الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Post-market Clinical Evaluation for the Safety of Defibrillators

Study Category:

☑ Post-market evaluation study (دراسة تقييم سريري)

☐ Risk analysis study (دراسة تحليل مخاطر)

BACKGROUND

Automated external defibrillators (AEDs) are portable, life-saving devices designed to treat people experiencing sudden cardiac arrest, a medical condition in which the heart stops beating suddenly and unexpectedly. The AED system includes accessories, such as a battery and pad electrodes that are necessary for the AED to detect and interpret an electrocardiogram and deliver an electrical shock [1].

Types of Defibrillators

There are several different types of defibrillators, and they work in different ways.

Automated external defibrillators (AEDs): These are found in public places and can be used by layperson in an emergency. They guide you through each step of the process. They will not give an electric shock unless it is necessary, so you can't harm people by using an AED. some of defibrillator models guide you how to deliver the shock, and other models deliver the shock automatically.

Manual defibrillators: health professionals use these — for example, in an ambulance or emergency department.

Implantable cardioverter defibrillators (ICDs): These are defibrillators that are surgically placed inside the body. They are designed for people who are at high risk of a life-threatening heart rhythm problem (such as those who may have had a recent heart attack or who have certain medical conditions).

Wearable cardioverter defibrillators (WCDs): These defibrillators are placed on the body. Patients who are recovering from a heart attack or who are waiting for a heart transplant usually use them. [2]

In this study, we evaluate the safety of the AED system, and collect information regarding the potential incidents that may require further actions from the manufacturer side. The scope of this evaluation report is Saudi healthcare facilities who used Automated external defibrillators, to assure the readiness of the medical professionals in hospitals and to make sure their remedy action is ready.

EVALUATION OUTCOMES

Part I: Methodology

This is a survey-based study, which is designed to collect and analyze feedbacks from the users of the AED who have dealt with these devices, such as medical professionals, nurses, and engineers. The survey was distributed over 40 healthcare facilities and it covered different sites in the Kingdom. The survey consists of 14 questions about the safety of the AED devices.

Part II: Results

The below table shows the result of the survey based on the responses received. The results indicate a satisfactory level of compliance for most of the requirements of the AED devices. However, there are some participants affirmed that there is no a back-up system in place, which affects badly the safe use of the device. One participant, said that the Processor board damaged during daily checkup, besides the capacitors was damaged, and this was discovered during the daily checkup. While another participant confirmed that Therapy Knob issues considered a negative part for the device. Regarding to device malfunction, some of participants encountered this problem. Moreover, only one participant encountered a pads/paddles failure.

The term	yes	No
1. Did you get a training for the use of the Defibrillator?	100%	0
2. Are you aware of the maintenance schedule for your AED at your site?	100%	0
3. Do you perform the Corrective Maintenance on time?	100%	0
4. Do you perform the Emergency Maintenance on time?	100%	0
5. Do you routinely perform the Preventative Maintenance?	100%	0
6. Are you aware of performing the daily inspections at your site?	100%	0
7. Is the device checked daily?	100%	0
8. Were there daily equipment checks sheet?	100%	0
9. Has the battery been used after expiration date?	0	100%
10. Have the pads been used after expiration date?	0	100%
11. Do you use an adapter or an extension with the hospitals sockets?	0	100%
12. Is there a back-up system in place?	72.7%	27.3%

13. Have you encountered a device malfunction during the recent 2 years?	18.2%	81.8%
14. Have you ever been encountered a pads/paddles failure?	9%	91%

Table.1: The distribution of the research sample according to the answers to the questions

Part III: Conclusion

The study results show that 27% of the study participants do not have a backup defibrillator, which is a factor of not readiness and noncompliance with the requirements of safe use of the device at health care facilities. Maintaining periodically, checking devices daily, and providing spare parts have significantly contributed to solving the defects of malfunctions of the devices. Some healthcare practitioners may find it challenging to deal with the device's technical errors; therefore, enhancing awareness of the use and troubleshooting AEDs is crucial.

SFDA RECOMMENDATIONS

Based on the study findings, the following actions are recommended:

Part I: Actions for SFDA:

1- Publish some leaflets and booklets about the safe use of automated external defibrillators and distribute these booklets among the medical staff.

Part II: Actions for healthcare providers:

1- Maintaining the defibrillator according to the manufacturer's recommendations.
2- The necessity to provide backup system, which makes it safer to use the device.
3- Conduct training sessions about the device use and service, done by the specialized and certified engineer for the medical staff, since having the ability to use the device correctly makes a tremendous positive difference in the safe use of the device at the Healthcare facilities.

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For further information or inquiries related to this study, you may contact us at: cia.md@sfda.gov.sa

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1 Approvals

Issued By: Sara alharthi
Position: **Date:**

Signature: SH **13-2-2022**

Reviewed By: Abdulmohsen Alhajlan
Position: **Date:**

Signature: AH **14-2-2022**

Recommendation: by: Mohammed Al-Hayan
Position: **Date:**

Signature: MSH **7-3-2022**

Approval: Dr. Mohammed Majrashi
Position: Executive Director of Surveillance and Biometrics **Date:**

Signature: MYM **8-3-2022**