

Technical aspects of management in the intensive care unit: A single center experience from a tertiary academic hospital

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Abstract

Background: Special technical issues arise in medical devices in intensive care units (ICU) that are related to their function and maintenance. This study explored the level of comfort of different ICU staff in dealing with selected equipment, the factors are associated with the staff's ease of adaptation of new technologies, and the role of technical support staff.

Methods: This is a single center cross-sectional questionnaire-based survey that was conducted in February

2018 and targeted nurses working in the ICUs of King Saud University Medical City (KSUMC) in Riyadh, Saudi Arabia.

Results: Among the 297 nurses who completed the survey, almost all of the respondents (99.3%) were aware of their ICU preventive equipment maintenance program. Most of the nurses received training on how to use infusion pumps (96.2%), cardiac monitoring systems (78.0%), and cardiac defibrillation devices (73.9%). Sixty nurses (20.2%) indicated that at least one super user was available for at least one device. About half of the staff reported one device whose user manual was available. Regarding updates on medical devices, most nurses reported they had no resource for the update.

Conclusions: The findings revealed an alarming need to address technical issues related to medical devices used in the ICU and to design a framework for the safe operation of medical devices based on international practices. It is necessary to empower the role of the super user and medical device clinical educator as well as optimize communication between the national regulatory body of medical devices and healthcare providers, especially those working in acute care areas.

Background

Intensive care units (ICUs) follow a multidisciplinary care model that ensures patients receive optimum care. The care environment in an ICU is complex, and an efficient workflow in this setting requires the knowledge and skills of the intensivist staff who work together to improve patient outcomes and safety.

In addition to relying on a multi-specialty approach to care, ICUs rely considerably on the most advanced technology. Medical devices, including ventilators, infusion pumps, and other consumables, provide an unprecedented opportunity to improve patient care and outcomes. [1] However, ICU staff may face challenges in safely operating, updating, and maintaining these devices. Additionally, there is the challenge of implementing guidelines to detect device misuse and report adverse events associated with the use of these devices to the appropriate authorities. [2] Thus, technical support teams should seek better recognition of user-friendly technologies to optimize patient care by properly managing technical issues related to different devices in ICUs.

In most ICUs, technical procedures are performed by various team members—most commonly by nursing staff. Although nurses' primary role is patient care, they are usually tasked with managing these technical issues. [3] Surprisingly, little has been described about the role of technical support staff in ICUs; these staff members are supposed to perform technical procedures, while medical and nursing staff provide medical care for critically ill patients. [4–6]

The objective of this work was to assess ICU healthcare workers' level of awareness of their roles and those of technical staff (biomedical engineers and technicians) in maintaining the safe operation of medical devices.

Specifically, this survey was conducted to 1) explore different ICUs staff's level of comfort in dealing with specific equipment in their work environment based on annex 1 of the German medical devices operation ordinance; 2) explore the factors associated with staff's ease of adaptation to new technologies—how ICU staff troubleshoot technical issues and how this process can be improved; and 3) determine whether the role of technical support staff is well-recognized and identify their level of involvement in the unit.

Methods

This study is a follow-up of a previously conducted research on the management of medical devices in the ICUs; the previous study was a single-center, cross-sectional questionnaire-based survey conducted in February 2018. [2] The research targeted nurses working in ICUs at King Saud University Medical City (KSUMC), Riyadh, Saudi Arabia. The required representative sample collected to ensure a 95% confidence and margin of error equal to 5% was composed of 218 nurses out of the 502 nurses working in the critical care units.

The survey (S1 Form) was distributed to all the critical care units of the hospital, including the Surgical ICU, Medical ICU, Pediatric ICU and Neonatal ICU. The nurses were invited to fill out the survey (electronic or paper-based) according to their preference.

The questionnaire was drafted by the authors based on a literature review of adverse events related to medical devices. A combination of evidence appraisals and expert opinions was used to design the questionnaire.

Electronic databases of MEDLINE and PubMed were searched for English language articles. Search terms included “medical,” “device,” “reporting,” “safety,” “usability,” and “adverse events OR critical care”. Potentially relevant articles were reviewed, and their reference lists were screened to identify other relevant articles. Next, four articles were used to design the questionnaire [8–11]. Then, a multidisciplinary team produced the final version of the questionnaire (Appendix I), which was reviewed by experts from the biomedical engineering department, nursing department, and critical care unit. A pilot survey was conducted in our department to assess the clarity of the questionnaire.

Ethics statement

Written informed consent was obtained from all participants. Participation was voluntary, and all participants were assured that their confidentiality would be protected. The Institutional Review Board of King Saud University granted permission to conduct this survey.

The questionnaire

The survey tool was a self-administered questionnaire consisting of three sections. The first section included demographic questions (age, gender, credentials, discipline, and working experience). The second part included questions that assessed respondents' overall comfort levels in dealing with various medical devices in the ICU. Participants were asked to rate their overall comfort levels in using different medical devices on a Likert-like scale from one to five. Additionally, they were asked whether they had received formal training in operating devices that are typically used in the critical care setting. Additionally, they were asked whether their unit had a designated super user and how they managed issues that arose with any of the devices. Finally, the third part was composed of questions that requested the participants to name the assigned person for certain procedures related to the medical devices in the ICU, such as equipment assembling, troubleshooting, and supply ordering, etc.

At the end, participants were requested to determine how do they receive updates regarding the different medical devices and if they faced an issue while operating these devices, how do they address it.

Statistical analysis

The non-parametric chi-square goodness-of-fit test was used to assess the statistical significance of the healthcare workers' perceived responsibility for troubleshooting medical devices assigned to different personnel. The test was performed under the assumption that healthcare workers would assign equal responsibility to every person as a posteriori hypothesis (expected) assumption when compared to the observed distribution.

Results

Demographic data

Two hundred ninety-seven nurses out of 502 nurses working in the critical care units of King Saud University Medical City responded to the survey, representing a response rate of 59%. The respondents were from different critical care disciplines: medical ICU (29.3%), surgical ICU (21.8%), Pediatric ICU (29.3%), and Neonatal ICU (19.5%). Most of the nurses had 6–10 years' working experience (26.3%), followed by those with 3–5 years' and more than 10 years' experience (24.9% each) (Table 1).

Table 1
 Respondents' demographic and professional characteristics

Variables	Frequency	Percentage
Gender		
Women	277	93.3
Men	20	6.7
Experience years		
1–2 years	71	23.9
3–5 years	74	24.9
6–10 years	78	26.3
> 10 years	74	24.9
Clinical Role		
Nurse	294	99.0
Head nurse	3	1.0
Discipline/working unit		
Medical ICU	87	29.3
Surgical ICU	65	21.8
Pediatric ICU	87	29.3
Neonatal ICU	58	19.5
Abbreviations: ICU, intensive care unit.		

Report on periodic preventative maintenance (PPM)

Most of the participants (99.3%) agreed that they were aware of their hospital's ICU preventive equipment maintenance program (Table 2). Approximately 95.5% of the nurses believed that the biomedical engineering unit was responsible for PPM in their units, and only 1.4% believed it was the responsibility of other staff members (physicians and vendors).

When asked to rate their comfort level on a Likert-type rating scale, the nurses had a high self-reported comfort level in dealing with equipment in their ICU (mean comfort level exceeding 4 out of 5 Likert points). As shown in Table 2, most nurses (96.2%) had received training on how to use infusion pumps, followed by cardiac monitoring systems (78.0%) and cardiac defibrillation devices (73.9%).

Super users

Sixty out of the 297 nurses (20.2%) indicated that at least one super user was available for at least one device (Table 2). Fifty-five percent indicated the existence of super users for infusion pumps, 63.3% for mechanical ventilators, 53.3% for cardiac monitors, 51.7% for electrocardiogram devices, and 48.3% for cardiac defibrillators.

User manual

Overall, 160 out of the nurses (53.9%) selected one device whose user manual was available. In most cases (89.6%), nurses indicated the availability of a user manual for infusion pumps, followed by that for mechanical ventilators (86.0%) and cardiac monitors (81.1%).

Table 2

Nurses' perceptions of periodic preventive maintenance and equipment training characteristics and factors

Questions	Frequency	Percentage
Are you aware of PPM for ICU equipment?		
Yes	295	99.3
No	2	0.7
Who is responsible for PPM in your unit?		
Nurses	28	9.5
Physicians	3	1.0
Biomedical engineers	280	95.2
Vendors	3	1.0
Other	4	1.4
Based on a 5-point rating scale, how comfortable are you in dealing with the following:		
Infusion pumps, mean (SD)		4.14 (1.1)
Mechanical ventilator, mean (SD)		4.21 (0.89)
Non-invasive BP monitoring, mean (SD)		4.6 (0.86)
Pulse oximeter, mean (SD)		4.74 (0.67)
ECG, mean (SD)		4.34 (1)
Defibrillator, mean (SD)		4.03 (1)
Please indicate if you were trained in using the equipment below (tick all that apply):		
Infusion pumps	254	96.2
Mechanical ventilator	159	60.2
Cardiac monitor	206	78.0
Electrocardiogram	121	45.8
Defibrillator	195	73.9
For each of the equipment listed below, do you have a super user? (n = 60)		
Infusion pumps	33	55.0
Mechanical ventilator	38	63.3
Abbreviations: BP, blood pressure; ECG, electrocardiogram; ICU, intensive care unit; PPM, periodic preventive maintenance; SD, standard deviation.		

Questions	Frequency	Percentage
Cardiac monitor	32	53.3
Electrocardiogram	31	51.7
Defibrillator	29	48.3
For each of the equipment listed below, do you have a user manual? (n = 164)		
Infusion pumps	147	89.6
Mechanical ventilator	141	86.0
Cardiac monitor	133	81.1
Electrocardiogram	105	64.0
Defibrillator	127	77.4
Abbreviations: BP, blood pressure; ECG, electrocardiogram; ICU, intensive care unit; PPM, periodic preventive maintenance; SD, standard deviation.		

Source of updates

The nurses' responses varied regarding the source of updates for the indicated devices, as shown in Table 3. In most cases, the nurses reported they had no resource for updates about the medical devices in their units.

Table 3
Nurses' resources for further information on medical equipment

Variables	No Resource	Head Nurse	Senior Nurses	Biomedical Engineer	Company
Infusion pump	246 (82.8%)	3 (1.0%)	12 (4.0%)	3 (1.0%)	33 (11.0%)
Mechanical ventilator	249 (83.8%)	4 (1.3%)	17 (5.7%)	0 (0.0%)	27 (9.1%)
Cardiac monitor	255 (85.9%)	1 (0.3%)	21 (7.1%)	0 (0.0%)	20 (6.7%)
Electrocardiogram	262 (88.2%)	1 (0.3%)	15 (5.1%)	0 (0.0%)	19 (6.4%)
Defibrillator	260 (87.5%)	0 (0.0%)	13 (4.4%)	1 (0.3%)	23 (7.7%)

Roles and responsibilities

Regarding the management and maintenance of medical equipment, more than half of the respondents (52.1%) indicated that biomedical engineers were responsible for assembling the equipment ($p < 0.001$).

Most respondents (66%) also reported that biomedical engineers were responsible for troubleshooting the equipment ($p < 0.001$; Table 4).

Regarding the ordering of medical supplies, 64.5% of the nurses responded that it was the head nurse's responsibility. Conversely, most nurses (86.3%) reported that biomedical engineers were responsible for maintaining and calibrating medical devices ($p < 0.001$; Table 4).

A significant proportion of nurses (78.4%) cited bedside nurses as those responsible for sterilizing and processing recyclable equipment ($p < 0.001$; Table 4). On the contrary, most nurses (58%) responded that biomedical engineers were responsible for the disposal of non-recyclable items ($p < 0.001$; Table 4).

Table 4
Nurses' perceived responsibilities for various medical equipment maintenance processes and transactions

Variables	Nurses	Head Nurses	Physicians	Biomedical Engineers	Manufacturers	p-value
Equipment assembly	66 (23.2%)	13 (4.6%)	7 (2.5%)	148 (52.1%)	50 (16.6%)	< 0.001
Troubleshooting equipment	76 (26.6%)	1 (0.3%)	7 (2.4%)	190 (66.0%)	3 (1.0%)	< 0.001
Ordering supplies	28 (9.4%)	182 (64.5%)	11 (3.5%)	50 (17.7%)	7 (2.5%)	< 0.001
Maintenance and device calibration	24 (8.4%)	4 (1.4%)	4 (1.4%)	246 (86.3%)	4 (1.4%)	< 0.001
Sterilization of recyclables	211 (78.4%)	4 (1.4%)	1 (.4%)	44 (16.4%)	7 (2.6%)	< 0.001
Disposal of non-recyclable items	74 (26.3%)	31 (11.0%)	0 (0.0%)	163 (58%)	13 (4.6%)	< 0.001

Discussion

The technical relationship between users, medical devices, and biomedical engineering staff in Saudi Arabia has been standardized and considered part of the accreditation requirements for healthcare institutions. These accreditation requirements have been issued under the umbrella of the Saudi Arabia Central Board for Accreditation of Healthcare Institutions (CBAHI), [3] which also ensures that healthcare institutions comply with their requirements.

Standards for safe operation

Although the CBAHI has certain requirements for the safety of medical devices, these requirements are not considered among the Essential Safety Requirements (ESR). [7] In contrast to other international

regulations, such as in those in the US and Germany, these requirements are obligatory, regardless of the overall weighted scoring criteria. [7]

One aspect addressed in the CBAHI standard is ensuring that hospitals have policies and procedures that regulate the management of medical devices. Within this requirement, the role and responsibilities assigned to each member of the clinical and technical staff are not well explained. However, the standard necessitates in section HR.7.1.3 that newcomers should attend an orientation program before working independently. [3] The content of the orientation program should include the safe operation of medical devices and troubleshooting.

Another factor that contributes massively to the safe operation of medical devices is the reporting of adverse medical device events. According to the CBAHI standards, healthcare workers (HCWs) should be aware of the official national requirements and channels for reporting adverse events. Here in Saudi Arabia, the national reporting system for adverse events related to medical devices is a web-based electronic system governed by the Saudi Food and Drug Authority (SFDA). [8–10]

Periodic preventative maintenance (PPM) and procedures related to medical devices

The responsibilities for the different tasks related to medical devices and equipment, such as PPM, sterilization, disposal of non-recyclable items, and ordering supplies, were well recognized and coordinated between the different team members from the ICUs and the biomedical engineering department, as indicated in the respondents' answers. Of note is that most of the respondents were aware of their roles and that of the biomedical engineering department. Such communication and multidisciplinary team work are important to optimize the management of medical devices in ICUs. [11]

It would be helpful to create a computer-based inventory system of all ICU devices accessible to all departments involved in the safe handling, processing, and managing of medical devices within healthcare facilities. Such a system would lead the multidisciplinary effort to maintain the safety and traceability of medical devices from all aspects.

The system can include educating users on the utilization and provision of checklists. Additionally, it can help the staff determine when PPM is needed and enhance the technical follow-up of devices, maintenance and repair logs, and the ability to promptly provide users with replacement devices, as well as provide criteria to decide when a device should be discarded.

Existence of super users

The HCWs indicated that when they want to learn more about a medical device within their unit, they tend to contact the device manufacturer first, followed by super users. The majority indicated that their units had no device "super users," and when they are occasionally present, their specific role as super user is not defined. This finding highlights the need for the official assignment of a super user for each device type or model in every unit. The super user could solve issues faced by the medical staff by leading all

aspects related to the use and operation of the device, as well as mentoring and training other users in-house.

The role of the super user, as identified in the German Medical Devices Operation Ordinance Medical Devices Clinical Educator, [7] is crucial for different aspects related to the safe operation of the medical devices assigned to the super-user. These obligations include attending training sessions on the safe operation of these medical devices that qualify the super user to train other users within the healthcare institution, organizing training on the use of the medical devices for other HCWs, documenting all the activities related to the medical devices, assuring the availability of the IFU of the medical devices, and monitoring PPM compliance.

Other roles for the super user might include organizing discussions to address safety issues regarding the operation of these medical devices with the users, competent authority officers (such as the SFDA), the manufacturer, the biomedical engineering department, and other departments involved in the operation of these medical devices (such as infection control). Super users also support the competent authority officer in preparing procedures for reporting adverse events, applying recall procedures for medical devices, and facilitating investigations.

Responsibilities and role of technical staff and troubleshooting

Any technical error encountered during the use of a medical device could have a highly negative impact on the safety of the patient or user. This survey found that 8% of respondents tended to reboot the system immediately once the alarm went off as the first step, 32% considered rebooting the device as a second step, and 22% considered it as the third step.

Ideally, when the alarm on a medical device goes off, the typical action is for users to respond and manage it according to the procedure standards they learned during training for that specific medical device. If they fail to identify and resolve the issue, they should consult the assigned super user. If the issue persists, they should contact the biomedical engineering department and then the manufacturer to manage it properly. It is risky to attempt to reboot and reuse the device when it starts functioning again because rebooting could keep any failure latent, which could result in a serious adverse event if the issue is not identified and managed properly.

Risk information communication

Most of our respondents relied heavily on the manufacturer's feedback for updates on the risks related to medical devices. A small proportion relied on their colleagues and the medical literature to get updates on the risks related to these devices. Of note is that only six respondents (2%) considered the SFDA to be a source of information about the risk of medical devices. This low percentage could be due to a lack of awareness about the role of the SFDA as a source of medical device risk information and recalls. [2] The apparent lack of knowledge among the respondents could also be due to a lack of communication between the SFDA and healthcare providers.

Conclusions

This study highlights the need to design a framework for the safe operation of medical devices based on international practices. In addition to empowering the role of the super user and clinical medical device educator, it is essential to optimize communication between the national regulatory body of medical devices and healthcare providers, especially those working in acute care areas.

Abbreviations

BP: blood pressure

CBAHI: Central Board for Accreditation of Healthcare Institutes

ECG: electrocardiogram

HCW: Healthcare Worker

ICU: intensive care unit

IFU: Instructions For Use

KSUMC: King Saud University Medical City

PPM: periodic preventive maintenance

SD: standard deviation.

SFDA: Saudi Food & Drug Authority

Declarations

Ethics approval and consent to participate: Written informed consent was obtained from all participants. Participation was voluntary, and all participants were assured that their confidentiality would be protected. The Institutional Review Board of King Saud University granted permission to conduct this survey.

Consent for publication: Not applicable.

Availability of data and material: All data generated or analysed during this study are included in this published article.

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Authors' contributions:

- FA: Conceptualization, Formal analysis, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing
- MT: Conceptualization, Methodology, Supervision, Writing – original draft, Writing – review & editing.
- AA: Conceptualization, Methodology, Supervision, Writing – original draft, Writing – review & editing.
- SG: Conceptualization, Data curation
- HI: Conceptualization, Data curation, Investigation
- OA: Resources, Software, Visualization, Conceptualization, Formal analysis, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing

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