Multi-criteria Decision Making for Medical Device Development

Houssem Barkaoui [a]

[a] National Engineering School of Tunis (ENIT), Université Tunis El Manar, Tunis, Tunisia, barkaoui.houssem@yahoo.fr

Helmi Ben Rejeb [a, b], corresponding author

[a] National Engineering School of Tunis (ENIT), Université Tunis El Manar, Tunis, Tunisia, Helmi.BenRejeb@enit.utm.tn
[b] Univ. Grenoble Alpes, Grenoble INP (Institute of Engineering Univ. Grenoble Alpes), G-SCOP, Grenoble, France

Abdelwahed Barkaoui [c, d]

[c] Laboratoire de Mécanique Appliquée et Ingénierie (LR-MAI), LR-ES19, Ecole Nationale d'Ingénieurs de Tunis, Université de Tunis El Manar, 1002 Tunis, Tunisia, Abdelwahed.Barkaoui@ipeiem.utm.tn

[d] Laboratoire des Energies Renouvelables et Matériaux Avancés (LERMA), Ecole Supérieure de l'Ingénierie de l'Energie, Université Internationale de Rabat, Rocade Rabat-Salé, Rabat-Sala El Jadida, Morocco

João Manuel R. S. Tavares [e]

[e] Institute of Science and Innovation in Mechanical and Industrial, Universidade do Porto, Porto, Portugal, tavares@fe.up.pt

Abstract:

The development of a new product is a complicated multi-stakeholder process with a significant risk of failure. This is particularly true in the medical device sector, where there are strict therapeutic, psychological, and normative constraints. This article presents a multi-criteria decision making process called "Define, Prioritize, Measure, and Aggregate" (DPMA). DPMA is designed to help engineering managers in decision making during the development process of new medical devices. The model is based on two sets of criteria linked to business and customer satisfaction. These criteria are weighted using the analytic hierarchy process (AHP) and group decision making (GDM) process. The performance of a medical device is measured according to each criterion. Furthermore, the final score of GO/NO GO alternatives are calculated with the simple additive weighting (SAW) method. A case study for the development of a new kind of femoral implant is presented to demonstrate the implementation of the DPMA process. This study shows that the application of the DPMA process during the design of a 3D

printed femoral prosthesis provided engineering managers the key elements and green light to go ahead with the development of this medical device.

Keywords:

Medical device, new product development, design parameter, innovation, decision making, analytic hierarchy process

Engineering managers and designers have been searching for tools and methodologies in order to optimize the use of resources and increase the effectiveness of both products and processes (Santos, 2013). This is particularly true in the health care sector where funding has dropped in many developed countries, leading to increasing pressure to reduce health care costs (Correia, Carapinheiro, Carvalho, Silva, & Dussault, 2017; Holland, 2017; Yip, Phaal, & Probert, 2014). This sector is extremely complex due to regulatory requirements, clinical testing requirements, and strong but highly competitive markets (Russell & Tippett, 2008; Salgado, Sanches da Silva, Mello, & Samaan, 2017).

Medical devices, their diversity, and innovation play an essential role to improve the quality and effectiveness of healthcare. Such devices encompass a wide range of products from simple bandages to the most sophisticated medical diagnostic equipment. However, this diversity and the need for innovation make the design and development of medical devices a challenging and unique process (Piuzzi et al., 2019). Decision making during the design of such devices is multifaceted; in addition to the technological science, such decision making involves ethical and economic considerations and input from stakeholders and decision makers from different fields (Carter et al., 2017; Floyd, Barker, Rocco, & Whitman, 2017). One critical decision that decision makers in the medical device industry must make is determining when they should move ahead a product concept from the design phase to the development and production phases (Fearis & Craft, 2016). Design phases are usually at the front-end of the development process. Although they are highly important phases, the investment and the risks of failure are at their lowest levels. On the other hand, the development phases require the most time and investment of all stages in the product development process. Therefore, the decision to proceed to development is critical (Russell & Tippett, 2008; Salgado et al., 2017).

Given the peculiarities of medical devices, this article presents the development of a decision-making process called DPMA (define, prioritize, measure, aggregate). The choice of these steps is based on the principles of multi-criteria decision aid (MCDA) methods, which consider various stages including stakeholder identification, definition of the decision problem, criteria definition, weighting criteria, definition of alternatives, scoring alternatives, and sensitivity analysis (Thompson & Friess, 2019). The DPMA process is intended for the upstream phases of a medical device development process. During new product development (NPD) processes,

engineering managers, designers, and decision makers would like to have tools and methods that help them in taking a GO or NO GO decision toward development phases. It may be helpful to determine technological strategies and may provide a road-mapping technique to identify suitable emerging technologies that need to be developed.

The layout of this article is as follows: after the literature review, an overview of the methodology with the tools and steps of the DPMA process are presented. Then, the implementation process is described using the development of a femoral implant as an example.

LITERATURE REVIEW

This section contains a literature review dealing with NPD processes that focus on the development of medical devices and decision making in the medical device sector.

New product development

Typical product design processes, such as the well-known stage-gate system proposed by Cooper, acknowledge the importance of decision making during the development process (Cooper, 2001). As Exhibit 1 indicates, this model makes a clear distinction between a set of five design and development phases or "stages" (scoping, building the business case, development, testing and validation, and launching) and decision phases ("gates").

Exhibit 1. The Stage-Gate System (Cooper, 2001)

According to the stage-gate system, Gate 3 ("Go to development") is the most critical decision point because it is the final gate before the development stage. The criteria for a pass are often difficult to meet and include critical financial reviews and risk assessments. According to Cooper, "the fuzzy front end - ideation, scoping the project, defining the product, and building the business case - is perhaps the most critical aspect of the stage-gate system" (Cooper, 2008, p. 75). Therefore, the quality of execution of Stage 2 ("Building the business case") is the cornerstone of a successful new product development process (Cooper, Edgett, & Kleinschmidt, 2002; Koen et al., 2002).

The stage-gate system has also the advantage of being a cross-industry model (Schultz, Globocnik, Kock, & Salomo, 2018) and is used for product development and innovation management (Cooper, 2008). Pietzsch, Shluzas, Paté-Cornell, Yock, and Linehan (2009) suggest that the stage-gate system is the predominant development model used in the medical device industry. In this sector, health technology management teams need to develop tools that can be applied to all phases of the lifecycle of medical devices from the upstream phases of the design process to the obsolescence and replacement of the product. Entering the development phases should also be supported by a well-established decision making processes and should take into consideration the views of different stakeholders (Eberhardt, Johnson, Kirkland, Dobbs, & Moradi, 2016; Russell & Tippett, 2008).

Decision making in the medical device sector

Griffin and Page proposed a set of generic criteria to assess a new project using a scorecard (Griffin & Page, 1996), which could be the development of any new product. In their research, three sets of project success criteria were determined: customer-based success, financial success, and technical performance success. However, according to Santos, Gazelle, Rocha, and Tavares (2012), these criteria do not take into account the peculiarities of the medical device sector such as compliance with legislation and clinical needs. Thus, several tools and frameworks must be developed to provide support for engineering managers along the holistic process of decision making in the medical device field. Some studies have tried to identify critical success factors for the success of NPD processes in the medical device industry; others have studied the best practices for innovation and the management of technology. Exhibit 2 provides an overview of past research in the medical device sector dealing with decision making processes and the tools that were developed.

Exhibit 2. Existing literature on decision making for the development of medical devices

This summary of the literature review allowed us to identify multiple factors that underlie decision making in the medical device industry and to determine the methods and models used. Initially it revealed that prioritizing and selecting new medical device concepts is a major issue because of the end of life replacement needs. In addition, it highlighted the lack of a holistic approach, which can combine the identification of critical success factors, the fulfilment of the requirements of different stakeholders, and a mathematical method for the selection of concept at the upstream phases of NPD. Moreover, it showed that the integration of user needs and requirements through direct user involvement in the design process has been widely addressed in the literature and is considered as an important success factor for any design activity in many sectors (Griffin & Page, 1996; Karlsen, 2002). Design in health care and particularly in the medical device sector is always challenging as it has to take into consideration expert users and end-user (the patient) (Gosavi, Cudney, Murray, & Masek, 2016; Hisarciklilar, Rasoulifar, Boujut, Thomann, & Villeneuve, 2009). Therefore, any decision aid method in this sector should integrate professional requirements and clinical needs. As the medical device sector involves human health and safety, users' needs and the particularities of regulation and high competition must be taken into account in the decision making process (Parthasarthy & Hammond, 2002; Russell & Tippett, 2008; Salgado et al., 2017).

Multi-criteria decision aid methods

A multi-criteria decision aid (MCDA) method is the most appropriate methodology in this context. This method offers a set of suitable tools such as the analytic hierarchy process (AHP), simple additive weighting method (SAW), weighted product model (WPM), and various other methods (Ray & Triantaphyllou, 1998). The AHP was developed by the mathematician Saaty

(Saaty, 1980), who used this methodology to evaluate alternatives for a decision-making tool based on solid mathematical foundations. Solving a problem using the AHP is common in multi-criteria analysis techniques because it allows researchers to model the problem and assess its parameters (Cho & Kim, 2003; Golden, Wasil, & Harker, 1989; Saaty, 1980). The AHP is based on pairwise comparisons among criteria at each level of the hierarchy, and experts are usually consulted to make decisions about the relative importance of each criterion. Although, in theory, there is no limit to the number of criteria that can be compared with AHP, Miller (1956) argues that it would be better if the number is limited to "seven plus or minus two", which is the limit of the human mind's capacity to be precise and to assimilate all the available information. The AHP is essentially made up of five steps, summarized here (Saaty, 1980):

1. Decomposition of the problem into a hierarchical structure
2. Pairwise comparisons (this step is based on answers from experts taken individually)
3. Prioritization of the criteria
4. Measurement of consistency, which is conducted to ensure that the pairwise comparisons of attributes are performed without any inconsistency of opinions (Kumar& Routroy, 2016).
5. Consistency improvement, which is added, if necessary, in order to improve the consistency of judgments

During the processes of medical device design as in many other sectors, decisions are made in groups as opposed to an individual (Ray & Triantaphyllou, 1998). Within this context, divergent points of view may appear. Therefore, a consensus indicator is carried out in order to evaluate the consensus of the group, which yields an estimate of the level of agreement on the calculated criteria weights among participants (del Moral, Chiclana, Tapia, & Herrera-Viedma, 2018). Then, the weights for the analysis can be obtained from the group decision-making (GDM) method. Since there is no relationship between the experts involved in this study and they work independently, the aggregation of individual priorities method is the most appropriate group decision-making method for this situation (Aull-Hyde, Erdogan, & Duke, 2006). This choice is dictated by the fact that if the number of experts is small, the geometric average is more appropriate than the arithmetic average because the latter mitigates any extreme values (Ben Rejeb & Ben Younes, 2018). In other words, "the geometric mean is less affected by extreme values than the arithmetic mean" (Aull-Hyde et al., 2006).

This literature review section demonstrates the peculiarities of the medical device sector in terms of product development and decision making processes. The processes in the following sections address uncertainties in the decision making steps, primarily when moving from the upstream phases to the development phases. In addition, it considers different success factors for the evaluation of the prototypes of medical devices.

METHODOLOGY

This article aims to support stakeholders and decision makers in assessing a GO or a NO GO decision during the development of new medical devices. With this method, decisions are based on various success factors and involve different stakeholders. Thus, a set of evaluation criteria must be defined with their relative importance assessed by a weighting system and a method to measure them must be established. The final step of the method is a mathematical approach for aggregating the performances of new product concepts for the evaluation criteria. This section describes the four steps of the proposed DPMA approach. Exhibit 3 provides a graphical flowchart of the DPMA process and a summary of the contents of each step.

Exhibit 3. DPMA process flowchart

Definition of the criteria: the "D" step

In this phase of the DPMA method, a set of criteria and success factors must be identified. The determination of this set of criteria may be carried out through brainstorming, literature reviews, or questionnaires and can be investigated in greater depth with advanced tools, such as the Kano model (Ahrens & Hehenberger, 2015).

The set of criteria is divided into two categories; this division takes into account the importance of external and internal stakeholders in the decision making process. Since our approach aims to highlight customer involvement in decision making, the first set of criteria is related to customer satisfaction; these criteria are intended to ensure that the product meets customer needs. The customer in this case refers to any person or entity that buys the medical device and/or uses it with patients. For some medical devices, the customer could be a hospital; for others, the consumer could be a physician or the patient. The second category represents the criteria relating to company satisfaction, and these criteria typically include financial and strategic factors. These two sets also include criteria to be applied in decision making by the various stakeholders involved in the design process.

Prioritizing the criteria and GDM: the "P" step

At the first level of prioritization, we cannot assume that the two categories have equal contributions in the decision making process. Therefore, experts should be consulted to decide the weight of each criteria category. At a second level, pairwise comparisons are carried out in order to prioritize the different criteria within each category. This choice is justified by the fact that it is easier and more objective for experts to compare criteria with the same purpose (which is either to satisfy the customer or to satisfy the enterprise) than comparing mixed criteria with different characteristics and goals. Prioritizing the criteria in each category and the relative importance of the two categories provide a set of weights that will be used in MCDA. Individual level consistency and group level consensus should be tested in order to ensure that preference relations have consistency before the selection process (Wu, Huang, & Xu, 2019). An

inconsistency is observed when a decision maker, considered individually, makes a set of contradictory pairwise comparisons (Brunelli, 2018). A consensus measures the difference in preference relations among an entire group of decision makers (Dong, Zhang, Hong, & Xu, 2010; Wu et al., 2019).

Prioritizing the criteria

The AHP is most appropriate when conducting a needs analysis for multiple stakeholders and a comparison of concepts according to the predefined criteria (Cho & Kim, 2003; Golden et al., 1989). Therefore, the AHP was chosen for this study. With the AHP, a complex decision problem is first broken down into a hierarchical structure of factors or elements. Generally, the hierarchy has at least three levels: the main goal, the criteria, and the alternatives. In our case, the first level is the main goal of the process, which is to support decision makers in GO or NO GO decisions during the development of medical devices (see Exhibit 4). The second level is the group of criteria according to the satisfaction of the enterprise and customer. The third level is composed of the criteria of each group.

Exhibit 4. The hierarchical tree of criteria

Application of the GDM method

This study involved several stakeholders in the decision making process in order to obtain a more objective criteria weighting. Each expert consulted provided a weight vector w_i for each set of criteria. Therefore, the number of vectors equals the number of experts consulted. After the consistency tests carried out during AHP, the weighting factors based on the opinions of the experts are aggregated into one single value using the geometric average.

Assuming that all experts have the same importance, the equation of the geometric average is calculated as

$$g_i = \sqrt[m]{\prod_{k=1}^{m} w_i^k}, \text{ i=1..n} \quad (1)$$

where

- g_i is the weight of criterion i;
- w_i^k is the priority assigned by expert k to criterion i;
- m is the total number of consulted experts whose answers were accepted;
- n is the number of criteria.

Then, the result of (1) is standardized using the following equation:

$$g_i' = \frac{g_i}{\sum_1^n g_i} \quad (2)$$

where g_i' is the standardized weight of the criterion i.

Exhibit 5 provides a flowchart for this phase of the DPMA process incorporating the AHP and the GDM method. The combination of the AHP and GDM method allows final weights to be

assigned to the different criteria of the model. Finally, the criteria can be ranked according to their priorities

Exhibit 5. Prioritizing the criteria and GDM flowchart

Measurement of the criteria: the "M" step

This section presents the GO or NO GO decision procedure. First, a score for each decision relative to each criterion is calculated. Then, an overall score is determined in order to make the final decision with the SAW method.

First, each criterion is assessed separately, and then the decision rules based on a set of indicators are defined. One or many indicators represent each criterion and all the indicators, relative to one criterion, have the same weight because they have the same objective and nearly the same contribution. Some indicators are easy to measure on a numerical scale while others are hard to assess numerically and are therefore evaluated on a three-dimensional qualitative scale (high: H, medium: M, low: L). A numerical assessment of these latter indicators would require a detailed study and would be dependent on the product already being designed.

Once the indicators have been evaluated, an overall score for each decision criterion can be calculated. Then, we can move on to the aggregation phase below and make the final decision using the SAW method.

Aggregation to decide (GO or NO GO): the "A" step

The SAW method is the most commonly used technique for decision making, especially in single dimensional problems based on several criteria with the same unit of measurement (Triantaphyllou & Mann, 1989). This technique allows the aggregation of mono-criterion values into a global multi-criteria value (Kunsch & Brans, 2019). As we require an overall index, this method is the most appropriate for our case.

The scores of both decisions, GO or NO GO, are calculated using the following equations:

$$D_{GO} = \sum_{i=1}^{n} g_i' * S_{GO}^i \quad (3)$$

and

$$D_{NO\ GO} = \sum_{i=1}^{n} g_i' * S_{NO\ GO}^i \quad (4)$$

where

- S_{GO}^i is the score of the GO decision regarding criterion i;
- $S_{NO\ GO}^i$ is the score of the NO GO decision regarding criterion i;
- g_i' is the standardised weight of the i^{th} criterion;
- D_{GO} is the score of the overall GO decision;
- $D_{NO\ GO}$ is the score of the overall NO GO decision.

Note that both scores are complementary, which means

$$S^{i}_{GO} + S^{i}_{NO\ GO} = 1 \quad (5)$$

and therefore

$$D_{NO\ GO} + D_{GO} = 1 \quad (6)$$

The decision is based on the highest score.

IMPLEMENTATION AND TEST OF THE DPMA PROCESS FOR THE DEVELOPMENT OF A FEMORAL IMPLANT

This section describes the implementation steps of the DPMA process through a case study for the development of a femoral implant.

General overview of the implant design

The DPMA approach was tested with a real case study of a medical device in order to determine if it is simple and possible to gather all the information required by the criteria and therefore create a score for the GO and NO GO decisions. In collaboration with a French university, a femoral implant was chosen as the medical device in this case study that required a decision of whether to proceed from design to development or not. The new implant is an osteosynthetic device designed to fix proximal femoral fractures, especially for the elderly. Osteosynthesis is a medical technique that has been widely used since the beginning of the twentieth century. This technique can be used to repair simple or complex fractures of the proximal femur, which is the upper part of the femur including the femoral neck and the femoral head (Wadstein, 1943). Various tools such as plates, nails, screws, pins, wires, staples, or external fixations are used. Osteosynthesis devices are usually developed with close collaboration between orthopaedic surgeons and mechanical engineers. Various models exist, and each is adapted to one or more types of fracture. These devices require specific tooling, which allows the positioning of the implant during the surgical operation. To deal with the different physical characteristics of the patients, hospitals must have a wide range of implants, both intra-medullary (inside the bone) and extra-medullary (outside the bone). This implies the existence of a large stock of implants and therefore extra costs for the hospital. The originality of the new implant in our case is that it is adaptable to most patient morphologies. For surgeons, this implant will lead to greater flexibility during the operations, and will reduce the inventory of surgical implants at health institutions. It was designed in a partnership involving two laboratories and two companies from France and Switzerland working within the framework of a regional cooperation program. The new implant had to meet the following set of objectives (Billard, 2014):

- The implant must compress the two parts of the fractured bone, which results in a faster consolidation;

- The implant should not prevent the bone from being reconstructed;
- The implant should be made of biocompatible material such as stainless steel or titanium;
- The implant must be suitable for fractured bones;
- The operation on the proximal femur must not last more than 57 minutes (Forthomme, Costenoble, Soete, & Docquier, 1993);
- The implantation technique should be minimally invasive, and incisions should be limited in size and number.

Before achieving the optimized implant geometry, several prototypes were made. The inner and outer parts of the implant were manufactured using various methods including rapid prototyping, metal prototyping, machining, and lost-wax casting. The geometry of the implant was treated to remove sharp edges that could pose a risk to the patient and the surgeon. The designed implant is both intra- and extra-medullary; it has an intra-medullary section which can be stretched and adapted for insertion into the medullary canal of the proximal femur. In addition, it has an extra-medullary section substantially parallel to the intra-medullary section. An external fixation tool, which comes with the implant, is an essential surgical instrument used to help the surgeon to position the implant accurately. This tool can be used to retrieve the implant screws and to measure the lengths required for different screws. A prototype of the implant was made in two stages by machining and 3D printing.

The DPMA method was useful for the stakeholders who were involved in making the decision whether to develop the implant and launch it onto the market. The following section presents the implementation of the DMPA method and how it helped shape the final decision to move from the prototype phase to development.

Definition of the criteria for implementation: “D” step

Based on a literature review, nine criteria were selected for Level 3 of the AHP hierarchy tree (Exhibit 4). Five criteria were related to enterprise satisfaction and four for customer satisfaction. The criteria related to enterprise satisfaction in terms of product development are related to financial profits and to the strategic view of the company. These criteria used to evaluate new products were summarized by Seamon (2004) and are strategic alignment, market attractiveness, synergies, technical feasibility, and financial value. The criteria for customer satisfaction consider the peculiarities of the medical device sector and were selected from a specific list presented for medical devices (Santos, 2013). These customer criteria are differentiation, effectiveness, price, and reliability.

In addition to these nine criteria, five more criteria that are essential in the decision making process and strongly related to the nature of medical devices as they have a significant impact on human health were included. Among these criteria, which were validated by experts on

medical devices, two are related to the company (compliance with legislation, environmental impacts and clinical need) and three to the customer (ease of use and maintenance and use expenditure). In total, fourteen criteria were selected: seven criteria related to the company and seven to the customer. These criteria are defined below starting from the seven company criteria, then the seven customer criteria.

Strategic alignment (SA)

This criterion is related to the long term view of the company and indicates the extent to which the new project (new-product development) fits into the strategic objectives of the organization in terms of marketing, targeting, and research and development. One particular factor that is widely acknowledged as being responsible for the majority of project failures is the lack of project alignment with corporate strategy (Cooper et al., 2002; Griffin & Page, 1996; Tidd & Bessant, 2013).

Market attractiveness (MA)

This criterion is an appraisal of the market in which the new device will be launched. It assesses the market opportunities and the nature of competition that the product will face. This assessment must be taken into account when making the decision to develop the product. The more attractive a market is, the greater the potential profits will be (Pauwels, Huys, Casteels, & Simoens, 2014).

Synergy (S)

There has always been a debate between synergy and trade-off perspectives. There is a positive relationship between synergistic interactions among new product development capabilities and the innovation successes of a company (Jayaram & Narasimhan, 2007). The synergy effect describes how the development of the new product leverages the core competency of the organization. Thus, the synergy effect is achieved according to Persaud (2005, p. 413) when "the company is able to accumulate and deploy new knowledge or recombine existing knowledge in order to create new products, processes and technologies, more effectively or efficiently through collaboration among its global R&D units."

Technical Feasibility (TF)

This dimension provides an idea about the level of technological barriers and impediments that may occur in developing such products, especially in the proof-of-concept phase. Companies should seriously take into consideration the technical feasibility in a way that can fulfil all the intended purposes for which the product has been designed (Markham, 2002). This dimension is particularly important during the transformation of a medical device concept to a final design, a task that is often referred to as "crossing the technological valley of death" (Harris, 2013; Park, Lee, Doo, & Yoon, 2016; Wessner, 2005).

Financial value (FV)

This criterion refers to the magnitude of the financial benefits that the enterprise will receive by developing a product. It is crucial for an organization to consider the notion of risk vs return on investment when making the decision of whether to invest. Financial value is critical in making forecasts on the profitability of the project as turning an idea or a new technology into a successful product requires investment over a long period (Kang & Montoya, 2014; Park et al., 2016).

Environmental impact (EI)

The awareness of the environmental impact of the production and the use of medical devices is becoming a major concern for many stakeholders (Hede, Nunes, Ferreira, & Rocha, 2013). Many policies and pieces of legislation are making the sector more stringent, such as the Waste Electrical and Electronic Equipment Directive and the Producer Responsibility Obligations (Packaging Waste) Regulations (Cahill, Grimes, & Wilson, 2011; Rotter, Chancerel, & Schill, 2011). In such competitive environments, cost, quality, and delivery have become criteria that manufacturers can no longer rely on to improve their competitive advantage. Environmentally sensitive products allow producers to achieve a significant competitive advantage on the market (Brook & Pagnanelli, 2014; Mayers, Lifset, Bodenhoefer, & Van Wassenhove, 2013). As a result, more and more companies have adopted environmental management systems to organize and evaluate the effects of their activities on the environment and meet the growing demand of customers and legislation for sustainable products (Marshall, Hinton, Wrobel, & Troisi, 2009).

Compliance with legislation (CL)

One of the most significant barriers that medical device manufacturers face is compliance with legislation. No medical device is allowed to be introduced into the market unless it receives clearance for commercialization. In the United States, the Center for Devices and Radiological Health, which is a department of the Food and Drug Administration (FDA), is responsible for medical device regulations (Maisel, 2004; Zuckerman, Brown, & Nissen, 2011). Each type of device is assigned by the FDA to one of three regulatory classes on the basis of its risk, safety, and effectiveness (Kramer, Xu, & Kesselheim, 2012). In Europe, the first European regulatory system was launched in 1993. Before 1993, legislation varied from one EU country member to another, and each member had its own registration (Fleur, 1997; Niederländer, Wahlster, Kriza, & Kolominsky-Rabas, 2013). In addition to the regional regulations, there are also other consensus statements, interpretative documents, and standards, which are created by organizations like the International Organization for Standardization and which manufacturers, suppliers and users must comply with.

Differentiation (D)

This criterion describes the advantages that a product has over the state of the art and if it will more effectively meet customer needs than existing similar products (Farhana & Bimenyimana, 2015; Thrane, Blaabjerg, & Møller, 2010).

Clinical Need (CN)

This criterion ensures that a medical device addresses a particular clinical need required by customers. In some cases, medical devices are designed according to clinical needs in a particular environment; therefore, when transferred to another health care ecosystem, they may not match the set of clinical needs in this new environment. This is especially true when medical devices are imported (Chaturvedi, Logan, Narayan, & Kuttappa, 2015).

Effectiveness (E)

Effectiveness is a qualitative parameter that measures the degree of success of a product concept in achieving the goals set by the designers and determines whether it is able to provide the medical effect for which it was designed and to respond to clinical needs (Santos, 2013).

Price (P)

This criterion simply describes the price that the buyer will pay in order to acquire the medical device. Setting the price is one of the most difficult steps in a new-product development process. The price of a technology carries a strong message about the value the product provides in terms of health outcomes (Markiewicz, van Til, Steuten, & IJzerman, 2016). Price is one of the determining factors of the commercial viability of new medical devices; its valuation is usually subject to uncertainty during the design phases, which leads to price reconsideration just before placing the device onto the market (Girling, Young, Brown, & Lilford, 2010).

Ease of Use (EoU)

This criterion reflects the level of complexity faced by the user of a device. In many cases, users point out many problems despite manufacturers' claims concerning the ease of use (Rogers, Mykityshyn, Campbell, & Fisk, 2001). A high level of complexity may represent a barrier for the user and may require special training to manipulate the product. Therefore, it is a major challenge for designers and engineers to develop effective and innovative medical devices that are also easy to use for both patients and health professionals. This objective cannot be achieved without taking into consideration human factors during medical device design, such as psychology and ergonomics (Nemeth, Nunnally, Bitan, Nunnally, & Cook, 2009).

Reliability (R)

The increasing complexity of medical devices brings two specific advantages, which primarily benefit the patient: improved survival rates in the case of illness or injury and considerable improvement in quality of life. However, for economic reasons, these advantages must be

highly reliable in order for the devices to be accepted by patients (Gerrish, Herrmann, Tyler, & Walsh, 2005; NIST, 2017). “It is a characteristic that must be planned for, designed, and manufactured into a device” (Fries, 2013, p. 33). A reliable product does what users want when they want to use it. Therefore, reliability refers to availability and non-failure (Burleson, Clark, Ransford, & Fu, 2012).

Cost of Use and Maintenance (CU&M)

Cost of use and maintenance refer to the value spent to use the device, namely medication, energy, and maintenance (Santos, 2013).

Prioritizing the criteria and application of GDM: “P” step

After defining the criteria for the assessment of a medical device, these criteria were analyzed according to the AHP to determine their relative weights, which is the objective of this prioritisation phase. During this phase, the AHP was applied following the hierarchy tree presented in Exhibit 4. In order to apply the AHP, a free tool called the BPMSG AHP Priority Calculator (available on the web) was used (Goepel, 2013). This tool uses pairwise comparisons in order to calculate the different weights based on experts scores according to Saaty’s scale (Saaty, 1980), which ranges from 1 to 9. The panel of four international experts, which was selected, included:

- a medical device designer from Switzerland
- an R&D expert in the field of medical devices from Portugal
- two professors, one from Tunisia and one from France, both of whom are engineering experts in medical device development

The number of experts involved in this study could be considered as too small to yield significant results. However, several similar studies or decision aid methods have yielded successful results based on a comparable number of experts, such as the works of Dong et al. (2010) and Wu and Xu (2012). In addition, Boje and Murnighan (1982) compared the effectiveness of using groups of three, seven, or 11 experts and found no significant differences among them, especially when the experts involved are well chosen and are confident in their estimates. These two observations are true in our study case. Besides, the AHP pairwise comparisons are structured and iterative and have a consistency procedure.

In addition to the pairwise comparisons, the BPMSG tool was also used to carry out the consistency test within AHP and to identify the causes of consistency errors if they occurred. The GDM method was then applied using the results of the criteria prioritization based on the answers of the experts in order to have a unique set of weights.

Prioritisation of the criteria categories

The results of the questionnaire regarding Level 1 of the hierarchy (the weights of the criteria categories) are given in Exhibit 6.

Exhibit 6. Prioritizing the criteria categories

The consensus indicator was calculated as 97.4%, indicating there was significant agreement among the four experts concerning the relative importance of the enterprise and customer satisfaction criteria. Then, the GDM method with geometric average was applied as described previously in order to combine the scores of the four experts into one unique score. Exhibit 7 describes the new weights assigned to the two categories of criteria after GDM.

Exhibit 7. Prioritizing the criteria categories after GDM

According to the four experts, enterprise satisfaction remains the main goal of decision makers (72.5%), although the contribution of customer satisfaction remains significant (27.5%). These weights assigned to each criterion will be crucial in any decision making since they directly determine the composite weight of each criterion.

As for the second level of prioritization, which is the level that concerns criteria within the same category, the AHP is applied as in the first level.

Prioritising enterprise satisfaction criteria

The pairwise comparisons among the seven criteria that make up the enterprise satisfaction category are given in Exhibit 8.

Exhibit 8. Prioritizing enterprise satisfaction criteria

The results of some experts had inconsistent weights because of some contradictory pairwise comparisons. To remediate these inconsistencies, an algorithm for consistency improvement was applied using the AHP Priority Calculator (Goepel, 2013). The numbers in Exhibit 8 are given after the correction of all inconsistency issues.

Although the weights assigned to the criteria differ from one expert to another, all the experts divided the set of enterprise satisfaction criteria into two subsets that can be classified by order of importance:

- The main group is composed of three criteria: compliance with legislation, financial value, and technical feasibility. They represent the main goals of a company regardless of the type of product to be commercialized. We can say that a company seeks to maximize its profits by commercializing a product that is technically feasible and cleared to be launched on the market.
- The secondary group is composed of the remaining four criteria: Strategic alignment, Market attractiveness, Synergy, and Environmental impact. They can be considered as managerial and organizational criteria. They also represent the criteria that make the

difference between one company and another, since they are overlooked by some companies and highlighted by others.

The GDM method was applied in order to yield one set of criteria weights using the geometric mean. Exhibit 9 presents the GDM method relative to the enterprise satisfaction criteria.

Exhibit 9. Group decision making relative to the enterprise satisfaction criteria

Prioritising customer satisfaction criteria

The second set of criteria was treated similarly to the first one passing through primary prioritisation via the AHP. Exhibit 10 presents the primary prioritization for the customer satisfaction criteria after correcting all inconsistency issues.

Exhibit 10. Prioritizing customer satisfaction criteria

According to the experts, customers are more worried about the effective reasons that push them to buy medical devices. Indeed, if there is no clinical need, there will be no reason to buy the medical device. Once there is a need, effectiveness and reliability are required. After these three main criteria, the four other criteria are secondary; they can be classified as innovative (differentiation and ease of use) and economic (price, cost of use, and maintenance).

It is interesting to question why customers are only mildly concerned about the economic criteria, especially the price. This lack of concern may be justified by the fact that the medical device sector involves human health; therefore, customers worry more about health than the amount of money that they will spend to benefit from the device. Another reason the economic criterion is considered secondary is that costs incurred by patients are usually reimbursed by national social security and health insurance organizations.

Similar to the first set of criteria, the consensus indicator revealed a strong consensus (94.1%) among the four experts. The results of the customer satisfaction criteria analysis were treated by GDM and are presented in Exhibit 11.

Exhibit 11. Group decision making relative to customer satisfaction criteria

According to the GDM results, clinical need is a key criterion. It has the greatest weight (0.3512) and describes the actual reason for the product. There is a gap between this weight and those of the next two most important criteria, which are reliability (0.1977) and effectiveness (0.1938). The remaining criteria are close to each other in terms of importance but of a lesser importance for the customer.

Combination of criteria (final prioritization)

In this section, the two sets of criteria (enterprise satisfaction and customer satisfaction) are combined into one vector taking into account the relative weight of each criterion from its group and the weight of each single set. Therefore, we obtain

$$g'_i = g'_m \cdot g'_{mn}; \qquad \mathrm{m} = 1..2;\ \ \mathrm{n} = 1..7;\ \ \mathrm{i} = 1..14 \tag{7}$$

where

- i is the index of the total number of considered criteria. In this case, 14 criteria as considered (seven criteria for enterprise satisfaction and seven for customer satisfaction);
- g'_i is the standardized weight of the criterion i in the decision-making process.
- g'_m is the standardized weight of the set of criteria; they are given in Exhibit 7 and are 0.725 for the enterprise satisfaction set of criteria and 0.275 for the customer satisfaction set of criteria.
- g'_{nm} is the standardized weight of the criterion n in its corresponding set of criteria m, according to Exhibit 9 and Exhibit 11.

Exhibit 12 provides the results of the calculations.

Exhibit 12. Combination of the criteria

After combining all criteria into one vector, despite the significant gap in terms of importance between the two sets of criteria (weights of 0.725 for the enterprise set and 0.275 for the customer set), some of the criteria in the enterprise category were ranked lower than some criteria in the customer category. Although most of the enterprise criteria were ranked highest, clinical need and reliability were ranked 4th and 7th, respectively, before market attractiveness and strategic alignment.

After ranking and combining all criteria into one vector, we moved to the next step, criteria measurement.

Measurement of the criteria for the new implant: the "M" step

This step consists of measuring and assessing the value of each criterion. Several meetings were arranged with the same four experts. They were also involved in the design of the implant in order to decide on the criteria assessment. For each criterion, one or more measurement indicators were identified and had to be measured according to a specific grid. The measurements were then used to determine a score according to the GO and NO GO decisions. When the criterion needed to be evaluated on the basis of several indicators, the relative weights of the indicators were specified to be able to calculate the decision score based on the weighted sum. Exhibit 13 provides a summary of the different criteria and the means to evaluate them.

Exhibit 13. Summary of the criteria measurements

Strategic alignment (SA)

According to the experts, the development of the new implant would fit in entirely or in part with the central goal of the strategy deployed by such companies operating in the field of surgical equipment. They considered it as a promising device in terms of market share and profits. It will target the same customers as other implant users as it addresses the same needs.

Therefore, the degree of alignment of the implant is high. The GO decision will have a score of 1 and NO GO decision will have a score of 0.

Market attractiveness (MA)

The three different indicators for this criterion, market size, market growth, and market competition, have to be evaluated. In their study of the long-term market trends for orthopaedic medical device based on worldwide sales from 1999 to 2015, Piuzzi et al. (2019) estimated the total orthopaedic device worldwide market to be $45 billion in 2015. The experts considered this as a medium-sized market with a moderately competitive environment. According to the same study, the market has grown over the entire period between 1999 and 2015 but has experienced a decreasing rate since 2008, which is a sign of a mature industry (Piuzzi et al., 2019). Therefore, the market is considered to have a moderate growth rate. Based on these evaluations, the market attractiveness is considered as medium, which yields a score of 0.5 for the GO and NO GO decisions.

Synergy (S)

Two indicators were defined to measure this criterion: marketing synergy and technological synergy. The marketing synergy indicator refers to companies that develop the implant, or any other medical device, and who may well keep the same level of synergy for their marketing policy since they will still be able to deal with the same providers and promote this and other new products. According to the experts, the technological synergy indicator highlights companies operating in the surgical tools sector that are able to develop the new implant with the existing machines and workforce, although they may require some new equipment, especially for the external fixation tool that must be provided with the implant in this case. Based on these factors and according to the rules of assessment, the evaluation will be high for the marketing synergy score and low for the technological synergy score. Therefore, the scores for the synergy criterion will be 0.75 for GO decision and 0.25 for NO GO.

Technical feasibility (TF)

This criterion describes the level of technological complexity that an enterprise has to overcome in terms of technological gap and technical uncertainty. According to the team that developed the implant prototype, most components could be manufactured with the usual production machines and techniques (milling, moulding, casting, polishing, and surface treatment), even though the cephalic screw (whose length can be adjusted to make the implant more adaptable) requires a high precision internal thread. This barrier can be overcome by advanced micro milling techniques. Because of these factors, the technical complexity was assessed as low and the score of the technical feasibility criterion is 1 for the GO decision.

Financial value (FV)

To measure the financial returns from developing a new product, the net present value (NPV) has to be calculated. It is a discounted cash flow technique, and it can be used as a capital expenditure appraisal method. The NPV can be calculated using the following formula:

$$\mathrm{NPV} = \sum_{t=o}^{n} \frac{(\mathrm{Benefits_t} - \mathrm{costs_t})}{(1+r)^t} \quad (8)$$

where

- $\mathrm{Benefits_t}$ refers to the sales at time period t;
- $\mathrm{Cost_t}$ refers to the sales and marketing costs at time period t;
- r is the discount rate;
- t is the year;
- n is the analytic horizon (in terms of years).

Based on the comparison with a similar competing implant and following the evaluation from the experts, the NPV was estimated to be €1,385.58; therefore, the score assigned to the GO decision relative to the financial value criterion is 1.

Environmental impact (EI)

SimaPro software was used to calculate the eco-score that summarizes the effect on ecosystem quality, radiation, toxicity, and human health. The eco-score ranges from 0 to 50. The higher the score, the lower is the environmental impact of the product. The software requires information regarding the composition of the product (low alloyed stainless steel with titanium, chrome, and some traces of aluminium) and other data on its lifecycle (estimated use to be 20 years). The eco-score given by SimaPro is 17.8. Therefore, the score of the GO decision regarding the environmental impact factor is 0.5.

Compliance with legislation (CL)

Devices must comply with all legislation related to the surgical sector. The new implant was designed in compliance with the "Standard Specification for Femoral Prostheses-Metallic Implants, ASTM F2068-09". While waiting for the premarket tests and final clearance, devices undergo compliance with the regulations (CL=1). Therefore, the score of GO decision regarding the compliance with legislation criterion is 1.

Differentiation

The new implant is considered by the experts as highly differentiated compared to the competition. It presents some unique features including an adjustable cephalic screw that makes it adaptable and multi-purpose, intra- and extra-medullary applicability, and minimal invasiveness. Due to these factors, the score for the GO decision based on differentiation is 1.

Clinical need (CN)

The experts estimated that there is a need for a multipurpose implant for proximal femoral fractures; therefore, there is a definite need by health care providers. They expressed this need very clearly at the beginning of the project. Therefore, the assessment of the GO decision for this criterion is 1.

Effectiveness (E)

According to the experts, the primary tests have indicated that the implant responds to the clinical needs and all intended purposes such as adaptability and operation times (under 57 minutes). Therefore, the degree of assessment is considered to be high, leading to a score of 1 for the GO decision.

Price (P)

The willingness to pay (WTP) of a customer is a relevant indicator that was used to evaluate the price. At this stage, it was difficult to estimate the real price of the device. Nevertheless, the experts were able to estimate a price. Concerning the WTP, the evaluation was based on a comparison with a competing product with similar functions and close sales volumes. The price turned out to be greater than the WTP. Therefore, the assessment for this criterion is 0 for the GO decision.

Ease of use (EoU)

This criterion was assessed with the complexity variable. An external fixation tool makes the use of the implant simple. In addition, there are no significant differences between this implant and others in terms of use and handling. Therefore, the complexity criterion was considered as medium, which yields a score of 0.5 for the GO decision.

Reliability (R)

The reliability limit set by the engineers in compliance with regulations in the surgical tools sector is 99.5% (Billard, 2014). After numerical simulations and mechanical tests on femoral bones, the implant and especially its materials were considered very reliable in terms of the regulations, and hence its reliability exceeds the threshold. Therefore, the evaluation of this criterion received a score of 1 for the GO decision.

Cost of Use & Maintenance (CU&M)

In order to assess this criterion, the cost of annual maintenance and use (CAMU) estimated by engineering managers and the maintenance and use expenditure limit (MUEL) are used, which refers to the value of expenditure that can be accepted by a customer. The indicator used to assess the cost of use and maintenance is the ratio MUEL/CAMU ratio. According to the experts, health care providers can accept, at most, a MUEL equal to 35% of the purchase price. It is possible to calculate MUEL value by considering the price that was previously determined.

Furthermore, given implant was designed to have a high reliability ratio, the risk of failure is small. Concerning the cost of use, like most implants, it is autonomous once implanted, so it does not require any further intervention after the initial surgery. Subsequently, the experts indicated that the CAMU is small compared to the MUEL. Hence, the ratio MUEL/CAMU is expected to be greater than 1. The assessment for the cost of use and maintenance will be at least at the medium level, and the score for the GO decision will be equal to 0.5.

Aggregation to decide: "A" step

Once all the scores of both the GO and NO GO decisions for each criterion were decided upon, the last step of the DPMA method was carried out. Each score was aggregated into one score, which led to a GO or NO GO decision. As described in the methodology section, the SAW method was used to aggregate all the criteria into one score for each decision (GO and NO GO). Exhibit 14 provides the weights for each criterion and their corresponding scores regarding the new implant evaluation. This information was then used to calculate the final scores of the GO and NO GO decisions, D_{GO} and D_{GO}, by using the SAW method.

Exhibit 14. Table of aggregation and final decision

According to this result, the GO decision score is significantly higher than the NO GO decision score. Product development managers have a clear idea about the chances of success of the new femoral implant; they can choose to move forward to the development phases. Their decision is based on the relative weights of the decision criteria (both according to the company and customer perspectives) and the evaluation of the performance of the new implant according to these criteria.

Using Equation 3, the GO score was calculated using the simple additive weighting. What could be the impact of the variation of the parameters of the model on the final GO score? A sensitivity analysis measures the impact of input uncertainty on the decision model output (Wu, Wang, Wang, Zhao, & Zhang, 2019). The score of the decision depends on the evaluations of the performance of the implant and the weights of the criteria. These weights are themselves a combination of the relative weight of each criterion among the enterprise and customer sets and the weight of each single set. Exhibit 15 analyzes the sensitivity regarding to the weights of the set of criteria.

Exhibit 15. Sensitivity to the variation of weights of the enterprise and customer sets

Several scenarios with different weights were tested which indicates that these variations have little impact on the final result. Therefore, the uncertainty on the final decision comes from the uncertainty of the weights of the criteria or the evaluation of the product performance on the criteria.

IMPLICATIONS FOR ENGINEERING MANAGERS

The DPMA process can be used in the context of decision making for medical device development since the first step has defined the evaluation criteria specifically for this kind of product. The second stage of prioritization and weighting of the criteria is also valid for this context. However, the last two steps of measurement and aggregation strongly depend on the type of medical device concept being tested. Testing the DPMA process on a real case study is important because it provides more robustness, presents the difficulties that may occur while carrying out the method, and opens opportunities for improvements. Nevertheless, this method can be criticized particularly when dealing with the "threshold effect," which occurs when the scores of the GO and NO GO decisions are close (for example, a GO score of 0.51 and a NO GO score of 0.49). In this case, decision-makers should not rely on the DPMA process alone; nevertheless, they would probably have a clear view of the reasons behind these close scores.

The DPMA method, which is a multi-criteria decision aid method for the design of a new medical device, highlights the difficulty for engineers and development managers in making a decision at a critical moment during the design process. In this study, many stakeholders from multiple countries and from various backgrounds (researchers, consultants, and engineers) were involved and underscores the importance of involving experts and practitioners. The DPMA approach is able to offer them a convenient tool, which directs engineering managers and product designers to the key factors that affect GO and NO GO decisions and highlight trade-offs, risks, and uncertainties. It can provide engineering managers with the information they need to map a technological strategy by proposing a holistic approach of product development and taking into consideration technological, business, financial, and marketing criteria. This research provides practical knowledge to the management of designs applied in the medical device sector. In this article, we highlight the fact that the literature dealing with the development of new medical devices is scarce, especially when it involves decision making in the upstream phase of NPD. Our work proposes a process that can support both practitioners and decision makers in delivering successful products and services. The method can also be used by engineering managers for decision making in the context of other products. However, it would be necessary to review not only the number and the definitions of the criteria defined in the first steps of the method but also the means to evaluate the product concept performance based on these criteria.

CONCLUSION

This article provides engineering and product development managers as well as other decision makers with a method to help in the process of selection and assessment of new product concepts and prototypes. This quantitative method supports the decision making process in the upstream phase of new product development processes specifically for the medical device

industry. This study tackles important issues facing every designer and engineering manager during the new product development processes, particularly the question of when and on what basis the "GO or NO GO to development" decision should be taken. The method, called the DPMA approach, was based on several multi-criteria techniques, namely the AHP, GDM, and SAW approach, and subject matter experts from the medical device sector were involved in this research. The DPMA approach was designed to be versatile and applicable to all medical devices because of the set of criteria selected at the beginning of this research; these criteria incorporate different aspects of the sector (economy, regulatory framework, innovation, and ergonomics). A set of performance criteria was defined and validated by experts and take into consideration the definition of success according to medical device manufacturers and customers. The AHP method was applied to obtain relative weights of the criteria and the SAW to obtain an overall score for the GO and NO GO decision. The approach was then used and tested on the development of a femoral implant with the collaboration of international partners from academic and industry backgrounds.

The case study for the development of the femoral implant revealed that DPMA was useful because it provided designers and product development managers with key elements needed to make decisions. It also demonstrated that further improvements could be made. In future research, we will explore the idea of developing a fuzzy DPMA approach that will be based on fuzzy multi-criteria decision-making methods, especially in the prioritization phase. Unlike Boolean logic (1 or 0), fuzzy logic can be used to give measures ranging between completely true and completely false. Instead of measuring each performance criterion on a three-level grid (low, medium, and high), a fuzzy measure could be made based on the probability of achievement. This fuzzy modelling will take into account the uncertainty of the situation and may mitigate the subjectivity of the opinions of the experts. Moreover, the decision was easy to make during the case study example because of the noticeable difference in GO and NO GO scores. However, what if there were very close scores between the two decision points? Our method is a decision aid tool and can never replace decision makers. Decision makers may have information, a vision, or simply intuition to decide upon a decision when the tool does not guide them to a clear choice. Finally, it would be interesting to test the limits and strengths of the DMPA process and evaluate its degree of robustness when it is applied to another medical device or any other product from another industry.

REFERENCES

Ahrens, M., & Hehenberger, P. (2015). Empathic-design assisted by the Kano method - A human-centered design method for medical devices considering patients. In *Proceedings of the International Conference on Engineering Design, ICED* (Vol. 9, pp. 1–10). Bovisa Campus of Politecnico di Milano, Milan, Italy, 27-30 July 2015.

Aull-Hyde, R., Erdogan, S., & Duke, J. M. (2006). An experiment on the consistency of aggregated comparison matrices in AHP. *European Journal of Operational Research*, *171*(1), 290–295. https://doi.org/10.1016/j.ejor.2004.06.037

Ben Rejeb, H., & Ben Younes, M. A. (2018). Proposition of a methodological framework for measuring innovation capacity of Tunisian companies. *International Journal of Technology, Policy and Management*, *18*(2), 89–124.

Billard, R. (2014). *Développement d'un implant à géométrie variable pour le traitement des fractures du fémur proximal chez les personnes âgées* (PhD Thesis). University of Grenoble, France.

Boje, D. M., & Murnighan, J. K. (1982). Group Confidence Pressures in Iterative Decisions. *Management Science*, *28*(10), 1187–1196. https://doi.org/10.1287/mnsc.28.10.1187

Brook, J. W., & Pagnanelli, F. (2014). Integrating sustainability into innovation project portfolio management - A strategic perspective. *Journal of Engineering and Technology Management - JET-M*, *34*(October 2014), 46–62. https://doi.org/10.1016/j.jengtecman.2013.11.004

Brunelli, M. (2018). A survey of inconsistency indices for pairwise comparisons. *International Journal of General Systems*, *47*(8), 751–771. https://doi.org/10.1080/03081079.2018.1523156

Burleson, W., Clark, S. S., Ransford, B., & Fu, K. (2012). Design challenges for secure implantable medical devices. In *Proceedings - 49th Annual Design Automation Conference, DAC '12* (pp. 12–17). San Francisco, CA; United States, 3-7 June 2012. https://doi.org/10.1145/2228360.2228364

Cahill, R., Grimes, S. M., & Wilson, D. C. (2011). Review Article: Extended producer responsibility for packaging wastes and WEEE - a comparison of implementation and the role of local authorities across Europe. *Waste Management & Research*, *29*(5), 455–479. https://doi.org/10.1177/0734242X10379455

Carter, S.-S. D., Costa, P. F., Vaquette, C., Ivanovski, S., Hutmacher, D. W., & Malda, J. (2017). Additive Biomanufacturing: An Advanced Approach for Periodontal Tissue Regeneration. *Annals of Biomedical Engineering*, *45*(1), 12–22. https://doi.org/10.1007/s10439-016-1687-2

Chaturvedi, J., Logan, A., Narayan, G., & Kuttappa, S. (2015). A structured process for

unmet clinical need analysis for medical device innovation in India: Early experiences. *BMJ Innovations*, *1*(3), 81–87. https://doi.org/10.1136/bmjinnov-2014-000010

Cho, K.-T., & Kim, S.-M. (2003). Selecting medical devices and materials for development in Korea: The analytic hierarchy process approach. *International Journal of Health Planning and Management*, *18*(2), 161–174. https://doi.org/10.1002/hpm.703

Cooper, R. G. (2001). *Winning at new products : accelerating the process from idea to launch* (3rd ed.). Cambridge, Massachusetts: Perseus Pub.

Cooper, R. G. (2008). Perspective: The Stage-Gate ® Idea-to-Launch Process—Update, What's New, and NexGen Systems. *Journal of Product Innovation Management*, *25*(3), 213–232. https://doi.org/10.1111/j.1540-5885.2008.00296.x

Cooper, R. G., Edgett, S. J., & Kleinschmidt, E. J. (2002). Optimizing the stage-gate process: What best-practice companies Do-I. *Research Technology Management*, *45*(5), 21–27.

Correia, T., Carapinheiro, G., Carvalho, H., Silva, J. M., & Dussault, G. (2017). The effects of austerity measures on quality of healthcare services: a national survey of physicians in the public and private sectors in Portugal. *Human Resources for Health*, *15*(1), 82. https://doi.org/10.1186/s12960-017-0256-6

del Moral, M. J., Chiclana, F., Tapia, J. M., & Herrera-Viedma, E. (2018). A comparative study on consensus measures in group decision making. *International Journal of Intelligent Systems*, *33*(8), 1624–1638. https://doi.org/10.1002/int.21954

Dong, Y., Zhang, G., Hong, W.-C., & Xu, Y. (2010). Consensus models for AHP group decision making under row geometric mean prioritization method. *Decision Support Systems*, *49*(3), 281–289. https://doi.org/10.1016/j.dss.2010.03.003

Eberhardt, A. W., Johnson, O. L., Kirkland, W. B., Dobbs, J. H., & Moradi, L. G. (2016). Team-based development of medical devices: An engineering-business collaborative. *Journal of Biomechanical Engineering*, *138*(7). https://doi.org/10.1115/1.4032805

Farhana, M., & Bimenyimana, E. (2015). Design driven innovation as a differentiation strategy - In the context of automotive industry. *Journal of Technology Management and Innovation*, *10*(2), 24–38. https://doi.org/10.4067/S0718-27242015000200003

Fearis, P. J., & Craft, B. (2016). Sustaining the success of medical device innovation. *Surgery (United States)*, *160*(5), 1130–1134. https://doi.org/10.1016/j.surg.2016.06.053

Fleur, F. (1997). “Medical devices and european regulatory” | “Les dispositifs medicaux et la reglementation europeenne.” *Annales Pharmaceutiques Francaises*, *55*(2), 73–76.

Floyd, M. K., Barker, K., Rocco, C. M., & Whitman, M. G. (2017). A Multi-Criteria Decision Analysis Technique for Stochastic Task Criticality in Project Management. *Engineering Management Journal*, *29*(3), 165–178. https://doi.org/10.1080/10429247.2017.1340038

Forthomme, J. P., Costenoble, V., Soete, P., & Docquier, J. (1993). Treatment of trochanteric fractures of the femur using the gamma nail (apropos of a series of 92 cases) | Traitement des fractures trochantériennes du fémur par le clou gamma (à propos d’une série de 92 cas). *Acta Orthopaedica Belgica*, *59*(1), 22–29.

Fries, R. C. (2013). *Reliable Design of Medical Devices.* (3rd ed.). Boca Raton, Florida: CRC Pr I Llc.

Gerrish, P., Herrmann, E., Tyler, L., & Walsh, K. (2005). Challenges and constraints in designing implantable medical ICs. *IEEE Transactions on Device and Materials Reliability*, *5*(3), 435–444. https://doi.org/10.1109/TDMR.2005.858914

Girling, A., Young, T., Brown, C., & Lilford, R. (2010). Early-stage valuation of medical devices: the role of developmental uncertainty. *Value in Health*, *13*(5), 585–591. https://doi.org/10.1111/j.1524-4733.2010.00726.x

Goepel, K. D. K. (2013). Implementing the Analytic Hierarchy Process as a standard method for multi-criteria decision making in corporate enterprises-A new AHP Excel Template with multiple inputs. In *Proceedings of the International Symposium on the Analytic Hierarchy Process*. Kuala Lumpur, Malaysia, 23-26 June. Retrieved from https://bpmsg.com/isahp_2013-13-03-13-goepel/

Golden, B., Wasil, E., & Harker, P. (1989). *The Analytic Hierarchy Process: Applications and Studies*. New York: Springer-Verlag.

Gosavi, A., Cudney, E. A., Murray, S. L., & Masek, C. M. (2016). Analysis of Clinic Layouts and Patient-Centered Procedural Innovations Using Discrete-Event Simulation. *Engineering Management Journal*, *28*(3), 134–144. https://doi.org/10.1080/10429247.2016.1195664

Griffin, A., & Page, A. L. (1996). PDMA success measurement project: Recommended measures for product development success and failure. *Journal of Product Innovation Management*, *13*(6), 478–496. https://doi.org/10.1016/S0737-6782(96)00052-5

Harris, A. (2013). Bridging the valley of death. *Engineering and Technology*, *8*(9), 78–81. https://doi.org/10.1049/et.2013.0910

Hede, S., Nunes, M. J. L., Ferreira, P. F. V., & Rocha, L. A. (2013). Incorporating sustainability in decision-making for medical device development. *Technology in Society*, *35*(4), 276–293. https://doi.org/10.1016/j.techsoc.2013.09.003

Hisarciklilar, O., Rasoulifar, R., Boujut, J.-F., Thomann, G., & Villeneuve, F. (2009). User-Designer Collaboration in the Design Process of Surgical Instruments: New Aspects for Annotation as a Communication Tool. In M. Norell Bergendahl, M. Grimheden, L. Leifer, P. Skogstad, & U. Lindemann (Eds.), *Proceedings of ICED 09, the 17th International Conference on Engineering Design, Vol. 8, Design Information and Knowledge, Palo Alto, CA, USA, 24.-27.08.2009* (Vol. 8, pp. 171–182). Palo Alto, CA, USA.

Holland, W. W. (2017). Health Improvement in a Period of Austerity: a Public Health Perspective. *Global Policy*, *8*, 30–37. https://doi.org/10.1111/1758-5899.12216

Jayaram, J., & Narasimhan, R. (2007). The influence of new product development competitive capabilities on project performance. *IEEE Transactions on Engineering Management*, *54*(2), 241–256. https://doi.org/10.1109/TEM.2007.893992

Kang, W., & Montoya, M. (2014). The impact of product portfolio strategy on financial performance: The roles of product development and market entry decisions. *Journal of Product Innovation Management*, *31*(3), 516–534. https://doi.org/10.1111/jpim.12111

Karlsen, J. T. (2002). Project Stakeholder Management. *Engineering Management Journal*, *14*(4), 19–24. https://doi.org/10.1080/10429247.2002.11415180

Koen, P., Ajamian, G., Boyce, S., Clamen, A., Fischer, E., Fountoulakis, S., … Seibert, R. (2002). Fuzzy-Front End: Effective Methods, Tools and Techniques. In P. Belliveau, A. Griffin, & S. Soremrmeyer (Eds.), *PDMA Toolbook 1 for New Product Development* (pp. 2–35). New York: John Willey & Sons.

Kramer, D. B., Xu, S., & Kesselheim, A. S. (2012). Regulation of medical devices in the United States and European Union. *New England Journal of Medicine*, *366*(9), 848–855. https://doi.org/10.1056/NEJMhle1113918

Kumar, C. V. S., & Routroy, S. (2016). Case Application of a Methodology for Determining a Manufacturer's Preferred Customer Status with Suppliers. *Engineering Management*

Journal, *28*(1), 25–38. https://doi.org/10.1080/10429247.2016.1139911

Kunsch, P. L., & Brans, J.-P. (2019). Visualising multi-criteria weight elicitation by multiple stakeholders in complex decision systems. *Operational Research*, 1–17. https://doi.org/10.1007/s12351-018-00446-0

Maisel, W. H. (2004). Medical Device Regulation: An Introduction for the Practicing Physician. *Annals of Internal Medicine*, *140*(4), 296–302.

Markham, S. K. (2002). Moving technologies from lab to market. *Research Technology Management*, *45*(6), 31–42.

Markiewicz, K., van Til, J. A., Steuten, L. M. G., & IJzerman, M. J. (2016). Commercial viability of medical devices using Headroom and return on investment calculation. *Technological Forecasting and Social Change*, *112*, 338–346. https://doi.org/10.1016/j.techfore.2016.07.041

Marshall, J.-L., Hinton, M., Wrobel, L., & Troisi, G. (2009). Designing sustainable medical devices. *Medical Device and Diagnostic Industry*, *31*(7).

Mayers, K., Lifset, R., Bodenhoefer, K., & Van Wassenhove, L. N. (2013). Implementing Individual Producer Responsibility for Waste Electrical and Electronic Equipment through Improved Financing. *Journal of Industrial Ecology*, *17*(2), 186–198. https://doi.org/10.1111/j.1530-9290.2012.00528.x

Miller, G. A. (1956). The magical number seven, plus or minus two: some limits on our capacity for processing information. *Psychological Review*, *63*(2), 81–97. https://doi.org/10.1037/h0043158

Nemeth, C., Nunnally, M., Bitan, Y., Nunnally, S., & Cook, R. I. (2009). Between choice and chance: The role of human factors in acute care equipment decisions. *Journal of Patient Safety*, *5*(2), 114–121. https://doi.org/10.1097/PTS.0b013e3181a974d9

Niederländer, C., Wahlster, P., Kriza, C., & Kolominsky-Rabas, P. (2013). Registries of implantable medical devices in Europe. *Health Policy*, *113*(1–2), 20–37. https://doi.org/10.1016/j.healthpol.2013.08.008

NIST. (2017). Medical Device Reliability. National Institute of Standards and Technology. Retrieved July 4, 2017, from http://www.nist.gov/mml/acmd/biological_environments/medical-device-reliability2.cfm

Park, W., Lee, K., Doo, S., & Yoon, S.-S. (2016). Investments for New Product Development: A Break-Even Time Analysis. *Engineering Management Journal*, *28*(3), 158–167. https://doi.org/10.1080/10429247.2016.1199747

Parthasarthy, R., & Hammond, J. (2002). Product innovation input and outcome: Moderating effects of the innovation process. *Journal of Engineering and Technology Management - JET-M*, *19*(1), 75–91. https://doi.org/10.1016/S0923-4748(01)00047-9

Pauwels, K., Huys, I., Casteels, M., & Simoens, S. (2014). Drug shortages in European countries: A trade-off between market attractiveness and cost containment? *BMC Health Services Research*, *14*(1). https://doi.org/10.1186/1472-6963-14-438

Persaud, A. (2005). Enhancing synergistic innovative capability in multinational corporations: An empirical investigation. *Journal of Product Innovation Management*, *22*(5), 412–429. https://doi.org/10.1111/j.1540-5885.2005.00138.x

Pietzsch, J. B., Shluzas, L. A., Paté-Cornell, M. E., Yock, P. G., & Linehan, J. H. (2009). Stage-Gate Process for the Development of Medical Devices. *Journal of Medical Devices*, *3*(2), 021004. https://doi.org/10.1115/1.3148836

Piuzzi, N. S., Ng, M., Song, S., Bigach, S., Khlopas, A., Salas-Vega, S., & Mont, M. A. (2019). Consolidation and maturation of the orthopaedic medical device market between 1999 and 2015. *European Journal of Orthopaedic Surgery & Traumatology*, *29*(4), 759–766. https://doi.org/10.1007/s00590-019-02372-z

Ray, T. G., & Triantaphyllou, E. (1998). Evaluation of rankings with regard to the possible number of agreements and conflicts. *European Journal of Operational Research*, *106*(1), 129–136. https://doi.org/10.1016/S0377-2217(97)00304-4

Rogers, W. A., Mykityshyn, A. L., Campbell, R. H., & Fisk, A. D. (2001). Analysis of a "simple" medical device. *Ergonomics in Design*, *9*(1), 585–591.

Rotter, V. S., Chancerel, P., & Schill, W.-P. (2011). Practicalities of individual producer responsibility under the WEEE directive: experiences in Germany. *Waste Management & Research*, *29*(9), 931–944. https://doi.org/10.1177/0734242X11415753

Russell, R. K., & Tippett, D. D. (2008). Critical success factors for the fuzzy front end of innovation in the medical device industry. *EMJ - Engineering Management Journal*, *20*(3), 36–43.

Saaty, T. L. (1980). *The Analysis Hierarchy Process*. New York: McGraw-Hill.

Salgado, E. G., Sanches da Silva, C. E., Mello, C. H. P., & Samaan, M. (2017). Critical Success Factors for New Product Development in Biotechnology Companies. *Engineering Management Journal*, *29*(3), 140–153. https://doi.org/10.1080/10429247.2017.1344504

Santos, I. C. T. (2013). *Product development methodologies: The case of medical devices* (Phd Thesis). Faculdade de Engenharia da Universidade do Porto, Portugal.

Santos, I. C. T., Gazelle, G. S., Rocha, L. A., & Tavares, J. M. R. S. (2012). Medical device specificities: Opportunities for a dedicated product development methodology. *Expert Review of Medical Devices*, *9*(3), 299–311. https://doi.org/10.1586/erd.12.3

Schultz, C., Globocnik, D., Kock, A., & Salomo, S. (2018). Application and performance impact of stage-gate systems - the role services in the firm's business focus. *R&D Management*, *(in press)*. https://doi.org/10.1111/radm.12341

Seamon, E. (2004). Achieving Growth Through an Innovative Culture. In P. Belliveau, A. Griffin, & S. Soremrmeyer (Eds.), *PDMA Toolbook 2 for New Product Development* (pp. 3–32). New York: John Willey & Sons.

Thompson, B. S., & Friess, D. A. (2019). Stakeholder preferences for payments for ecosystem services (PES) versus other environmental management approaches for mangrove forests. *Journal of Environmental Management*, *233*, 636–648. https://doi.org/10.1016/J.JENVMAN.2018.12.032

Thrane, S., Blaabjerg, S., & Møller, R. H. (2010). Innovative path dependence: Making sense of product and service innovation in path dependent innovation processes. *Research Policy*, *39*(7), 37–41. https://doi.org/10.1016/j.respol.2010.04.003

Tidd, J. J., & Bessant, J. R. (2013). *Managing Innovation: Integrating Technological, Market and Organizational Change* (5th ed.). New York: Wiley.

Triantaphyllou, E., & Mann, S. H. (1989). An examination of the effectiveness of multi-dimensional decision-making methods: A decision-making paradox. *Decision Support Systems*, *5*(3), 303–312. https://doi.org/10.1016/0167-9236(89)90037-7

Wadstein, T. (1943). Osteosynthesis with Screws in Medial Fractures op the Neck of the Femur. *Acta Orthopaedica Scandinavica*, *14*(1–4), 251–269.

https://doi.org/10.3109/17453674308988833

Wessner, C. W. (2005). Driving innovations across the Valley of Death. *Research Technology Management*, *48*(1), 9–12.

Wu, Zeping, Wang, W., Wang, D., Zhao, K., & Zhang, W. (2019). Global sensitivity analysis using orthogonal augmented radial basis function. *Reliability Engineering & System Safety*, *185*, 291–302. https://doi.org/10.1016/J.RESS.2018.12.028

Wu, Zhibin, Huang, S., & Xu, J. (2019). Multi-stage optimization models for individual consistency and group consensus with preference relations. *European Journal of Operational Research*, *275*(1), 182–194. https://doi.org/10.1016/J.EJOR.2018.11.014

Wu, Zhibin, & Xu, J. (2012). A consistency and consensus based decision support model for group decision making with multiplicative preference relations. *Decision Support Systems*, *52*(3), 757–767. https://doi.org/10.1016/j.dss.2011.11.022

Yip, M. H., Phaal, R., & Probert, D. R. (2014). Stakeholder Engagement in Early Stage Product-Service System Development for Healthcare Informatics. *Engineering Management Journal*, *26*(3), 52–62. https://doi.org/10.1080/10429247.2014.11432020

Zuckerman, D. M., Brown, P., & Nissen, S. E. (2011). Medical device recalls and the FDA approval process. *Archives of Internal Medicine*, *171*(11), 1006–1011. https://doi.org/10.1001/archinternmed.2011.30

ABOUT THE AUTHORS

Houssem Barkaoui, Ph.D, graduated from National Engineering School of Tunis (Tunisia) and received a PhD in industrial engineering from INSA Lyon (Institut National des Sciences Appliquées de Lyon, France). He currently works on decision support issues, using tools for simulation, optimization and multi-criteria analysis, etc., specialized in healthcare supply chain, logistics problems, and risk analysis.

Helmi Ben Rejeb, Ph.D, is an assistant professor at the department of industrial engineering in the National Engineering School of Tunis (ENIT), University of Tunis El Manar. He received a PhD in Industrial Systems Engineering from the University of Lorraine, France and an engineering diploma from ENIT. His primary research interests include the study of the innovation processes, users' needs analysis, rapid prototyping issues in design and design driven innovation.

Abdelwahed Barkaoui, Ph.D, is an associate professor of Mechanical Engineering at International University of Rabat. He obtained his University habilitation from university of

Tunis El Manar-(Tunisia) and his PhD from university of Orleans (France). He received a. M.S in mechanics from the INSA Lyon and an engineering degree in electromechanical from National Engineering School of Sfax (ENIS, Tunisia). Currently, he is associate professor of Mechanical Engineering and assistant director of LERMA laboratory at the International University of Rabat (Renewable Energies and Advanced Materials Lab, Morroco). His research mainly concerns problems in biomechanics, mechanobiology and biomedical engineering.

João Manuel R. S. Tavares, Ph.D, has a B.S Degree in Mechanical Engineering from the University of Porto. He obtained the M.S and PhD in Electrical and Computer Engineering also from the University of Porto. He got the Habilitation in Mechanical Engineering from the University of Porto in 2015. Since 2001, he is senior researcher and project coordinator at the Institute of Science and Innovation in Mechanical and Industrial Engineering. Currently, he is an associate professor of the Department of Mechanical Engineering of the Faculty of Engineering of the University of Porto. He has been (co-)chair of several scientific national and international conferences and workshops, (co-)chief-editor of scientific international journals, co-guest-editor of special issues of scientific international journals and (co-)author than more of 350 scientific publications, including the co-editing of various scientific books.

Contact: Helmi Ben Rejeb, Industrial Engineering Department, National Engineering School of Tunis (ENIT), Université Tunis El Manar, ENIT BP 37, 1002 Le Belvédère, Tunis, Tunisia; Helmi.BenRejeb@enit.utm.tn

EXHIBITS

Exhibit 1. The Stage-Gate System model (Cooper, 2001)

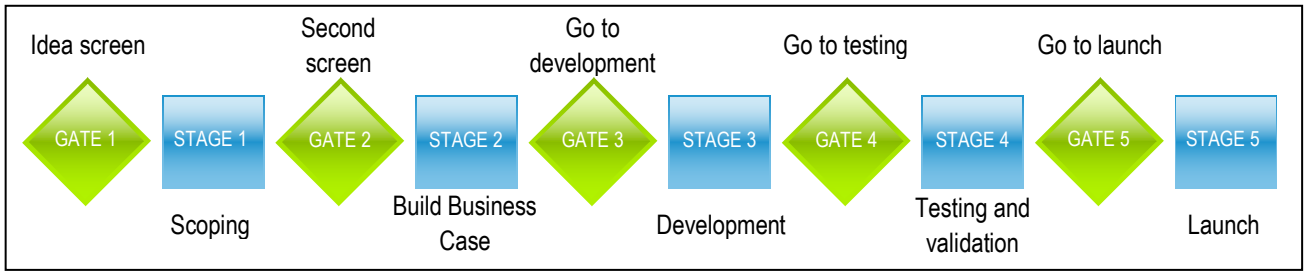

Exhibit 2. Existing literature on decision making for the development of medical devices

Reference	Objective	Method used/developed
(Santos et al., 2012b)	Medical device classification	Literature and regulation review
(Russell & Tippett, 2008)	Identification of critical success factors	Literature review
(Salgado et al., 2017)	Identification of critical success factors	Survey and descriptive statistics
(Santos, Gazelle, Rocha, & Tavares, 2012a)	Support for engineering managers along the development process	Business Process Model and Notation (BMPN)
(Fennigkoh, 1992)	Replacement of medical devices at end of life	Quantitative models
(Taylor & Jackson, 2005)	Replacement of medical devices at end of life	Quantitative models
(Ouda, Mohamed, & Saleh, 2010)	Replacement of medical devices at end of life	Quantitative models
(Mummolo et al., 2007)	Replacement of medical devices at end of life	Fuzzy approaches
(Chang, 2005)	Replacement of medical devices at end of life	Fuzzy approaches
(Christer & Scarf, 1994)	Replacement of medical devices at end of life	Robust optimization model
(Cho & Kim, 2003),	Prioritise medical devices during development	Analytic Hierarchy Process (AHP)
(S. Kumar & Bisson, 2008)	Prioritise medical devices during supply chain	Analytic Hierarchy Process (AHP)
(Ivlev, Vacek, & Kneppo, 2015)	Prioritise medical devices during supply chain	Analytic Hierarchy Process (AHP)
(Ivlev et al., 2015)	Prioritise medical devices in technology management	Analytic Hierarchy Process (AHP)
(Taghipour, Banjevic, & Jardine, 2011)	Prioritise medical devices in technology management	Analytic Hierarchy Process (AHP)

Exhibit 3. DPMA process flowchart

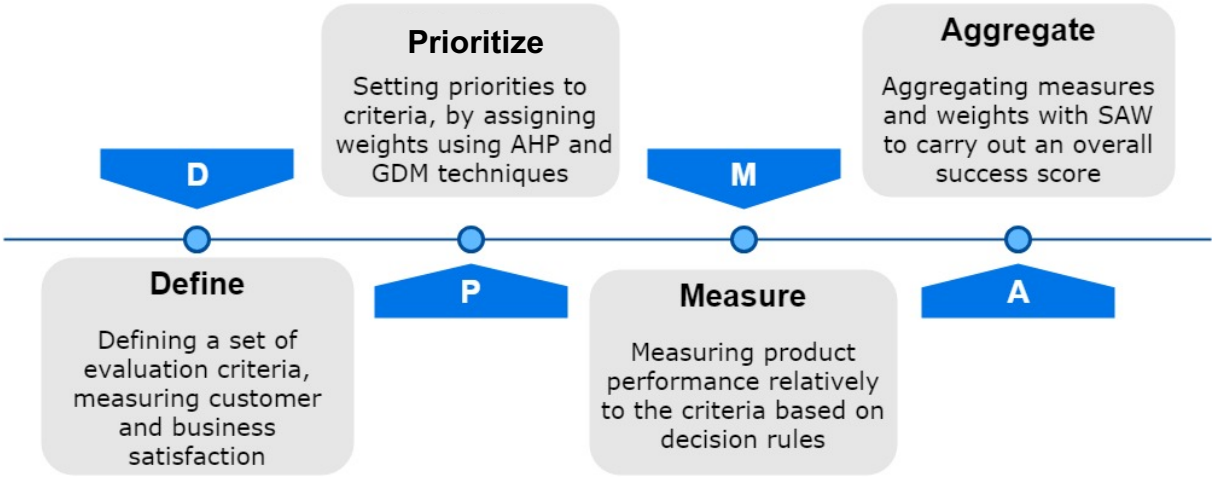

Exhibit 4. The hierarchical tree of criteria

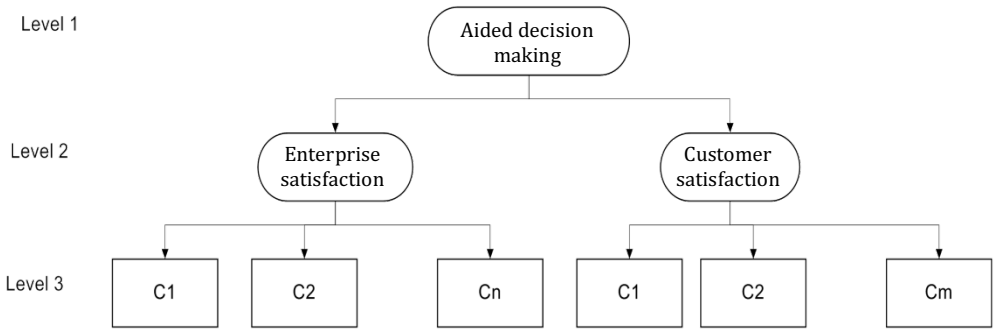

Exhibit 5. Prioritizing the criteria and GDM flowchart

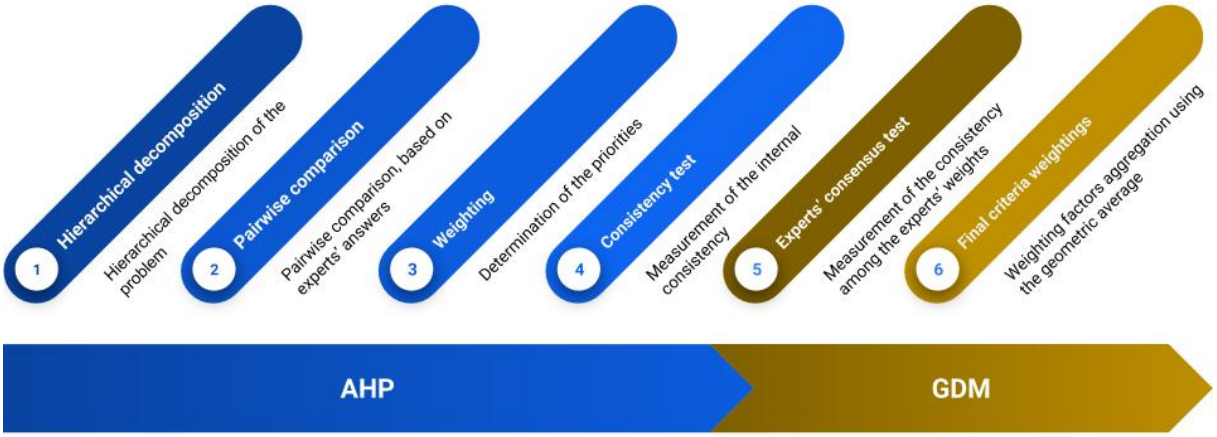

Exhibit 6. Prioritizing the criteria categories

Criteria	Expert 1	Expert 2	Expert 3	Expert 4
Enterprise satisfaction	0.750	0.667	0.800	0.667
Customer satisfaction	0.250	0.333	0.200	0.333

Exhibit 7. Prioritizing the criteria categories after GDM

Criteria	Average weight	Standardized weight	Rank
Enterprise satisfaction	0.718	0.725	1
Customer satisfaction	0.272	0.275	2

Exhibit 8. Prioritizing enterprise satisfaction criteria

Criteria	**Expert 1**	**Expert 2**	**Expert 3**	**Expert 4**
Strategic alignment	0.053	0.067	0.036	0.030
Market attractiveness	0.084	0.070	0.095	0.040
Synergy	0.131	0.081	0.087	0.059
Technical feasibility	0.136	0.137	0.119	0.147
Financial value	0.202	0.308	0.168	0.236
Environmental impact	0.038	0.084	0.030	0.038
Compliance with legislation	0.357	0.252	0.462	0.447
Ratio of consistency (RC)	*0.075*	*0.074*	*0.075*	*0.074*

Exhibit 9. Group decision making relative to the enterprise satisfaction criteria

Criteria	Average weight	Standardized weight	Rank
Strategic alignment	0.0443	0.0457	7
Market attractiveness	0.0688	0.0710	5
Synergy	0.0859	0.0887	4
Technical feasibility	0.1344	0.1387	3
Financial value	0.2229	0.2300	2
Environmental impact	0.0437	0.0451	6
Compliance with legislation	0.3692	0.3810	1

Exhibit 10. Prioritizing customer satisfaction criteria

Criteria	Expert 1	Expert 2	Expert 3	Expert 4
Differentiation	0.073	0.097	0.085	0.091
Clinical need	0.321	0.294	0.427	0.341
Effectiveness	0.269	0.181	0.147	0.178
Price	0.071	0.067	0.035	0.024
Ease of use	0.028	0.042	0.076	0.031
Reliability	0.192	0.203	0.139	0.255
Cost of use & maintenance	0.047	0.116	0.092	0.079
Ratio of consistency (RC)	*0.086*	*0.054*	*0.082*	*0.076*

Exhibit 11. Group decision making relative to customer satisfaction criteria

Criteria	Average weight	Standardized weight	Rank
Differentiation	0.0860	0.0882	4
Clinical need	0.3424	0.3512	1
Effectiveness	0.1889	0.1938	3
Price	0.0447	0.0459	6
Ease of use	0.0408	0.0418	7
Reliability	0.1928	0.1977	2
Cost of use and maintenance	0.0793	0.0814	5

Exhibit 12. Combination of the criteria

Criteria	$g_m^{'}$	$g_{mn}^{'}$	$g_i^{'}$	Rank
Enterprise satisfaction criteria				
Strategic alignment (SA)	0.725	0.0456	0.0331	9
Market attractiveness (MA)	0.725	0.0710	0.0514	8
Synergy (S)	0.725	0.0887	0.0643	5
Technical feasibility (TF)	0.725	0.1387	0.1005	3
Financial value (FV)	0.725	0.2300	0.1667	2
Environmental Impact (EI)	0.725	0.0451	0.0327	10
Compliance with legislation (CL)	0.725	0.38210	0.2762	1
Customer satisfaction criteria				
Differentiation (D)	0.275	0.0882	0.0243	11
Clinical need (CN)	0.275	0.3512	0.0966	4
Effectiveness (E)	0.275	0.1938	0.0533	7
Price (P)	0.275	0.0459	0.0126	13
Ease of use (EoU)	0.275	0.0418	0.0115	14
Reliability (R)	0.275	0.1977	0.0544	6
Cost of use & maintenance (CU&M)	0.275	0.0814	0.0224	12

Exhibit 13. Summary of the criteria measurements

Criterion	Indicator	Assessment	GO Score	NO GO Score	Weight	Criterion Calculation
Strategic Alignment (SA)	DA (Degree of Alignment)	High	1	0	1	Sum
		Medium	0.5	0.5		
		Low	0	1		
Market Attractiveness (MA)	MS (Market Size)	High	1	0	1/3	Weighted sum
		Medium	0.5	0.5		
		Low	0	1		
	MG (Market Growth)	High	1	0	1/3	
		Medium	0.5	0.5		
		Low	0	1		
	MC (Market Competition)	High	0	1	1/3	
		Medium	0.5	0.5		
		Low	1	0		
Synergy (S)	Marketing Synergy (Msy)	High	1	0	0.5	Weighted sum
		Medium	0.5	0.5		
		Low	0	1		
	Technological Synergy (Tsy)	High	1	0	0.5	
		Medium	0.5	0.5		
		Low	0	1		
Technical Feasibility (TF)	TC (Technical Complexity)	High	0	1	1	Sum
		Medium	0.5	0.5		
		Low	1	0		
Financial value (FV)	NPV (Net Present Value)	NPV > 0	1	0	1	Sum
		NPV = 0	0.5	0.5		
		NPV < 0	0	1		
Environmental Impact (EI)	ES (Eco-Score)	ES < 10	0	1	1	Sum
		10< ES ≤ 30	0.5	0.5		
		30< ES ≤ 50	1	0		
Compliance with Legislation (CL)	CL	1	1	0	1	Sum
		0	0	1		
Differentiation (D)	D	High	1	0	1	Sum
		Medium	0.5	0.5		
Clinical Need (CN)	CN	1	1	0	1	Sum
		0	0	1		
Effectiveness (E)	DE (Degree of Effectiveness)	High	1	0	1	Sum
		Medium	0.5	0.5		
		Low	0	1		
Price (P)	P and WTP (Willingness To Pay)	P > WTP	0	1	1	Sum
		$P \leq WTP$	1	0		
Ease of Use (EoU)	Complexity (Co)	High	0	1	1	Sum
		Medium	0.5	0.5		
		Low	1	0		
Reliability (R)	R and Ref (Reliability Reference)	R ≥ Ref	1	0	1	sum
		R < Ref	0	1		
Cost of Use & Maintenance (CU&M)	Maintenance and Use Expenditure Limit / Cost of Annual Maintenance and Use $\frac{MUEL}{CAMU}$	$\frac{MUEL}{CAMU} < 1$	0	1	1	Sum
		$1 \leq \frac{MUEL}{CAMU} < 1.5$	0.5	0.5		
		$1.5 \leq \frac{MUEL}{CAMU}$	1	0		

Exhibit 14. Table of aggregation and final decision

Performance Criteria	Weight	S^i_{GO}	$S^i_{NO\ GO}$
Strategic alignment (SA)	0.0331	1	0
Market attractiveness (MA)	0.0514	0.5	0.5
Synergy (S)	0.0643	0.75	0.25
Technical feasibility (TF)	0.1005	1	0
Financial value (FV)	0.1667	1	0
Environmental impact (EI)	0.0327	0.5	0.5
Compliance with legislation (CL)	0.2762	1	0
Differentiation (D)	0.0243	1	0
Clinical need (CN)	0.0966	1	0
Effectiveness (E)	0.0533	1	0
Price (P)	0.0126	0	1
Ease of use (EoU)	0.0115	0.5	0.5
Reliability (R)	0.0544	1	0
Cost of use and maintenance (CU&M)	0.0224	0.5	0.5
Decision Score (%)		**91.23**	**8.77**
		D_{GO}	$D_{NO\ GO}$

Exhibit 15. Sensitivity to the variation of weights of the enterprise and customer sets

	Base scenario	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Enterprise satisfaction	0.725	0.5	0.275	0	1
Customer satisfaction	0.275	0.5	0.725	1	0
GO Score (%)	**91.23**	**90.62**	**90.00**	**89.25**	**91.98**