IMPROVING INTRAVENOUS THERAPY: OPPORTUNITIES FOR DESIGNING THE NEXT GENERATION INFUSION SYSTEM

PART 3 – WORKFLOW EFFICIENCY & COST-EFFECTIVENESS
In this three-part series, we strive to provide an overview of the current status and apparent effectiveness from the user’s point-of-view of infusion pump design. We acknowledge the advances in the field while highlighting opportunities for future improvements. In focusing on some of the usability issues of current pump interfaces and insufficient interoperability, we highlight some of the existing pitfalls and offer human factors-based guidance for next-generation designs. Here, we define infusion pump usability as the relationship between the technology and clinicians’ ability to use that technology to attain their work goals effectively, safely, efficiently, and with both clinician and patient satisfaction.

In this, the third part of the series, we focus on issues related to the general usability, process efficiency and cost effectiveness of infusion pump use. We also address current shortcomings of the integration of infusion pump technology with medication management software.

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An important added benefit of optimal pump designs is the prospect of significant cost savings. Each preventable ADE has been reported to cost nearly $9,000,[1] and smart pumps could, through built-in designs to adhere to the “Rights,” decrease the incidence of ADEs (see Part 1 of this series for more information on this topic). Indeed, not only is avoidable patient harm wrong, it has proven to be expensive. Moreover, care process inefficiencies cost the healthcare system significantly in an era when we are spending far too much for the care quality offered.

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The Society for Actuaries suggested that the financial cost of medical errors was nearly $1 trillion per year when including both the direct and the indirect (e.g., lost and decreased patient life quality) costs.\textsuperscript{[2]} Considering the impact of IOM’s arguably conservative 2001 estimate of nearly 100,000 medical error-related deaths annually, researchers and policy experts have called medical error ‘America’s most important public health issue’. What might seem like a small error can snowball, producing exponential effects on the patient and their cost of treatment. Without a system-wide focus on quality of care, the moral and financial burden of avoidable injury and death will continue to plague healthcare systems worldwide. Preventable medical harm, as one of the top ten causes of death in the United States, is an epidemic that must be addressed through new approaches that are based on the best available evidence. Technology has a role in reducing injury and cost, but only if it is designed and implemented correctly. We now focus on opportunities for infusion technology to be contributors rather than detractors to the efforts to substantially improve the overall value of healthcare processes.

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Drug library creation and maintenance

A recent survey found that hospitals using smart pumps typically adopted this technology due to "inventory age and failure" rather than as part of an overarching "safety strategy." Moreover, these hospitals were unable to integrate their new pumps with other medication management technologies (i.e., CPOE, BCMA), thereby limiting the ability of their pumps to fully address the Rights. As one indication of the limitations of Dose Error Reduction Software (DERS), only about one-half of the hospitals surveyed implemented hard limits on their pumps. Further, a major reason for DERS noncompliance was incomplete or outdated hospital drug libraries.

For smart pumps to attain their safety improvement potential, drug libraries must be maintained and trusted by the staff. Many installed infusion pumps still do not have wireless functionality; these pumps need to have their libraries uploaded manually, a time-consuming (and therefore expensive) burden on the organization’s Healthcare Technology Management (HTM, formerly called clinical engineering) professionals. In most hospitals, the ongoing management of the pumps’ drug library typically falls to pharmacists. Given hospital pharmacists’ current workload and the rapidly changing landscape of available pharmaceuticals, it can be extremely challenging to keep a pump’s drug library up-to-date. To the extent that newly available medication safety information has not yet been implemented in a drug library, preventable harm may reach the patient. Another risk of an out-of-date drug library is that clinician users will not find a desired drug in the library and then bypass the DERS safety features in favor of unlabeled milliliter per hour infusions.
Much of inpatient nurses’ time is consumed by ‘low value’ tasks (bundled into what is often called ‘indirect patient care tasks’). Infusion pumps are a major contributor to these care process inefficiencies. According to modern quality improvement practices such as LEAN or Six Sigma, such tasks, which do not generate real value for the organization or the customer (in this case, our patients), should be minimized if not eliminated. In the case of infusion therapy, lower value time-consuming nursing tasks included searching for available pumps, priming tubing (including air elimination), manual pump programming, responding to false or unnecessary pump alarms, and managing tubing spaghetti (i.e., tangled plumbing) and secondary infusions. Redesign of infusion technology must consider and address these inefficiencies. Given the very high cost of nursing in most facilities, efforts to reduce these low value tasks will improve nurses’ job satisfaction and yield significant cost savings for the organization. In the following sections, we discuss specific opportunities for improvements in infusion therapy.

According to modern quality improvement practices such as LEAN or Six Sigma, such tasks, which do not generate real value for the organization or the customer (in this case, our patients), should be minimized if not eliminated.
When administering multiple infusions to a single patient, pump and tubing management is currently a frustrating, time consuming, and error prone task for both nurses and anesthesia professionals. As a worst-case example, imagine a cardiac surgery patient (either in the OR during surgery or in the ICU immediately afterwards) who is on a dozen or more infusions of vasopressors, inotropes, sedatives, analgesics, muscle relaxants, antibiotics, pro-coagulants, antiarrhythmics, electrolyte replacements, and blood products, each with its own pharmaceutical constraints (e.g., drug-drug interactions and incompatibilities, flow rate limits, etc.). These infusions, as well as carrier and volume replacement fluids, are infusing through multiple peripheral and central intravenous routes. You can see how difficult it can be for the clinician to maintain an accurate mental model of what drugs are administering into what catheters. Current infusion systems do little to support this critical management task. The clinician is constantly fighting with (and sometimes tripping over) equipment and tubing. Errors are common and adverse consequences have been well documented.

The effective coordination of concurrent therapy is important. Two medications being infused by different pumps may be contraindicated to be infused through the same IV line. The concurrent infusion of two drugs, one acidic and the other alkaline, can produce an insoluble salt that occludes the IV. Alternatively, one drug running through the same line may inactivate the other. Drug-drug incompatibilities can also occur when drugs are infused through different IV sites. For example, the effects of one drug can alter the effects of the second one. There are reports of inadvertent double dosing when one clinician starts an infusion, fails to notify another clinician (or the EHR system fails to do so), and then the second clinician gives a second dose of the same drug. A more subtle adverse consequence of numerous infusions in the same patient is fluid overload. In the patient on fluid restriction (e.g., someone with heart failure or brain injury) neither the pharmacist nor the bedside nurse may be aware that the myriad infusions of intravenous medications accumulate to a total fluid volume that exceeds the desired level of hydration. Thus, when there are multiple infusion pumps on the same patient, the pumps should communicate with each other thereby enabling appropriate bedside decision support related to drug-drug interactions, drug incompatibilities, and total fluid therapy goals.

In addition to a dearth of effective tubing management technology, the management of numerous infusion pumps is problematic. In the typical ward patient on just one or two infusions, the total space (or volume) and weight consumed by 1-2 infusion pumps, tubing, and an IV pole is usually manageable, although the risks of physical harm during transport is well described. But now consider our cardiac patient who may have as many as 16 pumps at the head of the bed (along with monitors, ventilators, and other supportive technology). The total weight and bulk of pumps, fluid sources, and tubing is a major impediment to rapid access to the patient as well as safe and efficient clinical practice. Further, current multiple line infusion pumps have numerous different bags of drugs and fluids hanging above them. Use errors are commonly reported related to the difficulties clinicians have trying to figure out which drug/fluid source is associated with which pump or pump channel. Thus, better methods of organizing, handling and transporting pumps and their associated drug/fluid sources and tubing need to be developed and promulgated. In addition to smaller, lighter, easier to use pumps, greater effort must be invested in tubing management systems and to allow clinicians to organize fluid/drug sources in different ways.
Most patients only have one IV and the most common use of that IV is for hydration administered as a milliliter per hour infusion of a crystalloid solution. Even when a patient who is able to take oral fluids (and thus does not need IV fluids) is on a regular IV drug regimen (e.g., intermittent IV antibiotics), it is still common to administer a low rate of IV fluids to maintain vein patency and to flush through the drug doses after they are complete. Thus, nurses often administer secondary or piggyback infusions in which the drug dose is attached to an already active IV fluid infusion at a Y-site above the infusion pump inlet. To assure preferential flow of the secondary infusion, that IV bag must be hung higher than the primary fluid bag. These secondary infusion sets use a back-flow (or check) valve to prevent retrograde flow from the primary to the secondary fluid sources. The desired dose of drug from the secondary source is then programmed into the infusion pump.

However, this very common bedside ‘plumbing’ arrangement is prone to medication errors. A 2012 report, Mitigating the risks associated with multiple IV infusions\(^{(5)}\) described how, without the proper set up, secondary infusions can infuse via pump at uncontrolled and often incorrect rates. Disturbingly, these flow rate errors can be insidious, without detection by the pump or the user. Therefore, secondary infusions should never include continuous high-alert medications. Smart pumps should be designed to eliminate the risks of secondary infusion errors and, further, should reduce the complexity currently associated with administering more than one drug or fluid to a patient through the same IV site.
Many clinicians naively believe that drugs administered by infusion pump at a specified rate always infuse continuously at the set rate with substantial accuracy. Instead, current infusion technology can administer fluids at highly discontinuous rates, including long periods of little or no infusion into the patient. The best examples of this flow discontinuity occur with small-bore IV catheters that cause high distal infusion pressures, and at low infusion rates. In such situations, as might be seen in a sick neonate, long periods (tens of minutes to even hours) may pass with little or no infusate actually entering the patient despite the indication on the pump of a ‘continuous’ rate. Moreover, in these circumstances, not only are flow rates typically far less accurate than the pump company’s advertised ±5% but a distal occlusion, say due to an infiltration or distal plumbing problem, may not produce an alarm for tens of minutes to even hours.

Further, clinicians do not typically appreciate the tremendous influence of downstream plumbing on flow continuity. While most clinicians are familiar with the occurrence of downstream alarms, for example, after giving a downstream bolus of drug or temporarily occluding a line to reposition it, far fewer appreciate the fluid dynamics of the resulting occlusion followed by a post-occlusion bolus due to the pent-up pressure. Next generation infusion technology must reduce flow rate fluctuations where possible and, more importantly, make the actual dynamic flow profile more transparent to the user.

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Patients rarely stay in the same place for very long. Even very ill patients can require transportation to imaging tests or procedures. In fact, based on better outcomes in recent studies[6], critically ill patients are now being routinely ambulated – Picture a patient with multiple life-threatening conditions receiving multiple infusions via pumps, on a mechanical ventilator, etc. walking (with assistance) the halls of the intensive care unit. The increasing emphasis on patient ambulation argues for next generation pumps to be smaller, lighter, and more portable. Further, during transport, electromechanical technology must be on battery power. While hospital-based pumps have battery power (typically allowing at least 4 and up to 8 hours off AC main power with a full battery), unlike dedicated ambulatory pumps, their design priority has not been on extended battery life.

Locating the missing pumps

It has been reported that as many as one in five infusion pumps in a hospital are “lost” at any one time thereby requiring hospitals to have far more pumps than they really need clinically. With deliberate investigation, these ‘lost’ pumps are typically found abandoned in remote parts of the facility (a corner in recreation therapy) or hidden (i.e., hoarded), for example, in a closet on a unit for ‘just in case’ use. Some hospitals have begun to use a location management technology such as active RFID to be able to keep better track of their pump inventory. Because current pumps do not typically have appropriate built-in technology, this feature becomes an expensive ‘add on’. Next generation pumps should include ‘location aware’ technology to facilitate not only asset tracking but improved adherence to the ‘Rights’ by being better able to associate specific pumps with specific patients.
The American healthcare system, like those in other developed nations, has begun to aggressively embrace health information technology (HIT) as a panacea for improving value (i.e., benefit/cost), safety, efficiency, and even patient satisfaction. In fact, there is only limited scientific evidence to support the widespread belief in this ‘technology elixir,’\textsuperscript{[7, 8]} and ample examples of false starts and abject failures.\textsuperscript{[9]} Nonetheless, HIT is here to stay and does provide opportunities to improve the safety and efficiency of infusion management. In this section, we discuss the potential for automated pump programming and administration documentation as well as opportunities for more patient-tailored therapy.
Automated programming and documentation

Why if the existing HIT already contains the essential patient-specific medication therapy information, is this not routinely and automatically sent and available on the appropriate infusion pump (i.e., ‘electronic data input’)? Why don’t pumps routinely and automatically send their infusion information to the existing HIT for therapy verification, clinical documentation, and other purposes like decision support (i.e., ‘electronic data output’)? These notions are not new nor are the impediments technological. Further, some pump vendors are already doing one or both with selected HIT vendors in a few “pilot sites.” There are many reasons (see Table 1) for the still infrequent occurrence of data interconnectivity between pumps and HIT, as well as other devices such as physiological monitors. However, it is hoped that these impediments can be overcome given the long list of potential benefits in terms of patient safety, care efficiency, therapy efficacy, and patient/clinician satisfaction such a new world order would engender.

What might this look like? Consider this future scenario:

Nurse Jim Smith receives a text message on his cell phone that an IV gentamycin dose is due on his patient Gilda Jones in Room A42 (who was admitted to the hospital with a pneumonia requiring IV antibiotics). Jim goes to the medication dispensing station and types in Gilda Jones’ name. Because it is due in a few minutes, the gentamycin order is presented at the top of the list of all of Mrs. Jones’ medication orders. After Jim reviews and selects the gentamycin, the correct unit dose is dispensed in an IV bag that also contains an RFID tag. Jim takes the bag into Room A42 and assesses Mrs. Jones. Jim then logs into the IV pump (currently administering maintenance fluid therapy) with his fingerprint and unique ID code. The pump then asks Jim to confirm the patient’s name and medical record number. He does this with a secure custom application on his cell phone, linked by Bluetooth to the pump, that reads the RFID tag on Mrs. Jones’ wrist band and transmits it to the pump. The pump then presents a list of pending orders for Mrs. Jones that shows the gentamycin order first (since there were no over-due orders and it is the most current order). After plugging the distal end of the gentamycin bag’s tubing into the pump’s secondary inlet port, Jim selects the gentamycin order, confirms all of the “Rights” on the screen and hits “start infusion.” The time that the infusion starts and its other attributes are automatically be sent to the EHR as well as to the Pharmacy’s computer system.

Table 1.

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<th>Some Impediments to Ubiquitous Data Transfer between Pumps and HIT</th>
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<td>Lack of robust national or international clinical data interconnectivity standards</td>
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<td>Lack of robust national and international standards for data terminology and format</td>
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<tr>
<td>Legacy device and software database architecture and other technological constraints that do not allow or facilitate data exchange</td>
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<td>Lack of incentives for HIT and infusion pump vendors to ‘play with each other’</td>
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<tr>
<td>FDA constraints and concerns</td>
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<td>Proprietary data formats and/or communication protocols</td>
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<td>Concerns about data integrity and accuracy (when received from an outside source)</td>
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<td>Cyber security concerns</td>
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To date, infusion pumps have accommodated patient’s weight and height as the only patient-specific attributes by which clinicians could assure medication safety. As but one example, if an infused drug to which the patient is allergic is inadvertently ordered, administration is the last chance to catch the error and prevent harm. If the pump ‘knew’ a patient’s medication allergies, it could generate an alert during pump programming. Unfortunately, few clinicians will be willing to enter patient allergies or other patient-specific data manually on an infusion pump (and manual entry is problematic due to potential data input errors). Hence, the value of a robust HIT system that is effectively interconnected to the infusion system software.

We know that many drugs’ effects are influenced by numerous pharmacokinetic (PK – the relationship between administered dose and blood levels) and pharmacodynamic (PD – the relationship between blood levels and both desired and undesired effects) factors. Patient age is perhaps the single most important factor affecting both PK and PD with reduced dosing generally warranted, all other things being equal, at both of the extremes of young and old age. Thus, an elderly patient may be much more sensitive to both the effects and potential side effects of a drug. Other important PK factors include patient gender, renal, and liver function. Other PD factors include heart, lung, and brain function, and the concomitant use of other drugs acting on those major organs. When two drugs acting on the same effect site are co-administered, the result is often more than additive (i.e., synergistic). If age and other PK-PD information was available in the infusion software then appropriate dosing guidance (e.g., during titration of a potent medication) or alerts/reminders could be appropriately activated and displayed on the pump. Access to this information at the time of programming about patient-specific dosing adjustments (i.e., effects on PK and PD) could substantially improve drug efficacy and safety while reducing unwanted side effects.
Electronic Dashboards

Additional HIT-integration benefits could be realized through the development and use of electronic displays of infusion therapy status. These displays, sometimes called dashboards, would be synchronized via wireless with all of a unit’s pumps. Such dashboards have the capacity to strengthen clinical workflow by highlighting issues and events as they occur and thereby allowing for intermediary action. For example, a dashboard on a tablet computer carried by a ward nurse who is covering 8 patients could inform her of an ongoing occlusion alarm in one room or a fluid infusion that has run dry. Similarly, an infusion dashboard at the central nursing station could highlight an air-in-line alarm in one room, or a new medication ordered to be administered to another patient. Nurses could thereby monitor multiple active pumps from a single screen, increasing efficiency, and more readily coordinating timely care with other clinicians on their team. Thus, with this technology, a fleet of pumps can be viewable and managed contemporaneously as they are being handled intelligently at the bedside. Such integrated task management technology could also reside as a web-app on a cell phone to provide the nurse with a continually updating “to do” list. Further, dashboards could help keep track of the pump fleet on a unit facilitate acquisition of an unused pump and avoid pump hoarding. With a different dashboard, pharmacists would monitor units’ pump fleets to identify when new infusions need to be mixed and delivered to the unit. Similarly, the pharmacist could identify any pumps that have not been upgraded to the latest version of the institution’s drug library. Another dashboard would allow healthcare technology managers to be able to monitor an entire hospital’s pump fleet for maintenance issues (e.g., need for battery replacement) or software upgrades. Much like the smart pump’s user-interface, these dashboards will need to provide usable, useful and actionable information.

DESIGN RECOMMENDATIONS
– EFFICIENT USE AND USABILITY

- **Cost reduction support.** Next generation infusion pumps, and their associated drug library software, need to better support modern healthcare’s emphasis on cost-reduction and value-based care through features that minimize waste, provide low cost alternatives, and decrease drug errors.

- **Greater healthcare worker efficiency.** Infusion technology must eliminate associated work process inefficiencies for nurses, pharmacists, healthcare technology managers, and anesthesia professionals. Pump fleets must be easier to locate, update, deploy and monitor. Individual pumps and sets must be easier to prime and program. Secondary infusions must be easier to fit into daily workflow, less time consuming to use, and safer.

- **Better pumps.** Next generation pumps must be smaller, lighter, more mobile, and able to run for extended times on battery power.

- **HIT integration.** Infusion pumps should do more to communicate with health care providers in real-time at the bedside and at the systems level to promote safety and clinical efficiency.
References


