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Clinical Summary

AED comparison usability study

Background

It is critical an Automated External Defibrillator (AED) is well-designed so lay users can use it safely and effectively to achieve the desired clinical outcome. While many brands of AEDs are currently available on the market, the level of usability varies significantly among defibrillators. This is especially evident in a study that compares lay user performances using four different models of AEDs, where the success rate of delivering a shock ranged from 44% to 100%, and the time from test users room entry to shock delivered ranged from 93 to 210 seconds.[1]

Defibrillation within 3–5 minutes of collapse can produce survival rates as high as 50–70%.[2] Thus, the performance differences observed in the study could have led to significantly different patient outcomes in the real world.

To obtain the best patient outcomes, defibrillation needs to be combined with CPR. According to the Public Access Defibrillation (PAD) Trial, survival rates doubled when bystanders provide CPR and use an AED to deliver a shock.[3] Accordingly, many AEDs now provide instructions on how to perform CPR, and CPR quality has become an important criteria used to evaluate the effectiveness of an AED.

Stryker's LIFEPAK CR2 defibrillator is designed for lay operator use in public access settings. It incorporates a number of features such as emergency response guidance, CPR coaching and detection technology, ECG analysis during CPR and variable sound tones and voice prompts to facilitate device use and patient resuscitation.

Purpose

This study aimed to gather objective data regarding device usability and CPR performance on the following four AED models:

- Stryker's LIFEPAK® CR2 defibrillator
- Stryker's LIFEPAK CR® Plus AED
- Philips HeartStart OnSite AED
- ZOLL® AED Plus®

Methods

Device usability was evaluated through simulated use testing, in which a lay operator used an AED to help a patient (manikin) in sudden cardiac arrest.

Data was collected from June 8 through July 31, 2015 (for Stryker's LIFEPAK CR Plus AED, Philips HeartStart OnSite AED, and ZOLL AED Plus), and on July 6, 2016 for (Stryker's LIFEPAK CR2 defibrillator). Evaluation was performed by human factor engineers with assistance from clinical specialists and a human factor consultant.

Sixty-one lay users (participants), recruited through Stryker's own outreach effort (in 2015) and through a third-party recruiting agency (in 2016), participated in the current study. Overall, participant demographics, including gender, age, education, and CPR training, were comparable amongst the four different device groups. The only exception was that fewer participants who tested the ZOLL AED Plus had previous AED training (33% vs. 70% for the other three devices). Because of this, the ZOLL AED Plus test results were further examined according to participants' previous AED training. The test devices were randomly assigned (ZOLL AED Plus, Philips HeartStart OnSite AED, Stryker's LIFEPAK CR Plus AED). The CR2 testing was conducted in one day.

The test scenario lasted a total of 5 minutes and included:

- Connecting AED to manikin (time to achieve varied with each participant).
- Delivering a shock
- Performing 2 minutes CPR
- Delivering second shock
- Performing 2 minutes CPR
- Delivering third shock
- Performing CPR until end of scenario (time for this segment varied due to time used to connect AED).

Equipment

All devices were set to a single language (English) setting and were of a semi-automatic type. The devices were slightly modified to allow for connection to a patient simulator for sensing electrode pad placement on the manikin and for shock delivery. This modification included the attachment of a six-foot (182.88cm) cable to the back of each device while other aspects of the user interface remained intact.

A Laerdal Resusci Anne® with QCPR manikin, with a shirt and jacket on its upper body, was used to simulate an adult male patient. During testing, the manikin was connected to a SimPad® SkillReporter™, a hand-held device which collected CPR performance data including compression depth, rate and compression fraction (the amount of time CPR was performed over the test case time, i.e., 5 minutes). The manikin and the SimPad SkillReporter were measured prior to the start of data collection (first in 2015 and again in 2016) so the measuring errors between the actual chest compression depths on the manikin and the SimPad SkillReporter readout were recorded and later used to adjust the

CPR depth measurement in the raw SimPad SkillReporter data files. The CPR depth data reported here are adjusted depths.

Procedure

Participants were tested individually following the same procedure:

- Test moderator first described the test scenario to the participant outside of the testing room.
- Participant entered the testing room and performed the task while test moderator and test assistant in the same room observed and took note of any issues.
- After participant completed the task, test moderator conducted post-test interview to obtain participant's subjective responses as well as answers to open-ended questions.

During each test session, test moderator used a moderator's guide to ensure interactions with all participants were consistent and the same information was obtained from each participant. In addition, each test session was video recorded and photographed for review for more granular data analysis.

Data analysis

Data analysis was conducted immediately after data collection on each brand was complete, and focused on the following:

- AED use time profile—One individual, the Senior Human Factors Engineer who moderated all test sessions, reviewed video recordings of all study sessions to obtain time stamps for turning on device, placement of both pads on patient, delivery of first shock and start of CPR for each participant.
- A Principal Clinical Specialist reviewed photographs of the placement of electrode pads on the manikin by each participant to determined whether or not the placement would lead to clinically effective shocks.
- The same Senior Human Factors Engineer analyzed CPR performance data based on SimPad SkillReporter data files with adjustment for measuring errors.

Task success rate

The overall criteria for task success was that the participant was able to deliver the first shock deemed clinically effective. The table below summarizes the number of participants who succeeded with each device:

	# Participants	# Who delivered first shock before CPR	# Who delivered first shock during 5-min CPR	# Who never delivered shock
LIFEPAK CR2 defibrillator	15	15 (100%)	0	0
LIFEPAK CR Plus AED	16	16 (100%)	0	0
Philips Onsite AED	15	15 (100%)	0	0
ZOLL AED Plus	15	7 (47%)	5 (33%)	3 (20%)
	AED trained: 5 Not AED trained: 10	3 (60%) 4 (40%)	2 (40%) 3 (30%)	0 3 (30%)

While all participants using the LIFEPAK CR Plus AED, Philips HeartStart OnSite AED and the LIFEPAK CR2 defibrillator were able to deliver a clinically effective shock before starting CPR, only 7 of 15 participants (47%) using the ZOLL AED Plus device were able to do so.

Time measures

The table above right shows the median times taken by participants to turn on the device, place pads on the manikin, deliver the first shock and start CPR. For the ZOLL AED Plus, time to open the device lid (after turning on the device) also is provided. The timer started when a participant entered into the camera view ready to reach for the device. Measurement errors are within 1-2 seconds.

	# Participants	Turn on device (seconds)	Open lid (seconds)	Place pads (seconds)	Deliver shock (seconds)	Start CPR (seconds)
LIFEPAK CR2 defibrillator	15	10.4	N/A	55.3	77.7	86.8
LIFEPAK CR Plus AED **Note:** Pressing ON button opens lid and starts device	14[a]	7.1	N/A	67.8	93.2	102.5
Philips OnSite AED	12[a]	10.1	N/A	79.1	102.1	131.6
ZOLL AED Plus	7[b] 5[c]	6.1 5.1	15.2 41.6	84.3 224.2	112.7 271.8	118.1 127.0[d]

a Participant attrition in the CR Plus and OnSite AED groups was due to 5 participants who started by performing CPR first (following their CPR training); therefore, their data were excluded from this analysis.

b Participants who delivered the first shock before CPR.

c These five users were not able to place electrodes on manikin before starting CPR (after being prompted by the device). After 2 minutes of CPR, device voice prompts instructed user to attach electrodes to manikin. These users eventually applied electrodes to manikin and delivered the first shock. Afterwards they resumed CPR following device voice prompts.

d For these five participants, the median time to start CPR (without delivering the first shock) was 127.0 seconds, and the median time to resume CPR after the first shock was 276.7 seconds.

CPR performance

Key CPR performance data includes compression depth, rate and compression fraction. Current ERC/AHA Guidelines recommend a compression rate of 100-120min beats per minute and depth 5-6cm (2.36 inches).[4,5] Participants' CPR performances are summarized below, with numbers representing the medians of each performance variable for each device (numbers in parentheses are ranges on a variable):

	# Participants	Compression depth (mm)	Compression rate (beats/minute)	Compression fraction (%)
LIFEPAK CR2 defibrillator	15	51.0	103 (85 – 106)	89 (87 – 92)
LIFEPAK CR Plus AED	14[e]	45.5	112 (65 – 144)	52 (34 – 67)
Philips OnSite AED	15	43.0	99 (94 – 149)	82 (26 – 85)
ZOLL AED Plus	15	59.0	101 (50 – 150)	74 (11 – 85)

e Due to a technical malfunction, CPR data were not collected for two participants in the LIFEPAK CR Plus AED group.

Subjective responses

Participants provided ratings on a 7-point scale with regard to device ease of use, ease of hearing device voice prompts and their own confidence level respectively, with 1 being the most negative response and 7 the most positive. The following table shows participants' average ratings after device use (numbers in parentheses represent the range). Note averages rather than medians are presented because individual ratings congregated in a small number of rating categories, so the average is more sensitive and accurate than the median.

	# Participants	Device ease of use	Ease of hearing voice prompts	Confidence level
LIFEPAK CR2 defibrillator	15	6.7 (6 – 7)	6.7 (4 – 7)	5.5 (3 – 7)
LIFEPAK CR Plus AED	16	6.1 (4 – 7)	6.6 (5 – 7)	4.8 (3 – 6)
Philips OnSite AED	15	5.9 (4 – 7)	6.5 (5 – 7)	5.2 (3 – 7)
ZOLL AED Plus	15	3.5 (1 – 6)	6.2 (5 – 7)	4.0 (1 – 6)

Discussion

The current study aimed to gather objective data regarding AED device usability and CPR performance. Simulated use testing showed lay operators' use of an AED is directly impacted by device usability. On several key performance measures, participants using the LIFEPAK CR2 Defibrillator outperformed those using both competitive AED models currently available on the market.

Specifically, all participants using the LIFEPAK CR2 defibrillator, LIFEPAK CR Plus AED and Philips OnSite AED successfully delivered the first shock even though 10 out of 46 participants did not have AED training. In comparison, only 47% of the participants using the ZOLL AED Plus were able to deliver a shock before CPR, and 3 of the 10 participants who did not have AED training never delivered a shock even after 5 minutes of CPR (during which the device paused CPR voice prompts to direct user to attach electrodes to patient). This suggests the first three AEDs are sufficiently intuitive and easy to use by lay users untrained on an AED, whereas for ZOLL AED Plus, previous AED training appears to be a prerequisite.

In sudden cardiac arrest resuscitation, time-to-shock is one of the most critical variables which determines the clinical outcome of defibrillation. Among the four devices tested in the current study, participants using the LIFEPAK CR2 defibrillator delivered the first shock within 78 seconds after the test started, an advantage of 24 seconds over Philips OnSite AED and 35 seconds over ZOLL AED Plus (note only 47% of the ZOLL AED Plus participants were able to achieve this level of performance). A closer look at the time profile shows LIFEPAK CR2 defibrillator's advantage was gained through reducing time spent placing electrodes on the patient and remained through the start of CPR (the advantage increased to 45 seconds when compared to Philips OnSite AED). The differences in times are the direct result of design features implemented in the devices.

With regard to CPR performance, participants using the LIFEPAK CR2 defibrillator and ZOLL AED Plus reached median compression depth of at least 51mm (2 inches). Even though all four device groups had median compression rates within the 100 – 120 beats/minute range recommended by the 2015 AHA/ERC Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, the CR2 defibrillator resulted in more consistent compression rates across participants than the other devices. This is likely due to the combination of the metronome and CPR coaching prompts. In addition, the LIFEPAK CR2 defibrillator group also had the highest compression fraction (89%), with all 15 participants performing remarkably consistent on this measurement (ranging from 87% to 92%), whereas for other devices individual differences using the same device were as high as 74% for the ZOLL AED Plus.

Corresponding to objective behavioral data, participants' subjective responses were also clearly impacted by device usability. Specifically, participants using the LIFEPAK CR2 defibrillator gave it the highest score on device ease of use (averaged 6.7 on a 7-point scale), and felt the most confident during patient resuscitation (5.5 on a 7-point scale). In comparison, participants who used the ZOLL AED Plus rated it negatively on the ease of use scale (3.5 on the 7-point scale) and reported the lowest confidence level (4.0 on the 7-point scale) amongst all the device groups.

Because simulated use testing of the four models was conducted at different times by two sets of personnel in different locations, it is important to examine if any of the extraneous variables contributed to the different outcomes reported above. To that end, were compared the LIFEPAK CR2 defibrillator results from the current study with the outcome of another LIFEPAK CR2 defibrillator simulated use test conducted in April-May 2016. The earlier study was conducted in the same setting where the LIFEPAK CR Plus AED, Philips OnSite AED and ZOLL AED Plus were tested, by the same personnel (a Senior Human Factors Engineer and a Clinical Marketing Specialist), and with 17 lay user participants who met the same criteria. Data analysis was conducted by the same Senior Human Factors Engineer who conducted data analysis for the current study. The LIFEPAK CR2 defibrillator tested in the earlier study resembled the LIFEPAK CR2 defibrillator used in the current study, with identical device hardware and CPR coaching voice prompts. The results showed the device use time profile in the earlier study was similar to the LIFEPAK CR2 defibrillator results from the current study. In particular, the times to turn on the device in the two studies (which was not impacted by voice prompts but a measure of how comparable the two studies are) were very similar (see data in below table). Therefore, we conclude that there is no evidence performance differences in the current study between the LIFEPAK CR2 defibrillator and the other devices were caused by differences in study settings, administration staff, or schedules.[6]

	# Participants	Time to Turn on Device	
		Median	Mean
LIFEPAK CR2 defibrillator in current study	15	10.4 seconds	9.9 seconds
LIFEPAK CR2 defibrillator in earlier study	17	7.9 seconds	10.4 seconds

Conclusions

The current study compared Stryker's LIFEPAK CR2 defibrillator with LIFEPAK CR Plus AED, Philips HeartStart OnSite AED and ZOLL AED Plus through a simulated use test by lay operators trained in CPR but not necessarily in AED use. The results showed participants using the LIFEPAK CR2 defibrillator had the first time-to-shock and the fastest time to start CPR by large margins. CPR performance of participants using the CR2 defibrillator met the AHA/ERC guidelines, with a median depth of 51mm (2 inches) and at a median rate of 103 compressions per minute over 5 minutes. In addition, these participants had the highest overall compression fraction (hands-on time) during CPR and performed in a remarkably consistent fashion.

Participants rated the LIFEPAK CR2 Defibrillator the easiest to use among all of the devices and reported a high level of confidence while using the device. The performance advantages and positive user experience offered by the LIFEPAK CR2 Defibrillator are the results of advanced device features and careful user interface design.

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE:
LIFEPAK CR® Plus and LIFEPAK EXPRESS® AEDs are indicated for use on patients in cardiac arrest. The patient must be unresponsive (unconscious), not breathing normally, and showing no signs of circulation (for example, no pulse, no coughing, or no movement). LIFEPAK AEDs are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program. The AEDs may be used with QUIK-PAK™ defibrillation pads only on adults and children who are 8 years old or more, or who weigh more than 55 lbs (25 kg). The AEDs may be used on children who are less than 8 years old or weigh less than 55 lbs (25 kg) with Physio-Control Infant/Child Reduced Energy Defibrillation Electrodes. The AEDs may be used with the CHARGE-PAK™ battery charger.

CONTRAINDICATIONS:
Do not use LIFEPAK AEDs when the victim is conscious and responsive.

WARNINGS: AED:
- LIFEPAK AEDs deliver up to 360 joules of electrical energy. Unless properly used, this electrical energy may cause serious injury or death. Do not attempt to operate AED unless thoroughly familiar with the function of all controls, indicators, connectors, and accessories.
- When instructed "Do not touch patient," "Stand by," or "Everyone clear," remain still, do not touch AED, patient, defibrillation pads or any material in contact with patient. Make sure no one is touching patient when AED shocks the patient. • Performing CPR or otherwise handling or transporting the patient while AED is evaluating the heart rhythm can cause an incorrect or delayed diagnosis. Keep patient as still as possible.
- Do not immerse AED in water or other fluids. Avoid spilling any fluids on AED or its accessories.
- Do not use in presence of flammable gases or anesthetics. Use care when operating close to oxygen sources. Turn off gas source or move source away from patient during defibrillation.
- Contact authorized service personnel for repair.
- Equipment operating in close proximity may emit strong electromagnetic interference (EMI) or radio frequency interference (RFI) which could affect performance of AED.
- Keep AED away from magnetic resonance imaging (MRI) equipment as it is unsafe.
- Always keep a CHARGE-PAK battery charger in AED. Routinely check that AED is ready for use. Replace CHARGE-PAK battery charger and QUIK-PAK defibrillation pads after each use of AED. Insert only CHARGE-PAK battery charger into well of AED.
- Use only parts and accessories specified by Physio-Control or Stryker. Using other manufacturers' accessories may cause AED to perform improperly and will invalidate safety agency certification.
- Using damaged or expired accessories may cause AED to perform improperly and may injure the patient or user.
- **Defibrillation pads:** Place defibrillation pads so they adhere to skin completely.
- Do not allow defibrillation pads to touch each other or any other material on patient's chest.
- Do not use damaged, expired, or dried-out defibrillation pads. If you cannot determine a child's age or weight, or if infant/child electrodes are not available, proceed with QUIK-PAK defibrillation pads.

CAUTIONS:
- If AED has been damaged, remove from use and contact qualified technician.
- Do not open device lid unnecessarily as this will reduce the internal battery power.

POTENTIAL ADVERSE EFFECTS (for example, complications):
- Failure to identify shockable arrhythmia
- Failure to deliver a defibrillation shock in the presence of ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT), which may result in death or permanent injury
- Inappropriate energy delivery which could cause failed defibrillation or post-shock dysfunction
- Myocardial damage
- Incorrectly shocking a pulse-sustaining rhythm and inducing VF or cardiac arrest
- Bystander shock from patient contact during defibrillation shock
- Interaction with pacemakers
- Skin burns around the defibrillation pad placement area
- Allergic dermatitis due to sensitivity to materials used in defibrillation pad construction
- Minor skin rash
- Fire hazard in the presence of high oxygen concentration or flammable anesthetic agents
- EMI from the AED impacting other devices especially during charge and energy transfers.

U.S. Federal law restricts this device to sale by or on the order of a physician.

Please consult the Operating Instructions at **www.strykeremergencycare.com** or call 800.442.1142 for the complete list of indications, contraindications, warnings, cautions, potential adverse events, safety and effectiveness data, instructions for use and other important information.

References

1. Andre A, Jorgenson D, Froman J, et al. Automated external defibrillator use by untrained bystanders: can the public-use model work? *Prehospital Emergency Care*, 2004;8(3), 284-291.
2. Perkins G, Handley A, Koster R, et al. European Resuscitation Council Guidelines for Resuscitation 2015. Section 2. Adult basic life support and automated external defibrillation. *Resuscitation*. 2015;95:83.
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5. Kleinman M, Brennan E, Goldberger Z, et al. Part 5: Adult basic life support and cardiopulmonary resuscitation quality. 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Care. *Circulation*. 2015;132(18 suppl 2):S419.
6. The LIFEPAK CR2 defibrillator CPR coaching voice prompts remained the same over the course of the two studies. In the earlier study, participants' CPR compression depth was also similar to the results of the current study, with a median of 53.0mm and a mean of 51.7mm. The median and mean of compression depth in the current study were 51.0mm and 52.0mm respectively.

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE:
LIFEPAK CR2 AED is indicated for use on patients 1 year of age or older in cardiopulmonary arrest. The patient must be unresponsive (unconscious), not breathing normally, and showing no signs of circulation (for example, no pulse, no coughing, or no movement). cprCOACH™ Feedback Technology in *CR2* AED is indicated for use on cardiopulmonary arrest patients and provides CPR guidance in accordance with AHA Guidelines for patients 1 year of age or older. AED is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support/AED, advanced life support, or a physician-authorized emergency medical response training program. The LIFEPAK CR2 Defibrillator is indicated to be used with the QUIK-STEP™ Pacing/ECG Defibrillation Electrodes and the LIFEPAK CR2 Lithium Battery.

CONTRAINDICATIONS:
LIFEPAK CR2 AED is not indicated for patients who are conscious and responsive.

DANGER:
Do not use LIFEPAK CR2 in presence of flammable gases or anesthetics.

WARNINGS:

- LIFEPAK CR2 AED delivers up to 360 joules of electrical energy. Unless used properly by following AED's visual and audio prompts, this electrical energy may cause serious injury or death.
- When instructed EVERYONE CLEAR, do not touch AED, patient, electrode pads or any material/fluid in contact with patient. Make sure no one is touching patient when AED shocks patient.
- Do not immerse AED in water or other fluids. Avoid spilling fluids on AED or its accessories.
- Do not store in presence of flammable gases, anesthetics or in direct contact with flammable material. Use care when operating close to oxygen sources. Turn off gas source or move it away from patient during defibrillation.
- Equipment operating in close proximity may emit strong electromagnetic interference (EMI) or radio frequency interference (RFI) which could affect performance of AED.
- Keep AED away from magnetic resonance imaging (MRI) equipment as it is unsafe.
- AED should not be used adjacent to or stacked with other equipment.
- Do not touch patient and USB connector on back of AED simultaneously.
- Replace battery immediately when AED indicates battery is low.
- Use only accessories specified by Physio-Control or Stryker. Using other manufacturers' accessories may cause AED to perform improperly and may invalidate safety agency certification. Contact authorized service personnel for repair.
- QUIK-STEP electrode pads: Place pads so they adhere to skin completely.
- Do not allow pads to touch each other or any material on patient's chest.
- Do not use damaged, expired, or dried-out pads. Dried out or damaged pads may cause electrical arcing and skin burns during defibrillation.
- Do not pull red handle to open electrodes until immediately before use.
- QUIK-STEP electrodes provided with *CR2* are not compatible with LIFEPAK 500 device. Emergency medical personnel should not connect these electrodes to LIFEPAK 500 device.

CAUTIONS:

- Damaged batteries may leak and cause personal injury or equipment damage; handle with extreme care.
- Do not open device lid unnecessarily as this will reduce internal battery power.

POTENTIAL ADVERSE EFFECTS (for example, complications):

- Failure to identify shockable arrhythmia
- Failure to deliver a defibrillation shock in presence of ventricular fibrillation (VF) or pulseless ventricular tachycardia, which may result in death or permanent injury
- Inappropriate energy delivery which could cause failed defibrillation or post-shock dysfunction
- Myocardial damage
- Incorrectly shocking a pulse-sustaining rhythm and inducing VF or cardiac arrest
- Bystander shock from patient contact during defibrillation shock
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For further information, please contact Stryker at 800 442 1142 (U.S.), 800 668 8323 (Canada) or visit our website at strykeremergencycare.com

Emergency Care Public Access

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