

Time to Get Off this Pig's Back?

The Human Factors Aspects of the Mismatch Between Device and Real-world Knowledge in the Health Care Environment

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Objectives: Automated piggybacks are purported to make drug administration safer and more reliable. We evaluated the human factors of piggyback infusion, investigated the practice in our institution, and analyzed incidents from an anonymous database to better characterize the practice and substantiate these assertions.

Methods: To find examples of problems with piggyback, or secondary infusions, we searched the Food and Drug Administration's on-line incident database for incidents involving piggybacks. As part of a task analysis, 19 senior nurses each programmed 2 of 4 different pumps for a simulated piggyback infusion. To characterize infusion practice, we evaluated data logs from 55 infusion devices used in our institution.

Results: Incidents from the database provided strong evidence that potential problems existed with piggyback infusions. Nurse behaviors suggested mismatches between the task, user, and devices that can lead to adverse events. Log files showed piggybacks were a common practice, and that available safeguards were not used.

Conclusions: Our multiple data sources suggest automated piggyback infusion practice is neither simple nor safe. Incident report analysis suggests these findings contribute to adverse events. Further study is needed to understand and improve the safety of this practice.

Key Words: patient safety, human factors, infusion pumps, medical devices, incident reporting, cognition

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Piggybacks, or secondary infusions, are a common method for the delivery of intravenous medications. In this article, we attempt to reveal vulnerabilities in piggyback practice related to poor matching of task, operator cognition, and working environment, and raise questions about its safety. We intend this article for both practitioners and organizations; our intent is to encourage the assessment of current practice, raise vigilance about the perils of piggybacks, and encourage the exploration of other techniques for safe medication delivery. We restrict our analysis to a single infusion practice, but we believe our methods are adaptable and useful to many aspects of health care safety.

Although proposed patient safety improvements are numerous, there are few data demonstrating substantive improvement. In some cases, safety initiatives introduce new hazards into complex systems. As an example, one of the most widely advocated strategies to improve safety in hospitals, computer physician order entry, has been associated with new forms of failure¹ and even increased mortality.² A major impediment to the development of functional solutions is the poor characterization of the work environment and operator cognition, the way one interprets and responds to information from that environment. Such characterizations facilitate event detection, ways to mitigate risk or manage failure, design solutions, and novel approaches to problems. Without adequate work characterizations, proposed solutions (e.g., new technologies, techniques, and even incident reporting) are poorly suited to produce a safer health care environment.

Human factors technique offer a window into the real world of safety. In the case of technology, the literature is replete with examples of how poor design leads to degraded performance.^{3,4} This often occurs because the technology ignores the working environment. This environment is the “sharp end” of health care, where operators (clinicians) have to make critical, high-stake decisions under time and resource constraints.⁵ Successful technological innovation requires a detailed understanding of the users' cognition, the nature and flow of work, and the interactions between users and devices.⁶ Data are acquired by task analysis, observation of users performing tasks, and incident analysis. Human factors proponents suggest a combined cognitive system engineering approach to technology design.⁷ Many new technologies arrive in clinical practice without rigorous investigation of their impact on safe practice.⁸ The marketing of pump convenience features belies the difficult application of these features to true practice. Subsequent application can have unpredictable, sometimes adverse results.⁹ Even safety features face difficulties in clinical application. An observation of “smart pumps,” with software to detect doses out of normal ranges, did not demonstrate an impact on serious medication error rate,¹⁰ and the authors have suggested technological and behavioral factors need to be addressed in future studies. Husch et al¹¹ prospectively observed infusion device use and found that the observed failures were diverse and, in most cases, unlikely to be prevented by available smart pump technology. These observations suggest current technologies are limited in their ability to act as barriers to complex system failures. Studying the relationship of technology, cognition, and environment offers a means for improvement.

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Recent infusion device research makes some use of human factors methods. Ginsburg¹² analyzed devices based on prospectively identified features and observed that usability problems were common, and that users' ratings of devices differed from objective evaluations. Taxis and Barber¹³ observed medication administration behaviors within the context of human error theory to show that latent failures were common, and they suggest that technology design was a contributory factor. Graham et al¹⁴ demonstrated the use of heuristic evaluation for infusion devices as a way to uncover potential usability problems. Looking at these observations, one might conclude that infusion devices, incompletely suited to human operators, might impede safe practice. Extension of this work, by observing user-pump interactions within the context of task analysis, might help characterize current technologies' abilities to aid or impede operator performance.

In complex systems, human operators bridge gaps in the continuity of care.¹⁵ They are the default caretakers for the reliable operation of unreliable technologies. For them, inflexible design compounds the difficulties of the clinical environment. Many are seduced by the assertion that poor performance with pumps represents a lack of training. Our previous research suggests that infusion device experience does not correlate with performance,¹⁶ supporting an alternative view that cognitive and environmental factors are much more important to safe operations. Lin et al¹⁷ showed that a redesign of an infusion pump interface based on human factors techniques improved performance even when nurses had little experience with the new interface. Limited understanding of practitioner performance and cognition limits progress in patient safety. Accident investigators and reporting system managers need to develop a heightened vigilance for user-technology interactions in adverse events and their potential to introduce sources of failure to clinical care.

A common infusion technique, the piggyback infusion, requires coordinated operations between the human operator, the work environment, and automation supposedly designed to make drug administration safer. Basic human factors engineering principles have the potential to characterize any mismatches and to compose useful solutions. Such characterizations may help increase the awareness of infusion hazard, especially regarding piggyback infusion; they also have the potential to spur design and practice improvement that can enhance practitioner operations. Piggyback infusions are a useful subject to study the ways practice and technology fail to improve, and even degrade, safety.

The purpose of a piggyback is to safely administer single-dose drugs through established intravenous access. A new drug is "piggybacked" into tubing upstream of the patient. One can administer piggyback infusions directly, using gravity, or through an infusion device. Many advocate using infusion pump techniques as a "safe" practice for piggybacks, with the goals of preventing rapid administration and detecting intravenous cannula infiltration. In most cases, the piggyback infusion bag is hung above the primary infusion bag to take advantage of gravity and prevent



FIGURE 1. Piggyback configuration. A modern infusion device (front plate covered) and infusion tubing. The piggyback bag hangs above the primary bag, and the tubing "piggybacks" into the primary tubing upstream of the infusion device.

coadministration with the primary infusion. A basic piggyback setup is illustrated in Figure 1. The clinician performs 2 tasks: he/she (1) rigs the tubing for piggyback administration and (2) programs the infusion device using the piggyback feature from the programming menu, entering the relevant data, including rate and volume to be infused. Once the volume of the piggyback infuses (a process that can take several minutes to a few hours), the primary infusion resumes. Piggybacks allow for unattended infusion, where the clinician may leave the infusion apparatus to tend to other duties.

Although many would believe automated piggybacks enhance safety, this practice can increase risk. It is difficult to ensure a program will run according to plan, and it is even harder to avoid failures when changing between 2 different drug administration plans. Without proper setup and programming, the device might operate, but deliver the piggyback or primary infusion in a way that is not intended. Although the infusion device is meant to be a safeguard, it cannot detect many sources of failure, and it cannot monitor the bag and tubing arrangement. Figure 2 demonstrates a "rogue's gallery" of piggyback tubing arrangements. Some or all of these setups might be possible with a particular device. Many produce an infusion other than that intended. The infusion device "assumes" that the user uses only one of the configurations (example E, the "correct" arrangement) and cannot detect out-of-spec setups. Variations in programming expand the range of possible failures. The piggyback practice illustrates how the use of complex technology to execute what seems like a simple task can produce new and unanticipated forms of failure. This popular technique is so

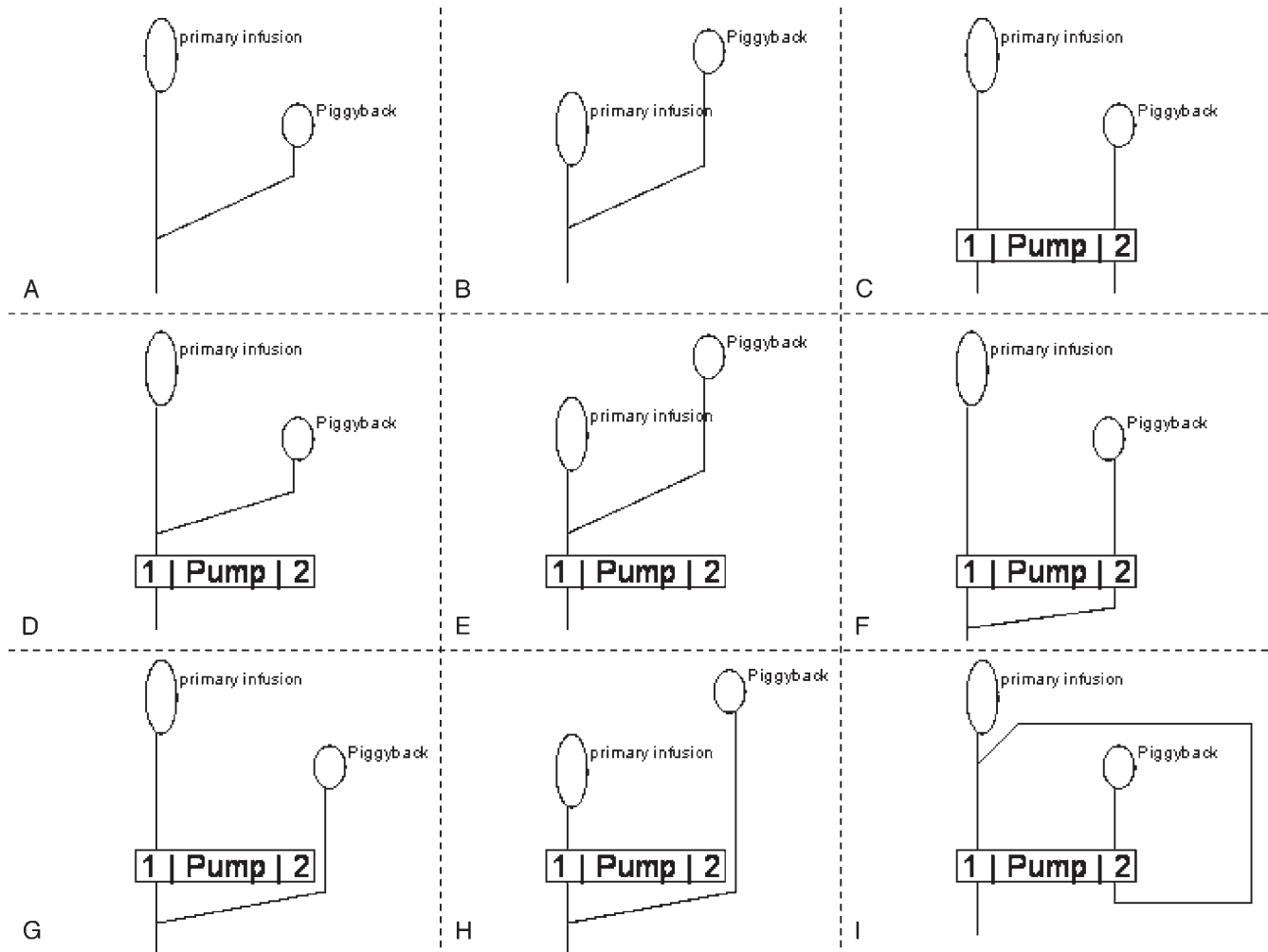


FIGURE 2. Various configurations of piggyback and primary infusions, using no infusion device, a single channel of a device, or both channels of a 2-channel device. All configurations are plausible. Each has the capacity to alter the way the fluids are delivered independent of the programming of the device.

common that even modest improvements in practice safety can have a substantial impact on adverse events.

We hypothesized that a simple task, piggyback infusion administration using modern infusion devices, would reveal the mismatch between design, user expertise, and clinical workload. Using incident reports, human factors analysis, and device logs, we characterized the challenges caregivers face when they administer a drug using a piggyback. We then explored the relationship between technology, operator, and the required task in the context of health care. Finally, we suggest human factors approaches to avoid the trap complex technologies introduce when applied haphazardly to complex working environments. This analysis can serve as a template for future research into technology and patient safety.

METHODS

To bring clarity to the problem, we performed a study to better characterize the ways piggyback infusions are actually

used, with the goal of uncovering mismatches between equipment, procedure, and cognition. These would represent latent failures. We used 3 techniques to characterize the failure modes associated with piggyback infusions. This article reports our findings from analyzing (1) a device-reporting database, (2) simulated tasks videotaped in a laboratory environment, and (3) pump operation log files collected from pumps in use in a major hospital.

The Manufacturer and User Facility Device Experience Database

To explore the relationship between mechanisms and real events, we sought incident reports to provide real examples of problems. We searched an existing incident database to see if the problems we witnessed were relevant to actual device operations. The Manufacturer and User Facility Device Experience (MAUDE) database of the Food and Drug Administration represents reports of adverse events involving medical devices. The data consist of

voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. During the years 2001–2004, the system recorded on the average 62,197 reports every year. This free anonymous reporting system is available on the World Wide Web at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm>.

We searched the MAUDE database for the keyword “Piggyback” from reports received in the years 2003–2004 regarding one particular infusion device.

Our next objective was to analyze actual programming behavior, to help uncover how failures might develop, and reveal the incongruities that might exist between the devices, the piggyback task, and users’ cognition.

Simulated Tasks

We have previously demonstrated the ways infusion technologies confound user attempts to complete a program using videotaped task analysis.¹⁶ We used similar techniques to analyze a specific task on multiple devices. We had 19 senior nursing staff each perform piggybacks on 2 different infusion pumps. Nurses were all trained in the intensive care unit (ICU), with a median clinical experience of 14 years, and were actively working in the ICU, either in patient care or nurse education. Pumps were 4 contemporary infusion devices selected from 4 different manufacturers. The directions for the task are reproduced below:

Set up a maintenance intravenous administration plus a piggyback by rigging the tubing and programming the pump: the maintenance intravenous administration will be a 1-L bag of lactated Ringer at 135 mL/h, but at the start, please deliver a piggyback: 50 mL of “antibiotic” over 15 minutes, after which the maintenance solution should run.

Participants were encouraged to verbalize their thoughts while manipulating the devices. The sessions were videotaped for later review. Nurses volunteered their time and were able to contribute approximately one-half hour to the project. Because we were interested in usability data, they did not receive training on the devices before the scenarios.

We analyzed the task tapes for user difficulties. Because most subject nurses lacked familiarity with the specific devices, we prospectively identified features in the videos that might indicate a mismatch between the manufacturer’s specified operation and users’ practice. We looked for features of setup, programming, and verbal cues that would suggest the users misunderstood the devices’ programming and setup requirements. All categorizations required consensus, and we conservatively judged dysfunctional behaviors, requiring an incontrovertible level of evidence to be counted. These features are listed below.

Confusion Between Piggyback and Primary

The task requires cognizance of 4 main parameters: primary infusion rate and volume, and piggyback infusion

rate and volume. The need to think about 2 sets of parameters would suggest a risk that infusion parameters might be switched. Medication solution bags hang above each other, and values are entered on the same or adjacent screens, leading us to hypothesize that variables might be transposed. We hypothesized users might confuse the parameters for the primary infusion with those for the piggyback.

Incorrect Calculations

Infusion devices are designed with the intent of aiding calculations. If users demonstrate difficulty, it suggests the device fails to assist the user in this capacity.

Users Getting Lost in Difficult Programming Menus

We have previously demonstrated how complex menu structures confuse users, often leading to them “getting lost.”¹⁶ We looked specifically for examples where users were sidetracked by irrelevant menus or confused by prompts such that they were unable to complete the task or did so only after taking considerable effort to find the correct programming features (e.g., turning off the pump and restarting it to get back to a familiar menu prompt).

False Assertions

Whenever users stated an assertion about the device that was untrue, it revealed a cognitive disconnect between user expectations and pump reality.

Failure to Manipulate Tubing

Because tubing setup is such a critical component of piggyback operation, we specifically assessed whether users made the necessary adjustments to bag height and connected tubing correctly. Nurses rarely accomplished the tubing rigging requirements despite being asked to do so. We therefore chose to score any manipulation of tubing or verbal mention of its necessity as completion of this component of the task.

Pump Operation Log Files

To determine how often the piggyback infusions are performed, and to search for patterns of operation, we analyzed the log files the infusion pumps save during their operation. During June and July 2005, we collected information from 55 infusion pumps that were in use in 3 different ICUs. Although these logs contained minimal data outside a piggyback number tally, one interesting feature about piggyback use was the way the clinician set the devices to return to deliver the primary infusion after piggyback delivery completion. The pump has 2 main features that support this process: (1) *Turn Over*, where the pump automatically switches from the piggyback to the primary infusion when the piggyback program concludes, and (2) *Call Back*, where the pump sounds an alarm to signal the clinician that the piggyback is over and that it needs attention before switching back to the primary infusion. Because of the physical changes required to deliver the piggyback, one would expect that the clinicians would prefer to be called back to attend to

TABLE 1. Manufacturer and User Facility Device Experience Reports From 2003 to 2004 Where Speculation About Problems With Tubing Setup Is Mentioned

Report No.	Intended Primary Infusion	Intended Piggyback Infusion	Circumstances of Failure	Clinical Outcome	Manufacturer Speculation
2016493-2004-00036	Saline solution, unknown rate	Potassium in dextrose/water, 200 mL at 66 mL/h	Infusion completed in 15–20 min	Patient was successfully treated for hyperkalemia (k+ = 8.4 meq/dL) with one ampule d50w and units regular insulin intravenous administration. No apparent harm reported	“...possibility exists that user did not clamp secondary set...”
1641965-2004-00010	Saline at 125 mL/h	Zosyn (antibiotic), 50 mL at 100 mL/h	Empty after <15 min	No patient injury occurred	Piggyback container connected to tubing after the pump
1641965-2004-00008	256 mL at 60.8 mL/h	88 mL unreported fluid at 950 mL/h	Primary bag had infused simultaneously	The patient was administered oxygen by nonrebreather due to pulmonary edema	Quotes operator’s manual: “sympathetic flow increases significantly when the piggyback rate is greater than 125 mL/hr”
6000001-2004-00106	Unreported	100 mL potassium solution at 100 mL/h	Patient felt burning in arm after 5 min, reprogram to 75 mL/h. Immediate burning. Piggyback stopped, primary started. Within 30 sec, only 30–40 mL left in bag	The patient called the nurse to the room complaining of a burning sensation to the arm. According to the nurse, no medical intervention was required, and no patient injury resulted	The nurse reported that when they stopped the piggyback infusion and started the primary infusion, they did not close the clamp on the piggyback set

the pump before switching back from the piggyback to the maintenance mode.

RESULTS

The MAUDE Database

Our search in the MAUDE database yielded 137 piggyback cases, which we then reviewed for relevance. Thirty cases specifically dealt with the infusion pumps and were potentially relevant to the topic. Of the 30 reports, 19 dealt with overinfusions, 9 reported underinfusions, 1 described a case of sympathetic, or simultaneous, infusion of piggyback and primary, and 1 described mixing of piggyback fluids into the primary bag. Incorrect tubing setup can plausibly account for all these cases; in 4 cases, this is alleged in the report. These cases are illustrated in Table 1. Although information is incomplete for the entries, it is notable that this cause is invoked. Setup difficulties represent

a real hazard to safe infusion practice; they are particularly important in the case of piggybacks.

Reports were generally limited in detail. However, we include a report from 2001 that provides a good example of a scenario in which the piggyback task might have contributed to an adverse event. In this case, the pump and clinician were “misled” about the situation, setting the stage for an adverse event. The device did exactly what it was programmed to do, but unfortunately, this was not what the user intended. Of particular interest, the pump operated assuming (incorrectly) the clinician had prepared it a specific way.

The MAUDE narrative is presented in Figure 3. In this case, the device log analysis provides tantalizing clues about the circumstances of this overinfusion. While the lipid infusion was running, an operator programmed a piggyback infusion. It seems the pump delivered the primary infusion at the high rate that was intended for the piggyback. The

Catalog Number 610-012

Event Type Malfunction

Event Description

Reportedly, the subject device was set to deliver a 24-hour dose of lipids. The attending nurse checked and noted that the infusion was complete after approximately 12 hours. There was no patient injury.

Manufacturer Narrative

Although the reported overinfusion occurred in 2001, the user facility did not report the incident to the manufacturer until 1 month later. The reported volumetric inaccuracy could not be duplicated during testing by the manufacturer. Review of the operation log for the reported incident revealed that the device was programmed to deliver 235 ml of lipids at a rate of 10 ml/hr. After six-and-a-half hours had elapsed, the device was put on hold and a piggyback dose was started. The piggyback was set to infuse 100 ml at a rate of 100 ml/hr. The device had indeed delivered a 24-hour dose of lipids in 12 hours, as the user had programmed it to do. Routine maintenance was performed before the device was returned to the customer facility, with a report of these findings.

FIGURE 3. The Food and Drug Administration’s MAUDE report no. 341062.

manufacturer's statement supposes that the piggyback rate accounts for the time to lipid infusion completion (≤ 12 h):

"The device had indeed delivered a 24-hour dose of lipids in 12 hours, as the user had programmed it to do."

There are many plausible mechanisms for this failure, including tubing setup (Fig. 2). Any tubing setup that allows for primary solution infusion in the place of the piggyback drug (e.g., A, C, D, F, G, H, and I in Fig. 2) can create this scenario. Piggyback infusion seems to be directly related to this event.

Although the database does not allow calculation of prevalence, these reports provide irrefutable evidence that problems are occurring—problems that certainly have the potential for patient harm.

Simulated Tasks

Four devices (A, B, C, and D) underwent user testing as described. A total of 19 subjects programmed 2 devices each such that device A was programmed 6 times; B, 8 times; C, 11 times; and D, 13 times. Device and subject availabilities limited the number of times pumps A and B can be programmed.

Task completion proved problematic. Both reviewers agreed that the subject failed to successfully complete the piggyback task in 20 (53%) of 38 scenarios. Table 2 demonstrates occurrence rates for the various features we initially identified. Failure to manipulate tubing was the most frequent scenario failure, occurring in 14 (38%; 1 scenario was excluded because the subject was not asked to set up the tubing) of 37 scenarios, followed by becoming lost in programming pathways (11/38; 29%), incorrect calculations (8/38; 21%), false assertions (6/38; 16%), and volume/rate mismatch (4/38; 11%). Primary and piggyback confusion did not occur in the 38 scenarios. The data set was of insufficient size for significant between-pump comparisons, but we observed a trend with becoming lost. This occurred in 3 (50%) of 6 clinicians for pump A versus 2 (25%) of 8 for B, 3 (27%) of 11 for C, and 3 (23%) of 13 for D.

We observed several behaviors of particular interest. Three nurses tried to adjust time of infusion iteratively, observing the changing infusion time display while adjusting other parameters instead of calculating the infusion rate before programming. In one of these cases, the volume to be infused was adjusted instead of the infusion rate, resulting in an incorrect piggyback program. There were various false assertions made about the devices. These included the conviction that the primary channel would infuse after piggyback completion when the device was not configured to do so (2 cases), confusion between rate and volume to be infused (1 case), the perceived need to clear primary infusion data (1 case), and the misinterpretation of a flashing number in the process of being edited as meaning an infusion was ready to go (1 case). In one case, the nurse misunderstood tubing setup requirements and stated that the B channel should be connected to the afferent tubing on channel A (Fig. 2, example I).

Pump Operation Log Files

The log files captured 8100 hours of drug delivery. During this period, the pump captured 124 piggyback events on 26 of the pumps (47% of our sample devices). Our data show that in 85% of the piggyback events (106 events), the pump used the *Turn Over* feature and switched from the piggyback to the primary infusion mode automatically. In 18 (15%) events, the clinician ended the piggyback delivery manually. The clinicians did not use the *Call Back* option even once.

DISCUSSION

The MAUDE Database

The MAUDE reports lack critical information necessary for competent analysis. These reports are poorly detailed, and valuable contextual information has been lost, in part because they are not composed by expert analysts. A properly trained investigator will see device/user mismatches where less skillful analysts will only see human error. The reports themselves are prone to distortion by their authors, and may reflect personal biases and agendas. Despite these substantial shortcomings, we believe our methods are useful. To our knowledge, they represent the first use of MAUDE data to understand how adverse events occur. What is plausible is as valuable as what actually happens. The incident reports reveal how failure can manifest, and our task analysis sheds light on the possible sources of failure. Other

TABLE 2. Behaviors Observed for Scenarios With Different Pumps Expressed as Absolute Numbers and Percentages of the Sample

Behavior	Pump A	Pump B	Pump C	Pump D	Total
Failed task execution, excepting tubing manipulation	2/6 (33%)	2/8 (25%)	7/11 (64%)	9/13 (69%)	20/38 (53%)
Failure to manipulate tubing when asked	4/6 (67%)	1/8 (13%)	6/10 (60%)	3/13 (23%)	14/37 (38%)
Becoming lost	3/6 (50%)	2/8 (25%)	3/11 (27%)	3/13 (23%)	11/38 (29%)
Incorrect calculation	2/6 (33%)	1/8 (13%)	4/11 (36%)	1/13 (8%)	8/38 (21%)
False assertions	2/6 (33%)	0/8 (0%)	2/11 (18%)	2/13 (15%)	6/38 (16%)
Volume/Rate mismatch	2/6 (33%)	1/8 (13%)	0/11 (0%)	1/13 (8%)	4/38 (11%)
Primary/Piggyback confusion	0/6 (0%)	0/8 (0%)	0/11 (0%)	0/13 (0%)	0/38 (0%)

incidents in the database are likely because of these types of problems, but the reports lack the detail necessary to evaluate this. Even without critical details, we can still obtain useful insights into the hazards attendant to piggybacks and infusion practice in general.

Simulated Tasks

The substantial failure rate and high incidence of prospectively identified dysfunctional behaviors suggests incongruous pairing of device and user cognition. Our study subjects, despite substantial clinical experience, struggled at times to produce the desired piggyback infusion. Indeed, only 6 (16%) of 38 of the pump scenarios were judged to be highly efficient by the 2 observers. Awkward matching of task cognition to device design is a likely contributor to the dysfunctional behaviors seen.

Curiously, no subject demonstrated confusion between primary and piggyback infusion parameters, as we would have predicted. This may result from a relatively small data set. However, the comparative frequency of other behaviors suggests that other problems might confound effective programming more often. All pumps have multiple features embedded in complex menus. These include various modes, alarm and infusion limits, drug libraries, and displays shared by different infusion channels. More variables can lead to increased confusion; our users clearly demonstrated difficulty in resolving the setup and programming requirements. Another explanation is that our subjects' previous clinical experience can diminish the confusion between infusion variables. Primary and piggyback parameter confusion might still be an important problem, but our observations would suggest it is only one of many potential failures.

This analysis is subject to several limitations but is still illustrative of difficulty. The study took place in a laboratory with the intention of evaluating new infusion devices. The different purpose and environment degraded the fidelity of our simulations and might have changed user behavior relative to what would occur in clinical practice. Our data set is relatively small; this is offset by the high frequency of programming difficulties.

Another concern is that study subjects generally had little, if any, familiarity with many of the devices tested. However, enormous clinical experience with piggyback infusions still qualifies them as experts, and these failures support the contention that device designs are not an intuitive extension of infusion skill. Furthermore, device A was a newer version of a device all the nurses used on a regular basis. The interface and programming structure were, for the operations tested, practically identical to the device the subjects were used to programming (the background color of the faceplate was different, and the menu enabled a barcode reader, which was not used). That the failure rate was higher with this device further suggests experience is not a significant confounder. Moreover, previous research suggests that users have the kinds of problems we observed despite substantial experience with a device.¹⁶ Complexities in the health care environment make training-independent usability the standard to which common devices should be judged. Additional training cannot compensate for poor design. The

programming behaviors we prospectively identified suggest confusions and false assertions, task complexities, and a workload shift to the practitioner. The iterative adjustments made by 3 of our subjects have the features of adaptive behaviors intended to arrive at a goal while bypassing demands that are incongruous with their own cognition. These nurses seemed to find gradual trial and error adjustments "easier." Our results demonstrate a poor matching of technology to task, and these should be less dependent on the environment in which they were elicited than other measures such as direct scoring of programming efficiency. A few clear examples such as the false assertions made by the subjects testify to the mismatch between task and technology.

Pump Operation Log Files

Log file data were limited and provided only part of the information needed to generate a clear picture of the clinical situation and device operation. Nonetheless, they raise 2 important points. First, they confirm that piggyback infusions are a common practice in our institution. Second, they uncover a possible hazard: the use of the automated *Turn Over* feature. Not only do the pumps permit unattended switches between infusions, in our sample, the users never set the devices to call them back when the infusion was complete. One might question if this type of feature should even be available in modern infusion devices. Given the types of problems we have already demonstrated with piggybacks, an unattended change in infusion would only seem to be another potential source of failure.

General Discussion

Our methodologies benefit from a multitude of sources. The data we sought for this work were complementary and varied. This strengthens our conclusions. We were able to look prospectively at user/device interactions and reinforce our impressions with reported incidents, lending added validity to our theories. We feel that a lot of what we describe should resonate with people who contend with this practice on a regular basis. That few in health care have attempted to describe work at this level of detail makes our results novel, but the findings should not be rarified. They simply "make sense."

CONCLUSIONS

The piggyback task represents a clinical practice whose advantages and risks merit careful consideration. Practitioners continue to have to set up the tubing for piggybacks; moreover, they are responsible for programming and juggling the multiple variables of primary and piggyback infusion schemes. This basic infusion task is actually quite complex and fraught with peril. Pump-administered piggybacks are supposed to make the process simpler and safer. Our analysis of the task refutes the first assertion. Our analysis of incident reports and user interactions challenges the second. In light of these problems, alternative strategies to the use of automated piggybacks should be considered. Many drugs delivered by piggyback infusion require slow administration. However,

rate precision is not as vital as cautious infusion speed. Gravity tubing may permit safe administration and avoid the hazard attendant to programming pumps for piggybacks. If precise rates are required, running the infusion through a second device substantially reduces tubing and programming complexities. Curiously, both of these practices also reduce the practitioners' cognitive and physical workload in comparison to using piggyback features of infusion pumps. It is for these reasons that we strongly advocate that institutions review their policies regarding piggyback infusions. Practitioners should be granted the autonomy to use alternative infusion strategies. Efforts to improve the piggyback infusion process from a human factors cognitive systems engineering perspective⁷ are needed. At the very least, practitioners should be aware of the types of problems we observed and the risk for allowing piggybacks to run unattended as part of an in-service training. Finally, we would advocate that features that permit unattended infusion resumption at the end of a piggyback program sequence not be used because this feature lessens vigilance at a critical time during a high-risk practice.

Infusion devices demonstrate a failure to understand the human factors of health care. This failure has produced a mismatch of pump design, users, and work, which in turn predictably creates the circumstances that produce many failures and incidents, including many of those in the MAUDE database. Proponents of new technology claim to improve patient care by enabling advanced treatments and promoting safeguards. Without better characterizations of its performance in the working environment, such promise might remain unfulfilled.

Much improvement is needed to make technology a "team player" in health care.¹⁸ Focusing specifically on piggybacks, the process needs to be questioned and alternatives considered. Addressing patient safety more broadly, studies of technical work, the binds, and trade-offs that practitioners face¹⁹ would address the poor understanding of the true nature of sharp end clinical practice. To understand task cognition is fundamental to truly assess the design of devices, and examples of workplace redesign based on human factors principles provide a template for study.²⁰ Principles of good design, oriented around specific tasks and the needs of those who must perform them, should be emphasized more than the marketability of multiple features and a "one size fits all" platform. Ideas such as transparency of operation, direct feedback, and easy mapping of operational activities to device function lie at the heart of good design.²¹ The criterion standard should be the ability of a device to reduce practitioners' workloads without adding additional tasks. As technology insinuates itself into multiple aspects of health care practice, improved understanding of how it might be helpful becomes a more urgent need. Until then, continued exploration of how tasks, users, and devices interact may reveal other unsafe "safe" practices.

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