

Original Articles

A Human Factors Analysis of Cardiopulmonary Bypass Machines

Douglas Wiegmann, PhD;* Thomas Suther, MS;† James Neal, CCP;‡ Sarah Henrickson Parker, MA;§ Thoralf M. Sundt, MD‡

*Department of Industrial and Systems Engineering, University of Wisconsin-Madison, Madison, Wisconsin; †Information Technology, Mayo Clinic, Rochester, Minnesota; ‡Department of Surgery, Division of Cardiovascular Surgery, Mayo Clinic, Rochester, Minnesota; and §Department of Psychology, University of Aberdeen, Scotland, UK

Abstract: The practice of cardiovascular surgery demands daily interface with sophisticated technologies including most commonly the cardiopulmonary bypass (CPB) machine. Although other industries have recognized the importance of considering human factors in the design of machines to reduce operator error, the evolution of the CPB machine over the past half-century has been characterized by incremental modifications of component parts with attention principally to mechanical efficiency and biocompatibility, but with little awareness of the impact of design changes on the human user. As a first step in the redesign of a safer pump, systematic observations of perfusionists during 10 adult and pediatric cases were conducted by staff cardiac surgeons and by human factors experts. Observations were classified according to accepted ergonomics principles. Perfusionists also performed usability evaluations and provided feedback concerning the design and functionality of bypass machines. Problems identified clustered around several usability themes. Issues with displays (8% of total comments) included location, legibility,

format, and integration. Multiple problems with controls (11% of total comments) including location, sensitivity, and shape were identified, as were issues with audible alarms (6% of total comments). Component integration (14% of comments) and workspace design (21% of comments) were suboptimal as well. Procedural and communication issues (21% of comments) related to pump utilization, rather than pump design, were also identified, which stemmed from a lack of standardized operating room practices. Clinical issues (14% of comments) surrounding care of the patient were also identified but were not further analyzed, because these comments did not pertain to the design of the perfusion pump. Our observations confirmed the hypothesis that opportunities exist to incorporate usability and ergonomics insights into CPB machine design to optimize the human/technology interface. Such fundamental design considerations may improve the safety of the conduct of CPB and, consequently, outcomes after cardiovascular surgery. **Keywords:** cardiopulmonary bypass, equipment, perfusion, patient safety. *JECT. 2009;41:57–63*

The practice of cardiovascular surgery demands daily interface with sophisticated technologies, and the most unique among these is the cardiopulmonary bypass (CPB) machine, the development of which is arguably the most important event in the evolution of the field. Within 2 years of its first successful application to a human in 1953 (1,2), the first series of “open heart” cases had been reported using a machine modified by the users (3). The mortality rate in the early days was ~50%; over the years, the

operative risk has dropped 10-fold. During that interval, incremental improvements in design of individual components of the CPB machine have been made to improve the mechanical efficiency and biocompatibility of the device, such as the replacement of the screen oxygenator (4) and disc oxygenator (5) with the bubble oxygenator (6) and ultimately the membrane oxygenator (7). Safety devices such as arterial line filters, bubble alarms, and automatic shut-offs have been introduced principally as add-ons; however, at no time has design of the entire machine been reconsidered along the lines of usability with safety and error management in mind.

Other high reliability industries, such as the nuclear power and aerospace industries have long recognized the importance of considering human factors in device design to reduce errors; however, the design of the CPB machine

Received for publication September 17, 2008; accepted February 24, 2009. Address correspondence to: Thoralf M. Sundt, MD, Cardiovascular Surgery, Mayo Clinic, 200 First Street SW, Rochester, MN 55905. E-mail: sundt.thoralf@mayo.edu

The senior author acknowledges that the authors have a grant with the Sorin Group and that their institution has a technology licensing agreement with The Sorin Group.

from the user's perspective has not changed appreciably. Within the healthcare community, there is a growing awareness of the role that poorly designed medical devices can play in favoring errors that cause patient harm (8). The US Federal Drug Administration, US Department of Health and Human Services, and Center for Devices and Radiological Health jointly published the report *Medical Device Use Safety: Incorporating Human Factors Engineering into Risk Management* (9), which stated, "The field of human factors provides a variety of useful approaches to help identify, understand and address (medical device) use-related problems. The goal is to minimize use-related hazards, assure that intended users are able to use medical devices safely and effectively throughout the product life cycle."

The favorable impact that good equipment design can have on performance and errors has yet to be realized fully in the practice of cardiovascular surgery or the design of CPB machines. To date, studies of perfusion-related incidents have focused primarily on documenting the context and rates of such events but have neglected human factors and design aspects of the machine that may have contributed to perfusion errors (10–12). The purpose of this study was to systematically identify issues related to the design and usability of CPB machines that may predispose surgical teams to make perfusion and/or related technical errors. This project is the first step in the process of developing a new perfusion pump system that is specifically designed to reduce operator errors and improve patient safety during cardiovascular surgery.

MATERIALS AND METHODS

This study was approved by the Mayo Clinic Institutional Research Board, and individual consent for the study was waived. Accepted human factors methods including direct observations, heuristic evaluations, structured interviews, and usability assessments were applied to equipment in daily use in our operating rooms. Because our aim was to evaluate general design and usability issues associated with the design of CPB machines broadly, no specific equipment will be identified according to manufacturer. The two CPB machines that were studied were both five roller pump-based heart lung machines (HLMs). The HLMs were both configured for the most part in the same manner, and pump assignments were the same. There were some differences between the two machines: one was a true five-pump base and one was a four-pump base with the arterial pump pole mounted to the side of the base. Also one machine had automatic safety features engaged. The other machine did not have this automatic feature engaged. The disposables were set up in a standard manner using a custom tubing pack, cardioplegia set, and oxygenator with open reservoir. The disposables varied between pediatric and adult

patients, but the oxygenators were of the same manufacturer family.

Direct Observations by Cardiac Surgeons

Systematic observations of perfusionists operating pumps during 10 adult and pediatric cardiac surgical cases (8 adult, 2 pediatric) were performed by seven senior cardiac surgeons. Surgeons were positioned directly behind the perfusionist and instructed to note problems associated with pump use during the case. They were asked not to interact with the perfusionist or the operating surgeon. Specifically, they were asked to identify any procedural or performance problems related to (i) difficulty in performing a task, (ii) timing of actions (premature, delayed, or out of sequence), (iii) repeated or multiple attempts to perform the safe action, and (iv) miscommunications between the perfusionist and the surgeon that may have impacted surgical flow or outcome.

Pump Evaluations by Perfusionists

Perfusionists performed heuristic evaluations to evaluate various aspects of a pump's design. A heuristic evaluation is a usability engineering method for finding problems in a user interface design (13) using a variety of general principles or "rules of thumb" for assessing interface design (14). Such heuristic evaluations are typically performed by a small set of experienced users of a device to judge the compliance of the interface with recognized usability principles including standardization and consistency of symbols and codes, useful help and documentation functions, limited demands on user's memory on how to perform a function, error correction and recovery capabilities, and clear feedback and functioning of the device at all times.

In this study, seven staff perfusionists who were very familiar with the pumps being evaluated were instructed on the purpose of the evaluation and provided generic examples of a variety of interface examples associated with design heuristics. They individually evaluated pump designs and recorded their observations using a standard pump evaluation form (Appendix 1) to note the problem/issue with the pump's design or the process of using the pump. A total of 14 evaluations were collected. The form did not require observers to identify problems with each heuristic or to classify an issue as being a problem with any specific design heuristic, but only to report design issues that caused them problems when using the pump. The type of design problem was analyzed after all data were collected. The pump evaluation form also required perfusionists to indicate (1) the specific aspect of their job that the problem affected (e.g., pump set-up, hook-up in the operating room, use during surgery, tear-down after use, and maintenance) and (2) the actual or potential impact that this issue may have on a variety of factors such as efficiency, errors, and safety. The form also contained a section for providing a brief description/explanation of each issue.

Interviews and Usability Assessments by Human Factors Experts

Two human factors/usability experts conducted structured interviews of perfusion staff and performed scenario-based evaluations during the various tasks performed by perfusionists during pump use (e.g., setting up the pump, making connections to the operative field in the operating room, operation of the pump during surgery, and tear down). These observations included the heuristic evaluation criteria described previously (13), as well as other specific factors related to the design of medical devices (8), such as whether (i) critical actions require confirmation, (ii), critical information is legible and in a useful form, (iii), connections are simple to perform and verify, (iv) disabling of life-critical alarms is prohibited, (v), alarms are effective in communicating the nature of the problem, (vi) settings are allowed to change automatically, and (vii) modes of operation are readily indicated and limited in number.

Human factors experts also interviewed perfusionists about potential problems with the design of various pumps. These interviews included questions targeted at specific potential design problems. Responses of perfusionists to these questions were integrated with the observational data.

Comments were all recorded into a Microsoft Excel data sheet and categorized according to content. Results obtained through the multiple research methods were integrated and analyzed to identify problems associated with CPB machine design and use. Problems generally clustered around a finite set of usability heuristics or "themes." These themes, including specific problems with pump design, such as displays, controls, alarms, and component integration, as well non-design issues such as miscommunication and a lack of standard operating procedures that impacted pump utilization, are presented in more detail below.

RESULTS

Content analysis of the participant feedback is shown in Table 1. A total of 8% of comments from all participants

Table 1. Content analysis of all comments.

Category	Percent of Total Comments
Issues with alarms	6%
Issues with displays	8%
Issues with controls	11%
Clinical issues	14%
Issues with component integration	14%
Issues with procedures and communications	21%
Workspace design issues	21%
Other	15%

Comments were recorded and were coded into the categories listed. Percents listed are the percentage of the total comments pertaining to each category.

pertained to problems with displays. Eleven percent of comments from all participants pertained to design of controls. Six percent of participants' comments identified problems with alarm systems on the perfusion pump. Comments pertaining to component integration accounted for 14% of comments. Issues with workspace accounted for 21% of all comments. Problems with communication and coordination of actions were one of the main issues reported by all participants in this study (21%). Each of the following sections will further detail each of these major design issues.

Problems with Displays

A variety of problems associated with displays mounted on or around the CPB machine were identified. These generally involved the integration, meaningfulness, legibility, and format of information. For example, some displays are generically labeled (e.g., Pressure 1, Pressure 2, Temperature 1, Temperature 2, etc.), requiring perfusionists to perform "work-arounds" such as after market labels put on top or below referenced information.

Another common problem with monitors is that information is not integrated into a single display. One surgeon noted that "there are three, or, depending on how you count them, four different monitors that the perfusionists observe during the case.... It seems to me that all of these data could be consolidated into one screen and that this screen could be set up to the right side of the perfusionists' field of view so that, again, there is less equipment and clutter between him and the operative field and the surgeon."

Another surgeon noted that "there is no on-line anticoagulation monitoring for the perfusionist. They must inquire as to the ACT. An ideal system would include a constant online assessment of anticoagulation." Other comments indicated that the hemochem display is placed across the room. The display is very poor for the task; the LCD display is small and sloped so that glare is a factor.

Problems with Controls

Multiple problems were identified with controls including failure to use different types of controls to perform different functions, sensitivity of controls, and location of controls. For example, on one machine, turning a rheostat-type control (i.e., knob) in the clockwise direction increased the desired action of the pump in all cases except one, for which a counterclockwise turn is required to decrease the gas flow levels, causing confusion and possible errors.

Other control design issues associated with rheostat controls (knobs) were apparent. For example, one perfusionist noted that "the knobs that control pump speed are not at the correct ratio for smooth operation. It is not obvious what is increase or decrease." In another instance, turning the knob moved a cursor up or down within a display and left and right arrow buttons increased or decreased a particular numerical value on the display. In contrast, the exact same rheostat control in a different location on the pump

did not affect the scrolling of a cursor but rather served the same function as the arrows on the other display (i.e., it increases or decreases a particular value on the screen), causing confusion and delays during the process of searching for information and setting the pump functions.

The location of the controls presented problems as well, with some positioned such that they are difficult to see while sitting at the pump. For example, the controls for adjusting water temperature on some machines are located at the base of the pump so that the perfusionist must control the water temperature without seeing the controls and must remember which knob is for the hot or cold water.

With regard to controls, one surgeon noted that "There is no automatic pump shut-off for arterial line pressure or cardioplegia pressure. Any clamping of line or kinking is a 'race between line blow out and the perfusionist's arm to knob.'" Another commented that "Perfusionist monitors the tube action and if jerking too much, perfusionist will occlude the tube to reduce flow. The control on the occluder is not helpful in that the perfusionists used to be able to dial in an occlusion number and know what would happen. Now they have to learn a dial that has no metric marking on it whatsoever."

Problems with Alarms

Concerns about the alarm systems on the pumps tended to focus on four main problems. The first is that alarms are generally the same, regardless of the type of problem to which the perfusionist is being alerted. For example, one perfusionist noted that "I cannot tell the difference between air detection, low level, or pressure limits alarms. I must look at the panel to see which is alarming prior to reacting. This adds a lot of time to the process and could cause errors."

Second, alarms can be turned off, with little if any indication on the pump displays. One surgeon noted that the "reservoir air detector alarm is often turned off and the perfusionist's memory is the only tool to turn it back on." Another noted that "perfusionist must remember to turn alarm on at start of case.... Even if alarm goes off, it does NOT stop the pump ... pump will empty in about 6 seconds after alarm." Another noted that "each perfusionist is able to set their own desired thresholds for alarms (e.g., 'line pressure level set by each perfusionist')." In one case, the "atrial line blew without setting off alarm (alarm set at 35 mmHg)."

The third problem is that not all critical parameters have alarms. For example, one surgeon noted that, on some pumps, "there are no alarms for several critical parameters' including pO_2 , pCO_2 , SaO_2 , Hg, Hct, K^+ , mean arterial pressure." Another surgeon noted that "there appears to be no apparent alarm on the Neo-Synephrine supply and no apparent alarm from the blood pressure. I noted that

the blood pressure remained in the 35- to 40-mm range for several minutes." A related issue of "delayed" alarms was also observed; for example "Water temperature is critical. The alarm to tell if water is too warm or too cold is slow in response to a problem."

Finally, it was noted by perfusionists that alarms are often difficult to hear, given the loud background noise in the operating room. One perfusionist reported that this ambient noise could "cause delays or failures in recognizing and reacting to alarms."

Component Integration and Workspace Problems

Several of the comments concerning the use of pumps during cases involved the integration of the CPB machine with other components connected to it. For example, one surgeon stated "the constant use pump sucker is at the far right end of the set up. Should be moved closer to oxygenator reservoir." Another commented that "there are seemingly too many cables and tubing running in different directions. This needs to be minimized for a clear workspace."

One surgeon commented that "the ergonomics of the current pump setup are extraordinarily awkward with the perfusionist needing to lean far to the left and far to the right. They sit not in front of the pump itself, but in fact in front of the oxygenator, and reach across to the pump. They are constantly sitting down and standing up to get an adequate view of the surgical field and still monitor the pump." Another stated that "the pumps are designed to work directly in the middle for best control and display viewing. The designers did not take into account the extra set of apparatus (filter, oxygenation, etc.) that moves the effective work position all the way to the left."

A second set of problems associated with workplace involved the size of the machine and its placement in the OR. For example, "work space is tight and perfusionist sometimes has to move equipment (pump) to open up space. They are also backed up against the wall, which reduces the walk flow pattern in OR." One perfusionist commented "with all the additional equipment in today's OR, a small pump system would be greatly appreciated."

Finally, on some pumps, there is limited workspace (i.e., desktop) for writing on and arranging instruments. "Space is limited for storing syringes and drugs that need to be administered. Places to put things are limited and the perfusionists have various "work-arounds" to solve the problem. Not all solutions are ideal. We need an explicit place to store drugs to be administered."

Communication/Coordination Problems

Problems with communication and coordination of actions were one of the main issues reported by all participants in this study. The two main themes of these communication problems were surgeon-perfusionist communication and perfusionist-anesthesiologist/nurse communication.

A major problem is that the perfusionist can not easily see what is happening at the surgical table. This makes it difficult for the perfusionist to coordinate his or her actions with the surgeon. For example, during a case, a perfusionist noted that "the only delay was when the surgeon asked for the heart to be filled. This takes time to get blood to the left ventricle. When the heart was not filled enough, the surgeon must ask the perfusionist for more volume. This is because the perfusionist can't see what is going on at the field." Most often, perfusionists must anticipate a surgeon's needs using the passage of time and by inferences made from the movements of surgical personnel at the table.

Conversely, surgeons are often unaware of the perfusionist's actions. For example, one surgeon noted that "in general the actions of the perfusionist are unknown to the surgeon, for example, the need for volume replacement, etc. If the perfusionist speaks up, the surgeon may look in the left chest for shed blood but the surgeon has no feedback on this requirement." Another commented that "the perfusionist increases and adjusts Forane independently on pump, without informing the surgeon."

Another type of communication problem/issue that can arise involves perfusionist-anesthesiologist/nurse interactions. For example, one surgeon noted that "the perfusionist had to seek the results of the ACT on a scrap of paper from the anesthesiologist. That seems an awkward means of communicating this critical information." Another noted that "hand signals are used with the anesthesiologist. Two fingers and zero on other hand. This can lead to communications breakdown. Are noise levels too high?"

Communication between perfusionists and anesthesiologists can also interfere with communication with surgeon. For example, one perfusionist noted that "there were repeated attempts to have the perfusionist turn the sucker up. The command by the surgeon was missed because the CRNA came back and handed the perfusionist some drugs to give and to discuss the patient's hemoglobin level. When the surgeon repeated the command louder, the perfusionist finally heard the command and turned the sucker up. This is the most common way a perfusionist misses a command."

Procedural Problems

The final set of problems involved the lack of standardization of certain procedures using the pump. For example, one surgeon noted that "Some of the changes in perfusion, e.g., lowering flow and beginning and ending cardioplegia infusion, are not completely clear, and the perfusionists have obviously learned the nuances of dealing with each surgeon. It seems to me that we should have a more standard way of addressing each of these steps in the operation, e.g., giving cardioplegia vent up, off, on, etc. I do not know whether it

would be possible to have standard commands or language and if this is done in other areas, e.g., the cockpit."

Another comment about procedures by a surgeon was "A final thought has to do with the differences in the way that surgeons separate patients from cardiopulmonary bypass and a different level of interaction from anesthesia.... The anesthesiologists were present as the patients were being weaned from the cardiopulmonary bypass, but their involvement and the way the patients were separated from bypass was quite different. It seems to me that standardization of this process would be helpful, both for the perfusionist and for training of residents."

Finally, a surgeon noted that "There is a problem with the procedure for calibration of blood gases. The calibration for blood gases on the monitors on pump were drawn at 9 minutes. The results came at 27 minutes. The K⁺ was 5.6 instead of 6.4."

DISCUSSION

This study is, to our knowledge, the first systematic analysis of the design and usability of CPB machines from a Human Factors perspective directed at understanding those characteristics that may predispose surgical teams to make perfusion and/or related technical errors. The human-machine interface is recognized as a particularly high-risk locale for error occurrence and is therefore a particularly opportune focus for efforts to improve patient safety (15). By using accepted prospective research methods including direct observations, heuristic evaluations, structured interviews, and usability assessments (13), we identified a number of correctable problems with the design of CPB machines. Because the safe conduct of CPB is central to the specialty of cardiovascular surgery as it is practiced today, these findings are of importance to all cardiovascular surgeons.

Among the problems we identified, appropriate information presentation for continual monitoring and integration by perfusionists is perhaps the most pressing. Currently, this information is distributed across multiple displays that are physically distributed at various locations on the CPB machine and/or in the operating room. Previous research in other domains indicates that spatial proximity between relevant and irrelevant information (proximity compatibility principle) is a dominant factor affecting performance and decision making (16). The converse is also true, with irrelevant information, or information that needs to be interpreted independently (not confused with other information), ideally located distant from other information. Simply applying this principle to improve the manner in which information is displayed for perfusionists on CPB machines could considerably reduce the risk of errors.

Readily correctable problems with the controls on the CPB machine were also observed. Currently, some controls are outside the view of the perfusionist. In addition, because perfusionists must often focus on several tasks at once, they are not always looking at a device while operating it. Furthermore, the effect of the control on the system can be inconsistent on CPB machines (e.g., clockwise turn of knob does not always mean an increase of a process). Therefore, it is important to make controls that look differently, are recognizable by touch, and whose movement results in a similar type of response. These findings are reminiscent of the situation that existed within the aviation industry decades ago. Poor cockpit design was responsible for numerous errors committed by pilots, including the infamous error of raising the landing gear while on the ground, which was caused by the similar shape and location of the lever used to manipulate wing flaps (16). A significant reduction in such errors has been achieved through the application of the basic design principles just described.

Disabling of life critical alarms was allowed on the CPB machines we analyzed. Indeed, several of the perfusionists had disabled the alarm system during an operation. This was because of the high false-positive rate of sensors triggering the audible alerts. This situation is an issue in other high-consequence industries such as aviation and nuclear power. In one perfusion incident recently reported to the CTSRS (17), a surgeon noted that the arterial blood in the pump was quite dark after going on bypass. After quickly troubleshooting the problem, the perfusionist identified that the oxygen inflow to the pump had not been turned on; the alarm for arterial blood saturations had been turned off as a matter of convenience to avoid false alarms associated with other perfusion parameters because the alarms on the pump are linked to roughly 10 parameters and cannot be individually adjusted or turned off. In this instance, the perfusionist decided to turn off all alarms. Clearly, more effort needs to be put into designing reliable alarms that allow the operator to adjust the thresholds and distinguish and prioritize the nature of warnings or alerts (18). The Joint Commission made clinical alarm safety a National Patient Safety Goal in 2003 in recognition of the fact that auditory alarm coverage continues to be a challenge in providing safe patient care (19).

Some non-design-related factors, including communication and coordination among surgical team members, was also observed to impact performance. This is not surprising given that the Joint Commission (18) reports "Communication" as the number one root cause (65%) of reported sentinel events between 1995 and 2004. This has been shown in the field of cardiac surgery specifically by our previous work (19). In this study, most communication problems related either not hearing a command/request or misinterpreting commands/requests. A method used in other industries for remedying these problems is to

establish a standard terminology (e.g., on-off, vs. start-off or on-stop, etc.) and a standard closed-loop protocol, such as the speak-reply-confirm method. Such procedures help reduce misinterpretations of commands and potentially misguided assumptions that another team member heard and understood a message. In addition to pump design and communication protocols, process redesign and standardized monitoring and alarm thresholds can also help improve quality and safety for patients.

There are limitations to our study. We did not observe all available machines, but rather the ones in use in our institution at the time of the study. Although newer machines have added features, none to our knowledge have been designed "from the ground up" according to ergonomic and usability principles, nor has their design been based on systematic observations such as were made here. The results reported here also represent only a limited number of observations. This was deliberate in our design to determine usability challenges that an experienced user might not consider notable because they are common workarounds and therefore seemingly unimportant. Without being experts in perfusion, our observers were able to easily identify common challenges in using the complex HLM interface. Finally, not all design issues identified lead to obvious errors, nor did all errors that were observed lead to adverse events (most did not). One could therefore question the "importance" of each issue identified. It is our observation, however, that this actually testifies to the ability of experienced individuals and teams to adapt to, or work around, poor design issues and to manage problems during routine care. The impact of these design issues, however, may become critically apparent in the face of emergencies. Improved design eliminating such compensation should free the team members to be better able to compensate for major events when they occur. Accordingly, we feel that the observations made in this study provide a good foundation for identifying general design problems to be remedied in the future and should be used to improve the design of CPB machines during the initial development and design process.

ACKNOWLEDGMENTS

This study was supported in part by a grant from the Sorin Group. The authors acknowledge the two anonymous readers for their expertise the perfusion staff that participated in this study.

REFERENCES

1. Gibbon JH Jr. Artificial maintenance of circulation during experimental occlusion of the pulmonary artery. *Arch Surg.* 1937;34:1105-31.
2. Gibbon JH Jr. Application of a mechanical heart and lung apparatus to cardiac surgery. *Minn Med.* 1954;37:171-85.
3. Kirklin JW, DuShane JW, Patrick RT, et al. Intracardiac surgery with the aid of a mechanical pump-oxygenator system (Gibbon

type): Report of eight cases. Proc Staff Meet Mayo Clin. 1955;30:201-6.

4. Miller BJ, Gibbon JH, Fineburg C. An improved mechanical heart and lung apparatus: Its use during open cardiomy in experimental animals. Med Clin North Am. 1953;1:1603-24.
5. Cross ES, Berne RM, Hirose Y. Evaluation of a rotating disc type oxygenator. Proc Soc Exp Biol Med. 1956;93:210-4.
6. DeWall RA, Gott VL, Lillehei CW, et al. A simple, expendable, artificial oxygenator for open heart surgery. Surg Clin North Am. 1956;36:1025-34.
7. Burns N. Production of a silicone rubber film for the membrane lung. Biomed Eng. 1969;4:356-9.
8. Wiklund ME. Eleven keys to designing error-resistant medical devices. Medical Device and Diagnostic Industry. 2002;86-88.
9. Kaye R, Crowley J. Medical Device Use Safety: Incorporating Human Factors Engineering into Risk Management. Guidance for Industry and FDA Premarket and Design Control Reviewers. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Division of Device User Programs and Systems Analysis, Office of Health Industry Programs; 2000.
10. Palanzo D. Perfusion safety: Defining the problem. Perfusion. 2005;20:195-203.
11. Mejak BL, Stammers AH, Rauch E, Vang S, Viessman T. A retrospective study on perfusion incidents and safety devices. Perfusion. 2000;15:51-61.
12. Stammers AH, Mejak BL. An update on perfusion safety: Does the type of perfusion practice affect the rate of incidents related to cardiopulmonary bypass? Perfusion. 2001;16:189-98.
13. Nielsen J. Heuristic evaluation. In: Nielsen J, Mack RL, eds. Usability Inspection Methods. New York: John Wiley & Sons; 1994:25-61.
14. Nielsen J, Molich R. Heuristic evaluation of user interfaces. Proceedings of the ACM CHI'90 Conference, Seattle, WA, April 1-5, 1990.
15. Strauch B. Investigating Human Error: Incidents, Accidents, and Complex Systems. Burlington, VT: Ashgate Publishing; 2004.
16. Wickens C, Hollands J. Attention in perception and display space. In: Wickens C, Hollands J, eds. Engineering Psychology and Human Performance. 3rd ed. Upper Saddle River, NJ: Prentice-Hall; 2000: 97-100.
17. CTSnet Cardiothoracic Surgery Safety Reporting System. Society of Thoracic Surgeons. Available with password at: <http://ctsr.ctsnet.org/sections/anecdotes/anecdotes.cfm>. Accessed June 27, 2007.
18. Edworthy J, Hellier E. Fewer but better auditory alarms will improve patient safety. Qual Saf Health Care. 2005;14:212-5.
19. Organizations National Patient Safety Goals, The Joint Commission. Oakbrook Terrace, IL, 2003.

Appendix 1. Pump evaluation form used for usability analysis.

Pump Evaluation Form

Describe the issue (pos/neg) associated with the pump's design or the process of using the pump.

What aspect of your job does this issue affect? (check all that apply):

Please explain:

- Pump set up
- Pump hook up in OR
- Pump use during surgery
- Pump tear down after use
- Maintenance
- Other _____

What is the actual or potential impact that this issue may have? (check all that apply):

Please explain:

- Inefficiency** (unnecessarily increases difficulty, complexity, or re-doing procedures)
- Distraction** (takes attention away from primary task)
- Frustration** (annoyed, stress, tension, etc.)
- Delay** (things take longer than they should)
- Workaround** (modification of equipment or procedure)
- Resource waste** (use of materials or other personnel that should not normally be required)
- Team coordination** (interrupting others, or delay in responding to surgeon's or other team member's requests/needs)
- Procedural error** (mistakes in decision making or failures of technique, etc)
- Patient inconvenience, discomfort or potential harm**
- Other** _____

What recommendation(s) would you make to fix the problem? Be as specific as possible. Draw a diagram if appropriate (space on back.)
