Upravljanje medicinskim uređajima u Objedinjenom hitnom bolničkom prijemu

Medical device management in the Emergency department

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Sažetak

Objedinjeni hitni bolnički prijem ustrojstvena je jedinica za prijem hitnih bolesnika u kojoj se provode trijaža, dijagnostički i terapijski postupci. Kako bi se postigao učinkovit odgovor u hitnim situacijama, neophodni su odgovarajući i ispravni medicinski uređaji. Medicinski uređaji koji su prema Pravilniku o minimalnim uvjetima za obavljanje djelatnosti hitne medicine potrebni za rad u hitnoj službi sljedeći su: aspirator, defibrilator, EKG uređaj, glukometar, infuzomat, perfuzor, kapnometar i transportni respirator. Medicinski uređaji doprinose učinkovitosti i poboljšanju kvalitete zdravstvene skrbi. Uređaj je klinički učinkovit ako se njime pravilno rukuje prema uputama proizvođača. Održavanje medicinskih uređaja važno je u svrhu smanjenja troškova bolesnika, smanjenja nezadovoljstva bolesnika, pravodobnog liječenja bolesnika i smanjenja smrtnosti tijekom skrbi. Sigurnost bolesnika i zdravstvenog osoblja ne smije biti ugrožena. Rizici povezani s korištenjem medicinskih uređaja moraju se minimizirati. Medicinske sestre trebaju uspostaviti proces upravljanja medicinskim uređajima i osigurati da je uređaj prikladan, da se koristi u skladu s tvorničkim uputama te da se održava u sigurnom stanju. Čest su uzrok pogrešaka nedostaci medicinske opreme u dizajnu, pogrešno rukovanje i kvar uređaja. Medicinske sestre u Objedinjenom hitnom prijemu glavni su korisnici medicinskih uređaja. Moraju biti upoznate s načinom korištenja medicinskih uređaja kako bi se smanjila mogućnost pogrešaka tijekom njihove primjene i kako bi se prevenirale moguće komplikacije koje utječu na sigurnost bolesnika.

Ključne riječi: medicinski uređaji, održavanje, objedinjeni hitni bolnički prijem, medicinska sestra

Kratak naslov: Medicinski uređaji u hitnom prijemu

Abstract

The Emergency department is an organizational unit for the admission of emergency patients, where triage, diagnostic and therapeutic procedures are carried out. Suitable and functioning medical devices are essential for the achievement of an effective response in emergencies. According to the Ordinance on the minimum conditions for the performance of emergency medical services, medical devices required for work in the emergency service include an aspirator, a defibrillator, an ECG device, a glucometer, an infusion pump, a perfusion device, a capnometer, and a transportable ventilator. Medical devices contribute to the efficiency and improvement of the quality of health care. A device is clinically effective when handled correctly, according to the manufacturer's instructions. Maintenance of medical devices is important for lowering patient costs, reduction of patient dissatisfaction, timely treatment of patients, and mortality reduction during care. The safety of patients and medical staff must not be endangered. Risks associated with the use of medical devices must be minimized. Nurses must establish a management process for medical devices and ensure that a device is suitable and used in accordance with the manufacturer's instructions, and maintained in a safe condition. Common causes of errors include design flaws in medical equipment, operating errors, and device failure. Nurses in the Emergency department are the primary users of medical devices. They must be familiar with the use of medical devices in order to reduce the possibility of an error during their use and to prevent possible complications that could affect patient safety.

Keywords: medical devices, maintenance, Emergency department, nurse

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Uvod

Hitna skrb vrlo je bitna komponenta zdravstvenog sustava. Ključna je za osiguravanje pristupačne i visokokvalitetne skrbi. Cjelovit je sustav s međuovisnim komponentama. Svaka je komponenta važna, ali sve one moraju biti povezane da bi imale trajan učinak na zdravlje ljudi. Kvalificirano i motivirano osoblje, odgovarajuće zalihe materijala, lijekovi, oprema, koordinacija i upravljanje orijentirani na potrebe bolesnika doprinose djelotvornosti te smanjenju smrti i invaliditeta. Objedinjeni hitni bolnički prijemi (OHBP) jedinstvene su ustrojstvene jedinice za prijem hitnih bolesnika s većinom prostorija potrebnih za obradu i skrb o bolesnicima i za zdravstvene radnike u kojima se obavlja zdravstve-

Introduction

Emergency care is an important component of the health care system. It has a pivotal role in ensuring accessible and high-quality health care. It is an integrated system with interrelated components. Every component is important, but they must all cooperate in order to have a lasting impact on a patient's health. Qualified and motivated personnel, an adequate supply of materials, drugs, and equipment, as well as coordination and management oriented to patient's needs all contribute to its effectiveness and a reduction of death and disability. Emergency departments (UEAD) are unique organizational units for emergency patient admittance that are equipped with rooms necessary for the

na djelatnost hitne medicine u jednom zajedničkom prostoru [1].

U OHBP-u provode se trijaža, pregledi, dijagnostički postupci i liječenje. Kako bi se uspostavio učinkovit odgovor u hitnim slučajevima, moraju biti dostupne odgovarajuća oprema i ispravni medicinski uređaji. Medicinska je oprema važna komponenta zdravstvenog sustava i predstavlja alat koji medicinske sestre koriste za prevenciju, dijagnosticiranje, praćenje i liječenje bolesti, kao i tijekom rehabilitacije. Nedostatak medicinske opreme, bilo zbog nedostupnosti ili lošeg funkcioniranja, prepreka je u pružanju kvalitetne skrbi. Svjetska zdravstvena organizacija (SZO) procjenjuje da između 50 – 80 % medicinske opreme u zemljama u razvoju ne funkcionira te da nedostaju sustavi procjene tehnologija i regulatorne kontrole koji bi spriječili uvoz medicinske opreme loše kvalitete [2].

Pružanje zdravstvenih usluga ovisi o dostupnosti, prikladnosti, pristupačnosti i prihvatljivosti medicinskih uređaja [3]. Nepostojanje sigurnih, učinkovitih i dobro funkcionirajućih medicinskih uređaja i opreme narušava pružanje zdravstvenih usluga, dovodi do loših ishoda kod bolesnika te predstavlja znatne rizike za zdravstveni sustav i bolesnikovu sigurnost.

Svjetska zdravstvena organizacija (SZO) definira medicinski uređaj kao predmet, instrument, aparat ili stroj koji se koristi u prevenciji, dijagnostici ili liječenju bolesti, ili za otkrivanje, mjerenje, obnavljanje, ispravljanje ili modificiranje strukture ili funkcije tijela u neke zdravstvene svrhe [4].

Prema Pravilniku o minimalnim uvjetima u pogledu prostora, radnika i medicinsko-tehničke opreme za obavljanje djelatnosti hitne medicine, medicinski uređaji potrebni za rad u hitnoj službi sljedeći su: aspirator, defibrilator, EKG uređaj, glukometar, infuzomat i perfuzor, kapnometar i transportni respirator [5].

Održavanje medicinskih uređaja

Medicinska oprema značajno pridonosi učinkovitosti i poboljšanju kvalitete zdravstvenih usluga. Svaki medicinski proizvod dizajniran je uzimajući u obzir sigurnost i performanse tako da se njegovo namjeravano djelovanje izvodi bez nedostataka. Kada se medicinskim uređajem pravilno rukuje prema uputama proizvođača, on proizvodi učinak koji se od uređaja očekuje u skladu s proizvođačem i zdravstvenim stanjem te je proglašen klinički učinkovitim. Održavanje medicinske opreme važno je za smanjenje troškova otpreme, smanjenje nezadovoljstva bolesnika, pravodobno liječenje bolesnika te smanjenje smrtnosti i rizika tijekom skrbi za bolesnike. Obično se mnogo više novca troši na održavanje opreme nego na njezinu nabavu [6]. Održavanje je definirano kao svaka radnja koja pomaže bolnicama da pruže odgovarajuću razinu usluge i da zaštite ili promiču učinak svoje opreme kako bi se rad učinkovito provodio.

Patil i sur. u svom su istraživanju utvrdili da gotovo 60 % ukupnih troškova bolnice uključuje medicinsku opremu [7]. Wang i sur. pokazali su da je najčešći uzrok zastoja medicinske opreme loše održavanje, planiranje i upravljanje opremom [8]. Mahfoud i sur. pokazuju da se gotovo 1 % ukutreatment and care of patients, as well as rooms for health workers, where emergency medical activities are performed in one common space [1].

Inside the Emergency department procedures of triage, examination, as well as diagnostic procedures and treatment are conducted. To establish an effective response in emergencies, suitable and functioning medical devices must be available. Medical devices are an important component of the health care system and a tool that nurses use to prevent, diagnose, follow, and treat illnesses, as well as during therapy. A lack of medical equipment, whether due to unavailability or poor functioning, is an obstacle to the provision of quality care. The World Health Organization (WHO) estimates that between 50 and 80% of medical equipment in developing countries are not in working order, and that technology assessment and regulatory control systems that would prevent the import of poor-quality medical equipment are nonexistent [2].

The provision of health services depends on the availability, suitability, accessibility, and acceptance of medical devices [3]. The nonexistence of safe, efficient, and functioning medical devices and equipment disrupts the provision of healthcare services, leads to poorer patient outcomes, and poses significant risks to the healthcare system and patient safety.

The World Health Organization (WHO) defines a medical device as an object, instrument, apparatus, or machine used in the prevention, diagnosis, or treatment of disease or illness, or to detect, measure, restore, correct, or modify the structure or function of the body for some health purpose [4].

According to the Ordinance on the minimum conditions regarding space, workers, and medical-technical devices for the performance of emergency medical services, medical devices required for work in the emergency service include an aspirator, a defibrillator, an ECG device, a glucometer, an infusion pump and perfusion device, a capnometer and a transportable ventilator [5].

Medical device maintenance

Medical equipment significantly contributes to the efficiency and improvement of the quality of healthcare services. Every medical product is designed considering its safety and performance so that it performs the intended action without shortcomings. When a medical device is handled properly according to the manufacturer's instructions, it produces the effect expected of the device according to the manufacturer's intention and the medical condition, and is declared clinically effective. Maintenance of medical equipment is important for reducing shipping costs and patient dissatisfaction, timely treatment of patients, and reducing mortality and risk during patient care. Usually, more money is spent on equipment maintenance, than on its acquisition [6]. Maintenance is defined as any action that helps hospitals provide an adequate level of service and protect or promote the performance of the equipment so that work can be carried out effectively.

Patil et al. have determined in their study that almost 60% of a hospital's total costs involve medical equipment [7].

pnog bolničkog proračuna troši na održavanje medicinskih uređaja [9].

Medicinska oprema ima značajnu ulogu u bolničkom sustavu, stoga su kupnja, održavanje i zamjena medicinske opreme ključni čimbenici u zdravstvenim ustanovama za provedbu zdravstvene skrbi. Dakle, da bi se osigurala kvaliteta medicinskih uređaja za provođenje zdravstvene skrbi, imperativ je procjena sigurnosti korištenja i upravljanja održavanjem u zdravstvenim ustanovama. Da bi postigle ove ciljeve, zdravstvene ustanove moraju imati razvijene kontrolne liste za procjenu koje identificiraju status izvedbe održavanja medicinske opreme. Za medicinske je sestre to bitno ne samo za poboljšanje kvalitete zdravstvene skrbi već i za predviđanje rizika povezanih s iznenadnim kvarovima medicinskih uređaja.

Medicinski proizvod treba biti osmišljen i razvijen osiguravajući da:

- su svi rizici povezani s korištenjem uređaja kompatibilni s visokom razinom zdravlja i sigurnosti;
- kliničko stanje ili sigurnost bolesnika, ili zdravlje i sigurnost zdravstvenog osoblja ili bilo koje druge osobe neće biti ugroženo u okolnostima i ciljevima kojima je uređaj namijenjen;
- osnovni koncept u dizajnu i razvoju medicinskog proizvoda je njegova sigurnost [10].

Uloga proizvođača

Proizvođač je odgovoran za rad medicinskog uređaja ako se isti koristi u skladu s njegovom namjenom. Kod uporabe medicinskih uređaja uvijek postoji rizik koji se može definirati kao kombinacija vjerojatnosti nastanka neželjenog događaja i težine neželjenog događaja. Proizvođač mora upotrebljavati kontrole dizajna i postupke upravljanja rizikom da bi osigurao da je medicinski uređaj pravilno dizajniran, razvijen i korišten prema indikacijama kako bi se osigurala njegova sigurnost i učinkovitost. Prema smjernicama, kontrola rizika proces je odlučivanja na temelju kojeg su poduzete određene mjere za umanjivanje rizika do određene razine ili njihovu potpunu eliminaciju [10]. Za svaki medicinski uređaj proizvođač treba provjeriti jesu li potrebne mjere smanjenja rizika za svaku opasnu situaciju, a ako se rizici pojave, tada ih treba kontrolirati u prihvatljivim granicama primjenom aktivnosti kontrole rizika. Za proizvođače je bitno identificirati sve potencijalne opasnosti povezane s namjeravanom uporabom medicinskog uređaja, izračunati rizike povezane sa svakom opasnom situacijom i pokazati da su poduzeli sve moguće mjere za smanjenje rizika povezanog s medicinskim uređajem koji oni proizvode. Također treba spomenuti poštivanje bitnih načela sigurnosti i učinkovitosti proizvedenog medicinskog proizvoda.

Medicinski uređaji dizajnirani su i proizvedeni sa specifičnom i predviđenom namjenom, odnosno za poboljšanje kvalitete života bolesnika i njihovu sigurnost. Da bi se to postiglo, medicinski uređaji moraju biti jednostavni za rukovanje i funkcionirati kako je predviđeno u uputama proizvođača bez ugrožavanja sigurnosti bolesnika, korisnika ili kliničkog stanja bolesnika, stoga medicinski proizvodi mo-

Wang et al. have shown that the most common cause of medical equipment downtime is poor equipment maintenance, planning, and management [8]. Mahfoud et al. show that almost 1% of the total hospital budget is spent on medical device maintenance costs [9].

Medical equipment plays a significant role in the hospital system; therefore the purchase, maintenance and replacement of medical equipment are key healthcare provision factors in healthcare facilities. Therefore, to ensure the quality of medical devices for the implementation of healthcare, it is imperative to assess the safety of using maintenance management in healthcare facilities. To achieve these goals, healthcare facilities must use developed assessment checklists that identify the status of medical equipment maintenance. For nurses, this is of utmost importance, not only for improving the quality of healthcare but also for predicting the risks associated with sudden failures of medical devices.

A medical product should be designed and developed to ensure that:

- all risks associated with the use of the device are compatible with a high level of health and safety,
- the clinical condition or safety of the patient, or the health and safety of health care personnel or any other person will not be endangered in the circumstances and purposes for which the device is intended,
- the basic concept in the design and development of a medical device is its safety [10].

Role of the manufacturer

The manufacturer is responsible for the operation of the medical device when the device is used according to its intended purpose. When using medical devices, there is always a risk that can be defined as a combination of the probability of an adverse event and the severity of the adverse event. The manufacturer must use design controls and risk management procedures to ensure that the medical device is properly designed, developed, and used as indicated to ensure its safety and effectiveness. According to the guidelines, risk control is a decision-making process based on which certain measures are taken to reduce risks to a certain level or eliminate them completely [10]. For each medical device, the manufacturer should state whether risk reduction measures are required for each hazardous situation, and if risks occur, then they should be controlled within acceptable limits by applying risk control activities. Manufacturers need to identify all potential hazards associated with the intended use of the medical device, calculate the risks associated with each hazardous situation, and demonstrate that they have taken all possible measures to reduce the risk associated with the medical device they manufacture. It should also be mentioned that essential principles of safety and effectiveness of the manufactured medical product must be respected.

Medical devices are designed and manufactured with a specific and intended purpose, i. e. to improve the patients' quality of life and safety. To achieve this, medical devices must be easy to handle, and they must function as desi-

raju biti u skladu sa standardima koje postavljaju bitna načela sigurnosti i izvedbe.

Pogreške u radu s medicinskim uređajima

Upravljanje održavanjem medicinskih uređaja ključno je da bi se osiguralo da uređaj radi u skladu sa specifikacijama proizvođača i jamči sigurnost bolesnika i zdravstvenog osoblja. Neispravnost medicinske opreme može utjecati na učinkovitost zdravstvenih usluga te uzrokovati teške ozljede bolesnika i štetu okolišu.

Proces upravljanja medicinskim uređajima osigurava da se rizici povezani s korištenjem medicinske opreme minimiziraju. Slijedom navedenog, odgovorne bi osobe trebale uspostaviti proces upravljanja medicinskim uređajima i pregledati ih da bi osigurale prikladnost medicinske opreme, korištenje u skladu s tvorničkim uputama za rad te održavanje u sigurnom i pouzdanom stanju [8].

Rizici povezani s medicinskim tehnologijama mogu se klasificirati s obzirom na čimbenike okoliša, ljudske čimbenike i tehnološke čimbenike. U svojoj studiji koja razmatra ljudske čimbenike u sigurnosti bolesnika, Ross raspravlja o važnosti latentnih i aktivnih čimbenika. Latentni se čimbenici više odnose na organizacijske ili vanjske komponente, dok se aktivni čimbenici mogu pripisati djelovanju pojedinaca, a mogu uključivati korištenje ispravnog uređaja, ali njegovu neispravnu upotrebu [11].

Iako medicinski uređaji poboljšavaju učinkovitost zdravstvene skrbi, smanjuju troškove, povećavaju kvalitetu skrbi i promiču sigurnost, tijekom njihova korištenja može doći do pogrešaka i neželjenih događaja. Prednosti medicinskih uređaja ne ostvaruju se zbog sljedećeg:

- neadekvatnog održavanja;
- neadekvatnog plana za implementaciju tehnologije u praksu;
- lošeg tehnološkog dizajna koji ne uzima u obzir ljudske faktore i ergonomska načela;
- lošeg tehnološkog sučelja [10].

Medicinski nedostaci i nedostaci opreme u dizajnu, pogrešno rukovanje, korisničke pogreške i kvar česti su uzroci pogrešaka. Pogreške zdravstvenog osoblja tijekom korištenja medicinskih uređaja često se mogu pripisati:

- razlikama u funkciji između uređaja različitih proizvođača;
- neadekvatnom testiranju;
- nedostatku standardizacije;
- lošem održavanju [12].

Ako dođe do kvara uređaja, medicinske sestre trebaju odmah ukloniti medicinski uređaj iz upotrebe, označiti ga naljepnicom koja opisuje problem i prijaviti incident odgovornoj osobi koja je dužna osigurati popravak ili zamjenu uređaja ako ga nije moguće popraviti. Proizvođači imaju testove i metode koji mogu otkriti nedostatke u njihovim uređajima.

gnated in the manufacturer's instructions without compromising the safety of the patient, the user, or the patient's clinical condition. Therefore, medical devices must comply with and meet the standards set by the essential principles of safety and performance.

Mistakes in the operation of medical devices

Medical device maintenance management is essential to ensure that the device performs according to the manufacturer's specifications and guarantees the safety of patients and healthcare personnel. Malfunctioning medical equipment can affect the efficiency of health services and cause serious injuries to patients and damage to the environment.

The medical device management process ensures that the risks associated with the use of medical equipment are minimized. Therefore, the persons responsible should establish a medical device management process and review it to ensure that the medical equipment is suitable, used in accordance with the manufacturer's operating instructions, and maintained in a safe and reliable condition [8].

Risks associated with medical technologies can be classified concerning environmental factors, human factors, and technological factors. In study researching human factors in patient safety, Ross discusses the importance of latent and active factors. Latent factors refer mostly to organizational or external components, while active factors can be attributed to the actions of individuals and may include the use of the correct device but used incorrectly [11].

Although medical devices improve the efficiency of healthcare, reduce costs, increase the quality of care, and promote safety, errors, and adverse events can occur during their use. Benefits from medical devices are not realized due to the following:

- inadequate maintenance
- inadequate plans for the practical implementation of technology
- poor technological design that does not take human factors and ergonomic principles into account
- poor technological interface [10].

Medical shortcomings and equipment design flaws, mishandling, user error, and malfunction are common causes of errors. Errors by healthcare personnel during the use of medical devices can often be attributed to:

- functional differences between devices from different manufacturers
- inadequate testing
- lack of standardization
- poor maintenance [12].

If a device malfunctions, nurses should immediately remove the medical device from use, label it with a label describing the problem, and report the incident to a person responsible for ensuring that the device is repaired or replaced if it cannot be repaired. Manufacturers provide testing and other methods for finding flaws in their devices.

Upravljanje kvalitetom

Implementacija učinkovitog sustava upravljanja kvalitetom oduvijek se smatrala glavnom metodom proizvođača za održavanje i poboljšanje kvalitete svojih proizvoda i usluga. Globalno, mnoga regulatorna tijela uključuju sustav upravljanja kvalitetom kao jedan od obveznih zahtjeva za regulatornu kontrolu visokorizičnih medicinskih proizvoda [12].

Standardi su u osnovi preporučeni procesi koje su razvili stručnjaci za predmet s ciljem opisivanja najboljeg mogućeg načina za postizanje krajnjeg cilja. Na primjer, standardi upravljanja kvalitetom osmišljeni su za poboljšanje učinkovitosti i izbjegavanje kvarova proizvoda. Slično, standardi upravljanja rizicima osmišljeni su da bi pomogli organizacijama u planiranju neočekivanih događaja i osigurali kontinuitet poslovanja. Ovo su samo dva uobičajena primjera brojnih standarda primjene za proizvođače medicinskih uređaja.

Međunarodna organizacija za standardizaciju (ISO) postavlja globalne standarde za kvalitetu i upravljanje rizicima za širok raspon proizvoda i poslovanja. Isto tako, Međunarodna elektrotehnička komisija (IEC) postavlja međunarodne standarde za sve električne, elektroničke i srodne tehnologije. Općenito, ISO se koncentrira na kontrole materijala i procesa, a IEC je usmjeren na proizvodnju i ispitivanje proizvoda.

Standardi pokrivaju širok raspon poslovnih i tehnoloških vrsta uključujući medicinske uređaje te elektroniku i softver koji ih prate. Usklađenost i certifikacija tehnički su dobrovoljni u mnogim slučajevima, ali ISO se smatra zlatnim standardom i najsuvremenijim, stoga ga medicinska regulatorna tijela često upotrebljavaju kao mjerilo za usklađenost s propisima. Razumijevanje najčešće korištenih IEC i ISO standarda za medicinske uređaje ključno je za održavanje usklađenosti s globalnim propisima.

Vrste specifikacija u standardima sljedeće su:

- specifikacije karakteristika proizvoda (dimenzije uređaja, testiranje ili kalibracija postupaka);
- specifikacije dizajna izlažu specifičan dizajn ili tehničke karakteristike proizvoda;
- specifikacije izvedbe osiguravaju da proizvod zadovoljava propisano testiranje (zahtjevi čvrstoće, točnost mjerenja, kapacitet baterije ili maksimalna energija defibrilatora);
- specifikacije upravljanja izlažu zahtjeve za procese i procedure koje postavljaju tvrtke (sustavi kvalitete za proizvodnju ili sustavi za upravljanje okoliša) [13].

ISO 13485 međunarodna je norma koja uspostavlja zahtjeve za sustav upravljanja kvalitetom specifičnom za sektor medicinskih uređaja [14]. Svaka vrsta i model medicinskog uređaja mora uspostaviti i održavati dokument koji definira specifikaciju proizvoda. U dokumentaciji je bitno definirati proces instaliranja i servisiranja.

Quality management

The implementation of an effective quality management system has always been considered the main method for manufacturers to maintain and improve the quality of their products and services. Globally, many regulatory bodies include a quality management system as one of the mandatory requirements for regulatory control of high-risk medical products [12].

Standards are recommended processes developed by subject matter experts to describe the best possible way to achieve an end goal. For example, quality management standards were devised to improve efficiency and avoid product failures. Similarly, risk management standards are designed to help organizations plan for unexpected events and ensure continuity of work. These are just the two most common examples of numerous other applicable standards for medical device manufacturers.

The International Organization for Standardization (ISO) sets global standards for quality and risk management for a wide range of products and businesses. Likewise, the International Electrotechnical Commission (IEC) sets international standards for all electrical, electronic, and related technologies. Generally, ISO focuses on the control of materials and processes, while IEC focuses on manufacturing and product testing.

Standards cover a wide range of business and technology types, including medical devices, as well as accompanying electronics and software. Compliance and certification are technically voluntary in many cases, but ISO is considered the gold standard and state-of-the-art, so medical regulatory bodies often use it as a benchmark for regulatory compliance. Knowledge of the most common IEC and ISO standards for medical devices is essential to keep them in line with global provisions.

Types of specifications in standards include the following:

- specification of product characteristics (device dimensions, testing, and calibration procedures)
- design specifications outline the specific design or technical characteristics of a product
- performance specifications ensure that the product passes prescribed testing procedures (strength requirements, measurement accuracy, battery capacity, or maximum defibrillator energy)
- management specifications set out requirements for processes and procedures set by companies (quality systems for production or environmental management systems [13].

ISO 13485 is an international standard that establishes requirements for a quality management system specific to the medical device sector [14]. Every type and model of a medical device must establish and maintain a document that defines the product specification. It is important to define the installation and servicing process in the documentation.

Provođenje edukacije

Medicinski uređaji kontinuirano se razvijaju i stoga je pristup cjeloživotnog učenja bitan među profesionalcima koji se koriste takvim tehnologijama [15]. U sestrinstvu učenje se odnosi na aktivno promišljanje o postojećim situacijama i potrebno je poduzeti konkretne radnje te generalizirati znanja i vještine. Od 1990-ih koristile su se metode učenja o načinu upotrebe medicinskih uređaja koje su uključivale učenje gledanjem videa, obukom na poslu ili prenošenjem informacija od druge medicinske sestre. Često se u učenju koriste upute proizvođača i korisnički priručnici.

Medicinske sestre u hitnoj službi glavni su korisnici medicinskih uređaja. Svakodnevno se susreću s medicinskim uređajima koji se upotrebljavaju za praćenje bolesnika, dijagnostičko testiranje te kirurške i terapijske intervencije. S vremenom su ovi uređaji postali sve složeniji i sofisticiraniji stvarajući više izazova za medicinske sestre. Ako medicinska sestra nije upoznata s pravilnim korištenjem uređaja, bolesnici su u riziku od pogrešaka prilikom primjene uređaja. Medicinske sestre mogu steći znanja sudjelovanjem u obrazovnim programima kako bi se osigurao siguran rad medicinskih uređaja kojima se koriste. Literatura sugerira da se edukacija medicinskih sestara usredotočuje na sljedeća područja:

- poznavanje namjene uređaja;
- proizvođačeve upute za uporabu, označavanje, upozorenja, kontraindikacije i poznate komplikacije;
- rezultate pravilne uporabe uređaja;
- važnost poštivanja datuma isteka (koje su dali proizvođači) koji ukazuju na vremensko razdoblje za optimalnu upotrebu ili rok trajanja;
- uvid u razlike u korištenju i dizajnu uređaja između sličnih uređaja [14].

Edukaciju o medicinskim uređajima u OHBP-u provode predstavnici tvrtki. Osobito je to važno prilikom nabave novog medicinskog uređaja. O provedenoj edukaciji mora postojati pisani dokaz. Uz svaki medicinski uređaj prilikom primopredaje daju se pisane upute na hrvatskom jeziku. U slučaju kvara određenog medicinskog uređaja, medicinska sestra isti prijavljuje glavnoj sestri OHBP-a koja kontaktira ovlašteni servis.

Zaključak

Medicinski uređaji, od jednostavnijih do složenijih, važan su sastavni dio zdravstvene skrbi s obzirom na to da imaju sve veću ulogu u dijagnostici i liječenju bolesti. Skrb za bolesnike u OHBP-u ne može se provoditi bez odgovarajućih medicinskih uređaja. Iako se sigurnost bolesnika usmjerava prvenstveno na pogreške u liječenju, medicinski uređaji također značajno pridonose ozljedama i negativnim ishodima liječenja.

Bitno je omogućiti sigurnost i učinkovitost medicinskih uređaja te da su proizvedeni u skladu s trenutnim proizvodnim praksama. Tehnologija medicinskih uređaja nastavit će se razvijati i stvarati izazov medicinskim sestrama u skrbi za bolesnike.

Provision of education

Medical devices are continuously evolving, and therefore a lifelong learning approach is essential among professionals who use these kinds of technologies [15]. In nursing, learning refers to actively reflecting on existing situations, and it is necessary to take concrete actions and generalize knowledge and skills. Since the 1990s, various methods of medical device use learning have been used, including learning by watching videos, on-the-job training, or getting information from other nurses. Manufacturers' instructions and user manuals are also often used in learning.

Emergency ward nurses are the primary users of medical devices. They use medical devices daily for patient monitoring, diagnostic testing, and surgical and therapeutic interventions. With time, these devices became more complex and sophisticated, creating more challenges for nurses. If a nurse is not familiar with using a device, patients are at risk of mistakes in the use of the device. Nurses can procure knowledge by participating in training programs to ensure the safe operation of the medical devices that they use. Literature suggests that nurse education concentrates on the following areas:

- knowing the purpose of the device
- manufacturer's instructions for use, labelling, warnings, counterindications, and known complications
- results of correct device use
- the importance of respecting the expiry date (provided by the manufacturer) that indicates the time frame for optimal use or the expiration date
- insight into differences in the use and design of devices when dealing with similar devices [14].

Training on medical devices in the Emergency department is performed by supplier representatives. That is especially important when new medical devices are procured. There must be written proof about the performed training. With every medical device, written instructions in the Croatian language are to be provided when the device is delivered. In case of failure of a certain medical device, the nurse reports it to the head nurse of the Emergency department, who contacts the authorized service.

Conclusion

Medical devices, from simpler to more complex ones, are an important integral part of health care, given that they play an increasingly important role in the diagnosis and treatment of diseases. Care for patients in the Emergency department cannot be conducted without appropriate medical devices. Although patient safety focuses primarily on medication errors, medical devices also contribute significantly to injuries and adverse treatment outcomes.

It is essential to ensure the safety and effectiveness of medical devices and that they have been manufactured in accordance with current manufacturing practices. Medical device technology will continue to evolve and challenge nurses in patient care.

U konačnici, rad u OHBP-u ne može se provoditi bez širokog spektra medicinskih uređaja, ali medicinski uređaji nisu učinkoviti bez odgovarajuće edukacije. Medicinske se sestre moraju kontinuirano educirati o sigurnoj upotrebi medicinskih uređaja. Redovita obuka i edukacija pomažu medicinskim sestrama u pružanju sigurnosti bolesniku i preveniraju mogućnost neželjenih događaja.

Nema sukoba interesa

Ultimately, work in the Emergency department cannot be conducted without a wide range of medical devices, but medical devices are not effective without proper training. Nurses must be continuously educated about the safe use of medical devices. Regular training and education help nurses provide safety to the patient and prevent the possibility of adverse events.

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Literatura / References

[1] Slavetić G, Važanić D. Trijaža u odjelu hitne medicine. Ministarstvo zdravlja RH i Hrvatski zavod za hitnu medicinu: Zagreb; 2012.

[2] Moyimane MB, Matlala FS, Kekana MP. Experiences of nurses on the critical shortage of medical equipment at a rural district hospital in South Africa: a qualitative study. Pan Afr Med J. 2017; 28: 100.

[3] World Health Organization. Medical devices: Managing the Mismatch (An outcome of the Priority Medical Devices project). Geneva; 2010.

[4] WHO Global model regulatory framework for medical devices including IVDS. Draft for comment. World Health Organization, Geneva; 2016.

[5] Standard medicinske opreme medicinskih uređaja i pribora za obavljanje bolničke hitne medicine, NN 80/2016. Dostupno na: https://narodne-novine.nn.hr/clanci/sluzbeni/full/2016_09_80_1816.html. Pristupljeno: 5. 5. 2022.

[6] Jamshidi A, Rahimi SA, Ait-kadi D, Bartolome AR. Medical devices inspection and maintenance; a literature review. In: Institute of Industrial and Systems Engineers annual conference proceedings; 2014.

[7] Patil PJ, Patil SP, Jaltade VG, Gupta SS. Departmental equipment maintenance system in Government Medical College. Int Arch Integr Med. 2015; 2 (3): 79–86.

[8] Hamdi N, Oweis R, Zraiq HA, Sammour DA. An intelligent healthcare management system: a new approach in work-order prioritization for medical equipment maintenance requests. J Med Syst. 2012; 36 (2): 557–567.

[9] Mahfoud H, El Barkany A, El Biyaali A. A hybrid decision-making model for maintenance prioritization in health care systems. Am J Appl Sci. 2016; 13 (4): 439–450.

[10] ISO 14971. Medical Devices: Application of Risk Management to Medical Devices. 2nd ed. International Organization for Standardization: 2007.

[11] Haken I, Allouch BS, Harten W. The use of advanced medical technologies at home: a systematic review of the literature. BMC Public Health. 2018; 18: 284.

[12] Li T, Tu WP, Liu LL, Wu SI. Assurance of Medical Device Quality with Quality Management System: An Analysis of Good Manufacturing Practice Implementation in Taiwan. Biomed Res Int. 2015: 670420. Dostupno na: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4449896/. Pristupljeno: 1. 6. 2022.

[13] Savović A. Medicinski uređaji i sigurnost pacijenta [Diplomski rad]. Sveučilište u Zagrebu: Zagreb; 2014.

[14] Oruč M, Čabrić E, Oruč M. Upravljanje kvalitetom za medicinske uređaje – ISO 13485 upravljanje kvalitetom medicinskih uređaja – ISO 13485. 10. Naučno-stručni skup s međunarodnim učešćem. Kvaliteta 2017. Neum; 2017.

[15] Keller J. Instructions included? Make safety training part of medical device procurement process. Manag. Health Care. 2010; 19: 26–29.