

Medical Devices Readiness in Private Outpatient Care Facilities in Riyadh Within the Saudi Healthcare System

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ABSTRACT

A significant transformation is observed in the Saudi healthcare system in response to the Saudi 2030 vision. Outpatient Care Facilities (OCF) are expected to carry more duties in providing healthcare services. The current study aims to analyze the readiness of medical devices in private outpatient care facilities (OCFs) in Riyadh. An on-site questionnaire-based study was conducted to assess medical equipment maintenance and its readiness in private OCFs in different regions of Riyadh, Saudi Arabia. A questionnaire was formulated following local and international guidelines and standards. The response rate to the study was 100%. Types of OCF were classified into general and specialized polyclinics, medical clinics, laboratories, and physiotherapy centers. The results of the questionnaire reveal that only 29.2% OCF have a medical device maintenance department, a periodic preventive maintenance protocol was present in 54.2% OCF, and only 12.5% OCF inspect their medical devices regularly. A lack of essential medical equipment maintenance practices was observed in the private OCF in Riyadh. Private OCF should comply with best practices in medical equipment rather than ignore Original Equipment Manufacturer (OEM) instructions, and local and international medical

device maintenance guidelines. Private OCFs in Riyadh should restructure their medical equipment practices.

Keywords: Saudi Arabia; Medical devices; Maintenance readiness; Outpatient care; Delivery of healthcare; CBAHI.

INTRODUCTION

Medical devices are considered one of the essential pillars in the healthcare sector irrespective of the size of the healthcare facility (small or large). Therefore, the readiness of medical devices in healthcare facilities is an essential requirement that cannot be overlooked. Similarly, the role of OCF in providing basic rudimentary healthcare services to the community is unquestionable worldwide, as it serves as the initial point of consultation or treatment for all patients. Outpatient care facilities tend to function and meet the health needs of the local community. The local community receives most of their pre-surgical and healthcare services at OCF [1]. The OCF operates and functions to promote, restore, and preserve health among local people [2]. Private OCF bridges local patients with full-scale hospitals if required [3]. The readiness and condition of the medical equipment in the OCF are the keys to providing patients with a safe and prompt diagnosis and treatment. Earlier studies showed that in order for healthcare facilities to provide adequate healthcare services, they should have well-maintained technology in terms of quality and quantity [1]. With the advancement in technology, progression is unavoidable among healthcare systems, and the rapid increase in the population requires OCF to be innovative and stay up-to-date with their equipment maintenance.

Healthcare facilities follow and comply with the World Health Organization (WHO) [4] and International Medical Device Regulators Forum (IMDRF) [5] guidelines and instructions to protect patients' and caregivers' safety [6-8]. In developed countries such as the United Kingdom, all medical facilities must comply with the Original Equipment Manufacturer (OEM) instructions for the calibration or adjustment of the medical device [9], the same practice is also followed in Australia [10] and the United States of America [11] for using medical equipment in healthcare facilities. The role of OCF in Saudi Arabia is undeniable in taking care of people's health in urban and rural regions. There are 2483 private OCFs in the Kingdom, and 818 OCFs are located in the city of Riyadh [12]. Thus, to strengthen the importance of medical equipment and its role in providing better healthcare services, all public and private healthcare facilities are required to follow the Central Board for Accreditation of Healthcare Institution's (CBAHI) guidelines. It is an official association that grants, regulates and monitors accreditations for all medical facilities (primary, secondary, tertiary and quaternary care centers) in Saudi Arabia. According to the law of private health institutions issued under Royal Decree No. M/40, OCF includes, but is not limited to, a general polyclinic center, a specialized polyclinic center, a medical clinic, a medical laboratory and physiotherapy center [13].

An earlier study has shown that there are frequent shortcomings and limitations in the maintenance of medical equipment [14, 15]. Inadequate condition of medical devices in OCF is due to the absence of proper health technology management and more focus to increase profit from the healthcare facilities across the world [16-18] same possibly be the case in Saudi Arabia. The lack of in-house skilled personnel for medical equipment maintenance and outsourcing medical equipment maintenance also causes poor medical equipment maintenance at healthcare facilities [19, 20]. Safe patient treatment or diagnosis requires the

use of well-maintained medical equipment at OCF. It is worth mentioning that private healthcare facilities charge an ample amount of money from patients for healthcare services [21, 22]. Thus, private OCF should have not only well-maintained medical devices to comply with healthcare laws but also as a moral obligation. First, appropriate in-house skilled personnel should be available at each OCF to monitor medical devices rather than outsourcing equipment maintenance. Second, medical equipment requires proper maintenance plans known as preventive periodic maintenance (PPM) according to OEM guidelines. Following OEM guidelines to improve patient safety and reliability of the medical services [23]. Lastly, the frequency of quality accreditation programs to verify and observe medical equipment maintenance at OCF in Saudi Arabia should increase.

Poorly maintained medical devices can cause harmful accidents that can cause severe injuries and death [24]. Therefore, the maintenance of medical equipment cannot be compromised or ignored. In the present study, we have focused on evaluating the readiness of medical devices at the private OCF in Riyadh. A questionnaire was designed following CBAHI guidelines and standards. The study mainly focused on the management aspects of medical equipment such as maintenance, protocols, adequate manpower, maintenance cost, and backup/alternate medical device, doing so will help to analyze the current state of medical devices at the OCF in Riyadh.

MATERIALS AND METHODS

Questionnaire Design

Keeping in mind the international ISO Standards of Medical Devices [25, 26] and local standards criteria [27], a questionnaire consisting of 18 questions is formulated to measure the maintenance of medical equipment and its readiness as detailed in Table 1. The questionnaire consists of multiple-choice and open-ended questions. However, to evaluate the ability of the questionnaire to cover the main aspects and standards of medical equipment readiness, three facilities were inspected as a pilot study to overcome and understand the limitations of the questionnaire. As a result of the responses to the pilot study, two questions were added (questions 8 and 18, Table 1) based on the on-site field observations and after feedback from the experts in the same field. The results of the three pilot centers are excluded from the study results.

Table 1. Questionnaire used in the survey study

No.	Questions
1.	Type of outpatient care facility.
2.	The number of employees present in the facility.
3.	Is there a medical device maintenance department?
4.	Does all equipment have a "PPM tag" or PPM sticker?
5.	Lab Refrigerators and Freezers display temperature chart logs?
6.	Does the facility have an emergency room?
7.	Is there ECG and bedside patient monitor present in the emergency room?
8.	Does the facility have an ambulance?
9.	Does the facility have a defibrillator?
10.	In the event of a device malfunction, is there a person responsible for reporting?
11.	What is the job nature of the person following and writing medical device malfunctions?
12.	Does the facility have an Asset Management System?
13.	Is there a medical device maintenance contract with external companies?
14.	If a device malfunctions, how long does it take to repair it?
15.	During the time of maintenance, what is the protocol followed?
16.	What is the average cost of maintenance of medical equipment?
17.	Does anyone conduct a self-testing of medical devices?
18.	Do the facility have a contract with a medical waste management company?

Data Collection

Twenty-four private healthcare facilities were only included in the present study in Riyadh. The selection criteria of the study sample were randomized and kept limited to n=24 for four constraints; firstly, the facility should be a private facility while public primary health care centers are not included in the present study, secondly, the facility should be one of the following 5 outpatient facilities such as general polyclinic center, specialized polyclinic center, medical clinic, medical laboratory, or physiotherapy center, thirdly, the study sample should cover the main regions of Riyadh city and lastly, the distribution and collection of the questionnaire was to be completed in 30 days due to mobility issues. Therefore, centers were selected from different areas of Riyadh. The geographical distribution of the 24 healthcare facilities was as follows; from the central part of Riyadh, 4-OCF were selected and 5-OCF were selected each from the eastern, northern, southern, and western part of Riyadh. The data collection time taken was 30 days. One of the authors was responsible for field visits to complete the survey by obtaining responses in healthcare facilities. Later, two authors further studied and analyzed the collected responses.

Statistical Analysis

Software SPSS (Statistical Packages for the Social Sciences) version 25 for Windows by IBM Corporation, Armonk, NY, USA was used for statistical analysis. Chi-square and student's *t*-test were used for finding the level of significance. Values were considered to have statistical significant associations between the responses, when P-values found to be $P < 0.05$.

RESULTS

A total of 24 private OCF were surveyed in different regions of the Riyadh city, Saudi Arabia. The questionnaire consists of 18 questions, 14 questions with two options answer, whereas 1 question with five options, and 3 questions with four options answer. One interview was from

each OCF, thus a total of 24 questionnaires were evaluated. The types of the 24 OCF included in the study are illustrated in Figure 1; 5 general polyclinics centers, 9 specialized polyclinics centers, 2 medical clinics, 4 medical laboratories, and 3 centers of physiotherapy.

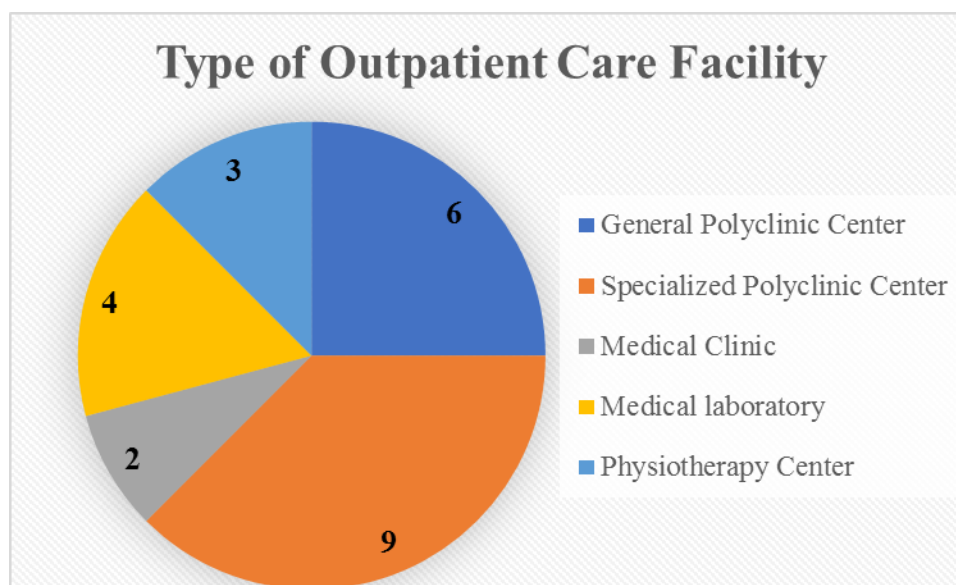


Figure 1 Showing different types of outpatient care facilities.

The results in Table 2 show that only seven (29.2%) OCF have a medical device maintenance department. Additionally, the PPM tags on medical machines were only present in 13 (54.2%) OCF. Similarly, only 13 (54.2 %) OCF maintained temperature chart logs for the laboratory refrigerator and freezers. Four of the polyclinic centers have an emergency room, with all having ECG machines and bedside patient monitors. The ambulance service was present at six OCFs out of the fifteen polyclinic centers. Only (37.5%) of the nine OCF have defibrillators.

Table 2. Responses to questions with two answer options

Question	Options, Responses (n) [%]		P-value *
Is there a medical device maintenance department?	Yes n=7 [29.2%]	No n=17 [70.8%]	.041
Does all equipment have a "PPM tag" or PPM sticker?	Yes n=13 [54.2%]	No n=11 [45.8%]	.683
Lab Refrigerators and Freezers display temperature chart logs?	Yes n=13 [54.2%]	No n=11 [45.8%]	.683
Does the facility have an emergency room?	Yes n=4 [16.7%]	No n=20 [83.3%]	.001
Is there ECG and bedside patient monitor present in the emergency room?	Yes n=4 [16.7%]	No n=20 [83.3%]	.001
Does the facility have an ambulance?	Yes n=6 [25.0%]	No n=18 [75%]	.014
Does the facility have a Defibrillator?	Yes n=9 [37.5%]	No n=15 [62.5%]	.221
In the event of a device malfunction, is there a person responsible for reporting?	Yes n=13 [54.2%]	No n=11 [45.8%]	.683
Do the facility have an Asset Management System?	Yes n=4 [16.7%]	No n=20 [83.3%]	.001
Is there a medical device maintenance contract with external companies?	Yes n=24 [100%]	No n=0 [0%]	.000
During the time of maintenance, what is the protocol followed?	Alternate device present n=7 [29.2%]	Device stops working n=17 [70.8%]	.041
What is the average cost of maintenance of medical equipment?	< SAR 3000/- n=20 [83.3%]	> SAR 3000/- n=4 [16.7%]	.001
Does anyone conduct a self-testing of medical devices?	Yes n=3 [12.5%]	No n=21 [87.5%]	.000
Do the facility have a contract with a medical waste management company?	Yes n=24 [100%]	No n=0 [0%]	.000
* For all P-value < 0.05 indicates presence of significance level.			

The presence of an individual responsible for reporting medical device malfunction was only in 13 OCF (54.2%). The asset management system was present in only 4 OCF (16.7%), the rest were maintaining manual records. However, all 24 private OCF included in the study have maintenance contracts with companies for corrective maintenance only. Seven OCFs (29.2%) have alternative medical equipment when any medical equipment needs maintenance, other OCFs stop their services until that particular machine maintenance is performed or fixed. The average corrective maintenance cost at 20 OCFs is less than 3 thousand riyals, and only 4 OCFs spend more than 3 thousand riyals quarterly. The results reveal that only 12.5% OCF inspect their medical device regularly by performing self-tests. Finally, the 24 OCFs were in contract with medical waste management companies.

Table 3 illustrates that the number of employees is less than 50 in 18 of the OCF, 3 OCF have 50-100 employees, 1 OCF only has 100-200 employees, and 2 OCF have larger than 200 employees. At 3 OCF, the nurse fulfilled the protocol to follow up on faulty devices, medical technicians were doing the same task at 7 OCF, at 3 OCF an administration staff is responsible

for the reporting task, while in the rest, no dedicated person was responsible. The repair time was less than 3 days at 19 OCFs, 3-7 days at 3 OCFs, and 8-14 days at 2 OCFs.

Table 3. Responses to questions with four answer options

Question	Options, Responses (n)				P-value *
The number of employees present in the facility.	< 50 n=18	50-100 n=3	100-200 n=1	>200 n=2	.000
What is the job nature of the person following and writing medical device malfunctions?	Nurse n=3	Medical device technician n=7	Administration staff n=3	No one n=11	.417
If a device malfunctions, how long does it take to repair it?	< 3 days n=19	3-7 days n=3	8-14 days n=2	> 14 days n=0	.000

DISCUSSION

The present study evaluated the status of the readiness for medical devices in private OCF in the city of Riyadh. Therefore, a survey was conducted to gauge and visualize the level of compliance with medical equipment standards and maintenance for patient safety. The lack of essential medical equipment maintenance practices was present in most private OCF. Various indicators were recorded in the study sample such as untrained technical personnel, lack of maintenance protocols, disregard of OEM guidelines, and a limited budget for the maintenance of medical equipment.

Currently, no accessible study is available to understand the readiness for the maintenance of private OCF medical equipment in Riyadh. Proper diagnosis and treatment of patients in the healthcare industry depend vitally on well-maintained medical equipment. It is in the best interest of both the caregiver and the patient's safety. A rapid increase in the population of Saudi Arabia demands more new medical technologies to diagnose and treat patients. In healthcare facilities, medical equipment requires adequate maintenance and firm protocols such as a rigid plan for PPM procedures to reduce the safety risks and achieve reliable healthcare service outcomes.

Earlier studies recommend the internal maintenance department of medical devices in primary healthcare centers [20, 28, 29]. Our findings show that the majority of OCFs does not have an in-house medical device maintenance department, only 29.2%. Similarly, PPM tags on medical equipment and temperature chart logs on laboratory refrigerators and freezers are also missing in a significant number of facilities (45.8%). It is concerning that such devices might miss regular PPM and probably be out of calibration, which can lead to severe incidents, incorrect diagnoses, or treatment.

Furthermore, emergency room, ambulance, defibrillator, and asset management system for medical devices was also not available in the majority of OCFs included in the study. All OCFs have contracts with medical device maintenance companies that may not follow the OEM instructions properly. When it comes to device malfunction reporting and following procedures

at some centers nurses, medical device technician, administration staff was responsible but few OCF do not even have a designated individual responsible to carry out the same task.

Several shortcomings are present in the maintenance of private OCFs medical equipment that put patient safety at risk and can lead to injury and prolong the patient suffering [30]. All private OCFs included in the study should reorganize their medical device management strategies by establishing a proper medical maintenance department on the premises with trained personnel so that patient safety is not compromised and patient satisfaction is also increased [31]. Furthermore, it will also help to meet local and international standards for medical devices. It is worth mentioning that a lack of skilled personnel leads to unsatisfactory maintenance of medical equipment maintenance [32, 33]. However, meeting the requirements of local accreditation bodies will increase the quality and standard of healthcare services. With an increased number of private OCF across Riyadh our findings would be further strengthened. Yet the outcome of our data might differ from other survey-based studies as a change in questionnaire and primary focus area could be the reason.

CONCLUSION

This study concluded that private OCFs in Riyadh should restructure their medical equipment practices rather than ignore OEM, local, and international medical device maintenance guidelines. Well-maintained medical devices are the fundamental component in the healthcare industry for the diagnosis and treatment of patients. Therefore, negligent maintenance of medical equipment would jeopardize both patient and caregiver safety. Consequently, it would be in the best interest of the people of Riyadh that the private OCFs look at its drawbacks in the maintenance of medical equipment and address them by designing a new framework for the management of medical devices and comply with the CBAHI guidelines. An internal medical device maintenance department should be formed in all outpatient healthcare centers.

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