FUZZY LOGIC-BASED HAZARD ASSESSMENT OF MEDICAL DEVICES IN A NIGERIAN HEALTHCARE FACILITY: A CASE STUDY OF FEDERAL MEDICAL CENTRE (FMC) UMUAHIA

***Ugboaja, S. G.[1], and Iroegbu, C.[2]**

[1]Department of Computer Science, Michael Okpara University of Agriculture, Umudike
[2]Department of Electrical/Electronic Engineering, Michael Okpara University of Agriculture, Umudike

*Corresponding Author: iroegbu.chibuisi@mouau.edu.ng

ABSTRACT

The growing complexity of medical devices in healthcare facilities requires effective hazard assessment methods to improve patient safety, equipment reliability, and healthcare delivery. This study developed a Fuzzy Logic-Based Hazard Assessment of Medical Devices in a Nigerian Healthcare Facility. Data were obtained through questionnaires, interviews, and document reviews to assess equipment procurement, utilization, maintenance, calibration, and training practices. A MATLAB/Simulink Fuzzy Logic-Based Hazard Assessment of Medical Devices model was developed using expert knowledge and two fuzzy inference stages to evaluate consequence factors and failure probabilities for overall risk estimation. Findings revealed that although maintenance procedures exist in the hospital, preventive maintenance practices need further improvement. The proposed fuzzy model effectively managed uncertainty and complex hazard relationships, providing a support tool for risk identification, prioritization, and medical equipment management. The study demonstrates the potential of fuzzy logic in providing medical device safety assessment, especially in resource-limited healthcare environments.

Keywords: Medical devices, Hazard assessment, Fuzzy logic, Risk assessment, Fuzzy inference system, Healthcare technology management, MATLAB/Simulink.

1.0 INTRODUCTION

Nigeria's healthcare system is organized into a three-tier structure comprising primary, secondary, and tertiary levels of care. Primary healthcare services, managed mainly by local governments, provide preventive and basic curative services through primary healthcare centers and community health posts. Secondary healthcare services are provided by state-owned general hospitals, while tertiary healthcare services are delivered through specialized and teaching hospitals under the supervision of the Federal Government. This decentralized structure is designed to ensure equitable healthcare delivery and an efficient referral system across all levels of care. Despite significant improvements in health policy and infrastructure, disparities in access to quality healthcare, inadequate funding, and shortages of medical equipment continue to pose considerable challenges to effective healthcare delivery in Nigeria (World Health Organization, 2024; Sampson *et al.,* 2024).

Disease prevention remains the cornerstone of Nigeria's healthcare policy; however, considerable investments have also been directed toward expanding hospital infrastructure and strengthening curative healthcare services. The increasing adoption of sophisticated medical technologies—including diagnostic imaging systems, patient monitoring devices, infusion pumps, laboratory analyzers, and Internet of Medical Things (IoMT) devices has significantly improved healthcare delivery. Consequently, there is an increasing demand for effective medical equipment management systems capable of ensuring equipment safety, reliability, maintenance, and regulatory compliance throughout the equipment life cycle (WHO, 2024).

Medical equipment encompasses a broad range of instruments, machines, implants, software, and diagnostic devices used in healthcare settings for disease prevention, diagnosis, treatment, monitoring, rehabilitation, and life support. These technologies are indispensable in modern healthcare because they improve diagnostic accuracy, treatment efficiency, and patient outcomes. However, their increasing complexity also introduces operational, technical, and safety hazards that require systematic assessment and continuous monitoring to minimize risks to patients, healthcare professionals, and healthcare institutions (WHO, 2024).

Hazard refers to any condition, event, or circumstance capable of causing injury, illness, damage, or disruption to an organization's operations. Hazard assessment is a structured process involving hazard identification, hazard analysis, risk evaluation, and implementation of appropriate control measures. It enables organizations to identify potential sources of danger, evaluate the likelihood and severity of adverse events, and determine whether existing controls are adequate to reduce risks to acceptable levels. Within healthcare environments, hazard assessment plays a critical role in ensuring patient safety, minimizing equipment failures, preventing medical errors, and supporting regulatory compliance (Okechukwu *et al.,* 2025)

Healthcare systems are characterized by uncertainty, incomplete information, and highly complex interactions among medical equipment, healthcare personnel, patients, and environmental conditions. Traditional risk assessment methods often rely on precise numerical data, making them less effective in situations where expert judgment and linguistic descriptions are required. Consequently, intelligent computational techniques such as fuzzy logic have gained widespread acceptance in healthcare risk assessment because they effectively represent uncertainty and approximate human reasoning.

Fuzzy logic provides a flexible framework for modelling complex decision-making problems involving imprecise, subjective, or incomplete information. By utilizing linguistic variables and fuzzy inference rules, fuzzy systems closely mimic human reasoning and expert knowledge, making them particularly suitable for hazard assessment applications. Unlike conventional binary logic, fuzzy logic accommodates varying degrees of truth, thereby enabling more realistic modelling of uncertain healthcare environments.

Furthermore, fuzzy logic allows multiple experts' opinions to be integrated into a unified decision-making model, even when those opinions differ or conflict. This capability makes fuzzy systems highly effective for evaluating multidimensional healthcare hazards involving equipment reliability, operational safety, maintenance prioritization, and clinical risk. Recent studies have demonstrated that fuzzy logic-based decision support systems significantly improve hazard identification, risk prioritization, and maintenance planning for medical equipment, thereby enhancing patient safety and healthcare service delivery (Amran, 2024; Pritika, 2024; Benbrahim *et al.,* 2024).

Despite the growing application of fuzzy logic in healthcare risk assessment, significant gaps remain in its application to comprehensive medical-device hazard assessment, particularly within resource-constrained healthcare environments in Nigeria. Existing studies have largely focused on clinical diagnosis, environmental health risks, healthcare cybersecurity, and general decision-support applications, with limited attention to the combined technical, operational, maintenance, human, and safety factors associated with medical equipment. Furthermore, many existing models rely predominantly on expert-defined rules and have limited validation using empirical data from actual healthcare institutions. There is also insufficient integration of medical-device hazard assessment with practical recommendations for maintenance, calibration, training, equipment replacement, and safety improvement. This study therefore addresses the identified gap by developing a fuzzy logic-based hazard assessment of medical devices in a Nigerian healthcare facility, using empirical information and expert knowledge from Federal Medical Centre (FMC), Umuahia. The proposed framework seeks to provide an interpretable and systematic assessment of medical-device hazards and support evidence-based strategies for improving equipment safety, reliability, and healthcare service delivery.

2.0 LITERATURE REVIEW

Medical hazard assessment is a systematic process of identifying, analyzing, evaluating, and controlling risks associated with healthcare delivery. These risks may arise from clinical procedures, medical devices, pharmaceutical products, biological agents, environmental conditions, and occupational activities within healthcare facilities. An effective hazard assessment framework is essential for improving patient safety, reducing medical errors, enhancing healthcare quality, and protecting healthcare workers from occupational risks. However, conventional hazard assessment techniques often encounter significant challenges due to uncertainty, incomplete or imprecise information, subjective expert judgments, and the complex interactions among multiple risk factors. These limitations have motivated researchers to investigate intelligent decision-support approaches such as fuzzy logic, which provides a mathematical framework for representing ambiguity and uncertainty in complex healthcare environments. Recent studies have demonstrated that fuzzy logic has become an important computational tool in healthcare because it effectively models uncertain clinical knowledge while maintaining transparency and interpretability for decision-making.

The theoretical foundation of fuzzy logic was established by Zadeh (1965) through the introduction of fuzzy set theory. Unlike classical Boolean logic, which classifies information into binary true or false values, fuzzy set theory allows elements to possess varying degrees of membership between 0 and 1. This innovation made it possible to represent uncertain, vague, and subjective information mathematically, thereby providing the basis for modern fuzzy inference systems widely applied in healthcare risk assessment and medical decision support.

Torres and Nieto (2006) reviewed the application of fuzzy logic in medicine and bioinformatics and concluded that fuzzy systems effectively capture uncertainty in clinical diagnosis and reasoning. Their findings showed that expert medical knowledge can be incorporated into interpretable computational models capable of improving diagnostic decisions while accommodating incomplete and uncertain clinical information.

Similarly, Ahmadi *et al*. (2018) conducted a systematic review and meta-analysis of fuzzy logic methods applied to disease diagnosis. Their study revealed that fuzzy inference systems significantly improve diagnostic accuracy in situations involving ambiguous symptoms and uncertain clinical evidence. The authors concluded that fuzzy systems simplify diagnostic complexity while providing transparent reasoning that enhances clinicians' confidence in decision-making.

More recently, Liu and Tang (2022) examined the application of the Fuzzy Analytic Hierarchy Process (FAHP) in medical risk assessment. Their review demonstrated that FAHP effectively integrates expert judgment with structured multicriteria decision-making techniques to evaluate complex healthcare risks and prioritize hazard mitigation strategies, particularly where precise quantitative information is unavailable.

A comprehensive review by Salvi *et al*. (2026) analyzed 91 studies published between 2017 and 2025 on fuzzy logic applications in healthcare. The review revealed widespread use of fuzzy systems in disease diagnosis, patient monitoring, treatment planning, and clinical risk prediction. The authors further observed an increasing trend toward hybrid intelligent systems that combine fuzzy logic with machine learning and deep learning techniques to improve prediction accuracy while maintaining the interpretability required for clinical decision support.

Likewise, Jamett *et al*. (2026) reviewed fuzzy logic methods for causal inference in healthcare and found that Fuzzy Inference Systems (FIS), Adaptive Neuro-Fuzzy Inference Systems (ANFIS), Fuzzy Cognitive Maps (FCM), and FAHP are increasingly adopted for healthcare risk prediction and hazard assessment. Despite their promising performance, the authors emphasized that many existing models rely heavily on expert-defined rules and require more extensive clinical validation and benchmarking against conventional statistical and machine learning approaches.

Kaur *et al.* (2020) proposed an ANFIS model for assessing security risks in healthcare web applications by integrating multiple security parameters into a neuro-fuzzy framework. Their results demonstrated that ANFIS significantly improved prediction accuracy compared with traditional rule-based approaches. Although the study focused primarily on healthcare information security, the methodology provides a useful framework for medical hazard assessment because clinical, environmental, and operational risk factors can similarly be incorporated into neuro-fuzzy decision-support systems.

Mohanta and Mishra (2020) developed a Fuzzy Inference System for integrating cancer and non-cancer health risks associated with aniline-contaminated groundwater. Their model successfully combined multiple environmental and health indicators under uncertain conditions, producing more comprehensive risk estimates than deterministic assessment methods. The researchers concluded that fuzzy inference systems are particularly effective when multiple uncertain variables interact simultaneously, making them applicable to broader healthcare hazard assessment problems.

Similarly, Do *et al*. (2020) proposed a hybrid framework combining semi-quantitative risk assessment, composite indicators, and fuzzy logic for evaluating hazardous chemical accidents. Their findings demonstrated that fuzzy logic effectively handles uncertainty in risk estimation and improves safety decision-making. Although the study was conducted in an industrial environment, its methodology is directly relevant to healthcare because hospitals routinely manage hazardous chemicals, infectious materials, pharmaceuticals, and medical waste under uncertain operating conditions.

Overall, the reviewed literature demonstrates that fuzzy logic provides a robust and flexible framework for medical hazard assessment by effectively representing uncertainty, integrating expert knowledge, and supporting multi-criteria decision-making. Fuzzy-based approaches including Fuzzy Inference System (FIS), Adaptive Neuro-Fuzzy Inference System (ANFIS), Fuzzy Analytic Hierarchy Process (FAHP), and Fuzzy C-Means (FCM) have been successfully applied to clinical diagnosis, occupational health, environmental risk assessment, healthcare technology management, and hospital safety evaluation. However, despite these advances, relatively few studies have focused specifically on comprehensive hazard assessment of medical equipment and healthcare systems in developing countries. This research gap underscores the need for improved fuzzy logic-based hazard assessment models tailored to the operational realities of healthcare institutions, particularly in resource-constrained settings.

3.0 METHODOLOGY

3.1. Study on Medical Device Management System

Pre-tested questionnaires were administered to healthcare professionals, patients, and biomedical engineers/technicians at the Federal Medical Centre (FMC), Umuahia. The questionnaire was designed to assess the hospital's practices regarding the procurement, utilization, maintenance, calibration, and training related to medical equipment. Responses were rated on a six-point Likert scale ranging from as 0 - Very poor: 0%, 1 - Poor: 20%, 2 - Fair: 40%, 3 - Good: 60%, 4 - Very good: 80%, and 5 - Excellent: 100% and the collected data were analyzed using the specified data analysis procedures.

To complement the quantitative survey, structured interviews were conducted with biomedical technicians to obtain further insights into the hospital's current practices for procuring and utilizing medical equipment. In addition, questionnaires were administered to Fifty-Six (56) primary users of medical equipment selected from the laboratory, radiology (X-ray), operating theatre, and intensive care unit (ICU) to evaluate the effectiveness of the hospital's medical equipment maintenance management system.

3.2. Degree of Device Standardization

Previous studies have indicated that inadequate standardization of medical equipment, particularly the use of different brands and models, can negatively affect equipment performance and management efficiency. Equipment standardization is commonly evaluated based on two key factors: the manufacturer and the specific model of the device.

$$STD = 1 - \frac{(MOD)+(MAN-1)}{2QTY-1} \tag{1}$$

where,
STD=degree of standardization
QTY = the number of device items sampled from a hospital
MOD = the number of different models in that set of equipment
MAN = the number of different manufacturers for that set of device.
Calculating the degree of standardization in this way was produced a number between 0 and 1, indicating the degree of standardization (McKie, 2019)

3.3. Sources of Data

The data for this study were obtained from both primary and secondary sources.

3.3.1. Primary sources

Primary data were collected from the respondents that are identified as people responsible for the equipment, users both health professionals and patient populations to collect first-hand information.

3.3.2. Secondary sources

We obtained secondary sources of data by analyzing different documents like guidelines, rules and regulation, reports which are related to medical instruments and hospital records were reviewed to acquire the back ground information about issue under study.

3.4. Types of Data and Tools/Instruments of Data Collection

The target populations of the study were people responsible for the equipment, users both health professionals and Federal Medical Centre (FMC) Umuahia inpatients that had undergone treatment from April 17 to May 17, 2026 were used as a source population. Participant of this study were bio medical engineers, health professionals and inpatients who had been admitted post-surgery for at least one day during the study period were taken as a study population. 8 bio medical engineers, 34 health professionals out of which 13 of them were medical intern students, 12 nurses, 8 normal doctors, 4 specialists. Since there is lack of time and resources 14 patient populations were selected. These participants were selected because of getting experience-based reflections or exploring data about the medical device and its impact on patient safety from these participant perspectives which make this research rich as well as relevant in its data finding and answering the research question set by the researcher. The population of study were summarized in the table under sampling techniques. Regarding the sample size of respondents, 34(60.17%) health professionals and

14(25%) patients were selected using stratified random sampling or quota random sampling, by dividing the health professionals in to department or subject related then taking using simple random sample in each department. patient then taking a simple random sample from each department. In addition, 8(100%) bio medical engineers were selected by judgmental sampling, because the population have manageable number of participants. Generally, from the total of 87 populations, 56(64.36%) samples were selected using the above-mentioned sampling techniques.

Table 1: Sample population, size and sampling techniques.

No	Respondents	Sample	response	%of the sample	Sampling technique
1	Biomedical Engineers	8	8	100	Available
2	Specialists	8	4	50	Purposive sampling
3	Doctors	20	12	60	Simple random sampling
4	Nurses	12	9	50	Simple random sampling
5	Patients	26	14	60	Simple random sampling
6	Intern students	13	9	56.25	Simple random sampling
	Total	87	56	68.3	

3.5. Data Gathering Procedures

The research instruments used for data collection were initially subjected to expert review and pilot testing to assess their validity, reliability, clarity, and suitability for the study objectives. Necessary modifications were made based on the feedback obtained before the final administration of the instruments. The data collection process was carried out over a period of three weeks, after which the collected information was systematically analyzed using appropriate qualitative and quantitative data analysis techniques.

For the quantitative analysis, the completed questionnaires were first retrieved, screened, and examined for completeness, consistency, and validity. A total of 14 questionnaires from patients, representing 53.84% of the distributed patient questionnaires; 34 questionnaires from healthcare professionals, representing 64.15%; and 8 questionnaires from biomedical engineers, representing 100% response rate, were successfully collected. After the validation process, the properly completed questionnaires were considered suitable for statistical analysis, while incomplete responses were excluded to ensure the reliability of the findings.

The qualitative data obtained through interviews with relevant respondents were analyzed using a thematic approach. The interview responses were carefully organized, reviewed, and grouped into major themes related to the objectives of the study. Key issues were identified, categorized, and examined to determine areas of agreement and disagreement among respondents. These findings were then compared with information obtained from other data sources to support, validate, or provide further explanations for the quantitative results.

The overall data analysis process involved several systematic steps. First, the collected information was organized according to the specific objectives and research questions of the study. Second, responses with similar characteristics, ideas, or patterns were grouped together and assigned appropriate categories or labels. Third, the summarized data were presented in tables and other suitable formats to identify significant relationships, trends, variations, and deviations from accepted standards or practices. In addition, findings obtained from secondary data sources, including relevant documents and previous studies, were incorporated to complement and enhance the interpretation of the primary data findings.

This integrated approach ensured a comprehensive evaluation of the medical equipment management practices by combining numerical evidence from questionnaires with detailed explanations obtained from interviews and secondary sources.

3.6. Classical method of Hazard assessment

Hazard analysis and assessment are essential components of safety management. The criticality of a hazardous activity is commonly evaluated using risk, which is defined as the product of the probability (P) of occurrence of an accident and the severity or magnitude (M) of the resulting impact or injury. This relationship is expressed as $R = P \times M$, and it remains a widely adopted approach in conventional risk assessment practices across many industries and organizations. The major steps for risk assessment by traditional methods are shown by figure 1.

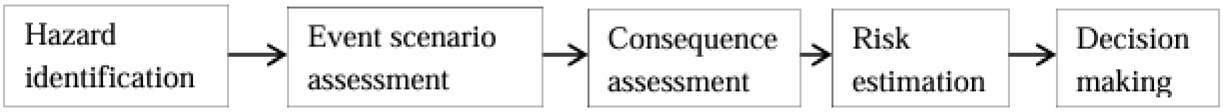

Figure 1: The major steps of traditional Hazard assessment methods

3.7. Fuzzy Logic Modeling

The structure of the overall fuzzy proposed for risk assessment is shown in the Figure 2. Fuzzy systems represent nonlinear mapping accompanied by fuzzy if-then rules from the rule base. Each of these rules describes the local mappings. The rule base can be constructed either from human expert knowledge or designer intuition (Jemal, 2011).

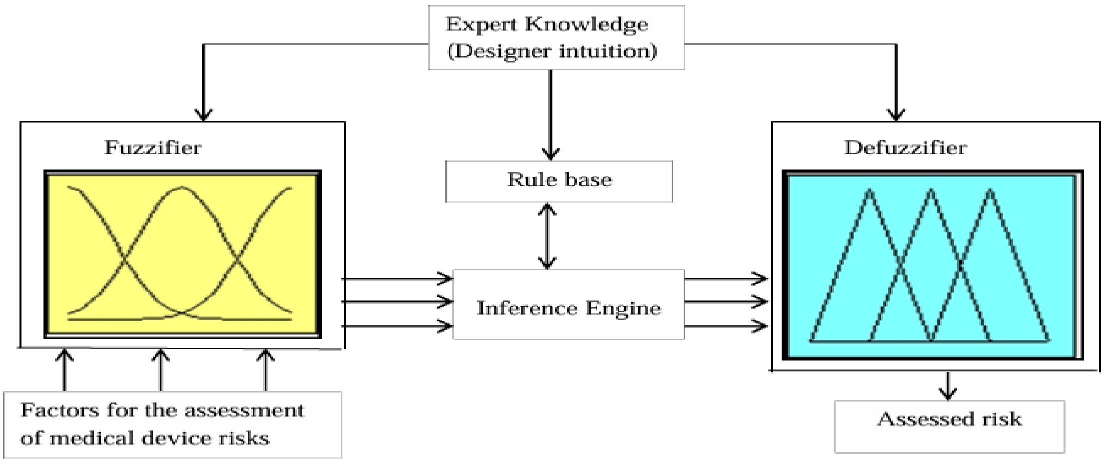

Figure 2: Overview of fuzzy controller steps

3.7.1. Fuzzification

The fuzzification phase includes a fuzzifier to transform crisp inputs into linguistic term through the membership functions. A membership function is a curve that maps the inputs to a membership grade between 0 and 1.

3.7.2 Rule base

The rule base is essentially the control strategy of the system. It is usually obtained from expert knowledge or heuristics and expressed as a set of IF-THEN rules. The rules are based on the fuzzy inference concept and the antecedents and consequents are associated with linguistic variables (Timothy, 2014).

3.7.3. The inference engine

The inference engine transfers fuzzy inputs to outputs by using Fuzzy rules or IF-THEN rules. Fuzzy rules (IF-THEN rules) have been prescribed as a key tool for describing pieces of knowledge in "fuzzy logic" (Timothy, 2014).

3.7.4 Defuzzification

The defuzzification phase converts fuzzy outputs of inference engine to crisp or quantifiable outputs. In order to obtain crisp outputs from the fuzzy outputs, we need to use a defuzzification method. There are many different defuzzification methods in literatures. Five most practical defuzzification methods are as follows: Centroid (Center of Area/Gravity) Method, Bisector of Area Method, Mean of Maximum (MOM) Method, Smallest of Maximum (SOM) Method, Largest of Maximum (LOM) Method. For a medical equipment hazard/risk assessment model, the Centroid method is the most practical choice because it considers the entire aggregated fuzzy output and produces a smooth numerical risk value rather than selecting only an extreme or maximum point.

3.8 An Overview of the proposed system

The inputs and outputs which were used to make this FIS are detailed in Figure 3. Mitigation, Distribution of nonconforming devices, Failure mode damage, Failure mode injury, Toxic injury,
Consequence, non-failure mode and non-toxic damage, non-failure and nontoxic injury.
As shown, two FIS models were established to calculate the risk factor: a consequence model FIS and risk model FIS. The major advantage of the two-stage FIS is that it decomposes a complex risk-assessment problem into smaller, logically connected decision stages. For this research, FIS 1 can determine the consequence, while FIS 2 combines the consequence with failure probability/frequency to produce the overall risk factor. This makes the proposed model more manageable, transparent, and scalable than a single-stage FIS. Different types of consequences considered as inputs to the first FIS and final.

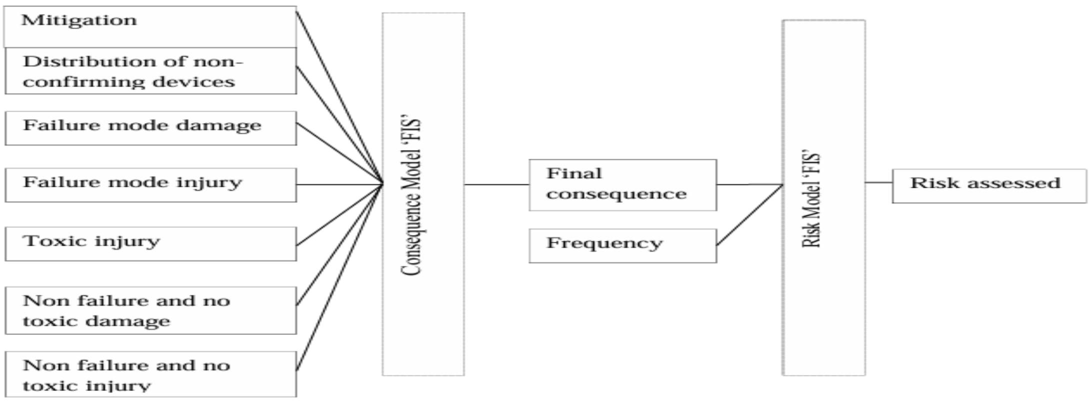

Figure 3: An Overview of the proposed system

3.9. Defining Universe of Discourse (UOD), Fuzzification of constraints

In this study, each of the constraint were fuzzified with their respective linguistic variables (fuzzy sets) and universe of discourse (UOD) as shown in table 2. The Universe of Discourse is the range of all possible values for an input to a fuzzy system or sometimes referred to as an input space.

Table 2: Values of membership functions

Gaussian membership function			
Variable	Universe of discourse	Membership functions	C
Mitigation	[0 100]	Perfect operation (PO)	0
		Good operation (GO)	25
		Medium operation (MO)	50
		Weak operation (WO)	75
		Very weak operation (VWO)	100
Distribution of nonconforming devices	[0 100]	Perfect confirming (PC)	0
		Good confirming (GC)	25
		Medium confirming (MC)	50
		Less confirming (LC)	75
		Very less confirming (VLC)	100
Failure mode damage Consequence	[0 100]	No damage (ND)	0
		Self-equipment devastation/damage (SED)	25
		Beside equipment devastation/damage (BED)	50
		Unit devastation/damage (UD)	75
		Device devastation/damage (DD)	100
Failure mode injury Consequence	[0 100]	No injury consequence (NIC)	0
		Injury of personnel (IOP)	50
		Death of personnel (DOP)	100
Toxic injury consequence	[0 100]	No injury consequence (NIC)	0
		Injury of personnel (IOP)	50
		Death of personnel (DOP)	100
Non failure mode and non-toxic damage consequence	[0 100]	No damage (ND)	0
		Self-equipment devastation/damage (SED)	25
		Beside equipment devastation/damage (BED)	50
		Unit devastation/damage (UD)	75
		System devastation/damage (SD)	100
Non-failure and non-toxic injury consequence	[0 100]	No injury consequence (NIC)	0
		Injury of personnel (IOP)	50

		Death of personnel (DOP)	100
Consequence (Severity)	[0 100]	Insignificant(I)	0
		Minor (Mi)	25
		Moderate (Mo)	50
		Major (Ma)	75
		Catastrophic (Ct)	100
Risk factor	[0 100]	Low risk (LR)	0
		Negligible risk (NR)	20
		Tolerable risk (TR)	40
		Undesirable risk (UR)	60
		Intolerable risk (IR)	80
		High risk (HR)	100

3.9. Types of FIS

The fuzzy inference system (FIS) is a popular methodology for implementing FL. There are three commonly used fuzzy inference systems as follows: Mamdani Fuzzy Inference System, Sugeno (Takagi–Sugeno–Kang) Fuzzy Inference System, and Tsukamoto Fuzzy Inference System. We used Mamdani FIS method because it uses defuzzification technique to produce the crisp outputs rather than calculating the weighted average unlike Sugeno.

3.10. Linguistic variables and design of membership functions (MF's)

Linguistic variables are the building blocks of FL. They may be defined (Zadeh, 1965) as variables whose values are expressed as words or sentences. A membership function (MF) is a curve that defines how each point in the input space is mapped to a membership value (or degree of membership) between 0 and 1. The input space is sometimes referred to as the universe of discourse, a fancy name for a simple concept.

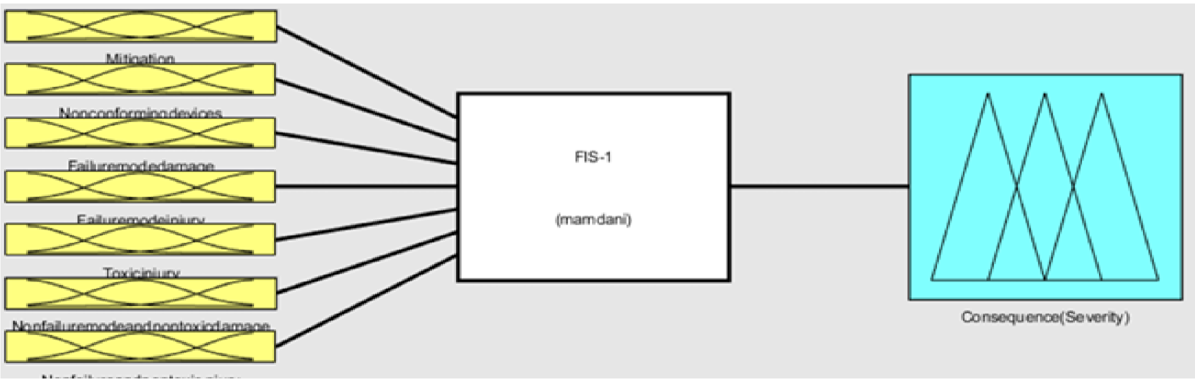

Figure 4: “Fuzzy inference system-1” design

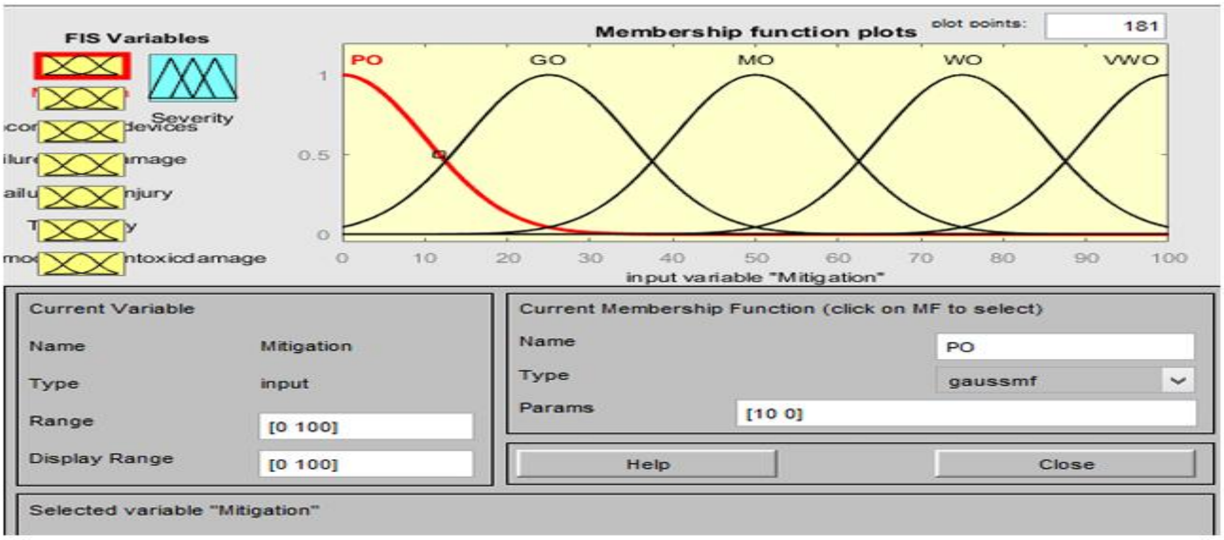

Figure 5: MFs for input – 'Mitigation'

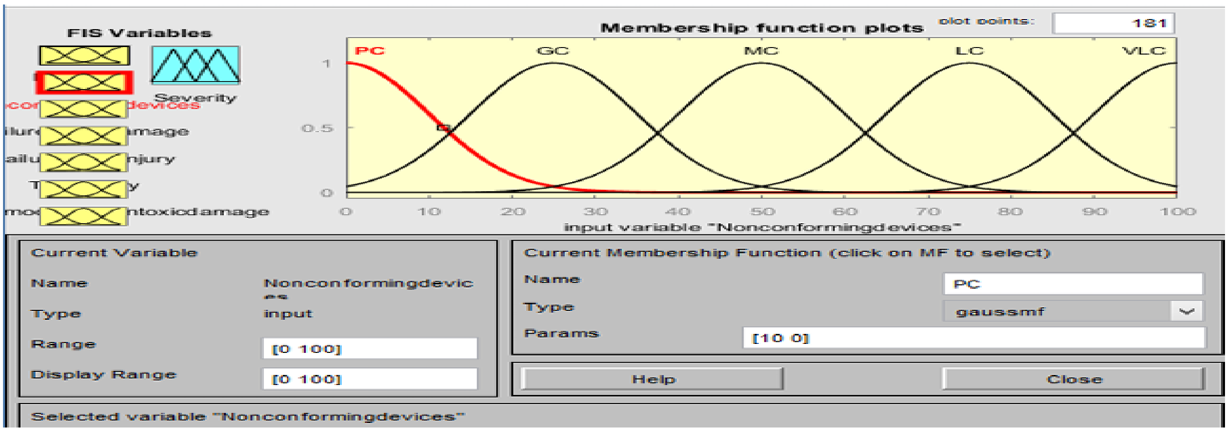

Figure 6: MFs for input – 'non-conforming devices'

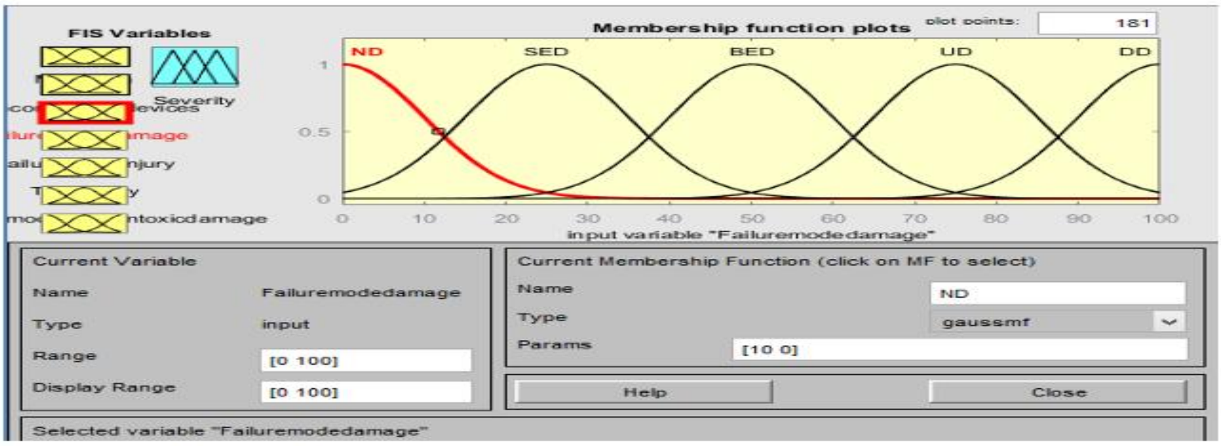

Figure 7: MFs for input – 'Failure mode damage'

3.11 Rule formats

Basically, a linguistic controller contains rules in the if-then format, but they can be presented in different formats. In this research, we have taken only four rules from the constructed rules for visualization purpose.

1. If (Severity((S) is Insiginificant) and (Frequency(F) is Imposible) then (Riskassessed(RA) is Lowrisk) (1)
2. If (Severity((S) is Insiginificant) and (Frequency(F) is Improbable) then (Riskassessed(RA) is Negligiblerisk) (1)
3. If (Severity((S) is Insiginificant) and (Frequency(F) is Remote) then (Riskassessed(RA) is Negligiblerisk) (1)
4. If (Severity((S) is Insiginificant) and (Frequency(F) is Occasional) then (Riskassessed(RA) is Tolerablerisk) (1)

Figure 8: Rule base construction sample

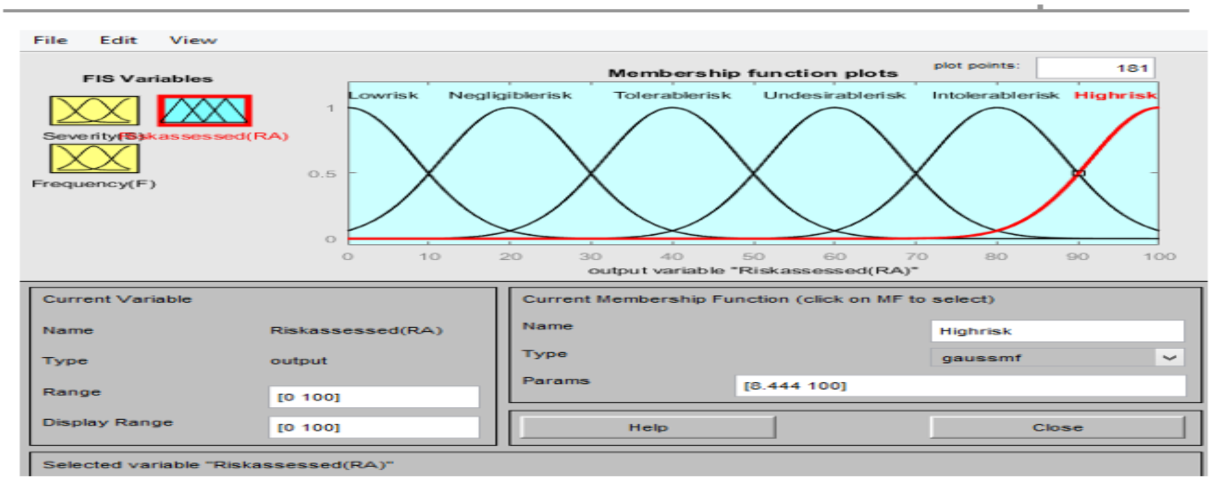

Figure 9: MFs for Output – 'Risk assessed'

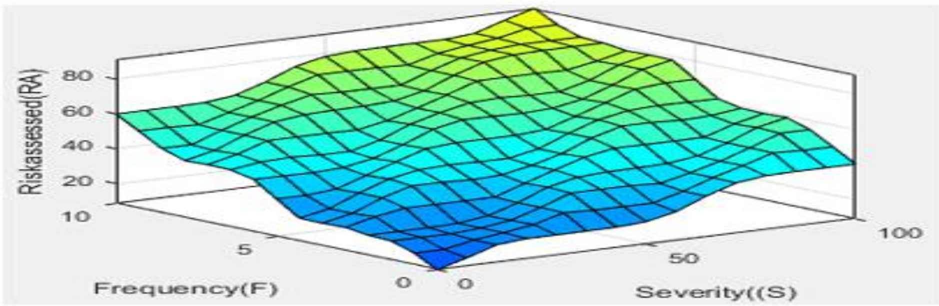

Figure 10: Surface viewer for 'FIS

As can be seen from the figure 9 if one has numerical value of the inputs in the scale of [0 100] for all the seven inputs, frequency [0 10] respectively, we can obtain the amount of risk factor associated in the scale of [0 100].

3.12. Simulink model of the proposed system

The proposed fuzzy reasoning model was developed in Mat lab Simulink software using fuzzy logic toolbox as shown in figure 11

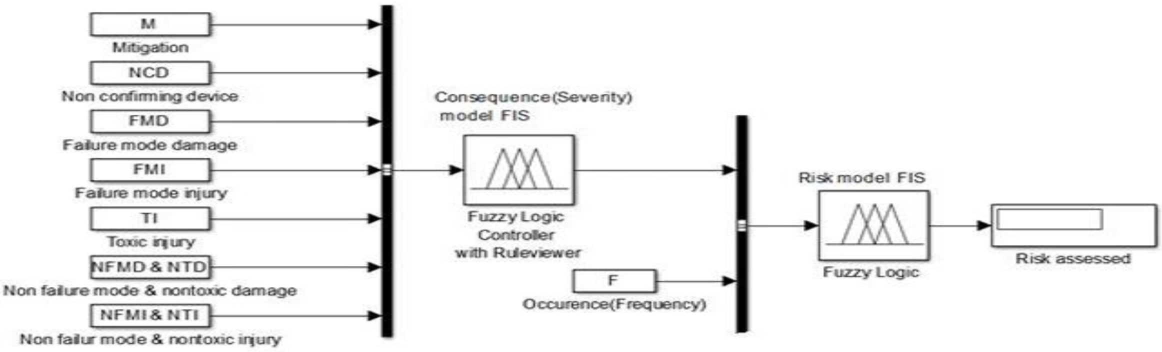

Figure 11: Overall Simulink Simulation Model

4.0 RESULTS AND DISCUSSION

4.1. Results

The percentage rating for the hospital medical equipment maintenance management is as shown below.

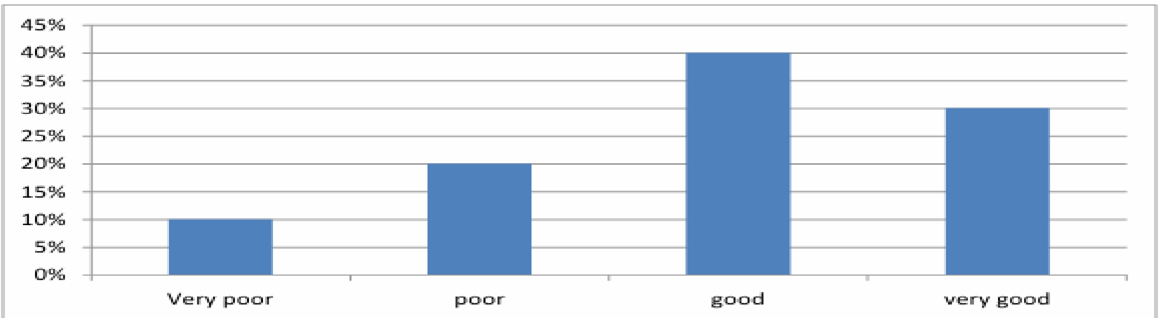

Figure 12. Management of medical device maintenance in FMC Umuahia

Most respondents indicated that the hospital has established procedures for maintenance management. Specifically, 40% of respondents rated the availability of clear maintenance management procedures as good, while 30% rated it as very good, 20% as fair, and 10% as very poor. The management of preventive maintenance practices was rated on a scale of 0–5, with an average score of 2, indicating a fair level of preventive maintenance management. Regarding preventive maintenance performance, 30% of respondents rated it as very poor, 30% as good, 20% as very good, and 10% as poor. Preventive maintenance activities within the hospital are mainly carried out by laboratory technologists and X-ray technicians, with limited involvement from nursing staff. This is attributed to the specialized training received by laboratory personnel on the operation and handling of laboratory equipment, which enhances their ability to perform routine maintenance activities. Furthermore, the hospital demonstrates good practice in the scheduled inspection, testing, and monitoring of medical equipment to ensure operational reliability and safety.

The following graph shows the relationship between complexity and performance of medical equipment.

Figure 13. Relationship between performance (%) and complexity of machines

Results of various simulations for different sets of inputs are shown below: Set 1: (M = 1; NCD = 1; FMD=1; FMI=1; TI=1; NFMD & NTD=1; NFMI & NTI=1 and F= 1). The simulation (t=2sec)

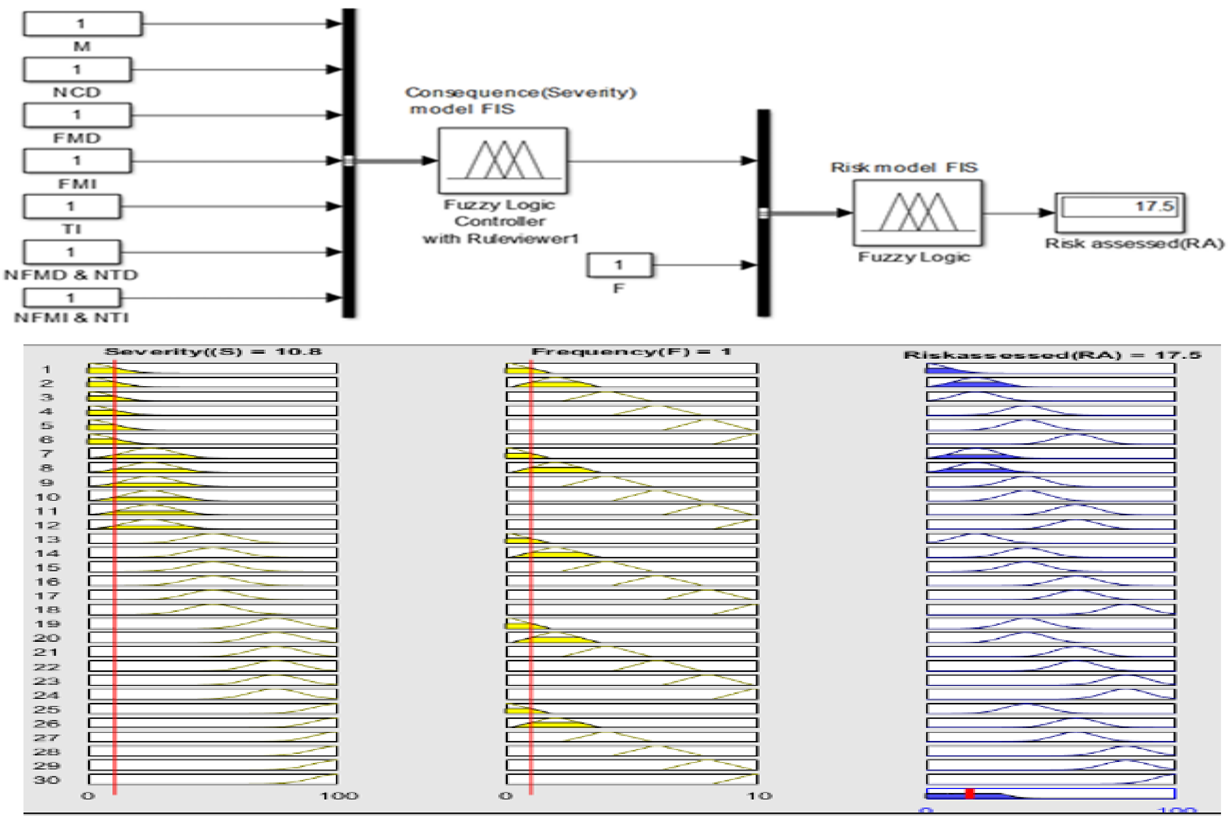

Figure 14. Simulation results of Set 1

As can be seen from the figure 14 the assessed risk rating is 17.5. A risk score of **17.5** suggests that:

i. The likelihood of the hazardous event is very low, because the frequency score is only 1.
ii. The potential severity is relatively low, at 10.8.
iii. The hazard is unlikely to result in serious injury, major equipment damage, significant environmental impact, or major financial loss, depending on what hazard is being assessed.
iv. Existing control measures may be sufficient, provided they are properly implemented and maintained.
v. The risk should still be monitored periodically, because a low risk does not mean that the hazard is completely eliminated.
vi. Additional controls may be considered where they are inexpensive and practical, particularly if the hazard could affect personnel or critical equipment.

Set 2: (M = 25; NCD = 25; FMD=25; FMI=25; TI=25; NFMD & NTD=25; NFMI & NTI=25 and F= 2.5). The simulation (t=2sec)

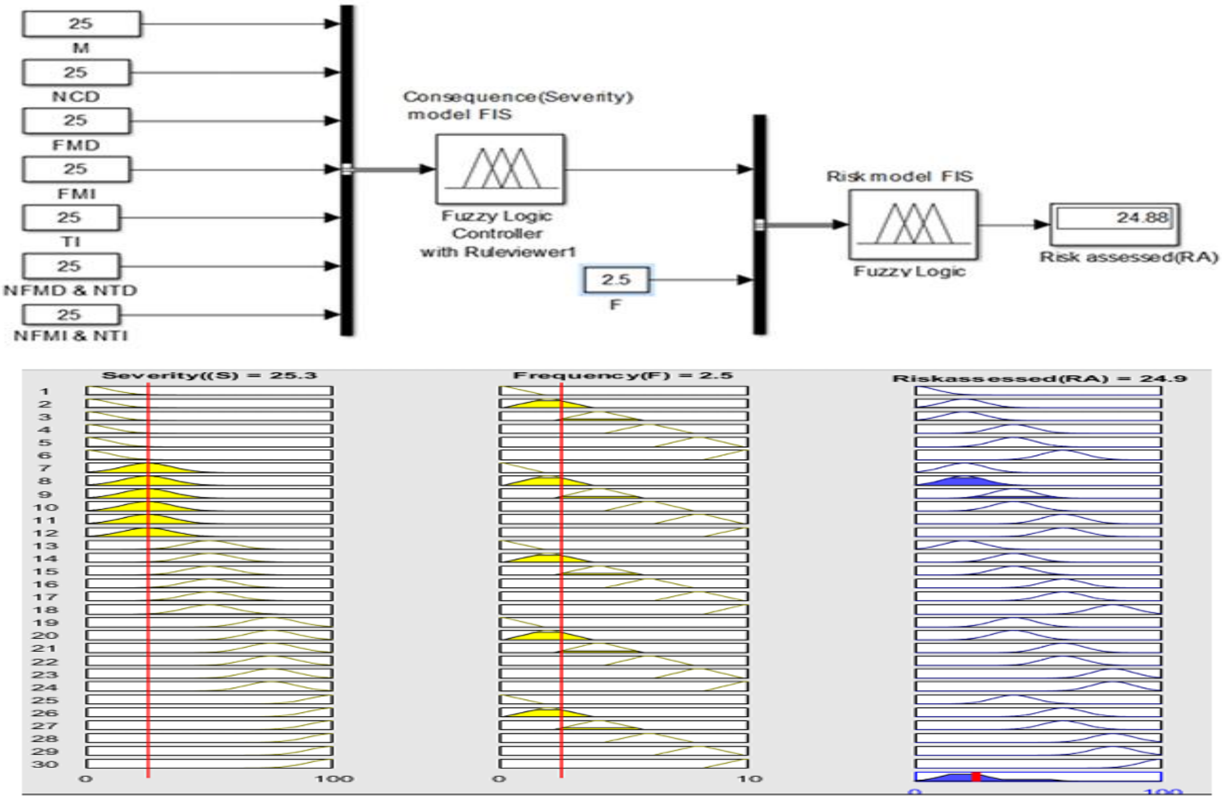

Figure 15. Simulation results of Set 2

As can be seen from the figure 15 the assessed risk rating is 24.9. A risk score of 24.9 suggests that the hazard should not simply be ignored, even though the frequency is relatively low. The main concern is that the severity of 25.3 means that, if the hazardous event occurs, it could produce meaningful consequences. Depending on the hazard, consequences could include:

i. Injury to personnel, potentially requiring medical attention.
ii. Damage to medical equipment or other assets.
iii. Interruption of operations or services.
iv. Financial losses arising from equipment repair, replacement, or downtime.
v. Reduced quality or reliability of service.
vi. Regulatory or compliance implications where applicable.
vii. Potential escalation to a serious incident if existing control measures fail.

For a medical-equipment hazard assessment, for example, a score around **24.9** could justify measures such as:

i. Regular inspection and preventive maintenance.
ii. Calibration and performance verification.
iii. Adequate user training.

iv. Appropriate operating procedures.
v. Warning labels and safety precautions.
vi. Incident/near-miss reporting.
vii. Periodic reassessment of the hazard.

Set 3: (M = 50; NCD = 50; FMD=50; FMI=50; TI=50; NFMD & NTD=50; NFMI & NTI=50 and F= 5). The simulation (t=2sec).

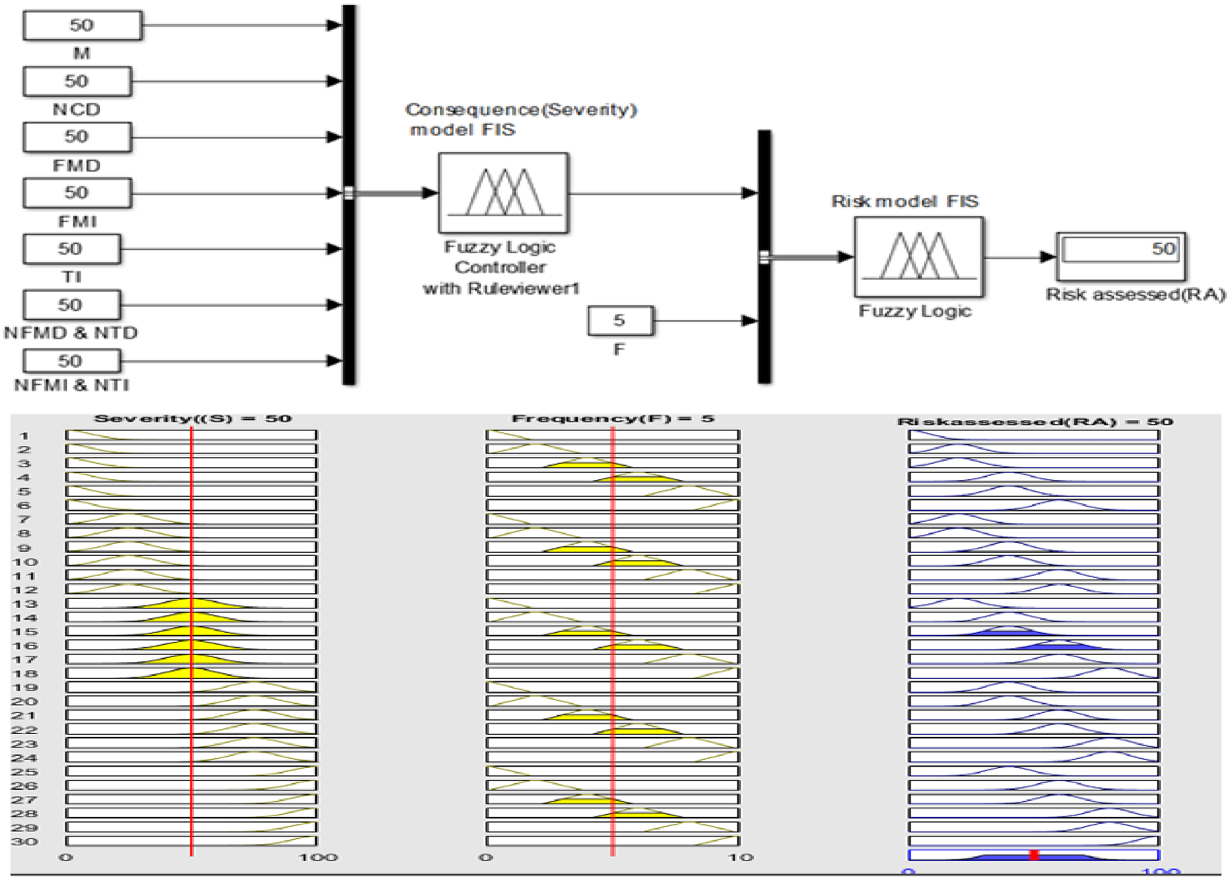

Figure 16. Simulation results Set 3

From the Figure 16, the assessed risk rating from the simulation is 50.
A risk assessment score of 50 on a 1–100 risk matrix, associated with a severity score of 50 and a frequency of occurrence of 5, indicates a significant level of risk. Although the frequency of occurrence is relatively low, the severity of the potential consequences is substantial. Therefore, the identified hazard requires appropriate control measures, periodic monitoring, and management attention to reduce the likelihood of occurrence and minimize its potential impact.

Set 4: (M = 50; NCD = 49; FMD=50; FMI=50; TI=50; NFMD & NTD=50; NFMI & NTI=50 and F= 4.9). The simulation (t=2sec)

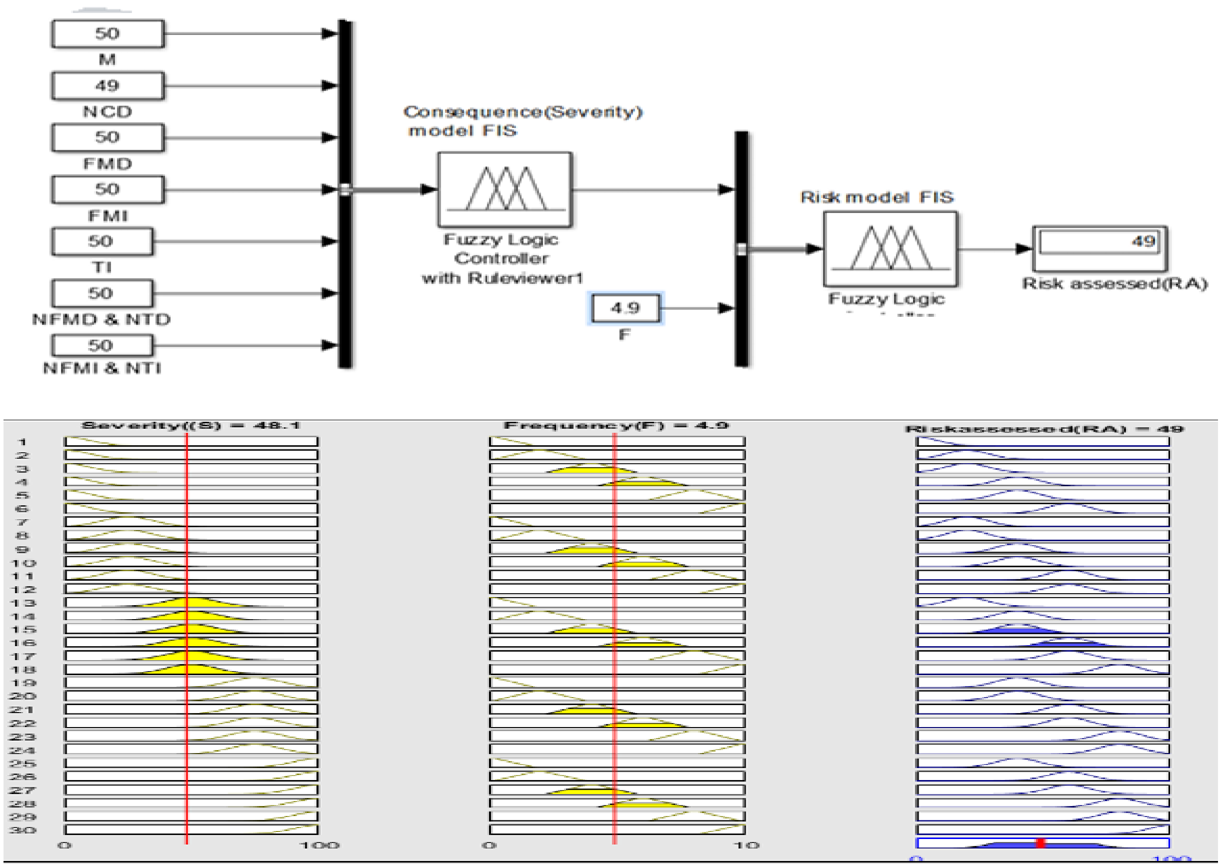

Figure 17. Simulation results Set 4

As can be seen from the figure 17, the assessed risk is 49.
On a 1–100 risk matrix, a risk assessment score of 49, with severity = 48.1 and frequency of occurrence = 4.9, generally indicates a moderate to high risk,
Comparing the two results obtained from Set 3 and Set 4, assessed risk were reduced by reducing one of the variables by insignificant amount (NCD=49). Also, the effect of changing only the frequency by insignificant amount (Let F=4.9) was equally felt.

4.2 Discussion

The simulation results demonstrate that the proposed two-stage Fuzzy Inference System responds systematically to changes in the input parameters. Under Set 1, where the input variables were assigned a normalized value of 1 and the frequency-of-occurrence parameter was 1, the model produced a risk rating of 17.5, with a corresponding severity value of 10.8. This result indicates a relatively low level of risk under the specified input conditions. Although the resulting risk is relatively low, continued monitoring and maintenance of existing control measures are necessary because a low-risk rating does not imply complete elimination of the hazard.
For Set 2, the input variables were increased to 25, while the frequency parameter was set at 2.5. The resulting risk rating increased to 24.9, with a severity value of 25.3. The increase from 17.5 to 24.9 represents an absolute increase of 7.4 points, corresponding to approximately 42.3% relative to the Set 1 risk value. This increase demonstrates that increasing the magnitude of the risk-related input variables results in a corresponding increase in the model output. The result indicates the need for continued preventive maintenance, equipment inspection, calibration, user training, and periodic reassessment.

Under Set 3, all principal input variables were assigned a value of 50 and the frequency parameter was increased to 5. The model produced a risk rating of 50.0, with a severity value of 50.0. Compared with Set 2, the risk increased by 25.1 points, representing an increase of approximately 100.8%. The result demonstrates that the fuzzy model responds substantially when the magnitude of the risk-related input parameters is increased. Such a result supports the logical behaviour of the proposed model because higher consequence and occurrence inputs should result in a higher overall risk output.

Set 4 was used to examine the sensitivity of the model to relatively small changes in the input parameters. In this case, NCD was reduced from 50 to 49, while the frequency parameter was reduced from 5.0 to 4.9. The resulting risk rating decreased from 50.0 to 49.0, representing a reduction of 1.0 point or 2.0%. The severity value decreased from 50.0 to 48.1, representing a 3.8% reduction. These results demonstrate that relatively small variations in the input parameters can produce measurable changes in the final fuzzy risk output.

Overall, the four simulation sets demonstrate the sensitivity and logical responsiveness of the proposed fuzzy model. The risk output increased progressively from 17.5 to 24.9 and subsequently to 50.0 as the magnitude of the input variables increased. The reduction from 50.0 to 49.0 following small changes in the input conditions further demonstrates that the model is responsive to variations in its input parameters.

5.0 CONCLUSION

A fuzzy logic-based approach was developed for assessing medical device hazards in hospitals. A MATLAB/Simulink fuzzy Hazard assessment model was implemented to estimate and manage risk levels by incorporating expert knowledge and addressing the uncertainty associated with human judgment. The proposed fuzzy logic-based hazard assessment of medical devices in a Nigerian healthcare facility provides a flexible and intuitive framework for risk evaluation, where input and output relationships are represented using linguistic variables. This improves adaptability to changing conditions, simplifies decision-making, and enhances the reliability and understanding of assessment results. The approach can be further extended by incorporating additional risk factors and applying advanced fuzzy techniques for complex healthcare risk management and other technology-based decision-making applications.

REFERENCES

Ahmadi, H., Gholamzadeh, M., Shahmoradi, L., Nilashi, M., & Rashvand, P. (2018). *Diseases diagnosis using fuzzy logic methods: A systematic and meta-analysis review*. Computer Methods and Programs in Biomedicine, 161, 145–172.

Amran, M., (2024). *Critical assessment of medical devices on reliability, replacement prioritization and maintenance strategy criterion: Case study of Malaysian hospitals*. Quality and Reliability Engineering International, 40(7), 3180–3208. https://doi.org/10.1002/qre.3447

Benbrahim, H. (2024). *A novel decision support system for proactive risk management in healthcare based on fuzzy inference, neural network and support vector machine*. International Journal of Medical Informatics, 188, 105442. https://doi.org/10.1016/j.ijmedinf.2024.105442

Do, H. T. T., Ly, T. T. B., & Do, T. T. (2020). *Combining semi-quantitative risk assessment, composite indicator and fuzzy logic for evaluation of hazardous chemical accidents*. Scientific Reports, 10, 18544.

Jamett, J., Melendez, P., Collao-Ferrada, X., (2026). *Fuzzy Logic Approaches for Causal Inference in Health Care: Systematic Review*. JMIR AI.

Jemal Hayato,(2011) "Design Of Self-Tuning Fuzzy Controller for Micro Hydropower Plants on Irrigation Dams" Addis Ababa University. Thesis, July, 2011

Kaur, J., Khan, A. I., Abushark, Y. B., Alam, M. M., Khan, S. A., Agrawal, A., Kumar, R., & Khan, R. A. (2020). *Security Risk Assessment of Healthcare Web Application Through Adaptive Neuro-Fuzzy Inference System: A Design Perspective*. Risk Management and Healthcare Policy, 13, 355–371.

Liu, J., & Tang, H. (2022). *Application of fuzzy analytic hierarchy process in risk assessment in medicine related fields*. Chinese Journal of Epidemiology, 43(5), 766–770.

Mohanta, V. L., & Mishra, B. K. (2020). Integration of cancer and non-cancer human health risk assessment for aniline enriched groundwater: A fuzzy inference system-based approach. Environmental Geochemistry and Health, 42(11), 3623–3639.

McKie, J. (2019). Management of Medical Technology in Developing Countries, 12(May):. Journal Biomed Engineering, 259-261.

Okechukwu, E., Ichoku, H., Olushola, O., & Ifeanyi, C. (2025). *Health infrastructure and equipment*. In Nigeria: Country Health Systems & Services Profile. World Health Organization Regional Office for Africa.

Pritika, Shanmugam, B., & Azam, S. (2024). *Risk evaluation and attack detection in heterogeneous Internet of Medical Things (IoMT) devices using hybrid fuzzy logic analytical approach*. Sensors, 24(10), 3223. https://doi.org/10.3390/s24103223

Salvi, M., Dogan, S., Inamdar, M. A., et al. (2026). *Evolution of fuzzy logic in medical applications: Methods, trends and clinical applications*. Expert Systems with Applications, 321, 132344.

Sampson, S., Umar, L., Obi-Jeff, C., (2024). *Assessment of the compliance with minimum quality standards by public primary healthcare facilities in Nigeria*. Health Research Policy and Systems, 22, 133. https://doi.org/10.1186/s12961-024-01223-6

Timothy J. Ross, (2014). "Fuzzy Logic with Engineering Applications", John Wiley & Sons Ltd, England, 2014.

Torres, A., & Nieto, J. J. (2006). *Fuzzy Logic in Medicine and Bioinformatics*. BioMed Research International, Article 91908.

World Health Organization, 2024). *Joint external evaluation of the International Health Regulations (2005) core capacities of Nigeria*. WHO.

Zadeh, L. A. (1965). *Fuzzy Sets*. Information and Control, 8(3), 338–353.