

Purchasing implantable medical devices in Egypt using a multicriteria decision analysis (MCDA) tool

Baher Elezbawy¹, Ahmad Nader Fasseeh^{1,2,3}, Bertalan Németh⁴, Mary Gamal⁵, Mariam Eldebeiky⁵, Remonda Refaat⁵, Amr Taha⁵, Shima Rabiea⁶, Marwa Abdallah⁷, Soha Ramadan⁸, Amr Ibrahim⁹, Hasnaa Noaman¹⁰, Amany Bahaa Eldin¹⁰, Hossam Mostafa⁶, Sara Nouh⁵, Asmaa Zaki¹¹, Mohamed Abdelrahman⁹, Sherif Abaza¹, Zoltán Kalò^{4,12}

1. Syreon Middle East, Alexandria, Egypt
2. Faculty of Social Sciences, Eötvös Loránd University, Budapest Hungary
3. Faculty of Pharmacy, Alexandria University, Alexandria, Egypt
4. Syreon Research Institute, Budapest, Hungary
5. The Egyptian Authority for Unified Procurement, Medical Supply, and Technology Management, Cairo, Egypt
6. Ministry of Health and Population, Cairo, Egypt

7. Suez Canal University Hospital, Ismailia, Egypt
8. Zagazig University, Zagazig, Egypt
9. Egyptian Drug Authority, Cairo, Egypt
10. Health Insurance Organization, Cairo, Egypt
11. The General Authority of Health care, Cairo, Egypt
12. Center for Health Technology Assessment, Semmelweis University, Budapest, Hungary

INTRODUCTION & OBJECTIVE

Based on experience, decision-makers in Egypt are aware that procurement decisions related to implantable devices are multifactorial. Yet only price and technical specifications are usually considered as there is no structured weighted framework to aid the decision-making process. Multicriteria decision analysis (MCDA) tool can be used to capture all attributes of specific products providing an objective and transparent methodology for choosing among the available options. We aimed to develop an MCDA tool to assist decision makers procure implantable medical devices in Egypt.

METHODS

To identify relevant criteria for the tool, we conducted a systematic literature review and interviews with local experts in procuring and tendering medical devices. The systematic review provided data about the criteria used for medical device comparisons globally. These criteria were used to guide experts to choose the relevant criteria for their local MCDA tool. A summary of the systematic review process is shown in Figure 1.

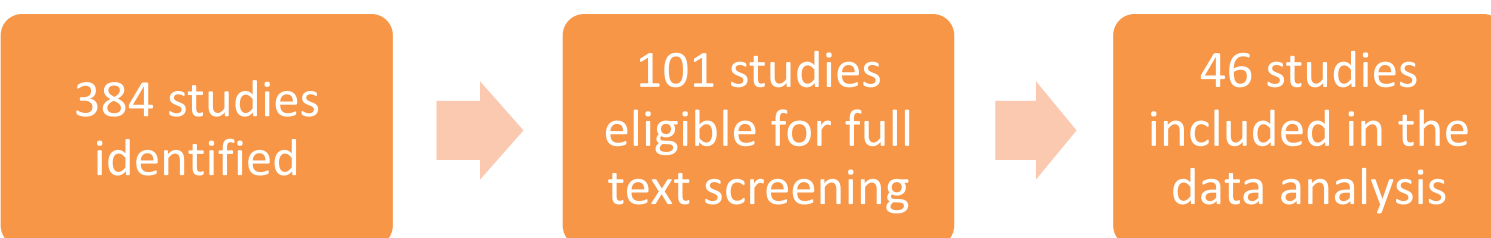


Figure 1: systematic review summary

A workshop was organized among experts in 2021 to choose the relevant criteria, rank them, assign weights, and define scoring functions for each criterion to develop a draft tool. The draft tool was used for a 1-year pilot phase, then another workshop was conducted in 2022 to fine-tune the tool. The tool was readjusted based on the experts' experience with the draft tool. Experts made their choices during the workshops through anonymous voting, and average results were calculated for each decision.

RESULTS

Twenty experts participated in the first workshop, and 14 experts participated in the final workshop. Experts agreed to include 8 criteria in the final tool. They ranked these criteria and provided a specific weight for each, as shown in Table 1.

Table 1: Ranks and weights of the included criteria

Rank	Criteria	Weight
1	Technical characteristics of the medical device	29.4%
2	Country of origin	19.5%
3	Use in reference countries	14.9%
4	Supply reliability	11.7%
5	Previous use in tenders	9.0%
6	Instant replacement within product variety	6.9%
7	Pharmacovigilance system	4.6%
8	Provision of refund or replacement	4.0%

Experts voted for the scores and scoring functions for each criterion. Each medical device is assessed according to the scores assigned. The scoring function and the score details for each criterion is presented in Table 2.

Table 2: Scoring functions of the criteria

Criterion	Scoring options	Score
Technical characteristics of the medical device	Fulfills 100% of the technical specifications required	100%
	Fulfills 90%-<100% of the technical specifications required	80%
	Fulfills 80%-<90% of the technical specifications required	60%
	Fulfills 70%-<80% of the technical specifications required	10%
	Fulfills <70% of the technical specifications required	Exclusion
Country of origin	Reference countries* for both legal and actual manufacturer or local product	100%
	Reference country* of the legal manufacturer or actual manufacturer	75%
	Non reference countries for both	40%
Use in reference countries	CFG certificate from FDA	100%
	Canadian free sale certificate + ((medical device active license + MDSAP certificate) or medical device establishment license)	80%
	European CE certificate + free sale certificate from a reference country*	75%
	European CE certificate only (for local products only)	50%
Supplier reliability	Supplier fulfilled more than 90% of the committed requirements in the last 3 years	100%
	Supplier fulfilled 70% - 90% of the committed requirements in the last 3 years	80%
	Supplier fulfilled 50% - 70% of the committed requirements in the last 3 years	60%
	Did not supply previously	50%
	Supplier fulfilled < 50% of the committed requirements in the last 3 years	10%
Previous use of the product	Listed in the UPA platform	100%
	Supplied to governmental or non-governmental organizations in the previous 2 years	70%
	Was not supplied previously	45%
Instant replacement	Supplier provides instant replacement within product variety (During surgery on shelf stock)	100%
	Supplier does not provide product replacement for different sizes/ types	15%
Pharmacovigilance system	Supplier has an efficient pharmacovigilance system	100%
	Supplier has a moderate quality pharmacovigilance system	70%
	Supplier has a low-quality pharmacovigilance system	20%
	No pharmacovigilance system	Exclusion
Refund/Replacement within product variety	The product was present in the stagnant report 1 time or less in the last year	100%
	The product was present in the stagnant report 2 times subsequently in the last year	70%
	The product was present in the stagnant report 3 times subsequently in the last year	50%
	The product was present in the stagnant report 4 times in the last year	20%

CFG: Certificate to Foreign Government, FDA: Food and Drug Administration, UPA: The Egyptian Authority for Unified Procurement, Medical Supply, and Technology Management, EDA: Egyptian Drug Authority, CE: Conformité Européenne, MDSAP: Medical Device Single Audit Program

*List of reference countries: Australia, Austria, Belgium, Canada, Denmark, Germany, Finland, Iceland, France, Ireland, Luxemburg, The Netherlands, New Zealand, Norway, Sweden, Switzerland, USA, UK, Japan, Italy, Spain, Portugal [21]

The tool assesses the devices for the 8 criteria and the device that achieves the highest final is considered the best. Price was not included in the MCDA tool due to the Egyptian tender regulations that separates between the technical evaluation phase and the financial evaluation phase. The price of the device will be added to the equation in the financial evaluation phase. The product that achieves the lowest price per point provides the best value for the resources incurred and should be chosen for reimbursement.

CONCLUSION

The MCDA tool can help decisionmakers take evidence-based decisions for purchasing implantable devices for the public sector in Egypt. The tool compares the available options, and provides a summary score for each, for flawless assessment and transparent decision-making.