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Review Article
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Electronic Health Records from the Perspective of Nurses

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ABSTRACT

Since the time of Florence Nightingale, the founder of modern nursing, data obtained by nurses about patient diagnosis have become the most crucial source in planning care. These data have now been transferred to electronic media. Electronic health records have increased the quality and safety of care and helped establish accessible and holistic health records. In this process, while nurses try to adapt to the electronic health record system rapidly, they also experience work stress due to the complex workflow and time pressure. However, in the current period of rapid digitalization, nurse informaticists, with their increased skills and observation of user experiences, can be the key health personnel for every institution to develop and improve electronic health records.

Keywords: Nursing, Nursing Informaticists, Electronic Health Records

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INTRODUCTION

Since the beginning of modern nursing, nursing data have been the most potent source for planning and improving the quality of care. Nurses have used the data obtained within the scope of their contemporary roles by transforming them into information. The need for the effective management of information in healthcare has led to the emergence of 'nursing informatics,' which integrates nursing science, computer science, and information science (Seçginli, 2022). This relatively new field, which has matured since the 1980s, is now defined as a "specialty that integrates nursing science with multiple information and analytical sciences to identify, define, manage and communicate data, information, knowledge, and wisdom in nursing practice" (ANA, 2014).

In healthcare institutions, it is imperative to access information promptly to increase the quality of services and financial efficiency. Information technologies have become the fastest way of rapidly accessing information in many areas, including healthcare. This transformation aims to improve communication between patients and nurses, share information based on automation, prevent medical errors, and increase evidence-based practices (HIMMS, 2018).

Electronic health records (EHRs) are defined as recorded patient data that is digitally stored, can be accessed by a large number of authorized users, and can be securely shared between parties (Hayrinen et al., 2008). In the current information and communication age, the use of EHRs is becoming increasingly widespread. It has been reported that in the USA, the rate of EHR use in hospitals is over 90%, and the rate of EHRs enriched with a decision support system has increased from 2 to 44% within the last decade (Henry et al., 2016). EHRs, especially those with comprehensive content, is now recognized as a method to reduce healthcare costs, increase efficiency, and optimize patient safety (Hessels et al., 2015; Walker-Czyz, 2016).

As the largest group employed in healthcare delivery settings, nurses are considered to be the absolute users of EHRs (IOM, 2010). The Institute of Medicine (IOM) underlines the importance of nursing in digital healthcare transformation, stating that nurses should interact with other healthcare professionals to redesign healthcare services. Nurses will be expected to interact with EHRs more frequently in the following years. According to IOM, almost all nursing practices will acquire a digital dimension in the future (IOM, 2010; IOM, 2011).

Currently, nurses use EHRs for documentation, medication management, clinical observation, and coordination of patient care (Kutney-Lee et al., 2019). In the literature, while some studies suggest that using EHRs provides safer and higher-quality care (Jarvis et al., 2013; Hessels et al., 2015), others indicate that some nurses consider the efficacy of this practice questionable in terms of improving patient care since it is time-consuming and complicates workflow (Howe et al., 2018; Kim et al., 2017). However, these negative views of nurses may be related to institutional factors and different characteristics of the clinical field. In Turkey, it has been stated that nurses' most frequently recorded data in EHRs are patients' vital signs and nursing observation notes (Erdat, 2020).

According to socio-technical theory, EHRs cannot be successfully designed or implemented without considering their suitability for nurses' use and existing care services, particularly the work environment (Carayon, 2012; Harrison et al., 2007). The results of studies on this subject also indicate that the lack of personnel compliance with EHR practices is one of the most likely causes of unfavorable outcomes related to record-keeping after login (Strudwick et al., 2016; Boonstra et al., 2014). Kutney-Lee et al. (2019) stated that nurses' increased use of EHRs improved the quality of care. In a study conducted at St. Joseph's Hospital in 2016, it was reported that nurses were able to adapt to technological innovations very quickly and provide individual-centered and high-quality nursing care. Using technologies reduced the associated cost and workload (Walker-Czyz, 2016). Consistent with these results, in another study, it was shown that using clinical decision support systems improved records on pressure ulcers and malnutrition, thus significantly reducing malnutrition rates (Fossum et al., 2011).

In healthcare, individuals and organizations need to acquire new skills and competencies to cope with the ever-changing and increasing digital developments (Gaskin and Skousen, 2016; Stevenson et al., 2010). The increasing use of information and communication technologies results in healthcare personnel continually gaining new skills and working under time pressure. However, increasing competence in using information technologies is not sufficient unless the technology works well (de Veer et al., 2011). While studies conducted in Texas and Norway showed that nurse satisfaction with EHRs was low

(Mcbride et al., 2017; Helleso and Sjetne, 2012), the most important determinant of satisfaction among nurses in Canada was reported to be the preferred working style, current practices, and professional values (Maillet et al., 2015). According to a study conducted by Vehko et al. (2019), the constant changes in and poor user-friendliness of EHRs create significant time pressure for nurses and become a source of psychological stress.

The timely and accurate recording of patient data in EHRs by nurses is essential in determining the physical, psychological, and sociocultural needs of the patient and helping create an appropriate care plan (Sahney and Sharma, 2018). Ensuring that all patient records are quickly and holistically accessible allows nurses to assess patients and prepare a more comprehensive care plan suitable for their needs (Yılmaz, 2014). In a study by Öztürk et al. (2022), 86% of nurses stated that computer-based care plans positively affected the quality of care. In another study, Demiray and Babaoğlu (2021) determined that nursing diagnoses in the system may be insufficient when changes occur in patients' conditions, and a system allowing for manual entries into the system might be effective in resolving this problem and providing personalized care. In the same study, it was stated that the use of EHRs by nurses not only improved patient outcomes but also facilitated their implementation of the care plan (Demiray and Babaoğlu, 2021). Such computer-based maintenance plans can also be used as a learning tool that guides nursing practices. In addition, there is a need to use a classification system that facilitates communication in planning care based on a common language in EHRs. When developing such software, institutions should include nursing classification systems in this process (Tastan et al., 2014).

In addition to planning care, EHRs are also crucial in providing data to conduct research and creating a legal source by documenting the care and treatment applied in a healthcare institution (Sahney and Sharma, 2018). Nurses perform large data entries into EHRs in their specific areas. Using a common language in the electronic environment is essential to ensure that the data entered are of national and international value and can be used for future research purposes (Jacquemard et al., 2020). Most of the 'big data' recorded on EHRs include the subjective and objective assessment of nurses. Nurses must access EHRs representing large databases to identify general problems and plan a

research process based on these problems (Kaplan, 2021). From this point of view, within the scope of the researcher role, nurses can retrospectively benefit from these data in developing their profession and revealing evidence of the care provided (Gedük, 2018; Persell et al., 2018; Tubbs-Coley et al., 2019).

Using information technologies, nurses can perform various roles, such as counseling and education, as well as providing higher-quality individualized nursing care (Machon et al., 2020). In this regard, it is recommended that nursing informatics systems, including EHRs, should be included in the curriculum starting from undergraduate nursing education (Konukbay et al., 2020). However, student nurses currently need access to EHRs in practice (Kaplan, 2021), which may result in inadequacies related to EHRs at the beginning of their professional lives.

The use of technologies in nursing practices has brought along a process of change, trusting essential responsibilities to nursing preceptors and leaders, including training, regulating the number of nurses, and allowing them to feel self-confident about using technologies. Nurse preceptors and leaders also need to research technologies adopted in other disciplines to increase their efficiency in the care environment (Cloyd and Thompson, 2020).

The success of an EHR depends on how usable software is for healthcare professionals, and there is a need for a comprehensive usability assessment before the system can be successfully implemented. However, not all nurses have the knowledge and skills necessary to perform extensive usability testing; therefore, as healthcare-related technology and software become more specialized, usability assessments should be conducted for EHRs under the guidance of nurse informaticists (Rojas and Seckman, 2014).

Fundamental changes that have occurred in nursing practice with the introduction of health informatics have increased the interest of nurses in the field of informatics (ANA, 2008). The evaluation of the usability of software by nurses will not only demonstrate the extent to which it meets user needs efficiently and effectively but also reveal whether this system helps reduce errors and improve the quality of care. A study on this subject showed that the involvement of nurses in the project process while structuring EHRs increased patient satisfaction, patient outcomes, and nurse productivity (de Sousa et al., 2012). From this point of view, well-designed EHRs developed under the guid-

ance of nurse informaticists by taking into account expectations, technological advances, and software complexity can benefit all outputs.

CONCLUSION

As essential stakeholders of healthcare services, nurses are expected to provide personalized, high-quality, and safe care by keeping pace with the astonishing speed of technological advances. While trying to adapt to this process quickly, nurses must also increase their competence in using information technologies. In addition, nurses should remain loyal to their professional principles and values. EHRs not only represent the ethical recording of many care practices performed by nurses in the clinical field but also reduce the workload and increase the reliability of records. As one of the most important stakeholders of this process, nurses should also assume roles that will contribute to improving and developing the systems used. From this perspective, it seems that the time has come for nurses to evolve from passive users to active creators of EHRs.

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Process Management and Improvement in Health Services: A Hospital Appointment System Example

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ABSTRACT

In today's competitive conditions, businesses that produce goods or services frequently benefit from process improvement and similar methods to achieve their goals. Being process-oriented means giving importance to the creation of quality, not quality control. The Hospital Appointment system is the admission of patients to polyclinics at certain time periods. The purpose of the appointment system for the patients is to organize and spread the time of the patients' arrival at the hospital outpatient clinics. In general, to solve the waiting problem in hospitals, health services are provided by distributing patients to certain time periods. However, due to the insufficient capacity of the hospital, the patients' demand for health services cannot be met, and therefore the appointment problem continues. Patients spend days on the internet and on the phone to get an appointment from some medical units. In this context, the aim of the study is to evaluate the problems experienced in the appointment

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process in health services in terms of quality, time, technique and customer satisfaction, to make improvements and evaluate results.
Keywords: Appointment System, Health Services, Process Improvement

1. INTRODUCTION

Healthcare entails a lot of responsibility. All hospital services should be carried out with professionalism and sensitivity. The most important thing patients expect from the hospital is to find healing or to be healed. The slightest mistake can have serious effects on human health. For this reason, it is essential that the interventions in the hospital are done correctly and on time.

The health service must be of high quality and reliable so that patients can trust their treatment. The most important indicator that determines the quality of service is patient satisfaction. The focus of health institutions, which are tasked with protecting and treating people from diseases, should be patients. While doing this, they should organize their processes according to the expectations of the patients as much as possible.

To provide quality service to patients, processes should be periodically reviewed and improved. This helps ensure that the care patients receive is of the best possible quality. It is necessary to apply process improvement methods to reduce errors and improve patient care. Process improvement activities help increase the efficiency and success of a process by quickly identifying and resolving problems. The process is analyzed comprehensively, and any issues found are resolved. To ensure high service quality, the elements that can reduce this are determined and eliminated.

The subject of the study is to carry out the improvement work in the process of making/giving appointments in health services and to evaluate the result. When the literature is reviewed, it has been observed that there are not enough studies on the process of making/giving appointments within the scope of hospital services, and it has been observed that there are improvement studies mostly related to polyclinic services. Studies with the appointment system process in the literature are also limited to the applications in public hospitals on the Central Physician Appointment System (MHRS) in the example of Turkey (Pekgör et al., 2017; Küçük et al., 2021). For this reason, it is aimed to contribute to the literature by guiding the health institutions that currently offer this

system with the improvements made in the process of making an appointment in a private hospital.

It is aimed to evaluate the applications and results of the appointment system, which is considered as an example of process improvement applied in a selected private hospital within the scope of the study, in terms of quality, time, technique, and customer satisfaction. For this purpose, the stages of the appointment system before and after the improvement in this hospital were interpreted by examining value stream maps. As a result, it was revealed that the new appointment system made significant contributions to the hospital management by means of process improvement in terms of time, quality, technique, and customer satisfaction, and suggestions given.

The study consists of four main parts. In the next section, process management and process improvement studies in health services, and in the third section, detailed information about the concept of health services and hospitals is given. In the fourth section of the study, the definition, classification, parameters, and functions of the hospital appointment system, which is the basis of the application, are mentioned. In the last section, the information about the hospital where the application was carried out was mentioned and the improved appointment service, which is one of the health services processes, was emphasized.

2. PROCESS MANAGEMENT

2.1. Concept of Process

The process of producing something includes a series of related steps that begin with an input. By adding value to this input, we can produce a specific output. Processes are considered as a set of activities that transform inputs into outputs that are useful to their customers (Hammer, 2015).

According to the Turkish Standards Institute, the process is a set of activities that create a product (output) for the customer by taking input and adding value. In this process, it is the conversion of inputs (equipment, methods, manpower/service, environment, and materials) into output form. This includes creating or adding value in form, time, and place. Value-related issues are examined in terms of form, time, and place (Bozkurt, 2005). A process can also be defined as a set of activities that create added value on various inputs and are used to achieve planned results. In other words, they are processes that

aim to obtain value-added output by using a series of inputs to create value for the customer (Özkan, 2015). It is a group of input items that are usually interrelated and grouped into five categories. These inputs can be listed as people, equipment, materials, methods, and environment (Dumas et al., 2013).

2.2. Process Management

The traditional management approach that prioritizes hierarchy (level) and division of labor (expertise) creates obstacles to the natural flow of the organization. The management approach that has come to the fore to save business processes from these obstacles is called Management with Processes, or in other words, Process Management. As a management technique, process management is defined as a series of activities carried out to monitor and improve processes regularly and continuously. In this respect, process management can also be applied in the new management approach (Bozkurt, 2005).

Process management is an umbrella term that encompasses all activities that help identify the needs of different stakeholders, establish processes, monitor performance, and make necessary changes. It can also be expressed simply as "the systematic management of processes". It is a way of systematically managing the processes of a system. Within the scope of process management, it is necessary to determine, improve, maintain, and update the ongoing works in the organization based on processes and ensure their continuity in line with the objectives and targets. Process management can also be considered in the context of monitoring, evaluating, and improving the functioning of the organization within the existing hierarchy (Rosemann and Brocke, 2015).

2.3. Process Improvement

In process management, it is very important to identify and eliminate activities that do not add value to any process. For this reason, companies must constantly monitor and control their business processes. (Türkan and Görener, 2017). In this way, faults can be detected, and action can be taken within the scope of improved processes. Especially in today's competitive business environment, various process improvement methods are used to provide customers with high-quality and low-cost services or products, and enable them to stay in business and stand out from the competition. One of the most important aim of these methods is to improve business processes that do not create value by providing financial benefits and customer satisfaction (Avunduk, 2019).

Improvements in processes are a culture that should be adopted by the companies which desire to retain their existing customers and increase their potential. Every service and/or product goes through a business cycle. The concept of process is a systematic set of activities performed in a specific order to produce goods or services. At the end of the process, the goods or services will be finalized (Parlak, 2017). The production process is the sum of the materials, people, methods, and other factors that interact to obtain a product (Arslan et al., 2015). The service process is the activities in which information replaces raw materials, configurations replace methods, and computer/information systems replace machines (Dumantepe, 2017).

Process improvement can be defined as the elimination of non-value-added steps that affect the workflow. When improvement practices cover all process activities, it reduces the waste, cost, and time spent on each activity. Thus, work will be carried out faster, easier, and at a lower cost. Process improvement research is a tool that is always on the agenda for companies with different concepts. This is done by companies to reduce errors, inventory, costs, and also to improve quality, speed up operations, and increase efficiency and productivity. In this context, processes are first defined in a successful process improvement application. An improvement team is formed by deciding which processes need to be improved. By determining the source of the problems in the processes, appropriate improvement methods are determined and then the most appropriate one is selected. Improvements are tested and evaluated. If positive results are obtained, it is expanded, but restoration works are started again if necessary (Eyüboğlu, 2012).

The preferred methods are very important for the success of the process improvement study. Because different businesses have different processes that need to be optimized for efficiency. Each business should use the most appropriate optimization method for its process. There are various ways to achieve an effective result, so making the right choice is important (Özan, 2021).

2.4. Process Improvement Methods

Process improvement is a set of activities that increase the performance of managers and other employees and complement each other (Kovancı, 1999). It is applied to recognize problems that may arise during process improvement and to find solutions. The most important expectation in process improvement

efforts is to determine what happens and improve the process by using the data obtained as a result of process activities (Öztürk et al., 2011). These improvement methods can be listed as six sigma (Ateekh-ur-Rehman, 2012; Bubevski, 2016; Çağlar and Kurt, 2016; Öztürk, 2010; Özveri and Çakır, 2012; Senger and Cengiz, 2018), kanban (Rauch et al., 2016), 5S (Çakırkaya and Cengiz, 2018; Acar, 2016), 8D, kaizen (Tatham and Worrell, 2011), simulation (Çil and Yalçın, 2018; Doğan and Takci, 2015), debugging poka-yoke (Farrington et al., 2018), cause-and-effect diagrams, FMEA, PFMEA, histograms, control charts, brainstorming, distribution charts, pareto chart (Yılmaz et al., 2021), work studies (Dora et al., 2015), performance chart (Jeyaraman and Teo, 2010), nominal grouping (Thomassey, 2014), flowchart (Fisher et al., 2011), value stream mapping (Kuğu and Köse, 2021; Ömürgönülşen and Çatman, 2018; Vinodh et al., 2016), strategy comparison (Yılmaz, 2019), dashboard and SWOT analysis (Kaygusuz, 2014). Due to the different business processes of the companies, there is not only one method that is applicable to all of them but a few of the techniques can be applied together. The current methods will vary depending on the process being improved. In this sense, the process improvement methods used in companies in the literature are given in Table 1 below.

Table 1. Methods Used in Process Improvement

Brainstorming	Flow diagram	Quality Circles
Nominal Group Technique	Pareto Diagram	Scoreboard Diagram
Cause-Effect Diagram	Product tree	Histogram Diagram
Matrix Diagram	Kanban	Relationship Diagram
Scatter Diagram	Experimental Design Methods	Simulation
Supply chain management	Simulation (Simulation)	Poka - Yoke Practices
Force Field Analysis	Total Efficient Maintenance	5S
Analytical Hierarchy Process	Kazien	Statistical Process Control
Total quality Management	Total Equipment Effectiveness	Theory of Constraints
Lean manufacturing	Failure Mode and Effects Analysis [PFMEA/FMEA]	Information Management
Six Sigma	EFQM	Quality Management Standards

In this study, Value Stream Mapping and brainstorming methods were used in practice. General information about these two methods is given below.

2.4.1. Value Stream Mapping (VSM)

The work and actions to be performed in the process are clearly defined with VSM. The technique provides a visual explanation of what needs to be done as well as a written explanation. In this way, the works to be done are listed in order and it will be determined by whom, in which time frame and how (Yalçınkaya, 1997; Andrade et al., 2016)

2.4.2. Brainstorming

Brainstorming is a group work done when it is desired to bring ideas, solutions, and basic reasons together on any subject (Eyüboğlu, 2012). The number of participants in the group cannot be less than 6 people and not more than 20 people. For many ideas to emerge, it is preferred for this method to have people in different age groups with different perspectives in the group. In addition to the experts, there should be people who are not directly involved in the subject to evaluate different perspectives (Çavuş, 2004).

The brainstorming application process includes the steps of defining the problem, generating unlimited ideas, categorizing, and evaluating the ideas produced. Instead of traditional brainstorming, reverse brainstorming can also be used for the same purpose. Although the same kinds of steps of the brainstorming technique are used in its application, the most important difference between them is the way how the problem is handled. In this method, the participant has to think about the problem or situation that has been turned upside down while generating an idea and reach an answer by returning to the problem (Karataş et al., 2016). For example, when considering the hospital appointment process, which is the main subject of this study, the problem statement in the traditional brainstorming method is "What are the problems encountered in the hospital appointment process?" While it is expressed as "How do we cause problems in the appointment process?" in the reverse brainstorming method.

2.5. Improvement Studies in Health Services Literature Review

Considering the subject of the study, when the academic papers on the appointment systems processes offered in health services are examined, it is seen that a group of studies consists of studies on the design and structuring of this

process (Gupta and Denton, 2008; Lian et al., 2010; Aktepe et al., 2015; Tekin and Erol, 2016; Zhao et al., 2017; Cox and Boyd, 2020). Among them, a subgroup reveals the aspects of the system that are open to improvement by creating profiles of patients using the existing appointment system or evaluating patient satisfaction (Samadbeik et al., 2018; Pekgör et al., 2017; Küçük et al., 2021).

When process improvement studies are examined in a broad sense; in general, it was seen that business problems were determined by brainstorming, causes of the problems were detected by the fishbone method, and also evaluated in order of their importance. Business processes were mapped using flow charts. By doing so, gaps in the processes were observed and eliminated. (Barber and Deste, 2021). In addition, the most important causes of the problems were revealed by using Pareto analysis (Kara, 2018). Improvements have been made using process FMEA methodology to detect possible malfunctions, to identify the causes of errors and their effects by observing business processes. Here again, it has been seen that statistical process control (IPC) was used to ensure that errors are detected at the source to increase the overall quality (Tanik, 2013). It is seen that the lean production approach based on achieving error-free production with fewer resources in the shortest time and preventing waste in the applications used is used in both manufacturing and service sectors for the efficiency of the business process (Cox and Ulmer, 2015; Yıldız and Yalman, 2015; Yılmaz et al., 2017).

Table 2. Literature Review

Author	Area	Improvement Method
Yamamoto et al., 2010	Insulin administration plans process improvement study	Six Sigma
Rexhepi & Shrestha, 2011	Rheumatology service process	Kazien and Value Stream Mapping
Laganga, 2011	Appointment scheduling system	Metrics and indicators
Mandahawi et al., 2011	Eye diseases processes	Six Sigma
Yeh et al., 2011	Health clubs management	Six Sigma
Papadopoulos, 2011	process improvement	Continuous Improvement Methods
Gul & Guneri, 2012	Pathology service process	Simulation
Mohammadi & Eneyo, 2012	Emergency service process	Theory of Constraints and Simulation
Efe & Engin, 2012	Radiotherapy unit patient flow process	Value Stream Mapping
Ince et al., 2013	Emergency service process	Value Stream Mapping
Lama et al., 2013	Film shooting process	Six Sigma
Toussaint & Berry, 2013	Hospital's service processes review	Value Stream Mapping
Ryan et al., 2013	Surgical service process	Value Stream Mapping and Theory of Constraints
Lightning, 2014	Emergency service process	Flow diagram
Öztürker et al., 2014	Outpatient services	Six Sigma
Mannon, 2014	Trabeculectomy surgery	Continuous Improvement Methods
Poyraz, 2015	Design of hospital processes	Workflow Studies
Amonge, 2015	Medical consumable process review	Theory of Constraints
Yükçü & Yüksel, 2015	Emergency service process	Theory of Constraints
Doğan & Ersoy, 2016	Medical imaging process	Value Stream Mapping and Simulation
Aguilar-Escobar, Garrido Vega & González Zamora, 2016	Physical Therapy and Rehabilitation unit improvement	Theory of Constraints
Gleich et al., 2016	Medical record logistics service	Six Sigma
Dumantepe, 2017	Patient transfer process	Process Flow Chart
Tagge et al., 2017	IVF center processes	Six Sigma
Alkinaidri & Alsulami, 2018	Children's hospital pre-operation processes	Six Sigma

Author	Area	Improvement Method
Deniz & Özçelik, 2018	Improving the dispatch system	Value Stream Mapping and Heijunka
Gage, 2018	Physical Therapy and Rehabilitation unit processes	Simulation
Grida & Zeid, 2019	Emergency service process	Simulation and Theory of Constraints
Toda & Ginj, 2019	Surgical unit services	5S and Kanban
Bauer, 2019	Procurement and workflow improvement in the pharmacy	Theory of Constraints
Colhan, 2020	Emergency service process	Kaizen
Akbal, 2021	Process improvement in healthcare workplace hazardous materials management	Theory of Constraints, Lean Manufacturing and Simulation

When the studies in the literature on process improvement methods used in health services are examined, it is seen that Hellström, Lifvergren, and Quist (2010) performed a pioneering, comprehensive, and descriptive study by analyzing all aspects of the business processes in a hospital in Sweden and revealed the important points that should be in the processes in this sector. Other studies carried out in the health sector on process improvement practices are given in Table 2 according to the area and improvement method.

3. HEALTH SERVICES AND HOSPITALS

3.1. Healthcare Concept and Features

The level of health services, which play an important role in the survival of people by improving and protecting their quality of life, is a strong indicator of the level of development of the population. The concept of health services could be described as all the services provided for the detection, treatment and rehabilitation of diseases and the activities carried out to prevent diseases and improve the health status of the society (Unsal, 2017). Health services are provided by health businesses and include multifunctional and comprehensive services that should be handled separately from delivery, financing, purchasing and stakeholder processes. The World Health Organization defines health care as "a permanent system used to employ different health professionals in specific medical settings, organized throughout the country to achieve goals that vary according to the needs and desires of the society". In addition, healthcare service is to provide individual and social health services with all kinds of

preventive and therapeutic activities. Again, health care can be defined as the effort of different types of health professionals to diagnose and treat diseases and protect health in different settings and institutions (Akar and Özalp, 2002).

Easy usability, quality, continuity, and efficiency are the requirements of an effective health service (Kavuncubaşı, 2000). Health services differ from other goods/services produced in many aspects due to their qualifications. These features can be listed as follows (Yazgan, 2009)**:**

- The service offered in health services is very diverse. Therefore, it is very complex and variable.
- The demand-supply relationship in health services is balanced. It is irreplaceable and unpredictable.
- In health services, patients cannot determine the quality and quantity of the service because they have limited information about the features of the services.
- The patient's expenses are uncertain, there is no negotiation.
- It is difficult to be homogeneous in health services.
- Health services are urgent, they cannot be postponed.
- The services provided in health institutions have a low tolerance for errors and uncertainties.

3.2. Hospitals

Health services are gathered in four main groups. These are preventive health services, treatment services, rehabilitation services and health promotion services (Aktan and Işık, 2009). Hospital is a service enterprise that provides diagnosis, treatment, rehabilitation, and preventive health services, enables scientific research and also functions as an educational institution. The delivery and activities of health services are planned in line with the goals and objectives. Having measurable and comparable activities, evaluating results, and measuring performance are the most important elements in terms of ensuring both service quality and patient satisfaction (Dereköy and Kalmış, 2013).

According to the World Health Organization, hospitals are "health care establishments that have organized medical and other professional personnel, inpatient facilities, health care and related services 24/7." In the Statistical

Yearbook of Inpatient Treatment Institutions, the hospital is defined as follows: "It is the institution where the sick and injured, those who suspect the disease and those who want to have their health status checked, are observed, examined, diagnosed, treated and rehabilitated, as well as give birth." (Erdemir, 2015).

4. HOSPITAL APPOINTMENT SYSTEM DEFINITION, CLASSIFICATION, PARAMETERS AND FUNCTIONS

4.1. Hospital Appointment System Definition

The hospital appointment system can be defined as a system that regulates the admission of patients to polyclinics at certain times according to predetermined rules (Şahin, 2010). Its main function is to set appointment dates and times for patients, to regulate the workload of physicians in the polyclinic, and to allocate sufficient time for patients' visits. First, patients request an appointment through methods such as call center, internet or in-person application. After the hospital evaluates these requests, the polyclinic gives appointments to the patients on certain days and hours by spreading the appointments to various times according to the number of physicians and other personnel (Kağan, 2014).

With an effective and successful appointment system, patient waiting times are reduced, patient satisfaction increases, there are no long queues at the doctor's door and the doctor provides better service. (Kağan, 2014). In appointment systems, the number of patients that a doctor will examine during the day and the examination times should be well organized. A well-planned appointment system enables both the time patients wait for the doctors and the doctors to use their time more effectively. (Alagoz, 2013).

4.2. Types of Appointment

Hospital appointment systems are designed to use the clinic efficiently and to reduce patient waiting times. It is of great importance to increase patient access to the hospital through the appointment system. In an effective appointment system, it is necessary to minimize the waiting times in clinics and polyclinics where patients come for examination, and to use the appropriate hours of health care physicians in an efficient and planned manner. When the current appointment systems are examined; It is seen that appointments can be made via telephone, internet, and kiosk device or by applying in person (Alagöz, 2013).

4.2.1. Appointment by Phone

In this method, patients are provided to call the call center of the hospital and make an appointment through the operator. In this system, where operators make appointments by entering the necessary information of the person, first, the working days of the doctors and the number of patients they will see are determined and these data are recorded in the Hospital Information Management System (HIMMS). Patients call the call center to request an appointment, and the operators who pick up the phone request their identity and contact information from the patient and save them in the appointment system. Afterwards, an appointment is made for the medical unit, day and time that the patients want. In the meantime, it is asked whether the patient has a particular preference for a doctor, and if there is, an appointment is made with the desired doctor, if not, with any doctor, in accordance with the desired day and time. The system continues until all appointments on the days determined in this way are filled (Arslan, 2011).

4.2.2. Online Appointment System

In the internet appointment system, patients can make appointments from the Ministry of Health Central Physician Appointment System (MHRS) website or from the websites of the hospitals themselves. The internet appointment system includes the medical units and polyclinics in the hospital, the doctors working in these polyclinics and the examination hours of these doctors. By making an appointment with the polyclinic of the hospital they want, they can be examined by the doctor they want on the day and time they want (Arslan, 2011).

4.2.3. Personal Application

The method of making an appointment with the hospitals through personal application is a manual process that allows patients to apply to the patient registration units and get an appointment from the physicians they want, at the appropriate hours. After the appointment, patients wait in the waiting rooms for the time they will receive service. In this system, patients who apply to busy institutions often must queue and wait in long lines both to get an appointment and to be examined by the doctor. However, when there are patients who make an appointment over the phone or the internet and do not come, the system is prevented, since the patient who comes with a personal application is taken to the examination. This appointment method is preferred by hospital adminis-

trations since examination hours are not empty by maintaining this method in parallel with the others (Alagöz, 2013).

4.2.4. Appointment with Kiosk Device

In the appointment systems where the device called kiosk is used, patients can get the outpatient clinic queue number from the device without the need for auxiliary personnel. This device, which works in integration with HIMS and other appointment systems, allows patients to get sequence numbers from the doctor with the medical unit they want (Arslan, 2011).

4.3. Classification of Hospital Appointment Systems

Hospital appointment scheduling and giving systems are classified in four ways: single block, individual block, block appointment systems and individual-block appointment systems (Soylu, 2017).

4.3.1. Single Block

In the single block appointment system, the diagnosis and treatment of patients who come at the same time are made according to the order of arrival of the patients. In the single block appointment system, it is not known how long the patient will wait and it is the oldest system used to date. Some medical centers still use this appointment system today. The main reason for this is that some specialist doctors and administrators argue that it is difficult to predict how long a patient visit will last and that patients often arrive late for their scheduled appointments (*Şahin*, 2010).

4.3.2. Individual Block

In individual block systems, a different appointment time is assigned to each patient to be seen during the day. Each subsequent appointment time is tried to be matched with the end of the previous person's examination process. In this way, it is possible to reduce waiting times for appointments and to benefit from health services effectively (*Şahin*, 2010).

4.3.3. Block Appointment Systems

In block appointment systems, the duration of the outpatient session is divided into several blocks. Instead of giving different hours to each patient, block planning is done for more than one patient. In general, the length of each block and the number of patients in the blocks are equal in the outpatient clinic. In this system, the risk of patients arriving late for an appointment, not showing up at all, or waiting in the same block for a long-time spread to all blocks (*Şahin*, 2010).

4.3.4. Individual Block Appointment Systems

In individual block appointment systems, some patients are first given a block appointment for an outpatient appointment. Individual appointments are then scheduled for the patient. This system aims to make an efficient planning based on a workload storage strategy at the beginning of the outpatient visit (Şahin, 2010).

4.4. Appointment System Parameters

The indicators in the determination of hospital appointment systems are the rates of absenteeism of the patients by appointment, patient arrival times, average examination time, patient admission interval and doctors' schedule (Alagöz, 2013).

Absence Rates: It is the ratio of the number of patients who did not come to their appointment in a certain time to the total number of patients who made an appointment at the same time. For example, a patient who makes an appointment from the hospital but does not come will extend the outpatient treatment period of the patients.

Patient Arrival Times: This parameter expresses the arrival time of the patient who made an appointment from the hospital. Arriving at the hospital before the scheduled time causes crowds in front of the outpatient clinic and waiting rooms. The patient's late arrival at the scheduled time also interferes with the system and prolongs the waiting time.

Average Examination Time: Refers to the average time doctors spend on a patient for examination and treatment. If the time allocated by the doctors to the patients in the polyclinics exceeds the time in the planning, the appointment times of the other patients will be interrupted in a chain, the waiting times will be longer and ultimately the patient will be dissatisfied.

Patient Admission Interval: It refers to the difference between the examination times of two patients who are given consecutive appointments. After a patient's procedures are over, the patient admission interval may be extended if the examination is interrupted due to the prolongation of the preparation time of the polyclinic for the admission of the new patient to the outpatient clinic, the doctor taking a break due to any needs of the doctor, and therefore the delay in the appointment time, the phone call to the doctor during the examination or the constant opening of the door of the doctor's room by the

patients. . In this case, there may be disruptions in the scheduled appointment times.

Doctor's Schedule: The doctor can terminate the health service before or after the scheduled time. Doctors completing the examination and treatment before or after the specified period may also cause disruption of the appointment system.

4.5. Hospital Appointment Systems Functions

There are some functions of hospital appointment systems where patients request an appointment by applying to hospitals via the internet, call center or in person (Şahin, 2010):

- The system should have functions such as making a new appointment, deleting the defined appointment, searching the registered appointment, confirming the appointment, and closing the appointment.
- The appointment system should cover the polyclinic units that accept patients.
- The work schedule including the working days of the doctors should be followed, and appointments should be made for free time according to the calendar.
- It should be possible for doctors to close their appointment times during leave, temporary assignment, or training-giving periods.
- Appointment start and end time must be specified.
- Whether the patients came to their appointments on time, and if they did not, the reasons for this situation should be followed up.
- If an appointment is cancelled, the reason should be stated.
- Two or more patients should not be given an appointment to the same doctor on the same day and time.
- Appointments should not be made without obtaining the contact (mobile phone) number used by the patients.
- After the appointment is saved, all previously saved appointments of the patient can be viewed.

5. A HOSPITAL APPOINTMENT SYSTEM EXAMPLE

5.1. General Information About the Hospital

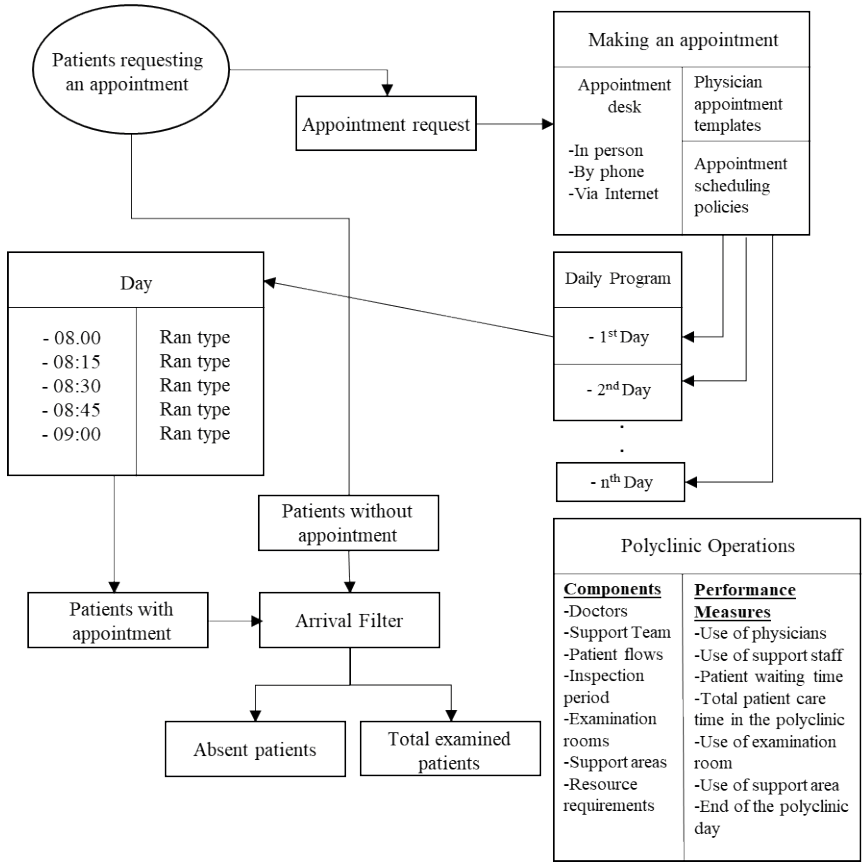
The application of the study was carried out in a private hospital operating in the health sector for many years in Istanbul and providing health services

to patients. The name of the hospital was not specified at the request of the authorities in the health institution that was the subject of the study, and it was named “X private hospital”. In the research, the flow of the appointment system in the X private hospital is discussed and this covers the whole process of making an appointment for the patients who come to the hospital to be examined. Appointment procedures in this institution; can be done in person, over the phone or online.

To evaluate the current situation of the appointment process, which is considered in the context of the purpose of the study, a team including the chief physician, assistant chief physician, business director, nursing services manager, quality management director, information technology director and call center manager in the hospital management is formed and the current situation analysis is made by brainstorming method. recommendations have been developed.

Total duration of the appointments made from the internet is 2,134,565 minutes. and 424,000 min. of the total annual duration of in-person appointments. appears to be. Looking at the performance indicator, the average processing time for making an appointment in person is 8 minutes, and the average processing time for an appointment from the internet is 6.50 minutes. and the average processing time to get an appointment from the call center is 10 minutes. was detected.

Figure 1. Value Stream Map of the Appointment Process



In the first step, as is value stream map of the appointment process was drawn by the team (see Figure 1) and the performance indicators of the previous year were examined. The route followed in the process of making/receiving appointments from the first step to the last step is mapped on the map containing the current situation. In the mapping process, different numbers of observations were made at different times, and the service flow was transferred from the beginning to the end, in a complete manner, into the value stream map of the current situation. When the indicators regarding the current situation are examined, the annual total duration of the appointments made from the call center is 682,220 minutes, and the annual

By drawing the as is map, the opinions of everyone in the team were taken

by brainstorming and the problems experienced were revealed. These identified problems are listed below:

- There are lost times due to personnel among the processes.
- Not using advanced software programs causes longer waiting times and conflicts in the appointment order.
- Doctors' appointment information in all buildings cannot be displayed on a single screen.
- The absence of different language options in the online appointment system directs patients to make an appointment through a call center or in person.
- Time losses cause delays in appointment times and increase in total service time.
- In addition, due to the short days of the doctor's calendar opened in the appointment system, it was observed that the patients could not make an appointment for examination when they wanted.

To solve the problems encountered in the current situation, the team carried out a new brainstorming in the next stage and the following suggestions were developed:

- Accelerating the appointment process with the technical development made in the appointment system software,
- Increasing the doctor's calendar created by the call center from 5 days to 10 days and updating the system accordingly,
- Ensuring that notifications are requested in case the appointment is canceled for appointments to be made over the Internet,
- Organizing customer service management, effective communication, and user trainings for the developed software for the personnel,
- Adding English and Arabic language options to the internet appointment system.

By making a simulation study of "to be" situation, the suggestions were evaluated, and it was decided to put into practice. The systemic changes implemented in the process improvement application are given below (see Figure 2-5):

1. With the development, patients who want to make an appointment can view the appointment information of existing doctors in all buildings on a single screen.

2. Doctor-based appointment links were created and directed to the doctor-specific 'make an appointment' buttons on the hospital website.

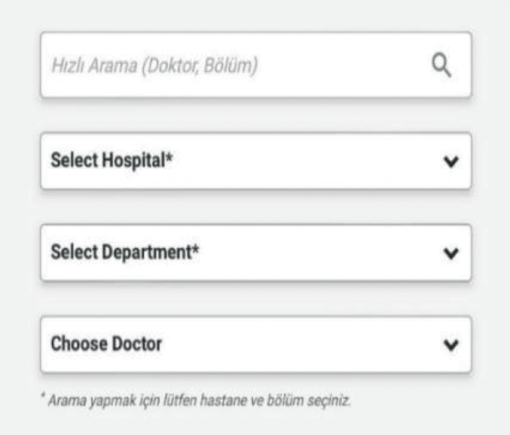
Figure 2. Make an Appointment System Display on the Doctor's Screen

3. If the doctor appointment slots are full, the "Call Me" system has been created, where patients will leave records.

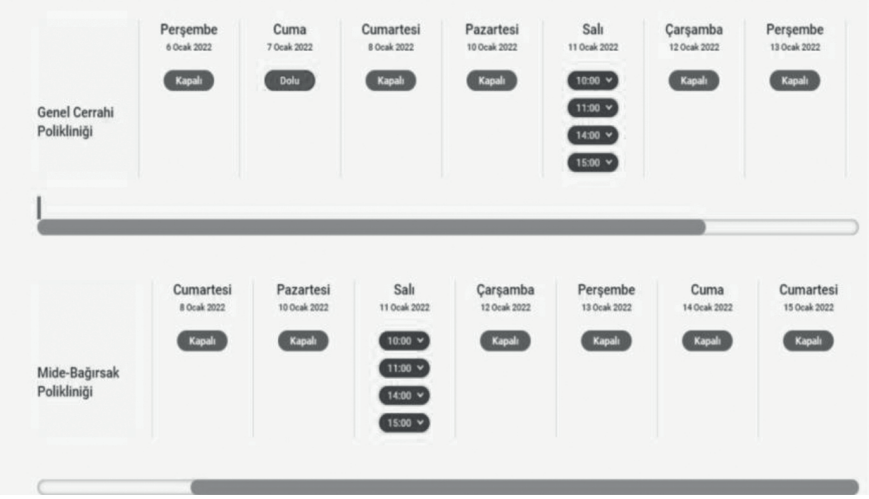
Figure 3. "Call me" System Display

4. English and Arabic language options have been added.

Figure 4. Language Options System Display



5. A structure has been established based on the polyclinic where appointments can be made 10 days in advance.



After the improvements made, the performance indicators of the new application were examined. Indicators for 2021 representing the pre-implementation and 2022 representing the aftermath are as follows:

- With the improvement in the appointment process, an increase in the number of patients visiting the polyclinic has been observed. While the number of patients who applied to the hospital in 2021 was 449,617, it was realized as .360 in 2022, an increase of 32% in patient capacity. This situation led the hospital management to increase the number of polyclinic rooms.
- While the number of foreign patients who applied to the hospital was 18,763 in 2021, this figure increased to 27,139 in 2022.
- When the duration of the appointment process is examined, the average processing time for making an appointment in person is 8 minutes, the average processing time for appointments from the internet is 6.50 minutes, and the average processing time for making an appointment from the call center is 10 minutes. The average process time of getting an appointment from the internet was 4.58 minutes, and the average processing time of getting an appointment from the call center decreased to 7.23 minutes. In general, the processing time has been shortened by 21.52% and time loss has been reduced.

Table 3. Appointment Compliance Rate

Appointment Compliance Rate by Channel	**2021**	**2022**
Call Center Appointment Compliance Rate	**81%**	**86%**
Number of Appointments Given by the Call Center Unit	68,222	45,800
Number of Patients Who Didn't Come to Their Appointment	12,879	6,380
Number of Patients Who Came to Appointment	55,343	39,420
Online Appointment Compliance Rate	**90%**	**95%**
Number of Online Appointments	328,395	509,560
Number of Patients Who Didn't Come to Their Appointment	32,789	23,261
Number of Patients Who Came to Appointment	295,606	486,299
In Person Appointment Compliance Rate	**64%**	**69%**
Number of Personal Appointments	53,000	38,000
Number of Patients Who Didn't Come to Their Appointment	18,943	11,758
Number of Patients Who Came to Appointment	34,057	26,242

- To measure customer satisfaction each year, the results of the survey conducted by the hospital in the center and in all additional service buildings with the participation of a total of 500 people were also compared. Accordingly, the patient satisfaction before the improvement was 63%, while the post-improvement rate was 89%.
- Indicators including appointment compliance of patients before and after process improvement are detailed in Table 3.

6. CONCLUSION AND RECOMMENDATIONS

In this study, the process followed in the provision of appointment service for hospitals was handled through the example of a private hospital, and the improvement of the current process was carried out by applying value stream map and brainstorming methods, and the results were evaluated through performance indicators determined on the value stream map.

According to the results obtained, the problems experienced during the appointment process are focused on quality, time, technique, and patient satisfaction. After the improvement, the process efficiency has increased compared

to the old system. Thanks to the new software developed with both a patient and doctor-oriented approach and as part of the improvement steps, the system has become more useful, and it has been observed that patient satisfaction and the number of patients examined have increased. At the same time, with these software developments, the processing times in the call center and online appointment processes have been shortened and time losses have been reduced. With the increase in the number of patients applying to the hospital, an increase of 32% was observed in the patient admission capacity. The absence of a foreign language option in the online application system was identified as a problem in the improvement work, and an increase in foreign patient capacity was observed by including English and Arabic languages for foreign patients in the system.

A survey was also conducted to measure patient satisfaction regarding the improved appointment system. These surveys were carried out with the participation of 500 people in total, both in the center and in all additional service buildings of the private hospital considered within the scope of the study. According to the survey results, the patient satisfaction before the improvement was 63%, while the post-improvement rate was 89%. This is another indicator of the effectiveness of the improvement work.

In studies dealing with hospital appointment processes, two important points stand out when we look at the literature that aims to design the process and to investigate patient satisfaction. First, it is recommended that the use of such systems directly affect patient satisfaction as it reduces patient waiting times, increases the importance of remote appointment systems especially after the Covid-19 pandemic, and also, various arrangements are made to facilitate the use of patients living in rural areas with low digital literacy. However, it is revealed that the central appointment system does not eliminate the inequality of high demand and low physician supply, and it is necessary to ensure the sustainability of this process by limiting the patients who come without an appointment. In this study, the problems encountered in the current process and the parallel improvement areas are aimed at reducing the number of patients coming without an appointment by increasing the ease of use and ensuring the effective use of the system. It is foreseen that the system will be able to use more advanced software by considering the long-term improvements, feed-

backs and similar problems of other hospitals experiencing problems in the sector. In this way, as a health institution that follows the developing technological developments and adopts innovative solutions in this context, a positive effect can be achieved to gain a place in the minds of patients. In future studies, the problems encountered by users in similar systems can be analyzed by process mining and applications can be made to identify new improvement areas.

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Comparison of Quality of Life of Dialysis Treatments: The Case of Ankara Province

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ABSTRACT

In this cross-sectional study, the quality of life of the patients who received Central Hemodialysis (CH), Home Hemodialysis (HH), and Peritoneal Dialysis (PD) treatments, which are the RRT methods applied in ESRD in Türkiye, is compared. This study aimed to offer suggestions for disseminating the application of the treatment method that provides life comfort. The Kidney Disease Quality of Life scale KDQOL 36 was applied to patients in Ankara diagnosed with ESRD and receiving central hemodialysis, home hemodialysis, and peritoneal dialysis treatments. The scale was applied by face-to-face interview method between 10.02.2022 and 01.05.2022. A simple random sampling method was used to determine the sample size, and all patients (n:574) with the sample size selected within the scope of the study were reached. In the evaluation of statistical tests, the level of significance was taken as α 0,05. It was observed that the mean quality of life of the physical and mental health components, which indicates the general quality of life of the patients, was below the average level with the values of 37.7±9.8 and 42.4±9.3, respectively. The mean of the effects of kidney disease in the sub-dimension was 58.9±24.5; The mean of the symptom list sub-dimension of kidney disease was 66.0±21.9. When the mean values of the sub-dimensions of the scale are evaluated as a whole, it is

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considered that the quality of life of the patients receiving dialysis treatment is low. Since home hemodialysis is superior to other types of dialysis in all sub-dimension mean scores of the scale, it is recommended that the Social Security Institution make encouraging regulations in the Health Implementation Communiqué to disseminate this practice.

Keywords: Chronic Kidney Failure, Dialysis, Quality of Life

INTRODUCTION

Chronic renal failure is a nephrological syndrome resulting in chronic, progressive, and irreversible kidney loss for various reasons (Süleymanlar, 2010). Although it is mostly preventable, or at least its progression can be significantly delayed when detected early, the low awareness level and early diagnosis do not allow this in many cases (THSK, 2014). For patients in the end-stage of renal disease (ESRD), a stage at which they could continue their lives, kidney transplantation or dialysis treatments, which are expressed as renal replacement therapy (RRT), should be applied (Acar, 2016). The ideal treatment for ESRD is kidney transplantation, in which all kidney functions are restored. However, due to the limitations of transplantation, most patients have to continue their lives with dialysis (USRDS, 2019). Hemodialysis is the process of reintroducing the blood taken from the patient to the patient by clearing the liquid and solute content by means of a semi-permeable membrane and a hemodialysis machine (Serdengeçti, 2009). Home hemodialysis (HD) is a hemodialysis treatment administered by the patient or their assistant in the patient's own home (San, 2009). Peritoneal dialysis (PD) is a treatment method that mimics some normal kidney functions. It got this name from the peritoneum (Peker, 2007).

Although quality of life is frequently discussed in various fields of expertise, especially in economics, social sciences, and medicine, there is no universal definition. Although the expressions used in different areas while defining the quality of life vary, according to the definition of the World Health Organization Quality of Life Group, the satisfaction level of the person's expectations from life, goals, and the level of sufficiency in providing the standards they have determined for themselves within the framework of the value system they live in means the quality of life (Kantarcı, 2017). Health-Related Quality of Life, on the other hand, came to the fore with the understanding that comes

from the World Health Organization's definition of health as "a state of complete physical, mental, and social well-being." This understanding has caused the concept of health to evolve from a limited biomedical model to a large-scale biopsychosocial model (Edisan & Kadıoğlu, 2011).

Many quality-of-life scales have been used in studies of ESRD, and the most widely used is the Kidney Disease Quality of Life Form (KDQOL), one of the disease-specific scales developed by Ron Hays et al. In the USA in 1994. KDQOL is a scale used to monitor patients with ESRD and the effects of treatment and is evaluated by self-reporting of the patient's well-being. KDQOL also allows for detailed monitoring of clinical pictures as a result of treatment by comparing different RRT methods (Cohen et al.,2019). The study is the first in which patients' quality of life in end-stage renal disease (ESRD), the stage in which patients received central hemodialysis (CH), ED, and PD treatments with RRT methods, was compared.

Peritoneal dialysis and central hemodialysis comparisons of the KDQOL 36 Kidney Disease Quality of Life Scale are frequently encountered in the literature, and the comparison of three dialysis types was made with this study for the first time since home hemodialysis practice has become widespread recently.

Within the scope of this study, analyses were carried out based on the following hypotheses.

Hypothesis 1: There is a statistically significant relationship between the sub-dimensions of the KDQOL-36 scale.

Hypothesis 2: There is a difference between the mean scores of the sub-dimensions (a. Symptom List of Kidney Disease, b. Effects of Kidney Disease, c. Burden of Kidney Disease, d. Physical Health Component, e. Mental Health Component) according to the type of dialysis.

MATERIALS AND METHODS

Purpose of the study

In this cross-sectional study, the quality of life of patients who received central hemodialysis (CD), HD, and PD treatments, which are the RRT methods applied in ESRD in Turkey, was compared. In light of the results obtained, suggestions were made to expand the application of the treatment method that provides the most life comfort to the patients intended.

With this cross-sectional study, it is aimed to compare the quality of life of patients who received central hemodialysis (MH), ED, and PD treatments, which are among the RRT methods applied in ESRD.

When the distribution of patients by dialysis type is examined, 59% of the patients are treated with CD, while 33% are treated with HD and 8% with PD. The socio-demographic characteristics of the patients are presented in Table 1.

Table 1. Distribution of Patients by Socio-Demographic Characteristics (n=574)

Socio-Demographic Characteristics	Category	n	%
Gender	Female	282	49,1
	Male	292	50,9
Dialysis Time	1-5 year	282	49,1
	6-10 year	163	28,4
	11-15 year	67	11,7
	16-20 year	59	10,3
	20 + year	3	0,5
Marital status	Married	432	75,3
	Other	70	12,2
	Single	72	12,5
Educational Status	Illiterate	57	9,9
	Primary school	187	32,6
	Middle School	99	17,2
	High school	134	23,3
	University	97	16,9
Income rate	Less Than Minimum Wage	167	29,1
	Equal to Minimum Wage	243	42,3
	More Than Minimum Wage	164	28,6
Age Groups	20-44	136	23,7
	45-64	256	44,6
	65-74	114	19,9
	75+	68	11,8

When the distribution of the patients according to dialysis durations is examined, it is seen that approximately 49.1% of them are dialyzed for 1–5 years, 28.4% for 6–10 years, 11.7% for 11–15 years, and 10.3% for 16 years. It is seen that they received dialysis treatment for 20 years. Three patients with kidney disease dialyzed for 20 years or more (Table 1).

When the patients' marital status is examined, it is seen that 75.3% of them are married. In the distribution of the number of patients by education, 32.6% were primary school graduates, 23.3% were high school graduates, 17.2% were secondary school graduates, 16.9% were university graduates, and 9.9% were illiterate. It appears not to be.(?) Considering the distribution of the patients in the study according to their income levels, it is seen that the income of 42.3% is equal to the minimum wage, 29.1% is less than the minimum wage, and 28.6% is more than the minimum wage (Table 2).

The relationship between the scores of the sub-dimensions of the KDQOL-36 scale is presented in Table 2, and the relationship between all the sub-dimensions of the scale was found to be statistically significant. There is a positive, linear, and strong relationship between the size of the Symptom List of Kidney Disease and the Impact of Kidney Disease size. Among other sub-dimensions, it is positive, linear, and moderate.

Table 2. The Relationship Between the Sub-Dimensions of the KDQOL-36 Scale (n=574)

		Kidney Disease Symptom List	Kidney Disease Effect	Kidney Disease Burden	Physical Health Component	Mental Health Component
Kidney Disease Symptom List	Pearson KK	1	,758**	,446**	,550**	,436**
	p value		,000	,000	,000	,000
Kidney Disease Effect	Pearson KK.	,758**	1	,559**	,553**	,460**
	p value	,000		,000	,000	,000
Kidney Disease Burden	Pearson KK	,446**	,559**	1	,580**	,472**
	p value	,000	,000		,000	,000
Physical Health Component	Pearson KK	,550**	,553**	,580**	1	,312**
	p value	,000	,000	,000		,000
Mental Health Component	Pearson KK	,436**	,460**	,472**	,312**	1
	p value	,000	,000	,000	,000	

** The Pearson KK is significant at the 0.05 level.

A comparison of the mean scores of the KDQOL-36 Scale Sub-Dimensions by Dialysis Type was made, and the mean values are presented in Table 3.

Table 3. Distribution of Patients' KDQOL-36 Sub-Dimensional Scores by Dialysis Type

	MH (n=341)			EH (n=45)			PD (n=188)		
	Ort.	Med.	Std. Sapma	Ort.	Med.	Std. Sapma	Ort.	Med.	Std. Sapma
Kidney Disease Symptom List	62,378	62,5	20,939	80,324	83,333	16,377	69,271	70,833	23,024
Kidney Disease Effect	54,426	56,25	24,077	68,919	68,75	20,728	64,706	65,625	24,405
Kidney Disease Burden	34,238	31,25	24,18	48,194	43,75	27,748	47,374	46,875	23,897
Physical Health Component	35,287	34,716	9,0802	45,229	48,015	10,732	40,16	40,25	9,462
Mental Health Component	40,968	39,864	8,9401	46,433	47,474	9,4612	43,957	44,368	9,4276

Whether the distribution of scores of the patients according to the type of dialysis in the subscales was normal or not was determined by the Kolmogorov-Smirnov test. The test results are presented in Table 4. It is seen that the distribution of each subscale according to the type of dialysis is not normal ($p<0.05$).

Table 4. Distribution of Patients' KDQOL-36 Sub-Dimension Scores by Dialysis Type Normality Test

Hemodialysis Group		Kolmogorov-Smirnov[a]	
		Statistics	p value
Kidney Disease Symptom List	CH	0,07	0
	HH	0,128	0,06
	PD	0,119	0
Kidney Disease Effect	CH	0,051	0,035
	HH	0,1	,200*
	PD	0,131	0
Kidney Disease Burden	CH	0,127	0
	HH	0,141	0,024
	PD	0,095	0
Physical Health Component	CH	0,037	,200*
	HH	0,144	0,021
	PD	0,057	,200*
Mental Health Component	CH	0,061	0,004
	HH	0,068	,200*
	PD	0,059	,200*

The test of whether there is a significant difference between the mean scores of the KDQOL-36 scale sub-dimensions of the patients among the dialysis types is presented in Table 5. According to the results of the Kruskal-Wallis analysis of variance, it is said that the change in the mean scores of all sub-dimensions according to the type of dialysis is statistically significant ($p<0.01$).

Table 5. Kruskal Wallis Analysis of Variance

	Kidney Disease Symptom List	Kidney Disease Effect	Kidney Disease Burden	Physical Health Component	Mental Health Component
Mean	66,042	58,929	39,634	37,662	42,375
Chi-Square	34,926	29,149	44,582	52,421	22,935
p-value	,000	,000	,000	,000	,000

The results of which dialysis types differ in each sub-dimension were investigated with the Mann-Whitney U test. Paired comparison results with the Mann-Whitney U test are given in Table 6. It was concluded that the differences between the mean scores of all sub-dimensions were statistically significant

(p<0.0016), and the difference between the mean scores of all sub-dimensions of the patients treated with ED and PD was not significant (p>0.0016).

Table 6. Types of Dialysis (Pairwise Comparison) Mean Subscale Scores Difference Test

		Kidney Disease Symptom List	Kidney Disease Effect	Kidney Disease Burden	Physical Health Component	Mental Health Component
CH ve HH	Mean	64,470	56,116	35,865	36,446	41,605
	Mann-Whitney U	3850,500	4880,500	5384,000	3721,500	4976,500
	p value	,000	,000	,001	,000	,000
CH ve PD	Mean	64,828	58,080	38,906	37,019	42,030
	Mann-Whitney U	26037,000	24592,000	21376,500	22872,500	26026,500
	p value	,000	,000	,000	,000	,000
HD ve PD	Mean	71,406	65,520	47,532	41,139	44,435
	Mann-Whitney U	3077,500	3823,000	4179,000	2978,000	3526,000
	p value	,005	,316	,900	,002	,083

DISCUSSIONS

The quality of life of kidney patients in the ESRD stage who receive dialysis treatment was evaluated with five main sub-dimensions: physical and mental components, symptoms of kidney disease, effects, and burden of kidney disease. As a result of the evaluation, it was seen that the lowest averages were in the physical health component dimension (37.7±9.8) and the burden of kidney disease dimension (39.6±25.2), respectively. These averages are well below the intermediate level. It was observed that the mean quality of life of the physical and mental health components, which indicate the general quality of life of the patients, was below the average level with values of 37.7±9.8 and 42.4±9.3, respectively. The mean of the effects of kidney disease in the sub-dimension was 58.9±24.5. The mean of the symptom list sub-dimension of kidney disease was 66.0±21.9. When the mean values of the sub-dimensions are evaluated as

a whole, it is considered that the quality of life of the patients diagnosed with ESRD who receive dialysis treatment is low. In the study of Cohen et al. (2019), which shows similar results, the mean burden of the kidney disease sub-dimension to patients was 51.3±29.8; the effects of kidney disease sub-dimension mean were 73.0±22.7; the mean of symptoms and problems of kidney disease sub-dimension was 78.1±16.7; the mean of the physical health component sub-dimension was 36.6±12.2; and the mean of the sub-dimension of the mental health component was 49.0±13.4. In the study of Fukuhura et al. (2003), the mean burden of the kidney disease sub-dimension of patients was 28.6; the effects of the kidney disease sub-dimension mean were 67.7; the mean sub-dimension of symptoms and problems of kidney disease was 75.8; the mean of the physical health component sub-dimension was 60.9; and the mean of the sub-dimension of the mental health component was determined as 81.7. Nisel et al.(2016), who showed different results with this study, found the lowest quality of life sub-dimension as the burden of kidney disease, with an average of 41.31 in their study in Turkey. When the averages of the other sub-dimensions are examined, the effects of kidney disease are 69.28; the mean of the symptoms and problems sub-dimension is 79.59. Kring et al. (2009) used the mean quality of life as 40.80 for the burden of kidney disease, 62.50 for effect size, and 71.10 for symptom and problem list dimension; they found 75.90 for the physical health component and 77.20 for the mental life component. It is seen that there are many studies in the literature to evaluate the quality of life of patients diagnosed with ESRD and undergoing dialysis treatment. In these studies, it is seen that there is no consensus on the superiority of dialysis treatment types over each other in terms of their effects on quality of life.

CONCLUSIONS

As a result of this study, when the mean values of the sub-dimensions of the scale are evaluated as a whole, it is considered that the quality of life of the patients diagnosed with ESRD and receiving dialysis treatment is low. The difference between the mean scores of all sub-dimensions of patients treated with MD and PD was statistically significant. It was concluded that the difference between the mean scores in all sub-dimensions of the patients treated with ED and PD was not significant ($p>0.0016$). In the studies in the literature, there is no certainty about the superiority of dialysis treatments over each other. How-

ever, since it was seen in the study that ED outperformed other dialysis types in all sub-dimension mean scores of the scale, it is recommended to expand this type of dialysis. It is recommended that the Social Security Institution make encouraging regulations in the Health Implementation Communiqué to disseminate this practice.

Ethical Approval: This study was initiated after obtaining ethics committee approval from Ankara University's Health Sciences Ethics Committee with a decision dated 16.07.2018 and numbered 160.

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Possible Consequences of Reclassification of Non-Invasive Brain Stimulating as Class III Medical Devices in Europe and Its Reflections on Our Country

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ABSTRACT

Neuromodulation techniques (NIBS) and devices that have emerged in the last thirty years continue to develop rapidly. NIBS, which initially appeared to be effective only for the treatment of some neurological diseases, have been found to be effective in increasing the capacities of normal people for education, sports, business life, and military fields over time. This has led to the production of home/individual-use versions of NIBS devices. On the one hand, individual use of these devices is increasing rapidly in many countries; on the other hand, many research studies on the effectiveness, safety, and new usage areas of the techniques continue. The production, placing on the market, and use of all these NIBS devices to be used for scientific research, treatment, or individual uses are directly or indirectly dependent on the rules and conditions in the Medical Devices Regulation (MDR) of the European Union (EU). Our country also complies with these rules. A new regulation numbered 2022/2347 has

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been published by the EU for the specification of non-medical product groups included in Annex XVI of Regulation No. 2017/745. NIBS devices, one of the product groups in question, have been subjected to a new classification due to this regulation, and this change has caused various objections from all stakeholders related to this field. Objections to the new classification stem from the fact that ethics committees will drastically change their approach to research in these areas and that these changes involve much more challenging conditions for researchers and device manufacturers than before. As a result of this situation, the main concern has emerged that the limitation of research will lead to the interruption of production and development activities in this field and even prevent patients from benefiting from these treatments.

In this study, the old and new regulations are analyzed together, and it is aimed to evaluate the appropriateness of the procedure and content of the regulation, its reflections on the field, and the criticisms brought to the regulation in the light of scientific data in the field. Based on this assessment, an attempt has been made to provide a perspective to the relevant stakeholders in Turkey, researchers, ethics committees that authorise/supervise research with these devices in line with the EU, and the competent authority that oversees the production, distribution, and conformity of medical devices, both on the current situation and what should be.

Keywords: European Union Medical Device Regulation, Non-invasive neuromodulation, MDR, Turkish Medicines and Medical Devices Agency (TİTCK)

INTRODUCTION

Today's world of technology is becoming a place where, on the one hand, mental power and capacity are becoming increasingly important in individual and social life, and on the other hand, a number of neurological disorders are rapidly spreading. Both of these situations have prompted researchers to further investigate the structure, functioning, possibilities, and limitations of the brain. In addition, newly developed technologies in the field of healthcare are now a candidate to change the classical provision of better but more expensive healthcare. For example, artificial intelligence-based follow-ups make it possible to reduce chronic and age-related diseases and contribute to the economy as well as health. In this sense, it can be said that neuromodulation techniques,

a groundbreaking approach that aims to improve the functions of the brain, which is the organ that controls every aspect of human thinking, perception, and behavior, in many ways, to increase its capacity and to correct it when damaged, have similar characteristics. With the simplest example, NIBS is a technology that has the potential to contribute to both health and the economy by reducing or even eliminating the use of medication in diseases such as depression and chronic pain, which are considered chronic and unsolvable today. Therefore, not only the use but also the production of these technologies are of strategic importance in the globalizing world.

These techniques are not only effective in the "clinical" field where they first appeared, such as the treatment of diseases, but also in many other fields such as education, sports, increasing productivity in business life, and military use, apart from clinical treatment (Da Silva et al., 2022; Wexler, 2017; Dündar-Coecke, 2021; Davis et al. 2019). In this context, household types of devices for individual use are produced and sold in many countries (Da Silva et al., 2022; Wexler, 2017). Proportionally, studies conducted both in our country and around the world to determine the effectiveness and safety in various fields of devices are rapidly replicating (Valiengo et al., 2020; Antal et al., 2017; Rossi et al., 2020). Our country, which has the ability to lead the world in terms of both research and production capacities in this field, regulates the decisions regarding devices in line with the EU accession process.

The legal regulations to be complied with these devices to be used for both scientific research and individual-purpose applications were regulated in many countries, including our country, and these legitim regulations are in accordance with the "Medical Devices Regulation (MDR)" published by the European Union (EU) in 2017 (EU, 2017/ 745). However, on December 1, 2022, a new regulation was made regarding the brain stimulation devices included in the non-medical products group in Annex XVI of this regulation, leading to a reclassification of these devices (EU, 2022/2347). With the new classification, these devices are included in the highest risk group, making the production and sale of these devices, and therefore scientific activities in this field, more difficult. The scientific community and device manufacturers, who conduct intensive research in this field in member countries, reacted strongly to this decision, which will affect all activities in the field, citing that it is not based

on scientific data (European Society for Brain Stimulation, 2023; Onarheim, 2023). Our country also implements these decisions in accordance with the EU membership process.

In this study, it is aimed firstly to clarify what the new regulation means for the use of devices and scientific research, and then to examine the new regulation and the criticisms brought against it in light of scientific data and to inform the authorities and interested parties in Turkey in a comprehensive manner.

What are Neuromodulation Techniques?

Neuromodulation is defined as the modulation of the nervous system through electrical, electromagnetic, chemical, or optogenetic methodologies for the purpose of long-term activation, inhibition, modification, and/or regulation of neural activity. With its rapidly growing popularity, it is applied in a wide range of treatments for neurological and neuropsychiatric disorders in an invasive and non-invasive technology-based manner (Budak and Hanoğlu, 2018).

If we take a short look at the history, the modern era of neuromodulation began in the early 1960s, first with deep brain stimulation and invasive methods. Today, however, we have a large number of predominantly "non-invasive" neuromodulation methods (Polat and Hanoğlu, 2021). Among them, the most common non-invasive techniques used are transcranial magnetic (TMS) and direct current (tES) which affect brain activity based on electromagnetic principles (Demirci and Hanoğlu, 2014) and finally trigger or modulate neuronal activity. TMS creates an instantaneous magnetic field with a power of up to 2 tesla (T) units, which is rapidly generated in less than 1 millisecond. This temporary magnetic field is applied to the surface of the scalp by focusing it with a coil (Chou et al., 2019). It is a very safe stimulation technique when appropriate precautions are taken and applied within the framework of certain principles (Farzan et al., 2016; Rossi et al., 2021).

Many studies have been conducted on the use of the TMS device in the treatment of different neurological and psychiatric diseases. Studies have been published showing the potential effects in the treatment of many diseases such as Parkinson's, Alzheimer's, epilepsy, ALS, MS, and tinnitus (Lefaucheur et al., 2020; Dougall et al., 2015; Pereira et al. ., 2016;). There are studies showing

rTMS can be effective in many psychiatric diseases such as depression, anxiety disorder, panic attacks, obsessive-compulsive disorder (OCD), post-traumatic stress disorder, and addiction (Lefaucheur et al., 2014; Berlim et al., 2012; Li et al. et al., 2014, Fregni et al. 2021). Finally, TMS was approved by the FDA for the treatment of depression in 2008, migraine aches in 2013, and OCD in 2018 (FDA, 2018).

The tES method, on the other hand, is a non-invasive brain stimulation technique that is effective due to the electrical waves transmitted through the electrodes placed in the determined area and changes the membrane potentials of the neurons so that the excitability of depolarized neurons increases, and the excitability of repolarized neurons decreases. In other words, although the electrical current sent is well below the cut-off level to create an action potential, it can contribute to the formation of an action potential by slightly lowering the excitability threshold.

tES is also divided into three types according to the types of electric currents transmitted through the electrodes if using a) direct current in the transcranial direct current stimulation (tDCS) method; b) alternating current in transcranial alternating current stimulation (tACS) and c) transcranial random noise stimulation (tRNS). The difference between tRNS and tACS is defined as a variable but not constant frequency and amplitude of the applied current (Paulus, 2011, Antal et al., 2017).

There are studies showing that tES methods are an effective treatment method for depression (Brunoni et al., 2016; Mutz et al., 2019; Moffa et al., 2020). Although there are some studies supporting its curative effect on schizophrenia symptoms, its effectiveness is still unclear (Liu et al., 2021; Valiengo et al., 2020). Apart from these, its effectiveness in treating neurological and psychiatric diseases is still unclear. However, recent meta-analysis studies have provided level A and level B evidence of indications (Lefaucheur et al., 2014; Fregni et al., 2021). Furthermore, individualization and possible interventions in the course of the disease at an early stage in neurodegenerative diseases have been on the agenda thanks to their application with neuroimaging in recent years (Hanoğlu et al. 2021).

The positive and promising results obtained in the studies without any significant serious side effects make both TMS and tES methods suitable and ef-

fective tools for the treatment of Alzheimer's disease, Parkinson's disease, etc., for which there is no effective neuroprotective treatment today. Also, current gaps in neuroprotective treatment approaches in the neuropsychiatry discipline make these techniques a serious treatment alternative for psychiatric diseases such as chronic pain, depression, and anxiety (Rossi et al., 2021; Fregni et al., 2021; Antal et al., 2017; Lefaucheur et al., 2017; Velioğlu et al. et al., 2021; Hanoğlu et al. 2022; Sarıcaoğlu et al. 2022). Especially attractive for many neuroscientists is also the pro-cognitive and positive effects on general physical capacity of these techniques, which have led to a widespread study activity in the field of non-clinical uses on issues suggested in many articles (Coffman et al., 2014; Dedoncker et al., 2016; Young et al., 2010; Aktürk et al. 2022). Hence, it was not surprising that the scope of the research carried out within the framework of these techniques has expanded to also include the improvement of performance in education as well as the use for military purposes (Dündar-Coecke, 2021; Davis et al. 2019) including persons from different disciplines, such as firefighters, police, surgeons, etc. There are even discussions suggesting that community service workers increase their skills by using these devices (Santoni de Sio et al., 2014) leading to scientific studies that aim to determine the effectiveness and reliability of all these areas. Finally, any legal regulation to be undertaken regarding these devices will cover a wide spectrum of uses and users and, hence, will have a significant impact on the field.

Classification of Medical Devices

According to MDR, *"devices shall be divided into classes I, IIa, IIb, and III, taking into account the intended purpose of the devices and their inherent risks"* (EU, 2017). Class I devices (stethoscopes, goggles, non-invasive electrodes, etc.) are low-risk devices subject to general controls, while class IIa (needles, syringes, electrical acupuncture, etc.) and class IIb devices (hemodialysis devices, urethral stents, dental implants, etc.) are moderate-risk devices. Class III devices (spinal needles, cardiovascular catheters, implantable active devices such as cochlear implants, etc.) are devices with a high risk of disease and injury (Wexler, 2015; EU Medical Device Coordination Group, 2021).

For each device to be put on the market legally, it is dependent on fulfilling a number of safety and performance requirements, namely conformity assessment procedures, determined according to the class it belongs to. In this

context, the conformity assessment procedure for class I devices is carried out only under the responsibility of the manufacturers due to the low sensitivity and risk of the devices in this group, while for class IIa, IIb, and III devices, the involvement of an authorized organization at certain levels is required (EU, 2017). Therefore, as the grade level increases, medical device manufacturers are subject to some special controls such as performance standards, private labeling, and post-market surveillance (Wexler, 2015).

Herein, classification rules are determined according to device types (non-invasive, invasive, and active) specified in Annex VIII of the relevant regulation. In addition, for devices that can be evaluated in more than one class due to some of their features, it is obligatory to be subject to the requirements of the highest class they belong to (EU, 2017).

Neuromodulation devices are active therapeutic devices defined in Annex VIII of the regulation as *"any active device used, whether alone or in combination with other devices, to support, modify, replace, or restore biological functions or structures with a view to treatment or alleviation of an illness, injury, or disability"* have been treated as class IIa devices since 2017 (EU, 2017). In addition, since these devices have non-medical uses, neuromodulation devices were also included in the last item of the "List of Products for Non-Medical Use" in Annex XVI of the regulation, but no regulation was made regarding the status of the devices on this list.

The new regulation numbered 2022/2347, approved on December 1, 2022, has been prepared in order to make the necessary specifications for these devices listed in Annex XVI of the Regulation (EU, 2022/2347). Article (7) of the new regulation on neuromodulation devices states: *"According to available scientific evidence on equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain as referred to in Section 6 of Annex XVI to Regulation (EU) 2017/745, such as those for transcranial magnetic stimulation or transcranial electric stimulation, the use of such products may cause side effects, for example, atypical brain development, abnormal patterns of brain activity, increase metabolic consumption, fatigue, anxiety, irritability, headaches, muscle twitches, tics, seizures, vertigo and skin irritation at the electrode site. While such equipment is not surgically invasive,*

the electrical currents or magnetic or electromagnetic fields do penetrate the cranium to modify neuronal activity in the brain. Such modifications can have long-lasting effects, and any unintended effects may be difficult to reverse. ***Such products should therefore be classified as Class III****"* (EU, 2022/2347).

Effects of Reclassification in the Field

The latest regulation includes neuromodulation devices in class III and imposes much stricter requirements on the production and sale of devices and the ethics committee requirements for research in the field. This situation will cause various disruptions and limitations in many countries that regulate medical device regulations in the light of EU decisions, such as in our country and the 28 EU member states. In addition, the fact that the devices in question are used for different purposes will primarily limit the access of many patients who benefit from neuromodulation techniques who will benefit from this treatment modality and will make it difficult to conduct scientific studies in the field of neuroscience, preventing the development of these techniques and methods. An important change for manufacturers will be to increase the production cost of the devices (Onarheim, ty). Indeed, the European Society for Brain Stimulation (ESBS), which describes itself as a professional association of participants interested in neurostimulation/neuromodulation, including representatives of national brain stimulation associations in Europe, medical doctors, psychologists, and neuroscientists, published a manifesto against these decisions a few months ago and sent a protest to the EU. The manifesto was published in the journal Brain Stimulation under the title "European reclassification of non-invasive brain stimulation as class III medical devices: A call to action" (Beaken, 2023).

Criticism of the Reclassification

It is seen that the criticisms of the people and institutions that are stakeholders in the production or use of neuromodulation techniques and devices are basically grouped under two headings. The first of these is about the preparation of the relevant article and the process of making this decision, while the second is criticism about the content of the article.

Criticisms of the Preparation Process of the Regulation

In the "Better Regulation Guide", which describes the criteria that will enable reaching the desired target in laws and policies in the most accurate way,

created by the EU, seven basic principles that should be in all stages of a legal regulation process such as design, preparation, acceptance, implementation and (if necessary) revision are mentioned. These principles are listed as an approach that is comprehensive, consistent, proportional, participatory, evidence-based, transparent and learning from experience (European Commission, 2021). However, it was stated that the "participatory approach" requirement, which is one of the seven principles for the relevant regulation, was violated, and it was criticized by claiming that the stakeholders were not included in the process. Because, this situation prevented first-hand access to reliable data to be obtained through the scientific community and the parties directly affected by the regulation, and thus opened the debate on the reliability of the reasons for the decision to debate (Beaken 2023, Onarheim, 2023).

Criticism of the Content of Article 7

Basically, three problematic points have been highlighted in the content of the reclassification item. The first of these is the fact that no differentiation of risk is taken into account for medical and non-medical use, and the devices have been increased from class IIa to class III, which is a high risk group, for all kinds of use (Onarheim, 2023). As a matter of fact, according to MDR, it was stated that the classification of devices depends on their intended use and the risks they carry due to their structure (EU, 2017/745). However, in the new regulation, it is evident that neuromodulation devices are classified without adhering this general rule, regardless of the purpose of use by only considering the risks due to their structure.

The risks claimed to be carried due to the nature of neuromodulation devices, which is expressed as the main and only reason for reclassification, is another problematic issue regarding the regulation. Because it is stated that the statements in Article 7 regarding the side effects of the devices such as *"atypical brain development, abnormal patterns of brain activity, increase metabolic consumption, fatigue, anxiety, irritability, headaches, muscle twitches, tics, seizures, vertigo and skin irritation at the electrode site"* and *" such modifications can have long-lasting effects"* are inconsistent with the existing scientific literature and that this decision was taken based on an erroneous assessment of the scientific literature on the safety of neuromodulation devices (Onarheim, 2023). As a matter of fact, no permanent or serious damage has

been reported in the studies conducted with neuromodulation techniques in the literature and in the meta-analysis of these studies (Antal et al., 2017; Rossi et al., 2020; Brunoni et al., 2011; Davis and Smith, 2019). This shows that the reclassification was made on grounds that clearly contradicted the scientific data, thus violating the "evidence-based approach" principle, which is one of the basic principles of Better Regulation (Beaken 2023, Onarheim, 2023).

The fact that the side effects or risks expressed in the regulation are expressed in a way that covers all brain stimulation devices without any discrimination is the third point that shows that the decision is quite problematic for devices that have different techniques and applications and therefore contain different risks and side effects. For example, skin irritation at the electrode site is a side effect that can be seen with brain stimulation devices (eg tDCS) that only use electrodes. Similarly, the claim to cause seizures is only available for TMS and rTMS among neuromodulation techniques, and this risk is too low to be supported by scientific evidence (Rossi et al., 2020; European Society for Brain Stimulation, 2023). In fact, the risk of seizures caused by rTMS (0.003%) is much lower than the risk of seizure formation (0.1-1.5%) of the drugs most commonly used in antidepressant treatment (European Society for Brain Stimulation, 2023). Moreover, this risk is absent in other neuromodulation devices such as low-density tDCS, tACS and tRNS (Pereire et al., 2016; European Society for Brain Stimulation, 2023). However, it is understood from the text of the decision that it is not paid attention to the fact that the devices in question contain different technologies and therefore have different risks and side effects, and that the risks listed in the examples are conveyed as if they apply to all devices. This again shows that the technological and scientific data on the devices are ignored, and the professionals and the scientific community are not included in the decision-making process (European Society for Brain Stimulation, 2023).

What should be done?

This decision taken by the EU regarding the reclassification of neuromodulation devices has been met with reaction from the scientific community and manufacturers due to the reasons stated above. The European Brain Stimulation Society (ESBS), on the other hand, criticizes the decision and made some recommendations to engage the relevant stakeholders in response to this

decision. Accordingly, stakeholders have been asked to contact their national institutions or authorized bodies in the EU and inform them about the implications of the amendment and its objectionable points. In addition, it was stated that academic publications should be produced to address the problems and propose solutions related to the decision, including the scientific facts in the literature about the risks listed in the decision (European Society for Brain Stimulation, 2023).

It is stated that this effort, which will be put forward collectively, can be effective in halting or withdrawing the decision made by the EU. Thus, it is reasonable to expect? that a new regulatory environment based on scientific evidence can be created in which all stakeholders are included in the process in accordance with the principles of "Better Regulation" (European Society for Brain Stimulation, 2023).

CONCLUSION AND IMPACTS ON OUR COUNTRY

In this study, the effects and justifications of the amendment made in 2022 regarding the classification of neuromodulation devices as medical devices by the EU, which are described in the light of the data in the literature, their types and areas of use, are tried to be evaluated through the criticisms and scientific data on the decision. Accordingly, first of all, it can be said that the regulation was not made in accordance with the EU's own standards. Such as decision which will severely limit the future of neuromodulation devices and the scientific studies conducted in this field, as well as access to the current treatment provided with these devices, has been made without a basic level of care and attention. Another handicap is that devices with different risks and side effects due to different techniques and applications are considered as a single device without any discrimination, while also not considering the latest meta-analyses regarding the safety of the devices suggesting that their rationale are not based on scientific data a indicating that it should at least be reconsidered.

From the point of view of our country, the direct implementation of these decisions of the EU, will impose unnecessary heavy ethical committee burdens of researchers from domestic research activities, which are already weak but have serious development potential. This is also suggested in the ESBS manifesto that these decisions will undermine the role of European researchers as world leaders in the field of NIBS (Beaken, 2023).

Likewise, other consequence for our country is that will cause serious damage to our national production and development capacity of the devices and equipment in question, which is still in its infancy, and will condemn our country to foreign-production devices. However, development in this field emerges as a result of the collaborative efforts of researchers and device manufacturers and is extremely fast. Another consequence of the implementation of these decisions is that we will always be dependent on technologies produced outside our country, and we will never be able to become a leading country developing new technologies in this field, which is entirely feasible and within our reach. For the end-user patients, it will be the emergence of restrictions on the development and use of much more effective innovative non-drug neuromodulation therapies in our country in chronic diseases that require the use of large amounts of medication such as chronic pain, depression, and in diseases such as neurodegenerative diseases and dementias that do not have effective treatments today.

This evaluation is especially directed to the Turkish Medicines and Medical Devices Agency, which is the authority responsible for the legal regulations related to NIBS devices in our country, and the relevant legislators, at the point of implementing the changes made in EU practices on the subject in our country. For this reason, there are some limitations in the article and areas that need to be developed in subsequent articles. It is of strategic importance for our country to produce NIBS devices in our country and to carry out effective and globally effective research in this field through researcher/producer platforms. However, this important part of the subject has not been sufficiently explained and processed. Similarly, a detailed review of the scientific background of the EU amendment decision and its problematic aspects were left out of the subject as they may be too technical. The possible effects of the new regulation in our country and especially the burdens it will bring to device manufacturers could be addressed in a relatively limited way.

Finally, it is recommended that the aforementioned regulation be evaluated together with the deficiencies and errors mentioned in the regulation, taking into account national and international criticism. This assessment should be conducted by Turkish Medicines and Medical Devices Agency, which is responsible for the legal regulations regarding NIBS devices in our country.

Ethical Approval: Ethical approval was not required as the study was a scientific review.

Authors' Contributions: All authors analyzed the legal regulations and amendments subject to the study in the light of scientific data in the literature and contributed to the evaluation of the effects of the decision in the field and in the scientific community.

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