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Article

# Technical Obstacles Facing Specialised Centres in the Use of Medical Devices

**Mohammad Abdullah Mirwais**[1]
1. Iraqi Ministry of Health, Kirkuk Health Department

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**Abstract:** This study records the medical equipment shortages in terms of availability, operating condition and maintenance related barriers of the medical equipment at the medical amenities that were studied. Thus, to enhance the quality of healthcare services, multi-sector partnerships and offers tailored to health facilities are imperative to address challenges of low medical equipment availability and functionality.

**Keywords:** Full range of medical equipment, supplies, technology, and services at the most modern specialized hospitals

## Introduction

Technology has changed a lot of things in the health sector, from how patients are assessed and diagnosed to how they are treated. However, technology has not been able to change the procedures in equipment maintenance in healthcare facilities. Poorly maintained equipment causes patients to be treated poorly due to long delays associated with malfunctioning equipment. It also increases the financial strain on the already limited funds in public health institutions. As we all know, medical equipment often consists of many small components which interact with each other, making a complex system. When a system of such nature fails, repairing the system without replacing the whole unit is much more cost effective than replacing the entire system. Most of the time periodic inspections are done on such systems. Of all the techniques of maintenance, preventive maintenance, is probably most frequently adopted when dealing with systems that can be repaired. [1]. This is typically done by periodic preventive maintenance (PM) inspections and servicing.

PM (preventative maintenance) helps clinical engineering protect both the safety and the performance of implantable medical systems. Preventative measures can be designed and installed to fix potential safety and performance hazards that are discovered during planned periodic examinations. No failure may occur in the system if PM is performed. Failures that will occur in the future may be avoided or reduced. [2].

Clinical engineering professionals at all levels discuss the economic implications of preventative maintenance (PM) interval length. The accrediting agencies and regulatory bodies in

many countries require PM intervals to follow the manufacturer's recommendations to avoid excessive and unnecessary PM. [3].

It doesn't seem like manufactures will be willing to help resolve these intervals in debates because they may not tell their customers about any documented data. This means we would not be able to make informed decisions when analyzing the results of maintenance and the replacement of parts done under a PM [4].

Other industries have demonstrated that traditionally used PM is usually unnecesary, and this has not escaped the notice of the clinical and biomedical engineering sector. Unfortunately, they still tend to focus on process measures as opposed to asset outcome analysis [5].

To ensure the safe and reliable use of essential devices, most hospitals and other healthcare facilities will have a Medical Equipment Management Program (MEMP). Typically, the MEMP includes a number of activities including PM, inspection and testing. These activities should be assessed repeatedly to address the needs and align with the rapid advancements of technology of modern healthcare services [6].

During the last two decades, many researchers have been focusing on predicting the reliability of medical systems during the design and development phases, whereas comparatively less literature is concerned with the prediction of the reliability of medical devices during their actual use [7].

This article provides a short description of medical-device maintenance management. It also covers approaches such as Reliability-Centered Maintenance (RCM), which have been used in other industries for many years [8]. RCM identifies an asset's maintenance needs with a high degree of sophistication. RCM is not an easy methodology. The first step in implementing RCM is the asset criticality evaluation and is very important when equipment fails in an unpredictable manner and can have important consequences on other assets [9] and [10].

Criticality is a measure of importance given to equipment in an organisation, but it is also a measure of work-focus given to an asset. A significant part of the criticality of assets is related to the impact of failure or failure of the asset, which is called the impact of failure. This effect can be evaluated through many factors including the timing of the breakdown, the level of impact, how easy it is to identify or how observable it is, how often it occurs, and the cost impact. [11].

**Background**

Public healthcare systems rely heavily on medical equipment for almost every aspect of disease prevention and control, patient diagnosis and treatment, and rehabilitation. Patients' rehabilitation and the quality of healthcare delivery is impacted by reliance on medical equipment that is substandard or out of order. Moreover, the difficulties associated with the use of medical equipment are exacerbated in low-resource areas. As such, this study aimed to assess the availability and functioning of medical equipment, together with related challenges, in public comprehensive specialized hospitals in Ethiopia's Amhara Regional State.

**Methods**

- The study used a cross-sectional mixed-methods design incorporating quantitative and qualitative components.
- Eight (n = 8) comprehensive specialized hospitals in the Amhara region were purposively selected.
- Availability and operating-status data were gathered for 78 medical-equipment items identified by the Ethiopian Ministry of Health as expected in these hospitals.
- Data were collected from 29 May to 18 June 2023 through structured self-administered questionnaires, observational checklists, and key-informant interviews.
- Quantitative findings were summarized using descriptive statistics, while qualitative findings were examined using a thematic analysis method.

**Results**

On average, each hospital had the potential to have 55.93% of the required medical equipment, whereas the surveyed hospitals only had 25.6% of available medical equipment. The medical equipment's overall functional status was 74.68%. This study reported that 75% of the biomedical engineers employed at a surveyed facility did not receive adequate workplace training. Out of the eight surveyed facilities, one was the only one to have spare accessory parts and medical equipment, and the other 87.5% had insufficient storage capacity for medical equipment and no formal equipment-management policies. The study revealed that the most common problems with the use of the Medical Equipment Management framework were inadequate spare parts and accessories, poor maintenance shops and insufficient user training.

The World Health Organization (WHO) defines health as a basic right of every individual. Responsive health systems ensure that certain communities have access to safe, effective and high quality medical equipment. It is imperative to utilize appropriate innovations that address the challenges of global health through science and medical equipment and technology. Medical equipment continues to be the backbone of health services and is utilized in the prevention, clinical diagnosis, treatment and patient rehabilitation (11, 12). Standardization, maintenance, equipment upgrades, operator training, and equipment removal are all aspects of the use of medical equipment. But access to functional medical equipment (13, 14) remains a challenge in many low and middle-income countries.

Approximately 50% to 80% of medical equipment in developing areas of Europe, Asia, and Central America does not work and is either damaged or scarce. As such, these hardware facilities of healthcare systems obstruct healthcare service delivery to patients. This challenge is more pronounced in hospitals (HLs) that are located in low-resource settings(12-15)

When the study of healthcare in South Africa's hospitals started, the main issues were identified as lack of functioning medical equipment and inadequate maintenance facilities(16).

Healthcare services are completely reliant on medical equipment. Therefore, health care centers and hospitals are required to appropriately arrange all medical equipment to meet the needs of healthcare staff, who rely heavily on scientific medical equipment for evaluating and diagnosing patients during the medical assessment and diagnosis (11, 17). A survey in the United Republic of Tanzania found that government officials at all levels were concerned with augmenting human and financial resources. Workshops for calibration, training, maintenance, and repair of medical devices were set up at national, regional and district levels (18) to support medical-device management and to ensure the functionality of medical devices.

Having an electronic medical-device management system enables health facilities and the Ministry of Health to monitor device status and identify repair and spare-part needs. The major causes of poor functioning and underutilization of medical equipment in developing countries are: non-scheduled preventive maintenance, inadequate capacity for maintenance, inadequate knowledge of proper use of the equipment, lack of accessories and spare parts, and lack of repair budgets. (19). The Ethiopian Hospital Service Transformation Guidelines (EHSTG) has enhanced Ethiopia's capacity to manage medical devices. Chapter 15 of the Hospital Services Transformation Guidelines (HSTG) outlines the processes that need to be followed for the proper management of medical equipment. Managing medical equipment also helps hospitals improve their services and still uphold the safety of the patients served. Challengingly, the provision of quality healthcare services using modern medical equipment in health facilities in Ethiopia has not greatly improved due to the poor management of medical equipment. (19).

According to the Medical Equipment Information Service data, under the Amhara Regional Health Bureau (ARHB), there are 8,260 equipments in total, of which 837 (10.1%) are not working and many others are not even installed. In addition, supervisory visits to hospitals in eight zones revealed that 368 out of 1,200 items of equipment inspected were not working and 64 items were not installed. Furthermore, data from public hospitals in Bahirdar and supervisory visits to health centers revealed the same problems and identified numerous additional problems in the area. (17, 18).

Efficient health care services must be provided by having medical equipment promptly available and maintained in all public health facilities. A greater challenge is posed by the absence and malfunction of medical equipment. This may even cause danger to the lives of patients. Therefore, the availability and operational status of equipment, as well as the root causes and medical equipment use practices that are causing the issue, particularly at the CSHs, should be assessed. Understanding the situation of the facilities is necessary in order to make future recommendations for policymakers and researcher budgeting solutions to deal with current problems and develop adequate solutions. A few studies in Ethiopia indicated that there were problems with access, availability, and functioning of medical equipment in public primary hospitals. Other studies also found that medical equipment and the services they support were both limited and a source of dissatisfaction to patients (18-11) There is still a lot to learn on the level of medical-equipment use and the factors limiting access to and efficient operation of equipment in health facilities. The current study area, the capital of the Amhara Regional State, Ethiopia, has very limited research and even less research in the Community Based Health Care Centers (CSHCs) in this region. Thus, the overall objective of this research was to assess the availability and functionality of medical equipment, describe the gaps in the use of medical equipment, and to explore the constraints of medical-equipment use in eight (n=8) CSHCs in Amhara region, Ethiopia.

The literature refers to the following sites: Gondar University CSH (GUCSH), Tibebe Ghion CSH (TGCSH), Debre Markos CSH (DMCSH), Felegehiwot CSH (FCSH), Debre Birhan CSH (DBCSH), Dessie CSH (DCSH), Wolideya CSH (WCSH), and Debre Tabor CSH (DTCSH). Each item of the unpublished list of medical equipment provided by the Ministry of Health (MOH) and ARHB was examined for medical equipment. Heads of biomedical engineering and pharmacy departments of the participating hospitals and biomedical engineers from ARHB were interviewed for the key-informant component.

**Methods and materials**

Study area and period

The ARHB is responsible for strengthening preventive and curative health services throughout the region.

- The regional system includes 98 hospitals: 8 CSHs, 15 general hospitals, and 75 primary hospitals.
- It also includes 917 health centers, 3,725 health posts, 5 health science colleges, 5 public health institutions (4 branches), 10 blood banks, and 2 oxygen plants.
- All eight comprehensive specialized public hospitals in Amhara National Regional State were included: Felege Hiwot, Tibebe Ghion, Gondar University, Debre Markos, Debre Birhan, Dessie, Debre Tabor, and Woldiya.
- The study period ran from 29 May to 18 June 2023.

**Study design**

All public comprehensive specialized hospitals in the Amhara region were selected and a cross sectional design was employed. Self-administered questionnaires and an observational checklist were used to collect quantitative data on medical-equipment availability and use in selected facilities, while interview guides were used to collect qualitative data on the challenges.

**Study population**

The data were collected based on the capital medical equipment available in all eight CSHs in Amhara region of Ethiopia. The qualitative part was interviews with biomedical engineers, heads of pharmacy, heads of biomedical engineering at ARHB and a representative of Ethiopian Pharmaceutical Supply Services (EPSS).

**Data collection tools and procedures**

Prior to collecting the study data, ethical approval was obtained from the Research Ethics Review Committee of the University of Gondar, College of Medicine and Health Sciences, School of Pharmacy (Ref No: S/A/P/41/2015).

- ARHB then sent a formal letter to each of the eight CSHs.
- Informed-consent forms were provided to participants before participation.
- After consent, quantitative data were collected using questionnaires and observational checklists, while interviews supplied qualitative data.

  Participant confidentiality and anonymity were ensured. A structured questionnaire, an observational checklist and a key-informant interview guide adapted from relevant literature to the local context were used to determine the availability and functional condition of the equipment (4, 8-10, 12, 13).

Two biomedical technicians were able to collect data one day after learning about study goals and methods of data collection. The heads of biomedical engineering departments in all hospitals were contacted and quantitative information was collected. Sociodemographic data of the study's participants and facilities along with data on the medical equipment's availability and functional state were collected using a self-administered survey, an observational checklist, and an interview guide with probing questions. Qualitative data was collected using the KI interview guide (Supplementary Table S1) by the principal researcher. KI (key informant) interviews were chosen since they involved direct engagement with medical equipment and their team management. This method was employed to interview the 16 KIs (heads of hospital biomedical, pharmacy and biomedical engineering) at the respective study facilities. The interviews were recorded to maximize recollection of what was said. Field notes were made during the interview as well.

In this study, the protocols of data collection on the devices used in the medical management system and the instruments used for data collection are outlined. Both the data collectors and the investigators were under close supervision. The data collectors and supervisor checked the completeness of the information each day during and after data collection.

**the maintenance and follow-up practices of the medical equipment**

The vast majority of KIs reported that their facility did not meet the manufacturer's recommended preventive maintenance for hospital equipment. In most MHLW hospitals, informants #4, #7, #9 and #16 each reported that "There were no written documents to manage the hospital medical equipment" (Informants #4, #7, #9, and #16). A further concern was the lack of buy-in for the Medical Equipment Management Information System (MEMIS). Most KIs noted, "In the MEMIS, there are 15 key performance indicators, and among them only the hospitals use the MEMIS for inventory purposes. However, if the MEMIS performed as intended, most challenges would be solved. This is because the MEMIS software was interoperable with medical equipment suppliers, medical equipment manufacturers, EPSS, MOH, and all administrative units of the MOH, including HFs. There were no regular follow-ups from the management, and there was no monitoring and evaluation system in place, and hospitals and RHB were not enforced to implement MEMIS for medical equipment management and were not evaluated as per the Key Performance Indicators (KPIs)" (Informants #7, #9, and #16).

The KIs wished for system updates by stating that "It is better for donors to offer a small number of new, modern medical equipment. Donation practices must have a system for monitoring and evaluation. Therefore, decision makers must know about the status of medical equipment and the different models and types of available medical equipment that can contribute to the maintenance and repair of medical equipment" (Informants #4, #9, #12, and #16).

The lack of medical-equipment maintenance workshops with essential mechanical, testing, administrative, electrical, biomedical, and software units, together with inadequate biomedical-engineering personnel was cited as a critical challenge. One KI noted that most hospitals lacked the basic facilities.

offer regular workshops. "As far as I know, there is no national medical equipment maintenance workshop to serve as a training center" (Informant #16). The informant noted that in most divisions, there may be a preventive-maintenance schedule but it is not always followed, and in the

emergency, ICU, and OR divisions, corrective maintenance is typically limited to selected equipment. Biomedical engineers are not always trained on the equipment they use, work orders are not always completed by users, and problems are not always reported in a timely fashion. So how to do corrective maintenance efficiently? (Informant #16)

The majority of the KIs indicated that as a result of the Ministry of Health and the hospital management failing to perform preventive maintenance, expensive, essential medical instruments became non-operational due to failure of less critical accessory sub-components. (Informants #9, #12, and #15).

Most of the KIs highlighted the following issues: closed systems equipment, power failures, inadequate training of users and operators, biomedical equipment and inadequate support from the management unit. The KIs indicated, "when closed-system hospitals, there were medical equipment management protocols, and Chapter 15 of the EHSTG described and elaborated on the management of medical equipment in hospitals. However, the information obtained from KIs showed that the protocols are nonexistent." Most KIs also stated that "there is no medical equipment decommission guideline in the hospitals or even in

The placement agreement was only available to the manufacturer or agent, and failure of medical equipment was costly. The electricity was interrupted and it was difficult to ensure regular services with the equipment available. (Informants #2, # 4, #6, and #10)

The majority of the KIs noted that higher education institutions' curricula for biomedical engineering fall behind the innovation of cutting-edge medical technology. This is another challenge to address. KIs noted, "There is no provision of regular and specific training for the medical equipment used in hospitals neither to biomedical engineers nor to the hospital staff" and "Failure of most of the medical equipment is due to the non-trained users of the medical equipment in different departments" (Informants #2, #4, #6, and #10). Other KIs noted, "Even if some fragmentary trainings are provided, it was not based on hospital's medical equipment, and unnecessary trainings did not cover the medical equipment technology" (Informants #9 and #12).

Concerning maintenance and follow-up practices at the surveyed facilities, some KIs explained that the absence of preventive maintenance for certain equipment was not their main concern, stating that "even though corrective maintenance differs by equipment type, our hospital has scheduled preventive maintenance for emergency, ICU, and NICU medical equipment; otherwise, preventive maintenance is.

as required in other departments (Informant #10). "Planned preventive maintenance is mainly for equipment in the emergency department" (Informant # 6).

"If the defect is easy to maintain, the equipment is maintained by the hospital's biomedical engineering professionals after the work order is filled and reported by users" (Informant #11).

**Discussion**

The study was conducted on access to and utilization of medical equipment, and the major challenges of equipment utilization in comprehensive specialized hospitals in Amhara region, Ethiopia. Assessing medical-equipment use can help determine barriers to capital-equipment use and can provide information that can be used to improve health-service delivery at CSHs (4). A healthcare provider is only as good as the tools available to them. If care is provided without the use of proper diagnostics and/or therapeutics, the outcomes of care can be detrimental to the patient resulting in high levels of dissatisfaction and death (2, 10). This study revealed that there was a significant lack of a basic part of the healthcare infrastructure, as only 25.6% of the hospitals surveyed had at least one item of capital medical equipment, and the average medical equipment availability in the CSHs was 55.93%. In most hospitals surveyed, critical medical equipment including x-ray systems (CT, MRI, radiography and digital-fluoroscopy) and x-ray mammography were found to be inadequate. The results were similar to another study conducted in Ethiopia, which reported that health facilities had nonfunctional medical equipment (2). An important finding in our survey indicated variable supply and demand for medical equipment among hospitals surveyed. The lack of medical equipment in comprehensive specialized hospitals has serious consequences on health care delivery. The results of our survey are

supported with similar surveys done at Jimma University Specialized Hospitals (JUSH) and Nekemte General Hospital. There has consistently been a lack of supply of medical equipment across different institutions (4). In addition, a study in South Africa found that there were also limited supplies of medical equipment and poor maintenance of hospital equipment (2). Since equipment- or service-based failures at individual hospitals impeded specific hospital-based service deliveries, we were unable to confirm the planned service deliveries at any of the hospitals. The troubling lack of medical equipment in this study may correlate with the fact that a number of hospitals within this region are undergoing an extension from a general hospital service to a comprehensive specially focused hospital service line, and that maintenance knowledge is limited. We feel that the government is not doing enough to support the sector in funding. As a result, the extension of the service lines occurred, but no significant medical equipment and related service support was provided. Many biomedical engineers and heads of pharmacies, who were the key persons handling medical equipment, were not aware of the capital medical equipment list, according to our survey. Beyond the survey, quantitative results, and within the qualified results, it was expressed that: "regular and focused training about the medical equipment installed is neither provided to the users nor to biomedical engineers found in the hospitals." Moreover, most hospitals do not have workshops that are working and most do not have trained biomedical engineers. In addition, there is no national medical-equipment maintenance workshop that is used as a training workshop. Some training had been provided to biomedical personnel, but this was inadequate and was out of date with the equipment in the hospitals. (Informant #2, #4, #6, #9, #10, and #12). Equipment standards provide information needed to make equipment purchases to meet priority health needs. Standards help buyers avoid wasting money on inferior products (14). One study reported that about half of the public hospitals in Ethiopia did not have plans for medical-equipment development (15). However, this study found that the absence of standards was not the only constraint to the purchase of equipment; the absence of clear requirements or standards leads to the inability to purchase equipment. The study's qualitative results show "there is no any medical equipment decommission guideline in the hospitals and even in the ministry of health. There were no written documents to manage the hospital medical equipment." (Informant #4, #7, #9, #16).

The role of the operational performance and maintenance of medical equipment in the successful provision of public healthcare services is not to be underestimated (16)

**Conclusion and recommendation**

The study focused on the availability and functional status of medical equipment in eight CSHs of Amhara region, Ethiopia and on the barriers to the use of medical equipment in these CSHs. The study revealed that there were critical shortages of medical equipment in CSHs in the Amhara Region, Ethiopia, both in terms of availability and functionality. The major issues were lack of spare parts and accessories, lack of a well-equipped and standardized maintenance workshop, lack of training and budget constraints. As investment increases and future research expands to cover a broader spectrum of healthcare settings, these challenges will be more easily met. Therefore, the CSHs, ARHB, EPSS and MOH need to cooperate and make full use of all the opportunities to increase the availability of medical equipment, review the allocation of the budget, develop new regulations and policies, strengthen medical-equipment management, continue to build capacity and train biomedical technicians, and increase the quality of medical-equipment maintenance services at all medical-service delivery points.

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