Human Factors evaluation of an advanced defibrillator for in-hospital cardiac arrest

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ABSTRACT

This research undertook a qualitative evaluation of an external Advanced Life Support defibrillator, the LIFEPAK® 20e, in one NHS trust. The study aimed to investigate the impact of system factors on the usability and safe use of a defibrillator/monitor used during adult resuscitation in a hospital setting. A systems model approach, a combination of the Systems Engineering Initiative for Patient Safety (SEIPS) model and the onion model has been used as a framework throughout the study. Merging these two models resulted in six components of the work system: People, equipment and devices, tasks and jobs, workspace, environment and organisation. A mixed methods approach has been applied to understand the complex work system and the processes around defibrillator use including expert consultation, device design evaluation, task analysis, semi-structured interviews with expert users and observations of simulation resuscitation training. A key outcome of this study is a representation of defibrillator use in the developed framework, which incorporates the interaction of factors relevant to defibrillator use on the six identified layers. The design of a defibrillator must be highly intuitive and robust for a dynamic clinical environment. Essential impact factors on the safe and efficient use of the defibrillator are non-technical skills of resuscitation providers such as teamwork, explicit task and role allocation, leadership as well as effective and open communication.

KEYWORDS

Medical device evaluation of defibrillator, Context of use, Impacting system factors

Introduction

The National Cardiac Arrest Audit 2016/17 reported 16,210 in-hospital adult cardiac arrest events in 183 participating hospitals in the UK and Ireland between April 2016 and March 2017 (NCAA, 2017). According to the Resuscitation Council (UK), high quality chest compressions and early defibrillation are key lifesaving interventions within the resuscitation process (Gwinnutt, Davies, & Soar, 2015). There is evidence that early defibrillation is linked to higher survival rates of in-hospital cardiac arrest patients (Spearpoint, McLean, & Zideman, 2000). Cardiopulmonary resuscitation (CPR) is a life-saving emergency procedure which involves a combination of chest compressions and artificial ventilation of the airway to reinstall or preserve the vital functions of a person in cardiac arrest (Cummins, White, & Pepe, 1995; Neumar et al., 2010). Defibrillators are medical devices designed for the emergency treatment of cardiac arrest events. External defibrillators deliver high energy electric shocks (up to 360 J) externally through the chest wall to the heart during an abnormal heart rhythm to restore a normal heart rhythm (British Heart Foundation, 2018; HeartSine Technologies, 2012). Defibrillators can be used in two different modes: advisory / automated and manual mode. The advisory function can be used by Basic Life Support (BLS) providers or medical laymen. In contrast, manual defibrillation can only be used by Advanced Life Support (ALS) providers. ALS defibrillators/monitors such as the LIFEPAK® 20e are clinical advanced defibrillators with a heart rhythm monitor which combine automated and manual defibrillation mode in one device (Resuscitation Central, 2018; Physio-Control, 2017).

Much work has been done on improving the design and functionality of external defibrillators (Fairbanks, Caplan, Bishop, Marks, & Shah, 2007; Ruiz et al., 2018; Varon, Sternbach, Marik, & Fromm, 1999). Considering the use of external defibrillators in hospitals, it is surprising that there is a lack of evaluation of the context of use and the impacting system factors in the literature. A Human Factors and Ergonomics (HFE) approach can be used to evaluate the usability of medical devices used in a clinical setting to identify system factors for safety for patients and clinicians. It is important to recognise that defibrillators are part of the more extensive process of resuscitation in hospitals. The healthcare system is highly complex and continually faces a multitude of challenges. Theoretical system models facilitate the understanding of challenges and can aid patient safety (Hignett, 2013).

The Systems Engineering Initiative for Patient Safety (SEIPS 1.0) model defines five “work system” components as potential contributing factors to patient safety: person, tasks, tools and technologies, physical environment and organisational conditions (Carayon et al., 2006). All five components of the work system interact and affect each other and consequently influence the work and clinical processes, which then lead to outcomes concerning the patients, employees and the entire organisation (Carayon et al., 2006). The SEIPS model was applied to describe the design of the complex system around defibrillator use and its impact on clinical processes. In this research study, a combination of both, the SEIPS 1.0 model by Carayon et al. (2006) and the traditional onion model by Grey et al. (1987) and Wilson (1995) are used as a framework to explain and discuss the context of use of an advanced defibrillator in a dynamic healthcare setting. More precisely, the applied framework draws from the five components of the SEIPS 1.0 work system (person, tasks, technology and tools, environment and organisation) and the seven layers of the onion model (people, tasks, equipment and machines, personal workspace, wider workspace, physical environment, work organisation and job design). Both models take a similar systems view of considering the person at the centre affected by various system factors. However, there are two distinct differences between the two models: the works-system of the SEIPS.1.0 model does not feature the “workspace” as a separate component, whereas the onion model comprises this component and breaks it down into "personal workspace" and "wider workspace". Merging these two models and applying them to healthcare resulted in six components: People, equipment and devices, tasks and jobs, workspace, environment and organisation. Using the SEIPS and the onion model as a framework allows considering all persons involved: from teaching, maintenance or cleaning staff to a broad variety of frequent and infrequent users. Further components of the SEIPS model such as processes and outcomes are beyond the scope of this research project.

Methodology

A qualitative mixed methods design of expert consultation, device design evaluation, task analysis, interviews and observations was applied. Each data collection phase was structured according to the six system components of the developed framework. The approach aimed to ensure consideration of the overall context of use including a broad spectrum of contributory factors.

Expert Consultation

Background information on clinical and technical aspects of the defibrillator was collected to inform the context of use of the device. Using a descriptive and informal approach was beneficial to elicit rich insider knowledge directly from experts who work with the device on a daily basis. The expert consultations involved a defibrillator walk-through with a Clinical Practice Educator and a Chief Technologist to understand the technical features and the processes concerning procurement, maintenance and replacement of the defibrillator. The results of the consultations were then used as a basis for the task analysis and the design evaluation of the device.

Device Design Evaluation

The design of the defibrillator was reviewed according to published Human Factors guidance and usability principles for medical device design (Wiklund & Weinger, 2010).

Task Analysis

The input of the defibrillator walk-through, as well as a review of the Resuscitation Guidelines by the UK Resuscitation Council, were used to develop a task analysis of the in-hospital adult resuscitation process (Soar, Deakin, Lockey, Nolan, & Perkins, 2015). The itemisation of work tasks helped to understand the resuscitation protocol in detail and later used to inform the discussion in the interviews.

Interviews

Semi-structured interviews were conducted with Resuscitation Officers, who deliver resuscitation training across the trust and use the defibrillator in emergency calls. Interviewing expert users aimed to identify contributory system factors on all six components of the work system.

Observations

The final data collection phase included observations of final-year medical students who receive simulation-based CPR training. High-fidelity simulation provides an ideal opportunity to identify usability issues and impacting environmental and organisational factors (Bisantz, Roth, & Watts-Englert, 2015). A direct observer-as-participant approach was combined with indirect audio-video observation creating a rich protocol of the performed activities (Bisantz et al., 2015; Robson, 2011).

Results

Data analysis and results were structured according to the developed framework.

Expert Consultation Findings

The expert consultations provided insights into essential non-technical skills such as clear leadership, explicit task-allocation and the leader's ability to maintain situation awareness. The importance of establishing effective communication strategies among all team members such as speaking loud and clearly, ensuring team members hear your message and obtaining feedback was highlighted. Consulting the Chief Technologist revealed significant maintenance issues. For example, the aggressive chemicals of clinical wipes, react with the plastic parts of the device and can lead to cracks.

Device Design Evaluation

The design of the LIFEPAK® 20e mainly fulfils established Human Factors design principles. However, the design lacks to accommodate appropriate mental models of the button colouring. The green "ON" button and the red "SHOCK" button are not in line with the mental model of traffic light colours such as green for "Go" and red for "Stop". Besides, the "SHOCK" button is only labelled with a lighting symbol and misses additional control text labelling.

Task Analysis

The task analysis shows the algorithm followed in adult cardiac arrest events in hospitals (Figure 1).

Interviews

The interviews revealed that during CPR clinicians can become absorbed in the technology, trying to interpret readings and formulate conclusions, meanwhile neglecting the patient. Related to this issue, one participant highlighted that a known problem during CPR is the misidentification of Pulseless Electrical Activity (PEA). PEA is a common condition which can occur during cardiac arrest situations (NCAA, 2017). In PEA the ECG monitor shows electrical activity in the heart resembling a normal sinus rhythm, but in fact, there is no mechanical contraction of the heart and thus no blood flow or pulse (Neumar et al., 2010). This fact can be deceiving in case the clinician only watches the monitor and concludes an intact peripheral circulation without physically checking the pulse on the patient. The NUH trust has a centralised staffing structure for organising emergency resuscitation. There is one on-call resuscitation team, consisting of four mandatory responders for each of the two hospital campuses, which are trained in either Intermitted or Advanced Life Support. In addition, the NUH trust has a team of nine ALS trained Resuscitation Officers who function as non-mandatory responders. Moreover, the entire clinical staff in the trust is BLS trained and therefore able to immediately start CPR. When the alarm goes off, it can take several minutes until the mandatory responders arrive at the scene to take over resuscitation. There is no specific task and role allocation within the resuscitation team and thus no team leader designated beforehand. Assignment of roles and leadership happens spontaneously and vary from event to event. As a result, in some cases, a cardiac arrest is managed without a designated team leader.

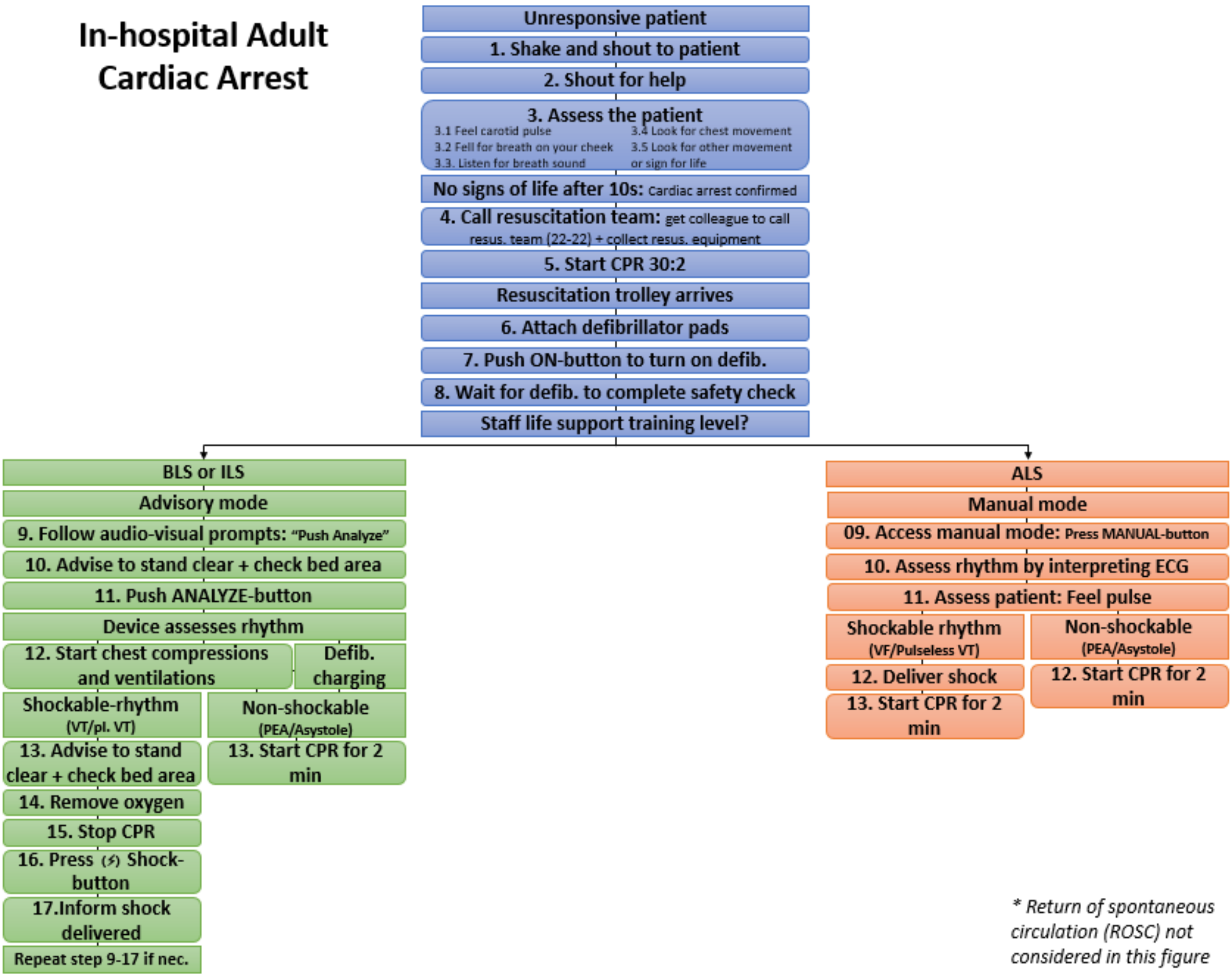

Figure 1. Task analysis of in hospital adult cardiac arrest.

Observations

Nine cardiac arrest scenarios were observed over three days with a different group and number of participants on each day. Those participants who interacted with the defibrillator during the scenes were able to operate the device without making any identifiable use errors. However, the observation of resuscitation activities revealed that there is a variety of other factors such as technical and non-technical skills, which are crucial for high-quality resuscitation. For instance, one group was not able to identify that the patient had PEA by failing to verify the monitor activity with the patient´s clinical state. Most scenarios with no evidence of clear leadership and allocation of duties showed delays in swapping chest compressions or pressing buttons on the defibrillator. In some scenarios, the participants frequently swapped between roles, resulting in a somewhat hectic approach. Regarding communication skills, the participants generally expressed a deficient sense of urgency during this life-critical event. The voice tone was typically monotone and emotionless across all teams.

Discussion

Model of in-hospital Defibrillator Use during CPR

Common themes arising from the data collection were combined in a HFE model for defibrillator use in hospitals by using a merger of the SEIPS 1.0 model by Carayon et al. (2006) and the original onion model by Grey et al. (1987) and Wilson (1995). Thus, the clinical context and the underlying concept of the SEIPS model were combined with the visual representation of the onion model which considers the person in the centre of all interactions (Wilson, 1995; Wilson & Sharples, 2015) (Figure 2).

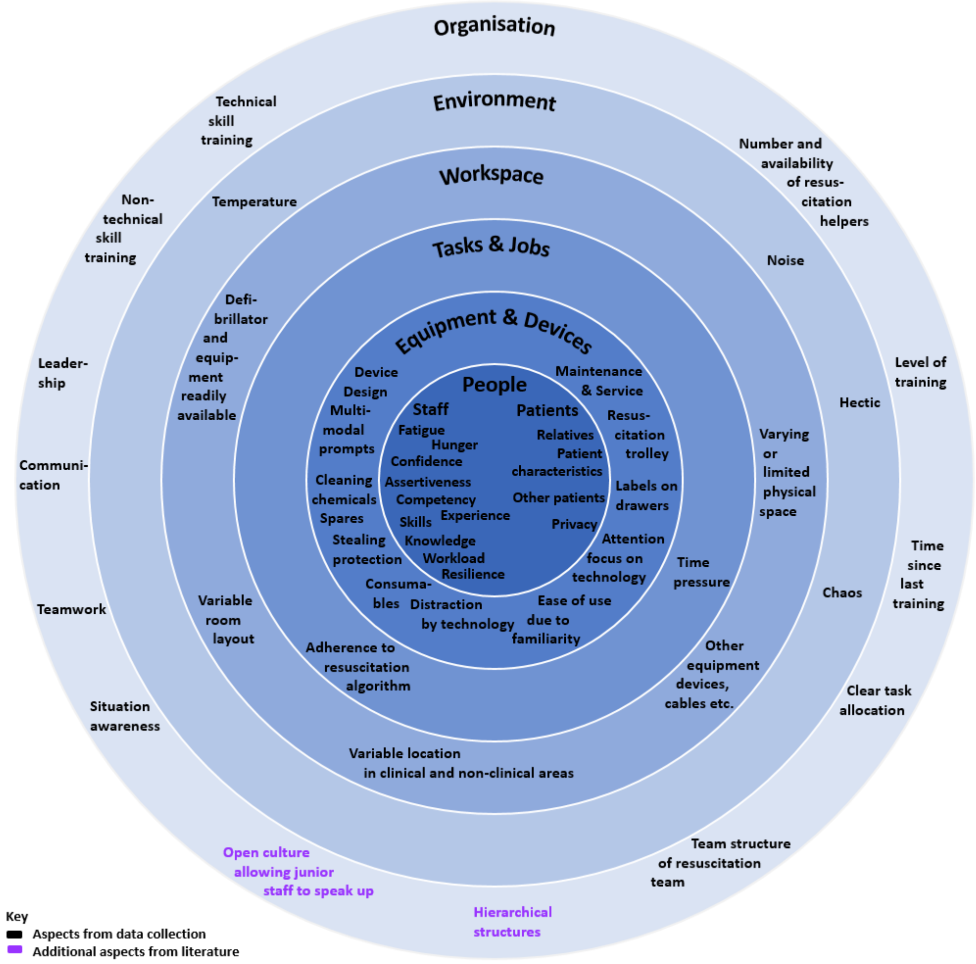

Figure 2. Model of in-hospital defibrillator use.

1. People

In a healthcare system, the people are hospital staff, patients, as well as their relatives and visitors (Wilson, 1995; Wilson & Sharples, 2015). Accurate, reliable and safe use of medical devices and management of medical emergencies is not only determined by the clinicians' skills, knowledge and experience but also by individual factors such as fatigue, hunger and workload (Gaba & Howard, 2002; Weinger & Ancoli-Israel, 2002; Wiklund & Weinger, 2010). All of these factors impact on the individuals' resilience, the ability to bounce back in a stressful and pressurised situation (Hollnagel, 2011). The capability to adapt to changes, to learn, respond, monitor and anticipate is an essential factor for clinical staff to perform in a dynamic healthcare setting (Hollnagel, 2011). Besides, the specific medical condition of the patient, present relatives and other surrounding patients can impact the resuscitation process.

2. Technology and Devices

The findings from this study confirmed that clinicians are prone to distraction by medical technology. Thus, there is the need to emphasise HFE approaches and user trainings and acknowledge the impact of data overload and sophisticated medical technology (AAMI, 2016). The effect of clinical cleaning chemicals on the surface of medical devices, such as the LIFEPAK® 20e defibrillator is an aspect, which has not been considered in the design of the device. Such clinical insights highlight the importance of holistic HFE evaluations and give valuable input to manufacturers for future models.

3. Tasks and jobs

This study revealed that there is a massive variation in how, when and under which circumstances the defibrillator is used and adherence to the full resuscitation protocol is not always given. As resuscitation is a life-critical emergency procedure, time pressure is a critical impact factor on defibrillator use. Thus, this emphasises the need for highly intuitive operation of the defibrillator and resilient organisational structures to support safe and efficient use of the device.

4. Workspace

As cardiac arrest can happen anywhere at any time, life support providers continuously need to adapt to new situations under stress and time pressure. With this in mind, the design of an emergency medical device such as a defibrillator needs to be adjusted to varying workspace conditions, for instance, different work locations and limited physical space to minimise the workload on clinicians.

5. Environment

The findings support the notion that the physical environment has a substantial impact on the use of the defibrillator. Mainly where temperatures are too high or too low and where auditory effects such as noise can affect the safe use of the device. Noise impact on clinicians can impair task performance and can lead to increased stress levels, which underlines the need to integrate multi-modal prompts and feedback mechanisms in the device design (Morrison, Haas, Shaffner, Garrett, & Fackler, 2003; Wiklund & Weinger, 2010).

6. Organisation

The relevance of non-technical skill such as teamwork, clear allocation of tasks and roles, leadership and team coordination, situation awareness and effective communication of cardiac arrest events became obvious throughout all phases of data collection. A lack of teamwork, leadership and explicit task allocation negatively affects the performance of CPR delivery (Hunziker et al., 2011; Marsch et al., 2004). Effective teamwork requires explicit task delegation, coordination and clear team leadership as well as communication (Fernandez Castelao, Russo, Riethmüller, & Boos, 2013; Hunziker et al., 2011; Marsch et al., 2004). Observing CPR simulation training showed that it is beneficial to allocate functions explicitly and early on to successfully follow the resuscitation algorithm. Scenarios with evident leadership and clear allocation of functions were less chaotic and produced less confusion amongst the participants. However, good leadership during critical medical interventions requires a set of skills such as effectively coordinating functions, understanding team interactions, the ability to maintain situation awareness and effective communication (Andersen, Jensen, Lippert, & Østergaard, 2010; Fernandez Castelao et al., 2013; Velzen et al., 2017, Yeung et al., 2012). Clear and effective communication is essential to high-quality cardiac arrest management (Fernandez Castelao et al., 2013; Gwinnutt et al., 2015). Effective communication can be achieved through 'closing the loop' by verbalising the thought process, specifying and directly addressing information to team members and requesting feedback (Fernandez Castelao et al., 2013). In essence, non-technical skills such as teamwork, effective communication, clear allocation of tasks and roles, leadership and situation awareness should be a core element of clinical practice and resuscitation training (Fernandez Castelao et al., 2013; Gwinnutt et al., 2015; Yeung et al., 2012). Resuscitation training is essential for the adequate performance of technical and non-technical skills whereas high-quality content and delivery and most of all a high training frequency is crucial (Yeung et al., 2012). Extended time intervals between sessions without further application of the content can impact the safe and efficient use of the defibrillator and hence affect the overall CPR performance and clinical outcome (Wiklund & Weinger, 2010). According to the Resuscitation Guidelines, it is recommended to deliver a defibrillator shock within three minutes of the patient's collapse (Gwinnutt et al., 2015). Due to the hospitals staffing structure of only having one mandatory resuscitation team per hospital and the hospital's large building complex, valuable time is lost when the resuscitation team attends to the cardiac arrest scene. However, ward staff near the patient should be able to immediately start CPR but often lack experience and routine with resuscitation and defibrillator use. To avoid delays, possible errors as well as a worst-case scenario of having two or more cardiac arrest events happening at the same time, it can be recommended to have several resuscitation ALS teams always readily available. A clearly defined assignment of roles and tasks can be beneficial for efficient resuscitation management. According to the latest Resuscitation Guidelines, it is recommended to have a designated team leader whose only function is to lead the arrest. The team leader should monitor and delegate tasks without actively participating in a job to maintain situation awareness and avoid distraction by own task performance (Gwinnutt et al., 2015). Thus, it can be recommended to assign leadership roles and deputy leadership roles within the team of mandatory responders.

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