Use Of Fuzzy Logic For Risk/Benefit Assessment In Medical/Biological Cases

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Abstract: In recent decade safety of medical and biological products has been concerned in the light of benefit/risks and risk assessment. For new medical products and new drugs, unanticipated side effects that rise after consuming the new product is a dominant factor in decision making. The aim of this project is to design a fuzzy inference system for risk assessment of medical cases. Classical risk assessment in the crisp space precisely determines boundary sharply dissevers safe state from unsafe one. In contrary, fuzzy set shows smooth change from safe to unsafe state. It indicates that safety can be considered as a fuzzy issue because plant safety cannot be strictly classified as safe or unsafe, as inherent hazards always occur.
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1. Introduction

Today's healthcare products are developed and used within a complex system involving a number of key participants (Report to the FDA commissioner, 1999). The choice to use a drug, biological product, or device involves balancing the benefits to be gained with the potential risks of using a product (Report to the FDA commissioner, 1999). In recent decades safety of medical products have been concerned in the light of several types of risks and risk assessment. For new products, unanticipated side effects that rise after consuming the new product is a dominant factor. In addition, FDAs focused on ensuring the appropriate use of products in medical practice. Some reports have focused on the human/economic costs of medication errors, as well as serious adverse events that have occurred even when a medical product has been used appropriately (Report to the FDA commissioner, 1999). Risks have different source, hence effective management of each is different. To understand the complexity of risk assessment and management of medical products, it is important to understand the types/source of risks and its assessment. Figure 1 shows, FDA evaluates the risks/benefits for the population, the prescriber manages risks/benefits for the individual and patients make decisions about treatment choices based on their personal assessment of benefits/risks.

Security in any system should be commensurate with its risks. However, the process to determine which security controls are appropriate and cost effective is quite often a complex and sometimes a subjective matter. One of the prime functions of security risk analysis is to put this process onto a more objective basis. There are a number of distinct approaches to risk analysis. However, these essentially break down into two types: quantitative and qualitative (www.security-risk-analysis.com) Quantitative risk assessment employs two fundamental elements; the probability of an event occurring and the likely loss should it occur. Quantitative medical risk analysis makes use of a single figure produced from these elements. This is called the 'Annual Loss Expectancy (ALE)' or the 'Estimated Annual Cost (EAC)'. This is calculated for an event by simply multiplying the potential loss by the probability. It is thus theoretically possible to rank events in order of risk (ALE) and to make decisions based upon this. The problems with this type of risk analysis are usually associated with the unreliability and inaccuracy of the data (www.security-risk-analysis.com) Probability can rarely be precise and can, in some cases, promote complacency. In addition, controls and countermeasures often tackle a number of potential events and the events themselves are frequently interrelated. Notwithstanding the drawbacks, a number of organisations have successfully adopted quantitative risk analysis (www.security-risk-analysis.com).

In this paper, a fuzzy logic system (Zadeh, 1965; 1968; 1973; 1984; Ramadan *et al.* 2012; Hanafy, 2011; Emarah *et al.* 2011;) is designed to perform a systematic risk assessment in medical globe. The presented system is applied for a case of medical risk analysis and the results are assessed and discussed.

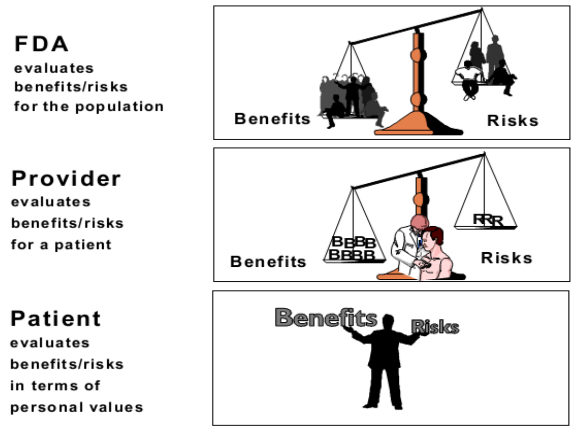

Figure 1. On balancing risks and benefits, FDA evaluates the risks/benefits for the population, the prescriber manages risks/benefits for the individual and patients make decisions about treatment choices based on their personal assessment of benefits/risks (Report to the FDA commissioner, 1999).

2. Constructed Fuzzy Inference System

The category of frequency of consequence is represented by numbers from 1 to 5, where category 1 is for very low frequency and opposite category 5 is for very high frequency. The member functions for frequencies are shown in figure 2.

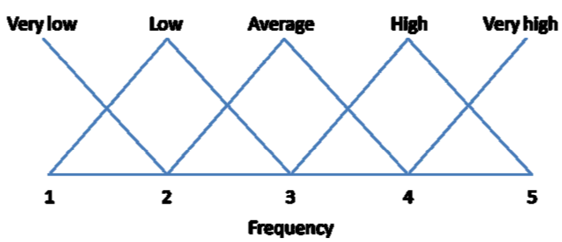

Figure 2. Fuzzy Set for the definition of Frequency

The category of severity of consequence is represented by numbers from 1 to 5, where category 1 is for negligible severity and opposite category 5 is for catastrophic severity.

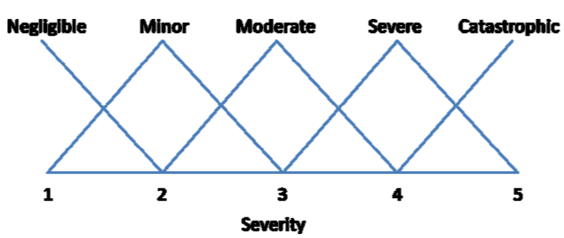

Figure 3. Fuzzy set for the definition of Severity

The category of medical risk is represented by numbers from 0 to 10 as demonstrated below.

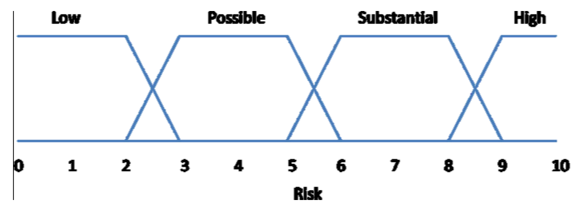

Figure 4. Fuzzy set for the definition of Risk

3. Fault tree

For this work, a simple fault tree could be considered as figure 5. This is a typical fault tree to be applied for a systematic fuzzy interface.

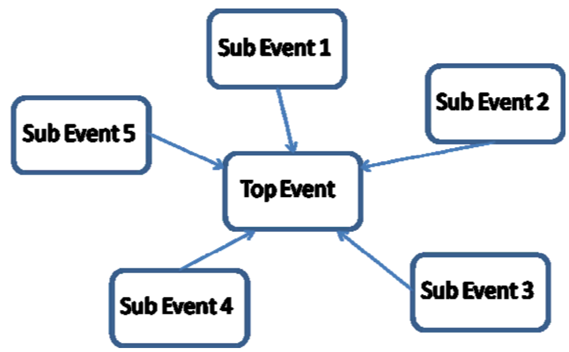

Figure 5. Typical fault tree

4. Rule Table

A set of 25 rules is prepared for this work. As an example "If Frequency is high and Severity is moderate then the risk is substantial". Such a rule table is constructed to predict the state of risk assessed for different states in severity and frequency. The performed table of variation in risk can be as table 1.

5. Data generation

We can normalize data points to be within a specific range. In this case, data points are normalized to the range of [0,1]. Although, raw data points could be used as they are all in the range of 1 to 5.

Table 1. A part of constructed fuzzy data base

Some sets of the fuzzy data base (32768 points)					
Frequency of medical sub event 1	Frequency of medical sub event 2	Frequency of medical sub event 3	Frequency of medical sub event 4	Frequency of medical sub event 5	Overall frequency
1.25 (0.75 V.low, 0.25 Low)	1.25 (0.75 V.low, 0.25 Low)	1.25 (0.75 V.low, 0.25 Low)	1.25 (0.75 V.low, 0.25 Low)	1.25 (0.75 V.low, 0.25 Low)	1.375
1.25 (0.75 V.low, 0.25 Low)	1.25 (0.75 V.low, 0.25 Low)	1.25 (0.75 V.low, 0.25 Low)	1.25 (0.75 V.low, 0.25 Low)	1.75 (0.25 V.low, 0.75 Low)	1.425
1.25 (0.75 V.low, 0.25 Low)	1.25 (0.75 V.low, 0.25 Low)	1.25 (0.75 V.low, 0.25 Low)	1.25 (0.75 V.low, 0.25 Low)	2.25 (0.75 Low, 0.25 Average)	1.575
1.25 (0.75 V.low, 0.25 Low)	1.25 (0.75 V.low, 0.25 Low)	1.25 (0.75 V.low, 0.25 Low)	1.75 (0.25 V.low, 0.75 Low)	2.25 (0.75 Low, 0.25 Average)	1.625
1.25 (0.75 V.low, 0.25 Low)	1.25 (0.75 V.low, 0.25 Low)	1.25 (0.75 V.low, 0.25 Low)	2.75 (0.25 Low, 0.75 Average)	4.75 (0.25 High, 0.75 V. High)	2.275
1.25 (0.75 V.low, 0.25 Low)	1.75 (0.25 V.low, 0.75 Low)	1.25 (0.75 V.low, 0.25 Low)	3.25 (0.75 Average, 0.25 High)	3.75 (0.25 Average, 0.75 High)	2.275
1.25 (0.75 V.low, 0.25 Low)	1.75 (0.25 V.low, 0.75 Low)	3.25 (0.75 Average, 0.25 High)	2.75 (0.25 Low, 0.75 Average)	4.75 (0.25 High, 0.75 V. High)	2.725
2.25 (0.75 Low, 0.25 Average)	2.75 (0.25 Low, 0.75 Average)	3.25 (0.75 Average, 0.25 High)	1.75 (0.25 V.low, 0.75 Low)	4.75 (0.25 High, 0.75 V. High)	2.925
3.25 (0.75 Average, 0.25 High)	4.75 (0.25 High, 0.75 V. High)	1.25 (0.75 V.low, 0.25 Low)	2.75 (0.25 Low, 0.75 Average)	4.75 (0.25 High, 0.75 V. High)	3.325
4.75 (0.25 High, 0.75 V. High)	4.75 (0.25 High, 0.75 V. High)	4.75 (0.25 High, 0.75 V. High)	4.75 (0.25 High, 0.75 V. High)	4.75 (0.25 High, 0.75 V. High)	4.62

Table 2. Normalized data base

Sample of the normalized training data base (32768 points)					
Frequency of sub event 1	Frequency of sub event 2	Frequency of sub event 3	Frequenc y of sub event 4	Frequen cy of sub event 5	Overall frequency
0.0625	0.0625	0.0625	0.0625	0.0625	0.09375
0.0625	0.0625	0.0625	0.0625	0.1875	0.10625
0.0625	0.0625	0.0625	0.0625	0.3125	0.14375
0.0625	0.0625	0.0625	0.1875	0.3125	0.15625
0.0625	0.0625	0.0625	0.4375	0.9375	0.31875
0.0625	0.1875	0.0625	0.5625	0.6875	0.31875
0.0625	0.1875	0.5625	0.4375	0.9375	0.43125
0.3125	0.4375	0.5625	0.1875	0.9375	0.48125
0.5625	0.9375	0.0625	0.4375	0.9375	0.58125
0.9375	0.9375	0.9375	0.9375	0.9375	0.905

6. Conclusions

The choice to use a new drug, biological product, or medical device involves balancing the benefits and risks of the product. There are many different approaches to medical risk assessment such as classical models based on possibility and probability and calculation of risk results from the product of frequency and severity. Fuzzy logic as a new approach to risk analysis is presented as one of the best ways to deal with all the types of risk assessment including lack of knowledge. In this paper, a fuzzy logic interface is applied for a systematic risk assessment on a simple fault tree. This shows how fuzzy logic could be applied to the aim of risk assessment. The fuzzy sets could be optimized based on the obtained results.

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