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Research Paper Management

Human Factors to Minimize the Human Error and Improving Patient Safety

*Sanjay Saproo**Dr. Sanjeev Bansal
***Dr. Amit Kumar Pandey

*,**,*** Amity University, Noida NCR Delhi India

ABSTRACT

5000 types of medical devices are used by millions of health care providers around the world, device related problems are inevitable (1). Poor design, not user friendly and poor quality which is the part of the human factors will increase the risk of unexpected breakdown, excessive repair cost; enhance the equipment down time and premature failure of the equipment thus leading to the medical error and unsafe patient care. Human Factors is an important part of the healthcare delivery system which works effectively in order to prevent similar occurrences and align the entire system for action to be taken for prevention of any mishap, slip or medical error. Human factors take into account the human aspects which can increase the risk of such incidents in the first place (behavioural differences, emotion, perception, personality, decision-making, cognition, fatigue, stress, etc.).Further human factor emphasis the partnerships between the health sciences, human factors, Technology and systems engineering to improve patient safety

Keywords : Human factors, ergonomics, human Performance, medical error, technology

Introduction
The concept of the human factor become more important in today's healthcare delivery systems where the usage of the technology devices has increased the patient safety and better patient outcome but this has led to the system related errors and human errors.

These technology devices are often not designed with human cognitive limitation in mind. Human factor plays a vital role in patient safety and error reduction if they pay attention to the following,

1. Human limitations and strength
2. Patients limitation and its need
3. End-user/operator/caregiver's mind set, limitation and strength
4. Human factor Engineering (HFE)
5. Ergonomics
6. Technology devices
7. Device Design
8. Circumstances within a healthcare
9. Complexities within the healthcare
10. Environment within which the healthcare is delivered
11. Organization
12. Organizational Development (OD)
13. Training and Orientation
14. Device maintenance and Implementation.

Statement of Problem
In a landmark report, "To Err is Human: Building a Safer Health System," the Institute of Medicine (2000) estimated that medical errors cause 44,000 to 98,000 deaths annually in U.S. hospitals.

Other safety-critical industries, such as nuclear power and aviation, have reduced human error by applying the techniques from human factors. This discipline focuses on the interaction between machine, man, and their work context. Leading experts have stated that the key to improving patient safety is to apply human factor into the healthcare delivery system so that the incidence of the medical errors can be reduced.

This research paper has identified that the problem of medical errors and mistakes within the healthcare are inevitable but how the human factor can be a catalyst in order to reduce these preventable medical errors while improving the patient safety. The objective of the research paper is to provide an introduction to the concept of human factors in healthcare and provide insight of how its elements can be applied by individuals and teams working to learn from these errors and find ways to prevent them from recurring which will improve the patient safety.

Discussion
In high risk systems, no matter how effective safety devices are, some types of accidents are inevitable because the system's complexity leads to multiple and unexpected interactions (2).

Human Error
Humans (i.e. doctors, nurses, caregivers etc) are a critical component of the complex health care delivery system and they are subjected to errors. "Human is err", a report issued in November 1999 by USA, Institute of Medicine (To Err is Human : Building a safer health system). Human error is estimated to cause or contribute to up to 90% of accident both generally and in medical devices (3) & (4). However this does not or should not lead to the blame over the individual who is just the part of the healthcare delivery system. The Human error is already on the tip of the iceberg. Broadly speaking the human error is the effect, a symptom of trouble deeper in the system (5). It is therefore essential to recognize that errors or preventable adverse events are simply the indicators of the deep rooted defects, malfunction within the healthcare delivery system and the need is to nip the bud by going into the depth of the system without the blame and the shame game.

The occurrence of human error in medicine may have been there ever since its first practice and, the earliest documented medical error-related death in modern times may be traced back to 1848 (6). Throughout the patient safety movement, health care leaders have consistently referred to the potential value of the Human Factors research on human performance and system failure (Leape et al., 1998).

One of the simplest definitions of human error is that it is any action or omission that causes results that users neither

foresee nor intend. Error is either the failure of a planned action to be completed as intended (error of execution) or the use of wrong plan of action (error of planning) to achieve the desired goals. Errors are further classified into two: Active error and Latent error. Active errors are those errors whose effects are felt immediately which may occur due to slips, lapses and mistakes. Latent errors remain longer and deep in the system and become visible when combined with other factors that breach the system's defenses. Latent errors are often preventable as they lies dormant in the system for a long time. Latent errors occur due to personal failure, system failure, failure of risk management, equipment design and human factors Engineering (2). Human factor plays a vital role in mitigating the human error and infusing the patient safety within the healthcare delivery system but its usage within the healthcare is at its infancy stage.

Human Factor

Human factors is an established science that uses many disciplines (such as anatomy, physiology, physics and biomechanics) to understand how people perform under different circumstances. In simple terminology human factor can be defined as the study of all the factors that make it easier to do the work in the right way (7). The history of human factors dates back to 1898, when Frederick W. Taylor performed various studies to determine the most suitable design of shovels(8).

Another definition of human factors is the study of the interrelationship between humans, the tools and environment they use in the workplace and the environment in which they work (9).

The study of human factors has traditionally focused on human beings and how we interact with products, devices, procedures, work spaces, and the environment encountered at work and in daily living (10).

The term human factors are used to describe interactions between three interrelated aspects: human, assignment undertaken and the workplace itself.

One human factors model that is increasingly well known in healthcare is the Swiss Cheese Model of organisational accidents (Reason 1990) (11). The Swiss Cheese Model hypothesises that in any system there are many levels of defence. Each of these levels of defence has little 'holes' in it which are caused by poor design, senior management decision-making, procedures, lack of training, limited resources etc. These holes are known as 'latent conditions'. If latent conditions become aligned over successive levels of defence they create a window of opportunity for a patient safety incident to occur. Latent conditions also increase the likelihood that healthcare professionals will make 'active errors.' That is to say, errors that occur whilst delivering patient care. When a combination of latent conditions and active errors causes all levels of defences to be breached a patient safety incident occurs. This is depicted by the arrow breaching all levels of defence in Figure 1 below,

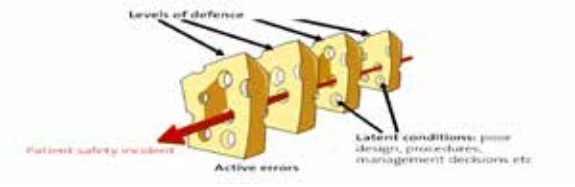

Figure 1

When such kind of incident, mistake, adverse event or error occurs it is not because of any one individual but because of the entire system. Everyone from top to bottom is responsible for any kind of error.

The concept of the human factor become more important in today's healthcare delivery systems where the usage of the technology devices has increased the better patient outcome but this has led to the system related errors and human errors. The Food and Drug Administration (FDA) in the US receives around 100000 reports through the medical device reporting (MDR) route and 5000 reports through the voluntary MedWatch program annually (12). A significant number of these reports are concerned with human factor problems.

In addition, medical device human factors-related problems include poor training, poorly documented instructions and limitations in the capabilities and experience of both professional and lay users (13).

Healthcare equipment/ devices are often not designed with human cognitive limitations in mind. Design creates error traps and is a frequent cause of patient safety incidents. Furthermore, when a healthcare organisation uses a large number of different medical devices there is an increased risk that staff will make errors resulting from applying their understanding of how one device functions to another device. So minimising the variability and number of different medical devices available and ensuring staff are trained in their use is important.

Some of the important sources for collecting human factors-related data are shown below in Figure 2. (14)

Figure 2 , Important sources for obtaining human factors related data.

Without a complete understanding of human factors, the tendency is to focus on human failures as the major source of error, and to focus attention on Technology in order to mitigate the preventable errors.

Technology

Medical Technology can be defined as a high precious machine, device and equipment used by the healthcare worker in order to deliver the medical care to people. Technology today in the 21st century has become the back bone of the today's healthcare delivery system and has shown promising results in eradication of the disease and better patient outcome and treatment.

Technology offers a vast array of opportunities to improve patient safety. Technology is an important thread running through many areas of patient safety: reporting and learning, systems thinking, human factors, training and culture change (15). Medical Technology includes not only medical devices, drugs, and biologics, but also the medical and surgical procedures they enable and the organizational and support systems within which they are used. Diagnosis, monitoring, treatment, and rehabilitation all rely on complex and sophisticated medical technologies (16).

One hand technology has become a vital part of the healthcare at the same time the improper usage of the same technology by the end user has resulted into the patient injury and death. The error made by the user in handling the technology or technological medical device is often called as user error. But these errors cannot be solely attributed to the user. It is therefore important to design and develop the technology as per the need of the end user rather blaming the end user.

The technological revolution in health care has increased the

relevance of human factors in errors because the potential for harm is great when technology is mishandled (17). The important factor is that we cannot eliminate the error or make the healthcare safer without involving the user/ caregiver and patient.

James Reasons reminds us that no matter how well work is organised, how good procedures are, how well equipment is designed, or how well teamwork is achieved, people will never perform better than what the organization will support (18).

Individual behaviours and performance is very much influenced by the organizational structure and its thinking. An error prone organization or an error prone system will leads to the individual errors. In other words the individual suffers or get blamed within any organization for any mistake or error which in turn is due to the wrong policies of the organization or poor organization structure. This poor organizational structure, poor policies, poor work environment, demotivated staff is the part of the latent error and is some were deep in the system which need to improve for the better healthcare quality and safe care.

The true organizational development thus should planned development and reinforcement of organizational strategies, structures, and processes for improving an organization's effectiveness (19).

Organizational development thus should act like a body of knowledge and practice that enhances organizational performance and individual development, viewing the organization as a complex system of systems that exist within a larger system, each of which has its own attributes and degrees of alignment. OD interventions in these systems are inclusive methodologies and approaches to strategic planning, organization design, leadership development, change management, performance management, coaching, diversity and work/life balance (20).

The application of human factors in engineering is called as human factors Engineering (HFE) which focuses solely on the device and technology. HEF is the discipline concerned with understanding human nature and characteristics and applying that knowledge and Technology to design the systems that are reliable, safe, and effective and user friendly for better patient safety and outcome.

HFE is used to design equipment/human interfaces in order to mitigate design errors, human errors, Implementation errors, Installation and commissioning errors and operation errors. The likelihood of user error increases significantly when a medical device is designed without giving proper attention to cognitive, perceptual and physical abilities of the user. If human strength and limitations are not taken into account in the design process, devices can be confusing or difficult to use, unsafe, or inefficient. It is equally important to focus on human behavior, human performance and methods of working within the given environment. Work environment can be disruptive, stressful and lead to unnecessary fatigue.

HFE should uses a team approach to design and develop any kind of Medical Technology devices which should include a patient, end user of the device, research and development engineer, designer of the device, cognitive psychologists, device maintenance engineer, Clinical research engineer, and ergonomics specialists. All of them should be open to the new ideas and implementation of the changes within the devices until a final product reach to the market.

Human factor involves two critical component of the healthcare which is Man and Machine. Although, there are many different types of man-machine systems, they can be grouped under three different categories as shown in Figure 3 below (21). ,

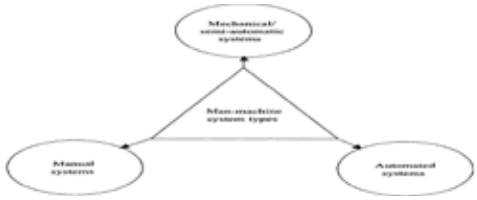

Figure 3 Types of Man Machine Systems

In manual systems the entire control lies with the operator, the user. Here the chance of the machine error is less and human error is more. In semi-automatic systems the control lies equally with the man and machine. Therefore both man and machine can be subjected to errors. In fully automatic system the entire control which include decision making, sensing, action and processing lies with the machine. However the human role here is to monitor, give command and maintain the system. The study indicates that the failure rate or the error in the automated system is lesser than any other system. But here the user should be well trained in order to use the system and the system should be well maintained. However the human intervention cannot be eliminated in any type of system.

During the design phase of any automated and semi-automated system many time the manufacturer has to choose which functions should be assigned to machine and which to human. Under such scenario, an effective knowledge on the capabilities, limitations and drawbacks of human and machine/Technology has to be clearly defined and understood. Designers can recognize the potential for and drastically reduce human errors. One easy way to evaluate the potential for error in human-machine system is to use the PEAR model. PEAR is an acronym for the four major components of human-machine systems. To reduce or eliminate human errors, it is necessary to consider the people who will use the device, the environment in which it is used; the action (or task) people will be doing that involve the device, and the other resources that will be available in the job environment.

Various studies conducted over the years have confirmed that humans have built in tendencies towards certain objectives and their motor/behavioral development varies with age. In order to minimize the occurrence of human errors, patient injuries and death the findings such as these must be carefully considered during the design and development of medical Technology products.

Over the years, human factors professionals have developed a checklist consisting of questions to be addressed to incorporate human factors into the designs of engineering systems. These questions can be specifically tailored to suit an individual situation under consideration. Some examples of these questions are as follows (22):

- Was adequate attention given to training and complementing work aids?
- Is it easy to identify each and every control device?
- Were the human factor principles considered in the workspace design?
- Were all visual display arrangements optimized?
- Were all controls designed by considering factors such as size, shape, and accessibility?
- Were human decision-making and adaptive capabilities used effectively in the design?
- Are the displays compatible with their corresponding control devices in regard to human factors?
- What type of sensory channels would be the most appropriate for messages to be sent through the displays?
- Were environmental factors such as temperature, illumination, and noise considered with respect to satisfactory levels of human performance?

Technologies can lead to patient safety improvement only if they are designed, implemented and used according to hu-

man factor and system engineering principles (23).

So while designing the machine: a medical Technology products following consideration should be kept in the mind which are related to the human behaviors (24),

- Humans get easily confused with unfamiliar things (avoid designing completely unfamiliar items).
- Humans have become accustomed to certain color meanings (strictly observe existing color-coding standards during design).
- Humans' attention is drawn towards items such as loud noise, flashing lights, bright lights, as well as bright and vivid colors (design in stimuli of appropriate intensity when attention requires stimulation).
- Humans expect that valve handles/faucets will rotate counter clockwise to increase the flow of liquid, steam, or gas (design such items according to human expectations).
- Humans will frequently use their sense of touch to explore or test the unknown (pay special attention to this factor during design, particularly to the product handling aspect).
- Humans often regard manufactured items as being safe (place emphasis on designing products so that they become impossible to be used incorrectly).
- Humans expect that to turn on the power, the electrically powered switches have to move upward, or to the right, etc. (design such items according to human expectations).
- Humans often tend to hurry (develop design so that it takes into consideration the element of human hurry).
- Humans usually possess very little knowledge about their physical shortcomings (develop appropriate design by carefully considering human basic characteristics and shortcomings)

Patient, caregiver and technology are the three pillars of the healthcare deliveries which are interdependent to each other and results into the medical error (25).

In the final analysis, the enemy of the safety is complexity and complex medical technology devices add fuel to the complexities, hence increases the medical errors. Technology and Technology devices should implement the following principles in order to promote patient safety (26) :

- Top management commitment to the change.
- Responsibility and accountability structure for the change.
- Structured approach to the change.
- Training.
- Pilot testing.
- Communication.
- Feedback.
- Simulation.
- End user participation.

There are many user interface device design problems that lead to the user errors. Some of these problems are as follows (27),

1. Poor device design resulting in unnecessarily complex installation and maintenance tasks
2. Unconventional or complex arrangement of items such as displays, controls and tubing.
3. Poorly designed or inadequate labels.
4. Difficult to remember , and /or rather confusing device operation instructions
5. Hard to read or ambiguous displays.
6. Poor device feedback or status indications that result in user uncertainty.
7. Unnecessarily intrusion or confusing device associated alarms.

Past experience indicate that on the average errors in the use of the medical devices results in at least three deaths or serious injuries per day (28).

Table below present the devices in the order of the least error prone to most error prone (29).

1. (Least Error Prone) Continuous ventilators (respirators)
2. External low-energy defibrillator
3. Transluminal coronary angioplasty catheter
4. Catheter guide wire
5. Catheter introducer
6. Peritoneal dialysate delivery system
7. Implantable pacemaker
8. Mechanical/hydraulic impotence device
9. Non-powered suction apparatus
10. Electrosurgical cutting and coagulation device
11. Urological catheter
12. Infusion pump
13. Intra -vascular catheter
14. Implantable spinal cord simulator
15. Permanent pacemaker electrode
16. Administration kit for peritoneal dialysis
17. Orthodontic bracket aligner
18. Balloon catheter
19. (Most Error Prone) Glucose meter

Past experience indicates that there are numerous operator associated errors that occurs during the operation of the medical devices or equipment. Some of these errors are (30),

1. Misinterpretation of critical device output.
2. Wrong decision making.
3. Taking incorrect action in critical situation.
4. Mistake in setting device/ equipment parameters.
5. Wrong improvisation.
6. Failure to recognize effectively the critical device output.
7. Failure to follow prescribed instruction and procedure effectively.
8. Inadvertent or untimely activation of control.
9. Wrong selection of the device/ equipment with regard to clinical requirements and objectives.
10. Over-reliance on automating features, capabilities or alarm of medical devices.

Some of the characteristics of well-designed medical devices with respect to users are as follows (27):

1. Logical and confusion free.
2. Consistent with the experiences of user community.
3. Immediately alert users when device-related problems occur.
4. Minimize the requirement for memory and performing mental calculations.
5. Stop users from making fatal errors.
6. Contain readable and comprehensible labels.
7. Avoid overtaxing strength, visual capacity, dexterity, strength, or auditory capacity of users.

During the installation of the Technology devices we should follow the following golden rules (31),

1. Ensure that the user instructions are comprehensible and the warnings are conspicuous.
2. Ensure that the components and accessories are properly numbered so that the defective ones can be effectively replaced with the good ones.
3. Ensure that connectors, tubing, leuers, cables, and other hardware are properly designed for easy installation and connection.
4. Ensure that textual complexity in maintenance documents is reduced considerably by adding in the appropriate graphics.
5. Ensure that the positive locking mechanisms are present when there is a possibility of compromising the integrity of connections by factors such as component durability, motion, or casual contact.
6. Avoid exposed electrical contacts as much as possible

Human factor is therefore valuable as it attempts to address complexities with the Healthcare delivery system for safer care.

Now as we are clear about the human factor and its role in the

safer healthcare delivery, we must emphasis on the patient self -managed -treatment where human factor will play a big role in supporting the patients. This means a partnership is needed between the human factor, healthcare delivery system and patient in order to bring the gap which will ensure the safety within the system.

Conclusion

Human Factors is an important part of the healthcare delivery system which works effectively in order to prevent similar occurrences and align the entire system for action to be taken for prevention of any mishap, slip or medical error. Human factors take into account the human aspects which can increase the risk of such incidents in the first place (behavioural differences, emotion, perception, personality, decision-making, cognition, fatigue, stress, etc.). There is no risk without people; as complex and erratic beings, humans interacting with and working as part of a technological, organisational and psychosocial system will inevitably produce variability, risk and, sometimes, error.

While recognizing that errors and adverse events are unavoidable within the healthcare delivery system, we must pay attention to the human factors (HF) and human factor engineering (HFE). Other safety-critical industries, such as nuclear power and aviation have reduced human error by applying the techniques from human factors. Human factors traditionally focused on human beings and how we interact with products, devices, procedures, work spaces, and the environment at work and in daily living.

Human is a critical component of the complex healthcare delivery system and humans have built in tendencies towards certain objectives and their motor/behavioral development varies with age. Therefore they are subjected to errors. Human error is the effect, a symptom of trouble deeper in the system and it is therefore essential to go into the depth of the system for improving the patient safety.

Technology or Technological device are the backbone of today's healthcare delivery system but at the same time the improper usage of technology results into the patient injury and death. Technology can lead to the patient safety improvement only if they are properly designed, implemented, used according to human factor, system engineering principles and after proper Training and orientations.

Manufacturer have to use the human factor engineering while designing theses critical medical devices which should take into the consideration the human limitations and flaws for better patient safety and outcome.

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