

Risk Analysis and Impact of Risk in Design Transfer of New Product Development (NPI)

Nilesh John Makasare, D. K. Shinde

¹Student, Veermata Jijabai Technological Institute (VJTI), Mumbai, Maharashtra

²Associate Professor, Veermata Jijabai Technological Institute (VJTI), Mumbai, Maharashtra

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ABSTRACT:New Product Introduction (NPI) projects in healthcare industries must take approval from multiple regulatory bodies. This will directly impact on the project's cost, scope, and timeline. Risk Management is one of the knowledge areas of Project Management that helps project managers to manage the uncertainty occurring in various fields. Project Managers usually define risk and its impact based on simple criteria such as High, Medium, and Low. But this method could not define it properly. This paper proposes a risk analysis to determine the risk and impact of risk in the design transfer of New Product Introduction (NPI). This paper uses fuzzy logic to quantify the risk associated with design transfer of New Product Introduction (NPI) which is 0.84 and Markov theory to determine the probability of risk occurrence 0.93 of it. Risk degree can be calculated by multiplying the impact of risk and the probability of risk occurrence.

KEYWORDS:New Product Introduction (NPI), Risk Management, Fuzzy Logic, Markov Process.

I. INTRODUCTION

Risk Management is considered as one of the most important knowledge areas among the 10 knowledge areas of Project Management. The success of any project can be measured by three parameters such as time, cost, and scope. The main barriers to these parameters are frequent changes in scope, time, and cost.

There are various definitions available for risk but according to the Project Management Book of Knowledge PMBOK (PMI, 2017, p. 395), an uncertain event or condition, that if it occurs, has a positive or negative effect on the project's objective. Every project has some risks, Negative risks are called as threats and Positive risks are called as opportunities. There are five ways to deal

with opportunities such as Exploit, Escalate, Share, Enhance and Accept. There are five ways to deal with threats also such as Avoid, Escalate, Transfer, Mitigate and Accept.

Naoshi Uchihira & Yuji Hirabayashi has defined the various risks associated with new technology in the New Product Introduction (NPI) of R&D project management (Uchihira et al., 2012, p. 1). The main objective of risk management is to increase the probability or impact of positive risk and to decrease the probability or impact of negative risk.

According to the Josef Oehmen & Alison Olechowski study, a major contribution of risk management to new product development projects is improved decision-making processes (Oehmen et al., 2014, p. 5). regulation of other engine valve parameters including variable lift and seating velocity.

B. Kayis & G. Arndt analysed the challenges of product design and development in concurrent engineering and provides a risk management approach in product development (Kayis et al., 2006, para 2). They used Expert Interview Facility to identify product, process, and project specific risks.

Maryam Gallab and Hafida Bouloiz used fuzzy sets theory to quantify risks and failures while performing maintenance activities in LPG supply chain (Gallab et al., 2019, p. 3). The Risk Priority Number (RPN) for the quantification of risk levels was calculated using three parameters such as severity, frequency of occurrence and detectability.

This paper will emphasize on identifying and quantifying risks occurred during the design transfer of New Product Introduction (NPI) projects in the healthcare sector. For quantifying the risk Fuzzy logic is being used. This paper also

emphasizes finding the probability of risk occurrence and the Markov Process is used for this which has three main elements such as Transition

Probability Matrix (TPM), set of states, and initial state probability.

II. RESEARCH METHODOLOGY

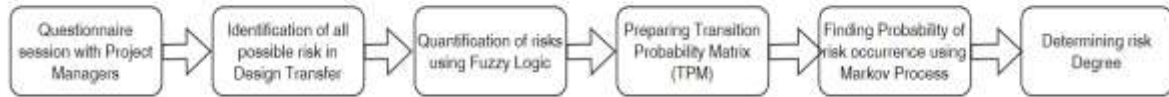


Fig 1 Research Methodology

After having a questionnaire survey with project managers, Program managers and leaders of R&D, Supplier Quality, and operations teams regarding all possible risks in design transfer of New Product Introduction (NPI) we found 15 risks and given the weightage as follows 1 for A (Low

Risk), 2 for B (Medium Risk), 3 for C (High Risk), and 4 for D (Very High Risk). After collecting survey reports from all and using the knowledge of statistics we have found overall difficulty and risk factors associated with it.

Table 1 Risk Description & Their Weightage

ID	Risk	Level			
		A (Low)	B (Medium)	C (High)	D (Very High)
1	Project Scope Change		o		
2	Design Changes				o
3	Product Introduction		o		
4	Schedule tightness			o	
5	Resource tightness		o		
6	Availability of Funding	o			
7	Large old stock inventory		o		
8	Material Unavailability			o	
9	Logistical Capability of				o
10	Manufacturing Capability			o	
11	Capability of Project		o		
12	Competition				o
13	Business relationship				o
14	Documentation	o			
15	Multiple Reporting		o		
	Overall Difficulty	39			
	Expert Risk Factor	0.7			

Fuzzy Logic

Prof. Lotfi Zadeh developed Fuzzy set theory in 1965 based on fuzzy logic which is superset of Boolean logic. In this research paper we are using Triangular Membership Function to evaluate impact value of risk factor because of ease of calculations. Triangular Membership Function can be defined as

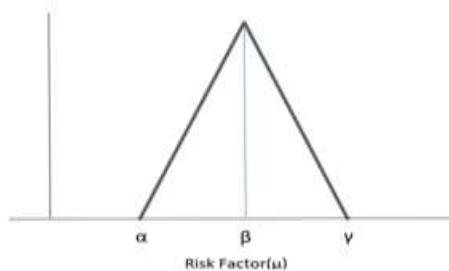


Fig 2 Triangular Membership Function

$$\begin{aligned} \mu &= 0 & \mu \leq \alpha \\ &= (\mu - \alpha) / (\beta - \alpha) & \alpha < \mu < \beta \\ &= (\alpha - \mu) / (\alpha - \beta) & \beta < \mu < \gamma \\ &= 0 & \mu > \gamma \end{aligned}$$

In union operation we need to select the common elements in both the fuzzy sets then we should select the element with maximum membership function.

$$\mu(A \cup B) = \max(\mu(A), \mu(B))$$

Where $\mu(A)$ and $\mu(B)$ are membership functions.

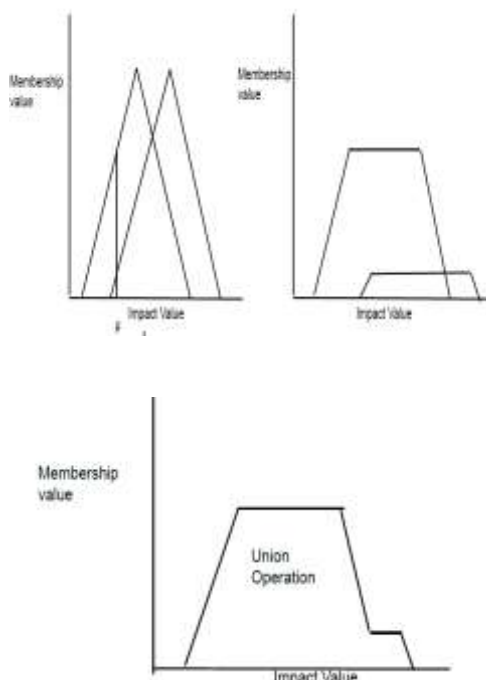


Fig 3 Union Operation in Fuzzy Logic

It is necessary to defuzzify the output from the union operator to convert the fuzzy membership function value into a non-fuzzy value. There are various methods that are available to defuzzify fuzzy logic such as Max Membership Function, Weighted average method, Mean Maximum Membership Function and Centre of Gravity Method. In this research paper we are using Centre of Gravity method to defuzzify membership function because it is the most powerful method and output (i.e., Non-Fuzzy Value) can be obtained

$$\text{Output} = \int \mu x dx / \int \mu dx$$

Markov Process

Markov Process is stochastic process describes a sequence of possible events in which the probability of each event depends upon of the state attained in the previous event. Seonmuk Park and Hoo-Gon Choi studied the elements of Markov Process are Transition Probability Matrix (TPM), a set of states and the initial state of probability (Park et al., 2011, p 2).

To get Transition Probability Matrix first we need to find out adjusted frequency of risk occurrence and it can be calculated by following formula (Choi & Ahn, 2010, p 8).

$$f_i'(x) = \begin{cases} F_x + \left(\frac{I_y - C_{x1}}{I_x} \right) X F_{avg1} & 15 \leq C_{x1} \leq 37 \\ F_x - \left(\frac{C_{x2} - I_z}{I_x} \right) X F_{avg2} & 38 \leq C_{x2} \leq 60 \\ 0, & F_x = 0 \end{cases}$$

Where, F_x = Frequency of risk occurrence in proto x , C_{x1} = Difficulty of proto x in Group 1, C_{x2} = Difficulty of proto x in Group 2, I_x = Total number of C_x in each group (15), $I_y = ((C_{min} + C_{max} - 1) / 2)$ Adjusted mean rounded off (37), $I_z = ((C_{min} + C_{max} + 1) / 2)$ Adjusted mean rounded up (38), F_{avg1} = Average frequency of risk occurrence in Group 1 (1.47), F_{avg2} = Average frequency of risk occurrence in Group 2 (1.33)

After finding out adjusted frequency of risk occurrence we can calculate Transition Probability Matrix as follows (Choi & Ahn, 2010, p 8)

$$P = \begin{bmatrix} P11 & P12 & P13 & \dots & P1n \\ P21 & P22 & P23 & \dots & P2n \\ P31 & P32 & P33 & \dots & P3n \\ P41 & P42 & P43 & \dots & P4n \end{bmatrix}$$

$$P_{ab} = \frac{Q_{ab}}{\sum_{b=1}^n Q_{ab}}$$

Where a, b = states

Now we can get Probability of risk occurrence P' by multiplying initial state of probability with Transition Probability Matrix (TPM)

$$P' = \alpha \cdot P$$

where α = Initial State Probability

An Illustrated Example of Risk Analysis Model Risk Factor Calculation

For example, we are considering data of past 30 prototypes of NPI if same risk can occur in 31st Prototype.

Table 2 Data of past 30 prototypes and evaluation taken by expert's opinion

Project No	1	2	3	4	5	6	7	8	9	10
Overall Difficulty	27	20	18	10	15	36	26	12	30	10
Frequency	1	2	0	1	2	2	1	1	3	3
Project No	11	12	13	14	15	16	17	18	19	20
Overall Difficulty	15	25	20	28	14	24	12	33	16	14
Frequency	2	1	1	4	5	3	1	1	1	1
Project No	21	22	23	24	25	26	27	28	29	30
Overall Difficulty	30	25	13	15	22	20	25	36	32	28
Frequency	3	2	0	0	1	1	2	4	2	0

There are different 45 membership functions but based on difficulty level 39 in Table (1) 22nd Membership function is selected for calculation

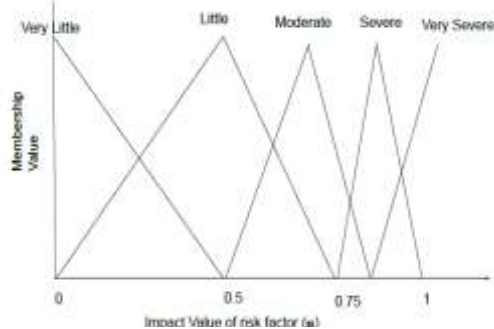


Fig 4 Membership Function 15

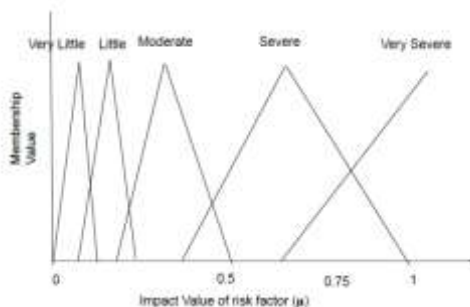


Fig 5 Membership Function 60

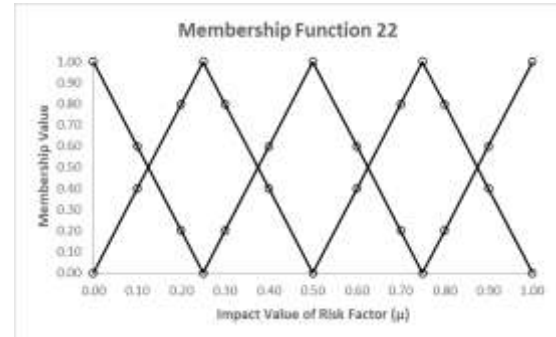


Fig 6 Membership Function 22

From Table 1 we get to know that overall difficulty for the proto 31 is 37 and 0.7 is the impact value given by expert. Therefore, we are going with 22nd membership function. The 0.7 line cutting the moderate line at (0.25) and severe line at (0.8) in membership function. Now we are using Centre of Gravity method for defuzzification.



Fig 7 Defuzzification

We are using linear Interpolation formula to find the equation of line

$$\frac{Y - Y_1}{Y_2 - Y_1} = \frac{X - X_1}{X_2 - X_1}$$

from a → b $Y = 4.445(X - 0.5)$

from b → c $Y = 0.8$

from c → d $Y = -5.205x + 5.0529$

from d → e $Y = 0.3684$

Therefore, from Equation we can calculate the output i.e., non-Fuzzy value

Output=0.8399

Probability of Risk Occurrence

To Find out Probability of risk occurrence we required Transition Probability Matrix, Set of states, and Initial state probability. For getting Transition Probability Matrix, adjusted frequency (Fi') and set of states required and that is given following table (3)

Table 3 Adjusted frequency of past 30 prototypes

Proto No	1	2	3	4	5	6	7	8	9	10
Cx	46	34	24	15	21	60	44	21	52	15
Fx	1	2	0	1	2	2	1	1	3	3
F'x	0.71	2.29	1.27	3.15	3.564	0.044	0	1.56	1.756	5.151
Set of States	S2	S1	S2	S3	S3	S2	S1	S2	S2	S4
Proto No	11	12	13	14	15	16	17	18	19	20
Cx	21	42	34	48	17	40	21	56	27	23
Fx	2	1	1	4	5	3	1	1	1	1
F'x	3.56	0.64	1.29	3.11	6.956	2.822	1.564	0.6	1.978	2.369
Set of States	S3	S2	S2	S3	S4	S1	S2	S2	S2	S3
Proto No	21	22	23	24	25	26	27	28	29	30
Cx	52	42	22	25	37	34	42	60	55	48
Fx	3	2	0	0	1	1	2	4	2	0
F'x	0.75	0	3.46	3.17	1.089	2.293	1.644	0.95	1.511	3.111
Set of States	S2	S1	S3	S3	S2	S3	S2	S2	S2	S3

Note: Difficulty (Cx), Frequency (Fx), Adjusted Frequency (F'x) S1: (F≤0), S2: (0<F≤2), S3: (2<F≤4), S4: (F > 4)

To get TPM, Qab (i.e., Number of transitions between states a b) is obtained first
 Q11 = 0 Q12 = 1 Q13 = 1 Q14 = 0 Q21 = 2
 Q22 = 6 Q23 = 6 Q24 = 1 Q31 = 0 Q32 = 7
 Q33 = 2 Q34 = 1 Q41 = 0 Q42 = 0 Q43 = 1
 Q44 = 0

Therefore, Transition Probability Matrix (TPM)

$$P = \begin{bmatrix} 0 & 0.5 & 0.5 & 0 \\ 0.133 & 0.4 & 0.4 & 0.067 \\ 0 & 0.7 & 0.2 & 0.1 \\ 0 & 0 & 1 & 0 \end{bmatrix}$$

And initial state Probability can be calculated by taking data from recent 8 prototypes such as number of each state is counted (i.e., S3 occurs 4 times in 8 prototypes)

$$\alpha = [0 \ 0.5 \ 0.5 \ 0]$$

Therefore, Probability of risk occurrence can be calculated by multiplying Transition Probability Matrix and Initial state Probability

$$P' = [0 \ 0.5 \ 0.5 \ 0] \begin{bmatrix} 0 & 0.5 & 0.5 & 0 \\ 0.133 & 0.4 & 0.4 & 0.067 \\ 0 & 0.7 & 0.2 & 0.1 \\ 0 & 0 & 1 & 0 \end{bmatrix}$$

$$P' = [0.0667 \ 0.55 \ 0.3 \ 0.0833]$$

Therefore, the probability of a risk not occurring in 31st Prototype, or that it occurs once or twice, or that it occurs more than once is 0.0667, or 0.55, or 0.93, respectively.

transfer in R&D project management:
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III. CONCLUSION

Identified all possible risks in design transfer of New Product Introduction (NPI) and used fuzzy logic to quantify them and found out the risk factor for 31st proto is 0.84. This indicates that the proposed fuzzy logic theory changes the expert evaluation into a high-impact value because the project is relatively more difficult than others. The probability of risk occurrence for 31st proto was found out to be 0.93 using the Markov process. Hence risk degree can be calculated as a product of the risk factor and probability of risk occurrence (i.e., $0.84 \times 0.93 = 0.7812$)

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