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Applying Human Factors Methods in a Clinical Engineering Setting to Reduce Medical Device Risks

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ABSTRACT

This paper describes the ways in which human factors methods can help to enhance the work of established clinical engineering teams by placing a new emphasis on error reduction and patient safety. This approach in many ways represents a natural evolution for departments that are looking to enhance their usefulness and relevance to healthcare. Several examples are given of points at which the introduction of human factors methods can reveal issues related to the safe use of medical devices that are not easily accessible by other means. Adoption and implementation of these methods offers the potential for clinical engineering departments to enhance their role in ensuring optimal patient safety.

Keywords – *Human factors, medical devices, error investigation, patient safety.*

INTRODUCTION

For clinical engineering teams, managing risks associated with medical devices is at the core of their work. Great attention is rightly paid to the effective maintenance of medical devices, to ensure that they are operating within specification and are inspected as required to support continued good performance. An ideal approach to this considers all phases of the medical device lifecycle, from acquisition planning to eventual decommissioning. The objective is that properly selected and maintained devices will help to ensure good patient outcomes during treatment.

In 1999, the Institute of Medicine (IOM) in the United States issued a landmark report titled: *To Err is Human: Building a Safer Healthcare System*,[1] which provided a harsh wakeup call to the healthcare community with an extrapolated estimate that at least 44,000 to 98,000 deaths were occurring each year in the US healthcare system as a result of generally preventable medical errors. This explosive statistic caused much debate and analysis within the healthcare community, both in the US and in other countries, and subsequent studies in other jurisdictions revealed remarkably similar rates of error when normalized for population size.[2] One of the results of this information was to place new emphasis on patient safety, and organizations began to search for methods that would allow them to study their current levels of safety, capture errors, and make improvements that would have a lasting effect on patient safety outcomes.

In the search for methods and approaches that might prove beneficial in healthcare, attention turned to the aviation and nuclear power industries, both of which had experienced significant catastrophic events that led to a clear demand for action. The discipline of human factors

combines principles and methods from psychology and engineering to understand how humans interact with the world around them, examining issues of cognition and the interaction between people and the environment that surrounds them. Leaders in the field, such as James Reason and Jens Rasmussen, have developed models that help to determine whether a system is well designed for safe human use by posing questions such as; Is it clear and logical to operate? Does it behave in a manner that is similar to other systems that the operator encounters? Does it reveal its operating state in a clear and concise manner?

These methods have proved remarkably effective at increasing the safety both in aviation and at nuclear power plants. Commercial aviation has become far safer in the past 40 years as a result of the standardization of various procedures and the use of tools such as checklists and safety interlocks.[3] These methods offer great potential for improving the safety of healthcare as well, but to date, the results have been mixed[4] and it is useful at this point to consider why it is proving so difficult to achieve truly significant reductions in error rates in healthcare. Healthcare providers spend many years of training to deliver the best possible care to their patients and are understandably distressed when errors occur during diagnosis or treatment.

Effective improvements in aviation and nuclear power safety have come about because of the standardization and codification of safe practices, and at first glance it appears that it might be possible to have a similar effect in healthcare, but there are some important differences that come into play which are making it much more difficult to have an impact on error rates.

(1) Healthcare processes are far more varied than the processes followed in an airplane cockpit prior to take off, for example (J Ruiter-Ligeti, MD, personal communication). They cannot necessarily be standardized to the same extent, and many healthcare providers have become expert at improvising in complex situations. The term "workaround" is one that is commonly heard in patient care environments as front-line care providers modify well-intentioned but restrictive protocols to try to provide optimal care for each patient.

(2) In an effort to improve safety, system planners in healthcare often seek to impose a level of standardization which restricts the ability of front-line staff to provide optimal care, leading to frustration and a sense that one must "go it alone" to provide optimal care. This often comes about when systems are imposed on users without a thorough understanding of the specifics of the work being done at the bedside. As an example, it is easier for an administrator to write a policy in response to an earlier error forbidding a particular practice, than to spend time in the care environment understanding why that practice is being used. Everyone wants to do what is best for the patient, but understanding what that looks like requires a very detailed knowledge of the actual environment of care.

(3) Healthcare is not a static entity. Indeed, big changes have occurred in the past 19 years since the IOM report, including the widespread adoption of computerization and the introduction of new types of medical devices. Both of these useful forces add complexity to an already complex environment, making safety an increasing challenge. Further, these systems and devices are often introduced in ways that fail to take into account the environment of care and the skills, abilities, and training levels of the users, leading to new possibilities for error.

Human factors methods can be brought to bear on all of these issues, and there are some early encouraging signs that these are taking hold. Interestingly, the application of human factors methods is not new in healthcare. A remarkable early example is the work of Dr. Jeff Cooper and colleagues in Boston with regard to anesthesia safety.[5] This work was way ahead of its time compared with other areas of healthcare and it had a profoundly positive impact on patient safety during anesthesia. Sadly, this approach did not gain a significant foothold in many other areas of care, and so we are now presented with the challenge of how to accomplish widespread adoption in the complex health environment of today, where devices are often networked together and information is aggregated in complex IT systems.

Clinical engineers and technologists are well-placed to champion the application of human factors methods in healthcare, at least regarding the role that medical devices play in errors. Jim Keller of ECRI Institute has

stated that their data reveal that 75% of errors that occur with medical devices are not due to device failure per se but are as a result of use error.[6] In the next section, a series of ways in which the clinical engineering team can participate in the application of human factors methods in the healthcare process are explained, and it is hoped that we as a profession will seize the opportunities that these tools provide to do our bit to try to ensure that medical devices are used as safely and effectively as possible.

HUMAN FACTORS ROLES FOR CLINICAL ENGINEERING

While it is unreasonable to assume that clinical engineering can solve all of the systemic error problems in healthcare, it is clear that a number of these relate in one way or another to the use of medical devices and IT systems. Medical device support has been the traditional domain of clinical engineering, and in recent years there has been a strong emphasis on clinical engineering becoming much more involved in the deployment of IT-based systems as well, since in many ways the issues posed by these mimic the ones posed by medical devices themselves; issues such as technical specifications, network connectivity, interfaceability, and overall user satisfaction. IT systems are often an extension of patient data collection, much of it initiated by medical devices at the front end, so this extension of activities is logical and sensible.

Clinical engineering is well-placed to bring a systems engineering approach to helping to reduce error, and this has the advantage of moving the approach away from opinion and conjecture and towards measurable parameters and outcomes; the classic tools of quality improvement. A full review of the various ways in which clinical engineering can engage in bringing a human factors approach to healthcare is beyond the scope of this paper, but a comprehensive treatment of this subject can be found online.[7] The following is a brief summary of the key areas where contributions are possible, and further reading is encouraged. There are a small but growing number of teams specializing in these methods in healthcare around the world, and it is hoped that in time, these methods will become widespread and routine, since they offer great potential to improve the level of safety associated with the use of medical devices and IT systems.

Use in Assessment and Procurement

The assessment and procurement of medical devices has long been recognized as a critical task for clinical engineering since decisions that are taken then have an impact of many years. A poor choice of technology can result in devices that are unreliable or difficult to operate. In most jurisdictions, the demand for new technology outstrips the available funding, so decisions need to be made carefully. Once made, the selected devices are long-term commitments that ideally should satisfy the needs of the healthcare system. Very often, medical device decisions do not involve many, or even any, of the end users who will ultimately have the task of trying to extract good performance from the chosen system. Traditional user assessments in clinical areas are often subjective and haphazard, and subject to bias. Using the human factors methods of work flow analysis and usability testing in a controlled simulated or real environment allows a high measure of objectivity to be brought to an evaluation of competing products from several vendors.

Representative end users are initially observed interacting with comparable technologies if present, to gain a thorough understanding of the ways in which the technology fits within the environment and associated work flows. Users are then recruited into a series of controlled interactions with competing technologies using scenarios that are scripted to represent typical tasks in the observed clinical work flows. The human factors team members passively observe the performance of each participant, paying special attention to areas where users experience confusion interacting with a device, or make errors during use. If multiple participants experience problems at a particular stage of use, that is a strong indication that some aspect of the device being tested is proving problematic for the entire user population, and an assessment should be made of the potential severity of the problem. Could it lead to an incorrect treatment or diagnosis, for example? Can it be bypassed or modified in some fashion?

Mounting tests of this kind requires some effort and knowledge of the evaluation methods used, but the investment of time for a major device acquisition is well worth

this effort. Institutions have to choose which device areas to subject to this rigorous evaluation, and as a general guide, the following filters can be applied; is the device one which has been associated with past incidents and errors? Is the device widely distributed in the organization and thus used by a variety of different people? Is there a major financial investment being made? If the answer to one or more of these questions is yes, then the upfront cost and effort associated with a human factors-based pre-purchase evaluation may well reap dividends over the lifetime of the equipment. One other important issue to consider is that when end users participate directly in this type of evaluation, they come to a better understanding of the capabilities and limitations of the device, and are more vested in the selected product, assuming that their experiences are used to help inform an optimal purchasing decision.

Use in Predicting and Investigating Errors

Even with careful device selections, errors will still periodically occur, and so the next area in which the human factors approach can play an assistive role is in the prediction and investigation of adverse events. Tools such as Failure Mode and Effects Analysis (FMEA) can be used proactively to assess the likelihood of certain events occurring during the use of device or a system. Each potential failure mode is identified and the associated effects from each are categorized, asking what the probability of occurrence is and what the impact will be should it occur. Once these are drawn up, a list of mitigating strategies can be identified and decisions can be made about which of these are realistically implementable. Note that all of this work is prospective. It is done ahead of implementing a particular device or system, and if the analysis is thorough, it offers the potential to significantly reduce the overall error rates associated with a particular system. Clinical engineering teams are often very well-placed to lead this analysis since they are aware of the details of implementation of a technology and also have a good grasp of the potential problem areas associated with its use.

Assuming that an incident has now occurred and that the institution has initiated an investigation, the Root Cause Analysis (RCA) method is a powerful tool grounded in human factors theory that can be used to try to understand the root causes behind the incident. With very rare exceptions, healthcare workers are deeply committed to the welfare of their patients and are traumatized when adverse events occur that compromise their patients' care. Sometimes the initial reaction to an adverse event is to criticize the people involved and ascribe it to poor judgment. This has the double effect of quickly identifying the "culprits" and reassuring the system that this was a one-off event, leading to a false sense of security that the underlying issues have been effectively addressed. The human factors approach helps us to look behind these assumptions to try to understand the root causes involved. Perhaps the healthcare provider was interrupted during a very critical task. Perhaps the system itself is so complicated that many users do not know how to properly operate it. Perhaps a user was presented with information that appeared to confirm that the system was performing as intended and failed to notice that the potential for an adverse event was evolving as a result of their actions. An RCA helps to uncover these issues, and once they are revealed, helps to guide those responsible for the system regarding the changes that are required to the system to try to minimize the likelihood of a recurrence. Again, clinical engineering is well-placed to take a lead role in aspects of this analysis, working with colleagues from other disciplines to uncover these root causes. By identifying and mitigating these issues, systems truly become safer in the long term.

Looking for No Fault Found Repair Reports

As mentioned at the beginning of this paper, clinical engineering departments are rightly charged with the effective maintenance of the medical devices used in their institution. Ask any hands-on service person in clinical engineering whether they have ever received a piece of equipment from a clinical area with a label on it saying "broken" only to find that when they test it on the bench, it is performing to specification. These are often referred to as "no fault found," since no fault was detected by the service team. A recent study[8] pulled data related to no fault found service events and then identified a range of devices that showed higher incidence levels of no fault found reports. When these devices were assessed for usability, a correlation was found between user difficulties and the likelihood of a no fault found event occurring. In

other words, users were experiencing difficulties using a device and some of them were giving up in frustration on the assumption that something must be wrong with the device itself, or simply taking the approach that if I can't get this unit to work, maybe I should get another one and send this one in for "repair." From this it can be seen that no fault found reports in clinical engineering departments are to some degree a proxy for devices that are difficult to operate. Further investigation can reveal whether interventions such as further user training can be effective at helping to reduce operating problems, or are the issues built into the design of the device such that the only effective remediation is replacement of the device altogether.

CONCLUSION

While not all of the approaches described above can be performed solely by the clinical engineering team in an institution, the application of these human factors methods can easily be developed and championed by it. With their technical background, the team is ideally placed to adopt and promote these methods, and will often find allies among clinical staff, administrators and risk managers, all of whom have a strong interest in reducing errors during care as much as possible. As clinical engineering adapts and grows, this area represents a high-impact extension to the work that they currently do, and it can be argued that promoting human factors methods is a challenge not unlike the one faced by clinical engineering 10 years ago regarding their involvement in information technology systems. That debate is largely resolved, and it is hoped that the next 10 years will see a similar outcome regarding the adoption of human factors methods by clinical engineering. To gain this knowledge, users are encouraged to learn more about this topic through reading and through contact with colleagues who have already worked in this area. Industrial Engineering and Psychology departments of nearby universities may have faculty with strong human factors knowledge who are interested in collaborating with people who are working in a live clinical environment. Also, there are an increasing number of labs whose work is focused specifically on the application of human factors methods to healthcare, and these represent expert sources of information and, potentially, collaboration.

In sum, clinical engineering departments have an excellent opportunity to play an important role in helping to make the provision of healthcare safer through the adoption and application of human factors methods in their work. Clinical engineering professionals are encouraged to seize this opportunity and make a contribution. Development of this area of expertise in healthcare will help to elevate clinical engineering from a technical support role to important players in ensuring optimal safety for patients.

CONFLICT OF INTEREST

The author declares that there is no conflict of interest regarding the publication of this paper.

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