

Between Choice and Chance: The Role of Human Factors in Acute Care Equipment Decisions

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Objectives: We report on a human factors evaluation project at a major urban teaching hospital that was intended to use human factors methods to assist the selection of a new infusion device among 4 commercially available models.

Methods: The project provided an expert evaluation of the pumps, collected data on programming each pump by a sample of practitioners, tabulated recent adverse event reports in the US Food and Drug Administration Manufacturer and User Device Experience database, and observed actual use in intensive care and hematology/oncology units.

Results: Programming by clinicians showed no correlation between clinical experience and ability to program any of the pumps under consideration. Field observations reflected diverse use patterns across services that required ease of use pumps did not offer. Upon review of a final candidate pump, purchasing preferences superceded clinical considerations.

Conclusions: Equipment and systems that are intended for use by clinicians must necessarily reflect an understanding of actual clinical practice to be well suited for use at the sharp (operator) end. However, purchase decisions for medical equipment including infusion devices are typically made by hospital staff members who are experienced in administrative and clinical matters but have no expertise in the evaluation of complex equipment. This project demonstrates how collaboration by human factors and clinical professionals can inform equipment decisions and assist clinician performance to improve patient safety. It also reveals how technical decisions that directly influence anesthesia staff performance and patient safety are subject to organizational factors such as social and political pressure.

Key Words: human factors, safety, information technology, infusion device, medical devices

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As the most widely used equipment in hospitals,¹ infusion device operation directly affects clinicians and patient safety. Infusion devices are sophisticated and complex, making them difficult to comprehend. Many of the devices that are currently on the market are less than optimal for human use² and contribute to adverse outcomes. Their cost and the number that is required for a facility can easily make pump purchase a multimillion dollar decision. Hospital staff members who make equipment purchase decisions are typically experienced in administrative and clinical matters, but have little to no expertise in device evaluation. An objective human factors evaluation of

equipment that is intended for use in acute care settings can help to inform such decisions.³ This article reports on the process that a large urban teaching hospital pursued to choose the replacement for their major infusion device. Over 600 of the aging pumps were in use in a range of clinical settings.

Our laboratory, which is staffed by a small team of anesthesiology and human factors professionals, conducted the study while the devices were being considered for purchase. The laboratory provided an expert evaluation of the candidate pumps, data on how a sample of practitioners used them, and a tabulation of recent adverse event reports on each pump from the US Food and Drug Administration (FDA) Manufacturer and User Device Experience (MAUDE) database. The approach demonstrates how collaboration by human factors and clinical professionals can inform equipment decisions and assist clinician performance and improve patient safety.

Background

In recent years, potent, short-acting intravenous agents have grown in popularity for use in anesthesiology and critical care medicine. Their administration requires a level of precision and accuracy that can be difficult to achieve using a traditional gravity-fed drip that are regulated by a simple manual fluid flow resistor placed in series with the infusion tubing. The advent of small cheap microprocessors led to the development of electromechanical infusion devices. Their consistent, accurate performance has led to their widespread adoption so that most infusions in US hospitals are now provided by such devices.¹ Infusions are provided by hanging a bag of premixed fluid or medication above the pump, inserting 1 end of the tubing into a port molded into the bag, running the tubing through the pump, then connecting the other end of the tubing to a manifold that allows the solution to flow into the patient's vein through a needle.

Administrators tend to equate device safety with technical accuracy and reliability.⁴ The complexity of infusion devices can make their consideration and purchase a difficult task for hospitals. Eskew et al⁵ reported on the Clarion health care system's efforts to choose an infusion device using 2 methods: a list of criteria and "pump show" exhibit to gather clinician reactions to devices they might consider for adoption. Their efforts resulted in the purchase of a commercially available multichannel pump. Both subjective preference lists and focus-group style reviews of products are qualitative marketing research methods that do not reveal how clinicians actually perceive and use this complex equipment. Actual operation of the device, not their speculation about what will happen, reveals how users and devices interact.

Engineering and the social sciences have developed and validated research methods⁶ that can be used to answer the complex questions that device purchase decisions impose. For example, Carayon et al⁷ describe the use of Failure Modes and Effects Analysis and usability assessment⁶ to review a single pump that had already been chosen using selection criteria. Ginsburg³ reported an evaluation (what the author termed

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heuristic”) of 3 infusion pumps against criteria that were derived from a variety of sources and by casual observation of a small number of clinicians in 5 care areas performing specified tasks using pumps. This paper describes a recent program that used human factors methods to evaluate infusion devices during the decision making process.

Human Factors Analysis

Our laboratory was invited to perform a human factors review of the 4 pumps under consideration for purchase based on experience gained from 4 years of research funded by the Agency for Healthcare Research and Quality.^{8,9} The purpose was to help a hospital equipment selection committee to choose 1 device by conducting a scientific analysis of the human factors issues for each device. We were asked to collect data on operator-pump interaction to see which candidate might be best suited to use in our clinical setting. Although medical center staff members had chosen infusion devices in previous years, this was the first time such an analysis was included as part of the selection process.

Figure 1 depicts each of the devices that were considered. Infusion devices O and P are single channel pumps that are capable of controlling a primary infusion of a larger (over 250 mL) volume of fluid such as Lactated Ringer solution. The pumps can also be programed to control a secondary infusion, often termed a piggyback, in addition to the primary. When device O is programed for a piggyback, the secondary bag and its tubing are connected directly to the primary infusion tubing, then hung at a higher level than the primary bag. For device P, the secondary and its tubing are also hung above the pump, yet the tubing is connected to the same a proprietary cassette as the primary. Fluid bag height does not matter with this pump, as the cassette, tubing, and bags form a closed system. Device S is a dual channel pump that is able to control 2 infusions with piggybacks, for a total of 4 infusions. Device C can be configured with 3 primary infusions with piggybacks, for a total of

6 infusions. All 4 devices are commercially available and in use by other health care systems.

A human factors analysis of infusion devices addresses all of the features that influence pump operation in clinical settings. This includes the tasks that a clinician needs to perform while setting up a pump for operation: preparation, initial programming, status checks, program changes, and troubleshooting. Success in these tasks requires interactions between the device and operator. The design of the device’s control-display interface makes these interactions possible. The interface provides cues to the operator on current state of the device, actions that are needed to complete the current task and how the device may be directed to perform some other task. The physical layout of the device provides some of these cues. For example, a lever needs to be rotated to open the housing for a tubing cartridge to be inserted or removed. A keypad makes it possible to enter digits. Visual or auditory displays cues provide messages on a screen or an audible alarm. Smooth successful operation occurs when the operator finds cues that correspond closely and accurately with the operator’s intentions and understanding. Mishaps occur when cues are absent, misleading, or when the operator’s understanding of the device state is different from its actual state. Some tasks such as the initial programming of a device require a series of steps. Each step in the series has its own complement of operator actions, device responses, and cues about the progress, capability, readiness, and completeness of the device and its program.

METHODS

Over a 6-week period, our laboratory staff used human factors analysis methods including expert analysis and usability assessment to obtain quantitative and qualitative data. The limited time that the pumps were available prevented us from performing other analyses such as finite state diagramming. One laboratory member’s (M.N.) extensive experience with the analysis of infusion device interfaces qualifies him as an expert

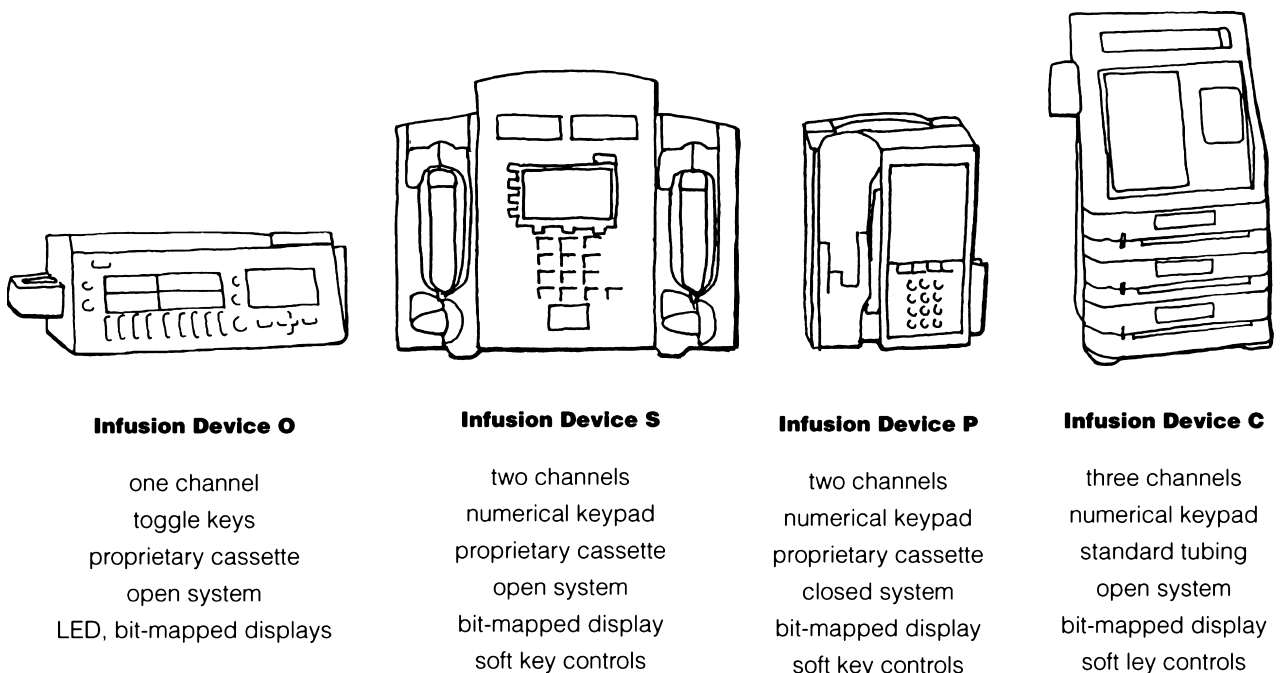


FIGURE 1. Four candidate infusion devices.

analyst. He spent an hour with each device to explore aspects of its operation.

For the usability sessions, a senior nurse educator recruited a 19-member sample that consisted exclusively of nurses. Experience ranged from 1 year to 36 years as a nurse. Many in the sample were nurse educators. Sample members reported familiarity with computers from 3 to 10 (average 6.8 on a scale of 1–10) and familiarity with infusion devices from 2 to 10 (average 7.7 on a scale of 1–10). There was no significant correlation between clinical experience and familiarity with computers (0.29) or familiarity with infusion devices (–0.004). Each subject read and agreed to the oral consent that had been previously approved by the Institutional Review Board. Manufacturer representatives provided pumps at different times, and subjects had limited time available. As a result, we collected data on 2 pumps at a time in sufficient numbers for a usability test.¹⁰ Pump order was counterbalanced to avoid order bias and transfer of training. Subjects came to the laboratory and each pump programming session was recorded on videotape (Fig. 2).

Video recordings including 4 different views documented each subject’s performance while programming an infusion. The usability session facilitator (C.N.) first collected background information from each subject using a simple 2-page questionnaire that was used to collect background variables such as prior experience as a nurse and using infusion devices, to record performance notes, and to record subject comments after the programming. Each subject received a brief orientation to pump operation before starting. The orientation’s brevity was intended to avoid any coaching that might compromise subject performance data. As each subject performed programming tasks, the facilitator made notes on subject actions and comments and collected qualitative data such as user impressions after the last task. Each subject performed the 4 tasks (Table 1) listed on a simulated physician order form that ranged from simple to moderately complex. The tasks were intended to find out how subjects deal with both typical clinical activities as well as technical problems such as programming a drug that had not yet been entered in the medication library software.

The project team also observed pump use over a month on 3 different services that would pose the greatest challenge for programming. A set of the pumps was installed for use on the hematology/oncology unit (HEM/ONC) and cardiothoracic care unit) CCU unit for 2 weeks, then pediatric intensive care unit (PICU) for 2 weeks. The laboratory team downloaded the



FIGURE 2. Four-camera composite view of subject programming infusion device.

TABLE 1. Infusion Programming Tasks

Task	Activity
1	Run maintenance fluids at 125 mL/h. The volume to be infused is 1000 mL.
2	Program dopamine (400 mg/250 mL, you have a 250-mL bag of drug) to run at 3 µg/kg/min for a 70-kg patient, and run the infusion.
3	Program Nesiritide 1.5 mg/250 mL (you have a 250-mL drug bag) at 0.01 µg/kg/min for a 70-kg patient, and run the infusion.
4	Set-up a maintenance intravenously, plus a piggyback by rigging the tubing and programming the pump: the maintenance intravenous 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 min, after which the maintenance solution should run.

complete programming memory files from one of the pumps that was used during the period.

Prior experience has also shown that failed batteries can cause drug library data to be lost, posing difficulties for clinicians who expect to use that information for programming. We examined each pump with regard to its performance under conditions of no external power supply by unplugging each unit, leaving them for a week, then evaluated the pumps on the 7th day.

RESULTS

Our research¹¹ had previously found that infusion pumps that are currently on the market tend to be similar in their operation. We expected that this would make it unlikely that any single pump in the study would demonstrate significantly better traits than the others, and the data we collected during this study bore that out. Each device has limitations and potential problems that operators may experience during its operation.

Table 2 depicts results and subject comments for each device according to 3 categories: mechanical, programming, and displays/labeling.

Mechanical issues include physical operation of the device and related items (such as device P’s cassette). Subjects considered the pumps to be physically cumbersome. Comments pointed out the amount of space that each pump would occupy on an intravenous pole and questioned whether multiple pump assemblies would become top-heavy, fall over, and risk injury to a clinician or patient.

Programming issues include user perceptions and performance while operating the control interface. Rather than search for the drug library, subjects readily programed a rate and volume for an infusion, even if it was a program to administer a powerful medication.

Device O is similar in many ways to a previous generation of the same pump (device H) that has been in use for 5 years at the hospital. This similarity could be expected to result in subjects doing better while programming device O. However, the data show that subjects did no better programming device O than the other pumps. This suggested that they did not benefit from their previous experience with device H, which eliminated any presumed advantage for device O that was based on the staff being familiar with device H.

During the field observation portion of the study, we found nurses in the HEM/ONC and CCU units disliked the need to switch among multiple screens to perform a simple task such as titration (incremental flow rate adjustment). Pump P’s bit-mapped screen was difficult to read at a distance. Nurses who

TABLE 2. Findings From 19-Subject Sample Study

	Mechanical	Programming	Displays, Labeling
Device S	<ul style="list-style-type: none"> It was difficult for subjects to understand how to load the cassette in the pump housing. 	<ul style="list-style-type: none"> Subjects were seen to switch from programming 1 channel to the other without being aware of it. The displays for channel A and channel B are swapped in the same screen, leading to confusion about the channel being programmed. 	<ul style="list-style-type: none"> The relationship between the soft keys and their labels is not clear, which may require operators to trace labels back to related keys. The Options key location on the right side implies it is related to the right channel when it controls both.
Device C	<ul style="list-style-type: none"> Some subjects who were not familiar with this device found it difficult to understand how to load the tubing using the automatic clutch. Use of the mechanical clutch option leads to significant programming difficulties, such as multiple alarms. 	<ul style="list-style-type: none"> The explicit mapping between display and channels appeared to minimize the confusion between channels that was observed with operation of the (device S) and (device P) devices. Subjects were regularly observed to select the “Program Options” section of the interface in search of the correct mode to program the pump. 	<ul style="list-style-type: none"> Prompt messages appear at various locations in the screen and can be difficult to detect. Symbols such as the icon indicating “piggyback” appeared to be informative for subjects and improved their confidence that a desired pump state had been achieved. “Program Options” invites attention but is only an administrative set-up section that cannot be used for programming.
Device O	<ul style="list-style-type: none"> One subject who was not familiar with this device found the cassette difficult to install. 	<ul style="list-style-type: none"> The pump interface offers the operator few clues about how to proceed. Subjects develop their own routine programming pathways to perform routine tasks as previously explained [2]. Set-up function in Dose Mode is sometimes misunderstood as the mode to use for pump programming. Some subjects were unable to relate the meds library and dose calculation modes. Subjects had difficulty programming “.01” infusion rate. 	<ul style="list-style-type: none"> The pump interface offers no prompts to help the user to understand what to do. Light emitting diode display can be difficult to read when viewed at an angle. Using individual keys to control each digit rather than a keypad requires the use of input skills that are unique to this particular device and prone to order of magnitude failures (eg, entry of 100 rather than 10).
Device P	<ul style="list-style-type: none"> It was difficult for subjects to understand how to orient and insert the cassette in the pump housing. Tubing for the primary and secondary infusions is connected to the cassette, and can be considered a closed system. Hydrostatic pressure within this closed system can be changed by raising or lowering the tubing, making it possible for fluid in 1 line to run “upstream” into the other line. This offers the potential to blend primary and secondary infusions, opening the way for precipitation and other undesirable effects. As nurses regularly “run out” infusion tubing to keep it untangled and to clear air in lines, this is likely to occur in practice 	<ul style="list-style-type: none"> Subjects were seen to switch from programming 1 channel to the other without being aware of it. The displays to program each channel are swapped in the same screen, making it possible to confuse which channel is being programmed. The “Options” menu in (device P) can be incorrectly chosen as a means to program the pump. 	<ul style="list-style-type: none"> Subjects found the blinking light emitting diode confusing. Some were not sure if it indicated “pumping,” “standby,” or “waiting.” The partition between primary and secondary infusions is not apparent. More than 1 subject who read the display screen terms “Pumping” and “Stopped” understood it to mean pumping had stopped rather than the primary was pumping and the secondary was stopped.

wanted to spare patients from excessive disturbances disliked having to walk into the room to read the display. Complex programming schemes sometimes took significant lengths of time to complete. In some instances, nurses resorted to using the older infusion pump (pump H) that was still available on the unit.

Pumps are used much differently in the PICU than on the HEM/ONC and CCU units. In the PICU, infusion pumps are typically used to administer maintenance fluids, such as saline

solution. Syringe devices are used to administer medications to small children. Pediatric intensive care unit infusion pumps were typically set up on an intravenous pole in tandem with a syringe pump. Only a few adolescent patients received medications using multiple device P’s. Although it was routine for additional “piggyback” medications to be added to the main infusion, programming in the PICU is generally simpler than programming complex oncology protocols. In the opinion poll, clinicians

TABLE 3. Performance After 1 Week Without External Power

	Condition
Device S	There was no apparent battery charge on the unit. It would not start without plugging the unit into a wall outlet. When turned on, the pump displayed an “equipment malfunction” message. Pressing the power button resulted in being able to program the pump using all functions. The drug library was intact.
Device C	The unit’s battery remained viable through the seventh day. On the eleventh day, the pump could not be turned on either when unplugged or plugged in. This suggests that a depleted pump battery may not be operational even when plugged in. We do not know for certain how long the pump has to be off an AC charge to arrive at this nonfunctional state. However, this may be a cause for concern.
Device O	The unit was not available for testing because the (device O) representative asked for the unit to be returned within a short time.
Device P	After 7 days, there was apparently a minimal charge remaining on the unit’s battery. The pump could be turned on without being plugged in. This made it possible for a user to program an infusion but unable to run it. When plugged into a wall outlet, the pump and be programed and operated. The drug library was intact.

considered the pump’s concurrent delivery feature (ability to infuse 2 channels at the same time) a plus. However, when one of our project team members (Y.B.) downloaded the pump’s memory after field use, the data showed that the concurrent delivery feature was not used.

Displays and labeling issues include subject perceptions of pump data representations and visual signals. For instance, multiple subjects misunderstood the “program options” label used in pump C’s interface. This was a function that the manufacturer provided for the facility to set up features on the interface. Clinicians in our sample understood the label to mean it was the location in the interface that they should use to program the pump. So many subjects got lost as a result of this that we considered it a deficiency in the device’s interface design.

Table 3 shows that pumps varied in their performance under low, or no, battery charge. Some pumps appeared to maintain a survival charge that made it possible to start the pump.

Our study also took others’ experience into account by reviewing 256 reports of adverse events from the US FDA’s MAUDE national database related to each of the candidate devices. The reports, which spanned the period of February 2003 to March 2005, fell into the 8 general categories shown in Table 4.

The MAUDE reports helped to identify certain aspects of pumps that deserved further attention. However, they also showed the MAUDE database’s difficulties. For example, MAUDE reports vary widely on the information they provide. One individual or location can report often, whereas others do not report at all. A newer device may receive fewer reports because it has not been in use for very long.¹²

DISCUSSION

Figure 3 shows 2 versions of the pump selection process that played out over 10 months. The time line at the left shows

the presumptive version of how a new equipment is selected. In this view, requirements are developed, potential candidate devices are reviewed, candidates that fare poorly are removed from consideration, the remaining candidates are evaluated, and the best of the lot is chosen and installed. The second time line, labeled “actual,” shows the highlights of the way this process actually evolved.

Based on the study, the laboratory concluded that device S and device P are significantly more difficult to operate and prone to mishaps in comparison with device O and device C. Although they were not as difficult to program, devices O and C still have characteristics that make it fairly easy to result in adverse outcomes.

The committee decided to eliminate 2 out of 4 candidates: device O and device S. That choice was based on both the laboratory’s analyses and compatibility with the medical center’s plans for information technology system integration. The laboratory team then encouraged the committee to compare the 2 remaining pumps, device P and device C, in actual work settings. The unexpected US FDA recall of device C that occurred at this moment left device P as the only device under consideration.

Aging pumps needed to be replaced, and 1 pump was under consideration. The selection committee’s attention shifted in the final month to pressing for adoption. Clinician objections about clumsy and cumbersome programming were downplayed. Difficulties were rationalized as “one time” incidents or as unique to circumstances of the pilot program. Ten months after starting the selection process, the committee decided to purchase pump P.

Issues that became evident during the process included a lack of specifications, dose limit software, methods, agendas beyond clinical issues, and what value the results of our study had for the selection process.

TABLE 4. Recent (September 2002 to March 2005) MAUDE Report Tabulation

	Over Infusion	Under Infusion	Noninfusion	Mechanical	Electrical	Free Flow	Contamination	Other
Device S	12			9		2	3	4
Device C	20	2			20	2		12
Device O	22		1	2 (32 additional tubing quality problem reports)				
Device P	40	10	18	9	15	5	1	15

Source: 256 reports from US FDA MAUDE (September 2002–March 2005).

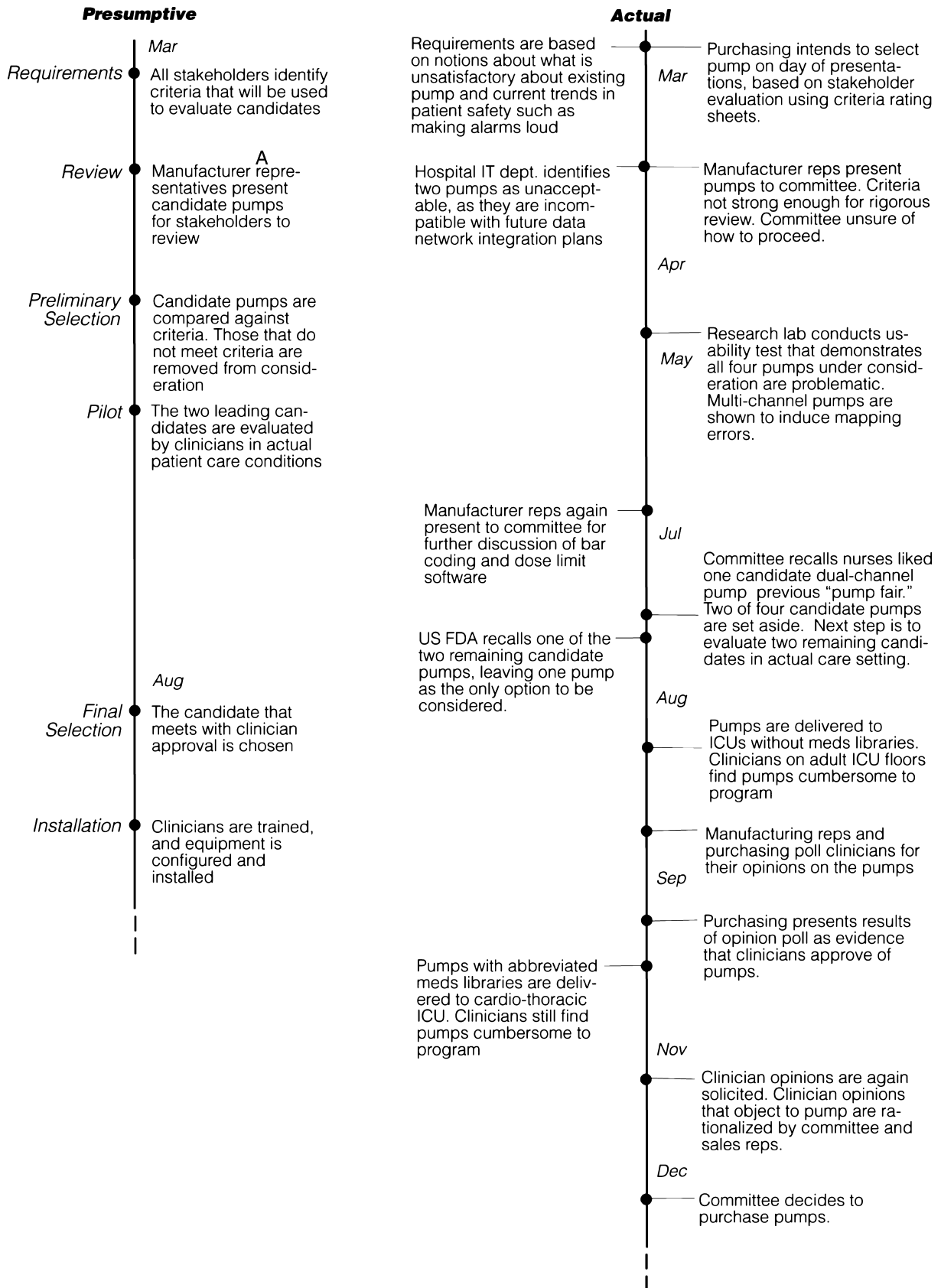


FIGURE 3. Presumptive versus actual infusion device selection process.

Lack of Specifications

Large organizations such as the military typically establish specifications for performance that are based on advance study. Manufacturers who seek to be approved follow those “specs.” Acceptance is a process of comparing performance with specifications. If stiff standards had been clearly stated as specifications for pump selection, the selection process would have been quite different. Instead, the criteria that the committee used had evolved from a kind of collective folk wisdom rather than clinical performance. For example, those who attended the first presentation of 4 candidate pumps were given a list of 13 criteria such as “easy to prime and load set” and asked to rate each pump on a scale of 1 to 5.

Dose Limit Software

Manufacturers have made dose limiting software part of their device’s interface in response to reports of medication misadministration and regulator insistence. The software limits the values that can be entered for medications that are listed in each pump’s pre-programmed library. The presumption is that such limits will avoid misadministration and adverse reactions. In actual practice, a medication can become available for use before the library on each pump is updated. The medications library can also be difficult to find in the pump interface. In either case, clinicians will look for a way to program the pump. One route is to directly enter rate and volume information to start an infusion. In our study, subjects regularly ignored dose limiting software. This rendered dose limiting software moot and points to significant safety issues in the administration of infusions.

It appears likely that clinicians will continue to have difficulty with the pump drug library. We recommended a deliberate and carefully managed process to introduce and maintain the drug libraries. We also recommended the investment of substantial effort to help pump users to understand the nature of the drug library, its updates, and its limitations. As part of our ongoing research into infusion devices, our laboratory will continue to review these data for further insights into clinician-pump interactions.

Methods

Eight or more subjects¹⁰ drawn from the clinicians who would be using the pump need to perform actual tasks on the pump in a clinical setting. Sessions need to follow appropriate experiment design and session procedures.⁶ Conducted correctly, this approach can generate data that have low deniability (demonstrate what users encounter) and are valid (are derived from actual tasks that users perform).

Video of pump operation by the highly qualified clinicians in the sample capture the difficulties that they encountered while programming even simple tasks. Brief interviews capture their thoughts on the pumps and their experience. Field observations validate the laboratory usability studies.

This was the first experience that the selection committee had with a scientific study of actual clinicians. The introduction of scientific analysis made a noticeable difference in the selection process. During committee meetings, nurses commented more than once how different, and better, their deliberations were compared with previous efforts that relied on sales presentations alone.

Despite the data that were collected by the laboratory, committee members and manufacturer representatives continued to rely on the solicitation of opinions as a way to determine how to proceed. Questionnaires were circulated to elicit comments on particular features of interest to the committee such as

whether sound alarms were “loud enough.” The approach tended to center attention on known issues and was used as a way to diffuse opposition to features that the clinicians found objectionable.

Agendas Beyond Clinical Issues

The inventory of pumps (device H) was aging, and fewer and fewer of them were available for use. The need to come to a decision was pressing. No pump was clearly superior during the laboratory’s evaluations. As a result, the technical information related to clinician use did not figure strongly in the purchase decision. This left an opportunity for other considerations to influence the outcome, such as compatibility with planned information technology systems.

Value

Human factors analysis of the devices revealed pump operating characteristics at the task level, which made it possible to develop insights about pump suitability for clinical use. The information was useful early in the process. Later, as the field of candidates was narrowed, the findings mattered less in the decision making process. When pump C was recalled, the process turned from comparison to confirmation, and stakeholders sought to control the process. Participants who continued to point out issues with pump P were marginalized or browbeaten to give the appearance of consensus so that possible future failure would not accrue to a particular individual.

CONCLUSIONS

Does a health care organization benefit from a scientific approach to making decisions about equipment? Our experience shows that it can, but that benefit accrues early in the consideration process. Our approach generated rich data that would otherwise not been available to those who were making the adoption decision. It also used actual clinician performance rather than a cursory review of appearances as a basis for comparison. If one of the candidates was superior, the data would have shown it. Human factors/ergonomics methods can serve other purposes beyond comparative evaluation. For example, the data that are collected during such a study may also support the development of training to help clinicians *anticipate*, rather than to be surprised by, the difficulties that are inherent in programming infusion devices. Beyond the medical center, the data would be of interest to the device manufacturer that is interested in improving pump safety, reliability, and efficiency.

Device evaluation relies on the collaboration of human factors and medical professionals. It requires the use of methods that are appropriate to equipment assessment. Expert analysis uses the depth of experience to provide deep insights, while usability assessment determines how clinicians perform while using the device. Infusion device selection has a direct effect on clinician work performance and patient safety. Our experience shows that a hospital staff that is assisted by human factors and medical professionals versed in equipment assessment can scientifically evaluate candidate devices. The scientific analysis can be used to inform purchase decisions and to balance the content of sales presentations that are necessarily biased.

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