Healthcare Technology Management (HTM) by Japanese Clinical Engineers: The Importance of CEs in Hospitals in Japan

Jun Yoshioka, Keiko Fukuta, Hiroki Igeta, Takeshi Ifuku, and Takashi Honma

Abstract

Japanese clinical engineer (CE) is a significant and unique profession compared with other nations with its dual clinical and technology focus and national licensing. The CE system of licensing was established in May 1987 under the Clinical Engineers Act. CEs are required to complete 3 to 4 years in designated schools and pass a national examination. It is a professional medical position responsible for the operation and maintenance of life-support and non-life-support medical device systems under the direction of physicians. In Japan, CEs support and operate various life-support medical devices. Technology developments have led to significant improvements in performance, making devices easier to break and requiring specialized maintenance. Some of our healthcare technology management (HTM) initiatives include: 1. Rental equipment: oversee use and conduct in-house testing and repair, avoiding faulty units. 2. Ventilator maintenance: a multi-year track record of assessing and replacing defective parts in-house, contributing to prompt repairs and reduced costs. 3. Battery-equipped devices: created a more efficient system for charge management. 4. Intermittent pneumatic compression device dedicated tester: reducing the incidence of thromboses and embolism in patients.

Keywords

Japanese clinical engineer • National licensing
Healthcare technology management

J. Yoshioka (✉)
Clinical Engineering Services, Yamagata University Hospital, Yamagata, Japan
e-mail: jyoshioka@med.id.yamagata-u.ac.jp

J. Yoshioka · K. Fukuta · H. Igeta · T. Ifuku · T. Honma
International Exchange Committee, Japan Association for Clinical Engineers, Tokyo, Japan

1 Introduction

It is important to ensure appropriate quality control of higher risk medical equipment, such as mechanical ventilators and anesthesia machines [1–3]. In the past in Japan, doctors and nurses performed maintenance for ventilators [4], with faulty devices repaired by the distributor. However, since the late 1990s, clinical engineers—who have a certificate of completion and have met and completed established course requirements—now perform this maintenance. We would like to introduce the benefits of having CEs in the hospital, how they can reduce the exposure of potential harm to patients.

2 What Are Japanese Clinical Engineers

In Japan, Clinical Engineer is a paramedical profession. CEs are medical technologists who work in the clinical field in hospitals and maintain and operate various life-support medical devices such as mechanical ventilators, hemodialysis units, heart-lung machines, and other medical devices. The demand for CEs is high, and the number has increased steadily since the specialty was introduced in 1987. As of January 2018, there are approximately 40,000 CEs working in Japan. CEs are required to complete 3 to 4 years of study in designated schools and pass a national examination. CEs practice under the direction of doctors. The CE's familiarity with medical equipment allows them to train doctors and nurses in its best use, a critical element for avoiding user error.

3 Department of Clinical Engineering, Yamagata University Hospital

The CE department was created in our hospital in 2011. There are currently sixteen CEs working in a broad variety of clinical areas such as in operating rooms, dialysis room,

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cardiac catheterization room, ICU, HCU, NICU, emergency room and hospital wards. The main CE activities include extracorporeal circulation, blood purification, hyperbaric oxygenation, HTM, and education. We currently have a large number of devices—a total of 2100, including mechanical ventilators, anesthetic machine, hemodialysis, heart-lung machines, PCPS (percutaneous cardiopulmonary support), IABP (intra aortic balloon pumping), defibrillators, pacemakers, incubators, foot pumps, continuous low pressure suction units, infusion pumps, syringe pumps, patient monitoring, electric scalpels, and endoscope devices except for the radiological equipment.

4 Safety Management

How do you know if medical equipment is reliable, accurate, and safe? Maintaining this equipment is a key safety issue. The stage of technology development is a critical aspect of safety management.

- **Earlier**: During the 1980s, general-purpose medical equipment was in use, with a simpler operating principles and few circuit boards and/or sensors. The equipment was rugged and did not break down easily. Operator error accounted for most of the sudden malfunctions.
- **Present day**: However, over the last two decades, technology development has led to significant improvements in the high performance medical equipment. Modern critical care medical equipment has numerous CPU boards and sensors, and more failure points. Thus, increased specialized maintenance of medical equipment is necessary. In our hospital, medical equipment is maintained using specialized analyzers/test equipment for incubators, defibrillators, ventilators, infusion devices, external pacemakers, electrical safety, electrosurgery, and others.
- **Key CE services**: (1) Overseeing equipment utilization and performing in-house repairs has avoided the use of faulty rental units. (2) Replacing non-functioning parts in-house has contributed to prompt service response and reduced repair costs. (3) Use of specialized test equipment has contributed to the discovery of previously undetected malfunctions in the new generation of high performance medical equipment. The CE department has decreased medical equipment failure, lowering potentially harmful risks to patients. (4) However, proactive maintenance does not preclude or prevent the sudden problems that can occur in daily practice. Clinicians using medical equipment must continue to exercise vigilance and good clinical judgment in order to ensure patient safety during care delivery; CEs partner with them to lower risk.

5 The Benefits of Having Clinical Engineers

- Ventilator example: The involvement of CEs in maintaining ventilators has ensured safe management [5]. Mechanical ventilator failures expose patients to unacceptable risks and maintaining consistent ventilator safety is very important. We examined the usefulness of maintaining ventilators by CEs using a specialized analyzer.

Table 1 shows the year-to-year comparisons of inspection times, cases of suspected ventilator failure, number of ventilators, minor problems, and failures. Tests to verify device accuracy were performed 2,430 times during the period from January 2004 to December 2010. There were a total of 151 (0.07%) cases of suspected ventilator failure. The number of faulty ventilators was 90 (0.04%) for ventilator volume, 39 (0.02%) for oxygen concentration, and 22 (0.01%) for malfunctions.

Faulty ventilators were repaired by calibration and by replacing sensors, circuit boards, and other components. The number of ventilators in use has increased each year. However, minor problems during daily practice that need to be handled on the spot have been reduced because of after-use maintenance of ventilators by CEs. These minor problems included oxygen or flow sensor calibration as a result of an inability to maintain parameters within acceptable limits, start-up problems, dead batteries, breathing circuit settings, faulty alarms, etc. Major failures, which necessitated a change out of the ventilator, have been reduced because of after-use maintenance of ventilators by CEs.

Table 2 shows the details regarding failures and whether a ventilator was repaired in-house or was sent to a distributor. In our hospital, patients experienced no long-term squealer, deaths, or serious injuries associated with failure during this study period.

The use of the PTS-2000 calibration analyzer has contributed to the discovery of previously undetected malfunctions in the new generation of high-performance mechanical ventilators. In this way, evaluating ventilation and carrying out in-house repairs has proved to be effective for obviating the chance of renting faulty units. Clinical engineering has decreased medical device failure which exposes patients to potentially harmful risks.

The most important item should be the checking of mechanical ventilators by CEs. CEs are certainly specialists in medical devices, and their involvement in maintaining mechanical ventilators is logical for the hospital, prompt, and most importantly safe. CEs fill an essential role for the safe operation of mechanical ventilators, and, more importantly, the CEs technology provides safe maintenance for many hospitals.

Table 1 Year-to-year comparisons of inspection times, cases of suspected ventilator failure, number of ventilators, minor problems, and failures

Year	2004	2005	2006	2007	2008	2009	2010	Total
Inspection times	275	290	250	339	388	430	466	2430
Cases of suspected mechanical ventilators failure	11	9	13	28	28	28	34	151
•Ventilatory volume	0	0	5	21	18	20	26	90
•Oxygen concentration	5	5	3	5	9	6	7	39
•Malfunctions	6	4	5	2	1	2	2	22
Number of mechanical ventilators	15	18	21	2 4	28	3 0	30	–
Minor problems	62	60	49	47	25	10	12	265
Failures	17	11	5	3	0	4	0	40

Case of suspected mechanical ventilator failure: There failures were discovers by using the PTS-2000 calibrator at the time of after-use inspections
Minor problems and failures: The incidents of mechanical ventilator that occurred while in use in general wards or the ICU

Table 2 Details of mechanical ventilator failures

Faulty parts		Result of accuracy test		Repair		
				Successful calibrated	Parts exchanges	
Ventilatory volume	Flow sensor	Decrease in tidal volume	24	12	12	☆
		Increase in tidal volume	4	2	2	☆
		Calibration error/breakdown	62	–	62	☆
			90	14	76	
Oxygen concentration	Oxygen sensor	Decrease in oxygen concentration	6	3	3	☆
		Increase in oxygen concentration	32	6	27	☆
			39	9	30	
Malfunctions	Circuit board	Ventilation defects	10	–	10	○
	Flow trigger sensor	Auto triggering	1	–	1	○
	Pressure trigger board	Auto triggering	1	–	1	○
	Battery and filter	Weak battery/deteriorated filter	10	–	10	☆
			22	–	22	

☆In-house: Parts could be replaced in-house by CEs
○Distributor: When in-house repair by CEs was impossible due to a serious problem, the ventilator was sent to the distributor for repair

- Development of the VOLT BANK

We are developing a better system for more efficient charge management of battery-equipped medical equipment [6]. Battery-power in medical devices is often an important function for mobile devices, yet not always checked by users. The VOLT BANK (Fig. 1-TAKASHIN, Japan) was developed by our institution to address this concern.

A charge-control box was created with various functions, and a special rack was incorporated. In the 100 V cutoff function, when the batteries are fully charged, the equipment automatically turns off the power supply of 100 V, in the order that they finish charging.

A maximum of 36 medical devices can be simultaneously charged and stored. This rack was thought to enable construction of a safe, smoothly operating system for battery-equipped medical equipment and efficient battery-charge management that prevents overcharge and electrical discharge.

- Development of the IPCD tester

Inspection to ensure the safe use of devices is an essential part of the daily checks vital to safety in the clinical field. Only basic checks of external appearance and operation checks were possible during maintenance control of intermittent pneumatic compression devices until now, and no specific tester had been available. The vinyl tube that connects the device to pressurized sleeves worn on the lower limbs can break easily and ways to conduct a thorough leak check have been in demand. An intermittent pneumatic compression device tester (IPCD Tester: Fig. 2-TAKASHIN, Japan) was

Fig. 1 Volt Bank, construction of sage operating system and efficient battery-charge management for battery-equipped medical equipment

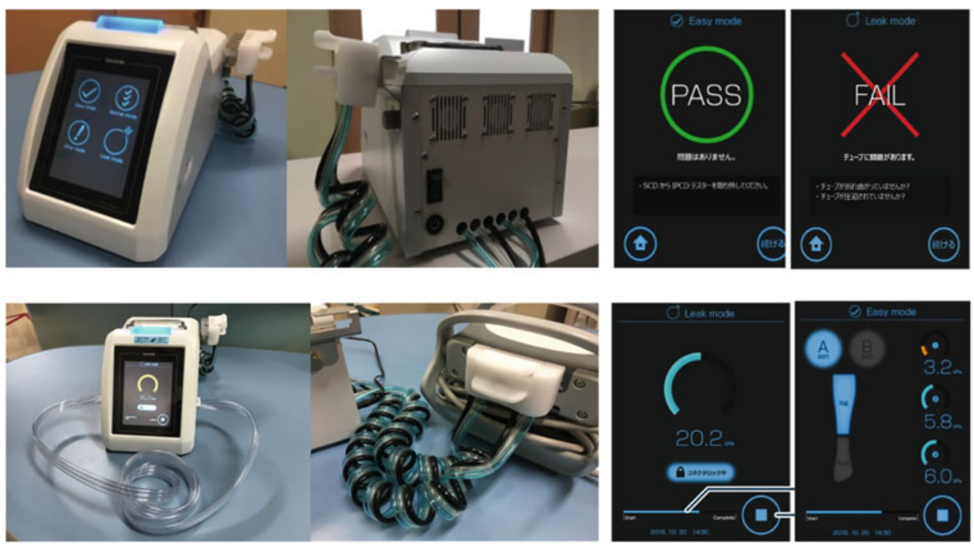

Fig. 2 IPDC tester

Fig. 3 Obtaining inspection results with high reliability by IPCD Tester

	Air pressure		System errors		Leak			
Pass	94		95				150	
Fail	5		4				48	
Location	In-house 2	Manufac-ture 3	Manufacture 2	2	In-house			
Dam-age parts					Connector 18		Tube 30	
Cause of damage	Air leak from air flow pas-sage	Compres-sor mal-function	Pressure trans-ducer malfunc-tion, Compres-sor malfunction	Un-known	Brea k 3	Crac k 15	Crac k 8	Pin-hole 22
Repair	Reconnected the air tube inside of SCD	Compres-sor Modu-lation2, Replace-ment 1	Pressure trans-ducer Calibura-tion1, Compres-sor Modula-tion1	Non				

co-developed and marketed in collaboration with a local company, and then applied to existing tests at our hospital [7]. This tester not only checks the air pressure value of the compressor (or "heart") and alarm function of the intermittent pneumatic compression device, but even checks the tube connector. Consequently, efficiency measurement, assessment of system errors, and testing of the easily broken sequential compression device (SCD) connector tube in intermittent pneumatic compression devices is now possible.

Introducing IPCD testers to existing tests allows detection and repair of issues in intermittent pneumatic compression devices. Lending out of broken devices can be avoided before it happens, thus reducing the incidence of thromboses and embolism in patients (Fig. 3).

Objects 99 intermittent pneumatic compression devices that is maintained by CEs at our hospital.

6 Conclusions

The combined user and maintenance role of CEs is unique in Japan. On one hand, as medical technologists operating high risk devices alongside clinicians, CEs decrease equipment user errors. On the other hand, the involvement of CEs in device maintenance demonstrably provides safer care delivery and cost-effective equipment management. Having these unique CE capabilities in hospitals also create value in other current and emerging aspects of safety management. In conclusion, clinical engineering in Japan has had a significant impact on improving patient safety.

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Conflict of Interest The authors declare that they have no conflict of interest.

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