PEER-REVIEWED PAPER

Human Factors Analysis of an ICU

Allison Rhodes Westover, Timothy Moog and William A. Hyman

Bioengineering Program
Texas A&M University
College Station, TX

The safe, effective and consistent use of medical devices requires that they be technically capable of achieving their desired functions, and that they be designed to address the potential for user problems that may arise during their use. While the issue of usability arises throughout the hospital, the intensive care unit has been shown to be an area with unique human factors problems. The reasons for this include the multiple devices often being used, the stress under which the staff works, and the condition of the patients that may make them more susceptible to device mishaps. To investigate this issue we examined the ICU at a local hospital for potential causes of human error. Our observations revealed a range of problems, including: multiple alarm use; excessive clutter; anthropometric limits; and the potential for confusion in the various interfaces between devices, disposables, and patients. Our investigation also included discussions with the nursing staff and a survey to see how they feel about the medical equipment they use. As a result of these investigations, several recommendations for in-house and manufacturer improvements are given.

Index Under: *human factors, ICU, system safety.*

INTRODUCTION

The Intensive Care Unit (ICU) is one of the most important places that a patient may stay during their visit to the hospital. Their lives literally may depend on the effectiveness of the interaction of the nurses and the medical equipment monitoring their condition and providing selected therapies. Any error associated with the use of this medical equipment could directly, or indirectly, cause serious injury or death to the patient. Observations during routine daily activities in the ICU have demonstrated that a variety of mistakes do occur, sometimes with severe consequences (Donchin et al, 1995). These mistakes, involving IV line, infusion, drug and ventilation errors, can include direct injuries. They can also include monitoring mishaps that lead to a failure to properly attend to the patient as a result of a monitor not alarming as expected, or the alarm not being perceived or properly acted on. While the potential for errors during the use of medical equipment is important throughout the hospital, the ICU presents some unique situations due to the typical condition of the ICU patient and the simultaneous use of a number of devices that are typically obtained from different manufacturers and "integrated" on site. In this setting, it is crucial to try to identify potential problems in equipment use that could lead to hazardous situations. In so doing, it must be assumed that where there is a potential for hazardous human error, it will actually occur, at least occasionally, if not frequently. While errors in the use of medical equipment are often blamed directly on the user, it is well-established that the user alone may not be the primary cause (Bogner, 1994). Other causes may include training, working conditions and the design of the facility and equipment. The principle that the design of equipment is a critical component in facilitating or reducing the potential for error falls under the discipline of human factors. This area has seen extensive discussion in literature (e.g. AAMI, 1996) and growing interest by the Food and Drug Administration (FDA) aimed at initial device design (FDA, 1996) and medical device reporting (Shepherd, 1996).

What is perceived as human error can result from a multitude of human factors problems occurring singularly or together to cause difficulties at the interface between the operator and the machine. Some of these problems occur as a result of the designer of the equipment not ade-

Journal of Clinical Engineering • Vol. 23, No.2, March/April 1998

quately considering the operator as an individual, or perhaps more importantly, in the context of the real conditions of use of the equipment.

The ICU has a history of having human factor problems, including clutter of the workspace, confusing alarms and alarm controls, inadequate or inconsistent color coding, and the lack of standardization between similar or interrelated devices from different manufacturers. Historically, alarms are one of the most important components of the medical equipment in the ICU, and are therefore particularly significant from a human factors standpoint (Meredith, 1995). The importance of alarms arises from the role of monitoring in the ICU, and the intentional or unintentional reliance on alarms to call attention to needs of the patient in a consistent and meaningful way. Relevant problems arise from the design choices for the tone and duration of the alarm, the number of alarms per device, and the number of devices in the system. There is also a variety of methods necessary to set alarm limits and volume and observe these settings, inappropriate "urgency mapping", and a lack of standards for such features. Many alarms have very acoustically similar sounds that can cause them to not be heard or properly identified by the operator when one or more alarms sound at the same time. Some of the difficulties in identifying the source of an alarm are defined as masking. Masking is a function of relative alarm intensity and frequency, e.g. a pure tone more effectively masks a tone higher than itself than one which is lower (Woodson, 1981). Masking can create problems in hearing an alarm or in determining its location. The operator can loose valuable time searching for the source. Furthermore, finding and fixing the alarm can divert attention from addressing the needs of the patient. Many alarms also typically have a very loud and obnoxious sound meant to get the attention of the operator, but the nurses have a countervailing tendency to turn the volume down, or turn the alarm function off, if those functions are provided. In the absence of these functions, instances have been identified in which users have "modified" the device to make the alarm dysfunctional or permanently disabled. The absence of an alarm due to reduced volume, shut-off or disabling can lead to a false sense of security for the other nurses on staff who expect the alarm to sound to alert them if the associated condition occurs. Excessively loud, frequent or annoying alarms can also be a problem for the affected or nearby patient.

Design decisions made by the manufacturer are one of the primary causes of alarm related human factors problems in the ICU. One problem is that there are not common user interface standards for similar types of medical equipment. For example, different companies may develop different alarm tones for the same function on their respective ventilators, while other manufacturers may use these same tones on non-ventilator equipment that is typically used in conjunction with ventilators. This inconsistency and duplication even occurs within the products of a single manufacturer. It is also a common problem for the nurse to have difficulty distinguishing a potentially hazardous situation from one that is not as significant. This is defined as urgency mapping. For example, the manufacturer of a food pump may make an alarm very loud and urgent sounding, while the manufacturer of a ventilator may have an alarm that has a weaker sound that signals a more urgent situation. A further common alarm problem is excessive sensitivity, which can cause too many false alarms. This, in turn, can lead to the possibility of the nursing staff disconnecting or disabling the alarms. Overall, the alarms in the ICU are an abundant source of human factors problems that could cause human error leading to patient injury or death.

Clutter is defined as being filled with things that get in the way. Clutter in the ICU arises from the large number of devices typically used to monitor and treat the patient and the associated wires and tubes interconnecting the system. Furthermore, most of the devices being used are designed as if they would be used alone rather than in a conglomerated system. Clutter is known to degrade human performance due to confusion and distraction. It is curious that the resulting complexity appears to be viewed with some pride in the medical setting rather than as a source of serious concern. Ideally, the patient would be free of wires, tubes, tape, and needles; and not be surrounded by numerous bulky machines. The reality is that modern medicine requires the monitoring of a wide variety of physiological functions, and current technology requires this to be done with a substantial patient interface. In fact, to date, technology has compounded the clutter problem far more than it has cured it.

Reaching problems have also been observed to be common in the ICU. There is a limited, and variable, distance over which arms can reach and perform tasks, or allow the user to work comfortably. Effective reach is limited by height, arm length, the angle between the arm and the body, and the task to be performed. When this limit is pushed beyond the user's capability needed tasks cannot be performed. At the edge of physical capability, performance will be degraded and fatigue increased. In addition, physical injury to the user may occur from being biomechanically compromised, either as a result of a single event, or following cumulative or repetitive damage. Problems with the visual field, like reach, arise from human capabilities, individual user characteristics, equipment design, equipment placement, and room lighting.

In the ICU, the variety, size and placement of equipment in the limited space around the patient can cause problems in a number of patient- and device-related tasks. Sometimes the compact nature of the bed station causes problems when one piece of equipment is blocking another piece of equipment, thus making it difficult for the nurse to obtain, use or observe the obstructed device. If unable

to move the item out of the way, the nurse must reach over or around the object to perform the necessary task. Even if the device is movable, the nurse may choose to not move it, or think that it shouldn't be moved. In either case, the required task is made more difficult and the potential is increased for it to be performed ineffectively. The fairly common approach of hanging monitors from the wall or ceiling seems like an easy fix. However, if not carefully done, it can cause one user to be unable to easily reach the controls or read the display, while other users repeatedly hit their heads on the equipment.

While many of the problems addressed above have been known for some time, they have seen relatively little correction. The objective of this paper was to observe the day-to-day operation of a community hospital's eighteen-bed surgical/medical ICU, to survey the nursing staff and to identify examples of ongoing use related problems.

Observations

In the ICU, we observed how the nurses interact with the patients and the medical equipment. It was obvious there were numerous human factors problems that could lead to serious consequences. One of the most apparent situations in the ICU was the degree of clutter around the patients. Each bed station typically included a ventilator, a patient monitoring system (oxygen, pulse, blood pressure and EKG), a food pump, and an infusion pump, all fit into an 8' X 10' area. This kind of scenario created mobility problems for the nurses, as well as a hazard potential, especially when the patient needed urgent care. It was also observed that having all of the medical equipment crammed into such a small space compounded problems in identifying and accessing the different tubes and wires from the various pieces of equipment. We frequently observed pieces of equipment, wires, or other items getting in the way of nurses performing their tasks. In one case the hazard was to the nurse treating a patient that just came from open-heart surgery and was connected to a pacemaker hanging from the ceiling. Every time the nurses came to the side of the bed to perform some task on the patient, she would bump her head on the pacemaker.

Another problem that was readily observed was the extended reach problem, where the nurses had to extend their arms to obtain objects that they needed to perform their duties. A common design problem of ICU bed stations is the effect of the placement of the built-in oxygen supplies, suction and air ports behind the patient's bed. While this headwall design has become a very common ICU feature, it was seen to force the nurse to reach long distances in order to access parts of the system, especially when there were other items on the sides of the bed. This causes undue stress on the nurse and can lead to error and time delay due to the inability of the hand to maintain dexterity while reaching.

Another potential reaching problem that was observed was the placement of the patient monitoring system. The base of the monitor was located approximately seven feet above the floor. On the bottom of the monitor in use there was a keypad the nurses could use to make changes regarding the displays and patient-specific parameters. The manufacturer who designed this monitor apparently thought that the base of the monitor might be too high for all of the nurses, so they designed a hardwired keypad that could be removed from the side of the computer screen monitor and brought down with a cord. However, the user still had to be able to reach fairly high to remove and replace the keypad. The remote keypad did not address the problem of the monitor having to be viewed from a sharp angle due the high mounting point. If the user is unable to reach or see the monitor well, error may occur when the user inputs or observes monitor functions and data. Furthermore, steps perceived as not critical, such as resetting alarm limits or other device parameters may be skipped if the task is too difficult.

The multitude of cables and tubing that were connected to the typical patient was also seen to be a problem. The majority of the cables in use were the same beige color regardless of their purpose and the device to which they were connected. It was apparent that this caused problems in distinguishing which cables went to which medical equipment. There were several instances observed where the patient was nearly engulfed in cables, and when a nurse had to check the machines or the cables, you could see her tracing each one from patient to machine. This is not necessarily a great problem when there is no emergency on hand, although it can degrade nursing performance and decrease efficiency. However, when there is a problem, or when the nurse is trying to isolate what is causing an alarm to be activated, the extra task of tracking the cables can be potentially dangerous. There was also a problem of cables hanging down around the patient from various monitors and equipment, and in general getting in the way. One manufacturer has recently provided a simple hanger to go on the side of their equipment to store unused or excessively long cables. This is a long overdue "innovation".

The manufacturers attempted some color coding on the patient monitoring system, but only on the tips of the connectors. This facilitated initial hook-up, although it required the user to look into the connector tip to see the color. When this type of connector is plugged into the monitor, the color marking is hidden.

Mechanical aspects of plugging multi-pin connectors into their respective ports were also a source of annoyance and connector degradation. On the blood pressure modules of the patient monitoring system, the female connection point of the 12-pin connector had wear grooves that were created during the many incorrect attempts at inserting the connector into its socket. This could have been caused by two things. First, nurses could have repeatedly

attempted to install an incorrect wire into the port. For example, they could have tried to insert the EKG connector into the blood pressure port. Nurses could also have repeatedly attempted to connect the blood pressure cable at an incorrect rotation. In either case, the problem was a lack of color-coding and alignment guides provided by the manufacturer. Obviously, if people had tried to force the plugs into the wrong ports, they had difficulty associating where the connectors should go. In addition to the limited use of color-coding, the cable-mounted connector does not provide a good way to let the nurse know the correct rotation for inserting the wire into the unit. As with the colored tip, some users would know to look into the connector to identify the proper alignment, and then handle the cable end in such a way as to maintain the proper orientation. However, this may not be obvious, and it is unnecessarily awkward.

During one observation session, there was an instance in which multiple alarms went off at the same time. One sounded like a very high-pitched telephone ring. The other was a high-pitched whining sound. As the alarms sounded, we walked around looking for the source of the "telephone" alarm. We initially disagreed about its location, and when the nurse turned off the alarm we found out that we were both wrong. In this instance, the nurse on duty knew the source of the alarm by experience. However, another nurse who was less familiar with the specific equipment in use and its configuration would likely have had the same difficulty we did.

Nurses' Survey

In order to assess nurses' reactions and interactions with the medical equipment and the setup of the ICU, we undertook a survey that would give us more information that could not be obtained from observation alone. The survey included questions about alarms, reaching difficulty, and clutter in the ICU. Twenty-four nurses completed the survey.

The survey provided more extensive information on alarm use than we were able to obtain by observation since we were only present for a limited number of alarm events. It also gave us the opportunity to hear directly how the nurses felt about the alarms. The results helped to confirm historical and current observations.

When asked if the alarms were too obnoxious or loud, 78% of the nurses answered "sometimes", and 17% responded "always". A question related to the volume of the alarms asked how often the nurses would turn down the alarms, if they could. The response was quite interesting: 80% said they sometimes would; 13% said they never would; and another 8% said they always would. This shows that the nurses are disturbed by alarm sounds, and are willing to turn the alarm down. This obviously could lead to potential problems, since a decline in the nurse's response could result from the lowered volume of the alarm. It also presents policy, procedure and risk management issues: who is authorized to adjust or eliminate audible alarms, and what are the criteria for a minimally acceptable alarm volume or setting? Clearly, an incident in which there is an adverse patient outcome related to a monitored condition for which there was an alarm, but for which the alarm was not heard because of user adjustments, would present a risk management challenge.

The results of our survey supported the historical observations on alarm masking, with 83% of the nurses responding that they sometimes have trouble distinguishing which alarm is sounding when several are sounding at the same time. The nurses were also asked if they ever had trouble distinguishing where the alarm was coming from, due to the acoustical properties of the alarm. In their responses, 87% of the nurses said that they sometimes had trouble distinguishing where the alarm was coming from versus 13% that indicated that they never had this problem. The nurses were also asked specifically which alarms disturbed them the most. The results indicated that the infusion pumps, food pumps, heater/humidifier on the ventilators, and an external compression device created the most bothersome alarms in this ICU. These results are interesting because, in previous studies, ventilators have not always been cited as being as annoying as some of the other alarms. Given the lack of standardization of alarm sounds, relative annoyance can be a local phenomenon, depending on the particular variety of equipment on hand.

Our observations confirmed that clutter appeared to be excessive, and it was therefore of interest to see if the users shared this perception. We asked if the cables and tubing coming from the medical equipment ever got in the way of duties and tasks: 71% of the nurses responded "sometimes", while 21% said they always had a problem and 8% said they never had a problem with it. Bumping into things was also a common problem observed in the ICU, and when asked how often they bumped into things while performing a task, the response was 68% sometimes and 32% always.

When asked about being able to distinguish patient lines, the nurses responded that the cables and tubing were hard to distinguish from each other because of their similar color, and 83% agreed that if the equipment had better coloring, their tasks would be easier to perform. When the nurses were asked if they ever had trouble reaching the equipment or other items necessary to perform a task, they commented that they find themselves using extended reaches often, with 74 % stating "sometimes" and 22% stating "always". Another important aspect of ICU medical equipment design is the vertical placement of the medical equipment around each bed. From our observations in the ICU, it appeared that the height of the patient monitoring system caused problems for the shorter nurses. When asked if the nurses felt that the equipment was made for their size, 48% of the nurses said that the equipment was made for someone taller than them. When asked if they

thought this made performing their task harder, 74 % agreed that it did impede their work.

Less structured conversations with the nurses also helped us understand the problems that are inherent in this ICU. Fortunately, they were very open about the equipment-related problems that they experienced in the ICU. This helped to give us more of an understanding of their needs and where human factors could be improved. One area in particular that they mentioned was that manufacturers of medical equipment do not come to the ICU to observe what their particular needs are or see what the interaction is between nurse and machine. Whether or not this occurs elsewhere during the design cycle, the nurses never saw it and didn't know about it. Thus, their perception reinforced an old stereotype that medical device designers do not understand the clinical environment and the needs of the user.

While talking to the head nurse on duty one night, we learned how she felt about a number of things in the ICU. She said that not only do the alarms of similar devices of the same general type sound different, but the sound for a newer model of the same machine will sometimes have a different sounding alarm than the previous year's model for similar functions. As a result, in this ICU, different sounds meant the same thing. She also described a problem in which the alarms on an older ventilator had the same warning sound for different conditions, such as high pressure, low pressure, apnea, and disconnect. This is confusing when trying to isolate the problem after the alarm sounds, and determining whether the problem is with the patient or the machine. She said she would like the patient monitoring system to be more user-friendly, wished that the printout could be in real time, and that more than two functions would be available. When sitting at the nurses' station, she said that the monitor above the patient's bed is just far enough away that the baseline is difficult to see. She also noted that she would like to have five or more functions displaying the status of the patient, but the installed monitoring equipment was limited to only four simultaneous functions. She also said that she wished that the manufacturers could have a unit that could be customized to the needs of each particular ICU unit, because different hospitals have different needs. This observation is interesting in that customization may in fact be available, but this nurse had never been involved in any decisions in this regard, and didn't know such capability existed. A number of these complaints seemed to reflect inadequate or ineffective nursing input during equipment selection.

Hardware Approaches to ICU Problems

The underlying principle of human factors analysis and engineering is that equipment must be designed to meet the needs and expectations of the user if consistent and effective performance is to be obtained. Specific standards and guidelines have been developed to aid in this effort (ANSI/AAMI, 1993; FDA, 1996). In this regard we looked at a number of hardware issues to identify design approaches to their correction. For the most part these issues have been addressed in the general standards and guidelines, yet they have not been adequately dealt with in actual equipment design and utilization.

Alarms: The issue of alarms and the sounds that they make has received so much attention that it is surprising that the same problems continue to exist. It is clear that during design more attention must be paid to the nature of sounds produced with respect to audibility, annoyance, the ability of users to locate the sound, and the correlation of the significance of the sound with the significance of the event. This must be done in the context of the real conditions of use, including other equipment that is likely to also be present. In addition, the meaning of an alarm with respect to the condition causing it must be made to be immediately and easily identifiable. Standardization is also needed so that similar events make similar sounds, regardless of the manufacturer, and also within the product lines of a single manufacturer. One approach might be to provide user selectable tones so that the user could configure all of the equipment to a locally consistent and effective series of outputs.

Alarm functions must be made a distinct part of prepurchase evaluation, and checked for effectiveness upon installation and during ongoing conditions of use. The addition of new equipment requires a reevaluation in the clinical setting to assess the impact of the new device's alarms on those already in place. User training must include the nature of existing alarms along with policies and procedures for their use.

We suggest an approach to alleviate the stress caused by the sound of the alarms in a children's hospital. To make the alarms less obtrusive to the children, and make the environment better for them, the alarms could be integrated with the interior design — a jungle, for example. The alarms could make sounds related to different nature sounds in the jungle. This would create a wide variety of sounds for the nurses to use to distinguish the different functions of the different pieces of equipment. Sounds could also be grouped to help define the location, type or urgency of the alarm. For example, bird sounds could be unique to the ventilator, using a mild chirping sound for an alarm that occurs more often but is not a serious priority, as compared to a more forceful call to signify a more serious alarm. A less fanciful approach would be to have centralized display stations that provide a labeled visual indicator for every alarm function for every piece of equipment in use. This would, of course, require a communication standard and system so that all of the devices could be easily interfaced with the display station. While these suggestions may have some practical limitations, they perhaps represent the types of integrative approaches necessary to solve the multiple alarm problem.

Monitor mounting: For the equipment observed in this study, the patient monitor key pad, which is currently mounted on the side of the unit, could be moved down to a level easily accessible to all of the nursing staff. This could be done by mounting the unit on the wall beside the bed, or on an easily adjustable hanger. This would allow the shorter nursing staff to easily reach the controls. A wireless keypad would also be a nice option, subject to concerns about its potential for disappearance and electromagnetic interference. Mounting configurations should be considered during pre-purchase evaluations, with specific reference to the design of the specific ICU. These aspects of workplace design are not adequately addressed in the AAMI standard (ANSI/AAMI, 1993) which has an unrealistic emphasis on the seated worker.

Lead Identification: The difficulty in distinguishing patient lines from each other and attaching them to the correct point on the hardware requires an integrated approach. The use of the same-color lead for various functions should no longer exist in our hospitals. Since the functions and connectors are unique anyway, there is no reason for them not to be color-coded. In the absence of manufacturer support in this area, in-house coding could easily be done that would signify the machine and port that they belong to. Even marking just the ends of the wires would be a substantial improvement. A related in-house fix would be to mark the rotational orientation of the connectors and ports in order to reduce difficulty with obtaining the correct rotation required to match pins to sockets. This would clearly make the equipment easier and quicker to use, and may extend connector life. This issue is addressed in general terms in the AAMI standard (ANSI/AAMI, 1993).

User interface: Another common design problem that should be taken care of is the user interface with the machine. There should be no question as to how a function should work, and the nurse should feel comfortable using the equipment, regardless of its complexity. Again, this issue is addressed in general terms in the AAMI standard (ANSI/AAMI, 1993). However, as with many standards and guidelines, knowledgeable and thoughtful designers still must translate statements of principle, and even some detailed specifications, into actual hardware.

Accessibility: The reach problem can be remedied by placing the equipment in a manner that doesn't make the nurses have to stretch to do their tasks. Some of the roll-in equipment could be integrated into permanent fixtures that would make them more accessible, while keeping them from surrounding the bed. This would leave the area surrounding the bed free for the nurse to get into a good position to do work on the patient without straining and risking injury to both parties. The key to doing this successfully is effective integration based on realistic task analysis. Hanging things from the ceiling or installing them in the wall does not automatically result in a more usable system.

Risk Management Consideration

Human factors issues present a very real risk-management concern since they have received a great deal of recent attention. Problems that are known, or should be known, are the ones that most clearly demand corrective action so that they do not lead to patient or staff injury and subsequent economic and public relations risks to the hospital. Similarly, equipment problems that can be readily identified by outside investigators, or those that have been the subject of published articles, present the greatest potential for embarrassment after an incident. The opinions of the hospital's own staff on such matters are also a possible source of difficulty from the risk-management perspective, especially if a nurse were to be questioned about aspects of equipment that he or she had know for some time were problematic.

The required approach to these problems is multi-faceted. At a minimum it must include effective human factors analysis in the pre-purchase evaluation and installation of equipment, in-house human factors surveys using direct observation and staff consultation to identify use-related problems. There must also be a corrective action program to address identified problems, and site specific staff training to address residual problems that the staff will have to confront.

CONCLUSION

The observations and survey results obtained in this study are more anecdotal than they are well-designed scientific research. However, they clearly illustrate that relatively simple and well-known problems continue to exist and plague nurses, and potentially put patients at risk.

Overall, the results were very useful in determining and distinguishing some of the human factors problems in this ICU and confirming that these problems fall into well-known areas. While equipment use problems in the ICU have been known for many years, our results showed that there are ongoing issues with alarm design and standards, reaching problems, clutter, lead identification and the lack of consistently user-friendly interfaces. It is clear that manufacturers must continue to address these issues, and acquire a more widespread understanding of the need for realistic human factors considerations, including continued work with ICU nursing staffs. In the interim, these problems must be rigorously addressed at the hospital level, through equipment selection and integration, user training and on-site observation. In the latter regard, the techniques used here can be easily applied within any hospital to identify and address local problems and user perceptions.

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BIOGRAPHIES

Allison Rhodes Westover received a BS degree in Biomedical Engineering from Texas A&M University in 1996. She currently works for KRUG Life Sciences as a Biomedical Engineer in the Cardiovascular Laboratory at the NASA Johnson Space Center.

Timothy John Moog received a BS degree in Biomedical Engineering from Texas A&M University in 1997. Since then, he has continued his studies with an emphasis on engineering design graphics and computer animation.

William A. Hyman is professor and chair of biomedical engineering at Texas A&M University and co-editor of the *Journal of Clinical Engineering*. His interests include human factors and system safety aspects of medical device design and utilization. He is a member of AAMI, ACCE and BMES.

Address all correspondence and reprint requests to William A. Hyman, Bioengineering Program, Texas A&M University, College Station, Texas 77843.