Analysis of Medical Equipment Management in Relation to the Mandatory Medical Equipment Safety Manager (MESM) in Japan

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Submitted December 2013. Accepted for publication May 2014.

ABSTRACT

Half a decade has passed since the fifth revision of the medical law and mandatory appointment of a medical equipment safety manager (MESM) in hospitals in Japan. During this period, circumstances have changed regarding maintenance of medical equipment (ME). We conducted a survey to examine these changes and the current situation in ME management. Maintenance of ME and related work were found to have increased in many hospitals, but the number of clinical engineering technologists (CETs) has only slightly increased. The appointed MESM was a CET or physician in most hospitals. In hospitals where physicians were appointed as the MESM, 81% had operation managers. Many respondents commented that it was difficult for one person to cover all the tasks required by the MESM, due to a lack of knowledge, too much work, or other reasons. This suggests the importance of an operation manager for ME to work under the MESM.

Keywords: medical equipment, survey, maintenance, management, clinical engineering technologist

1. INTRODUCTION

Accidents related to medical equipment (ME) may be caused by a lack of knowledge and skills regarding the ME and related medical procedures [1-5]. Underutilization of ME may also result in critical accidents. Therefore, it is important for medical institutions to perform adequate maintenance for ME and related facilities, including electrical services and those associated with medical gas. In Japan, the clinical engineer technologist (CET) license has been established since 1988 [6]. The Japanese CET Act defines the CET as engaging in operation and maintenance of life-support devices under a physician's direction. A CET may work in the operating room as a perfusionist, at a

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hemodialysis unit as a dialysis machine operator, and at a cardiac catheter laboratory as an operation and registration operator. Additionally, a CET engages in maintenance including periodic inspection, overhaul and repair, and component replacement for all kinds of ME:ventilators, artificial heart-lung apparatus, hemodialysis apparatus (life-support devices), infusion and syringe pumps, ultrasonic nebulizers, and cardioverter defibrillators (therapeutic apparatus). In recent years, administration and storing of ME have changed from individual management in a ward or section to centralized management in a facility such as a medical engineering center, based on operation rates and efficiency [7]. In addition, to promote more efficient administration, a number of computer-based ME administration systems have been developed and marketed [8-10]. These systems are mainly used in medium to large scale hospitals [11-13]. To address equipment availability, device location systems based on radiofrequency identification (RFID) have been recommended and developed [14-16], but these systems are not commonly used in Japan because of their costs [16]. Additionally, there is a shortage of manpower and working space for ME management in many hospitals [17].

With this background, the Ministry of Health, Labour and Welfare of Japan introduced the fifth revision of the medical law on April 1st, 2007 (Health Policy Bureau Announcement No. 0330010), with the goal of establishing a system of high quality medical service. This revision required each medical institution, including hospitals, clinics, and midwifery homes, to appoint an ME safety manager (MESM) and to adopt a system that ensures the security and safety of every piece of ME. The roles of the MESM include "providing training programs for medical staff", "planning and performing maintenance management", and "collecting safety or failure information from manufacturers and public sources and making this available to hospital staff". The revision of the law also identified 8 types of ME that should be maintained: (i) ventilators, (ii) artificial heart-lung apparatus and biventricular assisting devices including intra-aortic balloon pumping device (IABP) and percutaneous cardiopulmonary support device (PCPS), (iii) hemodialysis apparatus, (iv) closed circulation infant incubators, (v) defibrillators excluding automatic external defibrillators (AED), (vi) medical high energy radiation generators including medical linear accelerators, (vii) medical radiation irradiators including gamma knife devices, and (viii) medical corpuscular beam irradiators. CETs are the only allied health staff trained in safety management of ME and maintain 5 of the 8 specified types of ME (i to v) in many medical institutions. The other 3 types of ME (vi to viii) are specific radiological ME that are used in only a few institutions. Therefore, these devices are maintained by clinical radiologists with specialized expertise or by manufacturers. In the light of this situation, the Japan Association for Clinical Engineering Technologists and related organizations recommended that CETs are appropriate to serve as MESMs [18].

Most MESMs are physician or CETs and many hospitals have increased maintenance and in-service training in ME management, but employment of a CET for maintenance increased in only 13% of hospitals based on our 2008 report [19]. Half a decade has now passed since establishment of the MESM position and circumstances regarding ME management and CETs have changed. Furthermore, 25 years have passed

since the CET Act was established and the number of qualified persons is now over 30,000. To promote greater safety and proper usage of ME, since 2008, an ME safety management fee has been allowed for patients treated with life-support devices in a medical institution with a CET.

The establishment of MESMs has had several problems from the beginning of the most recent revision of the medical law. The MESM is required to have attributes such as "authority", "business experience", and "knowledge", is regarded as the general manager of ME at an institution; and should take the responsibility in the event of an accident related to ME. A previous survey suggested that many institutions thought physicians were most appropriate to serve as MESMs for the reason of authority [19]. However, many MESMs and related medical or allied health staff suggested that one person or occupation is not sufficient to fulfill all the requirements of an MESM in clinical practice because of limitations of their skills and experience as well as other clinical responsibilities. In this study, we conducted a survey to investigate the changes and current situation in ME management since the establishment of mandatory MESMs half decade ago, and to examine the adequacy of current ME management.

2. METHODS

2.1. Study Questionnaire

A questionnaire entitled "Survey of management of ME and the role of the ME safety manager over the last half-decade" was sent by surface mail to 356 general hospitals with more than 300 beds in Kanto region (the center of Honshu, including Tokyo metropolitan, Kanagawa, Chiba, Saitama, Ibaraki, Gunma, Tochigi and Yamanashi prefectures) from 9th October to 9th November, 2012.

The questionnaire included the following questions: a request for basic information (the position of the respondent, type of hospital, and number of beds); whether the hospital had a clinical engineering section; the quantity of ME maintained; the occupation of the present MESM and his/her predecessor; whether the hospital appoints operation managers in each section or unit; the role of the MESM and operation manager; thoughts on the responsibilities and occupation of the MESM; the number of full-time CETs working on maintenance; changes in the management of ME over the last half-decade; and satisfaction with current medical equipment management (Appendix 1).

2.2. Analysis and Statistics

Data for bed capacity, number of CETs, and quantity of ME were analyzed based on five categories of bed capacity. Statistical analysis was performed with Pearson product-moment correlation coefficient analysis. A probability of $P < 0.05$ calculated by Student t test was considered to be significant.

2.3. Scope of the Study

This survey was conducted in general hospitals with more than 300 beds in Kanto region, with the goal of understanding the response to the changes and current situation in ME management since establishment of the MESMs half decade ago. Medium to

large scale hospitals were targeted because these hospitals own a greater number and varieties of ME and employ more CETs than small scale hospitals. Findings may differ in hospitals with different characteristics, such as those with fewer than 300 beds.

3. RESULTS

3.1. Basic Information

We collected 162 completed questionnaires (45.5% response rate). The respondents were CETs (72%), physicians (8%), nurses (7%), and other professionals (13%). The responding hospitals included private medical corporations (35%), public hospitals (18%), self-governing hospitals (17%), private university hospitals (14%), and other hospitals (16%). Bed capacities were ≤ 399 beds (38%), 400 to 499 beds (25%), 500 to 599 beds (14%), 600 to 799 beds (14%), and ≥800 beds (9%) (Table 1).

3.2. Current Status of ME Management

Many of the hospitals with clinical engineering sections had large bed capacities (Figure 1). Management and storage systems for ME were fully centralized in 31% of hospitals, partially centralized in 60%, and separately administered in only 9%. The

Table 1. Basic statistics

Respondents	Clinical engineering technologist	118 (72%)
	Physician	13 (8%)
	Nurse	11 (7%)
	Clinical radiologist	7 (4%)
	Clinical laboratory technologist	3 (2%)
	Pharmacist	1 (1%)
	Desk worker	8 (5%)
	Other	1 (1%)
Type of hospital	Private medical corporation	57 (35%)
	Public hospital	28 (18%)
	Self-governing hospital	27 (17%)
	Private university hospital	22 (13%)
	National hospital	15 (9%)
	National university hospital	6 (4%)
	Other hospital	6 (4%)
Bed capacity	≤399	61 (38%)
	400-499	41 (25%)
	500-599	23 (14%)
	600-799	22 (14%)
	≥800	15 (9%)
	Total	162 (100%)

current administration system had been changed after the MESM assignment in 23% of the hospitals. The quantity of ME under CET management and maintenance increased with bed capacity (Figure 2). Full-time CETs were employed in 87% of the hospital, and increased with bed capacity. Among all CETs, 44% perform ME

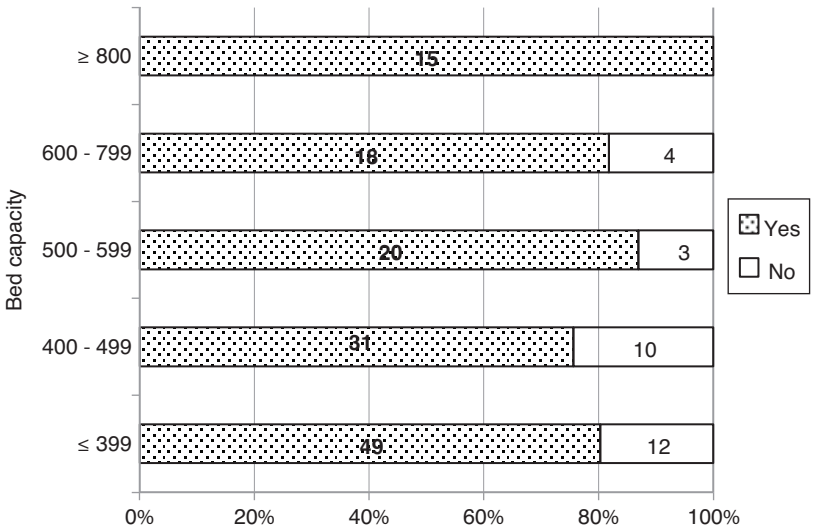

Figure 1. Existence of clinical engineering sections in hospitals.

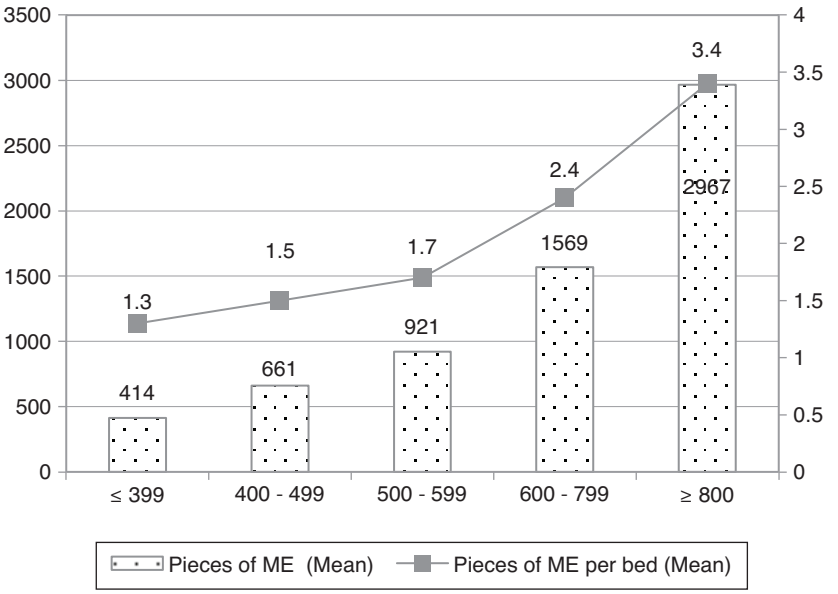

Figure 2. Data of ME.

maintenance in hospitals with 400 to 499 beds, but this percentage was only 21% in hospitals with ≥800 beds (Figure 3). The data showed that about 0.5 CETs per 100 beds perform ME maintenance. There was little difference in the number of CETs per 100 beds in hospitals with different bed capacities and quantity of ME. In contrast, the number of CETs per 100 pieces of ME decreased with bed capacity and quantity of ME (Figure 4). Several hospitals contracted out to maintenance services, and a high

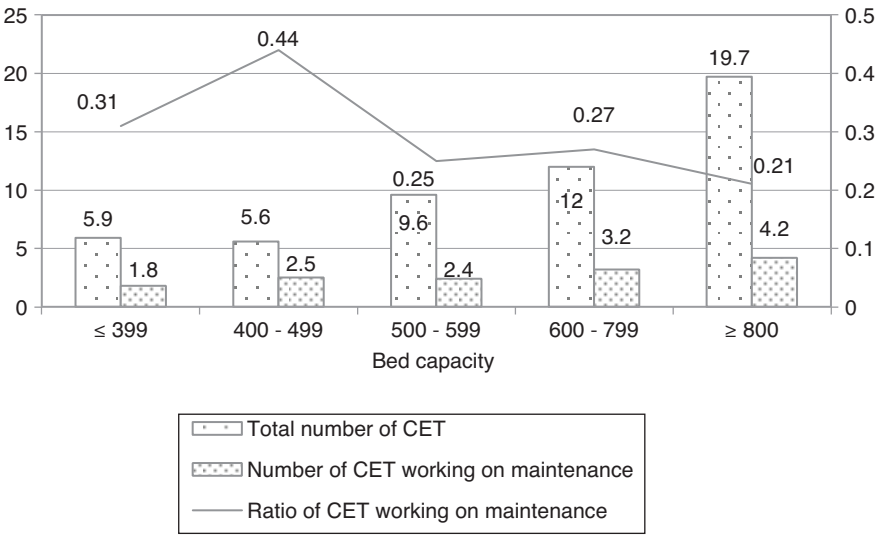

Figure 3. Data of CET.

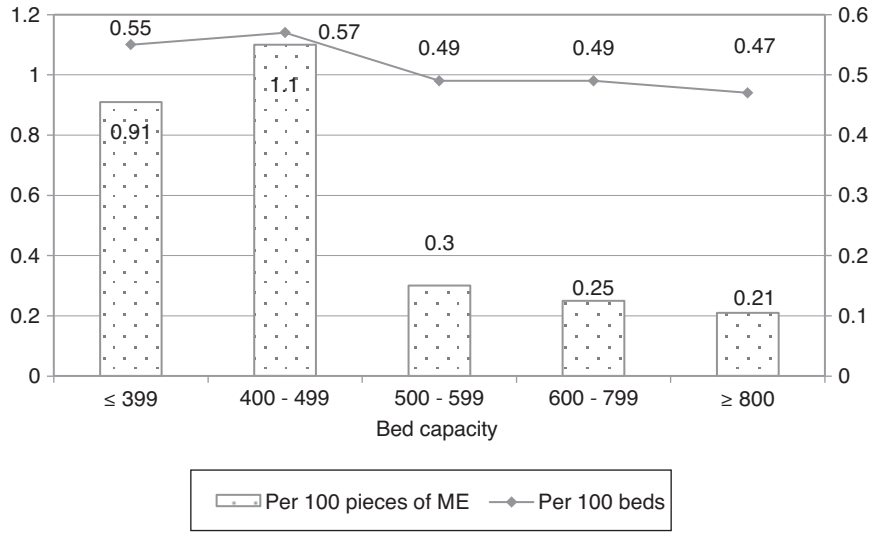

Figure 4. Data of CETs working on maintenance per 100 beds and per 100 pieces of ME.

percentage of hospitals with ≥ 800 beds contracted out (Figure 5). The quantity of ME maintained by each CET decreased and the number of CETs engaged in maintenance increased with the number of CETs in a hospital, whereas the quantity of ME maintained by each CET increased with the number of beds and quantity of ME in a hospital (Tables 2, 3). An analysis of the relationships among bed capacity, number of

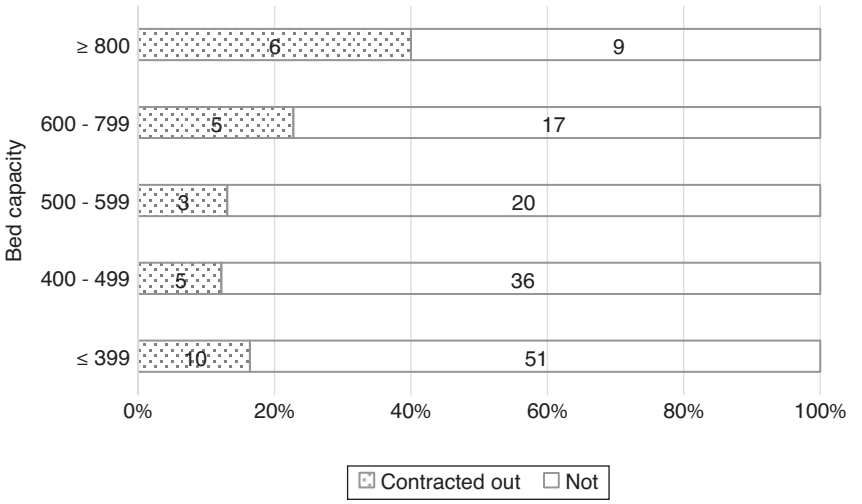

Figure 5. Data of hospitals contracting out maintenance.

Table 2. Quantity of ME managed per CET vs. number of CETs working on maintenance

Number of CETs	Quantity of ME maintainedby each CET
1	772
2	432
3-5	275
≧6	258

Table 3. Quantity of ME managed by CET vs. bed capacity

Bed capacity	Quantity of ME maintained by each CET
≦99	13
100-499	170
500-999	382
1000-1999	520
≧2000	1070

CETs, and quantity of ME showed positive correlations of bed capacity with quantity of ME ($r = 0.616$, $P < 0.001$, $n = 148$) and full-time CETs ($r = 0.558$, $P < 0.001$, $n = 158$). However, the number of full-time CETs engaged in maintenance had only weak correlations with bed capacity ($r = 0.321$, $P < 0.001$, $n = 135$) and quantity of ME ($r = 0.374$, $P < 0.001$, $n = 135$) (Table 4).

3.3. Changes in ME Management During the Past Half Decade

Circumstances regarding ME have changed since the most recent revision of the medical law. The quantity of ME has increased in 68% of hospitals and the number of types of equipment increased in 60% of hospitals. ME requiring maintenance increased in 68% of hospitals and in-service training increased in 72% of hospitals. The number of persons working on maintenance had increased in 33% of hospitals (Table 5). However, 63% of hospitals responded that they were at least somewhat dissatisfied with the number of persons working on maintenance and 33% of hospitals indicated some dissatisfaction with current ME management (Table 6). The respondents indicated a perceived need for 1.8 to 2.5 CETs on average. There

Table 4. Correlation of bed capacity, number of CETs, and quantity of ME

	Pearson correlation coefficient	P value
Bed capacity vs. Quantity of MEs	0.616	<0.001
Bed capacity vs. Total full-time CETs	0.558	<0.001
Bed capacity vs. Full-time CETs engaged in maintenance	0.321	<0.001
Quantity of ME vs. Total full-time CETs	0.485	<0.001
Quantity of ME vs. Full-time CETs engaged in maintenance	0.374	<0.001
Total full-time CETs vs. Full-time CETs engaged in maintenance	0.472	<0.001

Table 5. Changes in ME management

	Increased	Slightly increased	Unchanged	Slightly decreased	Decreased
Quantity of ME	62 (38%)	47 (30%)	47 (30%)	1 (1%)	1 (1%)
Types of ME	47 (30%)	47 (30%)	57 (36%)	6 (4%)	2 (1%)
Cases of maintenance work	58 (36%)	51 (32%)	49 (31%)	1 (1%)	0 (0%)
Cases of in-serve training	42 (27%)	55 (35%)	58 (36%)	2 (1%)	2 (1%)
Employment of maintenance worker	22 (14%)	30 (19%)	105 (66%)	1 (1%)	1 (1%)

Table 6. Degree of satisfaction with current ME management

	Satisfied	Somewhat satisfied	Neutral	Somewhat dissatisfied	Dissatisfied
Regarding people working on maintenance	10 (6%)	7 (5%)	42 (26%)	51 (32%)	49 (31%)
Attainment of institutional plans	20 (13%)	27 (17%)	58 (38%)	33 (21%)	19 (12%)

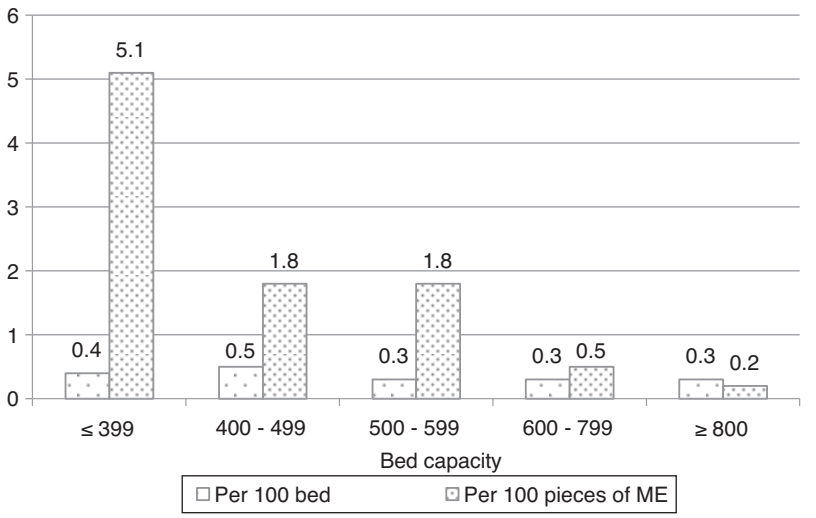

Figure 6. Perceived number of CETs needed to meet the current demands.

was little difference in the CETs needed to meet the current demands, but the CETs needed to meet the current demands per 100 pieces of ME was higher in medium-scale hospitals (Figure 6).

3.4. Occupations of MESM

The professionals appointed as MESMs were CETs (45%), physicians (35%), and nurses (5%) (Figure 7). Among the hospitals surveyed, 43% had appointed at least one new person as MESM during the past half decade. Among hospitals that changed the MESM, 62% did not change the MESM's occupation, but 17% changed to a CET (Figure 8). The reasons for the change in occupation included "the appointed person was retired" (41%), "the successor had more technical knowledge than the predecessor" (12%), and "the successor is in a powerful position in the hospital" (13%).

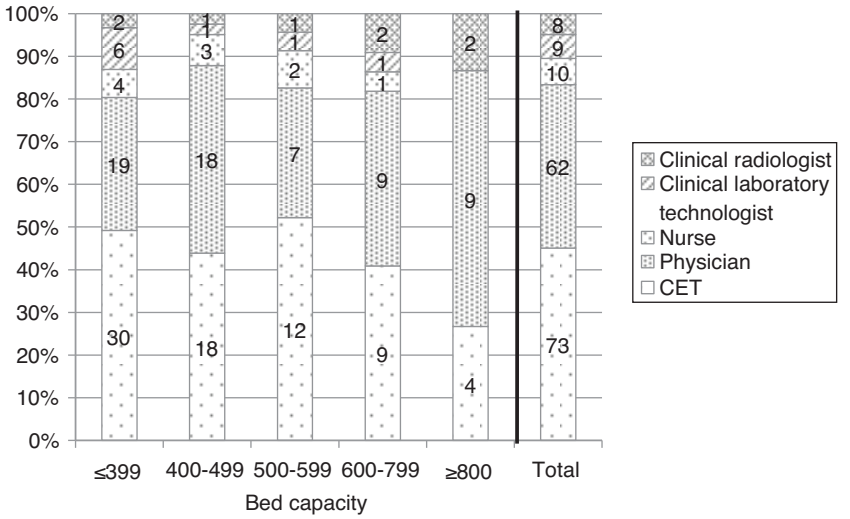

Figure 7. Occupation of current MESMs.

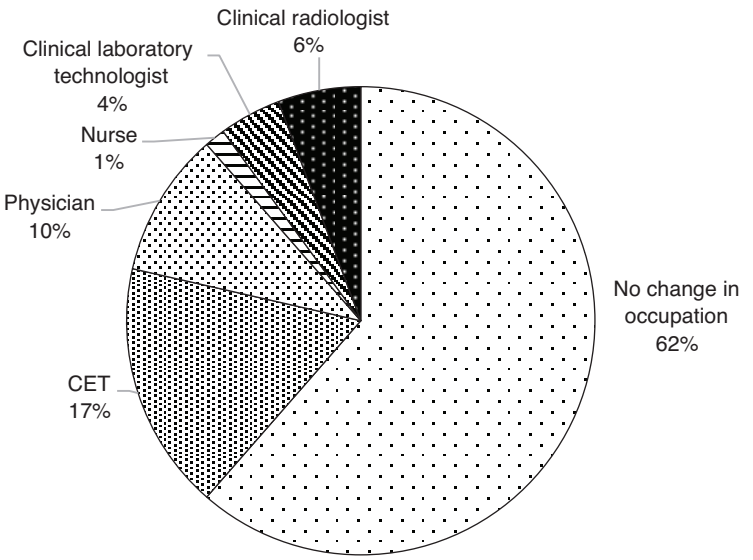

Figure 8. Change of occupation of MESMs during the past half decade.

3.5. Appointment of an Operation Manager and Role of the MESM

Operation managers are defined here as those working in sections such as clinical engineering centers, radiology departments, clinical laboratories, wards, operation rooms, intensive care units, and emergency centers, to support the MESM, deliver

instructions to the relevant section via the MESM, and maintain the ME on a daily basis. However, they are not mandated by the Japanese medical law or other medical standards, and the creation of such position is left to the judgment of each hospital. Our survey showed that 67% of hospitals had operation managers and 33% of hospitals did not. The roles of the MESM and operation managers were similar in hospitals with a CET as the MESM. In hospitals where physicians were appointed as the MESM, 81% had operation managers and the major roles of the MESM were "evaluation of safety management" and "collection of safety information". The roles of the MESM and operation manager based on occupation are shown in Figure.9. CETs appointed as MESMs and operation managers performed similar work. If an MESM had no knowledge or experience of ME outside their field of expertise, many respondents indicated that these pieces of equipment were entrusted to manufacturers or operation managers. About 20% of hospitals did not maintain ME themselves if the equipment was outside the fields of their staff's expertise.

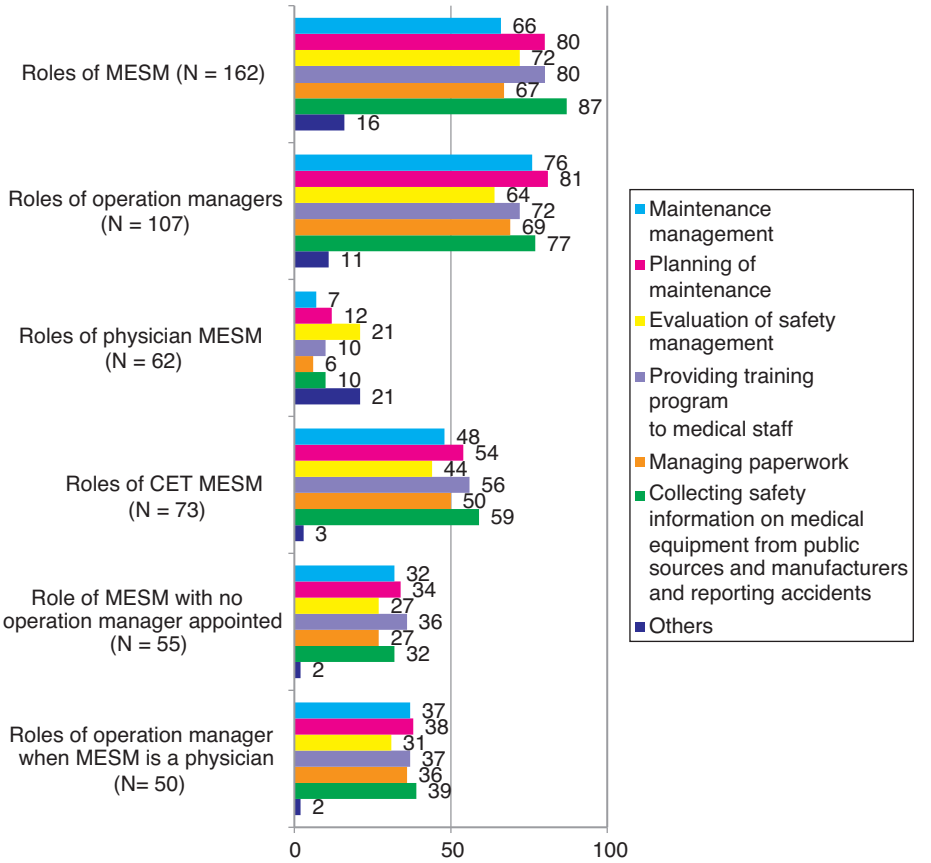

Figure 9. Role of the MESM and operation managers.

3.6. Comments on the Roles and Responsibilities of MESMs

Comments on the role of MESMs defined by the current medical law were made by 94% of respondents. These included "it is difficult for one person to cover all the requirements for MESMs" (N = 94 hospitals), "it is difficult to manage equipment outside the field of expertise" (N = 75), "it is difficult to perform both management and clinical works" (N = 70), "MESMs have too many responsibilities" (N = 64), and "there is a need to define the job of MESMs more clearly with respect to the number of beds and types of medical treatment" (N = 64).

4. DISCUSSION

We received responses from 162 hospitals, comprising about 45% of the 356 hospitals in the Kanto region. The percentages of categories of bed capacity in the 162 respondent hospitals and in the total 356 hospitals were similar (chi-square test, $P = 0.993$); therefore, we consider that our results reflect the entire region. The respondents in our past survey (2009, in hospitals with > 300 beds) were CETs (56%), physicians (19%), nurses (7%), and other professionals (18%) [19]. In the present survey, the percentage of CETs increased modestly and the percentage of physicians decreased slightly. Therefore, the fact that most respondents were CETs could have biased the survey results in favor of having a CET as MESM. Physicians appointed to serve as MESM may have different opinions. Thus, it may be necessary to do an analysis for physician versus CET composition similar to that conducted for bed capacity.

4.1. Clinical Engineering Technologists and Medical Equipment Management

4.1.1. Increased Quantity of Medical Equipment

There was little difference in the installation rate of clinical engineering sections between 2008 and 2012 (in hospitals with >300 beds) [19]. However, the quantity of ME that a CET managed and maintained per bed had increased in all hospitals. Along with establishment of MESMs, it was explicitly stated in the fifth revision of the medical law that ME must be managed and maintained. This revision was aimed at all ME in all medical institutions. Therefore, many institutions had increased the quantity of equipment that were managed and maintained.

4.1.2. Status of CETs Engaged in ME Maintenance

The number of CETs working on maintenance has not increased for half a decade. Satisfaction with the current situation was low and has not been improved since 2007. Comparison of ME management (quantity of ME per bed, and number of CETs working on maintenance per 100 beds and per 100 pieces of ME) between 2007 and 2012 are shown in Figure 10. These results indicate that employment of CETs has increased, but that the quantity of ME has increased even faster. In fact, persons with a CET license have increased yearly, but CETs are now required in roles other than ME management. In surgery, pacemaker implantation and cardiac catheterization was partly performed by manufacturers until April 2008, when the Japanese Federation of Fair Trade Conferences restricted these manufacturers from entering clinical areas to preserve impartiality. Thus, CETs are currently needed in these areas. In particular, the

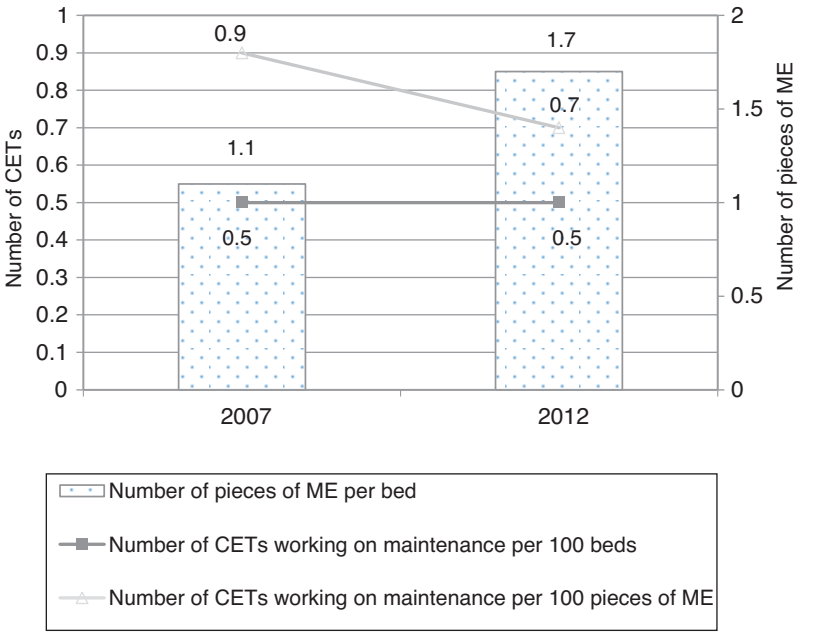

Figure 10. Comparison of ME management (quantity of ME and number of CETs working on ME maintenance) between 2007 and 2012

Table 6. Comparison of ME management between Japan and the United States

	Japan (2012)	U.S. (2010)
Number of pieces of ME per bed	1.7	12
Number of CETs working on ME maintenance per 100 beds	0.5	3.8
Correlation of Bed capacity vs. Number of pieces of ME	0.62	0.83
Correlation of Bed capacity vs. Total full-time CETs engaged in maintenance	0.32	0.81

work load of CETs employed at large medical institutions may be taken by clinical responsibilities. Such institutions also own a large quantity of ME. Therefore, it is difficult to increase the number of CETs working on maintenance in these institutions. A comparison of the current ME status in Japan with that in the United States [20] indicates that Japan suffers from a severe lack of CETs, because the correlation of bed capacity with the total number of full-time CETs engaged in maintenance is low (Table 6). This is apparently because the Japanese CETs have to perform both maintenance and clinical works, such as operating life-support devices, instead of just maintenance and management of ME, as in the United States.

4.2. Current Status of MESMs

4.2.1. Occupations of MESMs

Compared to our 2009 report [19], the percentage of CETs among all MESMs increased from 36% to 45% and that of physicians decreased from 52% to 38%. However, physicians were appointed to serve as the MESM at high rates in hospitals with > 800 beds, suggesting that these hospitals emphasized the importance of the responsibility and authority of the MESM position. The most common reason for an occupation change in appointing a new MESM was "successor had retired", but several hospitals responded that "the MESM was changed to a CET because of their knowledge and experience". In contrast, few respondents changed the MESM to a physician for the reason of authority. In 90% of hospitals where physicians were appointed as the MESMs, the appointment was made in 2008. Of the hospitals with physicians as the MESMs, 70% had operation managers working underneath the MESMs in the same section or unit. Thus, these hospitals compensated for the lack of qualification of the physician MESMs serving as the general managers by appointing operation managers with better qualifications to work under the MESMs. This may be a good compromise solution to the dual need for authority (which physicians typically have) and expertise (which CETs have).

4.2.2. Difficulty in Meeting MESM Requirements

Requirements of the role of MESM were fulfilled by the operation managers more than the MESMs themselves. These requirements were not commonly performed by the MESMs in hospitals where physicians were appointed as the MESMs, but were entrusted to the operation managers. MESMs must possess knowledge and experience in technology in order to accomplish these tasks and to plan management schedules for thousands of pieces of equipment and for in-service trainings. The respondents made it clear that an individual with a particular professional training/background cannot meet all the requirements of MESMs. Therefore, it seems reasonable to appoint an operation manager with a CET background for large institutions and/or when the MESM lacks technical expertise.

4.2.3. Roles and Responsibilities

Among the respondents, 40% felt that the responsibilities of MESMs are difficult to meet. Based on our results, it is clear that many hospitals have a low satisfaction level regarding the institutional plan for ME and insufficient staff for maintenance. The percentage of CETs performing ME maintenance was low in hospitals with large bed capacities. Many MESMs performed both clinical and management works, making it difficult to meet the MESM requirements on a part-time basis. The MESM is the general manager of ME in each medical institution and there is clearly a need to consider the burden of responsibility when a member of the medical staff is appointed as the MESM. Currently, an MESM is considered an expert with special knowledge on use and management of ME, a permanent staff member, excluding the director, and holding one of the 9 defined national medical licenses in Japan. Because a director cannot be designated as the MESM, 10% of hospitals appointed physicians who were

assistant directors. However, even in such a case, the MESM needs to possess knowledge of management and maintenance of ME.

4.2.4. Proposed Measures to Assist MESMs

Safety and MESM enactment after the fifth revision of the medical law may be improved by a novel hospital intranet-based ME management system for medical safety and management [12] and a risk triage sheet for ME in safety assessment for medical staff and the ME company [21]. Before this revision of the law, there were few institutions that managed and maintain closed circulation infant incubators in their own hospital. However, CETs started performing such maintenance themselves because of this revision, which stated that a closed circulation infant incubator should be maintained. This is also useful for further education of staff and cost-effectiveness of maintenance activity [22]. These findings suggest that an MESM may contribute to patient and medical safety and to improve operation of a hospital. However, more than 30% of hospitals commented on the need for clarification of the current job description for MESMs. These comments suggest that criteria for MESMs are needed based on bed capacity for different clinical departments. There is considerable divergence in the roles and responsibilities of MESMs among medical institutions and it is difficult for one person to cover all the requirements. Therefore, each medical institution may need to appoint an operation manager underneath the MESM to address current dissatisfaction with ME management. It is difficult for institutions to cover all the requirements, but the first step for patient and medical safety would be to review the current equipment management and maintenance plan (i.e., maintenance schedule based on the operation rates of ME, quantity of ME, and number of CETs maintaining the equipment) and revise the plan to comply with the fifth revision of the medical law and enhance patient and staff safety.

5. CONCLUSION

Based on the current survey, we found that medical institutions have increased the number of types of ME maintained by CETs, the amount of maintenance, and in-service training on ME. However, there is still a shortage of staff for maintenance, and many institutions responded that the current level of ME management was unsatisfactory. MESMs were mostly CETs and physicians, and many hospitals used CETs as operation managers. Many survey respondents indicated that it is difficult for one person to cover all the requirements of MESM and that the level of responsibility is very high. Our study suggests that there is widespread dissatisfaction with the current situation and that there is a need to reconsider the approach to ME management.

ACKNOWLEDGEMENTS

We sincerely thank the hospitals that responded to the questionnaire.

CONFLICT OF INTEREST

The authors indicated no potential conflicts of interest.

REFERENCES

[1] Sakai J. Coping with the effects of aging medical equipment in National University Hospital Surgical Center. *Jpn Medical Instrumentation*. 1995, 65(9):461–465.

[2] Hirose M, Sato E, Kobayashi H. Establishment of safety management system for medical equipment. *Jpn Soc Intensive Care Med*. 2004, 11(2):89–96.

[3] Kumada K, Yoshida S, Shirai K, Toyoda I, Ogura S, Nakaguchi S, Nagata J, Fukuda A. Safety management of medical equipment for respiratory support, hemofiltration, pump systems and others. *ICU & CCU*. 2011, 35(4):317–321.

[4] Wang B, Rui T, Balar S. An estimate of patient incidents caused by medical equipment maintenance omissions. *Biomed Instrum Technol*. 2013, 47(1):84–91.

[5] Kuda T, Sato K, Hatakeyama N, Shibata O, Nakata S. Role of clinical engineers in malfunctions of medical instrumentation in the surgical operation center. *J Jpn Assoc Operating Room Technology*. 2011, 32(3):224–229.

[6] Kanai H. Clinical engineering in Japan and the Bill for the Clinical Engineering Technician Law. *Front Med Biol Eng*. 1989, 1(3):177–182.

[7] Watanabe S. Comprehensive management of medical equipments. *Jpn Medical Instrumentation*. 1990, 60(3):16–120.

[8] Watanabe S, Kitama M, Arisawa J, Arisawa H, Matsuzaki T, Saka T. Database server built with open source software for medical equipment management . IEICE Tech Rep. 2010, 110(354):41–45.

[9] Bliznakov Z, Pappous G, Bliznakova K, Pallikarakis N. Integrated software system for improving medical equipment management. *Biomed Instrum Technol*. 2003, 37(1):25–33.

[10] Cram, N., Computerized maintenance management systems: a review of available products. *J Clin Eng*. 1998, 23(3):169–179.

[11] Murakami K, Hayashi K, Takahashi K, Ueda K, Takao K, Takahashi M, Okada H, Sumi Y, Sato Y, Tao N, Aoki G, Sasaki A, Utsumi M, Kataoka K, Chida S. Development and use of the medical electronics device operation system to use in a ward. *Jpn Medical Instrumentation*. 2013, 83(3):293–297.

[12] Nakamura M, Hirano K, Moriuchi M. A novel medical-equipment management system(iMARC S)based on hospital intranet - In response to the fifth revision of the medical care act-. *Jpn Medical Instrumentation*. 2012, 82(4):309–314.

[13] Shimazaki K, Kamata M, Kato T, Amaki H. The maintenance management if the medical device with a personal digital assistant (PDA). *Jpn Medical Instrumentation*. 2010, 80(1):14–19.

[14] Castro L, Lefebre E, Lefebre AL. Adding intelligence to mobile asset management in hospitals: the true value of RFID. *J Med Syst*. 2013, 37:9963.

[15] Wen Y, Chao-Hsien, C, Zang L. The Adoption and Implementation of RFID Technologies in Healthcare: A Literature Review. *J Med Syst*. 2012, 36:3507–3525.

[16] Atarashi H, Tanaka K, Tamai H, Ohe K. Development and evaluation of a WiFi -based location detection system for medical equipment management. *Jpn Medical Instrumentation*. 2009, 79(6):373–381.

[17] Hirose M, Suzuki H, Kano T, Tobata H, Ono N. Investigation Report About management of medical devices. *Jpn Medical Instrumentation*. 2007, 77(5):340–345.

[18] Kawasaki T. An Action of the Japanese Clinical Engineer Society as the Medical Equipment Safety Manager. *Jpn Medical Instrumentation*. 2008, 78(3):143–155.

[19] Ishida K, Mamorita N, Hirose M, Shinbo T, Tsurutra H, Takeuchi A, Ikeda N. Survey of medical equipment safety managers since the revision of the Medical Service Law. *Jpn Hosp*. 2009, 28:87–91.

[20] Wang B, Rui T, Fedele J,Balar S, Alba T, Hertzler LW & Poplin B. Clinical Engineering Productivity and Staffing Revisited: How should it bemeasured and how can it be used? *J. Clin. Eng*. 2012, 37(4):135–145.

[21] Nosawa Y, Otuka Y, Okamoto M. Development of a risk triage sheet to quantify risks of medical equipments in pre-service safety assessment. *Jpn Medical Instrumentation*. 2013, 83(4):354–361.

[22] Miwa M, Nagae Y, Tamai H. Maintenance and management for closed incubators–in reference to amendment to Japanese medical care low-. *Jpn Medical Instrumentation*. 2012, 82(1):40–48.

APPENDIX. SURVEY QUESTIONS

Q1. Who responded to the questionnaire?
CET / Physician / Nurse / Clinical laboratory technologist / Clinical radiologist / Pharmacist / Desk worker / Other

Q2. Number of bed capacities

Q3. Type of hospital
Private medical corporation / Self-governing body hospital / public hospital (Red cross, mutual-aid) / Private university hospital / National and public university hospital / National hospital /

Q4. Does the hospital have a clinical engineering section?
Yes / No

Q5. How many pieces of medical equipment does clinical engineer manage and maintain?

Q6. What are the occupations of the present and past MESM?
Physician / Dentist / Pharmacist / Birth attendant / Nurse / dental hygienist / Clinical laboratory technologist / Clinical radiologist / Clinical Engineer

Q7. Does the hospital place operation managers beneath the MESM in each section or unit?
Yes / No

Q8. Work contents of MESM and operation manager
Practical operation of maintenance / Planning schedule of maintenance / Evaluation of work contents of maintenance / Planning and providing in-serve training program / Management of product documents / Gathering safety information regarding medical equipment from public administration and manufacturers, and reporting to manufacturer about an accident / Others

Q9. How many full-time clinical engineers responsible for maintenance does hospital employ?

Q10. How have the circumstances of medical equipment management changed?
(a) Quantity of ME
(b) Types of ME
(c) Cases of maintenance work
(d) Cases of in-serve training
(e) Employment of maintenance worker
Increased / Slightly increased / Unchanged / Slightly decreased / Decreased

Q11. Satisfaction level of medical equipment management
(a) Regarding people working on maintenance
(b) Attainment of instituted plans
Satisfied / Somewhat satisfied / Neutral / Somewhat dissatisfied / Dissatisfied

Q12. The number of people who are satisfied with the present ME maintenance situation

Q13. Thoughts on the responsibilities and roles of the MESM

MESM has too many responsibilities / One person cannot cover all of the MESM tasks required / Need to define the job of MESMs more clearly with respect to the number of beds and type of medical treatment / Difficult to perform both management and clinical works / Difficult to manage equipment outside a field of expertise / Need supporting national guideline for MESM / Others / No opinion