

Managing the risks of display evaluation studies in the OR

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Aims. We describe methods for managing the potential risks to patient safety and reduction in productivity arising from evaluating a head-mounted display (HMD) in the operating room.

Background. We wanted to test whether the results from a program of simulation research [1,2,3] would generalize to clinical practice. The study involved anesthesiologists testing the HMD in the clinical environment and recording the procedures on video [4]. A concern was that changes to standard practice could, as for any intervention, create additional risk for the patient and/or hospital staff, while concessions could compromise the success of the study.

Methods. We identified the problems most likely to arise and implemented strategies to either prevent them from occurring or to mitigate their effects, as follows:

Patient issues. The risk of microshock was eliminated by ensuring that the HMD equipment was battery-powered and wirelessly connected. Privacy concerns were addressed by having an anesthesiologist (not performing the procedure) seek written informed consent from the patient.

Workplace and productivity: The HMD was wirelessly connected so that participants could provide anesthesia in the OR unencumbered. Early identification of suitable patients allowed participants to attend their cases even when not allocated the entire operating list. To avoid delaying other procedures, the experimental equipment was turned on and configured outside the OR using an uninterruptible power supply (UPS), and then moved inside during the downtime between cases. The privacy of hospital staff was maintained by seeking written informed consent from participating anesthesiologists and verbal consent for use of video from other staff.

HMD technology: The HMD was interfaced with the existing Philips IntelliVue™ MP70 patient monitor and Anesthetic Gases Module. Due to limitations of the MP70 (no CO₂ waveform export), to maintain the participants' familiarity with the equipment, CO₂ was measured using a secondary MP30 patient monitor hidden from the participant's view. To avoid equipment malfunctions from cutting power to the anesthetic and surgical equipment, the video recording equipment was powered using an isolation transformer and connected to an independent circuit.

Experimental method: To maximize statistical power from a sample of only 36 cases (due to practical limitations), a highly specific set of case selection criteria and a repeated measures design was used to minimize clinical variability. Furthermore, detailed video data was recorded from two field cameras, a head-mounted camera, and the patient monitor for objective data analysis offline.

Results and Conclusions. The study was successfully run with no adverse effects from the introduction of equipment into the operating room or from “swapping” anesthesiologists into the lists. The study successfully demonstrated the utility of the HMD for monitoring, and the feasibility of performing advanced display evaluations in the clinical environment.

References:

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