

Value engineering and multi-criteria decision making as a part of health technology assessment in medical devices

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Introduction:

The objective of this study is to design a methodology for evaluation of medical technology for the purpose of purchasing medical devices in hospitals. The selection of an appropriate medical device so that its purchase is transparent and not overpriced is a big problem not only in the Czech Republic. The methodology will serve as a basis for decision making in purchasing medical technology; we will evaluate devices not only by their technical and (if relevant) clinical aspects, but also whether they are cost effective and user friendly. This section dealing with effective purchasing will become a part of the whole decision making chain where the return on investment and the expected usability of the device must also be considered. Currently, the purchases of medical technology in the Czech Republic lack any coordination. This study, however, addresses solely the issues of the choice of a suitable device, not the issue of their deployment.

The principal difficulty in any evaluation of technology consists in solving the problem of evaluating the effective component of instrumentation. Instrumentation may not directly affect the parameters associated with the quality of life, nevertheless, it affects the quality of therapeutic and diagnostic processes, the attending physician's way of work and, last but not least, the patient's comfort. To this end, we have designed an application of Value Engineering and Multi-Criteria Decision Making methods. In both cases, there is a choice of several methods. First, the Value Engineering methods used for the assessment of competing alternatives were evaluated. All methods were applied to the selection of a lung ventilator for an ICU unit, a device for acute dialysis, and vital signs monitors. Individual evaluations were made together with biomedical engineers, clinicians from respective wards, and user properties of the devices were also assessed with an assistance of the users themselves (nurses). Based on the results, the optimum method for the assessment of criteria weights was designed. Subsequently, real data were processed using four methods of multi-criteria evaluation, and the best method for the selection of medical technology was chosen.

Methods:

The basic procedure and the links between individual methods are displayed in the chart below. Its individual blocks are described further below. All methods included in the study are shown.

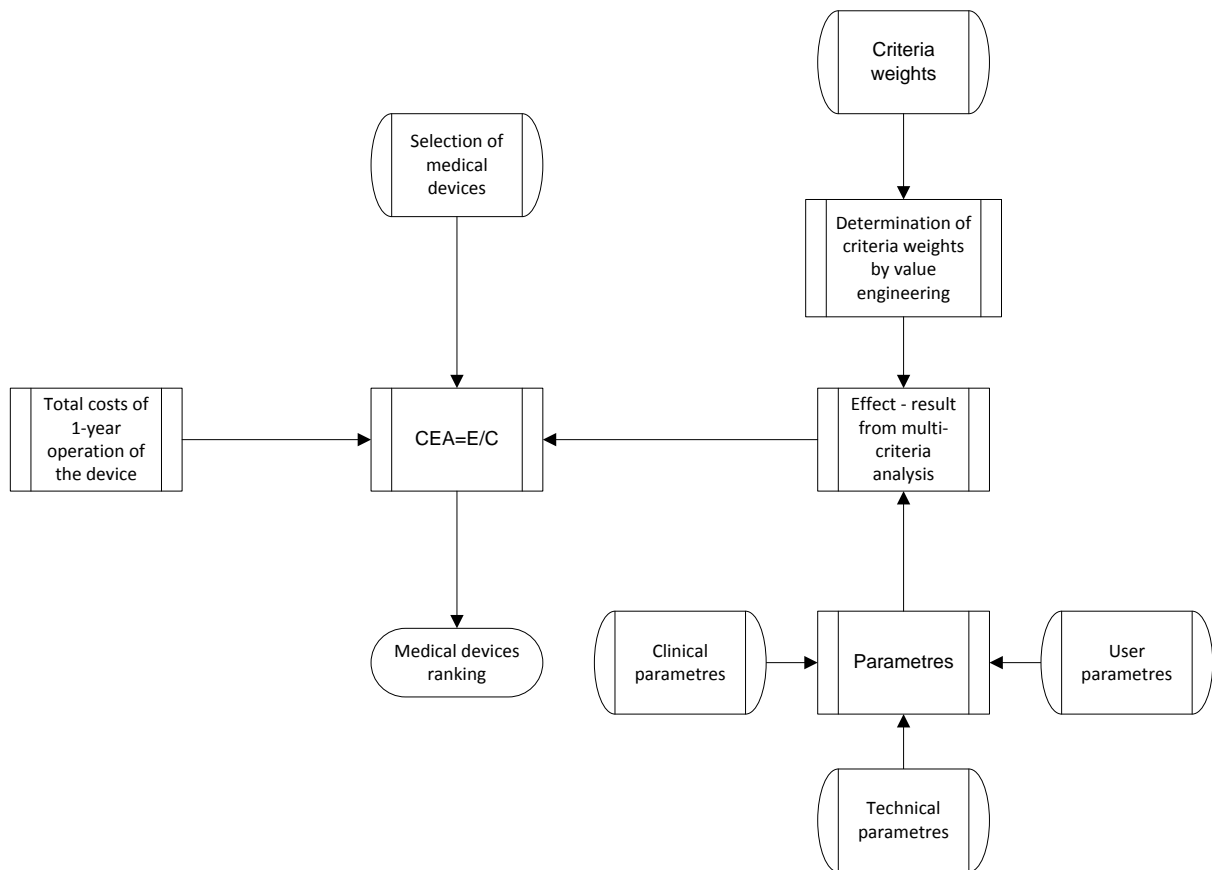


Fig. 1: Flowchart – Selection of medical devices

Total costs:

The total costs are calculated as the sum of all costs entering the process:

$$C_{total} = \sum C_P + C_S + C_N + C_{Ster} + C_M + C_E + C_Z ,$$

where C_P are acquisition costs recalculated over one year. This was based on the Czech legislation where the depreciation period is considered the potential time of using the device;

C_S are service costs and costs for safety and technical checks. These are average amounts considering potential servicing twice per year, and regular technical checks every two years. The servicing price

was only calculated starting from the third year of the device life as servicing costs covering the first two years are mostly included in the purchasing price of the medical device;

C_N are the costs for spare parts. Each spare part was calculated once for each device;

C_{STER} are estimated costs for the sterilisation of the components that are subject to sterilisation;

C_M are the costs for staff calculated according to the time spent by the preparation of a device for the respective intervention. If they were identical for all analysed devices, they were not considered;

C_E are energy costs calculated from the average price of energy in the Czech Republic and from power inputs;

C_Z are the costs of staff training. When purchasing the majority of devices in the Czech Republic, the initial training is free of charge, and, in most cases, it is repeated after two years because of staff fluctuation and additional training in the latest knowledge. Therefore, the calculation only covered eligible costs excluding the first two years.

Criteria weights

Evaluation criteria were defined for individual technical, user's or clinical parameters. In the case of devices analysed within this study, clinical parameters were not evaluated as they were always the same.

The following methods were one by one applied to assessment of the criteria weights.

Pair-wise comparison method

The pair-wise comparison method involves mutual comparisons of individual assessed parameters against each other and, subsequently, the normalisation of their weights using the formula

$$V_i = \frac{K_i}{\sum_i^n K_i},$$

where K_i is the non-normalised weight of the i -th criterion, V_i is the normalised weight of the i -th criterion, n is the number of criteria.

The pair-wise comparison procedure is that individual criteria are mutually compared according to their greater significance for a defined medical purpose. The comparison is performed using a matrix that is developed to allow pair-wise comparisons of individual pairs of criteria where the preference of a criterion in a given line over a criterion in the column is marked by the digit 1, e.g.:

Parameter (criterion number 1-5)	1	2	3	4	5
1	-	1	1	1	1
2	-	-	1	0	1
3	-	-	-	1	1
4	-	-	-	-	0
5	-	-	-	-	-

Tab. 1 – Matrix for pair-wise comparison

Based on pair-wise comparisons of parameters, the weights of individual criteria are assigned to them:

Parameter (criterion number 1-5)	Number of preferences	Criterion weight
1	4	0.4
2	2	0.2
3	2	0.2
4	1	0.1
5	1	0.1
Total	10	1.0

Tab. 2 – Pair-wise comparison of parameters

In this way, the weights of individual parameters of all groups of parameters of the whole medical technology purchase investment project are decomposed and evaluated, e.g.:

Group of parameters	Weight of the group	Partial parameters	Weight of the partial parameter in the given group	Resulting weight of parameters v_j
Technical parameters	0.50	parameter A	0.50	0.250
		parameter B	0.35	0.175
		parameter C	0.15	0.075
		Σ	1	-
User parameters	0.30	parameter D	0.7	0.210
		parameter E	0.3	0.090
		Σ	1	-
...
Total	1	-	-	1

Tab. 3 – Table of parameters results

Saaty's method

Saaty's matrix is based on the evaluation of relative significances which express in pair-wise comparisons how many times the first element in the pair is more significant than the second one. Decisions on how many times the i -th indicator is more significant than the j -th one are entered in the respective fields of a square matrix by integers v_i . The second element in a compared pair is evaluated by the fraction $1/v_i$.

Index	1	2	...	J	...	K	...	n
1	1	$s_{1;2}$...	$s_{1;j}$...	$\frac{1}{s_{1;k}}$...	$s_{1;n}$
2	$\frac{1}{s_{2;1}}$	1	...	$\frac{1}{s_{2;j}}$...	$s_{2;k}$...	$s_{2;n}$
...	1
j	$\frac{1}{s_{j;1}}$	$s_{j;2}$...	1	...	$\frac{1}{s_{j;k}}$...	$s_{j;n}$
...	1
k	$s_{k;1}$	$\frac{1}{s_{k;2}}$...	$s_{k;j}$...	1	...	$s_{k;n}$
...	1	...
n	$\frac{1}{s_{n;1}}$	$\frac{1}{s_{n;2}}$...	$\frac{1}{s_{n;j}}$...	$\frac{1}{s_{n;k}}$...	1

Tab. 4: Saaty's matrix

The objective evaluation is performed by means of eigenvalues of Saaty's matrix, which replaces the actual matrix of the relations among the elements compared in the matrix.

Calculation steps:

- 1) The sums of all n elements s_i , of each k -th column of the matrix are calculated:

$$\sum_{j=1}^n s_{j;k}$$

- 2) Individual elements of each column are divided by these sums. Thus, elements t of a new matrix T are calculated:

$$t_{j;k} = \frac{s_{j;k}}{\sum_{j=1}^n s_{j;k}}$$

- 3) The sums of all n elements t of each j -th line are calculated in the newly calculated matrix T :

$$\sum_{k=1}^n t_{j;k}$$

- 4) Line sums in the matrix T are added up:

$$\sum_{j=1}^n \sum_{k=1}^n t_{j;k}$$

- 5) Quantified values of relative significances of indicators w_j are subsequently calculated by the normalisation of the sums in individual lines:

$$w_j = \frac{\sum_{k=1}^n t_{j;k}}{\sum_{j=1}^n \sum_{k=1}^n t_{j;k}}$$

Multi-Criteria Decision Making methods

WSA method

This analysis consists of several steps where individual criteria are evaluated and their weights assigned to them using the methods mentioned above in this methodology. By their nature, individual criteria may either have a minimisation or maximisation character; hence, the essential part of this analysis is a transformation of individual criteria onto a uniform basis, i.e. either maximisation or minimisation. The next step is a determination of basal (D) and ideal (H) values of individual criteria and the transformation of identified values into normalised values by the formula

$$r_{ij} = \frac{y_{ij} - D_j}{H_j - D_j}$$

The last step in the analysis is a calculation of partial values of the benefit for both alternatives. These are subsequently obtained from the formula below, whose result is the weighted sum of individual criteria for both devices.

$$w_i = \sum_{j=1}^k r_{ij} v_j, \quad i=1, 2, \dots, n$$

TOPSIS method

Procedure for using TOPSIS method

The criteria values for individual alternatives are arranged in a criteria matrix $Y = (y_{ij})$, where y_{ij} is the value of the i -th alternative evaluated according to the j -th criterion.

The method is based on selecting the alternative that is the closest to the ideal alternative represented by the vector (H_1, H_2, \dots, H_k) , and the farthest away from the basal alternative represented by the vector (D_1, D_2, \dots, D_k) .

First of all, the normalised criteria matrix $R = (r_{ij})$ must be composed where the following formula has been designed for the calculation of normalised values:

$$r_{ij} = \frac{y_{ij}}{\sqrt{\sum_{i=1}^p (y_{ij})^2}},$$

where: $i = 1, 2, \dots, p$ and $j = 1, 2, \dots, k$.

Following this transformation, the columns in the matrix R form vectors of unit length. Subsequently, the weighted criteria matrix W is calculated so that each j -th column of the normalised criteria matrix R is multiplied by the corresponding weight v_j :

$$W = \begin{bmatrix} w_{11} & w_{12} & \dots & w_{1k} \\ w_{21} & w_{22} & \dots & w_{2k} \\ \vdots & \vdots & \vdots & \vdots \\ w_{p1} & w_{p2} & \dots & w_{pk} \end{bmatrix} = \begin{bmatrix} v_1 \cdot r_{11} & v_2 \cdot r_{12} & \dots & v_k \cdot r_{1k} \\ v_1 \cdot r_{21} & v_2 \cdot r_{22} & \dots & v_k \cdot r_{2k} \\ \vdots & \vdots & \vdots & \vdots \\ v_1 \cdot r_{p1} & v_2 \cdot r_{p2} & \dots & v_k \cdot r_{pk} \end{bmatrix}$$

The next step is an identification of the ideal (H) and the basal (D) alternative (these alternatives are identified with respect to the weighted criteria matrix), and the calculation of individual alternatives of these alternatives.

The formula for the calculation of the distance from the ideal alternative is

$$D_i^+ = \sqrt{\sum_{j=1}^k (w_{ij} - H_j)^2}.$$

The formula for the calculation of the distance from the basal alternative is

$$D_i^- = \sqrt{\sum_{j=1}^k (w_{ij} - D_j)^2}.$$

The distances from the basal and the ideal alternative are used for the calculation of the relative indicator of the distance from the basal alternative c_i using the formula:

$$c_i = \frac{D_i^+}{D_i^+ - D_i^-}.$$

Based on the falling indicator c_i , individual alternatives are arranged in the order from the most suitable alternative to the least suitable one.

Assessment of suitability of methods:

Individual methods were used to evaluate lung ventilators, monitors of vital signs, and acute dialysis devices.

Value engineering methods were assessed first. The mean and the maximum deviations from the ideal alternative were evaluated separately for each device. Based on the least deviations of the weights of

criteria from the ideal alternative, the method identified as a suitable tool for evaluation of weights of criteria was Saaty's method.

Then, Multi-Criteria Decision Making methods were evaluated, and the results were processed again on the basis of deviations from the ideal alternative. The method identified the TOPSIS method to be the most suitable one.

Data:

These methods have been applied to three cases of medical technology selection: vital signs monitors, lung ventilators and acute dialysis devices. Subsequently, the data are statistically evaluated and complemented by means of sensitivity analysis. The data for the evaluation of lung ventilators, vital signs monitors and acute dialysis devices were collected from two university hospitals and companies present in the Czech Republic based on detailed market research.

Input data for lung ventilators evaluation:

Technical parameters	Evita 4 (Dräger)	Evita XL (Dräger)	Galileo (Hamilton)	Avea (Cheirón)
Respiratory rate	0-100/min	0-100/min	5-120/min	1-120 d/min
Tidal volume	0.1 - 2 l	0.1 - 2 l	0.1 - 2 l	0.1-2.5 l
Expiratory volume per minute	0.1-41 l/min	1-41 l/min	0-50 l/min	0-75 l/min
Inspiratory flow	6-120 l/min	6-120 l/min	4-120 l/min	3-150 l/min
Inspiratory pressure	0-80 mbar	0-95 mbar	0-120 mbar	0-90 mbar
PEEP	0-35 mbar	0-50 mbar	0-50 mbar	0-50 m bar
Power input 240 V	1.3 A	1.2 A	0.9 A	2.0 A
Output	125 W	125 W	120 W	125 W

Tab. 5: Input data for technical parameters

Lung ventilator	Total cost (EUR)
Evita XL (Dräger)	41258
Galileo (Hamilton)	27694
Avea (Cheirón)	27244
Evita 4 (Dräger)	26573

Tab. 6: Input data for total cost evaluation

Technical specification for vital signs monitors evaluation:

Input data for vital signs monitors evaluation are only specified criteria to take into assessment, not their value, due to large comprehensiveness of data.

Technical data:

Display: display size, area of image, resolution, maximum number of curve traces, shift velocity, shift time.

ECG: tolerance of offset voltage of electrodes, input impedance, input leakage current, HR range, ST measurement range, alarm limits, curve imaging – sensitivity, alarm items.

Respiration: Measurement range, RR measurement accuracy, Sensitivity setup, Alarm, RR range, Accuracy.

SpO₂: Measurement range, SpO₂ accuracy, Alarm.

Non-invasive blood pressure: Measurement range, Alarm – Upper limit range, Alarm – Lower limit range.

Temperature: Measurement range, Accuracy, Alarm – Upper limit range, Alarm – Lower limit range.

Invasive blood pressure (IBP): Measurement range, Measurement accuracy, Alarm – Upper limit range, Alarm – Lower limit range.

Pressure of exhaled carbon dioxide, CO₂: Measurement range, RR measurement accuracy, Alarm – Upper limit range, Alarm – Lower limit range.

Function	Nihod Cohden	Chocemmed
Resolution	600x800	600x800
Number of displayed parameters	7	7
Number of displayed curves	5	5
Analysis of arrhythmias (types)	10	4
Number of electrodes for ECG scanning	3, 6	3, 5
Battery life	3 hours	2 hours
Weight	5 kg	4.7 kg

Tab. 7: Input data for users parameters

Input data for total cost evaluation in vital signs monitors:

Vital signs monitor	Total cost (EUR)
Nihon Kohden BSM-2351K	36588
Chocemmed MMED600DP	35880

Tab. 8 – Total cost data – Vital signs monitor

Input data for acute dialysis evaluation:

Input data for acute dialysis evaluation are only specified criteria to take into assessment, not their value, due to large comprehensiveness of data.

Technical data:

Power supply, Output, Arterial suction pressure, Alarm of arterial/suction pressure, Venous pressure/reverse flow pressure, Alarm of venous pressure/reverse flow pressure (if limits are exceeded), Pre-filter pressure, Flow through blood pump, Accuracy of flow through blood pump measurement, Flow through ultrafiltration/plasma pump, Accuracy of flow through ultrafiltration/plasma pump measurement, Flow through infusion pump of substitution fluid, Accuracy of flow through infusion pump measurement, Heating unit – temperature range, Heating unit – measurement accuracy, Trans-membrane pressure, Trans-membrane pressure – accuracy, Simplicity of control, Display brightness, Touch screen monitor, Dimensions.

Input data for cost evaluation in acute dialysis:

Acute dialyses	Total cost (EUR)
Hygeia	28624
Lynda	22271
Aquarius	26528

Tab. 9: Total cost data – acute dialyses

Results:

The methodology of Value Engineering and Multi-Criteria Evaluation was applied to lung ventilators, vital signs monitor and acute dialyses. In this study, results are described in detail according to the aforementioned procedure in lung ventilators. Monitors and acute dialysis are given only the final results.

Results for lung ventilators

Value engineering methods

Fuller's method – 1st step results

Technical parameters	Respiratory rate	Tidal volume	Expiratory volume per minute	Inspiratory flow	Inspiratory pressure	PEEP	Power input 240 V	Output
Respiratory rate	1,00	1,00	1,00	1,00	1,00	0,00	1,00	1,00
Tidal volume	0,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00
Expiratory volume per minute	0,00	0,00	1,00	0,00	0,00	0,00	1,00	1,00
Inspiratory flow	0,00	0,00	1,00	1,00	1,00	1,00	1,00	1,00

Inspiratory pressure	0,00	0,00	1,00	0,00	1,00	1,00	1,00	1,00
PEEP	1,00	0,00	1,00	0,00	0,00	1,00	1,00	1,00
Power input 240 V	0,00	0,00	0,00	0,00	0,00	0,00	1,00	0,00
Output	0,00	0,00	0,00	0,00	0,00	0,00	1,00	1,00

Fuller's method – last step

Parameters	Values
Respiratory rate	0,2
Tidal volume	0,2
Expiratory volume per minute	0,0857
Inspiratory flow	0,1714
Inspiratory pressure	0,1142
PEEP	0,1428
Power input 240 V	0,0285
Output	0,0571

Saaty's method – 1st step results

Technical parameters	Respiratory rate	Tidal volume	Expiratory volume per minute	Inspiratory flow	Inspiratory pressure	PEEP	Power input 240 V	Output
Respiratory rate	1	2	3	5	3	1/3	6	4
Tidal volume	1/2	1	3	6	3	4	5	3
Expiratory volume per minute	1/3	1/3	1	1/2	1/2	1/4	2	5
Inspiratory flow	1/5	1/6	2	1	3	2	5	4
Inspiratory pressure	1/3	1/3	2	1/3	1	2	6	4
PEEP	3	¼	4	1/2	1/2	1	3	2
Power input 240 V	1/6	1/5	1/2	1/5	1/6	1/3	1	1/2
Output	1/4	1/3	1/5	1/4	1/4	1/2	2	1

Saaty's method – last step results

Parameters	Values
Respiratory rate	0,2281
Tidal volume	0,2338
Expiratory volume per minute	0,0721
Inspiratory flow	0,1327

Inspiratory pressure	0,1164
PEEP	0,1486
Power input 240 V	0,0274
Output	0,0406

These results from two methods shows that Saatys's method is more accurate and precise differentiates differences between the parameters.

Multicriterial analysis

WSA – Input data – modified values - maximalization

Lung ventilator	Respiratory rate	Tidal volume	Expiratory volume per minute	Inspiratory flow	Inspiratory pressure	PEEP	Power input 240 V	Output
Evita 4 (Dräger)	100	1,9	40,9	114	80	35	0,7	125
Evita XL (Dräger)	100	1,9	40	114	95	50	0,8	125
Galileo (Hamilton)	115	1,9	50	116	120	50	1,1	120
Avea (Cheiron)	119	2,4	75	147	90	50	0	125

WSA – Standardized criterial matrix – last step of WSA method

Lung ventilator	Respiratory rate	Tidal volume	Expiratory volume per minute	Inspiratory flow	Inspiratory pressure	PEEP	Power input 240 V	Output
Evita 4 (Dräger)	0	0	0,0257	0	0	0	0,6363	1
Evita XL (Dräger)	0	0	0	0	0,375	1	0,7272	1
Galileo (Hamilton)	0,7894	0	0,2857	0,0606	1	1	1	0
Avea (Cheiron)	1	1	1	1	0,25	1	0	1
	0,2281	0,2338	0,0721	0,1327	0,1164	0,1486	0,0274	0,0406

WSA – Resulting effect values

Lung ventilator	Respiratory rate	Tidal volume	Expiratory volume per minute	Inspiratory flow	Inspiratory pressure	PEEP	Power input 240 V	Output	Effect values
Evita 4 (Dräger)	0	0	0,0018	0	0	0	0,0174	0,0406	0,0601
Evita XL (Dräger)	0	0	0	0	0,0436	0,1486	0,0199	0,0406	0,2529
Galileo (Hamilton)	0,1800	0	0,0206	0,0080	0,1164	0,1486	0,0274	0	0,5012
Avea (Cheiron)	0,2281	0,2338	0,0721	0,1327	0,0291	0,1486	0	0,0406	0,8852

WSA – Results of CEA

Lung ventilators	CEA (E/C)	Ranking
Evita 4 (Dräger)	2,2582	4.
Evita XL (Dräger)	6,1298	3.
Galileo (Hamilton)	18,0987	2.
Avea (Cheiron)	32,49338	1.

TOPSIS – Standardized criterial matrix

Lung ventilator	Respiratory rate	Tidal volume	Expiratory volume per minute	Inspiratory flow	Inspiratory pressure	PEEP	Power input 240 V	Output
Evita 4 (Dräger)	0,4594	0,4665	0,3831	0,4614	0,4108	0,3747	0,4576	0,5050
Evita XL (Dräger)	0,4594	0,4665	0,3747	0,4614	0,4878	0,5353	0,5230	0,5050
Galileo (Hamilton)	0,5283	0,4665	0,4683	0,4695	0,6162	0,5353	0,7191	0,4848
Avea (Cheiron)	0,5467	0,5892	0,7025	0,5949	0,4621	0,5353	0,0000	0,5050
Weights	0,2281	0,2338	0,0721	0,1328	0,1164	0,1486	0,0275	0,0407

TOPSIS – Weighted criterial matrix

Lung ventilator	Respiratory rate	Tidal volume	Expiratory volume per minute	Inspiratory flow	Inspiratory pressure	PEEP	Power input 240 V	Output
Evita 4 (Dräger)	0,1048	0,1091	0,0276	0,0613	0,0478	0,0557	0,0126	0,0205
Evita XL (Dräger)	0,1048	0,1091	0,0270	0,0613	0,0568	0,0795	0,0144	0,0205
Galileo (Hamilton)	0,1205	0,1091	0,0338	0,0623	0,0717	0,0795	0,0197	0,0197
Avea (Cheiron)	0,1247	0,1378	0,0507	0,0790	0,0538	0,0795	0,0000	0,0205
Max	0,1247	0,1378	0,0507	0,0790	0,0717	0,0795	0,0197	0,0205
Min	0,1048	0,1091	0,0270	0,0613	0,0478	0,0557	0,0000	0,0197

TOPSIS – Final effect results

Lung ventilator	Effect
Evita 4 (Dräger)	0,1809
Evita XL (Dräger)	0,0864
Galileo (Hamilton)	0,5327
Avea (Cheiron)	0,6608

Lung ventilator	Cost	CEA=E/C	Ranking
Evita 4 (Dräger)	26573	6,8086	3.
Evita XL (Dräger)	41258	2,0945	4.
Galileo (Hamilton)	27694	19,2338	2.
Avea (Cheiron)	27244	24,2543	1.

In terms of efficiency purchase lung ventilators in proportion, the best effect have ventilator Avea. Both methods are selected the same ventilators as the best one. The results were discussed with experts from hospitals in the Czech Republic and were evaluated very positively.

Results for vital signs monitors

This analysis served for a comparison of the costs and benefits of both types of patient monitors, i.e. the total (aggregate) benefit per monetary unit. This relation is expressed by the formula:

$$CEA = \frac{E1}{C1} > \frac{E2}{C2}$$

Vital signs monitor	Effect	Total cost (EUR)	CEA (E/C)	Ranking
Nihon Kohden BSM-2351K	8,3667	36588	22,8670	1.
Chocemmed MMED600DP	5,5333	35880	15,4215	2.

Acquisition costs for the particular type of patient monitor were used to express the costs. The results of multi-criteria analysis were used to express the effectiveness of devices, i.e. the benefit. The following table shows the results of CEA, i.e. the benefit of patient monitors based on the comparison of individual parameters per monetary unit.

Results for acute dialysis

Acute dialyses	Effect	Total cost (EUR)	CEA (E/C)	Ranking
Hygeia	12,3872	28624	43,2762	3.
Lynda	15,6245	22271	70,15657	2.
Aquarius	21,3872	26528	80,62123	1.

From the acute dialysis are the best dialysis Aquarius. All methods determine the final order of the same.

Subsequently, we calculated how much money might be saved on the respective technology, so that the quality of instrumentation may be maintained at the lowest cost. The largest financial losses are due to service charges and spare parts.

Conclusion:

Based on the above results, the methodology for medical technology evaluation before its purchase by healthcare facilities was designed as a support for the respective decision. The combination of Value Engineering and Multi-Criteria Decision Making methods appears a suitable tool in the purchase of medical appliances. The suitability of the use of these methods was discussed with specialists in respective branches. Nevertheless, it should be mentioned that such a purchasing process is linked to a number of other activities related to these issues, such as market research or appropriateness assessment of the particular technology purchase to be used for particular diagnoses in selected hospital departments.

Saaty's method seems to be the most appropriate method of the value engineering step, and the TOPSIS method seems to be the most appropriate method of the multi-criteria decision making step.

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