الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

An Evaluation of Issues Associated with Infusion Pumps within Saudi Healthcare Facilities

BACKGROUND

Evaluating healthcare facilities for the safe-use of medical devices was launched to ensure the implementation of "SFDA Requirements for Quality, Safety, and Effectiveness of Medical Devices at Healthcare Facilities". Up to August 2020, 140 healthcare facilities across Saudi Arabia were evaluated. These sites were selected based on certain criteria, bearing in mind the regional distribution among the Kingdom, and considering both governmental and private hospitals.

In this study, we present and analyze the data of 140 Saudi healthcare facilities that were evaluated for the safe-use of medical devices throughout 2019-2020, emphasizing the evaluation elements that relate to infusion pumps. With this in mind, the most common unsafe use of infusion pumps will be highlighted, along with suggesting some recommendations to overcome that to ensure a safe use of the devices.

EVALUATION OUTCOMES

Part I: Methodology

Data of this study are extracted from the evaluation reports of 140 Saudi healthcare facilities, through which 50 hospitals were evaluated on-site by 2019, while 90 hospitals were evaluated remotely during 2020, considering the consequences of the COVID-19 pandemic. Nevertheless, the study analysis will be specific for the evaluation requirements that relate to infusion pumps, during the device operational lifecycle.

As for the hospitals that were evaluated on-site; 6 elements are considered in the study analysis, which are the device PPM tag, the device physical condition, the device user and service trainings, beside the availability of the user and service manuals. However, and as for the sites that were evaluated remotely, only the user and service trainings are considered, due to the limitations of the remote evaluation.

It is important though to refer to the fact that the determination of the unsafe practices will be based on the requirements presented in the published guideline, entitled "Requirements for Quality, Safety and Effectiveness of Medical Devices at Healthcare Facilities" [1].

Part II: Results

Table 1 shows the overall percentage of compliance to safe-use requirements of infusion pumps at Saudi healthcare facilities. The results indicate a satisfactory level of compliance for the requirements of the device physical condition, where sample of the device at each site where evaluated against the potential cracks, and the inappropriate electrical connectivity and compatibility. Moreover, the practice of the routine cleaning of the device was considered during the evaluation, to ensure that no blood or liquids are located on the body of the device. The results also show accepted levels of compliance for the availability of the PPM tag, beside the user and service manuals. These elements are essential for ensuring suitable operations, and also contribute toward sustaining the device life-span.

However, the trainings for both user and biomedical engineers were the least complying requirements with levels of 59.2% and 52.42%, respectively. As per the SFDA requirements for the safe-use of medical devices, users and engineers must be trained by the device manufacturer about the proper use and service of the medical device. These requirements are crucial to ensure the utilization of the device as indicated by the manufacturer, to avoid potential incidents that may arise from the misuse of the medical device.

Evaluation Item	Description	Compliance level
PPM tag	Check the MMS for the PPM schedule and performance.	85.71%
Devices physical condition	Check the physical condition for a sample of devices: is there any cracks, exposed wires, blood or other liquids, …etc.	100.00%
User training	Is there evidence of user training (certificates, log sheets, ..etc)	59.20%
Biomedical engineer training	The person who maintain the device are certified to maintain the device (if it is not under contract)	52.42%
User Manual	Is the user manuals available and accessible?	97.14%
Service manual	Is there a service manual for each device?	82.86%

Table 1: Level of compliance to the safe-use requirements of infusion pumps at the Saudi healthcare facilities.

Part III: Conclusion

The study results indicate that more attention from the SFDA and the healthcare facilities should be considered for the training of users and the biomedical engineers, as they were the least complying items for the safe use of infusion pumps, and at level that requires to be enhanced. The biomedical engineer training is an important factor for the engineers/technicians to learn the proper way of servicing and maintaining the device according to the manufacturer instructions. For instance, further analysis also indicates that 100% of the hospitals that did not comply with the requirement of maintaining a proper PPM tag, were also in non-compliance with the requirement of the biomedical engineer training. This correlation reflects the necessity of the training in enabling a proper utilization of the device.

In conclusion, infusion pumps are used widely in healthcare facilities. As the case with any medical device, the misuse of this device may lead to incidents, and thus must be utilized in the best proper way, and as guided by the manufacturer recommendations. Such recommendations are difficult to be acquired without being trained, and thus, healthcare facilities must ensure equipping both users and engineers with the proper training that avoid the potential misuse.

SFDA RECOMMENDATIONS

Recommendations for Healthcare Providers

Saudi healthcare facilities are highly recommended to:

- Make sure that the safe-use requirements of infusion pumps are satisfied, as specified in the published guideline: “Requirements for Quality, Safety and Effectiveness of Medical Devices at Healthcare Facilities” [1].
- Request a biomedical engineering training when buying a new infusion pumps, or before the warranty is expired.
- For the obsolete infusion pumps, communicate with the current authorized representative of the device manufacturer to request a service training.
- Assure that the device users are provided with a proper training before using the device.

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

REFERENCES

[1] Requirements for Quality, Safety and Effectiveness of Medical Devices at Healthcare Facilities, Saudi Food and Drug Authority, 2019.