A Fuzzy Inference System as a Risk Analysis Tool to Prioritize Risks in Medication Dispensing Process

Salini Mettu, Rene V. Mayorga, Wei Peng

***Abstract*—** In this paper, a Fuzzy Inference System (FIS) is developed as a risk analysis tool to prioritize risks involved in drug dispensing process at pharmacies. The tool uses Bow-tie analysis and Fuzzy concepts to analyze and prioritize a risk by computing its score. The risks, risk factors, and impacts are identified based on reported events and expert's knowledge. Bow-tie analysis is used to determine the factors that cause the occurrence of a risk and the impacts of a risk. Fuzzy estimates for the risk factors and impacts are obtained from an expert. The developed Mamdani FIS is used to compute the risk score. The developed FIS risk analysis tool is applied to assess the risks in a drug dispensing process in a pharmacy. For comparison, Failure Mode Effects Analysis (FMEA) is also applied on the drug dispensing process and the results are shown to be similar. Proper mitigation plans are suggested to control the risk events based on their risk score, thus improving patient safety by reducing the number of risk events i.e., medication errors.

***Keywords*—** Mamdani Fuzzy Inference System, Patient Safety, Medication Dispensing Errors, Bow-tie analysis, Fuzzy Inference Systems, Risk Analysis

I. INTRODUCTION

One of the highest priority issue for all professionals like doctors, pharmacists, and health care providers is patient safety. It can be defined as "the prevention of harm to patients, from either errors of commission or omission", (Teinila et al., 2008). Many other countries have several research programs to deal with issues related to patient safety. Kohn (2000) defined medical errors as “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim”. Medical errors occur frequently. In Canada, medical reporting is not mandatory, so comprehensive accurate data on medical errors does not exist, (David, 2001). Therefore by analyzing US statistics related to number of deaths in US 1999, it is clear that deaths due to medical errors is greater than the deaths due to car accidents, breast cancer and AIDS, (Kohn, 2000). As of 2013, the third leading cause of deaths in US is medical errors, (Allen, 2013). One type of medical errors which causes adverse drug events is medication errors. “A medication error” is defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer" (Shah, 2009). They cause harm to patients as well as costly to the healthcare system. Extrapolation from the US information shows that an estimated 2% of hospitalized patients encounter a preventable adverse drug event and an expected 700 deaths for every year result from medication errors (Nair et al., 2010). Few medication errors, which happen due to unintended drug reactions, are unpreventable. But most of the medication errors which happen due to organizational failure can be controlled. To improve patient safety effectively, the occurrences of medication errors need to be reduced. "Medication errors occur during drug prescribing, drug dispensing and drug administration stages in the medication use process" (Shah, 2009). Drug prescribing is the process of giving authorization to a patient to use a medicine by a medical practitioner (such as doctors, dentists). Drug dispensing is the process of dispensing a drug as prescribed in the prescription. Typically, drug dispensing is done by pharmacists in a pharmacy. Drug administration is the path by which a drug enters into the body. Mostly drug administration is done by the nurses in many settings.

Occupational health and safety management program dedicates a substantial effort to risk analysis. This includes being conscious of risks, recognizing who might be at risk, deciding if existing control measures are satisfactory or if additional measures should be implemented, and protecting against injuries or illness. When executed at the designing or planning stage, prioritizing risks and the necessary control measures are essential to set up the plan. In health care industry, risks to patients are common. In order to reduce the risk exposure to patients, organizations must have suitable risk analysis tools to analyse and monitor risks. Many methods, such as: Root Cause Analysis, Failure Mode Effect Analysis, Bow-tie analysis and others exist to perform risk analysis (Jie et al., 2012). The work reported herein focuses on risk analysis of medication errors as the risk or risk event occurring in a

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pharmacy. The highest frequency of medication errors occurs during the drug dispensing process which is the paper research focus (Certina, 2010). In today's world, Intelligent Systems techniques from the Soft Computing field have proven to be very effective in solving many real world problems. Some of the available and widely used Intelligent Systems techniques include: Artificial Neural Networks (ANNs), Fuzzy Logic (FL) and General Algorithms (GAs). Applications range from characterization, identification, modification and control. Many decision making methodologies are based on Fuzzy Logic. Fuzzy Inference Systems (FIS) have the ability to handle real world problems that are based on user knowledge and experience and can also deal with uncertain, incomplete and vague data, (Aqlan and Ali, 2014). The purpose of selecting Intelligent Systems techniques is to create a convenient user interface and to reduce the amount of work to be done by the user.

Structure of the paper: Abstract**,** Introduction, Error reporting, Patient safety, Methodology framework, Case study, Conclusions.

II. ERROR REPORTING

Error reporting has become an important topic in pharmacy in Canada. Each province in Canada track and reports medication errors in different ways. According to National Association of Pharmacy Regulatory Authorities, total number of community pharmacies in Canada are 9,750 as of January, 1, 2016. Nearly 38,000 pharmacists dispense more than half a billion prescriptions in Canada annually. There is no consistent, mandatory or regulated process for reporting errors by pharmacists across Canada, (Pharmacy errors, 2015). However Nova Scotia has implemented a mandatory tracking tools for the pharmacists to report errors as well as near misses. In 2008, the province's mandatory but anonymous, SafteyNetRX, reporting system was first launched. Only 13 pharmacies participated and reported 813 potential errors in just eight months in its initial stage. Once the program became mandatory for all pharmacies in Nova Scotia, 75,000 medication errors were reported over three years period, (Howorun, 2016). COMPASS (Community Pharmacists Advancing Safety in Saskatchewan), a version of SafteyNetRX has been launched in the province of Saskatchewan recently. Most of the pharmacists use Root cause analysis method to find out the risk factors after the medication errors happened. In Canada, So far no risk analysis instrument exists in a Pharmacy that can be used to analyze and visualize risks, causes and consequences of potential adverse events in a prospective manner. If error reporting is made mandatory in Canada, then pharmacists would report each and every error along with the impacts on the patients. A more comprehensive analysis of risk and the affect on patient health could be modeled with the tool developed herein. Pharmacists can use the model on a monthly or weekly basis to check which error is mostly likely to happen then based on the frequency of risk that the model can adapt to the changing environment based on factors and corresponding impacts. Preventive measures to reduce the risk is recommended. A further feature of the tool is the reported errors to provide relevant risk analysis and corresponding preventive or corrective actions.

III. METHOD TO IMPROVE PATIENT SAFETY

Analyzing and assessment of risks and determining the possible causes is the first step to improve patient safety. Risk event is caused by a set of risk factors and has various impacts. Risk is defined as the "probability of occurrence of a risk event multiplied by the impact of that risk event. It has three components, namely, risk factors, the risk or risk event, and its impacts", (Aqlan and Ali, 2014). To develop useful methods for risk analysis in patient safety, this knowledge of Bow - Tie analysis risk management method as used in the high risk industries is applied to medication dispensing process.

A. Intelligent systems techniques

In today's world, Intelligent Systems techniques from the Soft Computing field have proven to be very effective in solving many real world problems. Applications range from characterization, identification, modification and control. Many decision making methodologies are based on Fuzzy Logic. Fuzzy Inference Systems (FIS) have the ability to handle real world problems that are based on user knowledge and experience and can also deal with uncertain, incomplete and vague data, (Aqlan and Ali, 2014). The purpose of selecting intelligent techniques is to create a convenient user interface and to reduce the amount of work to be done by the user. The health care industry is no stranger to the fuzzy logic applications. Recently Hussain A, Wenbi R, Xiaosong Z, Hongyang W & Silva A developed a personal home healthcare system for the cardiac patient using fuzzy logic, which can provide an innovative, timely resource and a supplement for the existing healthcare systems to treat efficiently to cardiac patients who lived alone at their homes. The research reported herein uses the fuzzy logic concepts to reduce the uncertainty in the estimated risk parameters.

B. Fuzzy inference system

The basic components of a Fuzzy inference system are rule base; It contains a set of well defined fuzzy if-then rules, data base; It defines the different membership functions that are used in the Fuzzy if-then rules, and reasoning mechanism; This performs the inference procedure upon the rules and given facts to derive a conclusion. Fuzzy inference system uses the concepts of fuzzy sets, fuzzy if - then rules and fuzzy reasoning altogether. Fuzzy inference system takes either fuzzy inputs or crisp inputs. The FIS output can be either crisp or fuzzy depending upon the type of FIS used in the Research. Different types of FIS models are used in solving variety of problems (Jang et al., 1997). This research used Mamdani fuzzy inference model.

C. *Bow-tie analysis*

Bow-tie analysis is based on the principles of event tree analysis and fault tree analysis, (Wierenga et al., 2009). It is a risk analysis instrument which is widely used in the petrochemical and other high risk industries. Bow-tie analysis combines risk factors, risk events, impacts and risk reducers in one model. Risk factors are the causes that triggers a risk event to happen in the system. Risk impact is the consequence of a risk event on the system. Each risk event is caused by a set of risk factors and has a set of impacts. Risk reducers are divided into two types: preventive barriers and protective barriers. Preventive barriers are used to prevent the probability of occurrence of a risk event; hence come before the risk event. Protective barriers are used to reduce the impacts of a risk event; hence follow the risk event (Aqlan and Ali, 2014). The Bow-Tie diagram analysis is illustrated in the Appendix in the Figure A-1 .

Now-a-days pharmacists use root cause analysis research approach to identify the root causes of failures or problems in the drug dispensing process. In root cause analysis, it is not possible to show a statistical correlation between risk factors and risk impacts. Also root cause analysis is applied only after a risk has happened. In contrast, Bow-tie analysis is used in advance i.e., before the occurrence of a risk event. It also gives the correlation between risk factors and impact. Hence by implementing proper mitigation plans, the occurrence of risk events can be controlled.

IV. METHODOLOGY FRAMEWORK

The objective of this research is to design a tool, which can be used in any pharmacy as a risk analysis tool. The steps involved in designing the fuzzy risk analysis tool are showed in Figure - 1

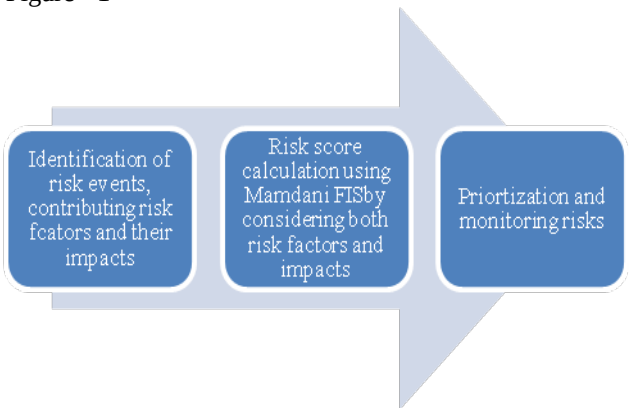

Figure - 1 Steps involved in Fuzzy risk analysis tool

A. *Identification*

Major risk events that can occur in the industry are identified in the first step. Identification of risk events can be done in many ways like based on the history of risk events that happened in the industry previously or by conducting interviews to the experienced employees working in the industry or from the available literature resources. In order to perform bow- tie analysis, major risk factors that contributes to the risk event and impacts of the corresponding risk events are identified. Each risk event can have one or more risk factor and also one or more impact. Bow-tie analysis is performed. Bow-tie diagrams are used to show the links between the risk factors, risk event and impacts. It is the best way to communicate risk assessment in a simple and effective manner.

B. *Risk score calculation*

It is very important to control and monitor those risks for the smooth function of the industry. Fuzzy estimate for the probability of occurrence of the risk factor and its impact are obtained. Risk score of a risk event is the combination of Probability of occurrence score and impact score. Calculating the risk score helps in prioritizing the risks and appropriate mitigation plans can be implemented. This research considers both risk factors and impacts of a risk event to calculate risk score using Mamdani fuzzy inference system (FIS). By using MATLAB 2010 a package, Mamdani FIS is applied in different scenarios. Each FIS shown in the Figures 2, 3 & 4 has different rules from each other that are based on their function. Risk score calculation involves following stages.

In *Stage* 1, Probability of occurrence score of a risk event is calculated by giving probability of occurrence of its risk factors as inputs to the Mamdani FIS. FIS gives the output based on the fuzzy if-then rules that are defined based on the human expertise. Suppose a Risk event RE- 1 is caused due to two risk factors, RF-1 and RF-2, then the design to compute probability of occurrence score is as shown in Figure - 2.

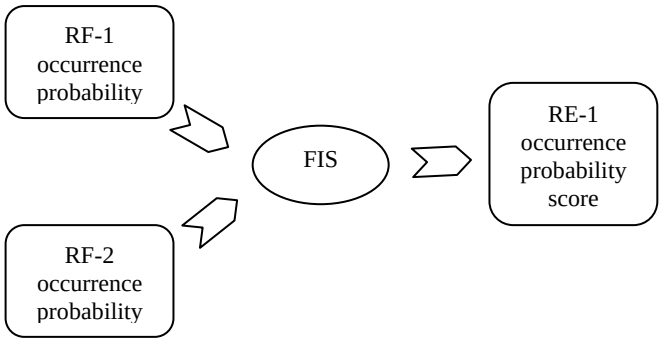

Figure - 2
Probability of occurrence score calculation

In *Stage* 2, Impact score of a risk event is calculated by giving the intensity level of each impact as inputs to the FIS. The output is computed based on the defined fuzzy if-then rules. Suppose the Risk Event RE-1 has two Impacts, IMP-1 and IMP-2, then the Impact score of a RE-1 is computed as shown in Figure -3.

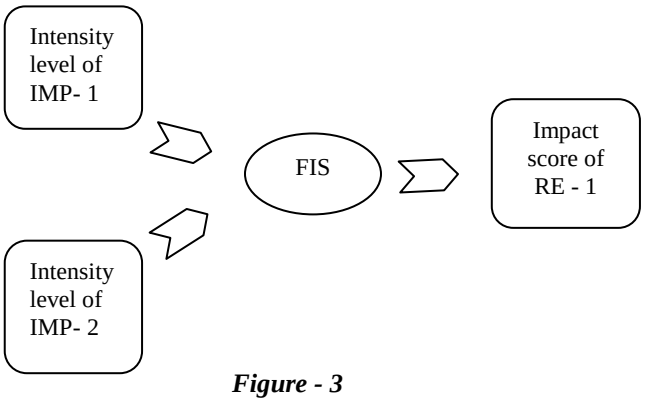

Figure - 3
Impact score calculation of a risk event

In *Stage* 3, risk score is calculated by using Probability of occurrence score and Impact score as inputs to Mamdani FIS as shown in Figure - 4.

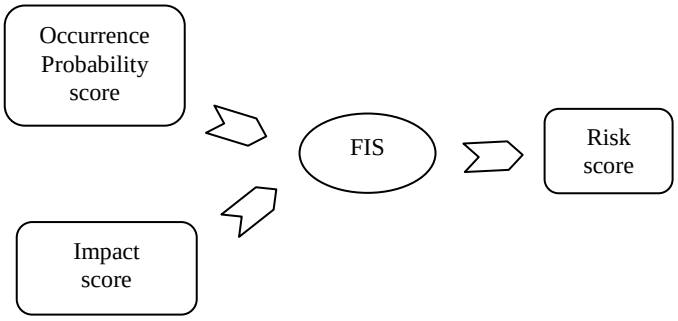

Figure - 4
Risk score calculation of a risk event

C. Prioritization and monitoring the risks

For any industry or organization, there are many risks, risk factors and impacts. Hence there are many blocks as explained above for calculating Probability of occurrence score, Impact score and Risk score. All these blocks are integrated into a single framework, which is illustrated in the Appendix in the Figure A-2.

Based on the computed risk score, the risks are prioritized. Risk events with high risk scores are identified and proper mitigation strategies are applied in order to avoid the risk events to happen in the industry.

V. CASE STUDY

The proposed FIS risk analysis model is used in the drug dispensing process in a pharmasave, keremeos, BC to improve patient safety. A pharmacist has been working in pharmasave since April, 2015. The pharmacist was interviewed about major risk events, risk factors and their impacts that happened in their store. She answered to the questions based on her experience. The inputs i.e., probability of occurrence of each risk factor and the intensity level of each risk impact are obtained from her. The rules in the fuzzy inference systems are defined based on her expertise. Medication error results a great negative impact on the patient life. The processes in which medication errors arise are Prescribing, dispensing and administration of the medication use process. Among these processes, medication errors happen most in drug dispensing stage, (Wierenga et al., 2009). Hence drug dispensing process is considered in this research. The main risk events identified in a drug dispensing process in a community pharmacy, their risk factors and impacts based on the interviews held to the pharmacists, are shown in Table 4 and Table 5 respectively. The overall framework to calculate risk score in pharmacy drug dispensing process using Mamdani FIS and Bow-tie analysis is shown in Figure A-2. In order to simulate various fuzzy inference systems that are described in the proposed methodology, MATLAB is used. The fuzzy models that are used in the proposed methodology are Mamdani fuzzy inference models. Triangular membership functions are used in the Mamdani fuzzy inference systems. Centroid defuzzification method is used to obtain a crisp value as output from the Mamdani fuzzy inference systems. The linguistic variables and fuzzy numbers used in all the Fuzzy inference systems in the proposed framework; Figure A-2 are tabulated in Table - 1, Table - 2 and Table - 3. The inputs that are obtained from the Pharmacist are Probability of occurrence of risk factors and level of intensity of impacts for corresponding risk events. These inputs are tabulated in the Table - 4 and Table - 5. The proposed methodology is applied to the pharmacy setting by using the tabulated inputs. The risk score to each risk event is shown in Table - 6. From Table - 6, it is clearly seen that RE - 5 and RE - 4 has high risk scores when compared to others. Hence mitigation plans related to RE - 5 and RE - 4 are first implemented.

Table - 1 Occurrence linguistic variables and their corresponding fuzzy numbers

Linguistic Variables	Characteristic function of fuzzy numbers
Expected	(0.7, 0.9, 1.0)
Possible	(0.5, 0.7, 0.9)
Unlikely	(0.3, 0.5, 0.7)
Very unlikely	(0.1, 0.3, 0.5)
Not expected	(0.0, 0.1, 0.3)

Table - 2 Impact linguistic variables and their corresponding fuzzy numbers

Linguistic Variables	Characteristic function of fuzzy numbers
High	(0.7, 0.9, 1.0)
Medium	(0.5, 0.7, 0.9)
Low	(0.3, 0.5, 0.7)
Very Low	(0.1, 0.3, 0.5)
None	(0.0, 0.1, 0.3)

Table - 3 Risk score linguistic variables and their corresponding fuzzy numbers

Linguistic Variables	Corresponding fuzzy numbers	Characteristic function of fuzzy numbers
High	80	(40, 80, 100)
Medium	40	(20, 40, 60)
Low	20	(0, 20, 40)

Table – 4 Probability of occurrence of risk factors

No.	Risk events	Risk factors	Probability of Occurrence
RE- 1	Transcription error	Ambiguous prescription	0.4
		Incorrect entry	0.3
RE - 2	Patient Misidentification	Similar names	0.2
RE - 3	Labeling error	Clutter on table	0.9
		Untrained staff	0.7
RE - 4	Interruptions	Phone calls	0.7
		Understaffing	0.8
RE - 5	Wrong drug dispensing	Look alike/sound alike drugs	0.7
		Skip patient's counselling	0.4
		Unorganized work flow	0.5
RE - 6	Pharmacist distraction	Meal breaks issue	0.5
		Improper room conditions	0.4

A. Preventive measures and protective measures for the identified risk events

Preventive measures and protective measures plays a very important role in any industry to avoid the occurrence of risk event and to reduce the impact of occurred risk event, respectively. This section discusses the preventive measures and protective measures for the drug dispensing process.

Transcription error

Preventive measures: Electronic exchange of information, usage of non-standard abbreviations must be avoided.

Protective measures: Read the complete drug name, read back to the caller (doctor), and document the clarifications.

Patient misidentification

Preventive measures: Develop standardized process requiring documentation of the second identifier, post info on the wall for patients explaining the importance of identity verification process.

Protective measures: Cross check with patient's medication allergies.

Labeling error

Preventive measures: Organizing the pharmacist table frequently, educate all pharmacy technicians on their roles.

Protective measures: Proper training should be given to the technicians, serious action should be taken on the person who does not deliver their duties properly.

Interruptions

Preventive measures: Separate phone line for doctor/pharmacist communication, non dispensing functions should be separated from prescription area, proper staff scheduling.

Protective measures: Specific staff to attend phone calls.

Table - 5 Impact intensity of risk impacts

No.	Risk events	Impacts	Impact intensity
RE- 1	Transcription error	Wrong medication to the patient	0.6
RE - 2	Patient Misidentification	Incorrect prescription released to the patient	0.5
		Side effects to patients	0.8
RE - 3	Labeling error	Delivery of wrong drug	0.4
RE - 4	Interruptions	Delay in medication dispensing	0.6
		Pharmacist inefficiency	0.5
RE - 5	Wrong drug dispensing	Patient side effects	0.9
		Patient mortality	0.7
RE - 6	Pharmacist distraction	Delivery of improper duties	0.5
		Prescription error	0.4

Wrong drug dispensing

Preventive measures: Picture of medication on the screen, to make sure all prescription stock bottles have their labels facing forward, checks should be done at every stage of drug dispensing, periodic inspection by the supervisor on the expiration of the drugs.

Protective measures: Follow “show & tell medication” in patient’s counseling, final check on the prescription container contents with the prescribed label.

Pharmacist distraction

Preventive measures: Proper scheduling of meal breaks to the pharmacists, Separate pharmacist service counter.

Protective measures: Check the filled in prescription and drugs container by second pharmacist

Hence by implementing proper mitigation plans, the occurrence of risk events can be controlled.

Table - 6 Probability of occurrence score (OS), impact score (IS) and risk score (RS) for all the risk events

No.	Risk events	OS	IS	RS	Rank
RE - 1	Transcription error	0.51	0.6	44.6	4
RE - 2	Patient misidentification	0.238	0.667	33.1	5
RE - 3	Labelling error	0.567	0.4	30	6
RE - 4	Interruptions	0.667	0.546	52.3	2
RE -5	Wrong drug delivery	0.522	0.767	55.8	1
RE - 6	Pharmacist distraction	0.591	0.517	46.9	3

B. Comparison of FIS Risk Analysis Tool Results on Pharmacy Drug Dispensing Process with FMEA

Failure Mode Effects Analysis (FMEA) is one of the risk analysis methods which is widely used in non - health care industries (Reiley, 2000). In FMEA risks are treated as failure modes. For each of the identified failure mode, three measures were done. They are "rate of occurrence", "severity" and "ease of detection" (Reiley, 2000). Each failure mode was assigned with a Risk Priority Number (RPN). Based on the RPN, the criticality of the failure modes were identified. Risk priority number is calculated as follows:

" RPN = rate of occurrence (O) x severity (S) x ease of detection (D) " (Reiley, 2000)

The inputs for occurrence, severity and detection to calculate the RPN for the identified risks are obtained from the pharmacist. Table 10 shows the risk ranking on application of FMEA method and FIS risk analysis methods on drug dispensing process at pharmacy. The ratings for the rate of occurrence, severity and ease of detections is shown in Table 7, Table 8, and Table 9 respectively. The results from the Table 6 and Table 10 are compared with each other. They are agreeable with each other and hence it shows the verification of the FIS risk analysis tool.

Table - 7 Rating the occurrence of failure mode effects (Greenall et al., 2007)

Frequency	Score
Yearly	1
Monthly	2
Weekly	3
Daily	4
Hourly	5

Table - 8 Rating the severity of failure mode effects (Greenall et al., 2007)

Severity	*Score*	*Description*
No effect	1	Effect is not noticeable
Slight effect	2	Less effects to the patient
Moderate effect	3	Minor performance loss
Major effect	4	High performance loss
Severe effect	5	Higher permanent loss

Table - 9 Rating the detect ability of failure mode effects (Greenall et al., 2007)

Detectability	Score
Always	1
Likely	2
Unlikely	3
Very unlikely	4
Never	5

It is important to mention that the FMEA doesn't consider the risk factors and impacts of a risk event while calculating the risk rank. Whereas, the proposed methodology considers them to calculate the risk score. This is the reason for different ranks allotment to risk events 4 and 5 in both methods.

Table - 10 RPN for the identified risks in the drug dispensing process at pharmacy

Risk event	O	S	D	RPN	FMEA rank	FIS rank
Transcription error	3	3	4	36	4	4
Patient misidentification	2	4	4	32	5	5
Labeling error	5	2	3	30	6	6
Interruptions	5	4	4	90	1	2
Wrong drug delivery	4	5	3	60	2	1
Pharmacist distraction	3	4	4	48	3	3

VI. CONCLUSIONS

On implementing this intelligent risk analysis tool in the pharmacy drug dispensing process, it was found that the risk events - wrong drug delivery and error due to interruptions occur frequently. Hence suggested protective and preventive measures in the Section 4.1 should be implemented to reduce the medication errors. However, the risk score to the risk events is completely based on the inputs given by the pharmacist. Hence the ranking of the risk events may vary dynamically based on the errors frequency in the pharmacy. This paper demonstrates that fuzzy modeling can be applied to drug dispensing process, providing an important and relevant improvement for risk analysis and related problems. These traits characterized this application as literature resources provided a large amount of data and with mandatory error reporting not required, the information is incomplete and based on the interview to define risk, uncertainty was present. The combination of Fuzzy Inference systems and Bow - tie analysis assigns a different risk score to each risk event. This makes easier for an organization to choose the mitigation strategies. The risk analysis tool developed in this paper is very useful for pharmacists as it provides an outlook of errors happening and controlling ways in the drug dispensing process. In order to verify the proposed FIS risk analysis tool, the results are compared against FMEA method results on drug dispensing process and the results are found to be similar.

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APPENDIX

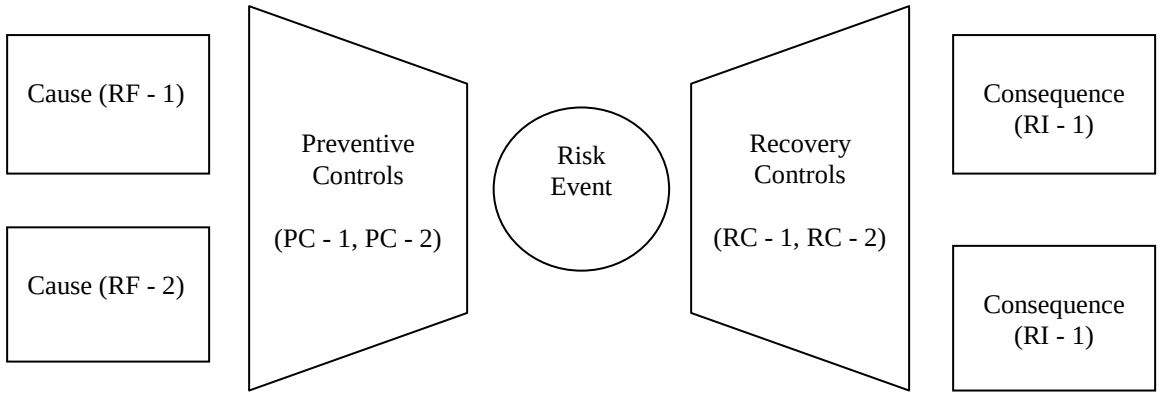

Figure – A-1 Bow-tie analysis (RF - Risk factor; PC - Preventive controls; RC - Recovery controls; RI - Risk impacts)

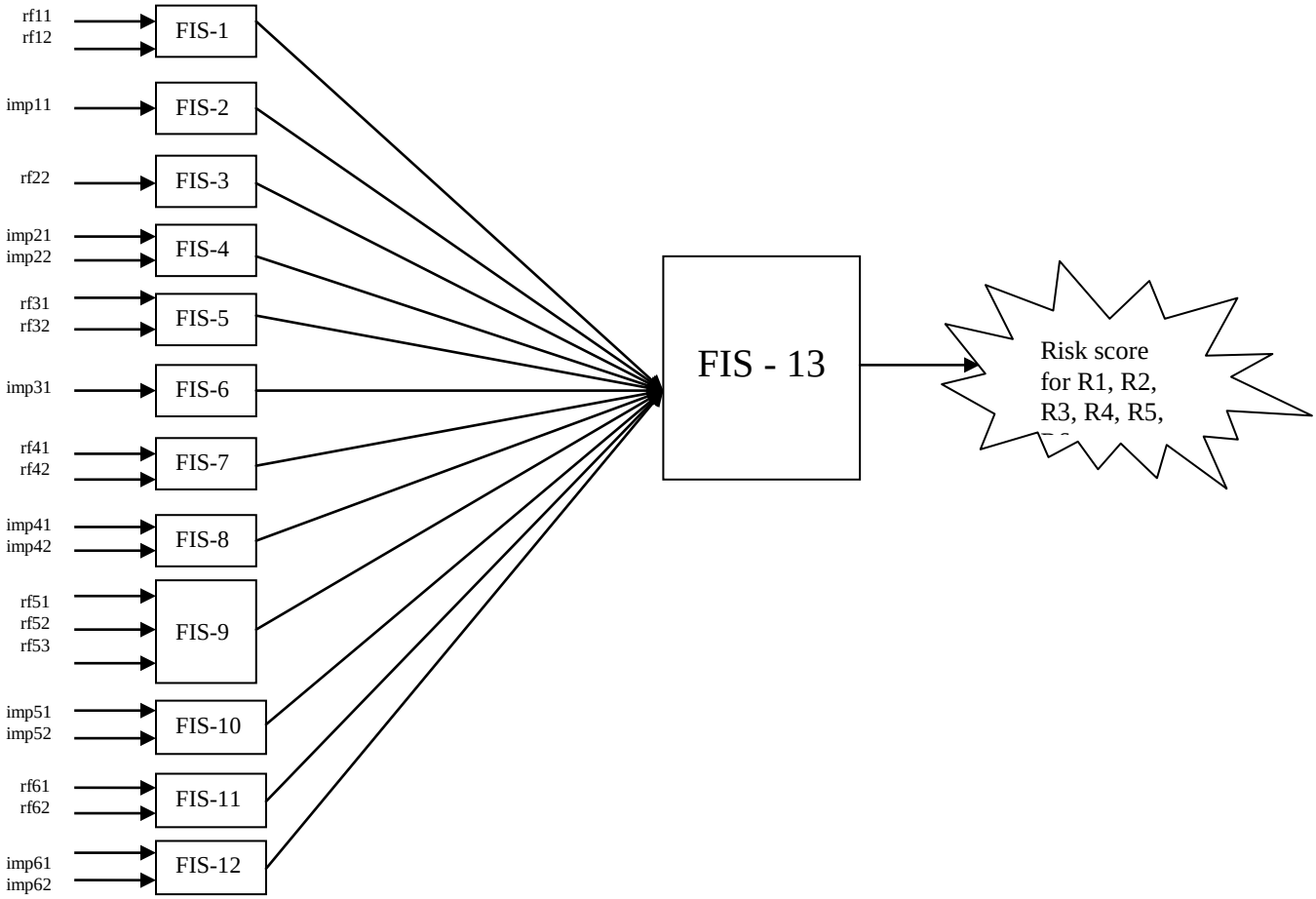

Figure – A-2 Complete framework to calculate risk score using Mamdani FIS and Bow-tie analysis