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Risk analysis in adopting FES-exoskeleton system in rehabilitation programs

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Abstract - *The rehabilitation of paraplegics patients is one of the current challenges of the biomedicine research and it represents one of the main challenges to translate this idea into reality. A relatively new method for the recovery of patients with neuromotor disabilities is the functional electrical stimulation - FES. The project aims to recover the functions of the upper limb disability. Electric stimulus was generated command replaces previously voluntarily. By activating the step lodges can get complex muscle movements that can improve the lives of patients. Such a system can be produced on a large scale and can be used for ambulatory exercises. Adopting this type of systems however involve risks that must be identified and analyzed. Given the complexity of today's economic and market dynamics, optimization activities are no longer the managers exclusive responsibility. The value of an investment project can be given only through a joint academic-economic contribution in the sense that engineers identify the deterministic models of the processes, the statisticians identify the probability models and computer scientists are developing the software for analysis of these models. During this multidisciplinary approach in an imperfect capital market the risk structure seems to be a key component to maximize the value of the project.*

Key Words: Rehabilitation, Risk, Disabilities, Deterministic Models

1. Introduction

Risk is uncertainty associated with any result on the likelihood of an event or the impact it will have if it will occur. More specifically, in practice, risk is defined as "the effect of uncertainty on objectives" [1]. The operation of a risk system refers to the probability of not respecting performance standards and costs that limits the risk budget. The risk element is any item that has a measurable probability to divert from the plan, objectives or performance indicators. Strategies and plans are elements that allow foreshadowing actual reality and then confrontation them with the expected achievements [2]. Risk analysis involves going through each of the steps of the risk management process. The results obtained have a decisive influence over decisions and over the effectiveness of the adopted strategy. The degree of a successful analysis depends strictly on the right approach and every mentioned aspect solved without introducing errors from one stage to another.

The robotic (FES-exoskeleton) is dedicated to the recovery of persons with motor disabilities, is adaptable and modular, it can be used throughout disease progression, saving training time and allows the patient to quickly adjust to new situations and is therefore suitable in daily activities. It is presented in Figure 1.

Fig -1: The Fes-Exoskeleton system

One of the main qualities is the ability to develop techniques capable of stimulating paralyzed muscles paving the way functional recovery of upper and upper limb coordination of which was wholly or partly lost following a stroke type accident, sclerosis, medullary lesions etc. However, consistent with cohesion policies, governments of emerging countries have realized the need for concrete measures to ensure healthy aging by ensuring equal access of all citizens to basic health care and improving the quality and safety of care.

2. Evaluation and assessment of the risk analysis

2.1. Objectives and Methodology

The recommended procedure for risk assessment is based on: As a first step, a sensitivity analysis, which is supposed impact that change has on the variables of performance indicators. A second step will be to study the probability distributions of selected variables and calculating performance indicators of the proposed solution. Sensitivity analysis has the following objectives:

* Determining the degree of uncertainty related to the implementation of a solution;
* Identify critical variables and potential impact on changing financial and economic performance indicators; * Verification of financial and economic performance indicators: financial internal rate of return on investment, net present value financial, economic internal rate of return and net present value economic.

To construct a probability distribution stochastic variables or probabilistic based on historical data or obtained by direct measurement procedure may be applied and consists in three stages:

1. Collection of data on the stochastic variable.
2. Group data on relative frequency histogram intervals and construction.
3. Analysis of the graph of the histogram of the relative frequencies to determine whether a distribution similar to known theoretical shape. Type the probability distribution can be appreciated trough line tests (Kolmogorov-Smirnov, Pearson or $\chi 2$) which measures the closeness of theoretical distribution and probabilistic distribution variable values obtained from historical walked through measurement series. Finally, we calculate the distribution parameters [3].

Kolmogorov - Smirnov calculated for each interval and values, absolute differences in the cumulative probability of theoretical function Ft_i and cumulative probability function obtained by simulation experiments FSIS n if:

$$\max \{| FT1 - FS1 |, | FT2 - FS2 |, \ldots, | FTK - FSK |\} < (1.36/\sqrt{n}) \quad (1)$$

then it can be considered that there is consistency between the two compared distributions, for a significance level of $\alpha = 0.05$ and $n > 30$ [4].

Pearson test (or $\chi 2$) calculated based on the distribution and frequency distribution theoretical frequencies FTI obtained by statistical simulation FSI.

$$\chi_{calculated}{}^{2} = \sum_{i=1}^{k} \frac{(ft_i - fs_i)^2}{ft_i} \quad (2)$$

If $\chi 2_{calculated} < \chi_{\alpha}$, υ 2 then it can be considered that there is consistency between the two distributions compared to a significance level α and υ number of degrees of freedom = kc-1, where k is the number of ranges of values for which s They led the theoretical and statistical frequencies, and c is the number of parameters analyzed the probability distribution. The value of χ_{α}, will be read from specific tables. The test cannot be applied if there is frequency FSI <5 [5].

Methodology for the calculation of the probability distribution presence:

* Risk analysis is only possible if there is reasonable information to define a probability distribution of critical variables (issue seriously and repeatedly ignored by many analysts, which calls for mandatory probability distributions and Monte Carlo analysis in all cases);
* Should be carried out assigning a probability distribution for each critical variable distribution (this can be obtained from literature, the beneficiary's own experience - where extensive and relevant statistics from the study of similar systems);
* Risk analysis can be expressed as mean and standard deviation estimated financial and economic performance indicators, if we can determine the probability distribution of critical variables;

Methodology for the calculation in the presence of probability distribution:

* Risk analysis is only possible if there is reasonable information to define a probability distribution of critical variables (issue seriously and repeatedly ignored by many analysts, which calls for mandatory probability distributions and Monte Carlo analysis in all cases);
* Should be carried out assigning a probability distribution for each critical variable distribution (this can be obtained from literature, the beneficiary's own experience - where extensive and relevant statistics from the sturdy similar systems);
* Risk analysis can be expressed as mean and standard deviation estimated financial and economic performance indicators, if we can determine the probability distribution of critical variables;

2.2. General techniques of statistical analysis

Because risks are analyzed with probabilistic techniques default distribution functions are used to describe the impact and likelihood of the projects objectives. Risk typical probability distribution of cost and time is a function that shows possible events cost or time planning for a particular activity, along the X axis and correlated with the probability of the different options along the Y-axis representation risks caused by the event. For example, an activity has on D as the most likely (the D is plotted on the X axis). The probability p associated with this data is most likely of all possible values (p-value is plotted on the Y axis) and will always be on the top of the distribution curve. It is not mandatory that this value represents the average data analyzed activity and it is likely to achieve a unimodal distribution because asymmetric media may be above or below in relation to the most probable value. Note that the date of the most optimistic and the most pessimistic date is the first and last value of X axis and correspond to the lowest probabilities.

Part of probability distributions can be used in risk analysis: triangular, normal and asymmetric.

Triangular probability distribution shows that uniform as optimistic grow up in an appropriate safety the greatest likelihood of uniform decrease to the point where pessimistic.
Normal distribution (Gauss-Laplace) is a symmetric function even in the event that media is most likely to occur and to calculate the standard deviation, a statistical indicator of the degree to which an individual value of a probable distribution tends to vary to media distribution. This dispersion is an element of forecasting extremely useful because help frame within allowable variations (establishing tolerances) [6].
Asymmetric distribution is the most common representation of risk frequency of cost and time planning.
Media is used for numerical data and symmetric distribution data. The median is used for ordinal data and non-symmetric distributions. Methods used for bimodal distributions. The geometric mean is used for observations measured on a logarithmic scale.
Monte Carlo method applies in general management because it provides a strategic distribution of calculated results. These results can be used to measure the risks identified of possible action strategies. Fundamental Theorem of Monte Carlo method: the integral of a function f on a domain D is the product of the mean function and volume V of the domain

$$\int_D f dV \approx V\langle f \rangle \pm \sigma \qquad (3)$$

$\langle f \rangle$ - defined on a sample of n points x_1 ... x_n, distributed randomly and evenly on D.
σ – standard deviation - uncertainty - a measure of deviation from the mean function f.
σ2– variance.

$$\sigma = V\sqrt{\frac{\langle f^2 \rangle - \langle f \rangle^2}{n}} = \frac{V}{\sqrt{n}}\sigma_f \qquad (4)$$

,where n is the number of samples.
Compared error deterministic integration formulas: - σ slowly decreases, the number of sampling points $n^{-1/2}$– does not depend on size. Importance sampling efficient domain D::
σ~ standard deviation function - the lowest since f is flatter; If the function is constant – it is sufficient the assessment in one spot to cancel the variance. If f has values significant in a restricted area - x_i evenly distributed on D generally samples insignificant values of the function → imprecise estimate [7].

3. Evaluation and assessment of the risk analysis

In the case of a robotic rehabilitation system type FES-exoskeleton we identify several risk elements, from the design phase until the end of the life cycle. Many clinicians have expressed a desire to use robotic systems but an inconvenience is their very high price. Robotic devices have been designed but, their use in clinics was poor due to their complexity and high cost. The rehabilitation process is difficult and complex. The shortcomings of health systems come largely from the perspective of continuous improvement of the cost / effectiveness in the field of health. The result would be reduced hospitalization periods more difficulties for reimbursement of costs of rehabilitation, and division of responsibilities between specialists.
Introducing new technologies on the market always come with supplementary risks, transferred from the designer to the vender. In financial terms, there are two categories of uncertainty: of budget proposal and of producing costs.
Using the decision models and Monte Carlo simulation from the software @Risk6, will be analyzed the probabilities that the Fes-Exoskeleton to be delivered within the budget proposed by the designer and how much contingency (additional funds) is necessary that the budget level to be achieved with a certain degree of confidence. It is assumes that each item's actual cost will be within a min-max range, and that Pert distributions are applicable to describe the possible costs of each item, see Figure 2. The distributions are assumed to be skewed, and the parameters have been chosen so that costs are more likely to overshoot than undershoot the base case. The minimum and maximum values indicate how low or high the inputs could be (in percentages or actual values).

Cost elements	Base Case	Minimum	Most Likely	Maximum	Minimum	Most Likely	Maximum	Sampled
6 sensors	30	85%	105%	130%	26	32	39	32
4 dc motors	7.000	80%	100%	125%	5.600	7.000	8.750	7.058
electrical wires	20	93%	100%	125%	19	20	25	21
support materials	150	90%	100%	125%	135	150	188	154
1 battery	100	95%	96%	110%	95	96	110	98
1 microcontroller	80	90%	100%	125%	72	80	100	82
2 drivers	300	95%	100%	110%	285	300	330	303
SSC	80	93%	100%	104%	74	80	83	80
Output								
Totals	7.760							7.827
Summary statistics								
Probability of meeting base case value	46,94%							
Total budget required for 95.0% confidence	8.825							
Contingency required for 95.0% confidence	1.065							

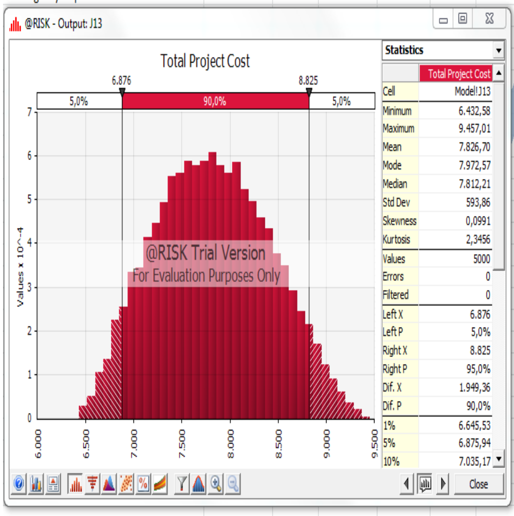

Fig -2 The Monte Carlo simulation

Using other distributions in place of the Pert, such as a binomial distribution, see Figure 3, the risk that certain specific adverse events may or may not occur can be represented.

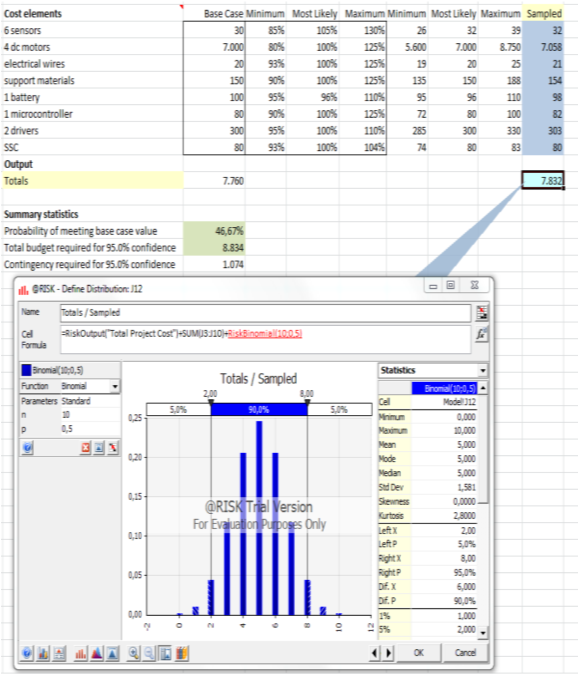

Fig -3 The binomial distribution

Another important step in creating a product strategy is to find which of the inputs have the largest effect on an output. As the created @RISK6 model has many uncertain inputs, the *TopRank* function was used to see which of many inputs are important enough to model with uncertainty. The values from D column to F were estimated. The values in the blue cells are calculated with the *RiskVary* function, where the arguments depend on how the lows and highs are entered in columns D and F: fourth argument 0 for percentages, 2 for actual values (see Figure 4).

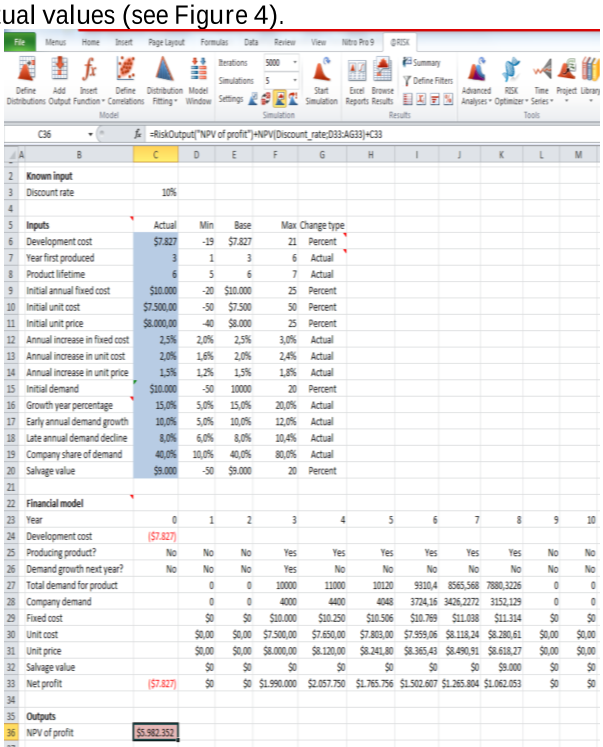

Fig -4 The variance table of the NVP of profit

When the simulations are running, the inputs vary one at a time, throughout their ranges to see how much the net present value output varies, where the output represents the sum of the present values of incoming and outgoing cash flows over a period of time. It reflects the profitability of an investment.

The results can be shown in different histograms, but the tornado chart (see Figure 5) is suitable because for each input, it uses a horizontal bar to show how much the output changes when this input varies over its range, with the longer bars placed at the top. The graphic version with correlation coefficients reflects a "distribution-free" approach because any distribution types may be correlated. Although the samples drawn for the two distributions are correlated, the integrity of the original distributions is maintained. The resulting samples for each distribution reflect the input distribution function from which they were drawn.

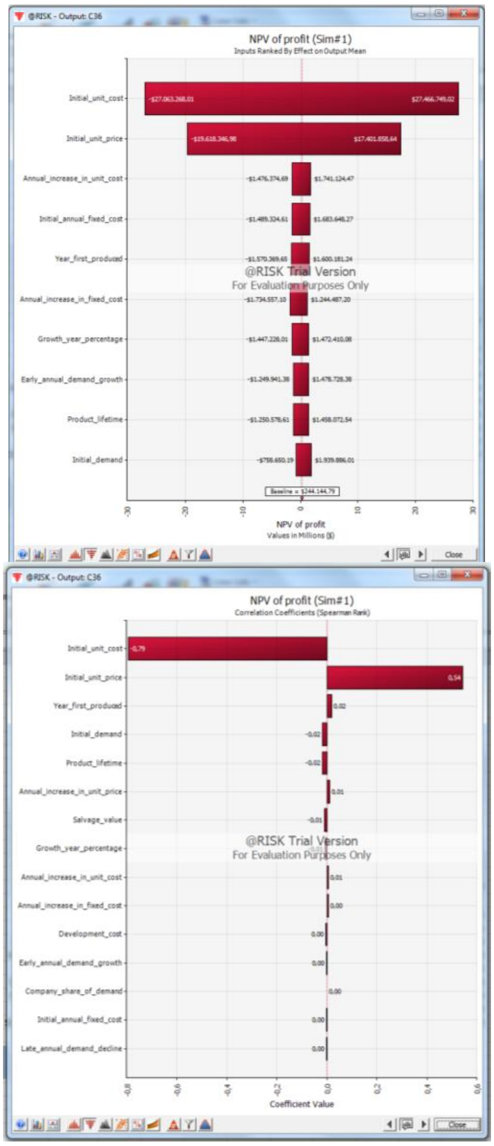

Fig -5 The tornado chart

It is clear from this chart that the initial unit cost and initial unit price are the three most important inputs. In contrast, the bottom seven inputs have a very small effect on the NVP of profit and they can be set at their base values.

4. Conclusions

A risk analysis Risk analysis in adopting FES-exoskeleton system in rehabilitation programs was performed using Monte Carlo simulation. Introducing new technologies on the market always come with supplementary risks, transferred from the designer to the vender. In financial terms, there are two categories of uncertainty: of budget proposal and of producing costs.
Using the decision models and Monte Carlo simulation from the software @Risk6, there were analyzed the probabilities that the Fes-Exoskeleton to be delivered within the budget proposed by the designer and how much contingency (additional funds) is necessary that the budget level to be achieved with a certain degree of confidence. The shortcomings of health systems come largely from the perspective of continuous improvement of the cost / effectiveness in the field of health. The result would be reduced hospitalization due to a successful Fes-Exoskeleton project.

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