

Covid-19 Pandemi Sürecinde 112 Personelinin Kullandığı Cihazlar, Validasyonu ve Karşılaştığı Sorunlar

Devices Used by 112 Personnel in the Covid-19 Pandemic Process, Validation and Problems Encountered

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Özetçe— Acil sağlık hizmeti, hasta ve yaralıları eldeki imkanlar doğrultusunda en iyi acil müdahaleyi mümkün olan en kısa zamanda vermek için birlikte çalışan, alanında özel eğitim almış kişilerden oluşan, kişilerin sağlık bakımından tam bir iyilik haline tekrardan döndürülmesi için yapılan bütün müdahalelere acil sağlık hizmeti denir. Bu bağlamda pandemi sürecinde verilen acil sağlık hizmeti sağlık çalışanları açısından özel prosedürlerin uygulanmasını gerektirmekle birlikte bu hizmetin verildiği sırada kullanılan biyomedikal cihazların validasyonunda önemlidir. Özellikle bu sürecin beklenmedik bir zaman diliminde gerçekleşen bir afet olması herkesin hazırlıksız yakalanmasına sebep olmuş ve bu durum sağlık çalışanlarının mevcut iş yükünün daha da artmasına sebep olmuştur. Biz bu çalışmada 112 acil sağlık hizmeti veren profesyonellerin pandemi döneminde yaşadığı sorunlara ışık tutmak ve bu personellerin ambulans içerisinde kullandığı biyomedikal cihazların validasyonunun nasıl olması gerektiğiyle alakalı literatür araştırması yaptık. Araştırmanın türü Tanımlayıcı araştırmadır. Covid-19 pandemisi bir vaka olarak kabul edilip bu vaka odak noktası olmak üzere literatür taraması yapılmıştır. Literatür taraması sırasında anahtar kelimelerde de belirtilen “acil sağlık hizmeti, Covid-19, afetlere hazırlık, acil yardım birimi çalışanları, biyomedikal cihaz teknolojileri” gibi konu bütünlüğünü bozmayan ve aynı zamanda güncel anahtar kelimeler taratıldı. Derleme kısmına dahil edilen çalışmaların akademik kılavuza uygun ve güncel çalışmalar olmasına özen gösterildi. Ayrıca araştırmanın validasyon bölümündeki kaynak kısıtlılığı nedeniyle ilgili mevzuatlar ve konunun uzmanı medikal şirket mühendislerinden ve sağlıkçıların

problemleri bölümünde de sahada aktif çalışan personelden yardım alınmıştır. Bu araştırmanın sonucunda ise sağlık çalışanlarının pandemi dolayısıyla yaşadığı sorunlarla alakalı kanuni düzenlemeler yapılması gerektiği ve cihaz validasyonlarıyla alakalı var olan standartların pandemi sonrası güncellenmesi gerektiği sonucuna ulaştık.

Anahtar Kelimeler— Acil sağlık hizmeti, Afetlere hazırlık, Covid-19, 112 Acil Yardım Birimi Çalışanları, Biyomedikal Cihaz Teknolojileri

Abstract—The emergency health service is for all interventions that are made up of people who have received special education in their field, who work together in order to provide the best emergency response to the sick and injured in the shortest time possible in line with the possibilities available. In this context, although the emergency health service provided during the pandemic process requires the implementation of special procedures for healthcare professionals, it is important in the validation of the biomedical devices used during the provision of this service. Especially the fact that this process was a disaster that took place in an unexpected time period caused everyone to be caught unprepared and this situation caused the current workload of healthcare workers to increase even more. In this study, we conducted a literature search to shed light on the problems experienced by 112 emergency healthcare professionals during the pandemic period and how the

validation of the biomedical devices used by these personnel in the ambulance should be. The type of research is descriptive research. The Covid-19 pandemic was accepted as a case and the literature was reviewed, with this case being the focus. During the literature search, up-to-date keywords such as "emergency health service, Covid-19, disaster preparedness, emergency aid unit employees, biomedical device technologies", which are also mentioned in the keywords, were scanned. Care was taken to ensure that the studies included in the review section were up to date and in accordance with the academic guide. In addition, due to the limitation of resources in the validation section of the research, assistance was received from the relevant legislation and expert medical company engineers and from the active staff in the field of healthcare professionals' problems. As a result of this research, we have reached the conclusion that legal regulations should be made regarding the problems experienced by healthcare professionals due to the pandemic and that existing standards related to device validation should be updated after the pandemic.

Keywords—Emergency health service, Disaster preparedness, Covid-19, 112 Emergency Aid Unit Employees, Biomedical Device Technologies

I. INTRODUCTION

Disaster is a natural, technological or human-based event that cause economic, physical and social losses, affects communities by disrupting ordinary life and human activities, and which the affected community cannot overcome with their own capacities and their consequences [17]. Disasters are important events that cause both psychological and physical trauma on individuals. In the disasters experienced, the health personnel working in disasters are affected along with the people living in the region, and some of these personnel and their families still continue to live and work in the same area. Another factor required for healthcare personnel to work at full capacity in disasters is that these personnel are informed by in-house trainings on issues such as working in disaster situations, implementing the relevant plan and taking responsibility, as well as other emergency care issues during the disaster preparation period. It is defined as the systematic and flexible use of special knowledge and skills related to the activities of healthcare professionals in disasters, activities that must be carried out in integration with other fields in order to ensure that the activities are in a way that will save the maximum human life and reach as many people as possible [35]. The aim of disaster workers is to bring the affected society and individuals to the best health condition as quickly as possible [19]. Disaster workers in all branches need to know how to carry out evaluation, prioritization, support and effective working processes in disaster situations [30]. The education of healthcare workers in disasters can reveal positive results such as decreasing mortality, improving the health of individuals and reducing financial losses in disasters [39]. In health institutions, especially the managing disaster worker has determined duties regarding the disaster situation. Because disasters

and emergencies require a rapid decision-making mechanism, managers need to have the basic knowledge and skills required for decision-making and control. In the event of a disaster, basic applications are often forgotten and the already complex system can become more complex. For this reason, healthcare professionals are required to reconsider their management functions related to pre-disaster planning, organization in case of disaster, command, coordination and control, and apply these basic functions more effectively. The management of each of these functions is of vital importance for every moment of the disaster, before, during and after the disaster [38]. Pre-disaster preparedness of disaster workers is considered as an extremely important issue for rapid response and effective disaster management during disasters. It is stated that all healthcare professionals at any level should participate in disaster prevention, mitigation, preparedness and rescue activities of the integrated disaster management system and increase their professional skills in order to provide adequate healthcare services before, during and after the disaster [19]. Today, employees in many countries; is held responsible for learning the knowledge and skills required against possible disasters and applying them in case of a crisis[30]. In a study conducted on physicians, it was found that 35.7% of 244 physicians working in Emergency Health Services provided healthcare services in disaster or extraordinary situations and 66.5% did not receive any training on disaster / ODD [6]. In the study carried out by Inal et al and in which health college students were selected as the sample, it was determined that 85.9% of the students did not have a disaster plan [17]. In the study conducted by Çakmak et al. On 112 employees, 51.1% of the participants stated that they were officially assigned in the Gölcük Earthquake [10]. Similar results are seen in other countries. In a study conducted on pre-hospital emergency medical teams after an earthquake in Taiwan, it was found that less than 25% of healthcare workers had disaster training. The medical personnel working in 112 Command and Control Center (KKM) and ASHI (Emergency Health Services Station) are the teams that will perform the first response at the scene during the disaster, as well as respond to all emergencies. Therefore, the personnel working in emergency health services should have basic knowledge about earthquakes, which is the most common type of disaster in our country [30]. There are biomedical devices to provide basic life support, which is stated as indispensable in ambulances used by emergency healthcare workers during the intervention. These are sets for minor surgical intervention, defibrillator, equipment for intubation and ventilation, airways of all sizes, vacuum device, cooler for serum and drugs, suture, scalpel, dressing set, bandages etc., surgical clamps and sutures, blood pressure devices, tracheostomy sets and they are the cabinets where all these will be kept. Considering the struggle of healthcare professionals to minimize the loss of life in almost every disaster (including the epidemic process we are in), the aim of the study is to identify the problems related to biomedical devices they encounter and to create more effective health

systems in disasters. According to this view, problems should be identified and new technical devices to be developed should be developed accordingly. Health workers; Regardless of their main field of work, they should be ensured to know disaster management and to work with safe biomedical equipment in all phases of integrated disaster management. That's why the Emergency Health Services in Turkey will be discussed during the study after identifying the problems mentioned will be given the information you need about the system. The strongest aspect of this study is that there are few studies on the subject in our country, thus making a significant contribution to the literature.

II. LIMITATIONS OF RESEARCH

The devices taken as basis throughout the research may not belong to the same company in all 112 stations affiliated to the Hatay Provincial Health Directorate. And again during the research, if the information about the validation parameters of the companies that perform the validation and calibration processes of the devices taken as a basis cannot be reached, the parameters of similar companies with the same features as the device will be used.

III. THE EMERGENCY HEALTH SERVICES IN TURKEY IN THE COURSES OF THE PANDEMIC

Emergency medical services in Turkey and in emergency situations can be evaluated in 2 ways, including in disaster. Emergency situations are defined as situations that occur in the normal course of life that affect a small number of people, but require urgent intervention. According to the law numbered 5902, it is defined as "the events that stop or interrupt the normal life and activities of the whole or certain segments of the society and require urgent intervention and the state of crisis caused by these events"[31]. In such emergencies, 112 etc. depending on the ministry of health. The task lists and work flow plans to be made by the units and personnel are determined. The process works differently in disasters. The process applied in disaster situations is more complicated. AFAD in 2013 within the institutions of the state depends on all stakeholders on a national scale that Turkey Disaster Response Plan was prepared. In this plan, all the duties and responsibilities of the institutions are determined. At this point, emergency health services in disaster situations are of vital importance for the survivors to maintain their vital functions and for the full participation of the victims in the recovery process by applying a complete treatment process [33]. Therefore, the system should be planned in an integrated manner with TAMP (Turkey Disaster Response Plan) and paying attention to every step [1]. The mission of every stakeholder who will take part in the system is to ensure that the right intervention is made to the injured person or emergency patient. This situation decreases the death and injury rates. For this purpose, the biggest role in the implementation of emergency health

services fell on to the T.R. Ministry of Health. The Ministry of Health carried out this task through ambulance teams, UMKE (National Medical Rescue Team) teams, central hospitals and field hospitals established in case of possible disasters. The General Directorate of Emergency Health Services within the ministry is responsible for the disaster preparedness, development, accessibility, efficiency and activities of all these units. In this context, these units are currently operational in case of disasters. In the Van earthquake, it started emergency health services simultaneously with the search and rescue works carried out within the first 72 hours. In the Syrian crisis, on the other hand, it started emergency health services by welcoming the injured individuals who are in need of emergency medical support both from across the border and from the border gates neighboring Syria with Ambulance and UMKE teams, and then continued to provide emergency health services and full treatment services through central hospitals. But of course, emergency health services in disasters should not be considered solely focused on intervention in the field. Another important task falls on hospitals. The issue to be considered here is that every hospital should have a HAP (Hospital Disaster and Emergency) plan and this should be regularly renewed in accordance with the changing conditions within the hospital. In addition, hospitals should have emergency evacuation plans considering the permanent damage in disasters. These services, which are essential for the delivery of emergency health services to the whole country, are to be carried out uninterruptedly, with a team understanding and accessible in a short time. In order to carry out these services, not only the General Directorate of Emergency Health Services, but also the Emergency Health Services Advisory Board, the Emergency Health Services Regional Education Research and Application Center and the directorates, the Provincial Emergency Health Services Coordination Commission (ASKOM) is formed. In addition to these, emergency health service units have been established for the purpose of intervention. These units consist of basic service and support service units. During the Covid-19 pandemic, which is the subject of this study, it is one of the periods when the emergency health services system in our country is tested the most. Although the work flow plans were determined in the national pandemic plan previously prepared by the ministry, the unpredictability of the disaster and its being an uncontrollable biological agent pushed the limits of the system. Before the Covid-19 virus appeared, the responsibilities of all institutions were determined in the Pandemic Influenza National Preparation Plan prepared by the Ministry in 2019 against the possibility of a possible influenza virus turning into a pandemic. The purpose of this plan prepared by the General Directorate of Public Health is to provide information flow that will help all institutions and

stakeholders in the country to recognize the influenza virus, to prepare in the most appropriate way to fulfill all the responsibilities assigned to them, and to act in coordination with each other in the event of a pandemic. In line with this plan, it is aimed to reduce the transmission of pandemic strain, the number of patients due to pandemic, inpatient treatment and disease-related deaths, to ensure the continuity of public services and to reduce the economic and social burden caused by the pandemic. According to this plan, the transportation of possible cases during the pandemic is the responsibility of the appropriate 112 personnel. Following detailed anamnesis and examinations, these cases should be transported to the designated hospitals with a properly equipped 112 ambulance, together with the possible case form. In this plan prepared for influenza virus, target groups to be vaccinated according to the severity of the pandemic in the possible pandemic were determined according to the Pandemic Severity Matrix. According to this matrix, 112 employees were identified as the first degree priority group. This situation has not changed for the Covid-19 pandemic period, and the first-degree priority group was determined among the target groups to be vaccinated when 112 and other healthcare professionals, the most risky group in combating the virus, came to our country. In the Covid-19 pandemic, process management started on January 10, 2020, before the virus was first seen in our country. The Coronavirus Scientific Committee, consisting of 38 experts in their fields, convened under the presidency of the Minister of Health of the period, Fahrettin Koca, was established [20-41]. This board is in the nature of an advisory board and has been delivering an opinion to the ministry on process management since the beginning of the process [9]. When we examine the Provincial Health Directorate of Emergency Health Services in Turkey at the local level it is the responsibility of the Emergency Medical Services Department. This unit has 3 sub-units: Emergency Health Services, Disaster Health Services and 112 Provincial Ambulance Service Chief Physician. Within the scope of this information, during the Covid-19 pandemic, which is a CBRN disaster, the Emergency Health Services unit and its sub-units have a great responsibility [2]. Especially in Hatay, health problems related to asylum seekers, which have already caused excess capacity for a long time, have increased even more during the Covid-19 period. In this process, fever measurement, symptom follow-up and so on for asylum seekers who apply to the ministry's Immigrant Health Center. He made referrals to the hospital afterwards. And again, the information determined as the ministry policy for the health personnel working in the Immigrant Health Center was translated into Arabic and provided hygiene material [24]. However, the conditions affecting the living conditions of the refugees such as living with more people and the difficulties in the supply

of hygiene materials caused the pandemic process to be further affected. And this situation further increased the workload of 112 personnel. When we look specifically at the Hatay Metropolitan Municipality, it has commissioned police units within the municipality and carried out regular inspections for hygiene, distance and mask rules in the city. Another problem that appears throughout the process is that 112 personnel are among the high-risk groups, as they fight the virus directly. Although ministerial measures were followed, unfortunately, the loss of life due to the virus could not be prevented.

In terms of professional satisfaction, healthcare personnel need to feel safe in order to work at the highest performance [11]. In a study conducted on nurses after the pandemic, it was reported that 36.3% read books written on mental health, 50.4% did activities to cope with social media, and 17.5% received professional psychological support [11]. In particular, the epidemic factor has been added to the stressful environment in which 112 personnel work as the usual income of the profession. In a study in which 11253 patients were evaluated before the pandemic, it was observed that 37.7% of the patients applied to the emergency department in an inappropriate place [40]. During the pandemic period, the number of false denunciations received by 112 call centers increased considerably. Especially when we evaluate it specifically for Hatay 112, it was determined that 85% of the 7 million 18 thousand 314 cases that came to the call center during 2020 were unfounded. Compared with the general Turkey Hatay province has become the 3rd call 112 maximum. In other words, while the workload of emergency health services before the pandemic was already intense, the workload of the personnel increased with the pandemic. Even if they do not get sick, they are not only the usual porter because they carry patients, but the possibility of carrying the causative virus to their homes and families after work increases the stress and psychological distress. This situation not only causes psychological problems, but also increases the rate of spread of the epidemic. During the pandemic period, healthcare workers who worked actively during the pandemic period had to isolate themselves from their own families, as can be seen in the posts that are frequently reflected in the social media and the press. The psychological effects of this condition on healthcare professionals are quite degrading. It has been observed that this pressure on mental health causes suicide cases among healthcare professionals. Especially when compared to other years, it has been observed that the number of suicide cases among healthcare professionals increased in 2021. During the pandemic period, stress, anxiety, feeling of helplessness, etc. that pose a risk to mental health. factors increase traumatic situations. Not only family factors, but also social isolation due to stigma among the public, negatively affects the mental state of 112

personnel. The pandemic period also affected the civil law decisions about healthcare professionals. Due to the fact that Cemile Deniz, an ambulance nurse in Ordu, was actively working and her child had chronic illness, the court gave custody of her child to her husband, who was divorced, although the correctness of the decision is debatable, it is clear that the pandemic negatively affects the relations of the 112 personnel with their family. Considering all these problems, Covid-19 is not considered an occupational disease, causing both healthcare professionals and their families to lose their rights. However, the Social Security Institution accepts that the health workers who died with the decisions taken specific to the incident died of occupational disease and gave death pension, etc. started to give the rights to his family. And this is true not only for a particular group, but also for all healthcare professionals in the state and private.

IV. BIOMEDICAL DEVICES USED BY 112 STAFF DURING THE PANDEMIC PERIOD AND THEIR VALIDATION

Validation is a set of methods used to test with certain parameters whether a material, product or device is suitable for its intended use. Analytical validation is a collection of parameters that show the validity of the results obtained from analytical applications and the applicability of the method. All validation results are expressed in terms of analytical parameters. Analytical method characteristics must be determined and calculated during method validation. These are: Accuracy, Precision, Selectivity, Specificity, Limit of Diagnosis (TS, LOD), Lower Limit of Detection (TAS, LOQ), Linearity, Range (Sensitivity), Robustness, Consistency (Ruggedness), Stability. Any factor that makes a meaningful change in results must itself be researched and controlled. If necessary, the methods are re-developed and the entire validation process is modified to include the new factor. In an analysis method developed and maintained, the method must comply with the validation tests in the steps from the first step of the analysis to the planning of the analyzes and the evaluation of the data obtained [29]. Biomedical, on the other hand, includes materials, materials etc. used for diagnosis and treatment in medicine. takes care of all. In our country, there are some mandatory regulations regulating the standards of these two concepts. The first of these is the document titled "Medical Device Regulation", which is the own legislation of the Ministry of Health. The purpose of this regulation is to determine the basic requirements that medical devices and accessories must have and to ensure that patients, practitioners, users and third parties are protected against dangers that may arise in terms of health and safety during the use of these devices and accessories. to regulate the procedures and principles for auditing. The other is the "TS EN ISO 13485" numbered technical specification of the Turkish Standards Institute [34]. This standard has been prepared under an instruction given to CEN by the

European Commission and the European Free Trade Association and meets the quality system requirements of the EU Medical Device Directives. Through this standard, the relevant parameters of medical devices in terms of quality management have been tied to certain conditions

A. Defibrillator

It is a device that aims to return the irregular vibrations in the heart muscle or the stopped heart to its normal rhythm by giving an electrical current to the heart [5]. Although there are findings that can be associated with a large number of cardiovascular system disorders in patients with Covid-19 infection, it is seen that the course of the disease worsens in patients with chronic cardiovascular system diseases [4]. Defibrillator devices generally consist of 6 parts: power supply, electrical circuit board, electrodes, sensors, printer and monitör [25-27]. The defibrillator used by the Hatay Provincial Health Directorate in 112 ambulances is the Mindray branded Biphasic Automatic Monitor Defibrillation device. Biphasic defibrillators are two-circuit. Biphasic defibrillators after electrical discharge in a positive direction for a certain time, then return and remain in the negative direction [8]. They produce a type of current that runs along. They can also electronically counteract transthoracic impedance changes by adjusting the waveform size and continuity. Although the validation of these devices is different for each brand, parameters such as ECG Pulse Test, ECG Amplitude Test, ECG Frequency Test, ECG Arrhythmia Test, Pacemaker Test, Energy Test, Charge Time Test, Synchronized Discharge Test are generally considered during the test and experiment phase of defibrillators [12].

B. Small Surgery Set

Although it is not used directly for Covid-19 patients in 112, ASY patients that occur during the pandemic period must be present in each ambulance in order to properly intervene in situations such as traffic accidents. Set includes holder, scalpel handle, clamp, hemostatic pliers, mosquito forceps and Kocher forceps [7-15-26]. While checking the suitability of the materials given in the general hard content, attention is paid to the production of stainless steel. The materials should have a surface that does not reflect light and should not have a sharp edge other than the intended use. Especially forceps and needle holders should not be stuck, they should open and close easily and they should be resistant to pressure. Finally, they must be made of a material that will not be sterilized.

C. Intubation Set

Intubation is a series of procedures applied to open the airway blocked for various reasons. Since the greatest damage caused by Covid-19 is in the respiratory tract, it is an essential procedure for the infected patient. But because Covid-19 is transmitted by droplets, it is equally dangerous for the health of the personnel who will perform the procedure. Therefore, 112 personnel should pay attention

to all personal protective rules when it is necessary to do so. The set includes Laryngoscope, Endotracheal Tube, Aspiration Catheter and Oropharyngeal Airway [14-36]. It is expected that the materials in the intubation sets have a slippery surface for ease of entry and exit into the larynx. It should be in a form that can take shape and an aluminum body with plastic protection is preferred [22]. In addition, the most important part is that the distal ends must be in a structure that will not damage the bones and tissues in the larynx.

D. ECG Device

Its full name is Electrocardiography device [16]. It tries to detect changes in electrical activity that is normally present in the heart [28]. For recording, the patient is placed on a flat place and the jewelry and buckles in the areas where the electrodes will be attached are removed. The voltage difference between the instantaneous electrodes is monitored in the ECG during the process. These values, which we call derivation, are monitored by electrodes placed in two different places, the extremities and the chest. Thanks to these leads, all electrical activity of the heart can be monitored. Although the validation of these devices is different for each brand, they are provided according to ISO 13485 and TS EN 62304 standards [32]. According to these standards, parameters such as Ventricular Test, Atrial Test, Printer Test, Conduction Defects Test, Superimposed Artifact Test, Premature Pulse Test, ST Rise and Collapse Test and Pacemaker Test are checked [13]. When looking at the ECG values of patients with Covid-19, the basal QT tended to be longer [21]. Since this situation increases the risk of arrhythmia, 112 teams should monitor the patient during the transfer process, especially if the patient has a history of chronic heart disease. Therefore, we can say that the validation and calibration of ECG devices has become even more important during the pandemic period.

E. Sphygmomanometer

It is an instrument that allows measuring the blood pressure of the patient. Almost all factors related to general living conditions affect the values of blood pressure, which is one of the most basic vital signs. When the vital values of patients with Covid-19 are evaluated, these values of chronic heart and kidney patients should be followed up, even if signs associated with the disease are not observed. Since the effects of the virus are more devastating especially in people over 65 years of age, 112 personnel should pay attention to these values in patients who are known to have chronic diseases and those over 65 years old. Validation of the manometer sphygmomanometer is done in two stages with a calibrator used for its calibration.

1) Pressure Verification Test

Calibrator and sphygmomanometer are connected to the same pressure line. The selected pressure values are kept constant by the manometer and the values seen in the calibrator are recorded. This process is repeated 5 times for each pressure value and all measurements are recorded.

2) Leak Test

The manometer pressure of the sphygmomanometer is fixed to 250 mm / hg. The leakage rate is read on the reference device 5 times at 1 minute intervals and the values found are recorded. It is expected to be consistent when the comparison is made on all the values obtained [3].

F. Cooler

In every unit of the health sector, drugs, vaccines, blood products, etc. must be protected under cold chain conditions. In case of breakdown of the cold chain, there is a possibility that the basic structure of the component to be used may deteriorate, but if this situation is not realized, blood poisoning of the component to be given to the patient, etc. It should not be forgotten that it can cause situations. At this point, almost every application performed by 112 teams is acute interventions, unfortunately, the damage caused by the application in case of component breakdown cannot be compensated. Therefore, the validation of the refrigerant is very important in order not to break the cold chain. There is no clear regulation for cold chain components. Institutions such as WHO, EC have guidelines. It has been stated by WHO that every activity in the distribution of pharmaceutical products must be carried out in accordance with the principles of Good Storage Practices (GSP) and Good Distribution Practice (GDP) in order to maintain the initial quality of pharmaceutical products. According to GSP, the storage areas of biopharmaceutical products should be designed or adapted to good storage conditions. In particular, areas must be clean, dry, sufficiently lit and maintain an acceptable temperature range. In cases that require special storage conditions (such as temperature and humidity), appropriate conditions should be provided, controlled, monitored and recorded [23]. According to the Q1A (R2) (Stability Tests of New Pharmaceutical Raw Materials and Products) study published jointly by ICH with other authorities, the thermal stability of a medical product under storage conditions, sensitivity to moisture and the possibility of solvent loss should be evaluated. Storage conditions; it should be chosen to be sufficient to accommodate storage, transport and subsequent use. It is stated that the accelerated and intermediate storage condition can be used to evaluate the effect of short-term temperature changes (for example during transportation) on the product, except for the storage condition on the label [18-23]. It is a known fact that pharmaceutical and medical companies on the subject spend more money on new technologies. Although the money spent by the pharmaceutical industry for coolers in 2015 was \$ 3.1

billion, the special circumstances brought about by the pandemic conditions undoubtedly increased this expenditure even more.

G. Ventilator

A ventilator is a device that allows the patient, who cannot breathe on his own, to breathe mechanically. This situation made the device much more important during the pandemic period. Due to the fact that the Covid-19 virus commonly affects the lungs and the virus is transmitted through droplets, ventilators are not safe for transmission, making 112 personnel more vulnerable to catching the virus. At the beginning of the pandemic, due to the density of patients, ventilator problems were experienced in both intensive care units and emergencies. Especially in a private hospital in Gaziantep, the death of 9 people in a fire that broke out after a problem with the ventilator has revealed how important the validation and calibration of ventilator devices are. There are artificial respiration parameters that need to be known for the validation of these devices. These parameters are Pressure, Volume, I / E Ratio, FiO₂, PEEP (Positive End-Expiratory Pressure), CPAP, Respiratory Frequency, Maximum Inspiratory Pressure and PIP (Peak Inspiratory Pressure) [37]. After the validation test made according to these parameters, the data are saved. It should be noted here that the error limit should not exceed 10%. If it is over 10%, the device is sent to the company from which the device was supplied for repair [37].

V. CONCLUSIONS AND RECOMMENDATIONS

As a result, according to the literature research we conducted and the information we obtained from the 112 personnel we interviewed, the conditions of the pandemic period forced 112 personnel not only physically but also psychologically. This situation caused a deep wear and tiredness of the 112 personnel. Although there were resignations especially in the early stages of the pandemic, resignation and leave bans that came from time to time further strained the psychological health of the personnel and even increased the idea of suicide. In this context, psychological support should be given not only to 112 personnel, but also to all healthcare professionals, regardless of state or private hospitals. In addition, 112 personnel, who passionately perform their profession, have been questioning the institutional affiliation and commitment to the institution. Therefore, not only psychological support is provided, but also encouraging actions should be taken to make the staff love their work again. And again, their problems should be listened to and taken into account to strengthen staff's commitment to the organization. Especially during this period, the increase in the workload that develops due to the number of patients and the inadequacy of personnel puts a strain on healthcare professionals. Therefore, working hours should be

organized and working conditions should be improved. In particular, healthcare professionals with chronic diseases should be kept away from the treatment process of patients with active Covid-19 transmission and a unit change should be recommended if necessary. In the long run, considering Covid-19 an occupational disease will be very beneficial in terms of protecting the rights of all healthcare professionals and their families. Although 112 personnel are careful about the hygiene and disinfection of the devices during the pandemic period, the effect of these procedures on the devices should be investigated and validated accordingly. Documents regulating medical device standards should be updated within the scope of lessons learned during the pandemic period. In addition, developments in biological sensors should be followed during this period and the devices used by 112 personnel should be updated if necessary. Especially if it is taken into consideration that the virus is transmitted by droplets, technologies that will increase the personal protective measures of the personnel should be followed.

In the post-pandemic period, in case of the possibility of a pandemic of this scale in the long term, CBRN trainings should be given to healthcare workers and they should be prepared for this issue. And again, for the post-pandemic period, what happened in this period should be evaluated as a real-scale exercise, lessons should be learned from what happened and should be sourced systematically. And technological studies in this field should be encouraged and investment should be made.

AUTHOR CONTRIBUTIONS

Ahmet Şanverdi is the responsible author of this study and has determined the concept and course of the study. The second author, *Eda Nur Karagöz*, ensured that the study was organized in accordance with the determined format. The third author, *Prof. Dr. Mehmet Lütüfi Yola*, conducted a literature search on the study and recorded one-to-one interviews with the people who needed to be interviewed. .

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REFERENCES

- [1] Afad. (2013, Aralık). Türkiye Afet Müdahale Planı. Received from afad.gov.tr:
https://www.afad.gov.tr/kurumlar/afad.gov.tr/2419/files/Afet_Mud_Pl_ResmiG_20122013.pdf

- [2] Afad. KBRN Sözlüğü. Received from afad.gov.tr: <https://www.afad.gov.tr/kbrn-sozlugu>
- [3] Akan, Ş. (2021, Şubat 27). Manometreli Tansiyon Aletinin Kalibrasyonu. (E. N. Karagöz, Interviewing)
- [4] Aktoz, M. (2020). Türk Kardiyoloji Derneği Uzlaş Raporu: COVID-19 Pandemisi ve Kardiyovasküler Hastalıklar Hakkında Bilinmesi Gerekenler. Türkiye Kardiyoloji Derneği: İstanbul.
- [5] Avcı, A., & Eriş, G. (2020). COVID-19 Hastalarında Kardiyovasküler Değerlendirme. Türkiye Diyabet ve Obezite Dergisi, 147-154.
- [6] Barış, E. (2011, Haziran 3). Afet tıbbi eğitiminin İzmir metropol andası Acil Sağlık Hizmetlerinde çalışan hekimlerin bilgi düzeyine etkisi. Afet tıbbi eğitiminin İzmir metropol andası Acil Sağlık Hizmetlerinde çalışan hekimlerin bilgi düzeyine etkisi. İzmir, İzmir, Türkiye Cumhuriyeti: Dokuz Eylül Üniversitesi.
- [7] Besamedikal. Portegü/İğne Tutucu. In Şubat 19, 2021 Received from besamedikal.com: <http://www.besamedikal.com/urun/portegu-igne-tutucu/#:~:text=Tamamen%20paslanmaz%20cerrahi%20porteg%C3%BC%2C%20di%C5%9F,parma%C4%9F%C4%B1%20ile%20%C3%BCstten%20desteklenerek%20kullan%C4%B1%C4%B1r.>
- [8] Beydilli, H. (2014, Mayıs 18). Defibrilatör Nasıl Çalışır? Received from file.atuder.org.tr: http://file.atuder.org.tr/_atuder.org/fileUpload/uzhiTj8dQDYu.pdf
- [9] Bilgiç, A. K. (2020). COVID-19 ile Mücadele Sürecinde Yerel Yönetimlerin Genel Görünümü. İdealkent, 2086-2112.
- [10] Çakmak, H., Aydın, R., Oz, Y., & Aker, A. (2010). Kocaeli ili 112 acil yardım birimlerinde çalışan personelin Marmara depreminde etkilene ve olası afetlere hazırlık durumlarının saptanması. Akademik Acil Tıp Dergisi, 83-91.
- [11] Çevirme, A., & Kurt, A. (2020). Covid-19 Pandemisi Ve Hemşirelik Mesleğine Yansımaları. Avrasya Sosyal ve Ekonomi Araştırmaları Dergisi, 7(5), 46-52.
- [12] Elmascan, N. (2021, Şubat 18). Defibrilatör Test Deney. (E. N. Karagöz, Interviewing)
- [13] Erdoğan, Z. (2021, Şubat 25). EKG Validasyonu. (E. N. Karagöz, Interviewing)
- [14] Gül, F. (2018, Kasım 16). Endotrakeal Entübasyon. Received from acilcalisanlari.com: <https://www.acilcalisanlari.com/endotrakeal-entubasyon.html>
- [15] Healthcare. (2018, Mayıs 26). Hemostatik Pensler. Received from slideshare.net: <https://www.slideshare.net/dental-market/hemostatik-pensler>
- [16] EKG. Ankara: Nobel Tıp Kitabevi.
- [17] İNAL, E., KOCAGÖZ, S., & TURAN, M. (2012). Temel Afet Bilinç ve Hazırlık Düzeyinin Saptanmasına Yönelik Bir Araştırma. Türkiye Acil Tıp Dergisi, 15-19. doi:10.5505/1304.7361.2012.05658
- [18] İzer, D. A. Soğuk Zincir Lojistiği İçinde Risklerin Azaltılmasında Yeni Teknolojiler. Received from Şubat 27, 2021 tarihinde d1wqtxts1xzle7.cloudfront.net: https://d1wqtxts1xzle7.cloudfront.net/53484161/Bildiri_soguk_zin_cir.pdf?1497344123=&response-content-disposition=inline%3B+filename%3DSOGUK_ZINCIR_LOJISTI_GI_ICINDE_RISKLERIN.pdf&Expires=1614443299&Signature=Fk9RhEMygDOvJjHzPfbpqqN52YGX-glR9eYBUFKlplgu0
- [19] Jennings Sanders, A. (2004). Teaching disaster nursing by utilizing the Jennings disaster nursing management. A. Jennings Sanders içinde, Nurse Education in Practice (s. 69-76).
- [20] Koca, F. (2020, Nisan 3). Received from twitter. twitter.com: <https://twitter.com/drfahtretinkoca/status/1246174959594016769>
- [21] Kocabay, G. (2021, Şubat 25). COVID-19 tedavisinde kullanılan ilaçların kardiyak aritmi riski. Received from psikiyatri.org.tr: <https://www.psikiyatri.org.tr/uploadFiles/75202019432-COVIDHcqTDPRiski.pdf>
- [22] Koyuncu, M. (2019, Haziran 14). Oral Airway. Received from acilcalisanlari.com: <https://www.acilcalisanlari.com/oral-airway.html>
- [23] Küçüktürkmen, B., & Bozkır, A. (2018). Özel saklama koşulu gerektiren veya soğuk zincire tabi ilaçlar ve uygulamalar açısından değerlendirmeler. Türk Hijyen ve Deneysel Biyoloji Dergisi, 305-322.
- [24] Mardin, D. (2020). Covid-19 Sürecinde Türkiye’de Göçmen ve Mültecilerin Durumu. Sağlık ve Toplum, 112-118.
- [25] Medibim. (2013, Temmuz 30). Defibrilatör test cihazı. Received from medibim.com.tr: <https://www.medibim.com.tr/TR/biyomedikal-kalibrator-test-cihazlari/defibrilatör-test-cihazlari/>
- [26] Medikal, c. (2021, Şubat 19). Cerrahi Kocher Pens 16 Cm. Received from can-medikal.com: <https://www.can-medikal.com/urun/kocher-pens-16-cm-duz#:~:text=Farkl%C4%B1%20b%C3%BCy%C3%BCKl%C3%BCkte%2C%20a%C4%9F%C4%B1z%20k%C4%B1sm%C4%B1%20C5%9Fubelerin,ameliyatlarda%20ve%20pansumanlarda%20s%C4%B1kl%C4%B1kla%20kullan%C4%B1lmaktad%C4%B1r.>
- [27] Megep. (2019). Defibrilatör Cihazlar. Received from megep.meb.gov.tr: http://www.megep.meb.gov.tr/mte_program_modul/moduller_pdf/Defibrilat%C3%B6r%20Cihazlar%C4%B1.pdf
- [28] Megep. (2021, Şubat 24). Ekg (Elektrokardiyografi). Received from megep.meb.gov.tr: [http://megep.meb.gov.tr/mte_program_modul/moduller_pdf/Ekg%20\(elektrokardiyografi\).pdf](http://megep.meb.gov.tr/mte_program_modul/moduller_pdf/Ekg%20(elektrokardiyografi).pdf)
- [29] Özkan, S. A. (2012). İlaç Analizlerinde Analitik Validasyon Ve İlgili Parametreleri. İlaç Analizlerinde Analitik Validasyon Ve İlgili Parametreleri. Hatay, Antakya, Türkiye Cumhuriyeti: VI. Ulusal Analitik Kimya Kongresi.
- [30] Taşkıran, G., & Baykal, Ü. (2017). Afetler ve Türkiye’de Hemşirelerin Afetlere Hazır Olma Durumları: Literatür İnceleme. Sağlık ve Hemşirelik Yönetimi Dergisi, 79-88. doi:10.5222/SHYD.2017.079
- [31] TBMM. (2009, Mayıs 29). 10449-10453. Received from mevzuat.gov.tr: <https://www.mevzuat.gov.tr/MevzuatMetin/1.5.5902.pdf>
- [32] TBMM. (2011, Haziran 7). Tıbbi Cihaz Yönetmeliği. Tıbbi Cihaz Yönetmeliği. Ankara, Ankara, Türkiye Cumhuriyeti: Resmi Gazete.
- [33] Toker, S. O., & Küçükylmaz, Ü. (2001). Acil Sağlık Sistemi Nedir? Türkiye’nin Ulusal Acil Sağlık Sistemine Genel Bir Bakış. DİRİM, 11-16.
- [34] TSE. (2012, Haziran). Tıbbi cihazlar - Kalite yönetim sistemleri - Mevzuat amaçları. Tıbbi cihazlar - Kalite yönetim sistemleri - Mevzuat amaçları. Ankara, Ankara, Türkiye Cumhuriyeti: TSE.
- [35] Usher, K., & Mayner, L. (2011). Disaster nursing: A descriptive survey of Australian undergraduate nursing curricula. Australian Emergency Nursing Journal, 75-80.
- [36] Uzman, S. (2008). Laringoskopi Ve Entübasyona Karşı Gelişen Hemodinamik Cevabın Baskılanmasında Dexmedetomidine Ve

- Esmololün Etkinliğinin Karşılaştırılması. Laringoskopi Ve Entübasyona Karşı Gelişen Hemodinamik Cevabın Baskılanmasında Dexmedetomidine Ve Esmololün Etkinliğinin Karşılaştırılması (Uzmanlık Tezi). İstanbul, İstanbul, Türkiye Cumhuriyeti: Haseki Eğitim ve Araştırma Hastanesi.
- [37] Üniversitesi, E. (2020). DENEY NO: 8 VENTİLATÖR TESTİ. Kayseri: Erciyes Üniversitesi.
- [38] Vatan, F., & Salur, D. (2010). Yönetici hemşirelerin hastanelerdeki deprem afet planları konusundaki görüşlerinin incelenmesi. Maltepe Üniversitesi Hemşirelik Bilim ve Sanatı Dergisi, 32-44.
- [39] Yan , Y. (2011). Disaster nursing skills, knowledge and attitudes required in earthquake relief: Implications for nursing education. . International Nursing Review, 351-359.
- [40] Yaylacı, S., Cimilli Öztürk, T., & Çelik Yılmaz, S. (2013). Acil Servise Ambulansla Başvuran Hastaların Aciliyetinin Retrospektif Değerlendirilmesi. Acıbadem Üniversitesi Sağlık Bilimleri Dergisi, 64-67.
- [41] Yener, D. (2020, Mart 24). Türkiye'nin koronavirüsle mücadele politikasına 'Bilim Kurulu' yön veriyor. Received from aa.com.tr: <https://www.aa.com.tr/tr/koronavirus/turkiyenin-koronavirusle-mucadele-politikasina-bilim-kurulu-yon-veriyor/1777215>