

Mock Trial: Role of Human Factors in Litigation Involving an Automated External Defibrillator (AED)

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This special joint session (sponsored by Health Care TG and Forensics TG) at the 2007 annual meeting of HFES presents an enactment of a court trial involving an automated external defibrillator (AED). The mock trial session presents human factors issues related to the design and use of the AED which lead to the death of an individual who collapsed in an airport. Human factors experts for the plaintiff and the defense will each weigh in on the circumstances surrounding the death of the victim, with examination from the respective attorneys, and cross examination from the opposing attorneys. A panel of commentators provides reactions and opinions after each side has given its testimony. However, no judgment or verdict on the case will be reached at the end of the session.

INTRODUCTION

In the US, Over 325,000 people die of sudden cardiac arrest each year (American Heart Association, 2007). This number can be reduced if defibrillation can be administered in time. A victim's chance for survival after arrest decreases by 10% with each passing minute (AHA, 2007). To provide quick response and easy access to defibrillation, automated external defibrillators (AED) have been made available in many public places (National Conference of State Legislatures, 2007). The AED is a compact, portable defibrillator that has been marketed as an easily accessible and easy to use device, even for the lay person. Once the machine is turned on, a voice prompt directs the user to apply two electrodes

(provided with the device) on the victim's chest. The machine then monitors the victim's heart rhythm for abnormalities. If a shock is required to re-establish effective rhythm, the machine charges itself and instructs the user to "stand clear of the victim" and press the shock button.

Currently, 49 out of 50 states and the District of Columbia have legislated Good Samaritan Laws for AED "good faith" use (US Department of Health and Human Services, 2007). Good Samaritan Laws encourage rescues by protecting users of AED from liability in cases of failed rescue. However, these laws vary from state to state: some require that users have had CPR and AED training, while others do not.

This mock trial presents an enactment of the testimony of human factors experts at a court trial

involving an automated external defibrillator (AED). Presented are human factors issues related to the design and use of the AED which led to the death of a patient who collapsed in an airport. Human factors experts for the plaintiff and the defense each discusses the issues surrounding the death of a woman, with direct examination from the respective “client” attorneys, and cross examination by opposing counsel. A panel of commentators discusses key issues after each side has given its testimony.

No judgment or verdict on the case is reached at the end of the session. The goal of the mock trial is to demonstrate the complexity of extending medical devices from the clinical environment to non-clinical applications. This session covers the wide range of human factors issues that are brought to bear on the product’s design and use. The mock trial is videotaped for future use as educational material in human factors, forensics, and law courses.

SPECIFICS OF THE CASE

Mrs. Brown, a 45-year old woman, was waiting at an airport when she collapsed with no detectable pulse. A bystander, Mr. Green, responded by administering CPR, while another bystander called 911 and then retrieved a nearby AED. After attaching the electrodes to Mrs. Brown, a voice prompt instructed Mr. Green to “stand back and prepare for shock.” This prompt thus interrupted the CPR (chest compressions and ventilations). Mr. Green then pressed the shock button but no shocking action was observed. The AED repeated its instructions to “stand back and prepare for shock”. Mr. Green pressed the shock button again. Again, no changes were observed.

When the machine prompt repeated the instructions for the third time, Mr. Green decided to remove the electrodes and restart the machine. This time, all steps were carried out as instructed. Mrs. Brown received a shock, but there was no return of pulse. Mr. Green again started CPR. CPR cycles were followed by AED rhythm analysis, which resulted in a “no shock advised” voice prompt. When the paramedics arrived, Mrs. Brown was in “asystole” (i.e., flatline, which cannot be shocked).

Continued resuscitation attempts in the ambulance and in the emergency department failed. The total duration between Mrs. Brown’s collapse and the delivery of the shock was eight minutes.

Plaintiff’s Claims

Plaintiff contends that flaws in the AED’s design caused Mrs. Brown’s death. Plaintiff claims that the self-charging mechanism failed, preventing delivery of the first shock to the victim. The second design flaw alleged by plaintiff is that the instruction to “stand back and prepare for shock” came too early (i.e., before the machine was at capacity to deliver shock), thereby interrupting the application of potentially life-saving CPR. Third, the repeated instruction to “stand back” created uncertainty on the part of Mr. Green, leading to a delayed response. Had it not been for Mr. Green’s quick thinking in restarting the machine, the shock delivery would have been further delayed. Nevertheless, plaintiff contends that the first delay was too long to save Mrs. Brown.

Defendant’s Claims

Defendant claims that there was nothing wrong with the software and hardware of the AED. The fault lies with the airport for not properly maintaining the AED battery as specified in the instructions. Since the battery must be maintained to ensure adequate power at a certain level to deliver effective shock when used, the airport authority is responsible for implementing a maintenance program which checks and replaces the battery every three months. If the battery were adequately charged, the voice prompt to “stand back and prepare for shock” would have been appropriate to safeguard the safety of bystanders. However, because the battery charge was only marginally maintained by the airport, the AED needed to be restarted in order to deliver a proper shock to the patient, after an unfortunately long and ultimately fatal delay. Therefore, the voice prompts, which were designed based on thorough application of human factors principles and usability testing during the design process, were adequate.

EXPERT TESTIMONY

Plaintiff's expert explains that when a product has a hazard associated with its use, as in this case, there are several basic, fundamental hazard control strategies that product manufacturers can use to reduce exposure. The first, and most effective, strategy is to "design out" the hazards so that they are eliminated from the product. In this case, there are both hardware (battery) and software issues (timing of prompts). If this design solution is not feasible, then a second strategy of hazard control is to guard or place a barrier to separate the hazard from the user. In this case, guarding issues are not relevant.

In situations where the hazards cannot be eliminated through design or guarding, then a third strategy is to provide a warning that informs users about the hazards (and the likely consequences), reminds them of those hazards, and provides specific ways to avoid them. The responsibility for ensuring that critical safety-related information reaches product users rests with the product designers and manufacturers since they are in a position of superior knowledge with respect to their products and their associated hazards. In this case, the hazard of a battery that is not fully charged needs to be addressed in a warning.

Plaintiff's expert also explains FDA labeling rules pertaining to medical devices.

Defendant's expert counters by explaining that the design and labeling were cleared by the FDA, and that the design control process did in fact follow good human factors engineering design principles as specified in FDA Human Factors guidance and in domestic and international

standards for human factors. In fact, warnings about the hazards of low battery charge were included in the instructions.

The panel of discussants responds to arguments presented by each side as the case proceedings unfold. Even though no judgment is reached in this case, the case ends with a comprehensive review of the complexities of human factors issues in medical device implementation.

CONCLUSION

The mock case involving an automated external defibrillator (AED) illustrates the complexities of designing and implementing medical devices in the non-clinical environment. Human factors issues need to be considered by the designers and manufacturers to reduce incidents of device failure that can lead to death.

REFERENCES

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