

Ambulatory Infusion Pump Technologies New Developments and How They Might Affect Alternate Site Care

The innovation that spawned the home and alternate site infusion therapy industry has always been—and still is—intertwined with developments in technology.

After all, the creation of the lightweight ambulatory infusion pump was what made infusion therapy outside the hospital possible in the first place. The fact that there was a market in offering services that both improved patient lives and created cost savings for payers is what continued to drive the sector's growth.

Now, no longer a fledgling industry, home infusion therapy is still evolving. And its evolution can still be tied to ongoing technological developments and the need to treat patients as cost-effectively as possible. As so many veterans have seen, these intertwined relationships can at times become frustrating. For example, when the cost of investing in new technology is a barrier to realizing operational efficiencies.

Data collection and trending, patient safety protections, instant interfacing between and among clinicians, patients, information systems, and more are all driving the innovations in devices that will eventually reach our market. A look up the pipeline, we can see what features are likely to trickle down into our market in the future.

Philosophical debates aside—for now anyway—medical devices will continue to change, adapting to the needs and priorities of the health care industry. Data collection and trending, patient safety protections, instant interfacing between and among clinicians, patients, information systems, and more are all driving the innovations in devices that will eventually reach our market.

With home infusion still such a small percentage of the overall health care market, pump manufacturers understandably design their leading pump technology for the inpatient market. These devices are then adapted and further developed for the outpatient market. So, by taking a look up the pipeline, we can see what features are likely to trickle down into our market in the future. For a brief history of how we got here, see the box on p. 21.

Patient Safety Features

Patient safety as it related to electronic infusion pumps has long been a focus of regulatory and accrediting bodies. In its 2007 Ambulatory Care Patient Safety Goals the Joint Commission established six key goals in this area, three of which are directly related to infusion technology including:

- ★ Improvement in the accuracy of patient identification
- ★ Improvement in the safety of using high-alert medications (i.e. PCA medications)
- ★ Improvement in the safety of using infusion pumps



These goals combined with the increased activity and focus by the Institute for Safe Medication Practices (ISMP), MedWatch, and the 2004 FDA enactment of bar code label requirements for the delivery of human drug and biological products have aided in heightening the attention the industry is placing on the development of new technology to improve safety and to assist health care providers in meeting potential new standards.

Ideally the use of bar codes on all medications, including IV solution containers, would help facilitate the implementation of a complete system within a health care facility or operation. Included in this system would be bar code scanners and computerized databases, where, among other things:

- ★ A patient would have his or her drug regimen information entered into a computerized database.
- ★ Each drug would have a bar code. The bar code would provide unique, identifying information about the drug that is to be dispensed to the patient.
- ★ In hospitals, health care professionals, such as pharmacists and nurses, would use bar code scanners to read the bar code on the drug before dispensing the drug to the patient and to read a bar coded wristband on the patient before giving the drug to the patient.
- ★ In an outpatient setting, the health care professional could scan the bar code on the drug and compare the scanned information against the patient's electronic prescription information before dispensing it to the patient.
- ★ The bar code scanner would transmit information to the health care provider's computer system where it would be compared and checked against the patient's drug regimen information.

Today health care product manufacturers are incorporating new technology and capabilities into their equipment to help providers meet this growing demand for greater medication delivery safety. Infusion pump companies are specifically focused on the development of "smart pump" technology, which is already being implemented in the inpatient setting—a recent report indicates that 37 percent of hospi-

Exhibit 1

Smart Pump Features and Capabilities

- ★ Integration with bar code technology
- ★ Hospital- and formulary-specific drug libraries
- ★ Dose calculation modes
- ★ Soft and hard programming limits for each drug
- ★ Customization options to meet best practices
- ★ Monitoring of patient vital signs such as blood pressure, heart rate, and respiration for patients on IV narcotics and other high-risk medications
- ★ Wireless network access, allowing real-time monitoring of infusions and alarm conditions
- ★ Real-time access to infusion status and data
- ★ Reduced manual programming steps

tals have adopted this technology (See Exhibit 1 for a list of "smart pump" features and capabilities).

As ambulatory infusion pump companies have found applications for these technologies outside the hospital, they have now begun to incorporate similar capabilities into their equipment. Today manufacturers of ambulatory devices offer a growing list of options that can help providers not only increase drug delivery safety, but potentially increase staff productivity as well.

Home infusion providers have a variety of existing technologies to choose from. Among the latest are:

- ★ **CME (www.cmedevices.com).** CME pumps offer downloadable 24-hour patient histories and 500 event history records. Models include: BodyGuard 323 multiple therapy pump, Body Guard 575 pain management pump, BodyGuard 545 epidural pump, BodyGuard 121 twin ambulatory dual-channel pump, and Applica 2002 multi-therapy children's pump.
- ★ **Curlin Medical (www.curlinmedical.com).** Curlin Medical (distributed through B.Braun Medical; www.bbraunusa.com) offers a line of ambulatory devices including: PainSmart™ and 4000 CMS™. Through their CMS™ Software Management System, which will work with Microsoft Windows™ operating systems, these pumps are capable of: uploading a pre-programmed and verified protocol from the drug library, being programmed with a prescription specifically written for a

patient from the Patient Library, and downloading a programmed therapy from the pump into a PDA or PC for documentation, validation, or verification. The system also has the capability to utilize a bar code package, which reads a 2D label, and aids in automating the programming of Curlin devices. Curlin Medical infusion pumps maintain up to 6,000 retrievable and printable infusion events in their memory.

★ **Delphi Medical Systems (www.delphimedical.com).**

Delphi Medical Systems, based in Troy, Michigan, manufactures and sells the IVantage™ a small, lightweight multi-therapy ambulatory infusion device that among other features maintains up to 1000 events in its history.

★ **Hospira (www.hospira.com).** Hospira, one of the three IV solution providers in the U.S. manufactures and markets the Gemstar® multiple therapy pump and pain management pump. The Gemstar® devices provide a 400-infusion event history log.

★ **Q-Core, Ltd. (www.q-core.co.il).** Q-Core, an Israeli-based company, manufactures a line of hospital and ambulatory infusion equipment based on their patented EFC™ technology (electromagnetic flow control). The company's AP-34 infusion pump provides a history of more than 4,000 events that can be viewed by either date or by specific error codes. Q-Core is in the process of introducing a new management system for its devices that uses integrated drug libraries and will enable real-time local and remote monitoring of the infusion process along with the ability to access patient and treatment histories. Q-Core products are not currently available in the US, but the company is targeting the fourth quarter of 2007 for introduction of their products into the US.

★ **Smiths Medical (www.smiths-medical.com).** Smiths Medical, located in St. Paul Minnesota, provides the market with a number of ambulatory electronic infusion devices including: CADD Legacy® infusion pumps, CADD MS™ (micro-infusion), CADD Prizm® PCS, and CADD Prizm® VIP. CADD Legacy® infusion pumps keep a history of the last 1,000 infusion events and the Prizm® devices maintain a history of the last 500 infusion events in their memory. Earlier this year Smiths Medical introduced its CADD – Sentry Pro™ medication safety software which provides enhanced safety systems for the programming of their pain management pumps (CADD Prizm® PCS II) and through the use of an external PC allows: entering and storing pre-established pain management protocols, saving and managing the protocols on the main computer

network, and programming their pain management pumps via a computer interface.


Research and development activities, in each of these companies continue to evaluate market trends and needs and work on various aspects of patient safety and remote communication capabilities to meet future provider requirements.

Other New Technologies

In recent years alternate site infusion providers have indicated that they are once again evaluating new equipment and looking to replace their existing infusion technology. This renewed interest, along with recent recalls of pumps in the market, have once again opened up opportunities for new infusion pump manufacturers and their technologies. New companies and the technologies they are developing include:

★ **Fluidnet (www.fluidnet.net).** Fluidnet, a New Hampshire-based start-up company, is developing a family of fully featured infusion devices. The devices, which are still in development, are being designed for use in both hospital and alternate site infusion environments. The product platform is based upon a closed-loop control system using a pneumatic fluid drive combined with real-time flow sensing, active air elimination and real-time volume sensing of the fluid container. The infusion devices can use any manufacturers' and any size IV containers and are designed to capture the entire IV container within its molded frame. The products, which the company has targeted to assist providers in reducing costs related to equipment, disposables, and service while improving nursing efficiency and patient safety, use an advanced open-architecture for information manage-





ment. Their wireless connectivity capabilities provide remote monitoring, troubleshooting and/or reprogramming within the hospital or at home. The system also offers an optional RFID (radio frequency ID) labeling and device reader to automate the programming process from the pharmacy label. This capability can be combined with Fluidnet's AutoDose multi-drug, multi-chamber fluid container to further simplify complex dosing and SASH therapy requirements. Fluidnet's devices are targeted to be available in the latter half of 2008.

★ **MAAS Medical.** MAAS Medical located in Irvine, California, is developing two new infusion systems for both hospital and alternate site IV deliveries. The large volumetric pump for the acute care market, ambulatory pump for closed-loop delivery of immune globulin as well as emerging biologic drug therapies are based off the same next generation platform technologies. These advances include:

- ★ Wireless connectivity for improved safety and fleet management
- ★ Closed-loop delivery for improved home care safety and productivity

These products also have enhanced interoperability and data management tools for quality improvement, clinician and patient training. MAAS Medical and their products are focused on providing technology that will improve patient safety and clinical productivity.

The More Things Change, the More They Stay the Same

While all these developments are great, providers are often left struggling with how to pay for them. For years, alternate site providers have faced the continuing dilemma of providing the best possible and safest care for patients, who are located a significant distance away from them, and doing it in the most cost-effective manner possible.

Many providers indicate that the majority of the therapies they administer do not require the sophistication that new technology provides. They argue that historically the delivery of alternate site IV therapy has been very safe and effective and in order to provide cost-effective care, they need to use a wide variety of infusion technologies, including a reliable stable of "workhorses" that do not have a variety of bells and whistles. For many, the level of information and communication capabilities that are being adopted in

the hospital setting just isn't necessary or in the realm of possibility for them. These providers have come to rely on some lower-tech methods, such as gravity infusions and devices such as:

★ **Freedom60 Syringe Infusion System.** Repro-Med Systems (www.rmsmedicalproducts.com), located in Chester New York, manufactures the Freedom60 syringe infusion system, a non-electronic constant flow syringe system that provides a constant infusion pressure with no bolus, no runaway, and no free flow features. It is simple to use and to train and has been successfully and widely utilized for the infusion of: antibiotics, vancomycin, desferal, chemotherapy, IV push medications, and subcutaneous immune globulin. The FREEDOM60-FM model is available with a Flow Monitor alert system and provides an intermittent audible tone should flow stop, or when the infusion has ended. Unlike other occlusion alarms, the FREEDOM60-FM monitors the actual flow rate of the pump and not over-pressure, since the FREEDOM60 cannot create an overpressure condition beyond 13.5 psi.

★ **ambIT® Infusion System.** Sorenson Medical (www.sorensonmedical.com), located in West Jordan, Utah, manufactures and markets a line of small, lightweight, ambulatory electronic infusion devices called ambIT®. The ambIT® product line consists of the ambIT® PCA, ambIT® PreSet, and ambIT® Continuous pumps. The PCA and PreSet models are designed for IV PCA, epidural blocks, continuous peripheral nerve blocks during and after surgery and the infusion of local anesthetics directly into surgical wound sites. The Continuous model is geared towards the ambulatory delivery of continuous IV medications, such as 5FU or Folfox in the outpatient setting. All the devices are programmable, incorporate a series of alarms, and provide a record of infusion history.

★ **Eureka Infusion Technology.** Universal Medical Technologies (www.umtinc.com), a Larkspur, California-based start-up company, is in the process of finalizing the development on their Eureka-IP and Eureka-LF infusion systems. Both systems are battery-operated, lightweight, low-cost devices. The Eureka-IP is designed primarily for the delivery of IV antibiotics and can infuse from standard Baxter or Hospira 50 mL or 100 mL IV containers. The Eureka-LF is a low-flow device with pre-

History Lesson: Pumps and Home Infusion

In order to understand what products and features manufacturers bring to you or any other market, it's essential to understand that, as businesses, they are reacting to the potential for sales in that market.

The first decade of the home infusion industry (1970s to 1980s) was marked by unparalleled growth, spawning a concurrent corresponding growth in ambulatory infusion technology to meet the market's changing and increasing infusion needs.

However, by the early 1990s, the landscape for the alternate site infusion provider began to change. Persistent ratcheting down of reimbursement resulted in a significant consolidation of providers and reduced profitability for the remaining companies. As such, providers wishing to survive had to quickly redesign operations and cut costs. This resulted in reduced staff, especially in-house nursing, and significant pull back on purchasing of new technology, especially new electronic infusion technology. Many providers relied on extending the lives of their existing pumps and reconsidering how certain therapies were delivered opting for lower-tech methods, such as gravity infusions.

During this period, which stretched into the early-2000s, alternate site infusion providers primarily focused on understanding and controlling their businesses and improving their internal business systems—this was not a time to invest in new technology. These changes had a ripple effect on the pump market and soon manufacturers began to experience bumps in their business landscape as well. As a result the market saw a significant reduction in the number of pump companies and a subsequent

reduction in the number of infusion devices that were available. Most importantly, manufacturers put the development of new technology on hold as they began to internally reevaluate their strategies and look for new market applications for their products.

Historically, ambulatory infusion pumps were primarily used by alternate site infusion companies were far different from the clunky, stationary models used inside the hospital. However, by the late-1990s and early-2000s that began to change; partly because pump companies were looking for new opportunities and partly because hospitals were interested in using smaller, ambulatory devices for certain patient populations, especially for pain and cancer patients being treated in their outpatient clinics.

This transformation corresponded with the draw-down in purchasing on the ambulatory side, so manufacturers began to focus their attention on new opportunities that were beginning to open up for them in the hospital market. As this new market began to take hold, two very significant occurrences shaped the market—and thus the devices that were developed.

First was a broadening and greater concern over patient safety, specifically related to medication delivery. The second was an overall trend toward further automation and real-time information sharing. Hospitals wanted pumps that could interface with their computerized patient care and billing systems and that demonstrated increased patient safety protections. Home infusion providers may soon find themselves investing in devices with these capabilities for the same reasons.



set flow rates of 1 mL, 2 mL, and 5 mL per hour. In addition, the company has a Eureka-LV device in development that allows IV fluids to be delivered at rapid flows (e.g., 500mL/5min).

Despite the need to keep operational and equipment costs under control, alternate site providers do recognize that the capabilities of the newest technology offer them advantages that the simpler-designed products lack. In a 2005 survey of home IV providers published in the July/August 2005 issue of *Infusion*, respondents ranked drug and concentration selections, pump history reporting (via remote download), pre-programmable dosage levels, medication error alerts, and remote programming ability among the infusion pump “smart features” they viewed as most important.

Although arguments can be made for the use of the computerized interfaces, drug and protocol libraries, and wireless communication capabilities that are being adopted in hospital environments, the implementation and adoption of such technology in the alternate site market is not as clear. The key questions facing alternate site providers is do they need the same level of sophistication as a hospital? What features are most applicable? How does the technology affect the cost of providing care to patients outside the hospital? And, what is the acquisition and implementation cost?

Advantages to adopting this technology include:

- ★ Improved patient safety through the use of bar coding or similar technology to confirm the Five Rights Test (right patient, right drug, right dose, right time, and right administration method)
- ★ Automatic programming for the correct infusion parameters—especially helpful when nursing personnel are unfamiliar with the pump
- ★ Communications capabilities to handle pump problems, reprogramming issues, etc., from a distance without having to send a nurse into the home
- ★ Ability to access infusion status information and history remotely over the Internet or via other computer technology

- ★ Enhanced training capabilities that can assist nurses, patients, and caregivers

In addition, the potential liability costs of medication delivery errors need to be considered against the cost of acquisition and implementation. With 54-percent of potential adverse drug events (ADEs) associated with IV medications and the median cost for resolving a preventable ADE at approximately \$750,000, the rewards of managing risk could far outweigh the initial costs of investing in equipment.

While these benefits on the surface seem very advantageous the implementation, in the alternate site environment, is far more complicated than it looks. First and foremost is the inherent cost in the conversion of existing technology to newer technology that incorporates these features, especially in light of the ongoing and continuing uncertainties related to reimbursement. While the connectivity issues that prevented earlier adoption of remote communications and product interface technologies have vastly improved they are still not totally perfected. In addition, needed interfaces with existing provider computer and software programs may be difficult to manage or not even possible.

At this point we don't know to what extent the use of the new medication delivery technology will be mandated and how broad those mandates may be. However, it can be envisioned that mandates for safer IV delivery in the hospital could easily be applied to IV delivery in all environments. This potential, along with the growing patient population in the alternate site environment and continuing pharmacy and nursing shortages, can make a strong case for adopting technology that allows the provider to interface and communicate with infusion equipment from a distance. Providers who are considering the acquisition of new infusion technology need to stay informed and be prepared to evaluate how these ever-changing devices fit into their practice. ■

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