Defibrillator Design and Usability May be Impeding Timely Defibrillation

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March 7th, 2017
Disclosure

• All funding was provided in conjunction between the University of Ottawa Department of Medicine Patient Quality and Safety research grant and The Ottawa Hospital division of Critical Care.
Delayed Defibrillation

• Between 75,000 – 150,000 patients suffer in-hospital cardiac arrest secondary to ventricular tachyarrhythmia with attempted cardio-pulmonary resuscitation each year in the United States.

• The only rhythm-specific therapy proven to increase survival to hospital discharge is timely defibrillation.

• Guidelines published by the American Heart Association recommend the defibrillation of an in-hospital cardiac arrest secondary to ventricular arrhythmia occur within 2 minutes of recognition of the arrest.
Delayed Defibrillation

• Patients who experience delayed defibrillation:
  o **Less likely to survive** to hospital discharge (22.2% when defibrillation was delayed versus 39.3% when defibrillation was not delayed).

• Even amongst those who survive:
  o Lower likelihood of having **no major disabilities in neurologic status** (odds ratio, 0.74).
  o Lower likelihood of having **no major disabilities in functional status** (odds ratio, 0.74).
Delayed Defibrillation

- National Registry of Cardiopulmonary Resuscitation:
  - Delayed defibrillation occurs in more than 30% of this patient population.
  - Average time to defibrillation was approximately 1 minute.

- Average time to defibrillation at The Ottawa Hospital (TOH):
  - 8 minutes in a critical care setting (ICU, CCU, PACU, ED).
  - 11 minutes on a medical ward.
Delayed Defibrillation

- Limited data is available regarding the **system-related factors** and the **patient-related factors** that are associated with a higher probability of delayed defibrillation.
We hypothesize that **flaws in defibrillator design** contribute to a delay in timely defibrillation.

We aim to identify such flaws via **high fidelity usability testing** in a simulated hospital environment.
Usability Testing

• A technique in which users interact with a product under controlled conditions and behavioral data is collected.

• This information is then applied to better understand:
  
  i. Human performance capabilities.

 ii. Human performance limitations.

 iii. How product design can be modified to meet these needs.

• Thought to be an essential component of safety engineering in other fields, usability testing has been reported to be underutilized in the health care system.
Methods - Design

• **Qualitative and quantitative prospective usability study** evaluating the use of a manual-mode defibrillator in a simulated hospital environment.

• Study protocol was approved by the **Ottawa Health Science Research Network Board**.
Methods - Setting

- TOH is an **academic quaternary care regional referral center** with over 1,100 inpatient beds.
- Operated in conjunction with the University of Ottawa and TOH, the uOSSC is the **largest medical simulation center in Canada**.
- Simulation was conducted in a **high-fidelity clinical exam room**.
- Tasks were performed using a full size **Human Patient Simulator**.
Methods - Participants

- Twenty-two internal medicine resident’s post graduate year (PGY) 1-3.
- All participants were certified in Advanced Cardiovascular Life Support (ACLS) and had completed ACLS certification training within the preceding 12 months.
- Senior residents (PGY2 – PGY3) are cardiac arrest team leaders at our institution while junior residents (PGY1) are member of the cardiac arrest team.
Methods - Intervention

Participants were asked to perform two simulated tasks typical of in-hospital cardiac arrest care:

- **DEFFIBRILLATION** - “Attach the defibrillator device to the patient, perform a rhythm check, confirm the presence of ventricular fibrillation, and then deliver 1 defibrillation.”

- **SYNCHRONIZED CARDIOVERSION** - “Attach the defibrillator device to the patient, perform a rhythm check, confirm the presence of an unstable atrial tachyarrhythmia, and then deliver 2 synchronized cardioversions.”
Outcomes

• Primary Outcome(s) -
  i. Time to defibrillation.
  ii. Proportion of participants able to deliver a defibrillation within 2 minutes.

• Secondary Outcome(s) -
  i. Objective observer evaluations.
  ii. Participants perceived usability of the manual-mode defibrillator.
  iii. Thematically coded qualitative participant feedback on usability.
Results

- Time to defibrillation:
  - Average time to defibrillation was 4 minutes 21 seconds ± 138 seconds.
  - Average time to defibrillation for senior trainees was similar to that of the group as a whole at 3 minutes 56 seconds ± 138 seconds.
  - Only 9.1% of participants were able to perform a simulated defibrillation within 2 minutes.
  - Average time to synchronized cardioversion was 1 minute 55 seconds ± 59 seconds.
### Objective Observer Evaluations

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Results

• Qualitative participant feedback was analyzed and grouped according to theme:
  
  o Negative participant feedback focused predominantly upon the process of attaching the hands-free defibrillator pads to the defibrillator.
  
  o All 22 participants commented upon at least one aspect of this core function in the post-exposure questionnaire.
  
  o Descriptors of the process included “unintuitive”, “inconvenient”, and “awkward”.
Discussion

- Participants in our study are educated predominantly senior trainees with a high degree of familiarity with the Philips HeartStart XL defibrillator and ACLS protocol.

- Despite this, the **average time to defibrillation was greater than two-times that which is recommended** by the American Heart Association.

- Based on these results, it appears likely that **delay in defibrillation are at least partially resultant of poor defibrillator design** and lack of usability.

- Even the most expert of users may make **continue to make errors** when confronted with a device that is illogical and poorly designed.
Discussion

• Expert observer evaluation and qualitative participant feedback were largely congruent in regards to which aspects of defibrillator design do not suit the end-user.
  
  o Inability to **attach the hands-free defibrillator pads** to the defibrillator.
  
  o Inability to **select an appropriate display**.
Hands-free Defibrillator Pads
Cable Locking Mechanism
Hand-held Defibrillator Paddles
• The Philips HeartStart XL defibrillator has the capability to **display information from multiple inputs** including ECG leads, hands-free defibrillator pads, and hand-held defibrillator paddles.

• The default display is that of **ECG lead II**.

• When using either the hands-free defibrillator pads or hand-held paddles the **input must be changed manually** to that of the desired component.
Discussion

• Modification of future defibrillator design may result in more timely defibrillation.
  
o  Engineering hands-free defibrillator pads as a single component.
  
o  Modifying the default display.
  
o  Re-locating the cable locking mechanism to a more accessible location.
Validity

• Largely dependent upon obtaining behavioral data from actual users of the device in the environment for which it is intended to be used.
  o Attempted to replicate many of the environmental factors typical of a hospital environment through high-fidelity simulation.
  o Physicians are responsible for defibrillator use during cardiopulmonary resuscitation at most large tertiary care centers. As such, we elected to evaluate physician usability of the manual-mode defibrillator which had not been studied previously.
Validity

- It remains somewhat unclear as to why so many of our participants were unable to compete a simulated defibrillation within 2 minutes.
  - Intuitively, we would have expected defibrillation to occur more rapidly in a simulated environment.
  - Role for improved training and education as the time to synchronized cardioversion was significantly less than that of defibrillation likely as a result of learning and recency.
  - Given the relatively low incidence of cardiac arrest it is impractical to train users frequently enough to maintain such proficiency.
Discussion

- Our study has several limitations:
  - Single center trial with a relatively modest number of participants.
  - Generalizability of our results to other defibrillator models is uncertain (given the discrepancy between real-world and simulated time to defibrillation at our institution relative to that of The National Registry of Cardiopulmonary Resuscitation).
Our study has several limitations:

- Participants were recruited on a voluntary basis raising the possibility of selection bias.
- The definition of “difficulty” completing a specific function used in our study has not been externally validated. Nonetheless, we think it is reasonable that a delay greater than one-half of the total time allocated for a task is significant.
Summary

• Most participants in our study were unable to perform a simulated defibrillation within 2 minutes.

• This delay in defibrillation was likely at least partially resultant of poor defibrillator design and lack of usability.

• Expert observation and qualitative participant feedback were largely congruent in terms of which aspects of defibrillator design do not suit the end-user.

• Modification of future defibrillator design may result in more timely defibrillation and subsequently improved outcomes for patients.
References


