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Incorporating new technology into healthcare: an analysis of performance, acceptance, and safety

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INCORPORATING NEW TECHNOLOGY INTO HEALTHCARE: AN ANALYSIS OF PERFORMANCE, ACCEPTANCE, AND SAFETY

by

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ABSTRACT

Each year, advances in the healthcare industry allows for better patient care and increased ability to save lives. Looking at standardized and common healthcare devices for both inside and outside the hospital environment, this research studied the tradeoffs and human factors that affect operator performance and patient survival. This research studied the impact of human factors and technology in the development and implementation of the automated external defibrillator for out-of-hospital use and the incremental advantages of SMArT infusion pump technology over traditional intravenous infusion pumps for in-hospital care. The study highlights the complex human factors of both products and establishes a need for more extensive user modeling and operator studies in order to better integrate the devices into the patient care system. Based on current results, minor changes to the design should provide significant positive impact to the overall effectiveness and performance of these devices.

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Finally, a sincere thank you goes to the members of American Red Cross – St. Louis Chapter, SSM Healthcare System – St. Louis, Phelps County Regional Medical Center, and Rolla Fire/EMS for their help and insight throughout the study. Without the dedication and patience shown, these studies would not have been possible.

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1. INTRODUCTION

Modern healthcare, along with modern society, is blossoming under the influences of technology. With each advancement in technology, medical insight grows and the opportunity for revolutionary devices expands. Prior to computers, one would never have dreamed about such advances as pacemakers, defibrillators, or any of the modern day imaging equipment that have each contributed to the comfort and longevity of modern life. Without advances in computer assisted drug synthesis, one can only imagine how many pharmaceuticals would never have been discovered and how many people would suffer from simple colds, flu, allergies, or high blood pressure.

Technology is also helping to make healthcare safer both in and out of the hospital setting. The advent of automated defibrillators that hang on walls in shopping malls and ride around in first responder cars is a perfect example of the potential technology holds for future healthcare challenges. To take a complex task such as reading and monitoring the heart rhythm of a patient and incorporating them into an automated system that also takes action to correct faulty rhythms without the operator needing any advanced degrees or special training was no small feat. The advanced safety considerations, risk analysis studies, human factors modeling and manipulations, and the immense legal hurdles of making such a device may even seem insurmountable, but with the advances of portable computer systems and precision electronics breaking down barriers, imagine the possibilities.

Similarly, looking further inside the hospital setting, imagine a treatment room with machines that are smart enough to know what medications the patient is prescribed, monitor these medications, monitor the patient, and automatically adjust themselves to compensate for changes in the patient's vital signs or laboratory tests. While this seems farfetched, modern medicine is on the cusp of this fantastic scenario. Advances in intravenous infusion technology allow the infusion pump to know information about the patient and characteristics of the medication being administered in order to recommend dosing ranges and intervene with alarms and hard stops if a medical professional misprograms an unsafe dosage of medication into the system. Incorporating bar code scanning, wireless connectivity, imbedded drug libraries, and loads of ergonomic upgrades, these pumps have come a long way from the days of "take 2 pills and call me in the morning".

PAPER

1. Automated External Defibrillator Innovation and Usability Design

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ABSTRACT

In emergency situations, time is critical. It takes time for an ambulance to arrive, leading many not-for-profits such as the American Red Cross and American Heart Association along with many local emergency medical service unions to encourage the public to be capable of performing CPR and using an Automated External Defibrillator (AED). AED technology can be life saving; however, there are several tradeoffs in design features and innovations that can be critical when designing or selecting the appropriate AED for a specific setting. This article focuses on the human factors engineering, that designers and manufacturers employed during the design and development of several modern AEDs, including a discussion of the tradeoffs involved, associated with the modern day AED.

KEY WORDS

AED Design, Defibrillator, Defibrillation, Automated External Defibrillation, CPR, Cardiopulmonary Resuscitation, Emergency Response

INTRODUCTION

Every day approximately 1,000 Americans suffer from sudden cardiac arrest. (Suri, 2000), (Occupational Safety and Health Administration, 2009) As the technology for

Automated External Defibrillators (AEDs) and Cardiopulmonary Resuscitation (CPR) advance, life-saving opportunities become cheaper and more available to the general public. An example of this is installation of AEDs at Chicago's O'Hare and Midway Airports. It is estimated that more than 300,000 U.S. citizens suffer from cardiac arrest each year, with 95 percent dying before reaching the hospital. (Arizona Department of Health Services) (American Heart Association, *Cardiac Science*) In June 1999 these airports installed AEDs in public locations, and in the first 10 months, 14 cardiac arrests occurred and 9 of the 14 survived (64%) due to the AED. (Occupational Safety and Health Administration, 2001) Statistically AEDs administered within the first few minutes of a cardiac emergency have a 60% survival rate one year following the incident. (Occupational Safety and Health Administration, 2003)

BACKGROUND

To understand how AEDs are used to save lives it is useful to briefly review the workings of the human heart. The human heart is a complex organ comprised of four main chambers, two atria and two ventricles, where a series of coordinated electrical impulses drive the four chambers in a way that pumps oxygen rich blood throughout the body. If these electrical impulses become uncoordinated (cardiac distress), the heart is no longer capable of performing efficiently, and if the condition is not corrected, the electrical impulses will stop all together (cardiac arrest). (American Red Cross, 2007) To put this in perspective, each year 25% of all deaths in the developed world are attributed to cardiac arrest, most of which typically happen outside the hospital, where the trained medical professionals are ready to handle the situation (Kroll, Kroll, & Gilman, 2008).

This is one of the main reasons that many employers and professional organizations have encouraged staff to be trained in CPR, but CPR rarely goes far enough. The survival rates for performing basic cardiopulmonary resuscitation (CPR) alone are 6% or below (Tilton, 2007). CPR alone cannot restart a heart that is not functioning correctly. The only way to correct an abnormal heart rhythm is using an electrical shock called defibrillation. (American Heart Association, *Cardiac Science*) Defibrillation for the heart is roughly the equivalent to pressing Ctrl + Alt + Del on a computer and works by temporarily stopping the heart so the natural electric impulses can reset and normal rhythms can return. (American Red Cross, 2007)

The history of defibrillation goes back to the early 1900s, as electric lighting was beginning to take its footing. Many of the workers stretching electrical lines were unexplainably collapsing and dying on the job. As research continued, a cardiac surgeon at the University Hospital of Cleveland by the name of Claude Beck, out of desperation during heart surgery, restarted a patient's heart using a research device designed to deliver a controlled electrical shock. (Kroll, Kroll, & Gilman, 2008) From this and many more breakthroughs, Dr. Paul Zoll was able to create the external manual defibrillator – the machine commonly depicted in medical dramas as the crash cart – which was then developed and implemented in hospitals across the world. (Bocka, 2009)

What about cardiac arrest patients outside the hospital; how crucial is their care? Research conducted in recent years shows that for each minute defibrillation is delayed following the onset of a cardiac emergency, the patient's chance of survival is reduced by

approximately 10%. (American Red Cross, 2007) Now taking into account the average response time for EMS, Emergency Medical Service, is over 11 minutes in populated areas and can be as long as 30 minutes in rural areas (Kroll, Kroll, & Gilman, 2008) and that survival rates if you wait for EMS to arrive fall to between 5-7% (Occupational Safety and Health Administration, 2003) it becomes apparent there needs to be a more accessible defibrillation device. These facts support the need for Automated External Defibrillators, which can be used outside the hospital.

Designing an AED to be used in highly stressful situations presents several unique design challenges. As the first AEDs were being developed, the designers realized they needed to encapsulate a very technical and complex medical machine into a system that was intuitive and easy to use, while still keeping the resulting product cost-effective. If one considers the human factor advances in the design of these devices, it becomes apparent that AED designers have succeeded in improving the products' usability.

USERS

Considering user challenges, the AED designers were tasked with making the machine operable by humans of varied ages, genders, physical sizes, physical abilities, visual acuity, hearing ability, literacy, and even mental abilities. The AED is designed to be hung on the wall and accessible for anyone, similar to fire extinguishers, (See Figure 1: Emergency Response Station) but there are many factors that could and do affect an operator's ability to use the AED effectively. The AED needs to be intuitive enough that the average person can grab it and effectively operate it without any training. In best-

case scenarios, there will be someone with training close enough to help handle the emergency, but designers must plan and prepare for the worst-case scenario. They also could not feasibly include a lengthy instruction manual with many different scenarios because in an emergency, the panic and stress level will not allow the operator to sit and read a manual.

Figure 1: Emergency Response Station

As depicted in the above image, many facilities have designated areas where emergency equipment is located. This example shows a wall mounted first aid kit, a first aid kit that may be carried to the scene of an emergency, an AED, and a fire extinguisher, as well as emergency instructions. *Photo by Tony Strawhun*

To test the impact training plays in the effective use of AEDs, the Occupational Safety and Health Administration (OSHA) preformed a study of AED deployment times in controlled cardiac arrest scenarios. Astonishingly the mean time of defibrillation was 67 seconds for trained emergency service technicians and only 90 for untrained 6th graders

(Occupational Safety and Health Administration, 2001) demonstrating that a device designed with effective instructions built in limits the role of training in effective AED operation.

It is insufficient to have directions written only in English if the operator only speaks another language or is illiterate. To overcome this challenge, many manufacturers have included easy to read, single page instructions in several languages, pictorial directions on the base unit and pads, and an auditory guide with selectable languages. Several examples of these instructions are shown in Figure 2. Designers of the early AEDs realized that the more descriptive the auditory instructions can be, the quicker the users will successfully complete the task. (Suri, 2000) Designers have since extended the instructions to provide increasingly more detail and information if the user delays in completing the task. For example, when the machine is first powered on the instruction "Apply pads to patient's bare chest" is announced and followed by "Follow pictures on pads to apply to patient's bare chest, then plug in connector". After a brief pause, if the user has not successfully plugged in the connector, the unit prompts, "Apply pads as pictured, then plug in connector next to the flashing light." Similar progressions of detail accompany instructions at all stages of operation to provide added direction only when needed. As soon as the step is successfully completed, the AED unit begins instructing the user towards the next step.

Figure 2: Examples of Instructions

The above images show the simple three task instruction cards packaged with most AED units. *Photos courtesy of American Red Cross*

To the other extreme, designers need to balance providing feedback to the operator with overwhelming him or her with too much information. Human beings are only capable of deciphering, processing, and remembering a small number of pieces of information simultaneously in their short-term memory. Yet, human decision-making relies on clear and diagnostic feedback in order to correct poor decisions. (Wickens, Lee, Liu, & Gordon Becker, 2004) If the designers have too many buttons, too many lights, make the buttons too small, or put the buttons too close together the chance for the operator making a mistake increases and the ability for the operator to correct these mistakes decreases. Many models of AEDs have been visually subdivided into chronological steps with only one button, screen, connection, or action per step. Figure 3 shows several examples of this design.

Figure 3: Base Units

These photos show the base units of several major brands of AEDs. Each is visually divided into separate chronological tasks critical to the operation of the AED and each has a redundant image of instructions for placement of the pads. *Photos by Tony Strawhun*

Designers also cannot predict how many people will be available at the scene of an emergency, so they needed to make the AED units operable by a single person. This forces them to make the system light enough for people of differing abilities to carry and the system must function with only one operator. Yet in the event that multiple rescuers are available, the system must be accommodating enough that it does not get in the way of other CPR and rescue equipment, nor interfere with the ability of additional rescuers/equipment to access the patient. According to research done by the American Heart Association, the first out-of-hospital defibrillators weighed over 110 pounds, while today they weigh a mere 8 pounds (American Heart Association, *CPR Statistics*) and currently the average AED is about 1 square foot. This small size and relatively

lightweight allow for the largest possible range of users to successfully transport and efficiently use the device.

PATIENTS

Focusing on the patient, the designers must make the AED compatible with a wide variety of people. Patients differ in age, weight, and body size. They can be on different medications, have different medical histories, and could even be experiencing additional medical emergencies beyond cardiac problems. Adults and children require a different amount of electricity from the defibrillatory shock due to the fact that children typically have smaller body structures and less muscle, fat, and other material that the electricity must penetrate. Another design issue, males usually have more hair on their chests, creating a barrier that can reduce contact between the system and the patient. This can force the operator or system to make accommodations. Most issues in patient variability can be easily eliminated with the electrode delivery pads.

The electrode delivery pads are the mechanism used to transmit the defibrillatory shock from the base unit to the patient. The commonly accepted industry practice is to have white or blue foam "stickers" that adhere to the patient's chest and connect to the base unit via electric wires. This ensures constant contact and keeps the operator free to perform other tasks. The adhesive used is embedded with salt solutions that electrically connect the pads to the patient and helps more evenly and effectively deliver the defibrillatory shock, reducing burns or electrical injury. These pads are also the key to the system distinguishing between patients. There are two different size pads packed

with each system, one large set designed for adults and a smaller set designed for children, addressing the need for different electrical characteristics in adults and children. Child-like symbols, such as teddy bears or rubber ducks, typically appear on the pads or the cable connector of the pediatric pads. These contain electrical components used to reduce the electricity delivered to child patients. (See Figure 4: Pediatric Pads). Other commonly accepted practice in the industry calls for items such as spare pads, razors for removing hair from the patient's chests, shears to remove patients' clothing, and other necessary supplies to be included in the case or packaging of most AED units to helps to ensure the operator has all necessary supplies with the AED and does not need to find or grab other bags in order to use the AED.

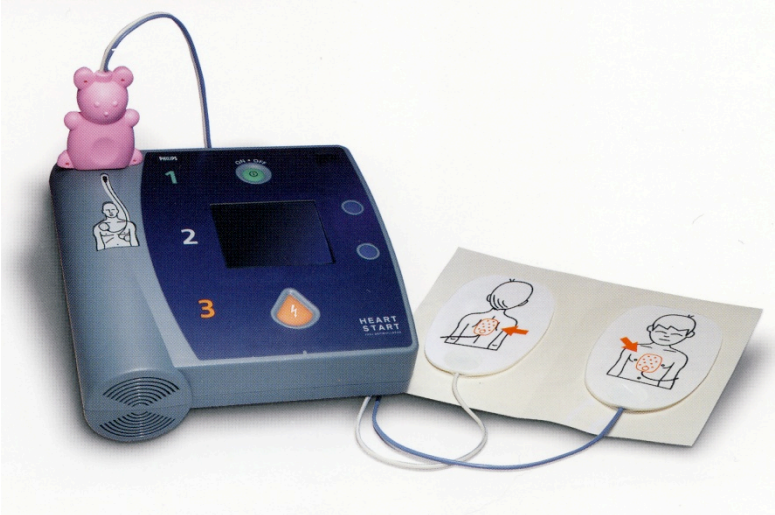

Figure 4: Pediatric Pads

The above photo shows pediatric AED delivery pads designed for patients under the age of 12. The pads are smaller than those designed for adults and have a teddy bear shaped connector to help distinguish them as pediatric equipment. *Photo by Tony Strawhun*

Each manufacturer has a proprietary pad design, some examples of which are shown in Figure 5**.** When the pads are separated, there is more chance of improper pad placement on the patient, and a slightly longer time to attach the pads, but this design adapts to the

anthropometrics of the patient and allows for a more effective defibrillatory pulse. Conversely, the connected pads are packaged such that they are already placed at the appropriate spacing and angle from each other and the connective material has markings to help operators center the pads on the chest and find appropriate hand placement for performing CPR, but this style is one size and does not account for different anthropometric characteristics and thus reducing the effectiveness of the defibrillatory pulse.

Figure 5: Examples of AED Pads

As depicted above, while each manufacturer has their own pad design, all have pictures showing their proper placement on the patient. This is redundant to images also placed on the base unit, providing operators a second location to find placement instructions. *Photos by Tony Strawhun*

SAFETY

The purpose of the AED is to deliver a dangerous, even lethal, electric shock to the patient without harming the patient or rescuers. If this shock came into contact with a person NOT experiencing cardiac problems, the shock could be capable of stopping the bystander's heart. The shock and the device producing it should not further injure the patient. This combined with the fact that most of the intended users do not have formal medical training, requires the device must be "smart" enough to recognize whether or not the patient needs defibrillation and then the machine must determine how much electricity to deliver. To accurately handle these issues, the base unit has three main functions. First is a series of complex electronics designed to analyze and interpret the patient's heart rhythm. Simplifying the functionality, these circuits read and interpret the electrical activity of the patient's body, and then make complex calculation as to how much electricity to deliver in the shock, and how long the shock needs to last. Second this analysis system must electrically disconnect from the rest of the system so that the shock capacitors can charge and deliver the defibrillatory pulse without destroying the analysis system. The final function of the base unit is data recording. This independent system records data from the unit regarding operation characteristics, analysis data, shock delivery data, and also has an audio recording device to capture the sounds from the scene. These recordings are designed to be used by the manufacturer to improve usability and operability of the product, but they can also serve as evidence in court if necessary.

REGULATIONS

There are currently no OSHA regulations or other federal oversight regulation governing the sale or use of FDA approved AEDs; however, there are guidelines and recommendations presented by OSHA in addition to several states that regulate or govern AEDs. A full list of regulations is available by visiting the American Heart Association website. (http://www.americanheart.org/presenter.jhtml?identifier=3024006)

Despite the lack of regulation, an average of 4.5 safety advisories are published annually regarding AED units or accessories. Since 1996, every major AED manufacturer has recalled products or accessories based on one or more of these advisories, yet as the complexity of the AED increases, the rate of AED related advisories has not increased significantly. Despite the continued presence of advisories and recalls, many affected units still remain in service. Manufacturers and consumers should increase efforts to remove defective or unsafe units from service until they can be properly repaired. (Shah & Maisel, 2006)

OPERATIONAL PROCEDURES

Designers have incorporated good human factors techniques when designing the operations of this unit. The first operational step is when the operator turns the unit on. Some systems turn on automatically when the case is opened and others have a designated on/off button. The operator is then instructed by the unit to place the delivery pads on the patient's chest. The pads must then be connected to the unit. (See Figure 6 – AED in Operation) Most units have the cables attached to the pads, but the end of the

cables still need to be plugged into the base unit. For these AED designs, the base unit verbally instructs the operator where to plug in the pads with a redundant signal of a flashing light next to the connection area. To reduce distraction, this is the only flashing or lit component at this point in the process.

Figure 6: AED in Operation

This image shows a man preparing to deliver a defibrillatory shock to a coworker using an AED as part of effective CPR. *Photo courtesy of the American Red Cross*

Once the cable is connected, the system analyses the patient's heart and instructs all bystanders and operators not to touch the patient. After analysis, the unit either states, "no shock advised…begin 2 minutes of CPR" or "Shock advised…Charging." After the unit is charged, it instructs the user to push the shock button, produces a loud siren, and makes the shock delivery button flash so the operator can easily identify it. These messages provide feedback to the user and reduce the chance the user will interfere with the functioning AED. As the operator pushes the shock button, the unit discharges the stored electricity to the patient, and the AED immediately goes back into analysis mode.

This process continues until the unit is shut off or the main operation battery becomes too weak to continue operation. (American Red Cross, 2007)

Another unique design feature becomes evident when the paramedics arrive. All AED pads are designed such that the paramedics can unplug the pads from the AED base unit, and the pad connectors fit directly into the paramedic's equipment, occasionally using an adapter. This saves time on scene and reduces pain and trauma on the patient because the paramedics do not have to attach separate pads and equipment to the patient. On many newer model AEDs, the base unit also has a data port where paramedics can retrieve the data being recorded by the unit and add it to the information they collect on the patient, allowing them and the hospital staff to better understand the patient's condition, and better tailor the advanced medical treatment to fit the his or her needs.

CONCLUSIONS

Designing an AED is one of the definitive human factors/ergonomic challenges. It requires balancing tradeoffs in performance criteria while considering user abilities and limitations of the widest possible population during a time of tremendous stress. Designers are faced with countless usability issues that can literally costs lives. For example, making the buttons bigger makes them easier to identify and operate, but at the same time increasing the button size increases the AED's size and weight. Integrating an auditory directions system requires additional power that cannot reduce or interfere with the defibrillatory shock. This feature will require designers to address different language requirements of potential users. There are thousands of these tradeoffs, some obvious

and others critical issues that the typical designer might overlook if human factors and usability are not considered during every step of the design process. In light of the tremendous stress associated with cardiac emergencies, it is reassuring to know that designers have carefully considered the human while developing these complex, life saving devices.

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2. An Assessment of Risk and Usability for Infusion Pump Technology

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ABSTRACT

Due to the large number of patients receiving intravenous (IV) infusions of medications each year, engineers and technologists have studied how effectively and safely the intravenous infusion pumps perform. Over the last decade, SMArT infusion technologies have been introduced and have grown to control a majority of the market. The manufacturers of these "smart" pumps claim that advanced features such as imbedded medication dosing limit libraries, the ability to run multiple infusion channels from the same pump controller, bar-code scanning of medication and patient information directly into relevant fields within the pump program, wireless communication of the pump controller to care facility computer systems are part of an integral system to reduce medication errors and improve overall patient safety. This study surveyed 28 nurses in the emergency and maternity departments of a local hospital. The results show that nurses feel that SMArT technologies are beneficial to patients, but must be implemented with caution. The nurses surveyed prefer hands on or simulated usage training methods where they can experience and troubleshoot pump operation. Nurses also recommended additional features related to medication compatibility to reduce potential for medication errors be included in the devices' imbedded libraries.

Key words: IV Pumps, Medical Safety, Medication Errors, SMArT Infusion Pumps

INTRODUCTION

As the library of clinical pharmaceuticals expands, medical care units such as emergency rooms, surgical centers, intensive care units, and in-home care medicine teams must be prepared to adapt their technology and procedures to accommodate medical advances. A great improvement was made with the advent of intravenous (I.V.) infusion pumps. These self-contained portable fluid pumps administer saline or other carrier fluids, medications, or blood products at controllable and variable dosing rates into the patient's vein via a continuous injection site. They allow care facilities to deliver a constant and consistent dose of pharmaceuticals to patients without the patient swallowing pills or syrups. This allows the care professionals to deliver life-saving medications to patients without the patient actively ingesting or inhaling medicine while providing a mechanism to administer controlled dosages over time.

The use of infusion pumps has become the industry norm in many care settings with 90% of hospital patients receiving I.V. medication, typically delivered via infusion pumps (Morgan and Siv-Lee 2009) but to effectively utilize this technology, the care professionals must correctly program the pumps and the pumps must correctly control the dose of medication being delivered to the patient. Healthcare professionals typically cite the five "rights" of safe medication administration – right medication to the right patient by the right route in the right dose and at the right time. (Morgan and Siv-Lee 2009)

Many care facilities state that patient safety and care are a top priority, but often fail to look at or acknowledge the potential risks associated with a care professional incorrectly or erroneously programming an infusion pump or delivering the wrong medication. "Of the 700,000-plus adverse drug events each year in U.S. hospitals, an

estimated 35-60% involve medication errors related to intravenous infusion." (Birk 2008) Or as another professional claims, the primary efforts of hospital safety efforts should focus on the prevention of IV medication errors, especially continuous infusions, which typically span multiple shifts of care professionals and are typically adjusted based on results of laboratory tests or patient reactions. (Danello, Maddox and Schaack 2009)

Blame for errors should not be entirely placed on the individual programming the machine, but also on the supervisor of that individual, the policy writers for the facility, and even the manufacturer of the device. Many of the errors in programming or operating modern day infusion pumps center around care professionals accidentally mistyping dosing rates (such as 100 instead of 10 or 1 instead of 0.1) or miscalculating the concentration of medication prepared for delivery to the patient. (J. M. Rothschild, C. A. Keohane, et al., A Controlled Trial of Smart Infusion Pumps to Improve Medication Safety in Critically Ill Patients 2005) (DiConsiglio n.d.) A simple way to avoid these issues would be to have standard concentrations and a redundant check of the dosage programming; however, this check takes time and is just one more step that can be overlooked in emergency situations or situations where the healthcare worker is overloaded.

SMART PUMPS

In recent years new advances in infusion technology have appeared in the market that claim to reduce the potential for costly programming errors and improper concentration calculation. Safe Medication Administration through Technology and Human Factors Infusion pumps (SMArT or SMArT^{HF} pumps) are a relatively new and expanding technology that incorporates user-centered design principles and human

factors engineering into the basic infusion pump in order to better address care facility safety concerns. According to a 2009 report by Pharmacy Purchasing and Products, SMArT pumps have now been implemented in 60% of hospitals nationwide. (Pharmacy Products and Purchasing 2009)

SMArT pumps are a classification of pump produced by a variety of vendors. They can include preprogrammed drug libraries, established by the care facilities, with hard and soft limit dosing constraints, barcode scanning, and wireless monitoring to allow care facilities the checks and balance coverage they previously could not effectively employ. The pump is knowledgeable enough about the proper distribution of many drugs that it can typically intervene when programming errors occur.

SMArT pumps also include an additional advantage for many care facilities: free-flow prevention cassettes. Free-flow occurs when the infusate flows freely under the force of gravity, without being controlled by the infusion pump. (The Joint Commission 2000) In many existing infusion pumps, when the control cassette (the part of the pump that actually controls and pumps the medication into the patient's I.V. line) is removed from the pump housing due to transfers to other care units, changing of dressings/linens/clothing, or while performing scans and other tests the cassette looses the ability to control the flow of the medication to the patient. This creates major complications and potential for adverse reactions for patients and increased potential for gaps in the patient's overall safety within the care facility. Many pharmaceuticals have limited dosing ranges for safe administration, and when medications are in free-flow, there is no control over the rate or concentrations of medications entering the patient's bloodstream, nor is it possible to measure the amount of mediation the patient is

receiving. Without proper control and measurement of medication, clinicians and other medical professionals have no adequate way to manage patient care and protect the lives of their patients.

ADVANCED FEATURES

Other advanced features in infusion technology, such as barcode scanning, color coded labeling, and wireless integration, have taken great leaps to help increase safety of the patient. Bar code scanning, sometimes referred to as BCMA (bar coded medication administration) is an integrated technology to track and assist in administering medications within the hospital setting. Typically patient demographics such as height, weight, age, and other relevant information are encoded into the barcode of the patient's id bracelet. Similarly, each container of medication or other infusate is marked with concentration, identification, and other information used by care professionals to program the infusion pump. With BCMA, the pharmacist or nurse administering the medication scans the patient's bar coded bracelet and the barcode on the infusate, and then only needs to program the dosing information into the pump. Some BCMA systems even incorporate dosing information into the barcode of infusate. (Rothschild and Keohane, The Role of Bar Coding and Smart Pumps in Safety n.d.)

With this advantage, the barcodes associated with the medication product, the patient, and the care provider automatically input information into the infusion pump programming system leaving less information for the care professional to input and less opportunity for mistake. This dramatically decreases the time required to correctly program the infusion and better utilizes the advanced features of the medication library.

Another bonus is the ability for wireless communication and integration of the infusion unit into the care facility system. Several modern infusion pumps are equipped with Wi-Fi access that a facility can integrate with their computer network and electronic records system. This connectivity allows the care facility to track each pump and constantly monitor the operations without having to constantly enter the patient room. This feature also allows data from the individual pump units to be automatically included in the patient's charts and accessible from any computer on the care facility network. Finally this allows the care facility to track data and usage statistics within the facility such as how often dosing alarms sound, how frequently certain medications are prescribed, how effectively the staff is utilizing the technologies available to them, and how frequently errors occur in daily operations.

PUMP DRAWBACKS

All these advanced features might grant SMArT pumps the illusion of being miracle safety systems that are constantly making patient care as safe as possible; however, several key drawbacks have hindered progress. "Nearly one in five SMArT pump customers say they would not buy their current pump again, with one notable exception, according to a new report from healthcare market research firm KLAS [a third party independent research organization]." (KLAS 2010) As quoted from another source,

> [T]he rapid expansion of pump use has inevitably created its own risks. Dosage problems. Programming errors. Embolisms. Vein occlusions. Not to mention such equipment malfunctions as motor and battery failures. 'Infusion pumps have been associated with greater safety issues…In general; you have sicker patients and more critical medications where the margin for error is small. That is why pumps evolved in the first place. But with any technology, you solve one problem and there's a tendency to potentially create another one.' (DiConsiglio n.d.)

The main selling point of the SMArT system over traditional systems is the library of common medications with standardized high and low dosing limits. This system creates the largest drawback due to the fact it is not a standardized library. Every care unit must individually program limits into the library and then ensure the updated library has been propagated to all the individual pump units. Because of the time and resource intensive processes to update the library, and the extra time needed to use the library in the patient's room, several studies have shown that care professionals simply bypass or override the library and manually calculate medication dosage. (J. M. Rothschild, C. A. Keohane, et al., A Controlled Trial of Smart Infusion Pumps to Improve Medication Safety in Critically Ill Patients 2005) (Husch, et al. 2005) (Morgan and Siv-Lee 2009) (Birk 2008) This simple alteration to the standard procedure removes several layers of protection to the patient and effectively negates the vast majority of the safety features that make the SMArT pump any different from traditional pumps.

Similarly, many systems have one library per department (ER, ICU, cardiology, etc.), but for care units that cater to both adults and children, this can prove deadly.

> A unique characteristic of pediatrics is the wide variation in patient size from infancy through adolescence and the associated physiological maturational changes that occur throughout childhood. This is in contradiction to the normal mature adult in whom physiology is predictable and size is uniform…It is well recognized that the variability in size and organ maturation complicates the determination of medication dosages for infants and children. Calculation errors are relatively common, particularly in high stress environments. (Felke, et al. 2009)

Coupled with the fact that pediatric doses for most medications need to be calculated individually for each patient, and each care facility has different procedures, obvious care is needed when treating pediatrics.

PREVIOUS STUDIES

Throughout the last decade researchers within and outside the healthcare industry have taken an interest in the advances in safety, error reduction, simplicity, and effectiveness afforded by SMArT infusion technology over the traditional infusion pump. Studies have looked at which style was easier for the care staff to use, which had better ergonomics or employed better human factors principles, which style was more prone to programming errors, which style created a better overall safer experience for staff or patients, which style afforded the better return on investment, and even simply which style was preferred by care professionals. No clear consistent results have been found. Some report that SMArT infusion technology has no statistically significant superiority over traditional technology from the viewpoint of safety and/or error reduction. Others have reported that the SMArT infusion technology is dramatically superior to traditional technology from the viewpoint of safety and/or error reduction.

The 2009 study by Trbovich, Pinkney, Cafazzo, and Easty created a close approximation to real world implementation of traditional, SMArT, and barcode capable infusion pumps and compared error resolution, pump programming accuracy, and success rate of secondary infusion, all as a function of pump type. Results from the study, which involved 21 infusions per participant with controlled quantities and types of planted errors/inconsistencies, showed that pump type did not significantly affect nurses' performance in detecting or remedying wrong drug errors; however, they were able to remedy approximately 60% of wrong drug events. The bar code scanner was significantly superior to traditional and non-barcode SMArT pumps in identifying and correcting wrong patient errors, but there was not a significant difference between the

traditional and non-barcode SMArT pumps. When faced with hard dosing limits, the SMArT and barcode pumps differed dramatically from traditional pumps with the only errors not corrected coming from infusions where the medication library (and thus safeguards) being turned off. No significant differences across pumps for soft limit or secondary infusion error corrections. The study also noted that its results corresponded with several other studies showing that "nurses often override soft limit alerts when clinically inappropriate [but] when faced with hard limit warnings, nurses respond in a safe manner." (Trbovich, Pinkney and Easty 2010) Finally, the study notes that several of the errors identified resulted from lack of integration with other elements of the medication delivery system.

Another study by Rothschild, et al. looked at a repeated measure variation between SMArT infusion pumps configured with point-of-care real-time decision support and pumps with this feedback system disabled over four eight-week data collection sessions with a two-week transition phase between. Based on the data collected, the study noted that several of the most common medications prescribed were not in the drug library of the study pumps and approximately 10% of infusions were undocumented verbal physician orders. There was no significant difference noted between the feedback and non-feedback configurations in intervening adverse or potentially adverse events with the most common error type of incorrect dosing of titratable drugs and incorrect intravenous drug rates. The study points out that 72% of preventable adverse drug events recorded during the study were life-threatening events and 94% of preventable events had the potential for serious or life threatening consequences. As an unintended observation during the study, the researchers noted an alarming rate of nurses bypassing the drug

library or overruling limit alerts generated. One explanation given for these phenomena was the high paced conditions in emergency infusions; however, the occurrence of these short-cuttings still outweighed such emergency situations. They note that safe medication practice depends on institutional factors and standardized procedures with proper explanation of why more time consuming procedures are necessary over short-cut procedures. (J. M. Rothschild, C. A. Keohane, et al., A Controlled Trial of Smart Infusion Pumps to Improve Medication Safety in Critically Ill Patients 2005)

Larsen, Parker, O'Connell, and Grant's 2005 study of SMArT pumps, standardized drug concentrations, and altered labeling in the pediatric setting looked at the impact of standardized medication concentrations and a more ergonomic label system for the medication connected with the safety features from the SMArT pumps. Based on the study, they noted a 73% reduction in the number of reported errors from 3.1 to 0.8 per 1000 doses. The study did not assess the impact of each change individually, and noted that the decrease was likely due to several factors. The study did stress that standard concentrations that correlate with standard models in the SMArT pump library was recommended overall to improve patient safety as it directly correlated the medication variables with variables in the pump safety software and reduced or removed potential failure points in the delivery process. (Larsen, et al. 2005)

Husch, et al. (2005) directly reflects real world situations as the study was designed to collect data from actual infusions on actual patients without nursing or physician staff knowing the study was taking place. The study observed medication administration and preparation, looking for and tracking errors in either stage. The study then compared their findings with trending data gathered from a third-party national

reporting agency that is standardized for reporting similar error information. Results from the study concluded that 67% of infusions during the study had one or more errors associated with their administration; however, 97% of those were viewed unlikely to have been prevented by SMArT technology. The study also noted that the national reporting service registered 45 incidents requiring documented reporting over a two-year period, while study researchers observed 55 such incidents in a nine-hour observation period. The discussion also remarked that many reportable incidents are not reported due to several factors including fear of repercussions, not feeling incidents worthy of report, lack of oversight, and lack of incentive. The study also notes that although errors associated with IV pumps are common, they are more epidemiologically diverse than expected and can be distributed over all aspects of implementation, not just dosing or concentration. (Husch, et al. 2005)

METHODOLOGY

This study gauges the care facility staff's familiarity with SMArT technology and evaluates how effectively the staff integrate infusion pumps' safety features into medication administration. A survey of the nursing staff in the emergency, intensive care, and maternity departments of a regional hospital identify which features industry professionals were familiar with, and based on those familiarities, collect general perceptions of SMArT and traditional pumps in terms of safety. This study also looked at which features the professionals felt held the greatest potential for benefits and detriments to the overall care and health of the patient. Additionally, the study team attempted to contact a major health care system currently transitioning from traditional pumps to SMArT pumps to gain insight into what models they were comparing, what features they

felt important, factors influencing the decision, and other decision elements that contributed to the choice of the final pump.

RESULTS

Responses were collected from 28 nurses, 19 of which were from the emergency or intensive care departments and 8 from maternity. One additional individual had significant experience in both emergency and maternity. This response was included in the overall results but was excluded from the subgroup data. Demographics of the respondents are shown in Table 1.

Table 1: Demographics from Study

Age	Under 30	10 (7 ER, 3 Mat)
	30-40	9 (6 ER, 3 Mat)
	40-50	6 (5 ER, 1 Mat)
	50-60	3 (1 ER, 1 Mat, 1 Both)
	60 and over	0
Gender	Female	24 (15 ER, 8 Mat, 1 Both)
	Male	4 (4 ER, 0 Mat)
Years of Experience in Healthcare	0-1 year	3 (3 ER, 0 Mat)
	1-5 years	4 (3 ER, 1 Mat)
	6-10 years	6 (3 ER, 3 Mat)
	11-20 years	12 (9 ER, 3 Mat)
	21-30 years	2 (1 ER, 1 Mat)
	31-40 years	1 (1 Both)
	41-50 years	0
	Over 50 years	0

The participants identified features present on the pumps used in their department by circling options from a provided list of features. The features listed are available on both the traditional and SMArT infusion pumps or only on the SMArT pumps. Using the same list, they identified which features they perceived most beneficial and most detrimental to patient care. The overall percentage of nurses who chose the respective

feature for each question is shown in Table 2 by hospital department. The percentage values do not add to 100% because respondents had the opportunity to mark all features that applied to each question. The B Braun Outlook 100 is the standard pump throughout the hospital. This pump does not have many of the advanced features of a SMArT pump. Half of the respondents (14 of the 28) had experience with SMArT technologies.

Table 2: Features List Response by Department

Feature	Current Model Contains		Beneficial to Patient		Detriment to Patient	
	ER	Maternity	ER	Maternity	ER	Maternity
Barcode Scanner	0%	0%	10.5%	25%	5.2%	37.5%
Imbedded Library	89.7%	87.5%	89.5%	89.7%	21.1%	50 %
Backlit Display	94.7%	100%	68.4%	87.5%	15.8%	12.5%
Multiple Channel Pumping	15.8%	50%	84.2%	62.5%	31.6%	50%
Wireless Connectivity	0%	0%	15.8%	25%	15.8%	37.5%
Variable Position Clamp	15.8 %	62.5 %	10.5%	62.5%	15.8%	37.5%
Tubing Organizer	26.3%	0 %	47.4%	50%	0%	11.11%

Several of the respondents marked that various features were both beneficial and detrimental to patient safety. Seven of the respondents were informally questioned as to why they had selected feature(s) as both beneficial and detrimental. Several stated that machines were sometimes unreliable and that they personally felt that "blindly trusting" or putting too much faith in the machine's abilities could lead to safety concerns or potential for misadministration of medications. At the same time, they noted that having

the machine double-checking calculations, administration rates, and medication interactions would be helpful as an additional protection from accidental programming error. The interviewed staff members also commented that having the ability to infuse multiple medications from the same pump or having smaller pumps would be appreciated because there is limited space in a hospital room for equipment, yet this feature added to the potential for medical error.

Respondents were asked through open-ended written questions, if there were any features they would add or modify on their existing pumps. Of the 15 respondents that answered this question, three responded they would like drug compatibility charts attached to or imbedded in the pump, four responded they wanted better user interfacing or easier programming, and eight asked for one or more features of SMArT pumps (multiple running channels, barcode scanner, wireless connection to central computer). Some of the nurses were asked informally to clarify what "better user interface" meant. They stated that different models by the same manufacturer had different parameters displayed in different locations creating confusion as to whether the programmed parameter correlated with the display for that parameter. They also called for more clearly labeled buttons, which were easier to correlate with their function.

Respondents were then asked to rate the significance of several factors on effective use of infusion technology using a Likert scale measurement from 1-5 with 1 being little impact and 5 being significant impact. Results are shown below in Table 3. All of the factors had an average value above midpoint on the scale.

Table 3: Significance Factor

Factors	Significance
Training	4.75 (4.95 ER, 4.25 Mat)
Operation Manual	3.11 (3.26 ER, 3.00 Mat)
Barcode Library	3.11 (3.06 ER, 3.25 Mat)
Medication Library	3.75 (3.83 ER, 3.63 Mat)
On-screen Directions	4.61 (4.79 ER, 4.25 Mat)
Alert/Error Designation	4.50 (4.74 ER, 4.25 Mat)

Additionally respondents were asked to use similar Likert scales to rate how effective they felt their training was and how safe they feel infusion pumps are. Average rating from all respondents was 4.04 (3.95 ER, 4.25 Mat) for training effectiveness and 4.21 (4.16 ER, 4.25 Mat) for overall safety. The nurses also identified the type(s) of training they received from a list of standardized training methods. Training method results are listed in Table 4. There were a wide variety of training methods identified within a single hospital; some respondents selected more than one method.

Table 4: Training Methods

Method	
Manufacturer's Manual	32.1% (21.1% ER, 50% Mat)
Site Specific Procedure Manual	10.7% (15.89% ER, 0% Mat)
In-service Training	64.3% (57.9% ER, 75% Mat)
Simulated Use Training	39.3% (42.1% ER, 37.5% Mat)
Shadowing Program	25.0% (36.6% ER, 0% Mat)
Video Demonstration	7.1% (10.5% ER, 0% Mat)
On-site Demonstration	85.7% (79.0% ER, 100% Mat)
Other (please list)	3.6% (5.3% ER, 0% Mat) New Hire Orientation and On the Job

DISCUSSION AND CONCLUSIONS

Infusion therapy requirements differ between emergency and maternity departments. Infusions in the maternity department are more standardized than many other departments in the hospital. Maternity patients are female, typically fall within a

limited age range, and generally require infusions from a finite list of possible medications. Emergency/intensive care staff has to be prepared for patients of all ages, genders, weights, and medical status. Typically emergency and intensive care staff get little if any warning before a patient requires infusions, and the potential list of medications to infuse is extensive. Emergency and intensive care infusions vary greatly depending on patient condition. There is less standardization or routine, and quick response time is required.

An overwhelming trend among respondents was the opinion that imbedded drug libraries with hard and soft limit data were both beneficial and detrimental to the patient's care. After follow-up verbal questioning of several respondents, they clarified this to mean that while it is nice to have suggested dosing and rate information available, they fear that the library would be relied upon too extensively by the staff or the potential to select the improper drug is too hazardous. They also noted fear that the person programming the library might make a mistake or the software might crash, causing unforeseen consequences. Many also noted that if the models they were working with had imbedded libraries, they would probably continue to calculate dosing and volume rates manually as a redundant check. However, it is not prudent to state that extra check will be sufficient to catch all errors. It is highly likely that after the manual calculation matches up with the library calculation long enough, the operator will become lax in performing the manual calculations and thereby weakening the overall safety potential for the device.

Another trend identified was a desire for medication compatibility cards or software to accompany the device. According to the survey subjects, many times

medications have incompatibilities with other medications while still in the IV line or will produce unforeseen consequences when they interact in the patient's body. Many pharmaceutical companies freely list these incompatibilities in the literature packaged with the medications, but the high paced and overworked hospital setting rarely allows for a care provider to stop and read all the literature. The survey subjects requested that since SMArT pumps already have dosing restrictions based on medication, and since there are typically multiple pumping chambers connected to the same control unit, manufacturers should incorporate a lockout type feature that will not allow incompatible medications to be administered together without proper authorization. This method allows for a qualified care professional to override the lockout if deemed necessary and medically prudent but provides the safety buffer to alert them in case of accidental incompatibility.

Finally, the survey subjects stated that training on the infusion pumps was critical to successful patient care. On a 5-point Likert scale, the respondents averaged a 4.75 when asked to what extend training affects performance. The respondents also felt that standard training leaves something to be desired. While 18 were given in-service training and 24 given on-site demonstration of the pumps, 13 requested more hands-on or scenario based trainings. Several noted either verbally or in writing on the survey that after their training they were not comfortable enough to effectively utilize the infusion technology at their facility and that a trial-by-fire or on the job method of training gave them that comfort, instead of in a controlled and monitored environment.

Based on these findings, it is clear that the healthcare field is a non-standard environment to try to implement technology and that medical professionals care greatly

for the safety and security of their patients. For new automated or technologically advanced devices to ever gain respect in the medical community, they need to prove to the care professionals that they really are safe and are in the patient's best interests. Healthcare professionals rarely will take the word of an outside source when it comes to the safety of a patient or coworker. They require all equipment and procedures to go through a review process where it is put through all its paces in a real life scenario and not a simulated attempt at a real life scenario.

Care professionals are also clearly calling for a more standardized human factors approach to their equipment. They ask for easier to interpret displays, clearer alarms, better interfacing, better/clearer instructions and controls, and more effective training before implementation. The healthcare field is a high paced and specialized environment where products and processes need to be specially designed and constantly tested to ensure they protect patients and staff and save lives.

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SECTION

2. CONCLUSION

As human factors specialists become more prevalent in different industries, it will become easier and more obvious that the human patient or human operator has limitations and that nothing can be viewed as obvious or normal. In order to design a product, especially for as fast paced and unpredictable field as healthcare, designers must take into account the humans in the system. If the care professionals do not trust safety features or do not understand why a feature exists, they will bypass or override it for manual or traditional methods. When a layperson is presented with a medical device, the initial reaction is fear they will err or injure the patient, creating a need to make complex systems easy to operate and relatively "idiot proof". Similarly, in the professional health setting, care providers fear the unknown and fear a machine thinking for them. They understand the impact a programming error could cause and must be thoroughly convinced the technology will accurately do its job before the human will relinquish control. Ultimately, care providers feel responsible for the safety of the patient and trust themselves more than they trust a machine.

Part of getting the human on board with the new technology is effectively training them and allowing them to become so familiar with the system that they can effectively predict the outcomes or effects of different actions. If a nurse is allowed to become so comfortable with a pump that he or she can break it, they then know the exact extent of that pump's limitations. Until a human can gain that extent of knowledge, he or she will doubt the abilities and limitations.

Technology is opening up doors to new and exciting possibilities in healthcare. As engineers, we need to understand the differing mindsets of the health professionals, patients, and lay responders that will use our equipment and design it such that they feel comfortable with incorporating it into their care routines. Without effective training and balance of human factors principles, our state of the art devices will be no more successful than the obsolete systems they are replacing because the user will revert to that system they are comfortable with instead of embracing change. Designers and engineers need to design to the client, not to the science or the technology.

VITA

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