Assessment of medical equipment maintenance management: proposed checklist using Iranian experience

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Abstract

Background: Effective maintenance management of medical equipment is one of the major issues for quality of care, for providing cost-effective health services and for saving scarce resources. This study aimed to develop a comprehensive checklist for assessing the medical equipment maintenance management (MEMM) in the Iranian hospitals.

Methods: This is a multi-methods study. First, data related to factors which affect the assessment of MEMM were collected through a systematic review in PubMed, ProQuest, Scopus, Embase, and web of science without any time limitation until October 2015, updated in June 2017. Then, we investigated these factors affecting using document review and interviews with experts in the Iranian hospitals. In the end, the results of the first and second stages were combined using content analysis and the final checklist was developed in a two-round Delphi.

Results: Using a combination of factors extracted from the systematic and qualitative studies, the primary checklist was developed in the form of assessment checklists in seven dimensions. The final checklist includes 7 dimensions and 19 sub-categories: "resources = 3," "quality control = 3," "information bank = 4," "education = 1," "service = 3," "inspection and preventive maintenance = 2" and "design and implementation = 3."

Conclusions: Developing an assessment checklist for MEMM provide a comprehensive framework for the proper implementation of accurate assessment of medical equipment maintenance. This checklist can be used to improve the profitability of health facilities and the reliability of medical equipment. In addition, it is implicated in the decision-making in support of selection, purchase, repair and maintenance of medical equipment, especially for capital equipment managers and medical engineers in hospitals and also for the assessment of this process.

Keywords: Hospital, Medical equipment, Medical devices, Maintenance management, Assessment
Background

Today's modern hospital is highly dependent on various types of medical equipment to assist in the diagnosis, monitoring and treatment of patients. It is impractical to provide health services without them [1, 2]. Medical equipment deals with patient care including ranging from small and simple devices to complex and big devices. This ranking can be found in different types of hospitals and primary care settings [3]. According to the studies conducted in Iran, about one-third of the costs of setting up and equipping the hospital is allocated for purchasing medical equipment [4]. Therefore, it should be maintained in good working condition and higher safety level to prevent from injuries occurred in patients as well as in users [5].

The maintenance of medical equipment is important for reducing dispatch costs, reducing patient dissatisfaction, timely patient treatment, and reducing mortality and risks during patients care [4]. It is an integral part of the life cycle of the device. Usually, much more money is spent on maintaining equipment over than on its procurement [6]. Maintenance is defined as any action which helps hospitals to provide an adequate level of service and to protect or promote the performance of their equipment to operate regularly and efficiently. Therefore, maintenance management is a fundamental aspect of hospital management [7].

Good maintenance management to have well planned and implemented programs that hospitals can minimize breakdowns or failures of the medical device. This is particularly critical in developing countries for providing good healthcare services and saving scarce resources and alternatives. The equipment maintenance management of the hospital not only makes them easily accessible when needed but also increases their reliability and reduces their failure rate [4, 8]. Despite the importance of maintenance, there was no clear system of maintenance. The guidelines are not properly performed in many countries including Iran. In addition, there is a lack of information about the assessment and evaluation of medical equipment decisions [9].

A survey indicated that nearly 60% of the total cost of a hospital involves medical equipment [8]. Wang et al. have demonstrated that the most common cause of medical equipment downtime is poor maintenance, planning, and management [3]. One study indicates that nearly 1% of the total hospital budget is spent on maintenance costs [10]. The literatures have indicated that a 500-bed hospital spends typically around $5 million/year [6]. A study of world health organization (WHO) has shown that nearly half of medical devices in developing countries are operated incorrectly or are not maintained properly due to inappropriate management policy. On the other hand, the potential to manage and maintain medical equipment in these countries remains rather weak [11].

Medical equipment plays a significant role in the hospital system; hence, the purchase, maintenance and replacement of medical equipment are key factors in hospitals to implement medical care service. Thus, to assure the quality of healthcare delivery medical devices, use-safety assessment of the maintenance management in hospitals is imperative [12]. To achieve these objectives, hospitals must develop assessment checklists which identify the performance status of medical equipment maintenance. It is essential for managers and engineers, not only to enhance hospital capability but also to predict the risks related to sudden failure. Given the lack of single and comprehensive checklists for maintenance management, the purpose of the current research is to design
and develop assessment checklists for medical equipment maintenance management (MEMM).

**Results**

Of 309 potentially relevant articles searched, 29 articles were included in this systematic review. Finally, 89 factors were identified that affect the medical equipment maintenance management. These factors categorized based on MOHME framework [13]. Five of the factors were found related to resources, 12 factors related to service, 4 factors related to education, 15 of these factors regarding to quality control, 19 factors related to inspection, 12 factors related to information bank and 22 factors was dedicated to management [14].

The results of qualitative study were categorized into seven main themes (resources, quality control, documentation, education, service, inspection and preventive maintenance (IPM), designing and implementation) [15].

Based on the findings of the first and second steps, a medical equipment maintenance management assessment checklist was developed as follows (Table 1).

The checklists have seven dimensions, each of which includes sub-categories, such as the provision of variety of financial, human and physical resources, which means physical resources to provide a safe and secure environment equipped with the necessary facilities. Human resources refer to the provision and allocation of experienced and skilled manpower based on need. Financial resources also include the allocation of sufficient and necessary funds and budgets, which should be based on the goal and be allocated to priority goals according to the operational plan of the medical engineer unit.

The dimension of quality control tests in the three sub-categories of safety test, performance test and calibration refer to all technical tests that require special equipment and are of special importance for the health of the patient and staff. The Inspection and Preventive Maintenance Item refers to the importance and priority of PM than repairing and assessing the user and performance of personnel. In this section, there are topics such as periodic inspections, development of maintenance standards, the existence of external supervisors, and the existence of written and comprehensive guidelines.

In the field of information bank, all activities related to the process of documentation and identification of medical equipment is listed. In the training section, both technical and user training for medical engineers and users are mentioned. The sub-categories of the service sector include after-sales service, repair and maintenance contracts, outsourcing of the decommissioning process, and so on. The last dimension is design and implementation, which refers to issues such as defining the level of user access, organizing joint committees, establishing inter-sectorial communication, policy development, purchasing medical equipment based on needs, and so on.

The scoring method is in three categories of zero, one and two. If the item meets the criteria, score 2, in case of partial compliance, one score and in case of mismatch, no points are awarded. For some items, one score is not included. That is, only two matching or mismatch modes are applicable and no intermediate states. Part of the checklist is about data collection that depending on the nature of the item, the collection method involves interview, observation and documentation review. Thus, the interview will
| Sub-categories                        | Standards                                                                 | Data collection method       | Data collection source              | Scores                      |
|--------------------------------------|---------------------------------------------------------------------------|------------------------------|-------------------------------------|-----------------------------|
| Resources                            |                                                                           |                              |                                     |                             |
| Physical resources                   | Providing appropriate physical space                                      | Observation                  | Head of Medical Engineering Unit    | Lack of space with           |
|                                      |                                                                           |                              |                                     | adequate access              |
|                                      | Providing a special place for repairing devices in hospitals               | Observation                  | Head of Medical Engineering Unit    | Enough space but inap-         |
|                                      |                                                                           |                              |                                     | propriate                   |
|                                      | Allocation of maintenance unit in medical engineering unit                | Observation                  | Head of Medical Engineering Unit    | Existence of a place with    |
|                                      |                                                                           |                              |                                     | adequate and sufficient      |
|                                      |                                                                           |                              |                                     | access                       |
|                                      | Providing a safe and healthy work environment                             | Observation                  | Head of Medical Engineering Unit    | There is no specific place    |
|                                      |                                                                           |                              |                                     |                             |
| requirement of computer and necessary| Providing localized medical equipment maintenance software                | Observation                  | Head of Medical Engineering Unit    | The maintenance unit         |
| facilities in medical engineering    |                                                                           |                              |                                     | is not assigned to the       |
| unit                                 |                                                                           |                              |                                     | medical engineering unit     |
|                                      | The establishment of a maintenance computer system                        | Observation–documentation    | Head of Medical Engineering Unit    | The maintenance unit is      |
|                                      |                                                                           |                              |                                     | assigned to the medical      |
|                                      | Provision of some technical checklists (test and repairs checklists)      | Observation                  | Head of Medical Engineering Unit    | The maintenance software     |
|                                      |                                                                           |                              |                                     | available in the world is    |
|                                      |                                                                           |                              |                                     | not used according to the    |
|                                      |                                                                           |                              |                                     | native conditions of the     |
|                                      |                                                                           |                              |                                     | country                      |
|                                      |                                                                           |                              |                                     |                             |
|                                      |                                                                           |                              |                                     | Equipped with telephone      |
|                                      |                                                                           |                              |                                     | line, fax and internet, with |
|                                      |                                                                           |                              |                                     | the necessary administra-    |
|                                      |                                                                           |                              |                                     | tive facilities              |
|                                      |                                                                           |                              |                                     |                             |
|                                      |                                                                           |                              |                                     | There are not enough         |
|                                      |                                                                           |                              |                                     | conditions to set up a        |
|                                      |                                                                           |                              |                                     | computer maintenance system  |
|                                      |                                                                           |                              |                                     | (CMMS)                       |
|                                      |                                                                           |                              |                                     |                             |
|                                      |                                                                           |                              |                                     | There are enough             |
|                                      |                                                                           |                              |                                     | conditions to set up a        |
|                                      |                                                                           |                              |                                     | computer maintenance system  |
|                                      |                                                                           |                              |                                     | (CMMS)                       |
|                                      |                                                                           |                              |                                     |                             |
|                                      |                                                                           |                              |                                     | Existence of complete        |
|                                      |                                                                           |                              |                                     | checklists required for      |
|                                      |                                                                           |                              |                                     | safety test and repairs      |
| Sub-categories                              | Standards                                                                 | Data collection method          | Data collection source                                                                 | Scores                                                                 |
|--------------------------------------------|---------------------------------------------------------------------------|--------------------------------|----------------------------------------------------------------------------------------|-----------------------------------------------------------------------|
| Existence of a specific system for recording failures | Observation–interview                                                    | Head of Medical Engineering Unit | There is no specific system for recording failures                                       | 0                                                                     |
| Access to up-to-date software in the field of maintenance | Interview                                                                | Head of Medical Engineering Unit | It is not possible to access up-to-date software in the maintenance area                 | 1                                                                     |
| Providing a stable and trained force for the medical engineering unit | Observation–interview                                                    | Head of Medical Engineering Unit—medical engineers and technicians | The available manpower has not been fixed and they have not received the necessary training | 2                                                                     |
| Allocation of medical engineering force based on need | Observation–interview                                                    | Head of Medical Engineering Unit | There are not enough skilled manpower (for every 100 hospital beds, at least one engineer and one technical technician) | 0                                                                     |
| Allocation funds to medical equipment maintenance | Interview—documentation review                                           | Head of Medical Engineering Unit | The required budget or credit is not estimated and provided each year in accordance with the Medical Equipment Maintenance Regulations | 1                                                                     |
| Assigning a revolving fund to the medical engineering unit | Interview—documentation review                                           | Head of Medical Engineering Unit | The revolving fund is not allocated for the medical engineering unit                       | 2                                                                     |
| Econometrics and cost–benefit calculation of equipment maintenance | Interview—documentation review                                           | Head of Medical Engineering Unit | Documents are not available                                                              | 0                                                                     |
|                                                  |                                                                          |                                | Documents are incomplete                                                                | 1                                                                     |
| Dimension                  | Standards                                      | Data collection method | Data collection source          | Scores                                |
|----------------------------|------------------------------------------------|------------------------|--------------------------------|---------------------------------------|
| Quality control tests      |                                                |                        |                                |                                       |
| Safety test                | Perform safety tests                           | Observation–interview  | Head of Medical Engineering Unit | None of the safety tests (electrical, physical–mechanical, radiation, chemical, user, etc.) are performed according to the regulations for the maintenance of medical equipment | Some safety tests (electrical, physical–mechanical, radiation, chemical, user, etc.) are performed according to the regulations for the maintenance of medical equipment | All safety tests (electrical, physical–mechanical, radiation, chemical, user, etc.) are performed according to the regulations for the maintenance of medical equipment |
| Calibration                | Ensuring quality controls performed by companies| Interview–documentation review | Head of Medical Engineering Unit | Quality controls performed by companies are not guaranteed (no specific obligations) | Quality controls performed by companies are guaranteed (have certain obligations) | Quality controls performed by companies are guaranteed (have certain obligations) |
|                            | Planning and conducting quality control tests  | Interview–documentation review | Head of Medical Engineering Unit | There are no specific program quality control tests | Quality control tests have a specific program | Quality control tests have a specific program |
|                            | Labeling of calibrated equipment               | Observation–documentation review | Head of Medical Engineering Unit | Calibrated equipment is not regularly labeled | Calibrated equipment is labeled but not regularly | Calibrated equipment is regularly labeled |
| Performance test           | Perform technical tests                         | Observation–documentation review | Head of Medical Engineering Unit | Technical tests are not performed by allowed agencies or service providers | Technical tests are not performed by allowed agencies or service providers | Technical tests are not performed by allowed agencies or service providers |
| Dimension                  | Standards                                | Data collection method                   | Data collection source            | Scores                                                                 |
|----------------------------|------------------------------------------|------------------------------------------|-----------------------------------|------------------------------------------------------------------------|
|                            |                                          |                                          |                                   | 0  | 1  | 2  |
| Perform practical tests    | Observation–documentation review         | Head of Medical Engineering Unit        | The relevant test is not performed by the trained user and is not according to the checklist provided by the manufacturer or legal representative and under the supervision of the Medical Engineering Unit | 0  | 1  | 2  |
| Perform laboratory tests   | Observation–documentation review         | Head of Medical Engineering Unit        | The relevant test is not performed by the trained user and is not according to the checklist provided by the manufacturer or legal representative and under the supervision of the Medical Engineering Unit | 0  | 1  | 2  |
| Perform clinical tests     | Observation–documentation review         | Head of Medical Engineering Unit        | The relevant test is not performed by the trained user and is not according to the checklist provided by the manufacturer or legal representative and under the supervision of the Medical Engineering Unit | 0  | 1  | 2  |
| Dimension | Standards | Data collection method | Data collection source | Scores |
|-----------|-----------|------------------------|------------------------|--------|
| **Inspection and preventive maintenance (IPM)** | Perform timely and regular preventive maintenance | Observation–documentation review | Head of Medical Engineering Unit | 0 |
| Management processes to extend the life of the device | Insufficient knowledge in the field of preventive maintenance | Interview | Head of Medical Engineering Unit—medical engineers and technicians | 1 |
| | Preventive maintenance priority over quality control and repair | Interview | Head of Medical Engineering Unit | 2 |
| Periodic, internal, case, practical inspection | Existence of some subrules | Interview | Head of Medical Engineering Unit | 0 |
| | Using accreditation measures to assess the maintenance of medical equipment | Interview | Head of Medical Engineering Unit | 1 |
| | | | | 2 |

0: A preventive maintenance program is not developed and implemented.
1: A preventive maintenance program is developed but it runs incompletely.
2: A preventive maintenance program is developed and implemented.

None of the employees of the Medical Engineering Unit have sufficient knowledge and awareness in the field of preventive maintenance.
Some employees of the Medical Engineering Unit have sufficient knowledge and information in the field of preventive maintenance.
All employees of the Medical Engineering Unit have sufficient knowledge and information in the field of preventive maintenance.

Preventive maintenance is not a priority in the medical engineering unit’s action plan.
Preventive maintenance is a priority in the medical engineering unit’s action plan.

The existing rules and regulations regarding maintenance are not necessary and appropriate.
The existing rules and regulations regarding maintenance are necessary but not appropriate.
The existing rules and regulations regarding maintenance are necessary and appropriate.

From accreditation measures are not used to assess maintenance activities and processes.
From accreditation measures are not used to assess maintenance activities and processes.
Table 1 (continued)

| Dimension                                      | Standards                                                                 | Data collection method                        | Data collection source                                                                 | Scores                                                                 |
|------------------------------------------------|---------------------------------------------------------------------------|-----------------------------------------------|----------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| Examination of medical equipment through human senses and specialized checklists | Interview                                                                 | Interview–documentation review                | Head of the University Medical Equipment Office or Experts introduced by him and the head of the medical engineering unit | Head of the University Medical Equipment Office or Experts introduced by him and the head of the medical engineering unit |
| Lack of investigate and supervision of all operations (review and monitoring of quality control tests of medical equipment, review of facilities and ancillary facilities related to equipment, review of the environment around medical equipment, assessment of device usage by user and assessment of the performance of technical personnel) (By checklist) | Lack of investigate and supervision of all operations (review and monitoring of quality control tests of medical equipment, review of facilities and ancillary facilities related to equipment, review of the environment around medical equipment, assessment of device usage by user and assessment of the performance of technical personnel) (By checklist) | Investigate and supervision of some operations (investigate and monitoring of quality control tests of medical equipment, investigate of facilities and ancillary facilities related to equipment, investigate of the environment around medical equipment, assessment of device usage by user and assessment of the performance of technical personnel) (By checklist) | Investigate and supervision of all operations (investigate and monitoring of quality control tests of medical equipment, investigate of facilities and ancillary facilities related to equipment, investigate of the environment around medical equipment, assessment of device usage by user and assessment of the performance of technical personnel) (By checklist) |
| Determining the time period of periodic visits | Interview–documentation review                                            | Head of Medical Engineering Unit              | Not according to the action plan                                                       | According to the action plan |
| Developing plan for periodic visits           | Documentation review                                                      | Head of Medical Engineering Unit              | An action plan has not been developed                                                   | An action plan has been developed |
| Existence of an external observer            | Interview                                                                 | Head of Medical Engineering Unit and Hospital Manager | The external supervisor has not been appointed to inspect and oversee the affairs of the medical engineering unit | The external supervisor has been appointed to inspect and oversee the affairs of the medical engineering unit |
| Developing standards in maintenance contracts | Documentation review                                                      | Head of Medical Engineering Unit              | The service, maintenance and repair contract have not a specific framework. (According to regulations) | The service, maintenance and repair contract have a specific framework. (According to regulations) |
| Dimension                                      | Standards                                                                 | Data collection method                | Data collection source                  | Scores                             |
|-----------------------------------------------|---------------------------------------------------------------------------|---------------------------------------|----------------------------------------|-----------------------------------|
| Preparing a list of essential equipment       | Documentation review                                                      | Head of Medical Engineering Unit      | The list of essential equipment has not been prepared and is not available to the departments | 0                                 |
|                                               |                                                                           |                                       | A list of essential equipment has been prepared but is not available to the departments | 1                                 |
|                                               |                                                                           |                                       | The list of essential equipment has been prepared and is available to the departments | 2                                 |
| Ensuring the existence of safe electricity (every six months, the hospital's electricity is controlled by an electrician and the available documents) | Observation                                                               | Head of Medical Engineering Unit      | The items mentioned in the regulations regarding electrical safety are not observed and performed | 0                                 |
|                                               |                                                                           |                                       | The items mentioned in the regulations related to electrical safety are incompletely observed and performed | 1                                 |
|                                               |                                                                           |                                       | The items mentioned in the regulations regarding electrical safety are completely observed and performed | 2                                 |
| Periodic review of the correct operation of the device by the user | Interview—documentation review                                             | Head of Medical Engineering Unit      | The correct operation of the device is not checked periodically by the user | 0                                 |
|                                               |                                                                           |                                       | The correct operation of the device is checked periodically by the user | 1                                 |
|                                               |                                                                           |                                       | The correct operation of the device is checked regularly by a medical engineer (existence of action plan) | 2                                 |
| Lack of uniformity of assessment checklists   | Documentation review                                                      | Head of Medical Engineering Unit      | The medical engineering unit does not have a specific checklist to assess the maintenance status of medical equipment | 0                                 |
|                                               |                                                                           |                                       | The medical engineering unit has a specific checklist to assess the maintenance status of medical equipment | 1                                 |
|                                               |                                                                           |                                       | Defective devices are checked regularly by a medical engineer (existence of action plan) | 2                                 |
| More visiting to defective devices            | Interview—documentation review                                             | Head of Medical Engineering Unit      | None of the medical engineering staff are aware of the regulations and instructions issued by the Department of Medical Equipment/not all employees know the rules clearly | 0                                 |
|                                               |                                                                           |                                       | Some of the medical engineering staff are aware of the regulations and instructions issued by the Department of Medical Equipment/some of employees know the rules clearly | 1                                 |
|                                               |                                                                           |                                       | All of the medical engineering staff are aware of the regulations and instructions issued by the Department of Medical Equipment/all employees know the rules clearly | 2                                 |
| Dimension                                                                 | Standards                                                                 | Data collection method                  | Data collection source | Scores                     |
|--------------------------------------------------------------------------|---------------------------------------------------------------------------|----------------------------------------|------------------------|---------------------------|
| Requirement to follow orders from high levels                           | Interview                                                                  | Head of Medical Engineering Unit       |                        | 0                         |
|                                                                          |                                                                          |                                        |                        | 1                         |
|                                                                          |                                                                          |                                        |                        | 2                         |
| Access to the booklet of the set of maintenance rules and regulations    | Interview–documentation review                                            | Head of Medical Engineering Unit       |                        | 0                         |
|                                                                          |                                                                          |                                        |                        | 1                         |
|                                                                          |                                                                          |                                        |                        | 2                         |
| Completion and observance of accreditation measures                      | Interview                                                                  | Head of Medical Engineering Unit       |                        | 0                         |
|                                                                          |                                                                          |                                        |                        | 1                         |
|                                                                          |                                                                          |                                        |                        | 2                         |
| Implementation of maintenance rules and regulations                      | Interview                                                                  | Head of Medical Engineering Unit       |                        | 0                         |
|                                                                          |                                                                          |                                        |                        | 1                         |
|                                                                          |                                                                          |                                        |                        | 2                         |
| Existence of written and comprehensive instructions                      | Documentation review                                                      | Head of Medical Engineering Unit       |                        | 0                         |
|                                                                          |                                                                          |                                        |                        | 1                         |
|                                                                          |                                                                          |                                        |                        | 2                         |
| Information bank                                                         |                                                                          |                                        |                        |                           |
| Providing medical devices ID (identification)                            | Electronic, comprehensive and intelligent electronic medical ID           | Observation–documentation review        | Head of Medical Engineering Unit | 0                         |
|                                                                          |                                                                          |                                        |                        | 1                         |
|                                                                          |                                                                          |                                        |                        | 2                         |
| Easy access to ID information                                            | Electronic, comprehensive and intelligent electronic medical ID           | Observation–documentation review        | Head of Medical Engineering Unit | 0                         |
|                                                                          |                                                                          |                                        |                        | 1                         |
|                                                                          |                                                                          |                                        |                        | 2                         |

Notes:
- Orders issued by the Department of Medical Equipment are not properly complied
- Orders issued by the Department of Medical Equipment are properly complied
- All of the staff members have access to the booklet
- None of the staff members have access to the booklet
- The unit meets some of the criteria on a regular basis
- The unit does not meet any of the criteria on a regular basis
- The rules announced by the Office of Medical Equipment do not run regularly
- The rules announced by the Office of Medical Equipment run regularly
- There are no comprehensive guidelines for maintaining medical equipment
- There are written guidelines for maintaining medical equipment, but they are not comprehensive
- There are comprehensive guidelines for maintaining medical equipment
Table 1 (continued)

| Dimension                                    | Standards                                                      | Data collection method                      | Data collection source                  | Scores                                                                 |
|----------------------------------------------|----------------------------------------------------------------|--------------------------------------------|-----------------------------------------|------------------------------------------------------------------------|
| Use of indigenous and global evidence        | Communicate with standard scientific references                | Interview–documentation review             | Head of Medical Engineering Unit        | 0                                                                      | 1                                                                      | 2                                                                      |
|                                              | Utilizing the information of the manufacturer in the assessment| Interview                                   | Head of Medical Engineering Unit         | The head of the medical engineering unit does not have access to scientific standard references (scientific articles, scientific sites, international standards, etc.) | The head of the medical engineering unit does not have access to scientific standard references (scientific articles, scientific sites, international standards, etc.) | The head of the medical engineering unit does not have access to scientific standard references (scientific articles, scientific sites, international standards, etc.) |
|                                              | Conducting studies and research in the field of medical equipment maintenance | Documentation review                       | Head of Medical Engineering Unit         | There is no access to the manufacturer's information and it is not operated accordingly | There is access to the manufacturer's information, but it is not operated accordingly | There is access to the manufacturer's information and it is operated accordingly |
| User guide                                   | Preparing and installing quick user labels                      | Observation–documentation review           | Head of Medical Engineering Unit         | Quick user tags are not provided and installed on all devices           | Quick user tags are provided and installed on all devices               | Quick user tags are provided and installed on all devices               |
|                                              | Preparation of manuals in both Persian and English for each device | Observation–documentation review           | Head of Medical Engineering Unit         | The manual of each device has not been prepared and has not been provided to the user of the device | The manual of each device has been prepared and has not been provided to the user of the device | The manual of each device has been prepared and has not been provided to the user of the device |
| Documentation                                 | Archive of executive processes (repair, quality control and PM documentation) | Observation–documentation review           | Head of Medical Engineering Unit         | Maintenance procedures are not fully documented and archived            | Maintenance procedures are fully documented and archived                | Maintenance procedures are fully documented and archived                |
|                                              | Use of HIS system in maintenance                                | Observation                                | Head of Medical Engineering Unit         | The medical engineering unit is not equipped with the HIS system        | The medical engineering unit is equipped with the HIS system           | The medical engineering unit is equipped with the HIS system           |
| Dimension                          | Standards                                      | Data collection method               | Data collection source                                      | Scores |
|-----------------------------------|-----------------------------------------------|--------------------------------------|------------------------------------------------------------|--------|
|                                   |                                               |                                      |                                                            | 0      |
|                                  |                                               |                                      |                                                            | 1      |
|                                  |                                               |                                      |                                                            | 2      |
|                                   |                                               |                                      |                                                            |        |
| Educating                         | Educational supervisor participation in user training | Interview—documentation review      | Head of Medical Engineering Unit/Educational supervisor | Educational supervisors do not cooperate with medical engineers in educating users | Educational supervisors cooperate with medical engineers in educating users |
|                                  | Targeted training courses                      | Interview                           | Head of Medical Engineering Unit, Medical Engineers and Technical Technicians/Department Employees | Training courses are not purposeful or useful | Training courses are purposeful or useful |
|                                  | Acquaintance of the officials of the medical engineering unit with the management | Interview                           | Head of Medical Engineering Unit, Medical Engineers and Technical Technicians | None of the medical engineering officers are familiar with medical equipment maintenance management | All of the medical engineering officers are familiar with medical equipment maintenance management |
|                                  | The effectiveness of training courses          | Interview                           | Head of Medical Engineering Unit, Medical Engineers and Technical Technicians/Department Employees | The trainings are not effective | The trainings are effective |
|                                  | Providing the possibility for all medical engineers to participate in training workshops | Interview                           | Head of Medical Engineering Unit, Medical Engineers and Technical Technicians | It is not possible for all engineers and technicians to participate in training workshops | It is possible for all engineers and technicians to participate in training workshops |
|                                  | Nurse’ level of education in the field of general equipment | Interview                           | Users                                                      | Medical equipment users have not been trained in general equipment | Medical equipment users have not been trained in general equipment |
|                                  | User retraining about essential equipment      | Interview                           | Users                                                      | Users are not retrained about essential equipment | Users are retrained about essential equipment |
| Dimension                                                                 | Standards                                                                 | Data collection method               | Data collection source                             | Scores                                                                 |
|--------------------------------------------------------------------------|---------------------------------------------------------------------------|--------------------------------------|---------------------------------------------------|-----------------------------------------------------------------------|
| Invitation of expert professors to teach                                 |                                                                           | Interview                           | Head of Medical Engineering Unit                  | 0 1 2                                                                 |
| Visiting the production lines of medical equipment and supplies companies |                                                                           | Observation                          | Head of Medical Engineering Unit, Medical Engineers and Technical Technicians | Expert professors are not invited to teach  
Medical engineers and technicians do not visit manufacturing companies  
Medical engineers and technicians visit manufacturing companies |
| Participate in in-service training for official and contact forces        |                                                                           | Interview–documentation review       | Head of Medical Engineering Unit, Medical Engineers and Technical Technicians | Medical engineers and technicians do not participate in in-service training  
Medical engineers and technicians visit manufacturing companies  
Medical engineers and technicians participate in in-service training |
| Conducting classes and training courses for managers, engineers and users |                                                                           | Interview–documentation review       | Head of Medical Engineering Unit, Medical Engineers and Technical Technicians/Users | Classes and training courses are not scheduled  
Classes and training courses are held as scheduled |
| Developing a training program based on the training needs of users and engineers |                                                                           | Interview–documentation review       | Head of Medical Engineering Unit                  | The training program is not developed based on educational needs  
The training program is developed based on educational needs |
| Service                                                                   |                                                                           |                                     |                                                   |                                                                       |
| Repair (corrective maintenance)                                           | Repair of medical equipment according to the regulations and supervision of device repair | Interview                           | Head of Medical Engineering Unit                  | The repair of medical equipment is not in accordance with the regulations and the medical engineer does not observe their repair by companies  
Medical equipment is repaired according to the regulations, but the medical engineer does not observe their repair by companies  
Medical equipment is repaired according to the regulations and the medical engineer does observe their repair by companies |
| Necessity of warranty and after-sales service in repair                  |                                                                           | Documentation review                 | Head of Medical Engineering Unit                  | Medical equipment has no warranty or after-sales service  
Medical equipment has warranty or after-sales service  
Some of the capital equipment is repaired by allowed agencies |
| Repair of vital and capital equipment by allowed agencies                 |                                                                           | Interview–documentation review       | Head of Medical Engineering Unit                  | Capital equipment is not repaired by allowed agencies  
Capital equipment is repaired by allowed agencies  
Some of the capital equipment is repaired by allowed agencies |

Table 1 (continued)
**Table 1 (continued)**

| Dimension                  | Standards                                    | Data collection method                                      | Data collection source                          | Scores                                              |
|-----------------------------|----------------------------------------------|-------------------------------------------------------------|--------------------------------------------------|---------------------------------------------------|
| Make it possible to repair  | Interview                                    | Head of Medical Engineering Unit                            | It is not possible to repair some medical equipment inside the hospital | It is possible to repair some medical equipment inside the hospital |
| the device inside the hospital |                                             |                                                             |                                                  |                                                   |
| Decommissioning             | Observation–documentation review–interview    | Head of Medical Engineering Unit                            | The decommissioning process is not followed according to the instructions and notification rules | The decommissioning process is followed according to the instructions and notification rules |
| Outsourcing                 | Interview–documentation review                | Head of Medical Engineering Unit                            | Medical engineering unit is not associated with reputable companies | Medical engineering unit is associated with reputable companies |
| Communication with          |                                              |                                                             | The performance of private companies is not monitored by the Department of Medical Equipment | The performance of private companies is monitored by the Department of Medical Equipment |
| reputable companies         |                                              |                                                             |                                                  |                                                   |
| investigate the performance of private companies |                                              |                                                             |                                                  |                                                   |
| The role of third parties in quality control | Interview                                    | Head of Medical Engineering Unit                            | Quality control is not done by private companies | Quality control is done by private companies |
| Buy maintenance software from private companies | Observation–documentation review             | Head of Medical Engineering Unit                            | Maintenance software is not purchased from private companies | Maintenance software is purchased from private companies |
| Cooperation and coordination of ministries and universities with private companies | Interview                                    | Ministry and university officials                           | The Ministry and the University do not cooperate with private companies | The Ministry and the University cooperate with private companies |
| Outsourcing of service, maintenance and repair | Documentation review                         | Head of Medical Engineering Unit                            | Outsourcing does not have a general framework according to the regulations | Outsourcing does not have a general framework according to the regulations |
## Table 1 (continued)

| Dimension                                      | Standards                                                                 | Data collection method           | Data collection source                      | Scores           | 1                                                      | 2                                                      |
|------------------------------------------------|---------------------------------------------------------------------------|----------------------------------|---------------------------------------------|-----------------|--------------------------------------------------------|--------------------------------------------------------|
| Designing and implementation                  |                                                                           |                                  |                                             |                 |                                                        |                                                        |
| Process management                            | Formation of joint committees by the Department of Medical Equipment      | Documentation review             | Head of Medical Engineering Unit           | The committee's minutes are not available | The minutes of the committee are available, but not complete | The minutes of the committee are complete             |
| Define the level of user access to medical equipment | Interview                                                               | Head of Medical Engineering Unit, Medical Engineers and Technical Technicians/Users | The user access level policy is not defined |                 |                                                        |                                                        |
| Inter-sectorial communication in hospitals     | Interview—observation                                                      | Head of Medical Engineering Unit, Medical Engineers and Technical Technicians/Users | The Medical Engineering Unit does not have a specific protocol for communicating with other departments and units |                 |                                                        |                                                        |
| Planning for maintenance in the office of medical equipment | Interview—documentation review                                             | Head of Medical Equipment Department | The Medical Engineering Unit has no plans for any medical equipment maintenance activities |                 |                                                        |                                                        |
| Develop and define internal policies           | Documentation review                                                      | Head of Medical Engineering Unit | No policy has been developed for the maintenance of medical equipment |                 |                                                        |                                                        |
| Develop an action plan for the medical engineering unit | Documentation review                                                      | Head of Medical Engineering Unit | An action plan for maintaining medical equipment has not been developed |                 |                                                        |                                                        |
| Management infrastructure in the medical equipment department | Interview                                                               | Head of Medical Equipment Department/Head of Medical Engineering Unit | The Department of Medical Equipment does not have a strong infrastructure |                 |                                                        |                                                        |
| Dimension                                                                 | Standards                                                                 | Data collection method               | Data collection source                                                                 | Scores 0                                                                 | Scores 1                                                                 | Scores 2                                                                 |
|-------------------------------------------------------------------------|----------------------------------------------------------------------------|--------------------------------------|----------------------------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------------------------|
| Existence of a specific assessment structure for maintaining medical equipment | Interview—observation Head of Medical Equipment Department/Head of Medical Engineering Unit | Medical equipment maintenance does not have a clear structure for assessing this process | Medical equipment maintenance does not have a clear structure for assessing this process | The administrative process is long and cumbersome                         | The administrative process is not long and cumbersome                  |                                                                       |
| Prolonged administrative processes                                      | Interview Head of Medical Equipment Department/Head of Medical Engineering Unit | The administrative process is long and cumbersome |                                                                       |                                                                       |                                                                       |                                                                       |
| Creating unity of procedure in the medical engineering unit             | Interview—observation Head of Medical Engineering Unit                   | The Medical Engineering Unit does not have the unity of procedure in the implementation of affairs | The Medical Engineering Unit has the unity of procedure in the implementation of affairs |                                                                       |                                                                       |                                                                       |
| Knowledge and attitude                                                   | Medical professional dominance in hospitals                                | Interview Head of Medical Equipment Department/Head of Medical Engineering Unit | Medical equipment maintenance does not have a clear structure for assessing this process | There is Medical professional dominance in hospitals to buy and choose medical equipment | There is not Medical professional dominance in hospitals to buy and choose medical equipment |                                                                       |
| Involvement of non-experts in the medical equipment department          | Interview Head of Medical Equipment Department/Head of Medical Engineering Unit | Non-experts are involved in decision-making and policy-making in the field of medical equipment |                                                                       |                                                                       | Experts are involved in decision-making and policy-making in the field of medical equipment |                                                                       |
| The correct understanding of management and users hospital about maintenance management | Interview Hospital management and users                                   | Hospital management and users are not familiar with maintenance management |                                                                       |                                                                       | Hospital management and users are familiar with maintenance management |                                                                       |
| Change the view of the officials to the medical engineering unit        | Interview Head of Medical Equipment Department/Head of Medical Engineering Unit | The medical engineering unit in the hospital does not have a specific and established position |                                                                       |                                                                       | The medical engineering unit in the hospital has a specific and established position |                                                                       |
| Dimension                  | Standards                                      | Data collection method | Data collection source                                      | Scores                                      |
|----------------------------|------------------------------------------------|------------------------|-------------------------------------------------------------|---------------------------------------------|
| Purchasing management      | Buy the device from the website of reputable companies | Documentation review | Head of Medical Equipment Department/Head of Medical Engineering Unit | 0: Medical equipment is not purchased from reputable companies, 1: Medical equipment is purchased from reputable companies, 2: Medical equipment is purchased based on the needs of the area and the target |
|                            | To buy equipment based on need                 | Documentation review   | Head of Medical Equipment Department/Head of Medical Engineering Unit |Medical equipment is not purchased based on the needs of the area and the target |
be used if we are looking for the views and attitudes of stakeholders. Dimensions that require documentation will be assessed through documentation review. The observation method is also for assessing physical items.

**Discussion**

In the field of medical equipment maintenance management, there is no single and standard checklist that includes all hospitals in the country. The only available checklists include accreditation measures that generally assess the tasks and activities of the medical engineering unit. Since the issue of maintenance management includes a wide variety of topics, and in the low- and middle-income countries, there is major weakness in this regard, so we decided to design a checklist for uniformity and accurate and comprehensive assessment using Iranian context. The Departments of Medical Equipment of some provinces in Iran have designed a checklist natively for its affiliated hospitals, the dimension and method of which are different. For example, the maintenance management evaluation checklist of Tabriz Medical Equipment Office includes 15 indicators (technical force, medical engineering unit, medical equipment ID, quality control tests, PM, training, medical equipment and spare parts storage, service and maintenance contract, the existence of purchase process, the existence of decommissioning process, the existence of recall system and reporting of adverse events, ensuring sound electricity, implementing a continuous maintenance improvement process, familiarizing with the general administration’s rules and website, management and allocating a separate budget for maintenance).

According to the medical equipment maintenance management criteria of the MOHME, some of these dimensions can be merged into one dimension and some can be separated. In addition, each of the indicators and sub-indicators can be expanded. That is, not all maintenance management issues are addressed. The scoring and classification of dimensions in this checklist does not have a specific standard and does not include all dimensions of maintenance according to the maintenance criteria of the MOHME and is generally designed.

Herrera-Galán [16] evaluated the performance of the maintenance function through management audits and their implementation in five hospitals. The aspects evaluated include equipment availability, response to a service request, monitoring and control of biomedical equipment, staff training, quality of work executed by the maintenance technicians, the workload of maintenance technicians, control of the work executed by the maintenance technicians, the effectiveness of annual maintenance planning and department performance. The results of this research show that the audit technique is a valuable checklist in the performance assessment of a hospitals. The application of the proposed method evidenced that the most critical component in the results of a management audit is the human resource [16].

An effective medical equipment maintenance program consists of three main elements. (1) Identifying the medical devices that need to maintenance program by the Ministry of Health. (2) Financial management, personal management, performance monitoring, operational management and performance improvement. (3) Proper implementation of the maintenance program. These three elements are also considered in the
designed checklists in different dimensions such as resources, designing and implement-
tation [17].

The maintenance and its management constitute a checklist that ensures the equip-
ment performance. There exist four criteria in which the hospitals coincide that they
should improve, even though each of them in different measure and sub-criterion.
These criteria are an organization of maintenance; human resources; planning, pro-
gramming and control of the maintenance and corrective maintenance. These crite-
ria are among the sub-categories of maintenance management assessment checklists
[18].

Amerion et al. [19] identified effective factors on the MEMM in a military hospital.
Among effective factors on the MEMM, 26 components were extracted. User training
components, human resources, commitment and the experience of users, the foreign
exchange market, periodic visits, and trade name were the most important components
which had more than 75% of the relative abundance. According to the results, factors
with high importance on the management of medical equipment maintenance should
be supported by the center's directors. Attention to the use of these components can
reduce maintenance costs, and therefore, increase the life of medical equipment. User
training and human resources are the two main dimensions of this checklist [19].

According to the current results, documentation and service are two dimensions
of MEMM. The problems of some hospitals in MEMM were introduced from the
aspects of maintenance time, maintenance record, maintenance service and self-
maintenance. Some measures were proposed including simplifying maintenance
process through PDCA, information maintenance record, cooperating with the third-
party maintainer and establishing self-maintenance team, so that precision and infor-
mation medical equipment management can be realized to maximize the benefit of
medical equipment management [20].

The medical equipment requires maintenance (both scheduled and unscheduled)
during its useful life. The medical equipment maintenance process should be planned,
implemented, monitored, and improved continually. This process requires careful
supervision by healthcare administrators, many of whom may not have the technical
background to understand all of the relevant factors. Maintenance management is the
most important function in overall medical equipment management. In this regard,
implementation of appropriate maintenance strategies requires the following types of
resources: human resources, material resources, financial resources and documenta-
tion. Our findings also point to the importance of these resources [21].

We need a comprehensive assessment checklist that covers all aspects of medical
equipment maintenance management in hospitals. In this regard, the identification of
influential factors is essential. Eighty-nine factors were identified that affect MEMM.
Five of the factors were found related to resources item, 12 factors related to service,
4 factors related to education, 15 of these factors regarding quality control, 19 fac-
tors related to inspection, 12 factors related to information bank and 22 factors were
dedicated to management. These factors are implicated in decision-making in sup-
port of selection, purchase, repair and maintenance of medical equipment, especially
for capital equipment managers and medical engineers in hospitals and also for the
assessment of this process. Identification and classification of influential factors can
be of help for raising critical alerts about the types of equipment more prone to maintenance problems [14].

**Strengths and limitations**

In our knowledge, this study is the first comprehensive study of its kind addressing all of the factors affecting an effective and efficient MEMM. It offers comprehensive checklists for assessing the status of MEMM. In addition, the present compiled checklist is the result of multi-method research in such a way that its components are determined through systematic review and obtaining the views of experts and specialists in this field. This indicates the validity and comprehensiveness of the checklists developed.

Lack of enough information concerning the concept of maintenance management, lack of specific guidelines and instructions were the most notable limitations.

**Conclusion**

Effective maintenance management of medical devices increases the efficiency and productivity of health technology resources, which is especially important when resources are limited. This allows patients to access medical equipment that can provide an accurate diagnosis, effective treatment, or appropriate rehabilitation. Several factors affect the management of medical equipment maintenance, and it is important to follow each of them to improve the performance of devices and provide medical services to patients. Therefore, before designing an assessment checklist, we need to consider a specific framework for the maintenance management process to include all maintenance activities. The medical equipment maintenance management assessment checklists allow for the timely identification of deficiencies and gaps in the medical equipment maintenance management process so that the necessary steps can be taken. It also can help managers and engineers to assess maintenance status and provide solutions and interventions for the decision makers and policymakers to improve its.

**Methods**

The present study was a multi-methods study in four stages. In the first stage, a systematic review on data related to factors which affect the assessment of MEMM was conducted. Then, a qualitative study was designed to investigate these factors from expert view and related documents. In the end, the results of the first and second stages were combined using content analysis and the final checklist was developed.

**Stage 1**

A systematic search of the following databases was conducted during October 2015 in the PubMed, ProQuest, Scopus, Embase, and Web of Science. The search was updated in June 2017. Our search strategy was as follow: (("medical device*"[Title/Abstract]) OR "medical equipment"[Title/Abstract]) AND "maintenance management"[Title/Abstract]) [14]. At first, we extracted the items, then categorized the extracted items based on the Ministry of Health and Medical Education of Iran (MOHME) framework in each category [13].
Stage 2
In the qualitative step, semi-structured interviews and documents review were used for data collection. The collected data consisted of the perspectives of medical and biomedical engineers concerning factors influencing MEMM. Related documents were regulations of MEMM, MEMM guidelines and other related regulations or reports developed by MOHME. The content analysis approach (inductive and deductive) was used to analyze the data. The extracted codes were sorted into both themes and subthemes based on comparisons between similarities and differences that were categorized into 7 main themes and 22 subthemes [15].

Stages 3
In this stage, the researchers combined the extracted data from systematic review and qualitative study using a content analysis and devised the first draft of the checklist. The primary checklist was developed in the form of assessment checklists in seven dimensions (providing resources, quality control tests, preventive inspection and maintenance, database, training, service, design and implementation).

Stages 4
We sent the primary draft of checklist through a Delphi to 20 experts who had sufficient scientific and information background in the field of MEMM for assessing the validity and reliability. Of them seven experts participated in this stages and send their comments. In the first round, experts commented on the content, dimensions, writing and appearance of the primary checklist. The research team modified the primary version based on expert’s comments and sends it again to experts. Eventually, the proposed checklist was finalized after approving the experts.

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Authors’ contributions
RB conceived of the presented idea. AI and LD were in charge of overall direction and planning. RB and MAZ drafted the manuscript. AI, LD, RB and MAZ contributed to the design and implementation of the research. All the authors discussed the results and commented on the manuscript. RB and MAZ revised the manuscript based on the reviewer’s comments. All the authors read and approved the final manuscript.

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Availability of data and materials
The datasets of this study are available from the corresponding authors upon reasonable request.

Declarations
Ethics approval and consent to participate
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Consent for publication
All the authors confirmed the consent for publication.

Competing interests
The authors declare that they have no conflict of interest.
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