, Dr. Sims convened a working group at Mass General in the early 1990s to take infusion pump innovation to the next level; the group included M. Ellen Kinnealey, BSN, RN, advanced infusion systems specialist at MGH, Margaret Clapp, director of the MGH Pharmacy, Harry Demnoaco, MS, director of the MGH Innovation Support Center, and Gayle Fishman, BSN, RN, MBA, vice president of Patient Care Services at Massachusetts Eye and Ear Infirmary and long-time consultant to the Sims Lab.

“Our goal was to improve the everyday technology so that it was as cutting-edge as the procedures and clinicians who depend on it,” says Dr. Sims. He is also an accomplished pilot who drew inspiration from aviation safety technology while tackling the re-invention of the drug infusion pump.

Dr. Nat Sims’ Smart Pump is the quintessential example of user-driven innovation, an important trend in the development and refinement of technological devices at the site of implementation.

The Sims team began developing prototypes of pump software designed to alert caregivers to potential dose errors throughout the infusion process as well as a program to manage drug libraries customized with pre-defined dose limits and other safety parameters for each patient care area. By 2009, the innovation had spread globally, and every pump at a patient bedside throughout the Partners HealthCare system was “smart” — providing electronic safety assurance to clinicians as they deliver highly complex drug therapies.

These critical improvements to pump technology have come not a moment too soon. Federal officials, concerned about the many reports of intravenous drug delivery incidents and serious injuries linked to malfunctioning infusion pumps in the U.S. since 2005, are tightening their regulation of the devices. They announced an “Infusion Pump Improvement Initiative” in April 2010, linked to major changes in the process by which the FDA grants device manufacturers approval to market medical devices.
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"I’m thrilled that the Smart Pump is seen by some as a harbinger of a new era of improved patient safety,” says Dr. Sims, who is currently serving as academic co-chair of the Association for the Advancement of Medical Instrumentation (AAMI) Infusion Device Committee, which is working with the FDA to develop more rigorous standards for the design and manufacture of infusion pumps. The anesthesiologist attributes much of his team’s success to the supportive environment at Mass General, a “one-of-a-kind hospital that provides a protected space for innovation in the thick of the day-to-day workload.”

Innovation, in fact, has become the routine for Dr. Sims and his colleagues in the Department of Anesthesia, Critical Care and Pain Medicine at Mass General. Dr. Sims is an inventor on more than 10 Mass General patents for medical devices. Among them is a flexible monitoring system, allowing patients to receive care outside of the intensive care unit, as well as a critical care transport system, developed in response to growing concern over hazardous and inefficient transport of patients between operating rooms (ORs), intensive care units and other acute care settings.

The breakthroughs Dr. Sims has made in his inventor’s shop are part of a long tradition of medical innovation at Mass General, birthplace of the anesthetic application of ether during surgery in the 19th century all the way up to the more recently developed port system, developed in response to growing concern over errors occur once in every 135 operative cases, the approximate daily surgical caseload at a hospital the size of Mass General. Dr. Levine’s group did some preliminary research and discovered that fewer than a quarter of syringes used in the OR were properly labeled. They wondered whether radical improvements might be possible by developing a user-friendly system involving prescription bar codes and automated syringe labels.

“We aimed to go above and beyond the Joint Commission standards at a time when basic compliance was itself a challenge,” says Wilton Levine, MD, clinical director of the MGH Department of Anesthesiology, Critical Care and Pain Management and leader of what soon became known as the Smart Label Project. The Joint Commission standards require each intravenous medication administered in the hospital to be labeled with information including medication name, concentration, dilution, preparation time and date, expiration time and date, preparer’s name and site-specific warnings and messages — all of which is traditionally hand-written on color-coded labels by caregivers in one of the fastest-paced settings in the entire hospital. Yet drug errors occur once in every 135 operative cases, the approximate daily surgical caseload at a hospital the size of Mass General. Dr. Levine’s group did some preliminary research and discovered that fewer than a quarter of syringes used in the OR were properly labeled. They wondered whether radical improvements might be possible by developing a user-friendly system involving prescription bar codes and automated syringe labels.

“We had a great idea — one that could minimize human error and make patients safer — but we weren’t engineers or programmers. We got stuck,” recalls Dr. Levine. “At any other hospital, we might have stayed stuck, but Mass General dedicated resources to fostering innovation.” Weeks into the Smart Label Project, Dr. Levine’s team reached out to Dr. Sims for guidance. The patient safety technology pioneer became “an instrumental father figure” to the fledgling project, providing technical recommendations as well as putting the team in touch with the Sims Lab-founded MGH Innovation Support Center and Partners Research Ventures and Licensing (RVL), both of which encourage the work of Mass General clinician-innovators.

By 2009, three years after Dr. Levine and his colleagues first assembled to address medication label errors, the Smart Label prototype was ready. Originally designed specifically for use in ORs, the Smart Label system is a relatively inexpensive, stand-alone technology that can be integrated seamlessly into the workflow of most patient care environments. It works by scanning a bar-code-labeled medication vial, providing visual and audible confirmation of drug name and concentration, delivering warning messages regarding patient allergies, expired syringes or recalled drugs, and printing color-coded labels to apply to each syringe.

Typically, the entire Smart Label process lasts seconds, printing out error-free labels before the syringe is fully prepared and saving time without compromising patient safety. In a recent pilot program, in fact, Dr. Levine’s team discovered that their Smart Label system eliminated labeling errors entirely. Incredible, the caregivers testing the product for the pilot required no training on the system and 97 percent of participants found it effective and easy to use.

“The Smart Pump and Smart Label systems developed here at Mass General are already making a difference for our patients,” says Gregg S. Meyer, MD, MSc, senior vice president of Quality and Safety at MGH. “Importantly, the work started here by Drs. Sims and Levine and their colleagues has been shared openly — providing a model of how to put information technology to work to improve patient safety.”

Dr. Sims chalks up much of his success to the culture that surrounds him. “The rich brew in which innovation can survive is mysterious — it’s deep-seated and complex and MGH can authentically lay claim to it,” he says. “An institution truly puts patients first if it encourages caregivers to speak up, to dedicate energy to raising standards.”

Adds Dr. Levine, “We as clinicians have an obligation to think about patient care very broadly. We help patients not just by performing surgeries or prescribing medications, but by staying vigilant and working to make the hospital a safe place to heal.”

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