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Supplier selection using the integrated MEREC – CoCoSo methods in a medical device company

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Abstract

The medical device industry is a rapidly developing industry that includes various dynamics. Developed technologies show continuous improvement depending on diagnosis and treatment applications in health services. To keep up with this change and survive in an increasingly competitive environment, medical device manufacturers must be engaged in continuous improvement activities. This situation, necessary for many companies producing in the industrial field, gains even more importance in the medical device sector when the direct impact of product safety and quality on human life is considered. In companies producing medical devices, the legal requirements of the product being a medical device are followed by the notified bodies and authorized authorities within the framework of standards and regulations within the scope of quality processes. Increasing costs and liabilities with MDR 2017/45 have pushed medical device manufacturers to question their methods. In this study, it was determined that customer requests could not be met in a company producing medical devices, and it was observed that delivery times increased. In evaluating the reasons for the increase in delivery time, it was determined that supplier selection could have been carried out more effectively. For this purpose, six suppliers and six criteria were selected because of the company's sector knowledge and the evaluations of the company managers. The Combined Compromise Solution (CoCoSo) method, one of the new generation multi-criteria decision-making (MCDM) methods, is proposed for ranking the suppliers in the supplier selection problem. Method The removal effects of criteria (MEREC) weighting method was used to weight supplier selection criteria. In this study, a new generation supplier selection method application in medical devices has been carried out. Considering the inadequacy of the studies on supplier selection in medical devices, the relevant research will contribute to the literature.

Keywords: MEREC; CoCoSo; Supplier Selection; Medical Device; MCDM

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1. Introduction

The medical device industry is a rapidly developing sector in the world that includes various dynamics. Developed technologies are improving depending on diagnosis and treatment applications in healthcare services. Medical device manufacturers must engage in continuous improvement activities to keep up with this change and maintain their existence in an increasingly competitive environment. For processes to be carried out efficiently and production activities to provide precise and effective results, they must engage in continuous improvement activities. The company must review its procedures, take the necessary actions, implement them when detecting a problem, and then control the impact and efficiency of its activities. This process, essential for many companies producing in the industrial field, becomes even more critical in the medical device sector, considering the direct impact of product safety and quality on human life.

It is monitored by notified bodies and competent authorities within the framework of legal requirements, quality standards, and regulations imposed by a product being a medical device. When placing their devices on the market or putting them into service, the manufacturer must ensure that their devices are designed and manufactured by the requirements of the relevant regulation. The manufacturer's obligations are specified in the applicable EU legislation and the rules published by the Ministry of Health in compliance with this legislation. After the Medical Device Regulation 2017/45 (MDR 2017/45), these requirements have increased even more, and quality management has gained critical importance. Rising costs and liabilities with MDR 2017/45 have made medical device manufacturers question their processes. Meeting customer demands while fulfilling all legal requirements becomes critical for manufacturers to avoid market loss. The harmony between the manufacturer's activities and customer expectations is crucial for the operation's success.

According to the Medical Device Regulation published in the Legal Gazette dated 02.06.2021 and numbered 31499, products that are used on humans with an indication as part of a diagnosis or treatment and show their effects by physical or mechanical means in the areas where they are used are considered medical devices. Their definition states that medical devices are high-risk products potentially affecting human life and public health. For this reason, these devices are monitored by approved organizations and competent authorities within the legal requirements, standards, and regulations of being a medical device. Manufacturers must fulfill the requirements of the relevant EU legislation to ensure the free movement of their products among European Union (EU) member countries [1].

Medical devices and equipment are essential for quality healthcare. For this purpose, medical device manufacturers must produce according to the relevant legislation and standard requirements. Effective execution of a quality management system has always been considered a good strategy for a manufacturer to maintain and improve product and service quality [2].

The quality management system in medical devices is carried out by the "ISO 13485 - Medical Devices Management System" standard. This standard can be defined as the harmonized version of the "ISO 9001 - Quality Management System" standard for medical devices. It sets forth quality system requirements for organizations operating in the medical sector. Effective execution of the quality management system directly affects product safety and performance.

Manufacturers need to meet customer demands without compromising product safety and performance. In medical device production, product safety is evaluated as a whole, considering patient and user health, and the process from raw material purchase to sales and subsequent follow-up, depending on the product class, is evaluated as traceability. Traceability begins when the order arrives and continues until its sale and destruction. The first critical step is the supply of raw materials/semi-finished products. Supplier selection is a factor that directly affects product quality and safety. Raw material/semi-finished product supply uses a large portion of the company's resources and is very important for the organization's success.

On the other hand, the fact that the product is a medical device brings some legal requirements. These requirements are supervised by competent authorities and notified bodies. After MDR 2017/45, these requirements increased even more, and supplier selection became critical. Therefore, the organization's success is measured not only by its sales figures and profit rates but also by its product quality and traceability success.

Although there are studies on supply chain management in the healthcare sector in the literature research, it has been seen that studies on supply chain management in the medical device industry need to be more comprehensive. It was concluded that there is an area in need of improvement.

Supplier selection in supply chain management may vary according to the needs, expectations and vision of the sector and the company. Correctly determining the criteria is a very critical step for successful supplier selection. Some supplier selection articles were examined, and some selected studies were evaluated in Table 1 based on field, methods, and criteria.

Table 1. Examples of some supplier selection studies.

Author	Field	Methods	Criteria
Vipul Jain et al., 2016 [3]	Automative	AHP and TOPSIS	Product quality, price, relationship quality, production capacity, on-time delivery, warranty, environmental performance, supplier brand name.
Fallahpour et al., 2017 [4]	Textile	Questionnaire, FPP, and FTOPSIS	Cost, quality, supply and service, flexibility, environmental management system, green product, green storage, eco-design, green transportation, green technology, employee rights, occupational health and safety, supporting activities.
Song et al., 2017 [5]	Solar Energy and Air Conditioning	DEMATEL	Economic criteria: Quality, delivery, cost price. Environmental criteria: Environmental management system, resource consumption, environmental design, reduce-reuse and recycle. Social Criteria: Occupational health and safety, employee rights and welfare, education, and community development.
Yazdani et al., 2017 [6]	Food Industry	DEMATEL, QFD and COPRAS	Price, quality, delivery performance, branding, reputation, flexibility, cost
Banaeian et al., 2018 [7]	Agriculture-Food Industry	TOPSIS, VIKOR and GRA	On-time delivery, after-sales service, supply capacity, quality, price
Abdel-Basset et al., 2018 [8]	Logistics	DEMATEL	Cost, delivery time, quality, innovation, reputation, location, response to customers
Yazdani et al., 2019 [9]	Construction	DEMATEL, BWM, and CoCoSo-G	Design, greenhouse gas pollution, distribution and flexibility, responsiveness and communication, finances, price offered, environmental management system.
Stević et al., 2020 [10]	Healthcare industry	MARCOS	Price, quality, product range, on-time delivery, innovation, organization and management, reliability, reputation, occupational and worker safety, information supply, employee rights, training, compliance with the law, environmental qualifications, environmental management system, recycling, pollution control, green R&D, green product, number of ISO Standards held.
Yazdani et al., 2020 [11]	Healthcare Industry	DEMATEL and BWM	Price, inventory capacity, batch volume, flexibility, use of technology, quality.
Sumrit, 2020 [12]	Healthcare Industry	VMI, Fuzzy DELPHI, SWARA and COPRAS	Past delivery performance, corporate trust, investment cost, information exchange and sharing, continuous improvement, supply chain process integration, information technology readiness, allocated resources, spatial complexity, prior knowledge and experience, risk/reward sharing
Göncü and Çetin,	Healthcare	DEMATEL and	Price, quality, logistics, and occupational health and safety

2022 [13]	business	ANP	
Nguyen et al., 2022 [14]	Steel manufacturing industry	Data Envelopment Analysis, SF-AHP and SF-WASPAS	Economic criteria: Production facilities, technological and financial competence, delivery time, flexibility, transportation cost, delivery, product price, quality. Environmental criteria: Environmental costs, Environmental Management Systems, Green R&D and innovation. Social Criteria: Health and safety, customer satisfaction, satisfaction of stakeholders, interests, and rights of employees

When it comes to the medical device industry, it is essential to effectively carry out the steps that affect product quality and safety, and this field has become a research subject for researchers.

The medical device industry has been one of the sectors whose importance has been most emphasized after the COVID-19 pandemic. This situation has pushed researchers to work on the problems experienced in the supply chain. The main problem encountered in the supply chain is the supplier selection problem.

In their study in 2014, Ghadimi and Heavey mentioned that supplier selection needs to be addressed in the medical device industry in the literature. They informed us that the criteria in the literature may be less than 100% suitable for supplier selection in the medical device industry. They conducted a study on sustainable supplier selection. Ghadimi and Heavey emphasized in their study that the supplier selection problem is the most crucial research topic for supply chain management. He suggested that the low number of studies on supplier selection in the medical device industry is due to companies' privacy concerns. In their research, the steps of the supplier selection process are applied, such as identifying potential suppliers, determining criteria and sub-factors, collecting company requirements, classifying the gathered requirements, and ranking potential suppliers. They evaluated sustainable supplier selection under the leading environmental, economic, and social headings. In addition, they assessed the requirements of the medical device manufacturer company ISO 13485-Quality Management System Standard under the headings of regulation, company responsibilities on the product, after-sales traceability, storage, and logistics [15].

In the study conducted by Ghadimi et al. in 2019, they developed the Multi-Agent System (MAS) method and demonstrated the application of this method on a medical device manufacturer [16].

Today, companies' perspectives have changed along with consumers' changing attitudes within the framework of the legal obligations to which the medical device industry is bound, and it has been understood that more than studies focused on financial profit are needed.

In his study conducted in 2023, Forouzeshnejad concluded that agility and sustainability are the essential criteria for agility and sustainability in the medical device industry and that flexibility, cost, reliability, smart factory, and quality are crucial criteria determined subsequently [17].

All companies manufacturing in the medical device industry must comply with the ISO 13485- Quality Management System Standard. This standard requires manufacturers to select suppliers from a pre-approved list. This restricts manufacturers, meaning companies can only go up to the approved suppliers accepted by authorized organizations. Therefore, supplier selection is very critical in the medical device industry. Decision-making in the supplier selection process is challenging because many criteria are used, and these criteria conflict with each other.

In supplier selection, it takes work to make the right choice among various selection criteria and multiple alternatives. Multi-criteria decision-making (MCDM) methods offer appropriate solutions to problems with more than one criterion and alternative. In this study of the supplier selection problem, it is suggested to use the Method the Removal Effects of Criteria (MEREC) method to weigh the supplier selection criteria and the Combined Compromise Solution (CoCoSo) method to rank the suppliers.

The reasons for choosing MEREC and CoCoSo methods in this study are as follows. In both methods, there is no need for decision-makers. All calculations are effectively made according to the actual values revealed by the initial decision matrix. In a sensitivity analysis of the MEREC method, Keshavarz-Ghorabaee et al. found that the MEREC method provides stable results compared to objective weighting methods such as Entropy and CRITIC [18]. In the CoCoSo method, the final ranking of suppliers is not based on just one evaluation score but rather on a score obtained by combining three different evaluation scores in one calculation. The literature review's conclusions indicate that companies that manufacture medical devices did not use the integrated MEREC-CoCoSo approaches when choosing their suppliers.

The MEREC approach was first introduced as an objective criterion weighting method in 2021 by Keshavarz-Ghorabaee et al. Using criterion weights, this method ascertains the impact of each criterion on the overall performance of the alternatives.

The overall and partial performance of the alternatives is also measured using a logarithmic function. MEREC assigns higher priority to criteria that significantly affect how well other options perform. MEREC can be used to determine the weights for each criterion while accounting for variations in each alternative's performance. If there is more variation in the performance of a criterion, that criterion is given a higher weight [18]. The MEREC method has become a research subject in many areas since its debut article. Some of these studies are the following:

While the MEREC method was used for criterion weighting in the coal supplier selection problem for the thermal power plant, the suppliers were ranked using the Multiple Criteria Ranking by Alternative Trace (MCRAT) method [19]. In their study, Trung and Thinh conducted sixteen experiments on the turning process based on the principle of using a cutting tool on the workpiece rotating around its own axis. In their experiments, they used four different MCDM methods to evaluate the effects of cutting speed, feed rate, and depth of cut parameters on surface smoothness and material removal rate and determined the weights of the criteria with Entropy and MEREC [20].

In the study conducted to decide the locations of distribution centers, Keshavarz-Ghorabaee used the Stepwise Weight Assessment Ratio Analysis II (SWARA II), Weighted Aggregated Sum Product Assessment (WASPAS) and MEREC methods together. The study proceeded through a decision matrix containing weights determined in two different ways, subjectively and objectively [21]. Nguyen et al. studied the MCDM problem using the MARCOS, TOPSIS and MAIRA methods, and used the MEREC method for criterion weighting [22].

In a different study carried out that same year, Nicolalde et al. determined the criterion weights using the Entropy and MEREC methods and selected the material to be used on a vehicle's roof using the Višekriterijumsko Kompromisno Rangiranje (VIKOR), Complex Proportional Assessment (COPRAS), and TOPSIS methods [23].

The use of robots is becoming more common in industrial settings, as noted by Shanmugasundar and his colleagues, who also discussed the challenge of selecting the right kinds of robots. The MEREC method was used to weigh the criteria, and the Combination Distance-based Assessment (CODAS), COPRAS, CoCoSo, Multi-attributive Border Approximation Area Comparison (MABAC), and VIKOR methods were used to finish the decision-making process [24]. In the Yu et al. study from 2022, which highlighted sustainability. The effectiveness of the method proposal was evaluated through a case study [25]. In a study by Do and Nguyen, they talked about the importance of the criterion weighting step in decision-making processes and used five different weighting methods, namely MEREC, EQUAl, ROC, RS and FUCOM, along with the CoCoSo, MABAC, MAIRCA, EAMR and TOPSIS methods in the solution ordering problem in the turning process [26]. Saidin et al presented a study on fuzzy MEREC. The fuzzy MEREC method, which they offer as a solution to the uncertainty problem experienced in MCDM problems, has been exemplified by using it in the evaluation of academic personnel [27].

Ayan et al. conducted a study comparing various weighting methods, including the MEREC method. The authors mentioned that the most effective criterion among the criteria in the problem under consideration in the MEREC method has the highest level of importance. In addition, he showed that one of the differences with other methods is that the decision matrix values must be greater than zero. He stated that the biggest advantage is ease of application because the calculations are easy to understand and simple [28]. In a study by Chaurasiya and Jain on information technology service selection in health services, the weights in the best software selection problem were determined by MEREC and SWARA, and the ranking of the alternatives was obtained by using MAR [29].

In this study, after obtaining supplier selection criterion weights with MEREC, it was suggested to use the CoCoSo method, first introduced by Yazdani et al. in 2019, to rank the suppliers. The CoCoSo method measures the distance of each performance level of the alternatives from the ideal. When making the final alternative ranking, three different scores are calculated [30]. Although CoCoSo method is a new-generation MCDM method, CoCoSo method has been the subject of study by many researchers.

Ecer et al. used the CoCoSo method to evaluate the organization of oil exporting countries according to 41 sustainable development criteria in 10 dimensions. They compared the results with existing multi-criteria decision-making methods and demonstrated the effectiveness of CoCoSo [31]. In the study emphasizing the importance of stock management, the CoCoSo method was applied together with ABC analysis and FUCOM (Full Consistency Method). The ranking of supplier alternatives was obtained by the CoCoSo method [32]. Wen et al evaluated cold chain suppliers to keep the logistics risks of medicines to a minimum. To solve this problem, they conducted a study in which they used the SWARA method to perform criterion weighting and the CoCoSo methods to make the final ranking of suppliers. In this study, which also included method application, they emphasized that the CoCoSo method gave reliable results [33].

Drawing attention to the importance of supplier selection in industrial organizations, Zolfani et al. They implemented an application in the steel industry where they used the Best Worst Method (BWM) and CoCoSo methods together [34]. Bagal et al. examined the effects of marble dust and fly ash on concrete mixtures. They used CODAS and CoCoSo methods to optimize process parameters. The study results were evaluated on the pairwise comparison matrix [35]. Barua et al. They presented a study in which they evaluated the mechanical behavior of hybrid natural fiber reinforced nano-sic particle composite. In this study, it was aimed to contribute to the decision-making process of process parameters with the CoCoSo method [36]. In the study carried out in the field of automobile industry, five alternative vehicles with different specific features were evaluated for the most suitable passenger car selection. While the criterion weighting is obtained by the CRITIC method, the alternatives are ranked by CoCoSo. The results have been validated with other MCDM methods [37].

Emphasizing the importance of the supply chain, Biswas addressed the supply chain problem of a healthcare institution operating in India in his study in 2020. In this study, while determining the criterion weights with PIPRECIA (PIvot Pairwise RElative Criteria Importance Assessment), three different rankings were obtained using MABAC, MARCOS and CoCoSo. These three methods have been shown to give consistent results [38]. In another study on supply chain management, weights were determined with fuzzy BWM, while the most appropriate supplier selection was ensured with CoCoSo and Bonferroni integration [39]. In the study conducted by Peng et al. in 2020, they emphasized the importance of evaluating financial risks and used the CRITIC and CoCoSo methods together to solve the comparison problem they encountered in this field [40]. Addressing the problem of selection of logistics centers, M.Yazdani et al. used the CoCoSo method integrated with data envelopment to choose among logistics service providers [41]. Altıntaş evaluated the knowledge performances of G7 countries according to the 2020 Global Knowledge Index (GKI) components using CoCoSo [42].

The method proposed in this study was applied to the supplier selection problem of a medical consumables manufacturer company that has been operating for more than 25 years and is in preparation for MDR 2017/45. It has been determined that the company that produces according to order cannot deliver its orders on time. Infusion and extension sets are made in this company. Extension sets are used as liquid carrier connection elements for transferring a medical liquid (such as serum, medicine, or vitamin) from a liquid source to a catheter to enter the liquid into the body and/or for collecting body fluids in a collection container from a catheter already attached to the human body. Infusion sets are used to safely transfer intravenous drugs and fluids to patients in all healthcare institutions that provide critical care and where IV drug administration is performed. The hose is the most vital part used in extension and infusion sets. As a result of the current situation analysis, it was determined that production delays occurred because the supplied hoses needed to be delivered on time and arrived dirty. After evaluating all these reasons with the company managers, it was decided to choose a supplier for the hose.

The rest of the study is organized as follows. MEREC and CoCoSo methods used in supplier selection are introduced in the second section of the study. In the third section, the application steps of the proposed method are explained, and the results of the sensitivity analysis are given. The last section mentions results, discussion, and future work. According to the results obtained, suggestions were made to the company regarding supplier selection.

2. Material and method

The steps of the proposed approach are given in Figure 1. Now, how to implement these steps will be explained step by step.

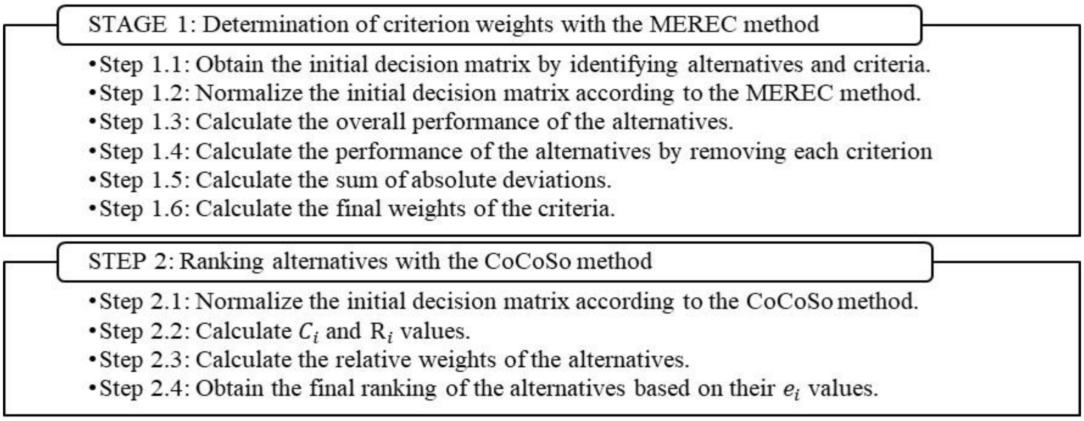

Fig.1. Steps of the proposed approach.

2.1. Stage 1: Determination of criterion weights with the MEREC method

The MEREC method determines the weights and priority of the criteria used in the decision-making process. This method evaluates the effect of removing each criterion used on the result. The steps of the method are given below [18].

Step 1.1: Obtain the initial decision matrix by identifying alternatives and criteria.

In the first step of the proposed method, after the alternatives ($A_i, i = 1,2, \dots, n$) and criteria ($k_j, j = 1,2, \dots, m$) are determined, the initial decision matrix (G) is obtained according to Equation 1. In Equation 1, $g_{(i,j)}, i = 1,2, \dots, n;\ j = 1,2, \dots, m$ shows the value of the jth criterion for the ith alternative.

$$G = \begin{bmatrix} g_{(1,1)} & g_{(1,2)} & \cdots & g_{(1,j)} & \cdots & g_{(1,m)} \\ g_{(2,1)} & g_{(2,2)} & \cdots & g_{(2,j)} & \cdots & g_{(2,m)} \\ \vdots & \vdots & \ddots & \vdots & \ddots & \vdots \\ g_{(i,1)} & g_{(i,2)} & \cdots & g_{(i,j)} & \cdots & g_{(i,m)} \\ \vdots & \vdots & \ddots & \vdots & \ddots & \vdots \\ g_{(n,1)} & g_{(n,2)} & \cdots & g_{(n,j)} & \cdots & g_{(n,m)} \end{bmatrix} \tag{1}$$

Step 1.2: Normalize the initial decision matrix according to the MEREC method.

In this step, the elements of the initial decision matrix given in Equation 1 are normalized using Equation 2.

$$d_{(i,j)} = \begin{cases} \frac{\min_k g_{(k,j)}}{g_{(i,j)}} & , \quad j \in B \\ \frac{g_{(i,j)}}{\max_k g_{(k,j)}} & , \quad j \in C \end{cases} \tag{2}$$

In Equation 2, the normalized initial decision matrix elements are $d_{(i,j)}, i = 1,2,..,n; j = 1,2,...,m$. Set B shows the index set of benefit type criteria, and set C shows the index set of cost type criteria.

Step 1.3: Calculate the overall performance of the alternatives.

In this step, the overall performance of the alternatives is obtained using a logarithmic measure with equal criterion weights. Using the normalized values calculated in Step 1.2, the performance of each alternative is calculated as in Equation 3.

$$Y_i = \ln\left(1 + \left(\frac{1}{m}\sum_{j=1}^{m}\left|\ln\left(d_{(i,j)}\right)\right|\right)\right), i = 1,2,...,n \tag{3}$$

Y_i given in Equation 3 shows the overall performance of the alternatives.

Step 1.4: Calculate the performance of the alternatives by removing each criterion.

Again, a logarithmic measure like that in Step 1.3 is used. The difference between Step 1.3 and this step is that the performances of the alternatives are calculated based on the separate impact of each criterion.

Therefore, there are m performance sets associated with m number of criteria. Regarding removing the jth criterion, the performance of the ith alternative is denoted by Y'_{ij} and is calculated as in Equation 4.

$$Y'_{ij} = \ln\left(1 + \left(\frac{1}{m}\sum_{k,k\neq j}\left|\ln\left(d_{(i,k)}\right)\right|\right)\right) \tag{4}$$

Step 1.5: Calculate the sum of absolute deviations.

The removal effect of the jth criterion is calculated according to the Y_{ij} and Y'_{ij} values calculated in Step 1.3 and Step 1.4. Equation 5 calculates each criterion's removal effect Z_j. With the removal effect, the weights are determined in proportion to their impact on the criteria.

$$Z_j = \sum_{i=1}^{m}\left|Y'_{ij} - Y_i\right| \quad j = 1,2,...,m \tag{5}$$

Step 1.6: Calculate the final weights of the criteria.

The weight of each criterion is calculated as in Equation 6, using the removal effects Z_j calculated in Step 1.5, where h_j is the weight of the jth criterion.

$$h_j = \frac{z_j}{\sum_k z_k}, \quad j = 1,2,...,m \tag{6}$$

In the rest of the study, the alternatives' final ranking will be obtained using the criterion weights calculated with the MEREC method in the CoCoSo method.

2.2. Stage 2: Ranking alternatives with the CoCoSo method

The CoCoSo method is based on simple and exponential weighting. The following steps are followed for the suppliers and selection criteria previously determined for the MEREC method:

Step 2.1: Normalize the initial decision matrix according to the CoCoSo method.

Depending on whether the criteria are benefit type (B) or cost type (C), the initial decision matrix is normalized using Equation 7.

$$d^*_{(i,j)} = \begin{cases} \frac{g_{(i,j)} - \min_i g_{(i,j)}}{\max_i g_{(i,j)} - \min_i g_{(i,j)}}, & j \in B \\ \frac{\max_i g_{(i,j)} - g_{(i,j)}}{\max_i g_{(i,j)} - \min_i g_{(i,j)}}, & j \in C \end{cases} \tag{7}$$

In Equation 7, $d^*_{(i,j)}$ represents the elements of the initial decision matrix normalized according to the CoCoSo method.

Step 2.2: Calculate the C_i and R_i values.

C_i , $i = 1, \dots, n$ values which express the sums of the weighted comparability sequences, are calculated using Equation 8. The power weight of the comparability sequences for each alternative is defined as $R_i, i = 1, \dots, n$ and is calculated with Equation 9.

$$C_i = \sum_{j=1}^{m} \left(h_j d^*_{(i,j)} \right), \; i = 1,2, \dots, n \tag{8}$$

$$R_i = \sum_{j=1}^{m} \left(d^*_{(i,j)} \right)^{h_j}, \; i = 1,2, \dots, n \tag{9}$$

Step 2.3: Calculate the relative weights of the alternatives.

Three evaluation scores are first obtained to calculate the relative weights of the alternatives. The first evaluation score (e_{ia}) represents the arithmetic average of the sums of the weighted sum and multiplication methods and is calculated as in Equation 10.

$$e_{ia} = \frac{R_i + C_i}{\sum_{i=1}^{n} (R_i + C_i)}, \; i = 1,2, \dots, n \tag{10}$$

The second evaluation score (e_{ib}) refers to the sum of the relative scores of the weighted sum and multiplication methods, and Equation 11 is used to calculate.

$$e_{ib} = \frac{C_i}{\min_i C_i} + \frac{R_i}{\min_i R_i}, \; i = 1,2, \dots, n \tag{11}$$

The third evaluation score (e_{ic}) is calculated as in Equation 12 by balancing the weighted sum and multiplication methods with λ. The weight rating λ is usually taken as 0.5.

$$e_{ic} = \frac{\lambda(C_i) + (1-\lambda)(R_i)}{\left(\lambda \max_i C_i + (1-\lambda) \max_i R_i \right)}, 0 \leqslant \lambda \leqslant 1, \; i = 1,2, \dots, n \tag{12}$$

Step 2.4: Obtain the final ranking of the alternatives based on their e_i values.

The calculations in Step 2.3 are used to obtain the final ranking of the alternatives. Using these calculations in Equation 13, $e_i, i = 1,2, \dots n$ values are obtained.

$$e_i = (e_{ia}e_{ib}e_{ic})^{\frac{1}{3}} + \frac{1}{3}(e_{ia} + e_{ib} + e_{ic}),\ \ i = 1,2, \dots, n \tag{13}$$

The final ranking of the alternatives is obtained, with the alternative with the largest e_i value being ranked first.

3. Application of the proposed method

In its Priority Medical Devices Project, the World Health Organization (WHO) suggests two potential causes for problems in healthcare delivery in low- and middle-income countries. The first of these reasons is that it targets high-income country economies, which it sees as having high-profit potential, and the second is the problems related to the inability to supply medical devices reasonably [9]. This makes supplier selection even more critical, especially for medium and small-sized companies operating in the medical device industry.

The method proposed in this study was applied in selecting hose suppliers in a company that produces biomedical devices. These hoses are used in the production of infusion and extension sets. It has been observed that the hoses supplied by the current supplier must have the desired features and be delivered on time.

In the following subsection, the application steps of the proposed method in selecting the hose supplier in the company are explained.

3.1. Application of stage 1: Determination of supplier selection criteria weights with the MEREC method

Step 1.1: Obtain the initial decision matrix by identifying alternatives and criteria.

As a result of the literature research and the evaluations of the company managers, six alternative suppliers $(t_i, i = 1,2, \dots ,6)$ and six criteria $(k_j, j = 1,2, \dots ,6)$ were determined to evaluate these suppliers. The determined criteria and definitions of the criteria are as follows:

- Product quality (k_1): It refers to the semi-finished product's raw material and performance quality. While scoring in the decision matrix, it was evaluated by company managers by giving a performance score out of 100.
- Quality certificate (k_2): It indicates how many years the supplier company has had the quality certificate. The length of time companies has this certificate indicates the year they produced by standard requirements. While scoring in the decision matrix, the year of the first issue of the quality certificate was taken as a basis.
- Lead time (k_3): It is the value of the lead time in weeks. It is the deadline companies give after ordering semi-finished products/raw materials.
- Price (k_4): It refers to the cost per meter of the product supplied in TL. The decision matrix includes the current prices of the products as of January 2023.
- Transportation costs (k_5): It refers to the transportation costs invoiced in the supply of semi-finished products. Transportation agreements made with companies vary. While some companies include this fee in the price, others ship by cargo. The difference in shipping costs varies due to shipping and customs costs (if it is an imported product). Values in Turkish Lira are shown in the decision matrix.
- Customer relations (k_6): It refers to the companies' tendency to cooperate during and after the supply period. The evaluation made with the company managers was scored out of 100, considering the company's past experiences.

  Six supplier alternatives were determined based on the company's experience and sector knowledge. Due to company confidentiality, suppliers will be indicated with t_i , $i = 1,2, \dots ,6$ in the next steps of the application. In the first step of the proposed method, after the alternatives $(t_i, i = 1,2, \dots ,6)$ and criteria $(k_j, j = 1,2, \dots ,6)$ are determined, the initial decision matrix (G) is created as in Equation 2. The initial decision matrix is given in Table 2.

Table 2. The initial decision matrix.

	k_1 ∈B	k_2∈B	k_3∈C	k_4∈C	k_5∈C	k_6∈B
t_1	90	13	2	1,23	1	100
t_2	80	20	2	1,04	200	65
t_3	100	19	4	0,73	10000	65
t_4	65	10	2	0,94	500	80
t_5	85	8	1	1,76	300	70
t_6	50	5	1	0,83	150	75

Step 1.2: Normalize the initial decision matrix according to the MEREC method.

In this step, the elements of the initial decision matrix given in Table 2 are normalized using Equation 2. Normalized values are shown in Table 3.

Table 3. The normalized initial decision matrix for the MEREC method.

	k_1 ∈B	k_2∈B	k_3∈C	k_4∈C	k_5∈C	k_6∈C
t_1	0.5556	0.3846	0.5000	0.6989	0.0001	0.6500
t_2	0.6250	0.2500	0.5000	0.5909	0.0200	1.0000
t_3	0.5000	0.2632	1.0000	0.4148	1.0000	1.0000
t_4	0.7692	0.5000	0.5000	0.5341	0.0500	0.8125
t_5	0.5882	0.6250	0.2500	1.0000	0.0300	0.9286
t_6	1.0000	1.0000	0.2500	0.4716	0.0150	0.8667

Step 1.3: Calculate the overall performance of the alternatives.

In this step, the overall performance of alternative suppliers ($Y_i, i = 1,2,..,6$) is obtained using a logarithmic measure with equal criterion weights. This measure is based on the formula given in Equation 3. The results obtained are shown in Table 4.

Table 4. The performance table of suppliers.

	t_1	t_2	t_3	t_4	t_5	t_6
Y_i	1.1116	0.7722	0.3952	0.6488	0.6904	0.7324

Step 1.4: Calculate the performance of the alternatives by removing each criterion.

There are m performance sets associated with the number of m criteria. The performance of the ith alternative regarding the removal of the jth criterion is denoted by Y'_{ij} and calculated with Equation 4. Calculation results are given in Table 5.

Table 5. The performance table of suppliers by removing each criterion.

Y'_{ij}	k_1 ∈B	k_2∈B	k_3∈C	k_4∈C	k_5∈C	k_6∈C
t_1	1.0789	1.0578	1.0729	1.0918	0.4083	1.0877
t_2	0.7354	0.6594	0.7174	0.7309	0.4138	0.7722
t_3	0.3142	0.2329	0.3952	0.2912	0.3952	0.3952
t_4	0.6257	0.5865	0.5865	0.5926	0.3464	0.6305

t_5	0.6451	0.6504	0.5673	0.6904	0.3437	0.6842
t_6	0.7324	0.7324	0.6147	0.6703	0.3222	0.7209

Step 1.5: Calculate the sum of absolute deviations.

According to the Y_{ij} and Y'_{ij} values calculated in Step 1.3 and Step 1.4, the removal effect Z_j of the jth criterion is computed using Equation 5 and given in Table 6.

Table 6. The sum of absolute deviations for all criteria.

	$k_1 \in B$	$k_2 \in B$	$k_3 \in C$	$k_4 \in C$	$k_5 \in C$	$k_6 \in C$
Z_j	1.1116	0.7722	0.3952	0.6488	0.6904	0.7324

Step 1.6: Calculate the final weights of the criteria.

The weight of each criterion (h_j) is determined using the Z_j removal effects calculated in Step 1.5 using Equation 7. The results are given in Table 7.

Table 7. The weights and the rankings of the criteria.

	$k_1 \in B$	$k_2 \in B$	$k_3 \in C$	$k_4 \in C$	$k_5 \in C$	$k_6 \in C$
h_j	0,0624	0,1228	0,1130	0,0807	0,6040	0,0171
Rank	5	2	3	4	1	6

After the weights were calculated using MEREC, the final ranking was made with the CoCoSo method.

3.2. Application of stage 2: Ranking alternatives with the CoCoSo method

Step 2.1: Normalize the initial decision matrix according to the CoCoSo method.

Depending on whether the criteria are benefit-type (B) or cost-type (C), the initial decision matrix is normalized using Equation 7. The matrix normalized according to the CoCoSo method is given in Table 8.

Table 8. The normalized initial decision matrix for the CoCoSo method.

	$k_1 \in B$	$k_2 \in B$	$k_3 \in C$	$k_4 \in C$	$k_5 \in C$	$k_6 \in C$
t_1	0.8000	0.5333	0.6667	0.5146	1.0000	1.0000
t_2	0.6000	1.0000	0.6667	0.6990	0.9801	0.0000
t_3	1.0000	0.9333	0.0000	1.0000	0.0000	0.0000
t_4	0.3000	0.3333	0.6667	0.7961	0.9501	0.4286
t_5	0.7000	0.2000	1.0000	0.0000	0.9701	0.1429
t_6	0.0000	0.0000	1.0000	0.9029	0.9851	0.2857

Step 2.2. Calculate the C_i and R_i values.

The sum of the weighted comparability sequences is denoted as $C_i, i = 1, \dots, n$ and the power weight of comparability sequences for each alternative is denoted as $R_i, i = 1, \dots, n$. Using the weights (h_j) obtained from the MEREC method, R_i and C_i values were calculated as in Equation 8 and Equation 9, respectively. R_i and C_i values are given in Table 9.

Table 9. The values of C_i and R_i.

	t_1	t_2	t_3	t_4	t_5	t_6
R_i	5.8149	4.8833	2.9916	5.6936	4.7478	3.9616
C_i	0.8533	0.8840	0.2578	0.7804	0.7696	0.7857

Step 2.3: Calculate the relative weights of the alternatives.

Supplier evaluation scores e_{ia}, e_{ib} and e_{ic} were calculated according to Equation 10-12, respectively, and the calculation results are given in Table 10. The λ value in Equation 12 was taken as 0.5.

Table 10. CoCoSo evaluation strategy scores.

	t_1	t_2	t_3	t_4	t_5	t_6
e_{ia}	0.2057	0.1779	0.1002	0.1997	0.1702	0.1464
e_{ib}	5.2542	5.0617	2.0000	4.9307	4.5726	4.3724
e_{ic}	0.9954	0.8609	0.4851	0.9664	0.8236	0.7087

Step 2.4: Obtain the final ranking of the alternatives based on their e_i values.

The calculations in Step 2.3 are used to obtain the final ranking of the alternatives. These calculations are used in Equation 13 to calculate $e_i, i = 1,2,\dots,6$ values. The scores of alternative suppliers are given in Table 11. In this table, the rankings are numbered from largest to smallest.

Table 11. The scores and the final rankings of the suppliers.

	t_1	t_2	t_3	t_4	t_5	t_6
e_i	3.1763	2.9521	1.3216	3.0158	2.7176	2.5109
Rank	1	3	6	2	4	5

The evaluation of the suppliers' scores concluded that the best supplier was supplier 1 (t_1).

3.3. Sensitivity analysis

To validate the findings and support the precision and deviation of the decision outcomes, a sensitivity analysis is used. By making minor adjustments to the main model, a sensitivity analysis test could assist decision-makers in demonstrating the results of their methods. In this section, the effects of MEREC, CRITIC, Entropy and Equal Weight (EW) methods used in criterion weighting on alternative supplier rankings were observed. First, the weights of the criteria were calculated using all methods and their rankings were obtained as in Table 12. The steps of the calculations can be found in studies [18], [43]-[44].

As seen in Table 11, although the MEREC and Entropy methods revealed similar criterion rankings, the criterion rankings differed when CRITIC and EW methods were used. The reasons for different criterion weights and rankings can be listed as follows. MEREC, Entropy and CRITIC methods are objective methods that reveal criterion weights according to the actual values of the initial decision matrix. Each method aims to achieve effective criterion weighting in a different way. The MEREC method uses criterion weights to calculate the impact of each criterion on the overall performance of the alternatives. It also uses a logarithmic function to measure the overall and partial performance of alternatives. MEREC gives greater weight to criteria that have a greater impact on the performance of alternatives [18]. In the Entropy method, uncertainty is greater in the data group with higher values [43]. CRITIC is a method in which the standard deviations of the criteria and the correlation between the criteria are used together

[44]. In this study, Spearman's correlation was used because the data did not comply with normal distribution. In the EW method, all criteria are given equal weight.

Table 12. The weights and rankings of the criteria using different objective criteria weighting methods.

	MEREC		CRITIC		Entropy		EW	
	h_j	Rank	h_j	Rank	h_j	Rank	h_j	Rank
C_1	0.062	5	0.160	4	0.014	5	0.167	1
C_2	0.123	2	0.183	1	0.061	3	0.167	1
C_3	0.113	3	0.176	2	0.071	2	0.167	1
C_4	0.081	4	0.174	3	0.028	4	0.167	1
C_5	0.604	1	0.153	6	0.818	1	0.167	1
C_6	0.017	6	0.154	5	0.007	6	0.167	1

The criterion weights given in Table 12 were used in the CoCoSo method and the supplier rankings are given in Table 13. In Table 13, it is seen that the ranks for all criteria weighting methods are the same. These results show that CoCoSo is an effective and robust method for alternative ranking.

Table 13. The e_i values and rankings of the alternatives using different objective criteria weighting methods.

	MEREC		CRITIC		Entropy		EW	
	e_i	Rank	e_i	Rank	e_i	Rank	e_i	Rank
t_1	3.176	1	2.428	1	5.502	1	2.450	1
t_2	2.952	3	2.093	3	5.224	3	2.087	3
t_3	1.322	6	1.394	6	1.287	6	1.381	6
t_4	3.016	2	2.182	2	5.255	2	2.189	2
t_5	2.718	4	1.810	4	5.003	4	1.820	4
t_6	2.511	5	1.660	5	4.783	5	1.660	5

4. Conclusion and discussion

The medical device industry is a rapidly growing sector that includes many parameters. Constantly evolving technologies contribute to advancing diagnostic and treatment practices in healthcare. Medical device manufacturers must continuously carry out improvement activities within the company to survive in an increasingly competitive environment and keep up with this change. The company should review its processes, identify problems, take the necessary precautions, implement them, and check the impact and efficiency of the implemented activities. This process becomes even more critical when considering the direct effect of product safety and quality on human life in the medical device industry because many companies produce in the industrial field.

In companies that produce medical devices, the legal requirements of the product being a medical device are followed by notified organizations and competent authorities within the framework of standards and regulations within the scope of quality processes. When placing its devices on the market or putting them into service, the manufacturer must ensure that its devices are designed and manufactured by the requirements of the relevant regulation. The manufacturer's obligations are specified in the applicable EU legislation and the rules published by the Ministry of Health in compliance with this legislation. Increasing costs and liabilities with MDR 2017/45 have made medical device manufacturers question their processes. Meeting customer demands while fulfilling all legal requirements becomes critical for manufacturers to avoid market losses. The harmony between the manufacturer's activities and customer expectations is essential for the operation's success.

Manufacturers need to respond to customer demands without compromising product safety and performance. Product safety is evaluated during the medical device production process, considering patient and user health. This process covers the sales and subsequent tracking process, depending on the product class, starting from the purchase of raw materials, and is considered traceability. Availability begins when the order arrives and continues until its sale and destruction. The first critical step is the supply of raw materials/semi-finished products.

This study addressed the supplier selection problem experienced in a company that is a medical device manufacturer and produces consumables. First, it was determined that the company could not meet customer demands such as on-time delivery and shorter lead times, and it was observed that delivery times increased. A group of company managers was determined, and the reasons for these delays were discussed. As a result of this evaluation, it was concluded that the main reason for the delivery times was the disruptions in the supply processes. It is envisaged that if the problems in supply are resolved, the disruptions in planning will be significantly reduced. In addition, it is anticipated that solving this problem will contribute considerably to the subsequent processes for the company, which is in the preparation phase for MDR 2017/45.

In this study, the supplier selection problem was identified at a medical device manufacturer. The hoses are the primary elements of extension and infusion sets. When the company's 2022 production data was referenced, it was observed that there was a problem with the hose supply, and this situation affected the production process directly.

There are many alternatives and criteria to be considered in the supplier selection problem. Due to the structure of supplier selection, MCDM methods are frequently used in the literature. For the hose supplier selection problem, first, alternative suppliers and selection criteria were determined using the company's industry knowledge and focus group evaluations. In the evaluation made with the focus group and considering the literature review, six criteria were determined: Product quality (k_1), year of quality certificates (k_2), delivery time (k_3), price (k_4), transportation costs (k_5), customer relations (k_6). In this study, the MEREC-CoCoSo integration is suggested for supplier selection. While the criteria weights were determined using the MEREC method, the hose suppliers were ranked using the CoCoSo method. The results were evaluated together with the company managers. According to the results of the MEREC method, the obtained criteria weights were calculated as $h_1 = 0.0624, h_2 = 0.1228, h_3 = 0.1130, h_4 = 0.0807, h_5 = 0.6040, h_6 = 0.0171$. According to these results, transportation cost criterion is the most weighted criterion. It has been determined that this criterion has a more significant impact on the result. The criterion weights are shipping costs, year of quality certificate, lead time, price, quality, and customer relations.

After determining the weights, the rankings of the alternatives were obtained with the CoCoSo method. It was concluded that the best supplier in the final ranking of the alternatives was the number 1 supplier. At the same time, this supplier has had a quality certificate for 13 years, and the supply period is two weeks, which can be considered a good choice. The results were consistent with the evaluations of company managers and engineers.

The contribution of this study to the literature is as follows [45].

- This study addressed the supplier selection problem for medical device manufacturers. In the literature study, although there are studies about supplier selection problems in the healthcare industry, these studies conducted in the medical device sector need to be more comprehensive and specific for this field. The healthcare industry is intertwined with the medical device industry, but it should not be overlooked that they are two different industries. The study anticipates contributing to the literature in this sense.
- Although MEREC-CoCoSo methods were used together in different areas, this was the first time the MEREC-CoCoSo method has been applied for supplier selection in the medical device industry. While determining the criteria, along with MDR 2017/45, the fact that the manufacturers and suppliers have quality certificates was considered.
- Considering the consistency of the results, this study is a guide for medical device manufacturers who are envisaged to review their supplier selection processes with the proposed method while preparing for MDR

2017/45, which will assist companies in directing their resources correctly. The relevant study is thought to help decision-makers in the criteria determination stage of medical device manufacturers with a high medical device class or operating as active device manufacturers, considering the product features, and intended use.

Future studies may include the following: The number of criteria and suppliers used in this study may be increased. The MCDM methods used can be differentiated and sensitivity analysis can be performed by comparing the results. The impact of decision makers on supplier rankings can be discussed by choosing subjective MCDM methods instead of the objective MCDM methods used in this study.

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