Risk-based maintenance of critical and complex systems

Thèse

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Résumé

De nos jours, la plupart des systèmes dans divers secteurs critiques tels que l'aviation, le pétrole et les soins de santé sont devenus très complexes et dynamiques, et par conséquent peuvent à tout moment s'arrêter de fonctionner. Pour éviter que cela ne se reproduise et ne devienne incontrôlable ce qui engagera des pertes énormes en matière de coûts et d'indisponibilité; l'adoption de stratégies de contrôle et de maintenance s'avèrent plus que nécessaire et même vitale.

Dans le génie des procédés, les stratégies optimales de maintenance pour ces systèmes pourraient avoir un impact significatif sur la réduction des coûts et sur les temps d'arrêt, sur la maximisation de la fiabilité et de la productivité, sur l'amélioration de la qualité et enfin pour atteindre les objectifs souhaités des compagnies. En outre, les risques et les incertitudes associés à ces systèmes sont souvent composés de plusieurs relations de cause à effet de façon extrêmement complexe. Cela pourrait mener à une augmentation du nombre de défaillances de ces systèmes. Par conséquent, un outil d'analyse de défaillance avancée est nécessaire pour considérer les interactions complexes de défaillance des composants dans les différentes phases du cycle de vie du produit pour assurer les niveaux élevés de sécurité et de fiabilité.

Dans cette thèse, on aborde dans un premier temps les lacunes des méthodes d'analyse des risques/échec et celles qui permettent la sélection d'une classe de stratégie de maintenance à adopter. Nous développons ensuite des approches globales pour la maintenance et l'analyse du processus de défaillance fondée sur les risques des systèmes et machines complexes connus pour être utilisées dans toutes les industries. Les recherches menées pour la concrétisation de cette thèse ont donné lieu à douze contributions importantes qui se résument comme suit:

Dans la première contribution, on aborde les insuffisances des méthodes en cours de sélection de la stratégie de maintenance et on développe un cadre fondé sur les risques en utilisant des méthodes dites du processus de hiérarchie analytique (Analytical Hierarchy Process (AHP), de cartes cognitives floues (Fuzzy Cognitive Maps (FCM)), et la théorie des ensembles flous (Fuzzy Soft Sets (FSS)) pour sélectionner la meilleure politique de maintenance tout en considérant les incertitudes.

La deuxième contribution aborde les insuffisances de la méthode de l'analyse des modes de défaillance, de leurs effets et de leur criticité (AMDEC) et son amélioration en utilisant un modèle AMDEC basée sur les FCM.

Les contributions 3 et 4, proposent deux outils de modélisation dynamique des risques et d'évaluation à l'aide de la FCM pour faire face aux risques de l'externalisation de la maintenance et des réseaux de collaboration. Ensuite, on étend les outils développés et nous proposons un outil d'aide à la décision avancée pour prédire l'impact de chaque risque sur les autres risques ou sur la performance du système en utilisant la FCM (contribution 5).

Dans la sixième contribution, on aborde les risques associés à la maintenance dans le cadre des ERP (Enterprise Resource Planning (ERP)) et on propose une autre approche intégrée basée sur la méthode AMDEC floue pour la priorisation des risques.

Dans les contributions 7, 8, 9 et 10, on effectue une revue de la littérature concernant la maintenance basée sur les risques des dispositifs médicaux, puisque ces appareils sont devenus très complexes et sophistiqués et l'application de modèles de maintenance et d'optimisation pour eux est assez nouvelle. Ensuite, on développe trois cadres intégrés pour la planification de la maintenance et le remplacement de dispositifs médicaux axée sur les risques.

Outre les contributions ci-dessus, et comme étude de cas, nous avons réalisé un projet intitulé "Mise à jour de guide de pratique clinique (GPC) qui est un cadre axé sur les priorités pour la mise à jour des guides de pratique cliniques existantes" au centre interdisciplinaire de recherche en réadaptation et intégration sociale du Québec (CIRRIS). Nos travaux au sein du CIRRIS ont amené à deux importantes contributions. Dans ces deux contributions (11e et 12e) nous avons effectué un examen systématique de la littérature pour identifier les critères potentiels de mise à jour des GPCs. Nous avons validé et pondéré les critères identifiés par un sondage international. Puis, sur la base des résultats de la onzième contribution, nous avons développé un cadre global axé sur les priorités pour les GPCs. Ceci est la première fois qu'une telle méthode quantitative a été proposée dans la littérature des guides de pratiques cliniques. L'évaluation et la priorisation des GPCs existants sur la base des critères validés peuvent favoriser l'acheminement des ressources limitées dans la mise à jour de GPCs qui sont les plus sensibles au changement, améliorant ainsi la qualité et la fiabilité des décisions de santé.

Abstract

Today, most systems in various critical sectors such as aviation, oil and health care have become very complex and dynamic, and consequently can at any time stop working. To prevent this from reoccurring and getting out of control which incur huge losses in terms of costs and downtime; the adoption of control and maintenance strategies are more than necessary and even vital.

In process engineering, optimal maintenance strategies for these systems could have a significant impact on reducing costs and downtime, maximizing reliability and productivity, improving the quality and finally achieving the desired objectives of the companies. In addition, the risks and uncertainties associated with these systems are often composed of several extremely complex cause and effect relationships. This could lead to an increase in the number of failures of such systems. Therefore, an advanced failure analysis tool is needed to consider the complex interactions of components' failures in the different phases of the product life cycle to ensure high levels of safety and reliability.

In this thesis, we address the shortcomings of current failure/risk analysis and maintenance policy selection methods in the literature. Then, we develop comprehensive approaches to maintenance and failure analysis process based on the risks of complex systems and equipment which are applicable in all industries. The research conducted for the realization of this thesis has resulted in twelve important contributions, as follows:

In the first contribution, we address the shortcomings of the current methods in selecting the optimum maintenance strategy and develop an integrated risk-based framework using Analytical Hierarchy Process (AHP), fuzzy Cognitive Maps (FCM), and fuzzy Soft set (FSS) tools to select the best maintenance policy by considering the uncertainties.

The second contribution aims to address the shortcomings of traditional failure mode and effect analysis (FMEA) method and enhance it using a FCM-based FMEA model. Contributions 3 and 4, present two dynamic risk modeling and assessment tools using FCM for dealing with risks of outsourcing maintenance and collaborative networks. Then, we extend the developed tools and propose an advanced decision support tool for predicting the impact of each risk on the other risks or on the performance of system using FCM (contribution 5).

In the sixth contribution, we address the associated risks in Enterprise Resource Planning (ERP) maintenance and we propose another integrated approach using fuzzy FMEA method for prioritizing the risks. In the contributions 7, 8, 9, and 10, we perform a literature review regarding the risk-based maintenance of medical devices, since these devices have become very complex and sophisticated and the application of maintenance and optimization models to them is fairly new. Then, we develop three integrated frameworks for risk-based maintenance and replacement planning of medical devices.

In addition to above contributions, as a case study, we performed a project titled "Updating Clinical Practice Guidelines; a priority-based framework for updating existing guidelines" in CIRRIS which led to the two important contributions. In these two contributions (11th and 12th) we first performed a systematic literature review to identify potential criteria in updating CPGs. We validated and weighted the identified criteria through an international survey. Then, based on the results of the eleventh contribution, we developed a comprehensive priority-based framework for updating CPGs based on the approaches that we had already developed and applied success fully in other industries. This is the first time that such a quantitative method has been proposed in the literature of guidelines. Evaluation and prioritization of existing CPGs based on the validated criteria can promote channelling limited resources into updating CPGs that are most sensitive to change, thus improving the quality and reliability of healthcare decisions made based on current CPGs.

Keywords: Risk-based maintenance, Maintenance strategy selection, FMEA, FCM, Medical devices, Clinical practice guidelines.

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Glossary of Used Abbreviations

MSS	Maintenance strategy selection
MCDM	Multi-criteria decision making
RB-MSS	Risk-based Maintenance strategy selection
FCM	Fuzzy cognitive maps
AHP	Analytical hierarchy process
FSS	Fuzzy soft set
FTA	Fault tree analysis
FMEA	Failure mode and effect analysis
RPN	Risk Priority Number
FAHP	Fuzzy Analytic Hierarchy Process
FANP	Fuzzy Analytic Network Process
NHL-DE	Nonlinear Hebbian learning- Differential evolution
CM	Corrective Maintenance
CBM	Condition-Based Maintenance
TBM	Time-based maintenance
OM	Opportunistic Maintenance
PDM	Predictive maintenance
FBM	Failure based maintenance
TPM	Total productive maintenance
TQM	Total Quality Maintenance
RCM	Reliability centered maintenance
MTBF	Mean Time between failures
MTTR	Mean Time to repair
ERP	Enterprise Resource Planning
CPG	Clinical Practice Guidelines
CN	Collaborative Networks

Dedication

I dedicate my dissertation work to my lovely parents, Mahdi and Rana

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Foreword

This thesis has been realized under the co-direction of Daoud Ait-Kadi Professor at the Mechanical Engineering Department Laval University, Québec, Canada and Angel Ruiz Professor at the Operations and Decision Systems Department of Laval University Québec, Canada. It has been prepared as an article insertion thesis.

The thesis includes 12 articles, co-authored by Pr. Daoud Ait-Kadi and Pr. Angel Ruiz. In all of the presented articles, I have acted as the principal researcher. As the first author, I have also performed the mathematical models development, coding the algorithms, analysis and validation of the results, as well as writing of the first drafts of the articles. Professors Daoud Ait-Kadi and Angel Ruiz have revised the articles to obtain the final version.

The first article entitled "An integrated framework for risk-based maintenance strategy selection" co-authored by Pr. Daoud Ait-Kadi and Pr. Angel Ruiz has been submitted to *the International Journal of Production Research.*

The second article entitled "Enhancing Failure Mode and Effects Analysis using Fuzzy Cognitive Maps" co-authored by Pr. Daoud Ait-Kadi and Pr. Angel Ruiz has been submitted to *the Journal of Expert systems with applications.*

The third article entitled "Dynamic risk assessment of complex systems using FCM", co-authored by Pr. Daoud Ait-Kadi and Pr. Angel Ruiz has been accepted for publication in *International Journal of Production Research*.

The fourth article entitled "Dynamic risk modeling and assessing in maintenance outsourcing with FCM" co-authored by Pr. Daoud Ait-Kadi and Pr. Angel Ruiz has been published in *Industrial Engineering and Systems Management (IESM), Proceedings of 2015* International Conference on (pp. 209 - 215) IEEE.

The fifth article entitled "A new decision support tool for dynamic risks analysis in collaborative networks", co-authored by Pr. Daoud Ait-Kadi and Pr. Angel Ruiz has been published as Book Chapter in "*Risks and Resilience of Collaborative Networ*ks" book Pages 53-62, Vol 463 of the series IFIP Advances in Information and Communication Technology, Springer International Publishing, DOI 10.1007/978-3-319-24141-8_5.

The sixth article entitled "A new framework for risk assessment in ERP maintenance", co-authored by Pr. Daoud Ait-Kadi and Pr. Angel Ruiz has been published in the proceedings of RAMS 2014: The annual reliability and maintainability symposium, Colorado.

The seventh article entitled "Medical devices Inspection and Maintenance; A Literature Review" co-authored by Pr. Daoud Ait-Kadi and Pr. Angel Ruiz has been published in the proceedings of *IIE Annual conference* (2014), Montreal.

The eighth article entitled "A risk-based Maintenance Strategy using Fuzzy HFMEA for Critical Medical Equipment" co-authored by Pr. Daoud Ait-Kadi and Pr. Angel Ruiz has been published in the Proceedings of *1st Annual World Conference of the Society for Industrial and Systems Engineering* (2012), Washington.

The ninth article entitled "A comprehensive fuzzy risk-based maintenance framework for prioritization of medical devices" co-authored by Pr. Daoud Ait-Kadi and Pr. Angel Ruiz has been published in the *Journal of Applied soft computing*, 32 (2015) 322–334.

The tenth article entitled "A comprehensive fuzzy risk-based framework for replacement of medical devices" co-authored by Pr. Daoud Ait-Kadi and Pr. Angel Ruiz has been published in the proceedings of *11th International Industrial Engineering Conference* (CIGI 2015), Quebec.

The eleventh article entitled "Influential criteria in updating clinical practice guidelines" co-authored by Pr. Daoud Ait-Kadi and Pr. Angel Ruiz has been submitted to *the Journal of Medical Informatics.*

The twelfth article entitled "A comprehensive prioritization framework for updating Clinical Practice Guidelines" co-authored by Pr. Daoud Ait-Kadi and Pr. Angel Ruiz has been submitted to *the International Journal of Medical Informatics.*

Chapter 1 .
General Introduction

1.1 Introduction

Complex high-technology devices and systems are in growing use in industry, service sectors, and everyday life. Their reliability and maintenance is of utmost importance in view of their cost and critical functions. The efficient functioning of these systems depends on the smooth operation of many complex systems comprised of several pieces of components that provide a variety of products and services. These include manufacturing plants, processing plants, hospitals (to provide services), transport systems, communication systems (television, telephone and computer networks), utilities (water, gas and electricity networks), and banks (for financial transactions) to name a few (Kobbacy & Murthy, 2008). When a complex system fails, the consequences can be dramatic. It can result in serious economic losses, affect humans and do serious damage to the environment as, for example, the crash of an aircraft in flight, the failure of a sewage processing plant or the collapse of a bridge. Through proper corrective maintenance, one can restore a failed system to an operational state by actions such as repair or replacement of the components that failed and in turn caused the failure of the system. With effective maintenance actions such as preventive maintenance, inspection, condition monitoring, and design-out maintenance, depending on the system, the occurrence of failures and their consequences can be reduced to a considerable extent.

Over the last few decades the maintenance of systems has become more and more complex. One reason for this is that systems consist of many components which depend on each other. On the one hand, interactions between components complicate the modelling and optimization of maintenance. Sometimes, the incident emerges from the interaction of major and minor faults which were individually insufficient to have produced this incident. On the other hand, variety of subjective/objective factors/criteria should be considered when deciding about best maintenance policy for a devices/component. Moreover, there is always uncertainties associated with experts' opinions which are mostly overlooked. It follows that planning accurate and economic maintenance actions is a big challenge and an advanced decision support tool is needed to consider all these aspects in maintenance planning of complex systems.

Risk analysis can be used for selection and prioritization of maintenance activities, and risk-based decision makings have been given increased attention in recent years. An effective use of resources can be achieved by using risk-based maintenance decisions to guide where and when to perform maintenance. The risk-based maintenance (RBM) strategy is an effective quantitative approach integrating reliability analysis and risk assessment to develop a cost-effective maintenance policy (Khan & Haddara, 2003). The risk-based maintenance methodology is broken down into three main modules, see Fig. 1:

1- Risk determination, which consists of risk identification and estimation,

2- Risk evaluation, which consists of risk aversion and risk acceptance analysis, and

3- Maintenance planning considering risk factors.

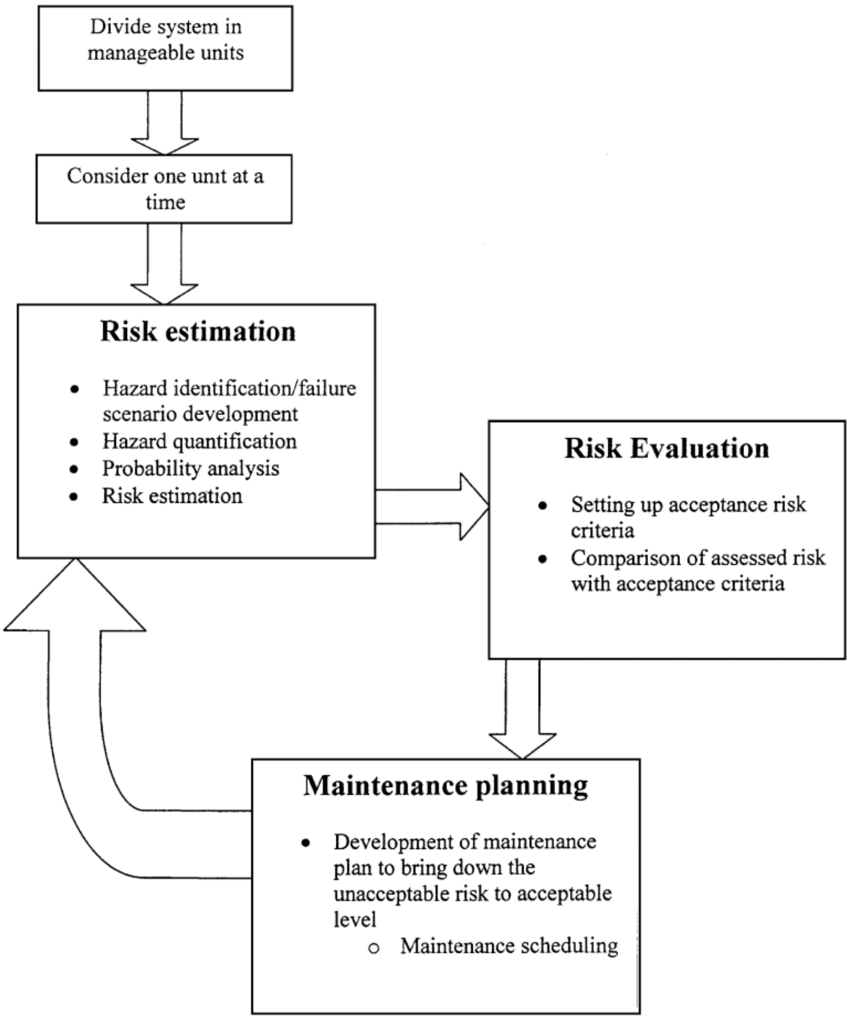

Figure 1-1 Architecture of RBM methodology

RBM methodology provides a tool for maintenance planning and decision making to reduce the probability of failure of equipment and the consequences of failure. The concept of risk-based maintenance was developed to inspect the high-risk components usually with greater frequency and thoroughness and to maintain in a greater manner, to achieve tolerable risk criteria (Arunraj & Maiti, 2007). The RBM strategy emerged in the 1990s and has received increasing attention from researchers in recent years. Khan and Haddara (2003) proposed a complete framework for the RBM strategy, in which the probability of the unexpected event was determined using fault tree analysis (FTA) and the consequences involved the estimation of system performance loss, financial loss, human health loss and environmental and/or ecological loss. Arunraj and Maiti (2007) reviewed research on RBM and risk assessment technologies. According to this literature review, there are several qualitative/quantitative risk analysis tools such as FTA, FMEA, etc. that have been applied in different applications. However, these traditional tools are not able to consider complex cause and effect interactions between failures/component in risk analysis of complex systems. In addition, no attention has been paid to possible dependencies among different criteria for selecting the best maintenance strategy or evaluating failures/risks. Considering these interactions and dependencies could lead to more accurate risk analysis and maintenance planning, while they are always overlooked. Moreover, Most of the risk analysis approaches are deficient in uncertainty and sensitivity analysis (Arunraj & Maiti 2007). By considering these shortcomings in existing risk analysis tools, it is evident that the existing traditional tools are not able to assess the risks/failures in complex systems accurately and any decisions based on misleading results may generate non-essential maintenance efforts. This misinterpretation will result in the failure to reduce or eliminate significant sources of risk. Last but not least, the existing risk/failures analysis tools are not able to predict the impacts of each failure/causes of failure on the other failures or on the system performance. Experts need to easily determine how any change in a failure or cause of failure will affect the other failure modes while this feature is not available in the traditional risk analysis tools such as FMEA.

This thesis addresses these major shortcomings in traditional risk/failures analysis and maintenance policy selection methods and propose several integrated frameworks by considering the level of experience and knowledge of experts and depending on the complexity of the system. The proposed frameworks are sufficiently general and could be applied in all critical industries for risk analysis and maintenance planning of complex systems. In addition, some of them could be adapted for complex Multi-Criteria Decision Making (MCDM) problems such as prioritization or selection issues by making some adjustments. We apply the proposed frameworks in variety of applications in order to show their applicability and efficiencies. At the end, as a case study in collaboration with *Center for Interdisciplinary Research in Rehabilitation and Social Integratio*n (CIRRIS), we develop a comprehensive priority-based framework for updating problem of Clinical Practice Guidelines (CPGs) by conducting a systematic literature review and international survey and based on our proposed frameworks in this thesis. Updating CPGs is a complex process in the lifecycle of CPGs for all healthcare organizations and substantial human and financial resources are being expended internationally for updating them.

In this chapter, we describe the five different problems related to risk analysis and maintenance of complex systems we are addressing in this thesis. As updating CPGs is considered as a case study, a brief description of CPGs and their updating problem is also presented. A brief review of literature on the existing approaches to address the five problems as well as the existing approaches for updating CPGs are also provided in this section. The objectives and outlines of the thesis is given at the end of this chapter. The following sub-sections (1.2.1-6) describe the five main problems and case study which have been addressed in this thesis.

1.2. Problem description

1.2.1. Risk-based maintenance strategy selection (RB-MSS) problem

Optimum maintenance strategy for a component or machine could have a significant impact on minimizing costs and downtime, maximizing reliability and productivity, improving quality and finally reaching the desired goals of companies (Karsak, 2001). Maintaining critical machines with poor attention can cause serious damages as well as lower utilization and productivity (Braglia, 2013; Murthy, 1999). According to Bevilacqua (2000), 15-70 percent of production costs of companies are due to maintenance costs. In addition, around 30% of these costs is wasted due to inappropriate maintenance policies (Mobley, 2002). Selecting the optimum maintenance strategy for a machine or system is a critical and complex task since variety of subjective/objective criteria should be taken into account (Arunraj, 2010). Moreover, considering the interrelationships between criteria that affect each other mutually makes the decision on optimum maintenance policy very complex. For example, when more money is spent on maintenance of a device, the level of risks will be reduced however, the cost effectiveness of a maintenance strategy in minimizing the risks has a significant effect in the final prioritization of maintenance strategies (Kumar, 2012). Due to high importance of MSS for all industries, variety of MCDM approaches have been applied in the literature. In most cases, AHP or a combination of AHP and some other decision making tools are proposed for finding the optimum maintenance policy (Arunraj, 2010; Bevilacqua, 2000; Al-Najjara & Alsyouf, 2003; Bertolini, 2006; Fouladgar et al. 2012). However, there are some drawbacks associated with these methods. First of all, the existing methods are very time consuming and sometimes confusing due to the need for answering several pairwise comparison by experts. The more maintenance alternatives and evaluation criteria are considered, the more comparisons is needed. In addition, some problems with consistency could arise. With a large set of comparisons, it is likely to be less consistent and it can take a long time to identify and fix all the inconsistencies. Second of all, the current methods are not able to consider the dependency and feedback effects among criteria, while considering the interdependencies could lead to a cost-effective and more accurate maintenance policy to organizations. In addition, very few risk-based approaches exist in the literature. Adopting a risk-based maintenance (RBM) approach helps in designing an alternative strategy to minimize the risk resulting from breakdowns or failures. In addition, is essential in developing cost-effective maintenance policies. Last but not least, no attention has been paid to the experience and knowledge level of maintenance experts in MSS. Since each expert has different knowledge and experience about the device and maintenance strategies, different weights should be assigned to each expert's opinion. The developed methods are still not able to fully address the existing gap in the literature of MSS, since the real industrial environment is much more complicated and several variables and factors should be considered and analysed at the same time for making decision about optimum maintenance policy (Arunraj & Maiti, 2007). The four specific research questions addressed in this study are as follows: (a) Do current MSS approaches consider all aspects of risks in finding optimum maintenance policy for a component or device? (b) Do current MSS approaches consider the dependencies between subjective/objective criteria? And if so, (c) is the impact of considering these dependencies in final prioritization of maintenance policies for a component/device is known? And (d) how can an advanced risk-based MSS method be developed so that it takes into account all aspects of risks, the possible dependencies among criteria and uncertainties in real industrial environment?

1.2.2. Enhancing traditional FMEA

Failure modes and effects analysis (FMEA) is a well-known and extensively used failure analysis method for identifying and mitigating potential failures in order to ensure the safety and reliability of components and systems. It is widely adopted in different industries such as manufacturing, aviation, healthcare, nuclear and services. Traditional FMEA analyses the risk of a component or process using risk priority number (RPN). The RPN is a product of three main criteria; the probability of the occurrence of failure (O), the probability of not detecting the failure (D) and the severity/consequences of the failure (S) ($RPN = O \times D \times S$). This approach is simple but not useful for risk analysis of complex systems since it suffers from some major weaknesses as follows:

(1) The relative importance among O, S and D is overlooked and the three criteria are assumed to have the same importance (Carmignani, 2009; Chang & Cheng, 2011; Chang et al., 2013; Kuei-Hu et al., 2014; Nepal et al., 2008; Peláez & Bowles, 1996; Sankar & Prabhu, 2001; Seyed-Hosseini et al. 2006; Zammori & Gabbrielli, 2011).

(2) The RPN criteria produce many duplicate numbers. This could lead to misclassifying high-risk failures as low risk (Carmignani, 2009; Chang & Cheng, 2011; Chang et al., 2013; Kuei-Hu et al., 2014; Seyed-Hosseini et al., 2006; Xu et al., 2002; Abbasgholizadeh Rahimi et al., 2015; Chin et al., 2008).

(3) Uncertainties in FMEA teams' opinions are neglected when scaling the RPN's subjective factors (Chang & Cheng, 2011; Chang, Chang, & Tsai, 2013; Seyed-Hosseini et al., 2006; Xu et al., 2002; Abbasgholizadeh Rahimi et al., 2015).

(4) Traditional FMEA only considers a single failure, while for a complex system with several components, there may be many failures and failure causes (Xiao, Huang, Li, He, & Jin, 2011).

(5) In complex engineering systems, the relationships and interdependencies among various failure modes (F), causes of failures (CFs), the relationships between CFs and Fs and vice versa are overlooked (Carmignani, 2009; Xu et al., 2002; Zammori & Gabbrielli, 2011; Nepal et al., 2008; Kuei-Hu et al., 2014; Chin et al., 2008). Many failures in critical systems and processes are dynamic and complex since several components interact with each other in so complex ways. This could lead to an increase in the number of failures in these systems since the failure of a component could lead to a failure of the same or another component or cause of a failure could be the cause of other failures. One of the main reasons for propagation of such failures in complex systems is the lack of in-depth understanding of the failure interactions and mechanisms.

(6) The level of experience and knowledge of experts are not considered in ranking failure modes (criticized by authors).

The aforementioned shortcomings crucially limit the efficiency of FMEA method and they could result in wrong decisions. Several attempts have been made in the past decade in order to address the shortcomings 1 to 3. However, very few authors have addressed the last three shortcomings (4, 5, and 6). There is a need for an advanced and powerful failure analysis tool to be able to consider this complexity in failure interactions of complex systems. However, the existing failure assessment tools are not able to consider failures interactions.

1.2.3. Dynamic risk modeling and assessing in complex systems

Nowadays, most of real-world systems and processes in engineering, manufacturing, healthcare, finance, sales, and other fields are complex and dynamic. The risks and uncertainties associated with these systems are often composed by several cause and effect relationships in so complex ways. This could lead to an increase in the number of failures in these systems if not assessed by an advanced risk assessment tool. Ordinary qualitative/ quantitative risk analysis tools such as conventional event fault tree analysis (FTA) or failure mode effects analysis (FMEA) methods are designed to illustrate static dependencies among logical variables, and do not consider process variables, time, or human behavior (which affect the system dynamic response) (Siu, 1994) and therefore could not be applied to risk assessment of these systems. In addition, some advanced modelling techniques such as Bayesian networks, Neural networks, etc. are not able to take into account the requirements demanded for risk assessment of such complex systems. There is a need for an advanced risk assessment tool which is able to take into account this cause and effect relationships among risk factors.

1.2.3.1. Dynamic risk modeling and assessing in maintenance outsourcing

Maintenance outsourcing is a common practice in many industries, such as aviation and medical equipment manufacturing. However, there is always some dynamic risks associated with outsourcing. Risk analysis of maintenance outsourcing projects is a complex task due to consisting of many risk factors with dependencies among them. As mentioned before, ordinary qualitative/ quantitative risk analysis tools such as conventional event fault tree analysis (FTA) or failure mode effects analysis (FMEA) methods are designed to illustrate static dependencies among logical variables, and do not consider the dependencies among risk factors and therefore could not be applied to risk assessment of these systems. In addition, some advanced modelling techniques such as Bayesian networks, Neural networks, etc. are not able to take into account the requirements demanded for risk assessment of such complex systems. Although there are some studies on maintenance outsourcing risks (Welborn, 2007; Bertolini et al. 2004; Gandhi et al., 2012), no attention has been paid to the risk analysis of maintenance outsourcing by considering the dependencies among risk factors. Considering the dependencies among risk factors could lead to more precise risks analysis and increase the success rate of outsourcing projects.

1.2.3.2. Dynamic risk modeling and assessing in Collaborative Networks (CNs)

Collaborative networks (CNs) such as virtual organizations, dynamic supply chains, professional virtual communities, collaborative virtual laboratories, etc. are complex systems associated with uncertainties in dynamic business environments. This uncertainty and complexity could lead to critical risks which could influence on the enterprises' performance. According to Munyon & Perryman (Munyon & Perryman, 2011), failure rate of alliances are estimated between 60% and 70%. Risk evaluation of CNs is a complex and critical task since several tangible and intangible risk factors should be considered in this process. In addition, there are always some dependencies among risks that can influence each other mutually and these dependencies make the evaluation process more complex and challenging. Therefore, an effective method for evaluating the risks is fundamental and essential. In recent decade, many problems related to CNs such as partner selection (Hexin & Jim, 2005) (Shah & Nathan, 2008) (Jarimo & Salo, 2007), modeling collaboration preparedness assessment (Rosas & Camarinha-Matos, 2008), etc. have been investigated. However, very little attention has been paid to the risk analysis of collaborative networks by considering the dependencies among risk factors (LI & Liao, 2007) (Zhou & Lu, 2012).

1.2.4. Risk assessment in ERP maintenance

In recent decades, companies across the world have implemented ERP systems. Proper ERP implementation has been a more explored issue. Specifically, numerous papers have presented the critical success factors in these projects. But even when the implementation finished satisfactorily, success in ERP adoption is not guaranteed (Lopez & Salmeron, 2012). It also depends on the effectiveness process in the post-implementation ERP systems. The maintenance of the ERP is necessary to correct and prevent systems risks as well as to enhance its performance and adapt continuously to the system (Aloini et al., 2007). A survey about ERP systems shows a growing activity in ERP maintenance. This trend has continued in recent years. However, ERP risks studies represent about only 12% of the ERP research (Salmeron & Lopez, 2010). Nevertheless, this is often managed intuitively and without taking into account the existing risks. In contrast, risks management in IT projects is a common practice because it decreases failure probability. In this sense, the maintenance managers need to know the importance of all risks by considering the possible interdependencies among them. In spite of this, there is no systematic and easy-to-use approach for evaluating and prioritization of potential risks that could affect the maintenance of ERPs.

1.2.5. Risk-based maintenance and replacement of Medical devices

Nowadays, safety of advanced medical device and the hazards associated with utilization of them is one of the critical issues for healthcare organizations across the world (Florence & Calil, 2007). Degradation in the performance of complex medical devices and inadequately maintained medical equipment create an unacceptable risk of patient injury. In addition, there are risks of injury to clinical staff from simple, direct hazards, such as accidental contact with electrified parts or from mechanical failures within the device (Ridgway, 2009), for example defects in ultrasound machines, defective artificial cardiac valves, leakage of insulin pumps, and high number of errors in CT scans which leads to patients receiving 10 times the intended dose of radiation in some cases (Fries, 2012). Thus, the maintenance and replacement of medical devices is fundamental and it calls for an effective and efficient framework to prioritize medical devices for maintenance/replacement activities based on key criteria and choose the best maintenance/replacement policy for each device. Although reliability engineering approaches have been successfully applied for decades in different industries and numerous inspection and optimization models are developed, the application of all these techniques and models to medical devices is new (Taghipour et al. 2010). Hospitals, due to possessing a large number of difference devices, can benefit significantly if the optimization techniques are used properly in the equipment management processes. Most research in the area of reliability engineering for medical equipment mainly considers the devices in their design or manufacturing stage and suggests some techniques to improve the reliability. To this point, best maintenance/replacement strategies for medical equipment in their operating context have not been considered. So, it is necessary to develop maintenance/replacement planning to minimize frequency and consequences of devices failures in healthcare industries.

1.2.6. Case study: Updating Clinical Practice Guidelines

As a case study in this thesis, we consider the common problem of updating clinical practice guideline (CPG) in all healthcare organizations. A CPG is a document that includes recommendations to assist physicians, healthcare practitioners, and patients in making decisions about diagnosis, management, and treatment for specific clinical conditions (NGC, 2014). The lifespan of CPGs is limited since new evidences emerge continuously (Aghbasi et al., 2014). New information needs to be assessed frequently and CPGs should be updated regularly based on the new evidence in order to remain valid (Garcia et al., 2011). Many organizations recommend a full update every 3-5 years. This could be a waste of the limited resources of organizations since the rate of new evidence for different fields is variable (Shekelle et al., 2001). Updating CPGs is a crucial and complex process in the lifecycle of CPGs for ensuring their validity and quality (Woolf et al., 1999; Clarck et al., 2006). Substantial human and financial resources are being expended internationally for updating existing CPGs (Aghbasi et al., 2014; Woolf et al., 1999; Vernooij et al., 2014; Shekelle et al., 2001). According to Shekelle (2001), conducting a systematic review in the US Agency for Healthcare Research and Quality (AHRQ) costs approximately $250,000 USD for each CPG. Considering the limited resources of organizations, dynamic and fluid environment of CPGs, and substantial cost and time needed for updating, it is obvious that updating all CPGs regularly is not feasible. Therefore, there must be some validated criteria and a systematic prioritization method in order to prioritize the existing CPGs for updating. Prioritization of existing CPGs for updating is an effective way of ensuring that resources are spent in an efficient and effective manner towards the upkeep of the CPGs that are the most relevant and of the highest priority (Aghbasi et al., 2014).

1.3. Thesis objectives

In this thesis, we address variety of problems related to risk-based maintenance of complex systems including risk-based maintenance strategy selection (RB-MSS), enhancing traditional FMEA method, the need for a dynamic risk analysis tool, risk-based maintenance and replacement of medical devices, and as a case study, we address the common problem of updating CPGs. We propose several systematic/comprehensive methods and frameworks in order to improve current maintenance strategies in the critical industries. Our main objective is to reduce overall risk in these industries. We intend to look into the challenges that experts are currently facing for maintenance management of critical and complex systems. On the other hand, we attempt to propose some models and methods that are sufficiently general and can be practically used in all industries.

The six main objectives of this thesis are as follows:

1. Improving the current maintenance and replacement activities in critical industries

2. Improving the existing methods for MSS

3. Enhancing traditional FMEA method

5. Proposing an advanced dynamic tool for risk assessment of complex systems

6. Proposing a comprehensive dynamic framework for updating CPGs

1.4. Contributions of this Work and methodology

The contributions of this thesis led to the papers published/submitted in scientific journals or international conference proceedings. A brief description of each contribution including the methodology is described in this sub-section. This thesis includes twelve contributions presented as articles.

In the first contribution, we address the shortcomings of current maintenance strategy selection methods and develop a risk-based framework using AHP, FCM, and FSS for selecting the best maintenance policy by considering uncertainties, level of experience and knowledge of experts, and dependencies among criteria. By performing a sensitivity analysis, we demonstrate that considering the complex dependencies among criteria has an impact on priority of maintenance policies. In addition, we show that the final priority of maintenance policies remained stable in all cases when the weights of the main criteria were increased/decreased for 25 percent.

The second contribution aims to address the shortcomings of traditional failure mode and effect analysis (FMEA) method and enhance it using FCM. This study proposes an innovative framework for analysis of failure modes in complex systems by considering the complex interactions among failures and cause of failures. The proposed framework is able to predict the impact of each failure or cause of failure on the other failure modes or on the system performance. In addition, it is able to take into account the level of experience and knowledge of experts, the uncertainties on failure analysis process, and multiple causes of failures and components. In contributions 3 and 4 we first propose a dynamic risk modeling and assessment tool using FCM for dealing with risks of maintenance outsourcing and collaborative networks. As an extension of contributions 3 and 4 (contribution 5), we generalize the developed tools in contributions 3 & 4 and propose an advanced decision support tool which could be applied in any complex system for predicting the impact of each risk on the other risks or on the performance of system. The main feature of this tool is the ability to model the behaviour of system and consider all the possible interdependencies among risk factors. This tool could help practitioners in critical industries to manage the risks of complex systems in a more effective and precise way and offer better risk mitigation solutions. In the sixth contribution, we address the associated risks in ERP maintenance and we propose another integrated approach using fuzzy FMEA and Grey Relational Analysis (GRA) methods for prioritizing the risks. The presented systematic framework is able to consider the interdependencies among risk factors. One of the main features of the proposed frameworks and methods in this thesis is that different weights are assigned to criteria and also the level of experience and knowledge of experts. In addition, the uncertainties in experts' opinions are taken into account using fuzzy logic techniques.

In the contributions 7-10, we address the maintenance issue of medical devices, since these devices have become very complex and sophisticated and the application of maintenance and optimization models to them is fairly new. We first perform a literature review regarding the maintenance of medical devices, Then, we revisit and reassess the major criteria and sub criteria that can affect medical devices risk scores. Finally, we develop one comprehensive and two integrated frameworks for risk-based maintenance and replacement planning of medical devices based on the reassessed criteria/sub-criteria.

In addition to above contributions, we have performed a project titled "Updating Clinical Practice Guidelines; a priority-based framework for updating existing guidelines" in collaboration with CIRRIS which led to two important contributions. In the first contribution, we performed a systematic literature review to identify potential criteria in updating CPGs. Then, based on the review's results, we conducted an online survey. The survey was sent by email to 83 public and private organizations across the world and 16 authors who have published relevant articles on the subject of updating CPGs. We validated and weighed all the identified criteria through an international survey. In the second contribution, we developed a comprehensive priority-based framework for updating CPGs based on the approaches that we had already developed and applied successfully in other industries. This is the first time that such a comprehensive framework has been proposed in the literature of guidelines. Evaluation and prioritization of existing CPGs based on the validated criteria and proposed quantitative framework can promote channelling limited resources into updating CPGs that are most sensitive to change, thus improving the quality and reliability of healthcare decisions made based on current CPGs. By implementation of this framework in healthcare, institutes will have a formal and rigorous process for deciding which guideline is in urgent need for updating and when a guideline should be updated.

Conclusion

In this chapter, we introduced the problems we are addressing, as well as a case study related to updating problem of CPGs in healthcare organizations. We also presented the main objectives of the thesis. Finally, the outlines of this thesis is provided. The following five chapters present the twelve original contributions of the thesis.

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Chapter 2.
An integrated dynamic framework for risk-based maintenance policy selection

The second chapter is earmarked to the article entitled “A new risk-based framework for maintenance policy selection by integrating FCM, AHP and Fuzzy soft set” submitted in April 2016 to the “International Journal of Production Research”.

2.1 An integrated dynamic framework for risk-based maintenance strategy selection

Résumé: La sélection des stratégies de maintenance (SSM) est une tâche critique et complexe de prise de décision à critères multiples (PDCM) pour toutes les industries. Diverses approches ont été développées au cours de la dernière décennie pour résoudre ce problème. Cependant, peu de recherches sur les SSM dynamiques basés sur le risque (RB-MSS) en considérant les incertitudes existent dans la littérature. D'autre part, les critères utilisés sont indépendants et ne reflètent pas les relations de cause à effet entre les critères. Cette étude identifie d'abord les critères et les politiques de maintenance les plus populaires utilisés pour le SSM en passant en revue la littérature et propose ensuite un cadre de sélection de stratégie de maintenance basée sur le risque en intégrant le processus d'analyse hiérarchique (PHA), les cartes cognitives floues (CCF) et les outils de la théorie des ensembles flous. Ce cadre dynamique fondé sur le risque est non seulement capable de considérer les dépendances complexes entre les critères mais aussi de prendre en compte les informations imprécises et les opinions de plusieurs experts dans tous les processus décisionnels. Ce cadre est continuellement mis à jour afin de minimiser les risques d'échec pour un composant / système. En effectuant une analyse de sensibilité, il a été révélé qu'en considérant les dépendances parmi les critères, la priorisation finale des stratégies de maintenance est affectée. Cette hiérarchisation est restée stable dans tous les cas où les poids des principaux critères ont été augmentés / diminués pour 25 pour cent. Un exemple de cas universitaires est fourni pour illustrer les étapes et l'applicabilité du cadre proposé.

Mots-clés: Maintenance axée sur les risques, Sélection de stratégies de maintenance, Prise de décision à critères multiples, Cartes cognitives floues, Ensemble flou, processus d'analyse hiérarchique.

2.1 An integrated dynamic framework for risk-based maintenance strategy selection

Abstract: Maintenance strategy selection (MSS), is a critical and complex multi-criteria decision making (MCDM) task for any industries. Various approaches have been developed in the recent decade to tackle this problem. However, few researches on dynamic risk-based MSS (RB-MSS) by considering uncertainties exist in the literature. On the other hand, the used criteria are independent and don't reflect the cause and effect relationships between criteria. This study first identifies the most popular criteria and maintenance policies used for MSS by reviewing the literature and then proposes a risk-based maintenance strategy selection framework by integrating the analytical hierarchy process (AHP), fuzzy cognitive maps (FCM), and fuzzy soft set (FSS) tools. This dynamic risk-based framework is not only able to considers the complex dependencies between criteria, but also takes into account the imprecise information and several experts' opinions in all decision making process. This framework is continuously updated in order to minimize the risks of failures for a component/system. By performing a sensitivity analysis, it was revealed that by considering the dependencies among criteria, the final prioritization of maintenance strategies are affected. This prioritization remained stable in all cases when the weights of the main criteria were increased/decreased for 25 percent. An academic numerical example case is included to illustrate the steps and applicability of the proposed framework.

Key words: Risk-based Maintenance, Maintenance strategy selection, Multi criteria decision making, Fuzzy cognitive maps, Fuzzy soft set, Analytical Hierarchy Process.

1. Introduction

Optimum maintenance strategy for a component or machine could have a significant impact on minimizing costs and downtime, maximizing reliability and productivity, improving quality and finally reaching the desired goals of companies (E.E. Karsak, 2001). Maintaining critical machines with poor attention can cause serious damages as well as lower utilization and productivity (Marcello Braglia, 2013; Murthy, 1999). According to Bevilacqua (Bevilacqua, 2000), 15-70 percent of production costs of companies are due to maintenance costs. In addition, around 30% of these costs is wasted due to inappropriate maintenance policies (Mobley, 2002). Selecting the optimum maintenance strategy for a machine or system is a critical and complex task since variety of subjective/objective criteria should be taken into account (Arunraj N. a., 2010). Due to high importance of MSS for all industries, variety of MCDM approaches have been applied in the literature. In most cases, AHP or a combination of AHP with some MCDM tools are proposed (Al-Najjar, 2003; Arunraj N. a., 2010; Bevilacqua, 2000; Bertolini, 2006; Mohammad Majid Fouladgar, 2012). However, there are some drawbacks associated with these methods. First of all, the existing AHP-based approaches are very time consuming and sometimes confusing due to the need for answering several pairwise comparison by experts. The more maintenance alternatives and evaluation criteria are considered, the more comparisons is needed. In addition, some problems with consistency could arise. With a large set of comparisons, it is likely to be less consistent and it can take a long time to identify and fix all the inconsistencies. Second of all, although several research works have been published on MSS, very few of them are risk-based (Kumar Sharma, Kumar, & Maiti, 2012). A Risk-based maintenance (RBM) approach could minimize the risk of failures to a great extent and lead to cost-effective maintenance policies. In a risk-based maintenance strategy selection (RB-MSS) approach, maintenance strategies are prioritized by assessing the level of risk for each failure mode. Zhaoyang et al. (Zhaoyang, 2011) proposed a risk-based method to find the suitable maintenance policy in an industrial process in China. At first, the authors calculated the risk score for equipment based on probability of failure and consequences parameters and by using RISKWISE software. They categorized the equipment into 5 risk levels based on their risk scores. Then, they applied AHP method and considered four criteria to find the best maintenance policy for each equipment. Arunraj and Maiti (Arunraj N. a., 2010) presented a risk-based hybrid method consisting of AHP and goal programming (GP) for selecting best maintenance strategy in a critical unit of a chemical plant.

Another issue regarding current MSS approaches is that these approaches are not able to consider the dependency and feedback effects among criteria. Considering the interrelationships between criteria that affect each other mutually makes the decision on optimum maintenance policy very complex (Jamshidi, Abbasgholizadeh Rahimi, Ait-Kadi, & Ruiz, 2015). For example, when more money is spent on maintenance of a device, the level of risks will be reduced however, the cost effectiveness of a maintenance strategy in minimizing the risks has a significant effect in the final prioritization of maintenance strategies (Kumar Sharma, Kumar, & Maiti, 2012). Considering these interdependencies could lead to a cost-effective and more accurate maintenance policy to companies and organizations. To the best of our knowledge, no study has addressed this shortcoming and the impact of considering the dependencies on the prioritization of maintenance policies are not known yet. Kumar and Maiti (2012) are the first and only authors who considered the dependency between two criteria for finding out the best maintenance alternative. They evaluated different maintenance strategies based on risk and cost factors and considered the dependencies between the two factors using Fuzzy Analytic Network Process (FANP). Despite the fact that ANP takes into account the dependencies between criteria, it suffers from some major shortcomings. First, the questions for comparing the importance of criteria are sometimes hard and not understandable for experts to answer (R. Yu, 2006). Second, ANP is able to consider only the direct dependencies among criteria while there could be some indirect dependencies among criteria which are ignored. Third, determining the true ANP structure for several criteria is hard since each structure produces a different result (J.W. Lee, 2000).

The developed methods are still not able to fully address the existing gap in the literature of MSS, since the real industrial environment is much more complicated and several variables and risk factors should be considered and analysed at the same time in a dynamic environment for making risk-based decisions about optimum maintenance policy (Arunraj & Maiti, 2007). In this paper, we first review the literature regarding the most popular criteria and maintenance policies considered in MSS and then propose an integrated dynamic risk-based framework for maintenance policy selection using AHP, FCM, and FSS theory in an attempt to overcome these shortcomings. This dynamic framework is continuously updated in order to minimize the risks of failures for a component/system. The presented framework consists of a three step decision process. In the first step, AHP is used to determine the initial criteria weights by comparing the relative importance of each criterion. In the second step, FCM as an effective dynamic tool for modeling the behaviour of complex systems is applied to take into account imprecise information, uncertainties, and the interrelationships among criteria. FCM has gained an increasing attention in the last years and it is being used in different complex decision making problems (Jamshidi, Abbasgholizadeh Rahimi, Ait-Kadi, & Ruiz, 2015; Jamshidi, Abbasgholizadeh Rahimi, Ait-Kadi, & Ruiz, 2015; Zhi Xiao, 2012; Salmeron, 2010). In order to overcome the FCM method's dependence for expert advice in the reasoning process, we use NHL-DE algorithm to train FCM and obtain the weight of each criterion. Finally, in the third step, a modified FSS model is formulated to prioritize the maintenance policies. FSS has gained increasing importance in the recent years since it is easy to use and less time consuming and confusing for experts in comparison with hierarchical methods. FSS has a rich potential to be applied in different industries for a variety of complex decision makings (Çelik & Yamak, 2013). To the best of our knowledge, no study has adopted the combination of AHP, FCM, and FSS in risk- based MSS. Then, in this paper, we firstly integrate and apply these decision making tools in RB-MSS. At the end, we perform a sensitivity analysis in order to evaluate robustness of the proposed framework and also assess the impact of considering dependencies in prioritization of maintenance policies.

The remainder of the paper is organized as follows. Section 2 provides a scientific literature review about current methods, popular criteria, and maintenance policies used for MSS. Section 3 introduces the preliminaries of FCM, hybrid algorithms and FSS. The proposed framework is presented in Section 4 and is illustrated using an academic example in section 5. The results of sensitivity analysis are reported in section 6. Finally, conclusions and future directions are drawn in Section 7.

2. Maintenance policies

In order to determine the most popular criteria and maintenance strategies used in MSS, we searched the literature (through ScienceDirect, Emerald, IEEE, and Google Scholar databases) from 1995 to 2016 for papers dealing with MSS. Publications in languages other than English, textbooks, and doctoral dissertations were not included. In addition, we only included papers that report on an approach for MSS by considering some criteria and maintenance alternatives. This implies that the papers which only deal with risk analysis methods and their improvements were excluded. Through this review, we identified 15 different maintenance policies from 21 papers (See Fig. 2.1) and it was revealed that the 8 most popular maintenance strategies considered in most of papers have been CM, PM, CBM, PDM, TPM, TBM, OM, and RCM, respectively. These policies are described in the followings.

1) Corrective Maintenance (CM): This maintenance is performed only after occurrence of a failure. In this policy, only repair or replacement actions are taken, but no action is taken to detect the cause of failure or to prevent failure. This policy is usually applied for non-critical equipment since it is very costly for critical equipment (Kumar, 2012). CM is also called as breakdown maintenance or failure based maintenance (Bashiri et al., 2011).

2) Preventive maintenance (PM): This maintenance doesn’t wait for a component to fail and is regularly performed in order to lessen the likelihood of component failing and their consequences. PM is more complex than CM since it needs maintenance schedule. In addition, it has some difficulties such as insufficient historical data, the need of decision support systems, and uncertainties in assessing the time to action (Al-Najjar, 2003). PM can be classified as TBM and CBM (Kumar, 2012).

3) Time-based maintenance (TBM): is a planned maintenance which is implemented at scheduled periodic intervals. The periodic intervals are scheduled based on the failure distribution of the equipment. This policy is not effective when various factors other than the elapsed time such as environmental and operational conditions have an impact on the failure rate of equipment (Kumar, 2012; Arunraj & Maiti, 2010).

4) Condition-Based Maintenance (CBM): In this strategy, the condition of equipment is monitored for some indicators and data are gathered continuously or at certain intervals. The maintenance is done when the gathered

data show that one or some indicators are approaching the predefined threshold level (Fouladgar et al., 2012). This strategy could be applied for both critical and non-critical equipment however, it is the most cost effective maintenance policy for critical equipment (Veldman, 2011).

5) Predictive maintenance (PDM): In this policy, the equipment failure is predicted at the early stages using different methods such as observation, vibration, etc. in order to avoid catastrophic failures. As CBM policy, PDM is a cost-effective maintenance strategy since the maintenance is performed only when it is required and then the maintenance frequency and downtimes are low. However, it could be costly in the cases that some expensive monitoring and specialists are required to analysis the data.

6) Total productive maintenance (TPM): This maintenance policy requires the active participation of the workforce in a plant in order to improve the overall equipment effectiveness (OEE).

7) Opportunistic Maintenance (OM): is very effective in oil and gas industry. This policy, gives an opportunity to maintenance staff to repair or replace the defective or yet non-failed components during the maintenance of other components/equipment or in a downtime opportunity in order to prevent future failures (Fouladgar et al., 2012).

(8) Reliability-centered Maintenance (RCM): In this policy, cost-effective maintenance strategies are determined for components based on a failure analysis using FMEA (Failure mode and effect analysis), FMECA, HAZOPS (Hazard and operability studies), FTA (Fault tree analysis), or RBI (Risk-based inspection) tools. This policy heavily depends on the availability of failure data and there is sometimes difficulties in its implication (Al-Najjar, 2003).

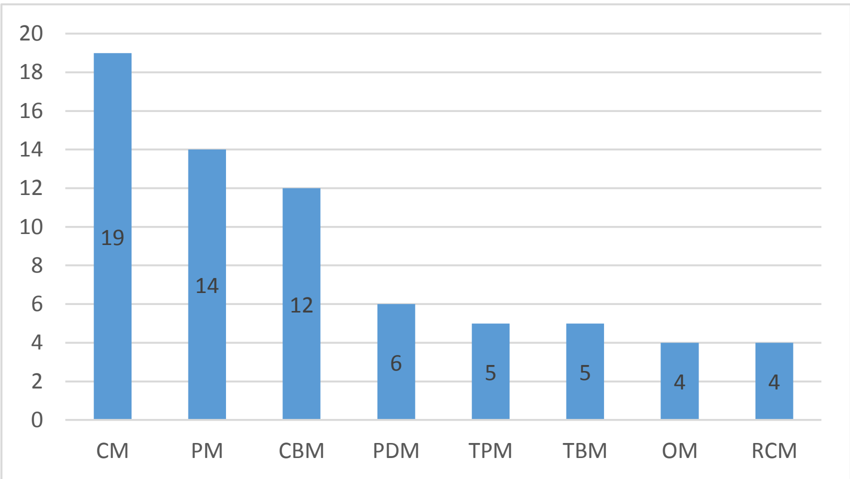

Figure 2. 1 The most popular Maintenance policies considered in MSS

Table 2. 1 The criteria and maintenance policies for MSS

Author	Criteria	Maintenance policies	Application
Al-Najjar et al. (2003)	Failure causes	CM, PM, CBM, TPM, RCM, TQM	Paper Mill
Labib (2004)	Failure occurrence, downtime	CM, Design out maintenance (DOM), CBM, Skill level upgrade (SLU), Fixed time maintenance (FTM)	Automotive company
Khalil et al. (2005)	Failure cost	CM, PM, CBM, operator asset care	Aero-industry
Sharma et al. (2005)	Failure causes	CM, PM, CBM, RCM and TPM	Process industry (Gear)
Luce, (1999)	Production loss, maintenance costs	CM, PM	Cutting presses for iron
Okumura and Okino (2003)	Production loss, maintenance costs	CBM, TBM, Breakdown maintenance (BM)	Manufacturing system
Triantaphyllou et al. (1997)	Cost, reparability, reliability, availability	-	Numerical Example
Bevilacqua & Braglia (2000)	Cost, damages, applicability, added value	CM, PM, OM, CBM, PDM	Italian oil refinery
Bertolini & Bevilacqua (2006)	Failure occurrence, its severity, its detectability	CM, PM, PDM	Centrifugal pumps in an oil refinery
Arunraj & Maiti (2010) (Arunraj & Maiti, 2010)	Risk of equipment failure, cost of maintenance	CM, TBM, CBM, Shutdown maintenance (SM)	Benzene extraction unit of a chemical plant
Ahmadi (2010)	- Benefit (Business, Planning flexibility, maintenance downtime, Procedural effectiveness) - Cost (Investment, Maintenance cost)	CM, Functional check, Restoration, Discard, Incorporation of PHM	Fuel System of aircraft
Azadivar (2010)	16 characteristic factors including MTBF, Job routing complexity, Resource availability, Repair load, Demand urgency, Allowed buffer size, etc.	CM, PM, OM, PDM, MTBF-based	JIT production systems
Maletic et al. (2014)	- Equipment and process related measures (OEE, MTTR, productivity, availability, breakdown frequencies, quality rate) - Financial measures (maintenance and production costs, maintenance savings) - Health, safety and environment measures (number of accidents)	CM, PM, TPM, RCM, TQM	Paper mill company
Wang et al. (2007)	Safety, Cost, Added-value, Feasibility	CM, CBM, TPM, PDM	Thermal power plant
Bashiri et al. (2011)	Benefit, Cost, MTBF	CM, PM, TBM, CBM, PDM	Numerical Example
Chan & Prakash (2012)	Capital cost, Running cost, downtime, Reliability, Capability, Repair load, Operator skills, Flexibility, Efficiency, Facility utilisation, Resource availability	TPM, TQM, CBM, PM, FBM	Numerical Example
Cheng & Tsao (2010)	Quality and efficiency, Cost and reliability, Safety	CM, PM	Rolling stock
Fouladgar et al. (2012)	Cost (Spare part stocks, Personnel wage, MTTR, MTBF), Accessibility (Technology, Human resource), Risk (Product loss, People damage, Environmental damage), Added value (Product quality, Efficiency, Intrinsic safety)	CM, TBM, CBM, PM, OM	Sungun copper mine
Kumar (2012)	Risk of equipment failure, cost of maintenance	CM, TBM, CBM, SM	A unit of a chemical plant
Nezami & Yildirim (2012)	- Business excellence/economic factors - Social/human contribution factors - Environmental factors	CM, PM, TPM, RCM, CB,	Car manufacturing company
Pariazar et al. (2008)	Safety, Cost, Added-value, Execution capability	CM, PM, OM, CBM, PDM	An industrial unit

2.2. Popular criteria in selecting best maintenance policy

According to the literature review, variety of criteria have been considered in MSS which some of them are quantitative such as MTTR, MTBF, reliability and some are qualitative such as safety and feasibility (See Table 2.1). Cost-based criteria such as cost of failure, maintenance costs, and production loss have been considered as the most important criterion in all of the identified 21 papers (See Fig. 2.2). Apart from the cost-based criteria, variety of other criteria have been considered such as safety, downtime, availability, etc. One point that should be mentioned is that less attention has been paid to the risk of failure while considering the risk of failures simultaneously with other criteria is crucial to the success of maintenance actions in industries. Only two papers consider the risk of failure as the main criterion along with cost of maintenance criterion (Arunraj & Maiti, 2010; Kumar, 2012). In addition, two papers consider the risk of failures by using Risk Priority Number (RPN) factors (Occurrence, Detection and Severity). The evaluating criteria for MSS depend on the organizational goals and objectives and could be decided in consensus with field experts. The most popular criteria considered in MSS are shown in Fig. 2.2.

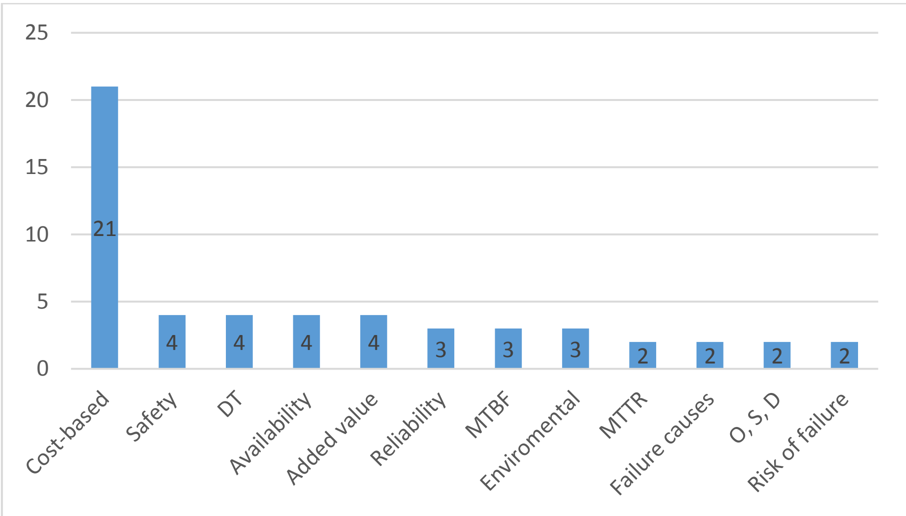

Figure 2. 2 The most popular criteria considered in MSS

3. Basic theories

In the followings, we review briefly some basic concepts of Fuzzy Cognitive Map, Hybrid based Learning Algorithms, and fuzzy soft sets which we have applied in our proposed framework.

3.1 Fuzzy Cognitive Map (FCM)

FCM is one of powerful decision support tools which was developed by Kosko in 1986 (1986) for modeling the behaviors of complex systems. FCM has gained an increasing attention in the recent years due to its simplicity, flexibility, applicability and adaptability to a variety of complex problems and has been used in different industries and applications including political decision making, fault detection, engineering science, decision analysis, medical decision system, and process control (Xiao, 2012). The AHP-based methods for MSS fail to take into account the complex interactions and feedbacks which might be present in the system. In order to overcome this limitation, in this study we apply FCM for considering all dependencies among criteria in MSS. We believe that application of FCM in MSS is not reported in the literature to date. Then, in this study we first apply FCM in risk-based MSS.

FCMs are designed based on the experience and knowledge of decision makers who know the operation and behavior of systems and are employed to represent both subjective and objective data in complex systems. FCM represents a complex system through a simple graph and by using some nodes and arcs among nodes. The nodes represent the important factors in the system and the directed arcs show the cause-effect dependencies between nodes (Xiao, 2012). The figures 2.3 and 2.4 show a simple FCM diagram with 5 nodes and 9 arcs and related initial weight matrix, respectively. Each node (C_i) takes value in the interval $A_i \in$ [0, 1], and each weighted arc (W_{ij}) takes value in the interval [-1,1].

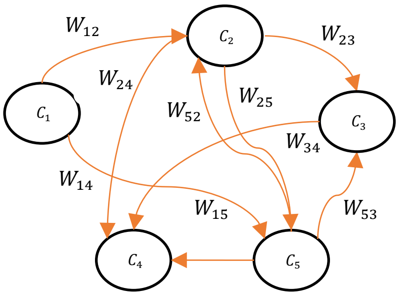

Figure 2. 3 An example of FCM graph

$$W^{Initial} = \begin{array}{c} \\ c_1 \\ c_2 \\ c_3 \\ c_4 \\ c_5 \end{array} \begin{array}{c} \begin{array}{ccccc} c_1 & c_2 & c_3 & c_4 & c_5 \end{array} \\ \begin{bmatrix} 0 & W_{12} & 0 & 0 & W_{15} \\ 0 & 0 & W_{23} & 0 & W_{25} \\ 0 & 0 & 0 & W_{34} & 0 \\ 0 & 0 & 0 & 0 & 0 \\ 0 & W_{52} & W_{53} & W_{54} & 0 \end{bmatrix} \end{array}$$

Figure 2. 4 The initial weight matrix of the above FCM graph

The sign of each weight between two concepts ($+$ or $-$) shows the same or opposite directions of two nodes. For example, if an increase in value of concept C_i will increase the value of concept C_j, it shows that both nodes have the same directions and then, the sign of W_{ij} should be positive (Papageorgiou, 2014). All the required information for designing a FCM graph including the types of nodes, interrelationships between nodes and their directions, and initial weights of nodes are heavily based on the experts' knowledge and experience. Therefore, the selection of right experts is an important issue since their opinions affect the results (Elpiniki, 2005).

Nomenclature			
C_i	node i /concept i	T_i	the mean value of interesting node DOC_i
W_{ij}	the initial weight between two nodes C_i and C_j;	$v_i^{(k+1)}$	new mutant vector
$W^{Initial}$	initial weight matrix	$w_i^{(k)}$	mutation operator
$w_{ji}^{(k)}$	modified weights using NHL algorithm	$F(W)$	fitness function
$W_{NHL}^{(k+1)}$	updated weight matrix using NHL algorithm	$D = \{d_1, \ldots, d_m\}$,	set of m devices
w_{ij}	the updated weight matrix using NHL-DE	$C = \{ c_1, \ldots, c_n\}$	set of n criteria
A_i	initial value of the node C_i	$P = \{P_1, \ldots, P_k\}$	set of k maintenance policies
$C^{Initial}$	initial concept vector	$f(x)$	threshold function
		Q_h	device-criteria matrix

C^*	the steady-state concept matrix	DC_h	weighted device-criteria matrix
C_N^*	normalized C^* matrix	R_h	criteria-policy matrix
A_i^{k+1}	the value of concept C_i at simulation step $k+1$;	DP_h^*	device-policy matrix
f	threshold function	$DP_{hil}{}^{**}$	defuzzified DP_h^*
DOC_i	Desired Output Concepts for node i	$DP_T{}^{**}$	final policy prioritization matrix
$w_{ji}^{(k)}$	the modified weights at iteration step k using NHL	W_h	weight of decision maker h
		CR	values of crossover constant
η	learning rate parameter	μ	mutation constant
γ	weight decay parameter	γ	weight decay learning parameter
F_1	the first termination function	η	learning rate parameter
F_2	the second termination function	DM_h	decision maker h

Once the FCM graph is designed by experts and the initial values for each node and the weights between nodes are determined, the initial value (A_i) of the node C_i is updated by calculating the influence of all connected nodes to C_i (Kosko, 1997) using Eq. 1.

$$A_i^{k+1} = f(A_i^{(k)} + \sum_{\substack{j=1 \\ j \neq i}}^{n} W_{ij} A_j^{(k)}), \quad (1)$$

where,

W_{ij} shows the initial weight between two nodes C_i and C_j;

A_i^{k+1} is the value of concept C_i at simulation step $k+1$;

f is a threshold function. The mostly applied threshold functions in the literature are; tangent hyperbolic ($f(x) = tanh(x)$), sigmoid function ($f(x) = 1/(1+e^{-\lambda x})$), bivalent function (f(x) = 0 or 1), and trivalent function (f(x) = -1, 0 or 1).

At each simulation step, a new value is produced for each node by Eq. 1 and the iterations end once FCM arrives at one of the following three steady state conditions (Papageorgiou, 2014).

1) The updated concepts' values are fixed in a point,
2) Reaching limited state cycle, and
3) Appearance of chaotic behavior.

In order to overcome the potential convergence of FCM to undesired steady state conditions, some learning algorithms such as particle swarm optimization (PSO) (Elpiniki, 2005), Differential Hebbian Learning (Papageorgiou, 2004) (Papakostas, 2011), and Simulated Annealing (SA) (Alizadeh et al., 2009) have been proposed recently. Learning algorithms are used to update/modify the initial weight matrix and can increase the robustness and accuracy of FCM. Three types of learning algorithms proposed in the literature for training FCMs are; 1) Evolution-based, 2) Hebbian-based, and 3) Hybrid-based. In this paper, a hybrid-based learning algorithm is applied to train FCM since this kind of learning algorithm has been proven to be the most effective and efficient (Papageorgiou, 2012; Papageorgiou, 2014).

3.2 Hybrid based Learning Algorithms

Hybrid-based learning techniques are a combination of Evolution-based and Hebbian-based algorithms (Papageorgiou, 2012). In this learning technique, the initial weight matrix is updated/modified by using the knowledge and experience of experts in a two-step process. Few hybrid-based algorithms have been proposed in the literature (Zhu & Zhang, 2008; Ren, 2012; Papageorgiou & Groumpos, 2005). Papageorgiou and Groumpos (2005) proposed NHL-DE hybrid algorithm for learning FCMs. This algorithm is consisted of Nonlinear Hebbian Learning (NHL) and Differential Evolution (DE) algorithms. They proved the efficiency of this algorithm by three experiments. The hybrid-based learning algorithms are more effective in modeling complex systems and have less limitations since they inherit the advantageous of both evolution-based and hebbian-based algorithms (Papageorgiou, 2014). In this study, we apply NHL-DE algorithm to train the FCM. The two steps for this algorithm is explained in the followings.

3.2.1 First step: NHL algorithm

This algorithm is based on the fact that all the FCM node are interacting with each other at each iteration and their values are changing. The value A_i^{k+1} of node C_i, at iteration step k + 1, is calculated through Eq. (2) in which, the NHL algorithm computes the impact of interrelated nodes with value A_j and by considering the modified weights $w_{ji}^{(k)}$ at iteration step k (Papageorgiou & Groumpos, 2005).

$$A_i^{k+1} = f(A_i^{(k)} + \sum_{\substack{j=1 \\ j\neq i}}^{n} w_{ji}^{(k)} A_j^{(k)}), \tag{2}$$

The initial weights between nodes (W_{ij}) are updated at each iteration k and modified weights ($w_{ji}^{(k)}$) are derived during these interactions. The weight updating rule of the NHL is as follows:

$$w_{ji}^{(k)} = \gamma . w_{ji}^{(k-1)} + \eta A_j^{(k-1)} (A_j^{(k-1)} - sgn\left(w_{ji}\right) w_{ji}^{(k-1)} A_j^{(k-1)})$$
(3)

where 0< η <0.1 and 0.9< γ <1 are the learning rate and weight decay parameters respectively. Experts could define some desired regions between [0,1] for some nodes as Desired Output Concepts (DOCs) (Papageorgiou & Groumpos, 2005). The DOCs are defined for those concepts which are important for the experts.

Two termination criteria are used to stop the execution of the NHL algorithm. The first one is based on the value of function F_1, which is computed as follows:

$$F_1 = \sqrt{\sum_{i=1}^{m} |DOC_i - T_i|^2}$$
(4)

where; T_i denotes the mean value of interesting node DOC_i, and $i = 1, \dots m$ indicates the number of DOCs. Note that the objective is to minimize F_1. The DOC_i could take values in the interval $DOC_i = \left[T_i^{min}, T_i^{max}\right]$. Therefore, the target value T_i of the DOC_i is determined as:

$$T_i = \frac{T_i^{min} + T_i^{max}}{2}$$
(5)

The second termination value (F_2) is calculated based on the variation between the values of $DOC_i^{(k+1)}$ and $DOC_i^{(k)}$ that should be smaller than the tolerance value e:

$$F_2 = \left|DOC_i^{(k+1)} - DOC_i^{(k)}\right| < e = 0.005, \tag{6}$$

The updated weight matrix (W^{NHL}), is obtained when the two termination functions are met.

A generic description of the NHL-DE learning algorithm adapted from Papageorgiou and Groumpos (2005) is given in Table 2.2.

Table 2. 2 Generic Model of the NHL-DE Algorithm

	First stage: Nonlinear Hebbian learning
Step 1	Read initial weight matrix $W^{Initial}$ and initial concept vector $C^{Initial}$
Step 2	Repeat for each iteration k
Step 3	Calculate $A_i^{(k+1)}$ using Eq. (2)
Step 4	Update the initial weights ($w_{ji}^{(k)}$) using Eq. (3)
Step 5	Compute the two termination criteria (F_1, F_2)
Step 6	Until the termination functions are met
Step 7	Return the final weights $W_{NHL}^{(k+1)}$to the second stage
	Second stage: Differential evolution
Step 1	Create de initial DE population in the neighbourhood of $W_{NHL}^{(k+1)}$
Step 2	Repeat for each input concept state (k)
Step 3	For $i = 1$ to NP
Step 4	Make Mutation operator ($w_i^{(k)}$) to create Mutant Vector
Step 5	Make Crossover operator to create Trial Vector
Step 6	Selection operator If F (Trial Vector) ≤ fitness function $F(w_i^{(k)})$, accept Trial Vector for the next generation
Step 7	End For
Step 8	Until the termination function is met

3.2.2 Second step: DE algorithm

This step uses the preliminary solution ($W_{NHL}^{(k+1)}$) obtained from step 1 and starts with initial population N. The new mutant vector is generated for each weight vector ($w_i^{(k)}$) using the Equation represented below (Papageorgiou & Groumpos, 2005):

$$v_i^{(k+1)} = v_i^{(k)} + \mu\left(w_{best}^{(k)} - w_i^{(k)} + w_{r1} - w_{r2}\right), \qquad i = 1, \dots NP, \tag{6}$$

where $\mu > 0$ refers to the mutation constant, $w_{best}^{(k)}$ presents the best population member of the last simulation, and w_{r1} and w_{r2} are two weight vectors which are randomly selected from the population. In order to decrease the diversity of the weight vectors, the crossover operator produces the Trial Vector. This trial vector will be accepted for the next generation if and only if its value is equal or less than the following fitness function (F). This operator ensures that the F starts steadily decreasing at some iterations (Papageorgiou & Groumpos, 2005).

3.2.3 Fitness Function (F)

This function is very important in obtaining the best solution in evolutionary learning algorithms since it helps define the problem constraints more precisely. The Fitness function proposed for NHL-DE algorithm is as follow (Papageorgiou & Groumpos, 2005):

$$F(W) = \sum_{i=1}^{m}\left[\left|A_i^{min} - A_i\right| + \left|A_i - A_i^{max}\right|\right] \tag{7}$$

where A_i, are the updated values of the concepts which are calculated using Eq. (1) and by considering w_{ji} matrix. A_i^{min} and A_i^{max} are the minimum and maximum values of the updated concepts (A_i) which are already determined by

3.3 Fuzzy soft sets

Many theories have been proposed in the literature for considering uncertainty in complicated problems such as rough set theory, fuzzy set theory, probability, vague sets, etc. However, these theories has some inherent drawbacks and limitations due to the inadequacy of the parameterization. To deal with these drawbacks, Molodtsov (1999) proposed the concept of a soft set as a general mathematical tool. This theory is being used conveniently in several directions. In this paper, FSS theory is applied in the last step of our proposed framework for selecting best maintenance policy. A brief definition of a FSS is presented in the following with an example.

Let E be a set of parameters, U be an initial universe and $FS(U)$ be the set of all fuzzy sets of U. A pair $(\hat{F}_{\{A\}}, E)$ is called a FSS over U, where $\hat{F}_{\{A\}}$ is a mapping given by $\hat{F}_{\{A\}}: E \rightarrow FS(U)$ (Maji, Biswas, & Roy, 2001).

For example, suppose that U be the set of 5 CNC machines (CNC_1, CNC_2, CNC_3, CNC_4, CNC_5) given by $U = \{d_1, d_2, d_3, d_4, d_5\}$ and E be the set of 5 criteria (Price, Quality, Maintenance requirements, Size, spare parts) given by E = $\{s_1, s_2, s_3, s_4, s_5\}$. In addition, let $A = \{s_1, s_2, s_3, s_5\} \subset E$ be consisting of the criteria that company X is interested in buying a CNC machine. The fuzzy soft set $(\hat{F}_{\{A\}}, E)$ can be indicated as the collection of the following fuzzy approximations:

$\hat{F}_{\{A\}}(s_1)$={d_1=0.2; d_2=0.4; d_3=0.9; d_5=0.7},
$\hat{F}_{\{A\}}(s_2)$={d_2=0.8; d_3=0.1; d_4=0.7},
$\hat{F}_{\{A\}}(s_3)$={d_1=0.6; d_2=0.2; d_3=0.8},
$\hat{F}_{\{A\}}(s_5)$={d_1=0.6; d_2=0.7; d_3=0.5; d_4=0.8},

Each of the above fuzzy soft sets describes the weights of the criteria for a certain CNC machine.

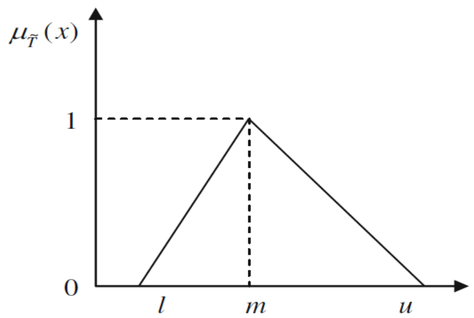

Figure 2. 5 A triangular fuzzy number

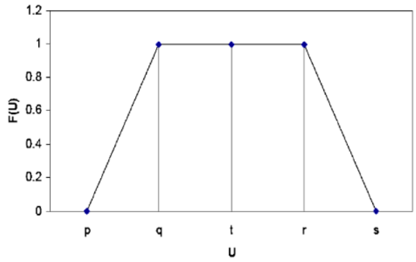

Figure 2. 6 A trapezoidal fuzzy numbers *(Çelik & Yamak, 2013)*

It should be highlighted that the elements of the fuzzy soft sets may be taken as fuzzy triangular numbers parametrized by a triplet (*l*, *m*, *u*) (Fig. 2.5) or a fuzzy trapezoidal numbers parametrized by a quadruplet *(p, q, r, s)* (Fig. 2.6) (Çelik & Yamak, 2013).

In the case of fuzzy triangular number, the defuzzification value t is calculated using the following Equation:

$$t = \frac{l+m+m+u}{4}$$

(8)

In this paper, we adopt the Çelik's presented algorithm (Çelik & Yamak, 2013) for medical diagnosis and modify it in order to be more effective for our proposed RB-MSS framework. The modified version of this algorithm is presented in phase 2 of our proposed framework.

4. The proposed model and algorithm

In this paper, we propose a novel integrated framework for selecting the best maintenance policy using AHP, FCM, and FSS tools. At first, we use AHP method for determining the relative priorities of the criteria (initial concept values) and then, we utilize FCM in order to find the criteria weights (updated concept values) by considering the dependencies among them. Finally, an adjusted FSS theory is proposed to prioritize the maintenance policies. One of the main advantages of the proposed FSS model is that there is no need for several pair vise comparisons for selecting best maintenance strategy. Therefore, it is less time-consuming in comparison with other methods such as AHP/ANP. In addition, experts can easily assign the linguistic terms for each maintenance policy based on the considered criteria and without getting confused by several pair vise comparison questions.

Considering the variety of criteria applied by different authors for MSS (See Table 2.1) and in order to propose a risk-based method, in this paper, "Detection", "Probability of Failure Occurrence (MTBF)", and "Failure's consequences" are considered as primary criteria in our model. It should be mentioned that these criteria are the three parameters of well-known FMEA method which are multiplied to produce RPN (Jamshidi, 2015). For the criterion Failure's consequences, we consider three sub-criteria as Cost of Failure (CF), Maintenance Cost (MC), and Safety (S) in order to consider all aspects of risk in MSS.

The proposed framework for finding the best maintenance policy is illustrated by an algorithm depicted in Figure 2.8, and its procedure is as follows:

Let us assume that there is a set of *m* devices, *D* = $\{d_1, d_2, d_3, \ldots, d_m\}$, set of *n* criteria *C* = $\{c_1, \ldots, c_n\}$ related to a set of *k* maintenance policies *P* = $\{P_1, P_2, P_3, \ldots, P_k\}$.

Phase 1:

Step 1: Establish a group of experts in order to identify the possible maintenance strategies and failure modes/risks for each component or device. The five primary criteria for evaluating the maintenance alternatives are D, MTBF, CF, MC, and S, as introduced above. In addition to these criteria, some additional criteria could be added depending on the goals and objectives of the companies. The additional criteria and maintenance policies are identified by experts and the experts should reach consensus on them.

Step 2: Derive the relative priorities of selected criteria (Initial concept values) using the group AHP method. Pairwise comparisons among criteria are made using Saaty's 9-point scale ranging as shown in Table 2.3.

Step 3: Establish the FCM diagram in order to show the cause effect relationships among criteria. Experts should first reach consensus on the sign and direction of arcs between criteria. In order to determine the level of influence of each criterion on the other criteria and vice versa, experts assign linguistic terms for each arc individually. Then, the opinions of decision makers are aggregated and defuzzified in order to find the initial influence weight ($W^{Initial}$).

Table 2. 3 Saaty's 9-point scale (Saaty, 1977)

Importance	linguistic terms
1	Equal importance
3	Moderate importance
5	Strong importance
7	Very strong importance
9	Extreme importance
2,4,6,8	Intermediate values

Step 4: By using NHL-DE algorithm (described in sections 3.2.1-3) and Eq. (1) train the FCM and obtain the steady-state concept matrix(C^*) and updated weight matrix (w_{ij}). In our proposed method, we use the following sigmoid threshold function.

$$f(x) = \frac{1}{1+e^{-\lambda x}} \tag{9}$$

where $\lambda > 0$ denotes the steepness of f (Xiao, 2012). We use this function since our concepts values are in the interval [0, 1].

Step 5: Normalize the C^* matrix and obtain C_N^* matrix using the following Equation:

$$C_N^* = \frac{c_j}{\sum_{j=1}^{n} c_j} \quad , \quad \Rightarrow \quad C_N^* = [C_1^*, C_2^*, \ldots, C_n^*] \tag{10}$$

where j= 1,2,…,n corresponds to the criteria.

Phase 2:

After obtaining w_{ij} and C_N^* matrices, in second phase we introduce an innovative algorithm for selecting optimum maintenance policy using FSS and by considering the experience and knowledge level of experts and uncertainties in their opinions.

Step 1- Risk evaluation: Build a fuzzy soft set Q_h= (F, D) over C where F is a mapping F: →F(C). The elements of this matrix (device-criteria) are fuzzy triplet numbers (d – 1, d, d + 1). The matrix Q_h is shown as follow:

$$\begin{array}{cccccccc} & D & MTBF & CF & MC & S & \dots & c_n \\ Q_h = d_i & [\tilde{a}_{11} & \tilde{a}_{12} & \tilde{a}_{12} & \tilde{a}_{12} & \tilde{a}_{12} & \dots & \tilde{a}_{1n}] \end{array}$$

where i= 1,2,…,m indicates the device number. In order to build this matrix, n questions should be asked from each expert. Regarding the criterion risk, the following question should be answered by each expert:

- *With regard to identified failure mode, how much is its chance of non-Detection?*
- *With regard to identified failure mode, how much is its probability of Occurrence (MTBF)?*
- *With regard to identified failure mode, how much is its Cost?*
- *With regard to identified failure mode, how much is its Maintenance cost?*
- *With regard to identified failure mode, how much does it threaten the Safety of system/staff?*

In order to answer these questions, the following linguistic terms table (Table 2.4) should be provided to each expert. In the case of criterion risk, a risk score could also be computed for each component or device and then it should be compared to the acceptable risk score for the company or organization. Based on this comparison, a linguistic term using should be assigned to the risk criterion by each expert. Questions related to qualitative criteria such as safety could be answered directly using Table 2.4.

Table 2. 4 Fuzzy triplet numbers and linguistic terms

Terms	Fuzzy number ($\tilde{d}$)	Fuzzy triplet numbers (d – 1, d, d + 1)
Absolute uncertainty (AU)	$\tilde{1}$	(0, 1, 2)
Very remote (VR)	$\tilde{2}$	(1, 2, 3)
Remote (R)	$\tilde{3}$	(2, 3, 4)
Very low (VL)	$\tilde{4}$	(3, 4, 5)
Low (L)	$\tilde{5}$	(4, 5, 6)
Moderate (M)	$\tilde{6}$	(5, 6, 7)
Moderately high (MH)	$\tilde{7}$	(6, 7, 8)
High (H)	$\tilde{8}$	(7, 8, 9)
Very high (VH)	$\tilde{9}$	(8, 9, 10)
Almost certain (AC)	$\widetilde{10}$	(9, 10, 10)

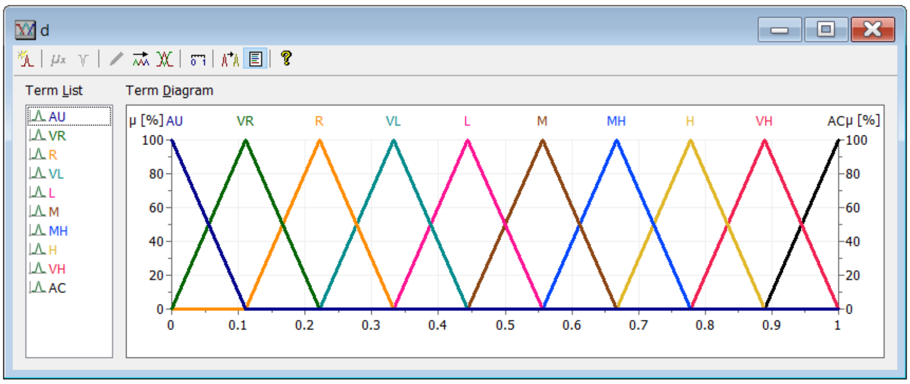

Figure 2. 7 Fuzzy membership functions for Q_h and R_h matrices

The fuzzy membership functions for Q_h and R_h matrices are shown in Fig. 2.7. This figure is drawn in FuzzyTech 8.20a Software (http://www.fuzzytech.com/).

Step 2: By multiplying the normalized concept matrix C_N^* (obtained from step 5 in phase 1) in Q_h matrix, obtain the weighted device-criteria matrix (DC_h) as follows:

$$DC_h = C_N^* \times [\tilde{a}_{11} \quad \tilde{a}_{12} \quad \dots \quad \dots \quad \tilde{a}_{1n}] = [\widetilde{C_N^* \times a_{11}} \quad \widetilde{C_N^* \times a_{12}} \quad \dots \quad \dots \quad \widetilde{C_N^* \times a_{1n}}]$$

$$DC_h = [\tilde{b}_{11} \quad \tilde{b}_{12} \quad \dots \quad \dots \quad \tilde{b}_{1n}]$$

The aim of this step is to consider the importance weight of each criterion in evaluating criteria for each device.

Step 3: Maintenance alternatives evaluation based on the identified criteria: Build another fuzzy soft set R_h = (*G*, *C*) over *P*, where *G* is a mapping *G: C*→*F*(*P*). Each element ($\tilde{e}_{ij}$) of this matrix (criteria-policy) denotes the importance of a certain maintenance policy with respect to a criterion. These elements are also taken as fuzzy triplet numbers. The matrix R_h is shown as follow:

$$R_h = \begin{array}{c} \\ c_1 \\ c_2 \\ \vdots \\ c_n \end{array} \begin{array}{c} \begin{array}{ccccc} p_1 & p_2 & \cdots & \cdots & p_k \end{array} \\ \begin{bmatrix} \tilde{e}_{11} & \tilde{e}_{12} & \dots & \dots & \tilde{e}_{1k} \\ \tilde{e}_{21} & \tilde{e}_{21} & \dots & \dots & \tilde{e}_{2k} \\ \vdots & \vdots & \vdots & \vdots & \vdots \\ \tilde{e}_{n1} & \tilde{e}_{n2} & \dots & \dots & \tilde{e}_{nk} \end{bmatrix} \end{array}$$

In order to build this matrix, n questions should be asked from each expert For example, for the first 5 criteria the following questions must be asked from each DM:

- *With respect to criterion Detection (D), how much each of k maintenance strategies could better detect the failure*?
- *With respect to criterion MTBF, how much each of k maintenance strategies could better reduce the MTBF*?
- *With respect to criterion Cost of failure (CF), how much each of k maintenance strategies could better reduce the cost of failure*?
- *With respect to criterion Maintenance Cost (MC), which one of k maintenance strategies costs lower and by how much*?
- *With respect to criterion Safety, how much each of k maintenance strategies could better increase the safety*?

In order to answer these questions, Table 2.4 should be provided to the experts.

Step 4: Perform the transformation operation $DC_h^* \otimes R_h$ and obtain the Device-Policy matrix DP_h^* as follows:

$$DP_h^* = d_i \begin{array}{c} \begin{array}{ccccc} p_1 & p_2 & \cdots & \cdots & p_k \end{array} \\ [\tilde{f}_{11} \quad \tilde{f}_{12} \quad \dots \quad \dots \quad \tilde{f}_{1k}] \end{array}$$

where:

$$\tilde{f}_{il} = \left(\sum_{j=1}^{n}(b_{ij} - 1).(e_{jl} - 1), \sum_{j=1}^{n} b_{ij} \, . \, e_{jl}, \sum_{j=1}^{n}(b_{ij} + 1) \, . \, (e_{jl} + 1)\right) \tag{11}$$

where l= 1,2,…,k is the maintenance polices.

Step 5: By using Eq. (8) defuzzify each element of the matrix DP_h^* and obtain the matrix $DP_{hil}{}^{**}$ for each DM as below:

$$DP_{hil}{}^{**} = [\tilde{\lambda}_{hi1} \quad \tilde{\lambda}_{hi2} \quad \dots \quad \dots \quad \tilde{\lambda}_{hik}]$$

where h= 1,…, g corresponds to the DMs.

Step 6: Aggregate all of $DP_{hil}{}^{**}$ matrices and obtain matrix $DP_T{}^{**}$ through the proposed procedure in Table 2.5. Then, find the best maintenance policy from matrix $DP_T{}^{**}$ which is $Max\ \sum_{h=1}^{g} W_h \tilde{\lambda}_{hil}$.

Table 2. 5 Aggregation of $DP_{hil}{}^{**}$ matrices for obtaining $DP_T{}^{**}$ matrix

$DP_{hil1}{}^{**}= W_1[\tilde{\lambda}_{hi1} \quad \tilde{\lambda}_{hi2} \quad \dots \quad \dots \quad \tilde{\lambda}_{hik}]$	$DP_T{}^{**}=[\sum_{h=1}^{g} W_h \tilde{\lambda}_{hi1} \quad \sum_{h=1}^{g} W_h \tilde{\lambda}_{hi2} \quad \dots \quad \dots \quad \sum_{h=1}^{g} W_h \tilde{\lambda}_{hik}]$
$DP_{hil2}{}^{**}= W_2[\tilde{\lambda}_{hi1} \quad \tilde{\lambda}_{hi2} \quad \dots \quad \dots \quad \tilde{\lambda}_{hik}]$	* The parameter W_h $(h = 1, \dots, g)$ indicates the weight of decision maker h, which is determined based on the knowledge and experience of decision maker. The sum of all decision maker' weights are equal to 1.
.	
.	
.	
$DP_{hilg}{}^{**}= W_g[\tilde{\lambda}_{hi1} \quad \tilde{\lambda}_{hi2} \quad \dots \quad \dots \quad \tilde{\lambda}_{hik}]$	

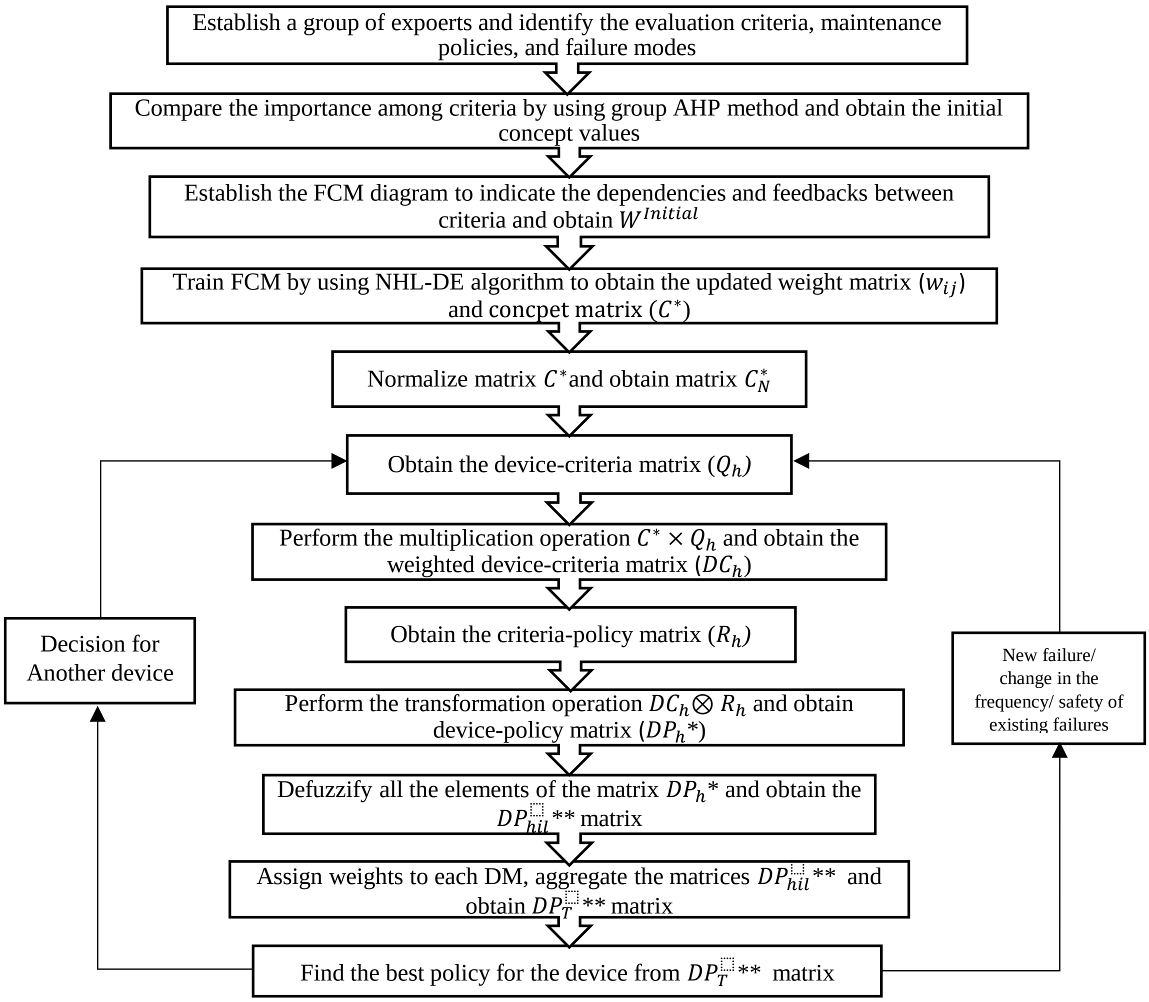

Figure 2. 8 The steps of the proposed framework

Step 7- Updating risk analysis: This step is performed in order to consider any change in the frequency or safety of existing failures or if there is a new failure after implementation of the selected maintenance policy. This step allows the continuous update of risks analysis and it leads to continues improvement of maintenance actions. As shown in Fig. 8, in order to update the risk analysis process, only Q_h matrix should be updated in order to assign new linguistic values to the criteria and the rest of information will be automatically updated. This is the same for maintenance decision making for another component/device. The risk analysis and its updating process could be connected to the Computerized Maintenance Management System (CMMS) of the company in order to collect the failure data automatically and facilitate the information transfer to the proposed framework.

5. Numerical Example

In this section, we illustrate the applicability of the proposed framework with a hypothetical numerical example. Suppose that a manufacturer company needs to select the optimum maintenance policy for a critical component. According to the explained steps in section 3, the proposed framework is illustrated in the followings.

Phase 1:

Step 1: In this numerical example, the five primary criteria introduced in this paper (D, MTBF, CF, MC, and S) as well as five maintenance strategies (CM, PM, PDM, CBM, and TBM) are selected by three DMs (DM1, DM2, DM3) to be evaluated.

Step 2: derive the relative importance weight between five criteria using AHP approach. Table 2.3 shows these judgment matrices which are evaluated by three DMs. The comparison process is performed in Expert Choice software (version 11.1.3238) and the result is shown through Fig. 2.9.

Table 2. 6 The judgement matrices of the maintenance policy selection's criteria

DM1	C1	C2	C3	C4	C5
C1	1	1/7	4	5	1/9
C2	7	1	8	6	1/2
C3	1/4	1/8	1	1/5	1/7
C4	1/5	1/6	5	1	1/4
C5	9	2	7	4	1
DM2	C1	C2	C3	C4	C5
C1	1	1/6	4	6	1/8
C2	6	1	9	8	1/3
C3	1/4	1/9	1	1/7	1/7
C4	1/6	1/8	7	1	1/7
C5	8	3	7	7	1
DM3	C1	C2	C3	C4	C5
C1	1	1/5	4	6	1/7
C2	5	1	8	8	1/3
C3	1/4	1/8	1	1/5	1/9
1/6	1/8	5	1	1	1/9
C5	7	3	9	9	1

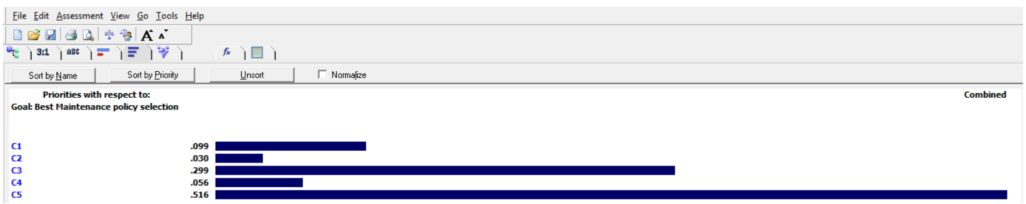

Figure 2. 9 The relative priorities of the criteria by using AHP method (Initial concept values)

Step 3: The FCM graph is depicted in Figure 10 to indicate the influence among criteria. Each expert is asked to determine the weight (W_{ij}) on each arc, by assigning linguistic variables using Table 2.4. Table 2.7 shows the assigned values by three DMs. Then, the opinions of all DMs are aggregated using the average value of the assigned linguistic values (fuzzy triangular numbers (l, m, u)) for each interconnection and the aggregated values are defuzzified using Eq. 8. Finally, the defuzzified values are divided by 100 in order to obtain the numeric impacts between [-1,1].

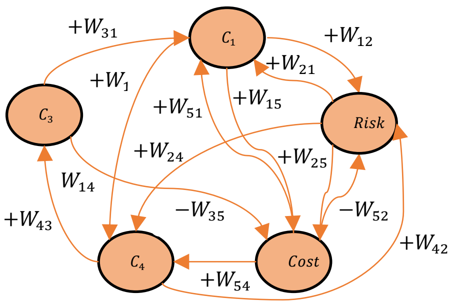

Figure 2. 10 FCM for Risk-based Maintenance Policy Selection

Table 2. 7 Fuzzifcation and defuzzification process for obtaining initial weight matrix

Node 1	Node 2	W_{ij}	Expert opinions			Fuzzifcation									Opinions' Aggregation			Defuzzif-ication	Numeric impact
						DM1			DM2			DM3							
			DM 1	DM 2	DM 3	l	m	u	l	m	u	l	m	u	l	m	u	$\frac{l+m+m+u}{4}$	
D	MTBF	$-W_{12}$	H	VH	AC	7	8	9	8	9	10	9	10	10	8	9	9.66	8.91	-0.089
D	CF	$+W_{13}$	AC	H	AC	9	10	10	7	8	9	9	10	10	8.33	9.33	9.66	9.16	+0.091
D	MC	$+W_{14}$	M	MH	M	5	6	7	6	7	8	5	6	7	5.33	6.33	7.33	6.33	+0.063
D	S	$-W_{15}$	VH	VH	AC	8	9	10	8	9	10	9	10	10	8.33	9.33	10	9.25	-0.092
MTBF	MC	$-W_{24}$	VL	R	VR	3	4	5	2	3	4	1	2	3	2	3	4	3	-0.03
MTBF	S	$+W_{25}$	VH	AC	VH	8	9	10	9	10	10	8	9	10	8.33	9.33	10	9.25	+0.092
CF	MC	$+W_{34}$	M	M	MH	5	6	7	5	6	7	6	7	8	5.33	6.33	7.33	6.33	+0.063
MC	D	$-W_{41}$	L	M	M	4	5	6	5	6	7	5	6	7	4.66	5.66	6.66	5.66	-0.056
MC	MTBF	$+W_{42}$	AC	AC	VH	9	10	10	9	10	10	8	9	10	8.66	9.66	10	9.5	+0.095
MC	CF	$-W_{43}$	VH	H	AC	8	9	10	7	8	9	9	10	10	8	9	9.66	8.91	-0.089
MC	S	$+W_{45}$	AC	AC	VH	9	10	10	9	10	10	8	9	10	8.66	9.66	10	9.5	+0.095
S	MTBF	$+W_{52}$	MH	M	L	6	7	8	5	6	7	4	5	6	5	6	7	6	+0.06
S	CF	$-W_{53}$	R	VR	L	2	3	4	1	2	3	4	5	6	2.33	3.33	4.33	3.33	-0.033

The initial weight matrix obtained through numeric impacts in Table 8 is shown in the following connection matrix:

$$W^{Initial} = \begin{bmatrix} 0.0 & -0.089 & +0.091 & +0.063 & -0.092 \\ 0 & 0.0 & 0.0 & -0.03 & +0.092 \\ 0 & 0.0 & 0.0 & +0.063 & 0 \\ -0.056 & +0.095 & -0.089 & 0.0 & +0.095 \\ 0.8 & +0.06 & -0.033 & 0 & 0.0 \end{bmatrix}$$

According to the Fig. 2.9, the initial vector with the concept values is:

c= [0.099, 0.030, 0.299, 0.056, 0.516];

In this numerical example, two DOCs have been defined for the concepts C_1 and C_5 with the following desired regions:

$0.9 \leq C_1 \leq 1, \qquad 0.5 \leq C_5 \leq 0.8$

Step 4: Update initial weight matrix ($W^{Initial}$) and initial concept vector (c) using Equation (1) and NHL-DE learning algorithm. To do so, MATLAB version R2012a software was used. For this numerical example, the population size is 50 and the values of crossover constant (CR), mutation constant (μ), weight decay learning parameter (γ) and learning rate parameter (η) are 0.5, 0.5, 0.98, 0.04, respectively. 1000 iterations was performed for the algorithm. The updated weight matrix is:

$$w_{ij} = \begin{bmatrix} 0.0 & 0.1656 & 0.0 & 0.5602 & 0.9728 \\ 0.2149 & 0.0 & 0.0 & 0.6034 & 0.1644 \\ 0.3639 & 0.0 & 0.0 & 0.0 & -0.3768 \\ 0.0 & 0.8537 & 0.4627 & 0.0 & 0.0 \\ 0.8411 & -.02596 & 0.0 & 0.7251 & 0.0 \end{bmatrix}$$

As shown in Fig. 2.11, the desired steady state is reached after 8 iterations:

$$C^* = [0.9224 \quad 0.8545 \quad 0.7734 \quad 0.9207 \quad 0.6260]$$

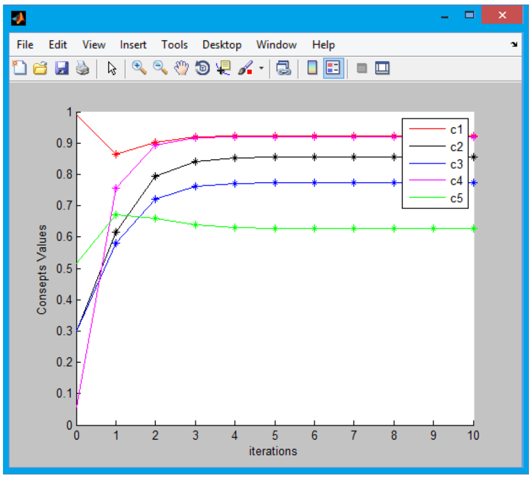

Figure 2. 11 The steady state for 5 criteria after 8 iterations

Step 5: Normalize the matrix C^* and obtain matrix C_N^* using Eq. 10.

$$C_N^* = [0.2251 \quad 0.2085 \quad 0.1887 \quad 0.2247 \quad 0.1527]$$

Phase 2:

Step 1: Suppose that the three DMs have assigned the following numbers to matrix Q_h.

$F\ (DM_1) = \{C_1/5,\ C_2/8,\ C_3/7,\ C_4/2,\ C_5/6\}$, $F\ (DM_2) = \{C_1/4,\ C_2/7,\ C_3/9,\ C_4/5,\ C_5/6\}$, $F\ (DM_3) = \{C_1/6,\ C_2/8,\ C_3/8,\ C_4/5,\ C_5/6\}$

The assigned values for Matrix Q_h by three DMs are shown in [1×5] matrices in the second row of Table 2.7.

Step 2: Perform the multiplication operation $C_N^* \times Q_h$ and obtain the weighted device-criteria matrix (DC_h) as shown in Table 2.7.

Table 2. 8 The proposed framework's calculations

	DM_1	DM_2	DM_3
C_N^*	(0.2251, 0.2085, 0.1887, 0.2247, 0.1527)		
Q_h	$[\tilde{5} \quad \tilde{8} \quad \tilde{7} \quad \tilde{2} \quad \tilde{6}]$	$[\tilde{4} \quad \tilde{7} \quad \tilde{9} \quad \tilde{5} \quad \tilde{6}]$	$[\tilde{6} \quad \tilde{8} \quad \tilde{8} \quad \tilde{5} \quad \tilde{6}]$
DC_h	$[\widetilde{1.12} \quad \widetilde{1.66} \quad \widetilde{1.32} \quad \widetilde{0.44} \quad \widetilde{0.9}]$	$[\widetilde{0.90} \quad \widetilde{1.45} \quad \widetilde{1.69} \quad \widetilde{1.12} \quad \widetilde{0.9}]$	$[\widetilde{1.35} \quad \widetilde{1.66} \quad \widetilde{1.31} \quad \widetilde{1.12} \quad \widetilde{0.91}]$
R_h	$\begin{bmatrix} \tilde{8} & \tilde{6} & 4 & \tilde{8} & \tilde{4} \\ \tilde{4} & \tilde{6} & \tilde{6} & \tilde{5} & 4 \\ \tilde{2} & \tilde{7} & \tilde{4} & \tilde{7} & \tilde{8} \\ \tilde{7} & \tilde{6} & \tilde{4} & \tilde{5} & \tilde{5} \\ \tilde{8} & \tilde{9} & \tilde{3} & \tilde{7} & \tilde{7} \end{bmatrix}$	$\begin{bmatrix} \tilde{4} & \tilde{6} & 7 & \tilde{5} & \tilde{3} \\ \tilde{6} & \tilde{5} & \tilde{7} & \tilde{2} & 9 \\ \tilde{2} & \tilde{8} & \tilde{5} & \tilde{6} & \tilde{6} \\ \tilde{9} & \tilde{8} & \tilde{1} & \tilde{4} & \tilde{3} \\ \tilde{5} & \tilde{4} & \tilde{6} & \tilde{8} & \tilde{7} \end{bmatrix}$	$\begin{bmatrix} \tilde{6} & \tilde{7} & 5 & \tilde{3} & \tilde{3} \\ \tilde{6} & \tilde{9} & \tilde{7} & \tilde{4} & 8 \\ \tilde{4} & \tilde{8} & \tilde{5} & \tilde{5} & 7 \\ \tilde{7} & 5 & \tilde{3} & \tilde{4} & \tilde{5} \\ \tilde{6} & \tilde{7} & \tilde{9} & \tilde{6} & \tilde{8} \end{bmatrix}$

DP_h^*	$[\widetilde{28.80}\ \ \widetilde{36.96}\ \ \widetilde{24.34}\ \ \widetilde{35.26}\ \ \widetilde{30.41}]$	$[\widetilde{30.45}\ \ \widetilde{38.95}\ \ \widetilde{31.64}\ \ \widetilde{29.44}\ \ \widetilde{35.82}]$	$[\widetilde{37.52}\ \ \widetilde{48.58}\ \ \widetilde{37.60}\ \ \widetilde{28.27}\ \ \widetilde{40.92}]$
$DP_{hil}{}^{**}$	[29.30 37.46 24.84 35.76 30.91]	[30.95 39.45 32.14 29.94 36.32]	[38.02 49.08 38.10 28.77 41.42]
$DP_T{}^{**}$	[29.37 **37.61** 29.32 27.53 33.15]		

Step 3: Next, suppose that DM_1 has assigned the following values for matrix R_h:

G (C_1) = {P_1/8, P_2/6, P_3/4, P_4/8, P_5/4}, G (C_2) = {P_1/4, P_2/6, P_3/6, P_4/5, P_5/4}, G (C_3) = {P_1/2, P_2/7, P_3/4, P_4/7, P_5/8}, G (C_4) = {P_1/7, P_2/6, P_3/4, P_4/5, P_5/5}, G (C_5) = {P_1/8, P_2/9, P_3/3, P_4/7, P_5/7},

The above fuzzy soft set (G, C) represents an approximate description by DM_1 for the five criteria and their relationship to five policies. The assigned values for matrix R_h by three DMs are presented in Table 2.7.

Step 4: Perform the transformation operation $DC_h^* \otimes R_h$ and obtain the device-policy matrix (DP_h^*) for each DM as shown in sixth row of Table 2.7.

where:

$\widetilde{28.80}$ = (18.51, 28.80, 41.09), $\widetilde{36.96}$ = (25.83, 39.96, 50.09), $\widetilde{24.34}$ = (15.60, 24.34, 35.09), $\widetilde{35.26}$ = (24.42, 35.26, 48.10), $\widetilde{30.41}$ = (20.49, 30.41, 42.33),

$\widetilde{30.45}$ = (20.04, 30.45, 42.87), $\widetilde{38.95}$ = (27.53, 38.95, 52.36), $\widetilde{31.64}$ = (21.42, 31.64, 43.86), $\widetilde{29.44}$ = (19.54, 29.44, 41.34), $\widetilde{35.82}$ = (25.29, 35.82, 48.35),

$\widetilde{37.52}$ = (26.10, 37.52, 50.94), $\widetilde{48.58}$ = (35.86, 48.58, 63.31), $\widetilde{37.60}$ = (26.45, 37.60, 50.75), $\widetilde{28.27}$ = (18.43, 28.27, 40.11), $\widetilde{40.92}$ = (29.34, 40.92, 54.50),

The above values are obtained from Eq.11.

Step 5: Defuzzify the matrix DP_h^* and obtain $DP_{hil}{}^{**}$ matrices as depicted in the Table 2.7 (row seven).

Step 6: Using the proposed aggregation method in Table 6, the three matrices have been aggregated in order to get the $DP_T{}^{**}$ matrix (last row in Table 2.8). In our numerical example, we set the weights of DMs (W_h) arbitrarily as 0.15, 0.5, and 0.25. The $DP_T{}^{**}$ matrix shows that the priority of policies are as P2>P5>P1>P3>P4 and the best maintenance policy for the device is second policy (Preventive Maintenance). The same process should be performed for finding best maintenance policy for other components/devices. This process would be very easy for other components/devices since only Q_h matrix should be updated and the rest of information will be automatically updated.

Step 7: This step is performed after implementation of the selected maintenance policy. The risk analysis is updated based on any changes in the frequency/safety of existing failures or with the advent of new failures in order to minimize the risks and also continuously improve the maintenance activities.

Through this numerical example, we illustrated the applicability and potential of our proposed dynamic risk-based framework as an advanced tool for maintenance strategy selection in different industries. We considered different decision makers' opinions and level of their knowledge and experience in evaluating the importance weights of criteria and interrelationships among them and also took into account the associated uncertainties in all decision making process. Then, the proposed approach could suggest more accurate and cost-effective maintenance policy. The proposed framework in this paper, has also the ability to be applied without considering interrelationships among criteria. This could be useful and less time-consuming for less critical components/systems. Table 2.9 shows the proposed framework's calculation process without considering dependencies among criteria.

6. Sensitivity Analysis

To ensure that final solution is stable and robust, we additionally applied sensitivity analysis. The aim of this sensitivity analysis is to explore how considering dependencies among criteria or any change in the weights of criteria affect the priorities of the selected alternatives. In the following three scenarios are presented.

Scenario 1

In the first sensitivity analysis, we performed our proposed framework for the same numerical example without considering the dependencies among criteria in order to evaluate its impact on the prioritization of maintenance policies. Table 2.8 shows the calculation process. Note that in this case we only consider the weights that are obtained through AHP method in Fig. 2.9. As it is clear from last row of Table 2.8, the best maintenance policy for the device is still second policy. However, the priority of policies have been changed to P2>P5>P4>P3>P1. Although the priority of the first two policies (P2, P5) are the same as Table 2.7, the priority of last three policies have been completely changed. This proves that considering the dependencies among criteria could significantly influence the priority of maintenance policies and as a result this could have an impact on minimizing costs and downtime and reaching the desired goals of companies.

Table 2. 9 The proposed framework's calculations without considering dependencies among criteria

	DM_1	DM_2	DM_3
c	(0.099, 0.030, 0.299, 0.056, 0.516)		
Q_h	$[\tilde{5}\ \ \tilde{8}\ \ \tilde{7}\ \ \tilde{2}\ \ \tilde{6}]$	$[\tilde{4}\ \ \tilde{7}\ \ \tilde{9}\ \ \tilde{5}\ \ \tilde{6}]$	$[\tilde{6}\ \ \tilde{8}\ \ \tilde{8}\ \ \tilde{5}\ \ \tilde{6}]$
DC_h	$[\widetilde{0.49}\ \ \widetilde{0.24}\ \ \widetilde{2.09}\ \ \widetilde{0.11}\ \ \widetilde{3.09}]$	$[\widetilde{0.39}\ \ \widetilde{0.21}\ \ \widetilde{2.69}\ \ \widetilde{0.29}\ \ \widetilde{3.09}]$	$[\widetilde{0.59}\ \ \widetilde{0.24}\ \ \widetilde{2.39}\ \ \widetilde{0.29}\ \ \widetilde{3.09}]$
R_h	$\begin{bmatrix} \tilde{8} & \tilde{6} & 4 & \tilde{8} & \tilde{4} \\ \tilde{4} & \tilde{6} & \tilde{6} & \tilde{5} & 4 \\ \tilde{2} & \tilde{7} & \tilde{4} & \tilde{7} & \tilde{8} \\ \tilde{7} & \tilde{6} & \tilde{4} & \tilde{5} & \tilde{5} \\ \tilde{8} & \tilde{9} & \tilde{3} & \tilde{7} & \tilde{7} \end{bmatrix}$	$\begin{bmatrix} \tilde{4} & \tilde{6} & 7 & \tilde{5} & \tilde{3} \\ \tilde{6} & \tilde{5} & \tilde{7} & \tilde{2} & 9 \\ \tilde{2} & \tilde{8} & \tilde{5} & \tilde{6} & \tilde{6} \\ \tilde{9} & \tilde{8} & \tilde{1} & \tilde{4} & \tilde{3} \\ \tilde{5} & \tilde{4} & \tilde{6} & \tilde{8} & \tilde{7} \end{bmatrix}$	$\begin{bmatrix} \tilde{6} & \tilde{7} & 5 & \tilde{3} & \tilde{3} \\ \tilde{6} & \tilde{9} & \tilde{7} & \tilde{4} & 8 \\ \tilde{4} & \tilde{8} & \tilde{5} & \tilde{5} & 7 \\ \tilde{7} & 5 & \tilde{3} & \tilde{4} & \tilde{5} \\ \tilde{6} & \tilde{7} & \tilde{9} & \tilde{6} & \tilde{8} \end{bmatrix}$
DP_h^*	$[\widetilde{37.71}\ \ \widetilde{34.76}\ \ \widetilde{21.08}\ \ \widetilde{33.61}\ \ \widetilde{27.04}]$	$[\widetilde{33.90}\ \ \widetilde{37.03}\ \ \widetilde{25.51}\ \ \widetilde{25.38}\ \ \widetilde{25.54}]$	$[\widetilde{40.93}\ \ \widetilde{43.69}\ \ \widetilde{34.06}\ \ \widetilde{27.24}\ \ \widetilde{36.53}]$
${DP_{hil}}^{**}$	[38.25 35.30 21.62 34.15 27.58]	[34.44 37.57 26.05 25.92 26.08]	[41.17 44.23 34.60 27.78 37.073]
${DP_T}^{**}$	[27.64 **39.59** 33.30 37.62 39.30]		

Scenario 2

In the second sensitivity analysis, we increased the weight of each criterion 25%. The results of this sensitivity analysis is presented in Fig. 2.12. As it is clear from this figure, although the values of ${DP_T}^{**}$ has been changed, the final prioritization of five maintenance policies has not been changed in any cases. This certifies the robustness and effectiveness of the proposed framework.

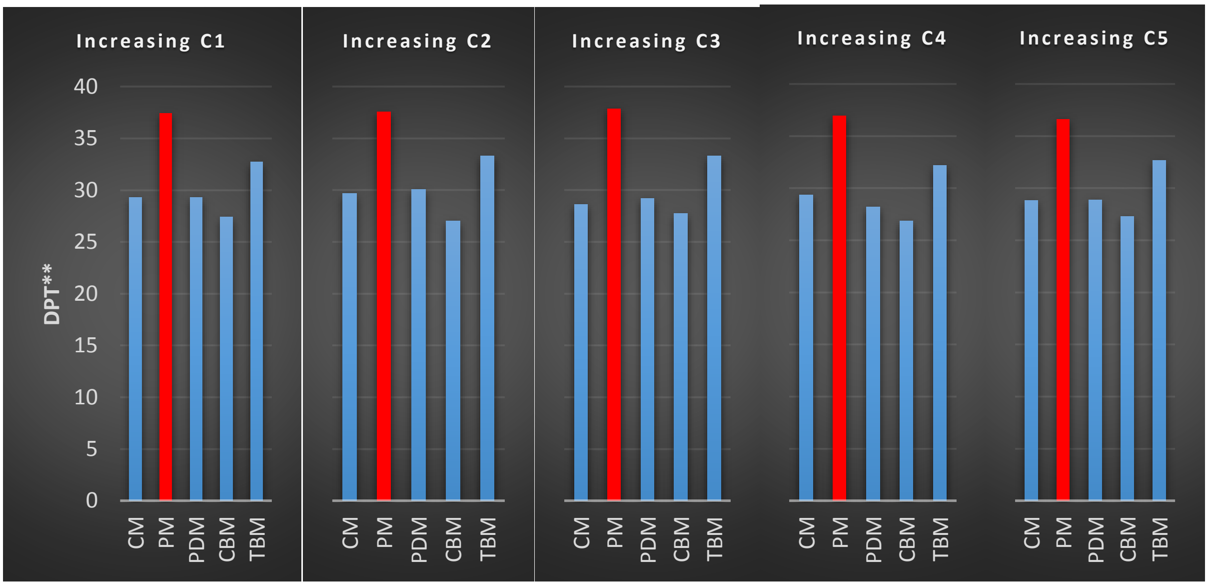

Figure 2. 12 Scenario 2, increasing the weights of criteria for 25%

Scenario 3

In the third sensitivity analysis, we decreased the weight of each criterion 25%. The results of this sensitivity analysis revealed that decreasing the weight of each criterion for 20% as increasing has no significant influence on the priority of the maintenance policies. This sensitivity analysis as scenario 2 certifies the robustness and effectiveness of the proposed framework. Due to lack of space the results of this analysis are not shown.

6. Conclusion and future directions

In this paper, after a literature review on the most popular criteria and maintenance policies in MSS and also shortcomings of current MSS methods, a new integrated framework was proposed using AHP, FCM, and FSS tools for finding the best maintenance policy. In the first phase of the proposed framework, group AHP is applied to calculate the importance weights of criteria as initial concept values for FCM technique. In the second phase, FCM is established to consider the interrelationships between criteria. In order to train FCM, we applied NHL-DE hybrid algorithm. The hybrid-based learning algorithms are more effective in modeling complex systems and have less limitations since they inherit the advantageous of both evolution-based and hebbian-based algorithms. Finally, in the third phase of the proposed framework, an innovative algorithm based on Çelik's FSS model is developed for identifying the best maintenance policy by considering the uncertainties.

Some features makes our proposed framework distinguished from other works; 1) the proposed framework is risk-based and it is able to take the risk of the component/system failure into account in a dynamic way and by considering uncertainties, then it can lead to a safer and more cost-effective maintenance strategy, 2) the interrelationships between variety of criteria as well as importance weights of criteria has been considered, and 3) The proposed maintenance policy prioritization process using FSS is less time consuming in comparison with AHP/ANP-based methodologies due to the fact that there is no need for several confusing pair vise comparisons. Depending on integrated FCM-based models as powerful decision support systems, the managers and experts can decide more precisely and accurately on the best maintenance policy in complex systems. The proposed approach can also be adopted as an advanced multi criteria decision making tool in critical industries such as aviation. Nevertheless, the main limitation of FCM-based models is their dependency to the experts' knowledge. Special attention should be paid to the selection of experts since their opinions could significantly affect the final results and could lead to wrong decisions. In future works, we will evaluate the performance of the proposed tool in a large-scale practical environment. As a future research topic, this study could be extended in different directions. For example, application of other learning algorithms could be considered for training FCM. In addition, considering the cause and effect relationships among failure modes and cause of failures in risk analysis process could be an interesting future research topic. Finally, development of a user-friendly software based on the proposed framework in this study would be very useful in order to streamline the implementation of the proposed MSS framework in practice.

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Chapter 3. Enhancing Failure Mode and Effects Analysis

The third chapter is dedicated to the following article:

[1] "Enhancing Failure Mode and Effects Analysis using Fuzzy Cognitive Maps" A. Jamshidi, S. Abbasgholizadeh Rahimi, D. Ait-kadi, A. Ruiz, submitted in June 2016 to the journal of "Expert Systems With Applications".

3.1. Enhancing Failure Mode and Effects Analysis using Fuzzy Cognitive Maps

Résumé: Les systèmes actuels hautement complexes dans des industries de pointe telles que l'aviation, le pétrole et les soins de santé ont besoin d'un outil avancé d'analyse de défaillance pour considérer les interactions des défaillances des composants dans différentes phases du cycle de vie du produit et assurer des niveaux élevés de sécurité et de fiabilité. L'Analyse des modes de défaillance et de leurs effets (AMDE) est l'une des méthodes les bien connues pour évaluer les défaillances potentielles et a été largement utilisée dans la littérature. Cependant, l'AMDE traditionnelle a été critiqué pour certaines lacunes majeures telles que le nombre élevé de doublons et son ignorance des interdépendances entre les défaillances. Cet article propose un cadre innovant pour l'analyse des modes de défaillance dans les systèmes complexes en intégrant l'AMDE floue et les cartes cognitives floues (Fuzzy Cognitive Maps (FCM)). Le cadre proposé permet de considérer les interactions complexes directes / indirectes entre les défaillances (F), la cause des défaillances (CF), CF et F, et vice versa, ce qui est utile pour prédire l'impact de chaque défaillance ou sa cause sur l'autre mode de défaillance. En outre, il est capable de prendre en compte le niveau de l'expérience et la connaissance des experts, les incertitudes et l'information imprécise, et les causes multiples des défaillances et des composants. Le cadre proposé est général et peut être appliqué dans toutes les industries essentielles pour hiérarchiser les défaillances potentielles et les atténuer. Cette étude aidera les experts à trouver l'analyse de défaillance la plus sûre et la plus précise pour les composants critiques et les systèmes complexes. Un exemple inspiré du monde réel lié aux pales des turbines d'avions est présenté pour illustrer la performance et l'applicabilité du cadre proposé.

Mots clés: Analyse de mode de défaillance et leurs effets, cartes cognitives floues, numéro de priorité de risque, hiérarchisation, systèmes complexes.

3.1. Enhancing Failure Mode and Effects Analysis using Fuzzy Cognitive Maps

Abstract: Current highly complex systems in critical industries such as aviation, petroleum, and healthcare need an advanced failure analysis tool to be able to consider failure interactions of components in different phases of the product life cycle and ensure the high levels of safety and reliability. Failure Mode and Effects Analysis (FMEA) is one of well-known methods for assessing potential failures and has been widely used in the literature. However, traditional FMEA has been criticised for some major shortcomings such as high duplication numbers and overlooking interdependencies between failures. This paper proposes an innovative framework for analysis of failure modes in complex systems by integrating fuzzy FMEA and Fuzzy Cognitive Maps (FCM). The proposed framework is able to consider the complex direct/indirect interactions among failures (F), cause of failures (CF), CF and F, and vice versa, which is useful for predicting the impact of each failure or cause of failure on the other failure modes. In addition, it is able to take into account level of experience and knowledge of experts, uncertainties and imprecise information, and multiple causes of failures and components. The proposed framework is general and can be applied in all critical industries for prioritizing potential failures and mitigating them. This study will help experts find the safer and the more accurate failure analysis for critical components and complex systems. A real world inspired example related to aircraft turbine rotor blades is presented to illustrate the performance and applicability of the proposed framework.

Key words: Failure mode and effect analysis, Fuzzy cognitive maps, Risk priority number, Prioritization, Complex systems.

1. Introduction

Many failures in critical systems and processes are dynamic and complex since several components interact with each other in so complex ways (Papageorgiou E. , 2014). This could lead to an increase in the number of failures in these systems since the failure of a component could lead to a failure of the same or another component or cause of a failure could be the cause of other failures. One of the main reasons for propagation of such failures in complex systems is the lack of in-depth understanding of the failure interactions and mechanisms. There is a need for an advanced and powerful failure analysis tool to be able to consider this complexity in failure interactions of complex systems. However, the existing failure assessment tools are not able to consider failures interactions. Failure modes and effects analysis (FMEA) is a well-known and extensively used failure analysis method for identifying and mitigating potential failures in order to ensure the safety and reliability of components and systems. It is widely adopted in different industries such as manufacturing, aviation, healthcare, nuclear and services. Traditional FMEA analyses the risk of a component or process using risk priority number (RPN). The RPN is a product of three main criteria; the probability of the occurrence of failure (O), the probability of not detecting the failure (D) and the severity/consequences of the failure (S) ($RPN = O \times D \times S$). This approach is simple but it suffers from some major weaknesses as follows:

(1) The relative importance among O, S and D is overlooked and the three criteria are assumed to have the same importance (Carmignani, 2009; Chang & Cheng, 2011; Chang, Chang, & Tsai, 2013; Kuei-Hu, Yung-Chia, & Yu-Tsai , 2014; Nepal, Yadav, Monplaisir, & Murat, 2008; Peláez & Bowles, 1996; Sankar & Prabhu, 2001; Seyed-Hosseini, Safaei, & Asgharpour, 2006; Zammori & Gabbrielli, 2011).

(2) The RPN criteria produce many duplicate numbers. This could lead to misclassifying high-risk failures as low risk (Carmignani, 2009; Chang & Cheng, 2011; Chang, Chang, & Tsai, 2013; Kuei-Hu, Yung-Chia, & Yu-Tsai , 2014; Seyed-Hosseini, Safaei, & Asgharpour, 2006; Xu, Tang, Xie, Ho, & Zhu, 2002; Abbasgholizadeh Rahimi, Jamshidi, Ait-Kadi, & Ruiz, 2015; Chin, Chan, & Yang, 2008).

(3) Uncertainties in FMEA teams' opinions are neglected when scaling the RPN's subjective factors (Chang & Cheng, 2011; Chang, Chang, & Tsai, 2013; Seyed-Hosseini, Safaei, & Asgharpour, 2006; Xu, Tang, Xie, Ho, & Zhu, 2002; Abbasgholizadeh Rahimi, Jamshidi, Ait-Kadi, & Ruiz, 2015).

(4) Traditional FMEA only considers a single failure, while for a complex system with several components, there may be many failures and failure causes (Xiao, Huang, Li, He, & Jin, 2011).

(5) In complex engineering systems, the relationships and interdependencies among various failure modes (F), causes of failures (CFs), the relationships between CFs and Fs and vice versa are overlooked (Carmignani, 2009; Xu, Tang, Xie, Ho, & Zhu, 2002; Zammori & Gabbrielli, 2011; Nepal, Yadav, Monplaisir, & Murat, 2008; Kuei-Hu, Yung-Chia, & Yu-Tsai , 2014; Chin, Chan, & Yang, 2008).

(6) The level of experience and knowledge of experts are not considered in ranking failure modes (criticized by authors).

The aforementioned shortcomings crucially limit the efficiency of FMEA method and they could result in wrong decisions. Several attempts have been made in the past decade in order to address the shortcomings 1 to 3. However, very few authors have addressed the last three shortcomings (4, 5, and 6). Since a full review of literature regarding the proposed approaches for improvement of traditional FMEA has been carried out recently by Liu, Liu, and Liu (2013), in this study we focus in the few papers that have dealt with resolving the aforementioned shortcomings, in particular shortcomings 4, 5, and 6. Xu, Tang, Xie, Ho, and Zhu (2002) proposed a fuzzy FMEA method, which considers the relationships between failure modes and effects of a turbocharger system. However, they didn't consider the dependencies between causes of failures and failure modes nor the possible connections among causes of failures. In order to consider the relationships between failure modes and effects, they proposed several fuzzy "if-then rules". As criticized by several authors, fuzzy rule-based techniques suffer from several limitations. For example, large number of rules should be constructed for each RPN model and this requires a vast number of judgments and therefore it may be very time-consuming in the case of complex systems (Liu, Liu, & Liu, 2013). In addition, some fuzzy if–then rules with different antecedents have the same consequences. Then, it is not possible to prioritize the failure modes accurately based on these if–then rules. Seyed-Hosseini, Safaei, and Asgharpour (2006) proposed the application of decision making trial and evaluation laboratory (DEMATEL) approach in a system FMEA in order to consider indirect relations between components. The major problem with this methodology as mentioned by Chang and Cheng (2011) is that when each CF is assigned to only one potential failure mode, the prioritization results obtained by DEMATEL approach and the traditional RPN method are the same. To solve this problem, Chang and Cheng (2011) integrated fuzzy ordered weighted averaging (OWA) and DEMATEL approach to prioritize the risk of failure. Although this integrated method overcame the problem of DEMATEL approach, this approach is very time-consuming and complex. Recently, Chang, Chang, and Tsai (2013) proposed an integrated approach using grey relational analysis (GRA) and DEMATEL in order to lower the high duplication rate and consider the cause and effect relationships between failure modes and effects in a system. However, none of these studies take into account the relationships between CFs, F, CFs and Fs and vice versa. Zammori and Gabbrielli (2011) integrated FMECA and analytic network process (ANP) in order to consider possible relationships between causes of failure in the criticality assessment (CA). They split O, S and D into sub criteria which the lowest level contains the causes of failure. The proposed model computes RPN scores by making several pairwise comparisons. Despite the fact that ANP takes into account the interrelationships between causes of failures, it suffers from some major shortcomings. First, the questions for comparing the importance of a failure to another are sometimes hard and not understandable for experts to answer (Yu & Tzeng, 2006). For example, '*how the possibility that the ith cause leads to the jth failure is greater than the possibility that the kth cause leads to the jth failure*? (Zammori & Gabbrielli, 2011). Second, ANP is able to consider only the direct dependencies among failure modes and their causes while there could be some indirect dependencies between them which are ignored. Third, determining the true ANP structure for several failure modes and causes of failures is hard since each structure produces a different result (Lee & Kim, 2000). Besides, performing pair-wise comparisons of failure modes and their causes are very time-consuming and almost impossible in the case of complex systems.

FCM is a useful artificial intelligence technique that is used to model the behaviour of complex systems by graphical representations and based on experts' perceptions. It is able to take into account imprecise information, uncertainties, and the interrelationships among criteria based on several experts' opinions (Jamshidi, Abbasgholizadeh Rahimi, Ait-Kadi, & Ruiz, 2015). Due to these features, FCM has gained an increasing attention and it is being used in different complex decision making problems such as medicine, engineering, information technology, prediction (Jamshidi, Abbasgholizadeh Rahimi, Ait-Kadi, & Ruiz, 2015; Xiao, Chen, & Li, 2012; Salmeron, 2010). However, direct applications of FCMs to FMEA are extremely scarce in the literature. Peláez and Bowles (1996) were the first and only authors who applied scenario-based FCM and min–max inference approach to FMEA in order to consider failure interactions and assess the effect of different failure modes on the system. However, this approach is very time consuming and infeasible when performing analyses of complex systems with several failure causes and effects. In addition, the analysis of the effect of different failure causes on the system is only based on the cause and effect relationships between failure modes and the risk scores (RPN) of failure causes are not taken into account. Considering the risk score for each failure mode or cause of failure and taking into account the failure interactions and dynamic behaviour of system simultaneously, could lead to more precise failure analysis process.

Motivated by abovementioned studies and their shortcomings, this paper proposes a new integrated framework by using adjusted FCM and Fuzzy FMEA tools. At first, a fuzzy FMEA model is proposed to determine the initial RPI scores for all CFs. Then, an innovative FCM-based FMEA model is proposed to consider all possible relationships including direct/indirect relations between CFs, F, CFs and Fs and vice versa by updating the initial RPI scores. Finally, by using a hybrid learning algorithm, initial values are trained and the most critical failure mode and cause of failure are identified. The proposed framework is dynamic and able to predict the effects of failure/causes on the other failures/causes or on the system performance. In addition, it takes into account uncertainties, imprecise information, and level of experts' knowledge and experience. The rest of this paper is organized as follows. In section 2, the proposed framework is described. Section 3 illustrates the real world numerical example. In section 4, the main features of the proposed framework in contrast with other similar methods are discussed. Finally, conclusions are drawn in Section 5.

2. The proposed method

In this paper, FCM is adjusted for a fuzzy Failure Modes and Effects Analysis (FFMEA) method to model the behavior of complex systems. At first, a fuzzy FMEA model is proposed to determine the initial RPI scores for all CFs. Then, an innovative FMEA-based FCM model is developed to take into account all possible relationships between CFs, F, CFs and Fs and vice versa. Finally, using NHL-DE hybrid learning algorithm, initial values are trained and the most critical failure mode and cause of failure are identified. Pelaèz and Bowles (1996) where the first who applied traditional FCM proposed by Bart Kosko (1986) to FMEA for predicting the impact of failures on the system operation. In this model, experts assign linguistic terms to all dependencies among concepts/nodes. Then, some "what-if" analysis scenarios are developed and in each scenario, a failure is activated. Then, the impact of activated failure is calculated using min-max inference approach. The value of activated failures in the initial concept vector ($C^{Initial}$) is considered as 1 and for the rest of failures this number is 0. In order to achieve precise results, for each failure, all of the possible paths (scenarios) should be taken into account, starting from all of failures, and the total effects for each failure should be evaluated to determine their influences on the system operation. Although scenario-based FCM is applicable and effective for analysing the impact of activated failures, its main drawback is the inherited inability to change scenarios dynamically and therefore it is very time consuming and it needs a high simulation time and in the case of complex systems with several failures and causes of failures it is almost infeasible to define and simulate all possible scenarios/paths. For example, for evaluating the impact of only 16 causes of accidents on 12 major accidents in an Italian refinery, Bevilacqua et al. (2012) defined a total of 20336 paths and calculated the total effect for each factor using the mini-max inference approach. In this paper, inspired by Pelaèz and Bowles (1996) and Bevilacqua et al. (2012) studies, we propose a new framework for analysing the failures of complex systems based on FCM in which, the initial concept values ($C^{Initial}$) is updated by using initial weight matrix ($W^{Initial}$), Eq. 2, and a learning algorithm until it arrives at one of the three steady state conditions. The updated concept values (C^{*}) shows the impact of each failure or cause of failure on the other failures or on the system performance. The procedure for the proposed framework is as follows:

Step 1. Form a panel of experts ($E_k = \{E_1, E_2, E_3, \ldots, E_k\}$) to identify the potential failures ($F_i = \{F_1, F_2, F_3, \ldots, F_m\}$) as well as their causes ($CF_j = \{CF_1, CF_2, CF_3, \ldots, CF_n\}$) and effects on the system.

Step 2. Derive the weights of RPN factors (w_O, w_S, and w_D) using group AHP method. These weights could be different based on organizational goals and objectives and therefore they should be obtained based on the opinions of experts in each organization.

Step3. Calculate the weight of each expert (w_k) using one of weighting methods. Various methods for finding the weights exist in the literature such as AHP, ANP, ELECTRE, Shannon Entropy, VIKOR, etc. Each organization could apply one of these methods depending on the type of criteria (Subjective or Objective) they consider. Some criteria such as highest level of education and years of experience could be considered for determining the weight of experts.

Step 4. In this step, each expert individually assigns linguistic variables (as shown in Table 3.1) for each CF_j by considering three RPN factors.

Table 3. 1 Fuzzy ratings for O, S, and D factors

Occurrence	Severity	Detection	Fuzzy rating
Very Low (VL)	Very Low (VL)	Very high (VH)	(0, 0, 1.5)
Low (L)	Low (L)	High (H)	(1, 2.5, 4)
Moderate (M)	Moderate (M)	Moderate (M)	(3.5, 5, 6.5)
High (H)	High (H)	Low (L)	(6, 7.5, 9)
Very high (VH)	Very high (VH)	Very Low (VL)	(8.5, 10, 10)

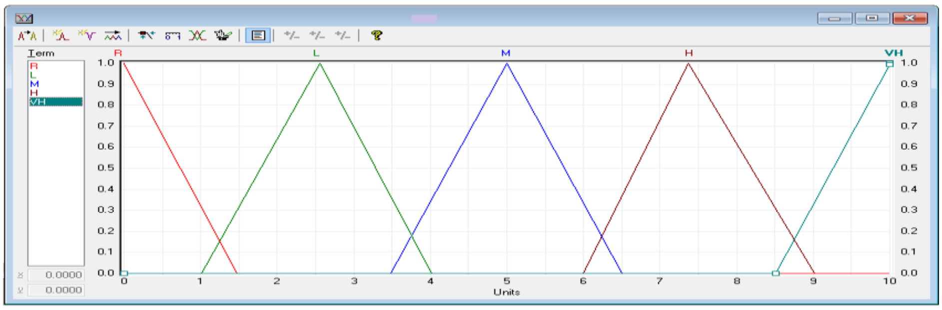

Figure 3. 1 Fuzzy membership functions for O, S, and D factors

Then, all of the linguistic terms (assigned by different experts to each of RPN factors) are fuzzified using the triangular membership functions (indicated in Table 3.1 and Fig. 3.1) and finally defuzzified. This process is explained in the followings:

Let O_{ijk}, S_{ijk}, and D_{ijk} be the occurrence, severity, and detection values for failure mode i, cause of failure j and evaluated by expert k. In this paper, we have considered the triangular fuzzy membership functions as follows:

$$O_{ijk} = (LO_{ijk}, MO_{ijk}, UO_{ijk}), \quad \text{where } 0 \leq LO_{ijk} \leq MO_{ijk} \leq UO_{ijk} \leq 10 \tag{9}$$

$$S_{ijk} = \left(LS_{ijk}, MS_{ijk}, US_{ijk}\right), \quad \text{where } 0 \leq LS_{ijk} \leq MS_{ijk} \leq US_{ijk} \leq 10 \tag{10}$$

$$D_{ijk} = \left(LD_{ijk}, MD_{ijk}, UD_{ijk}\right), \quad \text{where } 0 \leq LD_{ijk} \leq MD_{ijk} \leq UD_{ijk} \leq 10 \tag{11}$$

The following equations (12-14) are used to aggregate the opinions of experts by considering their weights (w_k).

$$O_{ij} = \frac{\sum_{k=1}^{k} O_{ijk} w_k}{k} \tag{12}$$

$$S_{ij} = \frac{\sum_{k=1}^{k} S_{ijk} w_k}{k} \tag{13}$$

$$D_{ij} = \frac{\sum_{k=1}^{k} D_{ijk} w_k}{k} \tag{14}$$

Equations (15) to (17) are used to obtain the O, S and D values for each cause of failures.

$$O_j = \prod_{i=1}^{m} O_{ij} \tag{15}$$

$$S_j = \prod_{i=1}^{m} S_{ij} \tag{16}$$

$$D_j = \prod_{i=1}^{m} D_{ij} \tag{17}$$

In order to take into account the importance weights of RPN factors (O, S and D), a pairwise comparison should be done between these factors to obtain w_O, w_S, and w_D. Then, these weights are multiplied in O_j, S_j, and D_j values to obtain the fuzzy membership function $\mu(RPI_j)$ as follow:

$$\mu(RPI_j) = w_O\mu(O_j) + w_S\mu(S_j) + w_D\mu(D_j) \tag{18}$$

The obtained fuzzy membership function for each cause of failure should be defuzzified to obtain crisp numbers. To defuzzify a triangular fuzzy number (*L*, *M*, *U*), in this paper the following Equation is applied (Çelik & Yamak, 2013):

$$t = \frac{L+M+M+U}{4} \tag{19}$$

Finally, defuzzified risk priority score for each cause of failure (RPI_j) is obtained using the following Equation.

$$RPI_j = DO_j \times DS_j \times DD_j \tag{20}$$

Step 5. Establish the FCM diagram in order to show all the interactions between F_m and CF_n and obtain $W^{Initial}$ matrix based on experts' opinions. Experts should first reach consensus on the sign and direction of arcs between criteria. In order to determine the level of influence of each criterion on the other criteria and vice versa, experts assign linguistic terms (as indicated in Table 3.1 and Fig. 3.1) for each arc individually. Then, the opinions of decision makers are aggregated and defuzzified in order to find the initial influence weight ($W^{Initial}$). In this study, we propose the following $W^{Initial}$ matrix:

Table 3. 2 The proposed $W^{Initial}$ matrix

E_k	F_1	.	F_m	CF_1	.	CF_n
F_1	w_{F1-F1}	.	w_{F1-Fm}	w_{F1-CF1}	.	w_{F1-CFn}
.	.	.	.	.	.	.
F_m	w_{Fm-F1}	.	w_{Fm-Fm}	w_{Fm-CF1}	.	w_{Fm-CFn}
CF_1	w_{CF1-F1}	.	w_{CF1-Fm}	$w_{CF1-CF1}$	.	$w_{CF1-CFn}$
.	.	.	.	.	.	.
CF_n	w_{CFn-F1}	.	w_{CFn-Fm}	$w_{CFn-CF1}$	.	$w_{CFn-CFn}$

Step 6. Make an initial concept vector ($C^{Initial}$), as follows:

$$\begin{array}{cccccccccccc} & F_1 & F_2 & . & . & F_m & CF_1 & CF_2 & . & . & CF_n \\ (C^{Initial}) & [0 & 0 & 0 & 0 & 0 & RPI_1 & RPI_2 & . & . & RPI_n] \end{array}$$

Note that in this vector the RPI_j scores are used as initial values of CFs and the values for Fs are considered to be zero.

Step 7: By using NHL-DE learning algorithm, initial concept vector ($C^{Initial}$), $W^{Initial}$ matrix, and Eq. (2) train the FCM and obtain the steady-state concept matrix (C^*). In our proposed method, we have used the following sigmoid threshold function:

$$f(x) = \frac{1}{1+e^{-\lambda x}} \tag{21}$$

where $\lambda > 0$ denotes the steepness of f. We use this function since our concepts interval is in [0, 1] range. This step will identify the most critical failure mode.

Step 8: The aim of this step is to identify the most influential CF_j on the identified critical failure in step 7. To do so, make new $C^{Initial}$ vectors each time by activating only one cause of failure involved in the occurrence of identified failure mode in step 7. Note that in each new $C^{Initial}$ vector, the value of all *Fs* and *CFs* are considered to be zero except the activated CF_j which its value is considered as RPI_j.

$$\begin{array}{lcccccccccc} & F_1 & F_2 & . & . & F_m & CF_1 & . & CF_j & . & CF_n \\ (C^{Initial}) & [0 & 0 & 0 & 0 & 0 & 0 & 0 & RPI_j & 0 & 0] \end{array}$$

After making new $C^{Initial}$ vectors, each of FCMs are trained and finally the most critical CF_j is identified through comparing the values obtained for identified failure mode (in step 7) in each C^*.

3. Numerical example

In this section, we illustrate the performance and applicability of the proposed framework through an academic numerical example related to rotor blades of an aircraft turbine. Rotor blades are the major components of an aircraft turbine and consist of compressor and turbo rotor blades (Yang, Huang, He, Zhu, & Wen, 2011). These components move in high-speed rotation, under the severe load conditions in complex work environments, and have the thin-form. Therefore, they are one of the components having the highest failure rates in aircraft turbines. Any failure with these blades could affect seriously the overall aircraft turbine reliability and security. Jianping et al. (2011) recognized 17 potential failure modes related to rotor blades. According to the explained steps in section 3, the proposed framework is illustrated in the following.

Step 1. In this numerical example, five potential failure modes (F_1, F_2, F_3, F_4, F_5) and five causes of failures (The improper material (CF_1), low intensity due to improper heat treatment (CF_2), high centrifugal stress due to engine overspeed (CF_3), the low blade strength due to overtemperature (CF_4), and low yield strength caused by the improper material and heat treatment technology (CF_5)) are taken form Yang, Huang, He, Zhu, and Wen (2011) and will be evaluated by three Experts (E_1, E_2, E_3). Note that some failure modes have the same causes of failures and this increases the complexity of failure analysis.

Table 3. 3 Failure modes and causes of failures of an aircraft turbine

Component	Failure modes	Causes of failures
Compressor rotor blades	Fracture (F_1)	CF_1
		CF_2
		CF_4
		CF_5
	Blade tip wear (F_2)	CF_1
		CF_2
	Deformation (F_3)	CF_3
		CF_4
		CF_5
	Deflection (F_4)	CF_2
		CF_4
Turbo rotor blades	Deformation (F_5)	CF_3
		CF_5

Step 2. Relative AHP is employed to determine the weights of RPN factors (w_O, w_S, and w_D) (Abbasgholizadeh Rahimi, Jamshidi, Ait-Kadi, & Ruiz, 2015) and the numbers ‘‘0.4809, 0.1652, and 0.3538’’ are achieved for O, S, and D factors, respectively (as shown in second column of Table 3.4).

Step 3. Values under header “Exp (w_i)” in Table 3.4 represent the weights assigned to each of experts. In our numerical example, we set them arbitrarily as 0.3, 0.5, and 0.2. The same weights are applied in step 5 for obtaining $W^{Initial}$ matrix.

Table 3. 4 Assigning linguistic terms for each RPI factor

RPI Factors	Exp (w_i)	F_1				F_2		F_3			F_4		F_5	
		CF_1	CF_2	CF_4	CF_5	CF_1	CF_2	CF_3	CF_4	CF_5	CF_2	CF_4	CF_3	CF_5
S	1(0.3)	L	M	VH	VH	M	VL	L	VH	L	VH	M	H	M
	2(0.5)	L	L	M	H	M	L	VL	H	L	VH	M	M	H
	3(0.2)	M	L	M	VH	H	L	L	H	M	VH	M	M	H
O	1(0.3)	H	H	M	M	M	VL	H	M	H	L	VH	M	M
	2(0.5)	VH	H	H	M	L	L	VH	H	VH	L	H	L	L
	3(0.2)	H	VL	H	L	M	L	H	M	H	VL	H	M	M
D	1(0.3)	VL	VH	L	L	H	H	M	VL	VL	L	VL	L	H
	2(0.5)	VL	VH	L	VL	M	H	VH	VL	VL	L	L	VL	M
	3(0.2)	VL	H	VL	L	M	VH	H	L	VL	L	VL	L	VH

Step 4. Construct fuzzy FMEA assessment tables for all of failures and related causes. Each RPI factor is evaluated by three experts based on linguistic terms. Tables 4.5-9 illustrate this step.

Table 3.5 shows the linguistic terms assigned by three experts to each cause of failure. Using Table 3.1 and Equations 9-11, the linguistic variables are converted into triangular fuzzy numbers as indicated in Table 3.5. In Table 3.6, the fuzzy triangular numbers in Table 3.5 are multiplied by experts’ weights (w_i) and the opinions of all three experts are aggregated using Equations 12-14. It should be mentioned that due to lack of space the values of some columns in Tables 4.5 and 4.6 are not shown.

Table 3. 5 Assignment of fuzzy triangular numbers

RPI Factors	Exp(W)	F_1						.	F_5			
		CF_1			CF_2	CF_4	CF_5	.	CF_3	CF_5		
S	1(0.3)	1	2.5	4	·	·	·	.	·	3	5	7
	2(0.5)	1	2.5	4	·	·	·	.	·	6	7.5	9
	3(0.2)	3	5	7	·	·	·	.	·	6	7.5	9
O	1(0.3)	6	7.5	9	·	·	·	.	·	3	5	7
	2(0.5)	8	9	10	·	·	·	.	·	1	2.5	4
	3(0.2)	6	7.5	9	·	·	·	.	·	3	5	7
D	1(0.3)	0	1	2	·	·	·	.	·	6	7.5	9
	2(0.5)	0	1	2	·	·	·	.	·	8	9	10
	3(0.2)	0	1	2	·	·	·	.	·	8	9	10

Table 3. 6 Aggregating experts’ opinions by considering their weights

RPI Factors	F_1				.	F_5	
	CF_1	CF_2	CF_4	CF_5	.	CF_3	CF_5

S	0.46	1	1.53	0.53	1.08	1.63	.	.	.	1.3	1.92	2.53	1.7	2.25	2.8
O	2.33	2.75	3.16	1.6	2.06	2.53	.	.	.	0.67	1.25	1.83	0.67	1.25	1.83
D	0	0.33	0.66	2.53	2.9	3.26	.	.	.	0.17	0.58	1	2.47	2.85	3.23

Table 3. 7 Aggregation of same causes of failures

RPI factors	CF_1			CF_2			CF_3			CF_4			CF_5		
S_j (0.1652)	0.015	0.05	0.1	0.001	0.01	0.028	0.01	0.03	0.069	0.015	0.041	0.086	0.008	0.028	0.061
O_j (0.4809)	0.36	0.79	1.34	0.011	0.12	0.383	0.36	0.79	1.343	0.624	1.382	2.574	0.15	0.573	1.377
D_j (0.3538)	0	0.12	0.27	0.08	0.28	0.592	0.05	0.21	0.409	0.001	0.016	0.064	0	0.025	0.095

Table 3.7 shows the aggregation results of same causes of failures (CF_j) using Equations 15-17. Then, Equation 19 is used to defuzzify the weighted O_j, S_j and D_j values for each cause of failures as shown in Table 3.8. Finally, RPI scores are obtained using Equation 20 as indicated in the last row of Table 3.8.

Table 3. 8 Defuzzified S, O, and D values for obtaining RPIs

RPI factors	CF_1	CF_2	CF_3	CF_4	CF_5
DS_j	0.33	0.45	0.21	1.68	1.15
DO_j	1.71	0.67	1.71	6.44	2.89
DD_j	0.35	2.45	0.63	0.2	0.29
RPI_j	0.203	0.748	0.22	2.11	0.96

The obtained results for RPI_j in Table 3.8 show the criticality of each cause of failure. From these results, it is clear that $CF4 > CF5 > CF2 > CF3 > CF1$. However, the impact of these CFs on the failures 1-5 are not determined. In addition, the possible dependencies among *Fs* and *CFs* are not considered in this CF ranking. Then, using RPI_j scores as initial values, the next steps will identify the most critical failure and cause of failure by considering the dependencies and through establishing the FCM diagram.

Step 5. Establish the FCM diagram based on three experts' opinions and obtain $W^{Initial}$ matrix. Fig. 3.2 shows the FCM structure for potential failures and their causes of rotor blades. This contains 36 arcs. Table 3.9 shows the linguistic terms assigned for each relationship among *Fs*, *CFs*, *Fs* and *CFs*, and vice versa. In order to make the $W^{Initial}$ matrix, experts individually determine the level of dependency. Then, the linguistic variables are aggregated and defuzzified through Eq. 19 to obtain crisp numbers. The initial weight matrix, is shown in Table 3.10.

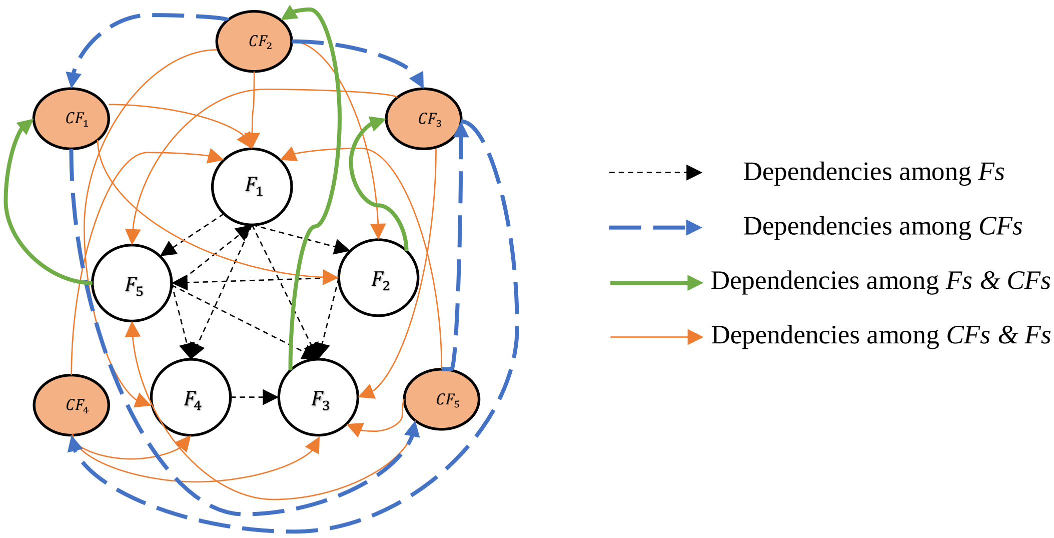

Figure 3. 2 FCM structure for 5 failures (F_i) and 5 causes of failures (CF_j)

Table 3. 9 Assigning linguistic terms for level of dependencies among failures and their causes

EXP.1 (0.3)	F1	F2	F3	F4	F5	C1	C2	C3	C4	C5
F1	0	H	VL	M	H	0	0	0	0	0
F2	0	0	M	0	H	0	0	L	0	0
F3	0	0	0	0	0	0	VH	0	0	0
F4	0	0	VL	0	0	0	0	0	0	0
F5	H	0	M	VL	0	M	0	0	0	0
C1	H	H	0	0	0	0	0	0	0	M
C2	L	M	0	VH	0	L	0	VH	0	0
C3	0	0	VL	0	M	0	0	0	M	0
C4	H	0	L	VH	0	0	0	0	0	0
C5	VH	0	M	0	L	0	0	VL	0	0

EXP.2 (0.5)	F1	F2	F3	F4	F5	C1	C2	C3	C4	C5
F1	0	VH	L	H	H	0	0	0	0	0
F2	0	0	L	0	H	0	0	VL	0	0
F3	0	0	0	0	0	0	VH	0	0	0
F4	0	0	L	0	0	0	0	0	0	0
F5	VH	0	M	M	0	M	0	0	0	0
C1	VH	M	0	0	0	0	0	0	0	H
C2	M	L	0	VH	0	M	0	VH	0	0
C3	0	0	L	0	M	0	0	0	M	0
C4	M	0	M	H	0	0	0	0	0	0
C5	H	0	M	0	VL	0	0	L	0	0

EXP.3 (0.2)	F1	F2	F3	F4	F5	C1	C2	C3	C4	C5
F1	0	H	L	M	M	0	0	0	0	0
F2	0	0	M	0	H	0	0	M	0	0
F3	0	0	0	0	0	0	H	0	0	0
F4	0	0	M	0	0	0	0	0	0	0
F5	H	0	H	VL	0	H	0	0	0	0
C1	VH	VH	0	0	0	0	0	0	0	H
C2	M	VL	0	VH	0	L	0	H	0	0
C3	0	0	VL	0	M	0	0	0	M	0
C4	H	0	L	M	0	0	0	0	0	0
C5	VH	0	M	0	VL	0	0	L	0	0

Table 3. 10 $W^{Initial}$ matrix

$W^{initial}$	F_1	F_2	F_3	F_4	F_5	CF_1	CF_2	CF_3	CF_4	CF_5
F_1	0	0.275	0.068	0.208	0.233	**0**	**0**	**0**	**0**	**0**
F_2	0.033	0	0.125	0	0.25	**0**	**0**	**0.075**	**0**	**0**
F_3	0	0	0	0.06	0	**0**	**0.24**	**0**	**0**	**0**
F_4	0	0	0.085	0	0	**0**	**0**	**0**	**0**	**0**
F_5	0.275	0	0.183	0.1	0	**0.18**	**0**	**0**	**0**	**0**
CF_1	0.285	0.1	0	0	0	**0**	**0**	**0**	**0**	**0.225**
CF_2	0.142	0.2	0	0.3	0	**0.13**	**0**	**0.29**	**0**	**0**
CF_3	0	0.3	0.058	0	0.167	**0**	**0**	**0**	**0.17**	**0**
CF_4	0.208	0.4	0.125	0.248	0	**0**	**0**	**0**	**0**	**0**
CF_5	0.275	0.5	0.167	0	0.048	**0**	**0**	**0.068**	**0**	**0**

As already mentioned, some ranges could be defined by experts for the weights in Table 3.10. Besides, experts could define some desired regions between [0,1] for some concepts in $C^{Initial}$ as Desired Output Concepts

(DOCs). The DOCs are defined for those concepts (failures or cause of failures) which are important for the experts.

Step 6. Make an initial concept vector ($C^{Initial}$) using the RPI_j scores obtained in Table 3.8, as follows:

$$\begin{array}{cccccccccccc} & F_1 & F_2 & F_3 & F_4 & F_5 & CF_1 & CF_2 & CF_3 & CF_4 & CF_5 \\ C^{Initial} & [0 & 0 & 0 & 0 & 0 & 0.203 & 0.748 & 0.22 & 2.11 & 0.96] \end{array}$$

Step 7: Train the FCM and obtain the steady-state concept matrix (C^*) as follows:

$$\begin{array}{cccccccccccc} & F_1 & F_2 & F_3 & F_4 & F_5 & CF_1 & CF_2 & CF_3 & CF_4 & CF_5 \\ C^* & [0.6838 & 0.7505 & 0.6469 & \mathbf{0.7576} & 0.7453 & 0.9687 & 0.7626 & 0.7789 & 0.801 & 0.806] \end{array}$$

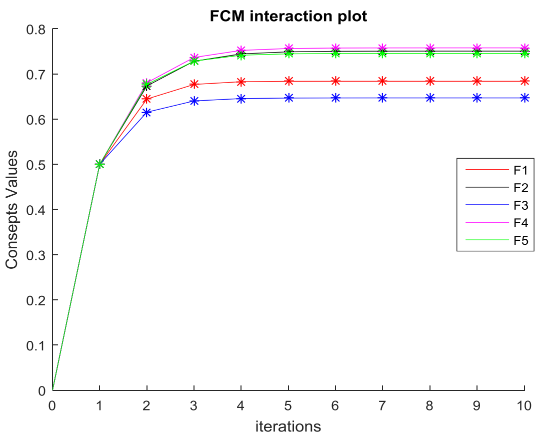

Figure 3. 3 The variation of five failures modes for 10 cycles: convergence region

All the initial data are imported into Matlab R2015b as a code. For this numerical example, the population size is 50 and the values of crossover constant (CR), mutation constant (μ), weight decay learning parameter (γ) and learning rate parameter (η) are 0.5, 0.5, 0.98, 0.04, respectively. 1000 iterations were performed. According to the matrix C^* and Fig. 3.3, the most critical failure mode is F_4 (0.7576) followed by F_2, F_5, F_1, F_3. The results of the comparison of FCM simulations are shown graphically in Fig. 3.3.

Step 8. In order to figure out which cause of failure has the most impact on F_4, all the cause of failures involved in the occurrence of failure mode F_4 should be activated separately. To do so, in each new $C^{Initial}$ vector, the value of all *Fs* and *CFs* are considered zero, except the activated CF_j which its value is considered as RPI_j obtained in Table 3.8.

Table 3. 11 Activating CF_2 and CF_4 and obtaining C^* vectors

	F_1	F_2	F_3	F_4	F_5	CF_1	CF_2	CF_3	CF_4	CF_5
$C^{Initial}$	0	0	0	0	0	0	0.748	0	0	0
C^*	0.829	0.752	0.760	**0.755**	0.845	0.688	0.794	0.922	0.803	0.746
$C^{Initial}$	0	0	0	0	0	0	0	0	2.11	0
C^*	0.820	0.885	0.758	0.749	0.844	0.744	0.850	0.882	0.905	0.809

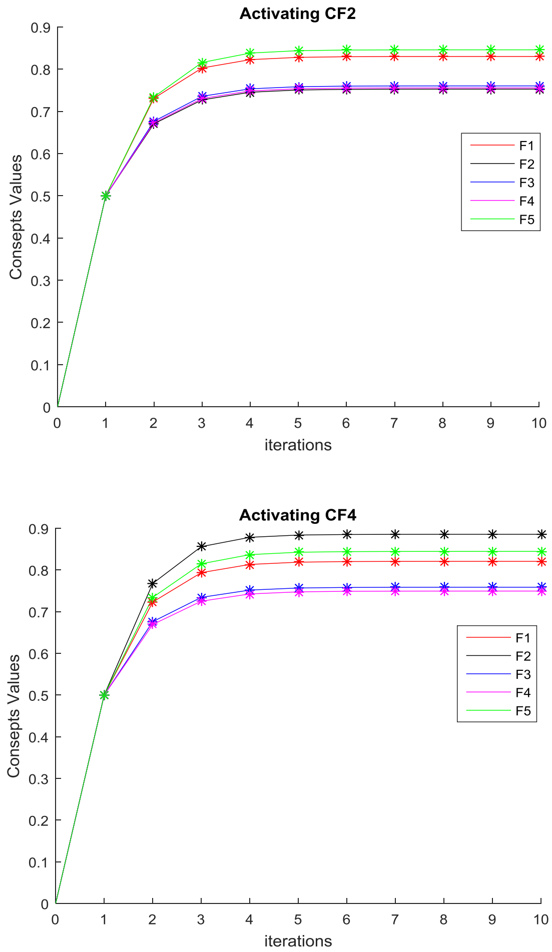

Figure 3. 4 The variation of five failures modes by activating CF_2 and CF_4 for 10 cycles: convergence region

The information obtained from steps 7 and 8 provide practitioners with variety of valuable information for effectively and more accurately preventing critical failures and their related causes. The findings in Table 3.10 show that by activating CF_2 and CF_4, CF_2 has a strong influence over F_2 rather than CF_4. On the other words, CF_2 is more critical than the other cause of failures over F_2 and should be given priority in prevention activities. In addition, the findings show the range of impact and the average impact of each cause of failure. For example, the range of impact of CF_2 on the five failure modes is [0.611,0.766] and the average impact is 0.715[*]. Moreover, this process could be carried out for all of the other cause of failures by activating each cause of failure at each time, in order to analysis the impact of each CF_i on each failure modes. This will determine if cause of failure CF_i occurs, which failure will be affected mostly.

4. Discussion

This paper aims to enhance the efficiency of the traditional FMEA method by integrating it with FCM tool. In fact, it intends to propose an advanced FCM-based FMEA tool which is able to fairly accurately model the behaviour of complex cause and effect relationships among failures/cause of failures in order to evaluate and prioritize such failures/causes and predict their effects on the other failures/causes or on the system performance.

[*] The mean was calculated by adding up the values of failures and dividing by the number of failures.

Table 3.12 shows the principal requirements for such an advanced failure analysis tool and indicate whether the existing methods including our proposed tool meet the demanded requirements. Note that we have selected the similar methods such as DEMATEL from literature based on the fact that they are able to consider Direct/Indirect relationships between failures/causes. When a method meets a requirement, this is indicated in Table 3.12 with ☑.

Table 3. 12 Comparing the proposed framework with other similar methods in terms of requirements

Requirements	Direct/Indirect relationships	Predicting the effects of failure/ causes	Uncertainties and imprecise information	Ability to consider several components with same/different F_i and CF_j	Ability to consider the level of experts' knowledge and experience	Dynamic system With feedback
DEMATEL	✓					
OWA & DEMATEL	✓					
GRA & DEMATEL	✓		✓			
FMECA & ANP						
FCM- based FMEA	✓	✓	✓	✓	✓	✓

As it is clear from this Table, FCM-based FMEA is the only modelling tool which meet all the requirements demanded. Due to these features, this artificial intelligence tool has gained an increasing attention and it is being used in different complex decision making problems. Although some of the existing methods such as DEMATEL are able to consider the direct/indirect relationships among failure and causes of failures, none of them take into account the possible connections between failure modes (or failure causes). For example, some failures could have effects on other failures, for example F_1 in our numerical example has effects on the failures F_2, F_3, F_4 and F_5. Considering all possible connections in failure analysis provides a possible tool for helping to automate the reasoning required in FMEA. The proposed FCM-based FMEA is also able to provide valuable information for predicting failure effects and causes on the system performance. In particular, experts can easily determine how any change in a failure or cause of failure will affect the other failure modes while this feature is not available in the other methods. One of the other features of our proposed tool that is that it is dynamic, meaning that it involves feedback and by changing the value of a concept the values of other nodes could be affected. Last but not least, using causal graphs, experts can better understand and rate all of the dependencies among failure and their causes. The most significant weaknesses of the FCMs are their critical dependence on the experts' opinion and the potential convergence to undesired states. Learning algorithms can help overcome this shortcoming by increasing the efficiency and robustness of FCMs. As a future research topic, application of other learning algorithms for training FCM could be considered.

5. Conclusion

This study presents an integrated dynamic framework for advanced failure analysis of complex and critical systems by considering failures and causes of failures interactions under uncertainty. At first, a fuzzy FMEA model is proposed to determine the initial RPI scores for all causes of failures by considering experts' weights. Then, an innovative FMEA-based FCM model is developed to take into account all possible relationships between nodes. Finally, using NHL-DE hybrid learning algorithm, initial RPI scores are trained and the most critical failure mode is identified. Besides, the most influential cause of failure on the most critical critical failure is determined by activating the cause of failures involved in the occurrence of this failure. Depending on the proposed FCM-based FMEA framework, experts can identify the critical failure modes and causes more precisely and accurately by predicting their impacts on the system and assign the limited resources to the most serious failures. The proposed framework is not only novel but sufficiently general and it could be adapted as an advanced risk assessment tool in all critical and complex industries for prioritizing critical failures and causes and mitigating them. Although it is not possible to conclude that the proposed tool is indeed effective due to lack of information, the distinguished features of this tool encourage us to continue our research. In future works, we plan to evaluate the performance of the proposed tool in practice on a complex system. Also, we will develop a user-friendly software based on this framework in order to facilitate its implementation in practice.

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Chapter 4. Dynamic risk modeling and assessing in complex systems using FCM

The forth chapter is dedicated to the following articles:

[1] Dynamic risk assessment of complex systems using FCM; A. Jamshidi, D. Ait-kadi, A. Ruiz, M.L. Rebaiaia, Accepted for publication in International Journal of Production Research.

[2] Dynamic risk modeling and assessing in maintenance outsourcing with FCM, 6th International Conference on Industrial Engineering and Systems Management (IESM 2015), Seville, Spain. Afshin Jamshidi, S. A. Rahimi, D. Ait-kadi, A. Ruiz. 2015, pp. 209-215. doi: 10.1109/IESM.2015.7380159.

[3] A new decision support tool for dynamic risks analysis in collaborative networks, A. Jamshidi, S. A. Rahimi, D. Ait-kadi, A. Ruiz, Risks and Resilience of Collaborative Networks Book, Pages 53-62, Vol 463 of the series IFIP Advances in Information and Communication Technology, Springer International Publishing, DOI 10.1007/978-3-319-24141-8_5.

4.1 Dynamic risk assessment of complex systems using FCM

Résumé: L'analyse du risque des systèmes complexes actuels est délicate en raison de la nature complexe et dynamique des systèmes. Les outils actuels d'analyse des risques ne sont pas en mesure de prendre en compte les interactions complexes entre les risques et ne peuvent donc pas prédire avec précision le comportement des risques. Pour tenter de remédier à cette lacune, nous proposons un outil généralisé d'aide à la prise de décision utilisant les cartes cognitives floues (FCM) pour l'évaluation dynamique des risques des systèmes complexes. L'outil proposé est capable de prévoir l'impact de chaque risque sur les autres ou sur les résultats des projets au fil du temps en considérant la probabilité d'occurrence et les conséquences des risques en tenant compte des dépendances complexes entre les facteurs de risque. Cet outil pourrait aider les praticiens des industries critiques à gérer les risques des systèmes complexes de manière plus efficace et plus précise et à offrir de meilleures solutions d'atténuation des risques.

Mots-clés: Évaluation des risques, Cartes cognitives floues, Systèmes complexes, Incertitude, Systèmes dynamiques.

4.1 Dynamic risk assessment of complex systems using FCM

Abstract: Analysing risk of today's complex systems is challenging due to the complex and dynamic nature of systems. The current risk analysis tools are not able to take the complex interactions among risks into account and therefore they can't predict the behaviour of risks accurately. In an attempt to overcome this shortcoming, this paper proposes an integrated generalized decision support tool using Fuzzy Cognitive Maps (FCMs) for dynamic risk assessment of complex systems. The proposed tool is able to predict the impact of each risk on the other risks or on the outcomes of projects over time by considering probability of occurrence and consequences of risks and also taking into account the complex dependencies among risk factors. This tool could help practitioners in critical industries to manage the risks of complex systems in a more effective and precise way and offer better risk **mitigation solutions.**

Keywords: Risk assessment, Fuzzy cognitive maps, Complex systems, Uncertainty, Dynamic systems.

Introduction

Modern systems and processes in manufacturing, healthcare, engineering, finance, sales, and many other fields are becoming more complex and dynamic. The risks and uncertainties associated with these systems and processes are often composed by several cause-effect relationships in so complex ways. This could lead to an increase in the number of failures in these systems if not assessed by an advanced risk assessment tool. Ordinary qualitative/ quantitative risk analysis tools such as traditional fault tree analysis (FTA) or failure mode effects analysis (FMEA) methods are designed to illustrate static dependencies among logical variables, and do not consider process variables, time, uncertainties (Abdo & Flaus, 2016), or human behavior (which affect the system dynamic response) (Siu, 1994) and therefore could not be applied to risk assessment of these systems. In addition, some advanced modelling techniques such as Bayesian networks, Neural networks, etc. are not able to take into account the requirements demanded for dynamic risk assessment of such complex systems.

FCMs are useful graphical tools for modeling and simulating dynamic systems. Due to their simplicity, recently, they have been employed widely as an advance decision support system in different domains such as engineering, medical decision system, business, software engineering, environmental sciences, political decision making, decision analysis, fault detection, process control, data mining in internet, and modeling LMS critical success factors (Salmeron & Papageorgiou, 2012; Zhi Xiao, 2013; Nassim Douali, 2014; Azadeh, Salehi, Arvan, & Dolatkhah, 2014; Núnez-Carrera, Espinosa-Paredes, & Cruz-Esteban, 2011; Lakovidis & Papageorgiou, 2011). In addition, some FCM extensions have been proposed in order to enhance its structures inheriting characteristics and advantages of other intelligent techniques. These extensions are designed to overcome three FCM shortcomings; uncertainty modeling (FGCM, iFCM, BDDFCM, RCM), dynamic issues (DCN, DRFCM, FCM, E-FCM, FTCM, TQFCM), and rule-based knowledge representation (RBFCM, FRI-FCM). More information about the different extensions of FCM are available in (Papageorgiou E. I., 2014).

FCM is considered as a useful artificial intelligence technique which represents and analyzes the dynamic behavior of complex systems composed of interrelated variables (Kosko B. , Fuzzy cognitive maps, 1986). Due to this fact, in addition to its application as an advanced decision support tool, recently this tool has been applied successfully for evaluating risks in complex and critical environments such as healthcare. Papageorgiou et al. (2015) proposed a decision support approach using FCM to accurately assess familial breast cancer risk factors and to evaluate the risk grades. In a similar work, Subramanian et al. (2015) proposed a NHL-FCM model for predicting breast cancer risk grade based on demographic risk factors identified by domain experts. Bevilacqua et al. (2013) used FCM for understanding the cognitive mechanisms that influence the errors of drug management activities. Ahmad and Kumar (2012) assessed the effects of risks on the success of Enterprise Recourse planning (ERP) maintenance through FCM modeling. At first, they identified risks to ERP maintenance success. Then, they specified which goals must be reached so that ERP maintenance will be considered successful. Finally, a FCM was created to forecast risk effects on ERP maintenance goals and simulate distinct scenarios. Lopez and Salmeron (2012) built a dynamic simulation tool using FCM that allows ERP managers to foresee the impact of risks on maintenance goals. Salmeron (2010) analyzed IT projects implementation risks and the relationships between using FCM. Bevilacqua et al. (2012) analysed the injuries in an Italian refinery by presenting a FCM approach to explore the importance of the relevant factors in industrial plants. For this purpose, industrial plants were described in terms of factors that affect injury risk and the causal relationships involved. Recently, the authors demonstrated the application of FCM in risk analysis of collaborative networks (Jamshidi, Abbasgholizadeh Rahimi, Ait-Kadi, & Ruiz, 2015), and maintenance outsourcing risks (Jamshidi, Abbasgholizadeh Rahimi, Ait-Kadi, & Ruiz, 2015).

In this paper, we focus on risk assessment feature of FCM and propose an adjusted integrated six steps approach to enhance its capability and generalize its application for dynamic risk assessment of complex systems in all industries and organizations. A major contribution of this paper is to develop an advanced dynamic risk assessment tool using FCM tool which is able to consider interdependencies between risk factors in risk assessment process and also predict the impact of each risk on the other risks or system outcomes by developing several what-if analyses. To the best of our knowledge, this is the first time that the dependencies among risk factors are included in the risk assessment process. We show how considering interdependencies including direct and indirect relationships between risk factors could significantly change the final prioritization of risk factors. In addition, we show how any changes in the value of risk factors could affect the other risks or system outcomes be defining nine different scenarios. The reminder of this paper is organized as follows. Section 2 presents the theoretical foundations of fuzzy logic and FCM. Sections 3 introduces some existing learning algorithms for training FCMs and compare them, while section 4 details the proposed approach. Section 5 illustrates the proposed approach with a hypothetical numerical example. Finally, the conclusions are drawn in Section 6.

2. Theoretical background

2.1. Fuzzy Theory

Definition 4.1. A fuzzy set is built from a reference set called universe of discourse. The reference set is never fuzzy. Assume that $U = \{x1, x2, \ldots, xn\}$ is the universe of discourse, then a fuzzy set $\tilde{T}$ in U ($\tilde{T} \subset U$) is defined as a set of ordered pairs $\{(xi, \mu_A(x_i))\}$ where $x_i \in U, \mu_{\tilde{T}}: U \to [0, 1]$ is the membership function of $\tilde{T}$ and $\mu_{\tilde{T}}(x)$ $\in [0, 1]$ is the degree of membership of x in $\tilde{T}$ (Werro, 2015).

Definition 4.2. A fuzzy variable determined by the triplet $\tilde{T}$=$[l, m, u]$ of crisp number with ($l < m < u$) is called a triangular fuzzy linguistic variable, which is characterized by the following member function:

$$\mu_{\tilde{T}}\ (x) = \begin{cases} \frac{x-l}{m-l}, & if\ l \leq x \leq\ m \\ \frac{u-x}{u-m}, & if\ m \leq x \leq\ u \\ 0, & otherwise \end{cases}$$

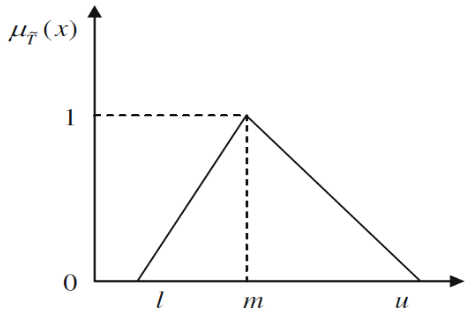

Figure 4. 1 A triangular fuzzy number.

Figure 1 shows a simple fuzzy triangular number. The values $l, m,$ and u indicate the lower, medium and upper bound for the assigned linguistic term. The aim of considering lower and upper bounds for each linguistic term is to take into account the uncertainties in experts' opinions.

2. 2. Fuzzy Cognitive Maps

FCM was originally introduced by Kosko (1986) as a soft computing technique which is able to take into account the dependencies among the main concepts/nodes and analyse inference patterns (E.I. Papageorgiou, 2004). FCMs constitute a modeling methodology that combines fuzzy logic and neural networks and are used to represent both qualitative and quantitative data (Elpiniki I. Papageorgiou, Fuzzy Cognitive Maps Learning Using Particle Swarm Optimization , 2005). FCMs are developed based on the experience and knowledges of experts through an interactive procedure of knowledge acquisition. Various methodologies such as Delphi could be used in order to reach a consensus among the experts in FCM (Glykas, 2010). Table 1 shows the requirements demanded in the modelling tool selection. As shown in this table, FCM is the only modelling tool that meets all the requirements demanded in risk analysis of complex and dynamic systems. Considering these benefits of FCM in comparison with other existing tools, it is evident that why FCM is evolving and gaining importance each day.

Table 4. 1 Comparing the modeling techniques in terms of the requirements demanded (Salmeron J., 2010).

Requirements	Modelling techniques			
	Systems dynamics	Bayesian networks	Neural networks	FCM
Capable of representing all possible connections	*	*	*	*
Does not ignore the uncertainty		*	*	*
Directed graph with cycles	*			*
The propagation does not follow an established pattern	*			*
Assumes information is scarce			*	*

Fuzzy Cognitive Maps (FCMs) are graphs which consist of nodes and weighted arcs between nodes. The following figure illustrates a FCM graph with 5 nodes and 9 arcs. The value of each concept C_i stands in the interval [0, 1], and the weighted arcs among nodes C_i and C_j (W_{ij}) can range in the interval [-1, 1] which represent the influence of each node on the others.

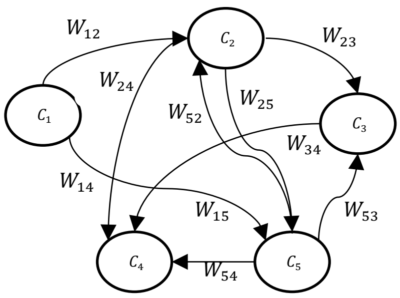

Figure 4. 2 A simple Fuzzy Cognitive Map.

The values of initial weight matrix (W_{ij}) are suggested by different experts using fuzzy linguistic terms such as Very High (VH), Low (L), etc. in order to determines the dependencies among nodes. Then, the linguistic variables are aggregated and defuzzified to numerical values (Papageorgiou E. I., 2014). When the FCM is initialized, it converges to a steady state through the interaction of equation (1). At each simulation step, the value A_i of the concept C_i is influenced by the values of concepts connected to it and it is updated through the following reasoning process (Papageorgiou E. I., 2014):

$$A_i^{k+1} = f(A_i^{(k)} + \sum_{\substack{j=1 \\ j \neq i}}^{n} W_{ji} A_j^{(k)}), \tag{1}$$

where, W_{ji} shows the initial dependencies weight between concepts C_j and C_i;

A_i^{k+1} is the value of concept C_i at simulation step $k + 1$;

$A_j^{(k)}$ is the value of concept C_j at simulation step k;

The initial values of concepts are shown by initial concept vector c as $c = [A_1, \dots, A_j, \dots, A_n]$;

k shows the simulation step;

f is a threshold function, which is used to restrict the concept value into [0,1] range. The most common types of f are: bivalent function (f(x) = 0 or 1), tangent hyperbolic ($f(x) = tanh(x)$), trivalent function ($f(x)$ = -1, 0 or 1), and sigmoid function ($f(x) = 1/(1 + e^{-\lambda x})$) (Glykas, 2010). In this study, sigmoid function is adopted.

At each iteration, values of all concepts are recalculated and this process continues until FCM reaches one of the following states (Papageorgiou E. I., 2014):

1) The value of concepts have stabilized at a fixed equilibrium point,
2) A limited state cycle is exhibited, and
3) Chaotic behavior has appeared.

A major deficiency of FCM is its potential convergence to undesired steady states. In order to overcome this shortcoming, some learning algorithms have been developed such as particle swarm optimization (PSO) (Elpiniki I. Papageorgiou, Fuzzy Cognitive Maps Learning Using Particle Swarm Optimization , 2005), Differential Hebbian Learning $[11, 14]$, Simulated Annealing (SA) (Somayeh Alizadeh, 2009), and etc. The next section discusses the developed learning algorithms for FCM.

3. Learning algorithms for FCMs

The main objective of developed learning algorithms in the literature is to update the initial knowledge of decision makers or any other knowledge obtained from historical data in order to produce learned values/weights (Papageorgiou E. , 2012). Learning algorithms can increase the efficiency and robustness of FCMs by updating the initial weight matrix ($W^{Initial}$) (Elpiniki I. Papageorgiou, Fuzzy Cognitive Maps Learning Using Particle Swarm Optimization , 2005). The learning techniques could be categorized into three groups; Hebbian-based, population-based and hybrid, combining the main aspects of Hebbian-based and population-based type learning algorithms (Papageorgiou E. , 2012). Each one of these learning categories has its advantages and limitations, which make it appropriate to specific type of problems according to the data and knowledge availability. Table 2 gathers the most significant advantages and limitations of each learning category.

Table 4. 2 FCM learning comparison (Papageorgiou E. I., 2014).

	Advantages	Limitations
Hebbian-based	-No time consuming -Ease of use -No multiple historical data -Connections have a physical meaning -Connections keep their signs	-Higher simulation errors -Low generalization ability -Small deviations of weights from the initial ones -Dependence on experts, initial states and connections
Population-based	- Low simulation error - Increase functionality -Robustness - Generalization ability -Model concepts with precise values -Cost function optimization	-Time consuming -Adjustment of enough learning parameters -Availability of historical data -Problem with convergence issues -Learn FCM from multiple observed response sequences -Large number of historical data -Large number of processors

According to Papageogiou (Papageorgiou E. , 2012), the hybrid based algorithms which are based on functionalities of Hebbian and population-based learning algorithms and inherit the advantages and disadvantages of both of them, emerge fewer limitations as most of them can overcome from the fusion of both computational methods. Thus, their operation could be more advantageous in the case of modeling complex systems and systems with time evolving since they can ensure near-optimum solutions in the weights search space. Several attempts have been made recently for developing learning algorithms for FCMs (E.I. Papageorgiou, 2004; Elpiniki I. Papageorgiou, Fuzzy Cognitive Maps Learning Using Particle Swarm Optimization , 2005; G.A. Papakostas, 2011; Papageorgiou E. , 2012; Somayeh Alizadeh, 2009). However, no commonly used tool has been proposed for simulation of FCMs because of the application of FCM technique to a wide variety of scientific areas (Papageorgiou E. I., 2014).

3.1 Hebbian-based Learning Algorithms

In Hebbian-based learning algorithms, the weight values of the arcs between nodes (W_{ji}) are updated based on the available historical data and several modifications of the Hebbian theory. Variety of Hebbian-based algorithms have been proposed for learning FCMs such as Differential Hebbian Learning Algorithm, Balance Differential

Hebbian Learning Algorithm, Nonlinear Hebbian Learning Algorithm, Active Hebbian Learning Algorithm, and Data-Driven Hebbian Learning Algorithm. For more information regarding Hebbian-based learning algorithms please refer to (Papageorgiou E. , n.d.).

3.2 Population-based Learning Algorithms

In Population-based algorithms, the experts are substituted by historical data and the corresponding learning algorithms or optimization algorithms are used to estimate the weight values of the arcs between nodes (W_{ji}). The population-based learning algorithms attempt to find models that mimic the input data (Papageorgiou E. I., 2014). Several population-based algorithms have been introduced for training FCMs such as: Ant Colony Optimization (ACO), Particle Swarm Optimization (PSO), Artificial Bee Colony, Genetic Algorithms (GA), Game-based learning, Immune Algorithm, Real Coded Genetic Algorithm (RCGA), Memetic Algorithms (MAs), Simulated Annealing (SA), Chaotic Simulated Annealing (CSA), Evolutionary Strategies (ES), Tabu Search (TS), and Bing Bang-Big Crunch (BB-BC). For more information regarding population-based learning algorithms please refer to (Papageorgiou E. , n.d.).

3.3 Hybrid based Learning Algorithms

Hybrid-based learning techniques are a combination of Population-based and Hebbian-based algorithms (Papageorgiou E. , 2012). In this learning technique, the initial weight matrix is updated/modified by using the knowledge and experience of experts and historical data at a two-step process. Few hybrid-based algorithms have been proposed in the literature (Y. Zhu and W. Zhang, 2008; Ren, 2012; Papageorgiou & Groumpos, 2005). Papageorgiou and Groumpos (2005) proposed NHL-DE hybrid algorithm for learning FCMs. This algorithm is consisted of Nonlinear Hebbian Learning (NHL) and Differential Evolution (DE) algorithms. They proved the efficiency of this algorithm by three experiments. The hybrid-based learning algorithms are more effective in modeling complex systems and have less limitations since they inherit the advantageous of both evolution-based and hebbian-based algorithms (Papageorgiou E. I., 2014). In this study, we apply NHL-DE algorithm to train the FCM.

4. Proposed dynamic risk assessment model

In this paper, we propose an integrated approach for dynamic risk analysis of complex systems by using FCM. At first, we calculate risk score for each risk factor using Eq. 2 and then use it as initial value for designing the adjusted FCM model. The main objective of this study is to develop an advanced dynamic risk assessment tool which is able to prioritize the complex risks (by considering the probability of occurrence and consequences of risks and also taking into account dependencies among risk factors) and predict the impact of each risk on the rest of the risks and also system outcomes by developing several what-if analyses and eventually to avoid undesired outcomes. The steps of our proposed model are as follows:

Step 1: Form a group of experts in order to identify and scale the risks. A heterogeneous group is usually preferred for designing FCM models (Salmeron & Lopez, 2012). To the best of our knowledge, no study has been conclusive with the optimal number of experts in a heterogeneous group. However, according to Salmeron & Lopez (2012), the greater the heterogeneity of the group, the fewer the number of experts is recommended.

Step 2: In order to take into account the probability of occurrence and consequence of each risk factor in predicting its impact on the other failures, we first calculate the risk score using the well-known risk assessment method (Eq. 2) and then, in an innovate manner, consider it as initial concept value in step 4.

$$RS = \; Probability\; of occurrence \times Consequences \tag{2}$$

The probability of occurrence estimates the likelihood that each specific risk will occur. The consequence parameter investigates the potential impact of the risk on the system. These fundamental parameters as well as dependencies among risk factors are expressed by linguistic terms as shown in Table 3.

Table 4. 3 Fuzzy ratings for occurrence and consequences parameters.

Occurrence	Consequences	Dependencies	Fuzzy rating
Very Low (VL)	Very Low (VL)	Very Low (VL)	(0, 0, 1.5)
Low (L)	Low (L)	Low (L)	(1, 2.5, 4)
Moderate (M)	Moderate (M)	Moderate (M)	(3.5, 5, 6.5)
High (H)	High (H)	High (H)	(6, 7.5, 9)
Very high (VH)	Very high (VH)	Very high (VH)	(8.5, 10, 10)

In this study, fuzzy triangular numbers parametrized by a triplet (*l*, *m*, *u*) (Fig. 2) are used in order to consider the uncertainties in experts' opinions.

Risk can include variety of risks such as risks for patients, risks of supplier selection, risk of accidents for labor force and maintenance personnel in the case of chemical process industries or other critical industries, environmental risks, etc. Note that different approaches such as FMEA (Jamshidi, Abbasgholizadeh Rahimi, Ait-Kadi, & Ruiz, 2015) could be used for calculating the risk score and variety of criteria or sub-criteria could be applied depending on the objectives of the organization. As shown in Table 3, we have considered the same five-terms fuzzy rating for occurrence, consequences, and dependency parameters. However, different fuzzy ratings and linguistic terms could be defined based on the criticality of the problem and objectives of the organization/company.

Step 3: Normalize RS and obtain RS_j^* using the following equation (Abdullah & Jamal, 2011):

$$RS_j^* = \frac{RS_j}{\sum_{j=1}^{n} RS_j} \tag{3}$$

where j= 1,2,…,n corresponds to the nodes (risks).

In this study, as a new contribution, the value of activated risk/s in the initial concept vector (c) is considered as RS_j^* (instead of A_j), and this number is 0 for the rest of the risks which are not activated. Therefore, Eq. 1 could be defined as Eq. 4.

$$RS_i^{*\,k+1} = f(RS_i^{(k)} + \sum_{\substack{j=1 \\ j\neq i}}^{n} W_{ji} RS_j^{(k)}), \tag{4}$$

where, W_{ji} shows the initial dependencies weight between risks C_j and C_i;
$RS_i^{*(k+1)}$ is the value of risk factor i at simulation step $k+1$;
$RS_j^{(k)}$ is the value of risk factor C_j at simulation step k;

Step 4: Depict the FCM for the identified risk factors and obtain the initial weight matrix ($W^{Initial}$). Experts should first reach consensus on the sign and direction of arcs between risks. In order to determine the level of influence of each risk on the other risk and vice versa, each expert individually assigns a linguistic term for each arc (W_{ij}) using Table 3. Then, for each arc, the opinions of all expert are aggregated using the average value of assigned linguistic terms in order to obtain the overall linguistic weight. Finally, the overall linguistic weight should be defuzzified in order to find the initial influence weight ($W^{Initial}$). There are different defuzzification methods available in literature (Talon & Curt, 2017). In this paper, we apply the defuzzification method proposed by Çelik & Yamak (2013). According to this method, the defuzzification value t of a triangular fuzzy number (l, m, u) is equal to:

$$t = \frac{l+m+m+u}{4} \tag{5}$$

$$W^{Initial} = \begin{bmatrix} w_{11} & \cdots & w_{1n} \\ \vdots & \ddots & \vdots \\ w_{n1} & \cdots & w_{nn} \end{bmatrix} \tag{6}$$

Step 5: Dynamic analysis of FCM requires the definition of an initial scenario, which represents a proposed initial situation to assess (Lopez & Salmeron, Dynamic risks modelling in ERP maintenance projects with FCM, 2012). In this step, several "what-if" scenarios should be defined. In each scenario, a risk or a set of risks are activated. In order to achieve precise results, all of the risks should be taken into account and the total effects for each risk should be evaluated to determine their influences on the other risks or consequences using the following initial concept vector:

$$c = [0, 0, 0, RS_J^*, 0, 0, 0] \tag{7}$$

where J is a subset of nodes (risks) on the map.

Step 6: Calculate the impact of activated risks by updating the initial concept vector (c). To do so, each initial concept vector is trained through Eq. 4 using a learning algorithm in order to obtain the steady state vector C^*. The aim of this step is to identify the impact of each risk on the other risks. This process is illustrated through a numerical example in the following section.

5. Numerical example

In this section, we illustrate the applicability and potential of the proposed tool in general for dealing with complex risks with a hypothetical numerical example. To do so, we derived the supplier selection risks from Xiao et al. study (2013). Identification and assessment of supplier risks is one of the most important areas of supply chains risk (Zhi Xiao, 2013; Aqlan & S. Lam, 2015). These risks could be different for each organization/company based on its perspective and they should be identified by each organization (Blackhurst, Scheibe, & Johnson, 2008; Ho, Zheng, Yildiz, & Talluri, 2015). Xiao et al. integrated the FCM and fuzzy soft set (FSS) model for solving the supplier selection problem by considering risk factors. The related FCM diagram is shown in Fig. 3 and the risks are shown in Table 4. The authors applied FCM in order to consider the dependencies among risk factors in supplier selection problem. In this study, we apply the same risks and present another feature of FCM which is the ability in prioritizing risks by considering the dependencies among them and also in predicting the impact of each risk or a group of risks on the other risks or on the outcomes of projects over time.

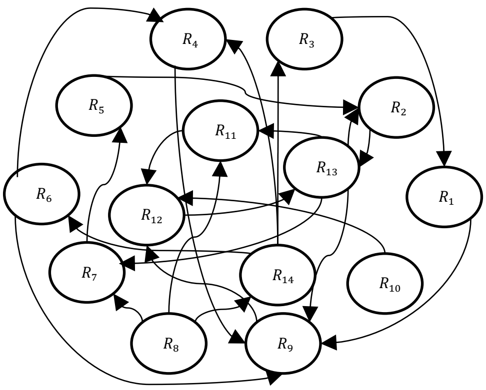

Figure 4. 3 FCM of supplier risk factors [17]

Step 1: In this numerical example, fourteen risk factors adopted from Xiao et al. (2013) are considered to be evaluated by three Experts (Ex.1, Ex.2, Ex.3).

Step 2 & 3: Table 4 indicates the hypothetical linguistic values assigned for each risk factor using Table 3. These values are converted into fuzzy triangular numbers as shown by two sets of columns "L, M, U" and then are defuzzified using Eq. 5 in order to obtain the normalized risk scores (RS_j^*). The last column of this table indicates the ranking of fourteen risk factors as R4>R2>R14>R1>R12>R10>R11>R9>R3>R8>R6>R7>R5>R13. This ranking reveals that remedy for quality problem, on-time delivery rate, and technological capacity are the three most important risks identified by three experts.

Table 4. 4 Prioritization of supplier selection risks.

	Risks	Exp.	Occ	Con	Occurrence			Consequence			Multiplication			Opinion aggregation			RS_j^*	Rank
					L	M	U	L	M	U								
Quality risk of the product	R1 Rejection rate of the product	Ex.1	H	VH	6	7.5	9	8.5	10	10	51	75	90	33.08	52.08	71.08	0.102	4
		Ex. 2	H	H	6	7.5	9	6	7.5	9	36	56.25	81					
		Ex. 3	M	M	3.5	5	6.5	3.5	5	6.5	12.25	25	42.25					
	R2 On-time delivery rate	Ex.1	H	H	6	7.5	9	6	7.5	9	36	56.25	81	43.08	64.58	79.83	0.123	2
		Ex.2	VH	VH	8.5	10	10	8.5	10	10	72.25	100	100					
		Ex.3	M	H	3.5	5	6.5	6	7.5	9	21	37.5	58.5					
	R3 Product qualification ratio	Ex.1	M	M	3.5	5	6.5	3.5	5	6.5	12.25	25	42.25	12.25	25	42.25	0.051	9
		Ex.2	M	L	3.5	5	6.5	1	2.5	4	3.5	12.5	26					
		Ex.3	M	H	3.5	5	6.5	6	7.5	9	21	37.5	58.5					
	R4 Remedy for quality problem	Ex.1	H	H	6	7.5	9	6	7.5	9	36	56.25	81	53.08	77.08	90.33	0.145	1
		Ex.2	H	VH	6	7.5	9	8.5	10	10	51	75	90					
		Ex.3	VH	VH	8.5	10	10	8.5	10	10	72.25	100	100					
Service risk	R5 Response to changes	Ex.1	VL	H	0	0	1.5	6	7.5	9	0	0	13.5	0	0	7.25	0.004	13
		Ex.2	VL	VL	0	0	1.5	0	0	1.5	0	0	2.25					
		Ex.3	L	VL	1	2.5	4	0	0	1.5	0	0	6					
	R6 Technological and R&D support	Ex.1	L	M	1	2.5	4	3.5	5	6.5	3.5	12.5	26	5.583	13.33	26.08	0.028	11
		Ex.2	L	L	1	2.5	4	1	2.5	4	1	2.5	10					
		Ex.3	M	M	3.5	5	6.5	3.5	5	6.5	12.25	25	42.25					
	R7 Ease of communication	Ex.1	VL	L	0	0	1.5	1	2.5	4	0	0	6	5.250	12.50	24.75	0.027	12
		Ex.2	L	M	1	2.5	4	3.5	5	6.5	3.5	12.5	26					
		Ex.3	M	M	3.5	5	6.5	3.5	5	6.5	12.25	25	42.25					
Supplier's profile risk	R8 Financial status	Ex.1	M	H	3.5	5	6.5	6	7.5	9	21	37.5	58.5	11.41	22.91	38.91	0.047	10
		Ex.2	L	L	1	2.5	4	1	2.5	4	1	6.25	16					
		Ex.3	M	M	3.5	5	6.5	3.5	5	6.5	12.25	25	42.25					
	R9 Customer base	Ex.1	M	M	3.5	5	6.5	3.5	5	6.5	12.25	25	42.25	20.16	35.41	55.16	0.071	8
		Ex.2	H	H	6	7.5	9	6	7.5	9	36	56.25	81					
		Ex.3	M	M	3.5	5	6.5	3.5	5	6.5	12.25	25	42.25					
	R10 Performance history	Ex.1	H	H	6	7.5	9	6	7.5	9	36	56.25	81	36.08	52.08	62.33	0.099	6
		Ex.2	VH	VH	8.5	10	10	8.5	10	10	72.25	100	100					
		Ex.3	L	VL	1	2.5	4	0	0	1.5	0	0	6					
	R11 Production facility and capacity	Ex.1	M	H	3.5	5	6.5	6	7.5	9	21	37.5	58.5	26	43.75	66	0.088	7
		Ex.2	H	M	6	7.5	9	3.5	5	6.5	21	37.5	58.5					
		Ex.3	H	H	6	7.5	9	6	7.5	9	36	56.25	81					
Long-term cooperation risk	R12 Supplier's delivery ratio	Ex.1	M	VH	3.5	5	6.5	8.5	10	10	29.75	50	65	31.83	52.08	70.33	0.101	5
		Ex.2	M	VH	3.5	5	6.5	8.5	10	10	29.75	50	65					
		Ex.3	H	H	6	7.5	9	6	7.5	9	36	56.25	81					
	R13 Management level	Ex.1	VL	M	0	0	1.5	3.5	5	6.5	0	0	9.75	0	0	4.75	0.002	14
		Ex.2	VL	VL	0	0	1.5	0	0	1.5	0	0	2.25					
		Ex.3	VL	VL	0	0	1.5	0	0	1.5	0	0	2.25					
	R14 Technological capability	Ex.1	H	VH	6	7.5	9	8.5	10	10	51	75	90	38.08	58.33	74.08	0.112	3
		Ex.2	VH	H	8.5	10	10	6	7.5	9	51	75	90					
		Ex.3	M	M	3.5	5	6.5	3.5	5	6.5	12.25	25	42.25					

Step 4: The initial weight matrix is shown in Table 6. In order to obtain this matrix, each expert is asked to determine the weight (W_{ij}) on each arc, by assigning linguistic variables using Table 3. It should be noted that the sign and direction of arcs between risks are adopted from Xiao et al. (2013). Table 5 shows the assigned values

by three experts. Then, the opinions of all experts are aggregated using the average value of the assigned linguistic values (fuzzy triangular numbers (l, m, u)) for each interconnection and the aggregated values are defuzzified using Eq. 5. Finally, in order to obtain the numeric impacts between [-1,1], the defuzzified values are divided by 10.

Table 4. 5 Fuzzifcation and defuzzification process for obtaining initial weight matrix.

Node 1	Node 2	W_{ij}	Expert opinions			Fuzzifcation									Opinions' Aggregation			Numeric impact
			Ex. 1	Ex. 2	Ex. 3	Ex.1			Ex.2			Ex.3						
						l	m	u	l	m	u	l	m	u	l	m	u	
R1	R9	$-W_{1,9}$	VL	L	L	0	0	1.5	1	2.5	4	1	2.5	4	0.667	1.667	3.167	- 0.179
R2	R13	$+W_{2,3}$	H	H	VH	6	7.5	9	6	7.5	9	8.5	10	10	6.833	8.333	9.333	+0.821
R3	R1	$+W_{3,1}$	M	H	H	3.5	5	6.5	6	7.5	9	6	7.5	9	5.167	6.667	8.167	+0.667
R4	R9	$+W_{4,9}$	VH	VH	VH	8.5	10	10	8.5	10	10	8.5	10	10	8.500	10.00	10.00	+0.963
R5	R2	$+W_{5,2}$	VL	VL	M	0	0	1.5	0	0	1.5	0	0	1.5	0.000	0.000	1.500	+0.038
R7	R5	$+W_{7,5}$	M	H	M	3.5	5	6.5	6	7.5	9	3.5	5	6.5	4.333	5.833	7.333	+0.583
R8	R7	$+W_{8,7}$	L	M	M	1	2.5	4	3.5	5	6.5	3.5	5	6.5	2.667	4.167	5.667	+0.417
R8	R11	$+W_{8,11}$	VH	VH	H	8.5	10	10	8.5	10	10	6	7.5	9	7.667	9.167	9.667	+0.892
R8	R14	$+W_{8,14}$	VL	M	VL	0	0	1.5	3.5	5	6.5	0	0	1.5	1.167	1.667	3.167	+0.192
R9	R12	$+W_{9,12}$	M	M	M	3.5	5	6.5	3.5	5	6.5	3.5	5	6.5	3.500	5.000	6.500	+0.500
R10	R12	$+W_{10,12}$	H	VH	H	6	7.5	9	8.5	10	10	6	7.5	9	6.833	8.333	9.333	+0.821
R11	R12	$+W_{11,12}$	M	M	L	3.5	5	6.5	3.5	5	6.5	1	2.5	4	2.667	4.167	5.667	+0.417
R12	R13	$+W_{12,13}$	L	L	L	1	2.5	4	1	2.5	4	1	2.5	4	1.000	2.500	4.000	+0.250
R13	R11	$+W_{13,11}$	H	H	H	6	7.5	9	6	7.5	9	6	7.5	9	6.000	7.500	9.000	+0.750
R13	R7	$+W_{13,7}$	L	VL	L	1	2.5	4	8.5	10	10	1	2.5	4	3.500	5.000	6.000	+0.488
R13	R2	$+W_{12,13}$	H	H	M	6	7.5	9	6	7.5	9	3.5	5	6.5	5.167	6.667	8.167	+0.667
R14	R3	$+W_{14,3}$	VH	H	VH	8.5	10	10	6	7.5	9	8.5	10	10	7.667	9.167	9.667	+0.892
R14	R4	$+W_{14,4}$	M	M	M	3.5	5	6.5	3.5	5	6.5	3.5	5	6.5	3.500	5.000	6.500	+0.500
R14	R6	$+W_{14,6}$	VL	VL	L	0	0	1.5	0	0	1.5	1	2.5	4	0.333	0.833	2.333	+0.108

Table 4. 6 Initial weight matrix ($W^{Initial}$).

	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10	R11	R12	R13	R14
R1	0	0	0	0	0	0	0	0	-0.18	0	0	0	0	0
R2	0	0	0	0	0	0	0	0	0	0	0	0	0.821	0
R3	0.667	0	0	0	0	0	0	0	0	0	0	0	0	0
R4	0	0	0	0	0	0	0	0	0.963	0	0	0	0	0
R5	0	0.038	0	0	0	0	0	0	0	0	0	0	0	0
R6	0	0	0	0	0	0	0	0	0	0	0	0	0	0
R7	0	0	0	0	0.583	0	0	0	0	0	0	0	0	0
R8	0	0	0	0	0	0	0	0	0	0	0	0	0	0.192
R9	0	0	0	0	0	0	0	0	0	0	0	0.5	0	0
R10	0	0	0	0	0	0	0	0	0	0	0	0.821	0	0
R11	0	0	0	0	0	0	0	0	0	0	0	0.417	0	0
R12	0	0	0	0	0	0	0	0	0	0	0	0	0.250	0
R13	0	0.667	0	0	0	0	0.488	0	0	0	0.75	0	0	0
R14	0	0	0.892	0.5	0	0.108	0	0	0	0	0	0	0	0

Step 5 & 6: In this step, we first assess the impact of considering dependencies among risk factors in their final ranking (Scenario 1) and then, we define five different scenarios (2-6) in order to assess and interpret the impact of each risk category on the other risks.

Scenario 1, activating all risk factors at the same time

In order to assess the impact of considering dependencies among risk factors in prioritization of supplier selection risks, at the initial time all of fourteen risk factors are activated as follows:

$C^{Initial}$= [0.102, 0.123, 0.051, 0.145, 0.004, 0.028, 0.027, 0.047, 0.071, 0.099, 0.088, 0.101,0.002, 0.112]

Note that in this scenario the values of $C^{Initial}$ sum to 1. This is because all of risk scores (RS_j^*) are activated and adopted from Table 4 and according to Eq. 3, the sum of all risk scores should be equal to 1. In order to train FCM, in this paper we apply NHL-DE algorithm which is a combination of nonlinear Hebbian learning (NHL) and differential evolution (DE) algorithms (Papageorgiou & Groumpos, A new hybrid method using evolutionary algorithms to train Fuzzy Cognitive Maps , 2005). The training process in NHL-DE has two steps. The first step starts with NHL algorithm and in the second step, the result of first step is used to seed the DE algorithm. For more knowledge about this algorithm please see (Papageorgiou & Groumpos, A new hybrid method using evolutionary algorithms to train Fuzzy Cognitive Maps , 2005). We imported the data into Matlab code in order to obtain the updated concept matrix (C^{*}). The values of learning rate parameter (η), mutation constant (μ), crossover constant (CR), and weight decay learning parameter (γ) have been selected as 0.05, 0.5, 0.5, 0.97, respectively. The population size is considered 500. It should be mentioned that 1000 iterations for the algorithm per experiment and 50 independent experiments were performed. Using $W^{Initial}$ matrix, Initial concept vector $C^{Initial}$, Equation (4) and NHL-DE learning algorithm, the updated concept vector is obtained as follows:

C^{*} = [0.5007, **0.8110**, 0.7951, 0.7513, 0.4948, 0.6774, 0.7467, 0.6590, 0.8049, 0.6590, 0.8096, **0.9010, 0.8417**, 0.7097]

As it is clear from above steady state vector (C^{*}), the ranking of risk factors has been completely changed to R12>R13> R2>R11>R9>R3>R4>R7>R14>R6>R8,R10>R1>R5 and the three most affected risks are R12, R13, and R2. This is while the three most affected risks were R12, R13, and R2 (See Table 4) in the case of overlooking the dependencies among risk factors. These findings contrast with the results of Table 4. This result proves that considering the dependencies among risk factors could significantly influence the priority of risks and as a result, this could have an impact on minimizing risks, costs, downtime and reaching the desired goals of companies. The values of 14 risk factors in 11 iterations for reaching the desired steady state is given in Fig. 4.

Table 7 shows the inputs and outputs for the nine scenarios. In addition, Figure 5 shows the simulation results.

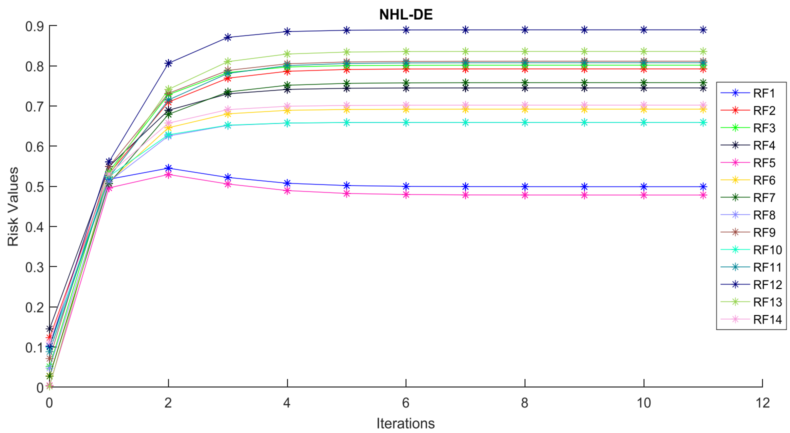

Figure 4. 4 The values of risks (RFs) in 11 iterations for scenario 1.

Table 4. 7 Inputs and outputs of the scenarios.

Sc.	Description	"Quality risk of the product"				"Service risk"			"Supplier's profile risk"				"Long-term cooperation risk"		
		R1	R2	R3	R4	R5	R6	R7	R8	R9	R10	R11	R12	R13	R14
1	Activating all risks	0.102	0.123	0.051	0.145	0.004	0.028	0.027	0.047	0.071	0.099	0.088	0.101	0.002	0.112
	Results	0.5007	**0.8110**	0.7951	0.7513	0.4948	0.6774	0.7467	0.6590	0.8049	0.6590	0.8096	**0.9010**	**0.8417**	0.7097
2	Activating risk set 1	0.102	0.123	0.051	0.145	0	0	0	0	0	0	0	0	0	0
	Results	0.4976	0.7855	0.7940	0.7403	0.4951	0.6858	0.7479	0.6590	0.7900	0.6590	**0.8004**	**0.8885**	**0.8208**	0.6827
3	Activating risk set 2	0	0	0	0	0.004	0.028	0.027	0	0	0	0	0	0	0
	Results	0.5159	0.7833	**0.8045**	0.7519	0.5001	0.6962	0.7661	0.6590	0.8033	0.6590	0.8014	**0.9083**	**0.8249**	0.6873
4	Activating risk set 3	0	0	0	0	0	0	0	0.047	0.071	0.099	0.088	0	0	0
	Results	0.5052	0.7965	0.7935	0.7424	0.4929	0.6662	0.7815	0.6590	0.8128	0.6590	**0.8148**	**0.9047**	**0.8575**	0.7025
5	Activating risk set 4	0	0	0	0	0	0	0	0	0	0	0	0.101	0.002	0.112
	Results	0.4957	0.7774	0.8074	0.7374	0.4934	0.6723	0.7693	0.6590	**0.80494**	0.6590	0.80491	**0.9027**	**0.8507**	0.6978
6.1	20% increase in Set 1	0.1224	0.1476	0.0612	0.174	0.004	0.028	0.027	0.047	0.071	0.099	0.088	0.101	0.002	0.112
	Results	0.4906	0.8047	0.7958	0.7381	0.4975	0.6835	0.7652	0.6590	**0.8145**	0.6590	0.7911	**0.8843**	**0.8489**	0.6818
	20% decrease in Set 1	0.0816	0.0984	0.0408	0.116	0.004	0.028	0.027	0.047	0.071	0.099	0.088	0.101	0.002	0.112
	Results	0.5001	0.7852	**0.8101**	0.7606	0.5075	0.7027	0.7408	0.6590	0.8069	0.6590	0.8014	**0.8953**	**0.8300**	0.7091
6.2	20% increase in Set 2	0.102	0.123	0.051	0.145	0.0048	0.0336	0.0324	0.047	0.071	0.099	0.088	0.101	0.002	0.112
	Results	0.5037	0.8000	0.7913	0.7516	0.5001	0.6799	0.7684	0.6590	**0.8071**	0.6590	0.7993	**0.8994**	**0.8592**	0.6706
	20% decrease in Set 2	0.102	0.123	0.051	0.145	0.0032	0.0224	0.0216	0.047	0.071	0.099	0.088	0.101	0.002	0.112
	Results	0.5067	0.7950	**0.8170**	0.7562	0.5034	0.6897	0.7794	0.6590	0.8148	0.6590	0.7953	**0.8984**	**0.8275**	0.6955
6.3	20% increase in Set 3	0.102	0.123	0.051	0.145	0.004	0.028	0.027	0.0564	0.0852	0.1188	0.1056	0.101	0.002	0.112
	Results	0.4964	**0.8122**	0.7952	0.7502	0.4764	0.6869	0.7552	0.6590	0.8073	0.6590	0.8003	**0.8994**	**0.8635**	0.6972
	20% decrease in Set 3	0.102	0.123	0.051	0.145	0.004	0.028	0.027	0.0376	0.0568	0.0792	0.0704	0.101	0.002	0.112
	Results	0.4944	0.7840	0.7927	0.7466	0.4891	0.6864	0.7430	0.6590	0.7990	0.6590	**0.8009**	**0.8951**	**0.8522**	0.7140
6.4	20% increase in Set 4	0.102	0.123	0.051	0.145	0.004	0.028	0.027	0.047	0.071	0.099	0.088	0.1212	0.0024	0.1344
	Results	0.5040	0.7699	**0.8115**	0.7581	0.4976	0.7014	0.7687	0.6590	0.7894	0.6590	0.8023	**0.8972**	**0.8354**	0.6946
	20% decrease in Set 4	0.102	0.123	0.051	0.145	0.004	0.028	0.027	0.047	0.071	0.099	0.088	0.0808	0.0016	0.0896
	Results	0.4871	0.7644	0.7937	0.7513	0.4859	0.6725	0.7618	0.6590	0.8138	0.6590	**0.8211**	**0.9041**	**0.8388**	0.6811

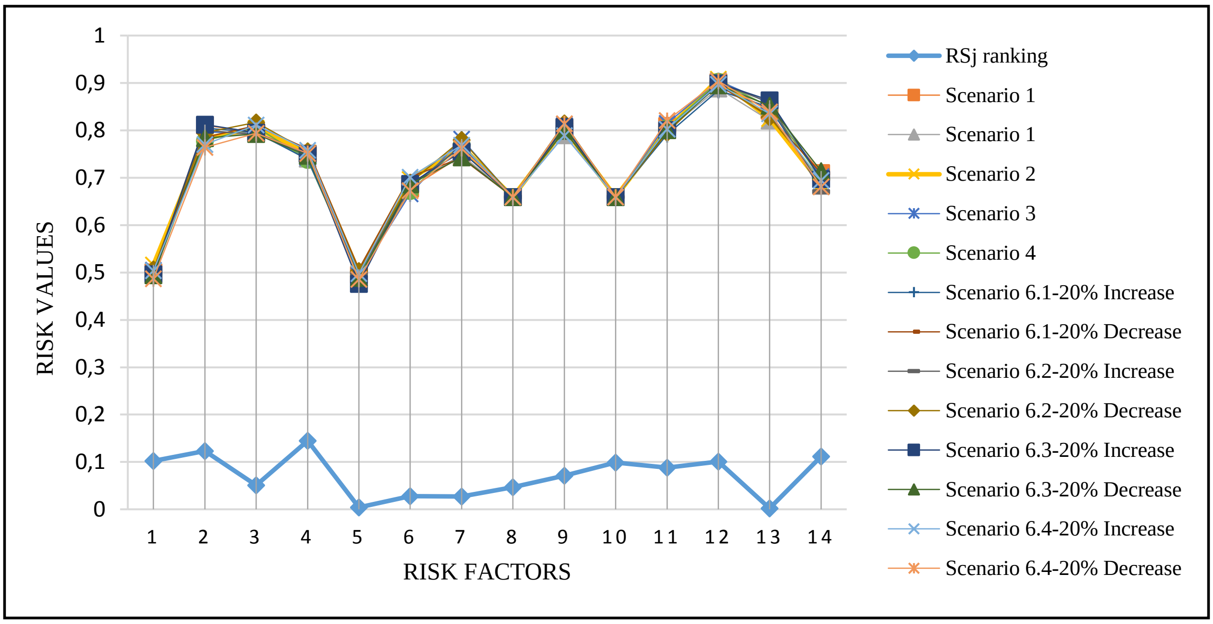

Figure 4. 5 Simulation results.

Scenario 2, activating quality risks of the product

In the second scenario, we assess the impact of "quality risks" set on the other risks. In this scenario, at the initial time only quality risks (R1, R2, R3, and R4) are activated as shown in Fig. 6 (green highlighted nodes). To do so, we apply the RS_j^* scores related to "quality risks" set from Table 2 (0.102, 0.123, 0.051, 0.145). The results of scenario 2 reveals that the impact of "quality risks" were from 0.4951 to 0.8885. The average influence was 0.7229. This indicates that activating quality risks has a high and positive impact on the rest of the risks. The average influence was calculated by adding up the values of supplier selection risks (except quality risks) and dividing by the number of risks (R5-R14). As shown in Table 7, The three most highly affected risks are R12 (0.8885), R13 (0.8208) and R11(0.8004). This shows that quality risks strongly affect the "Supplier's delivery ratio", "Management level" and "Production facility and capacity". However, long-term cooperation risk set was the most highly affected risk category (mean = 0.7973). The mean for each risk category was calculated by adding up the values of risks in that category reached in learning process and dividing by the number of risks in that category.

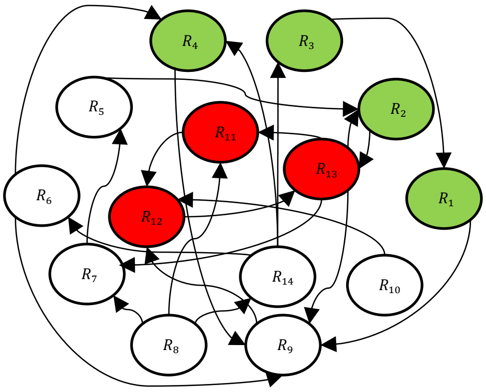

Figure 4. 6 Activating quality risks of the product (R1-R4) and their impact on R12, R13, and R11.

Scenario 3, activating service risks

In the third scenario, we assess the impact of "service risks" set on the other risks. In this scenario, at the initial time only service risks (R5, R6, and R7) are activated. The steady state vector C^* in Table 7 reveals that these impacts were from 0.5001 to 0.9083. The average influence was 0.7453. This indicates that the activated risks have a strong and positive influence on the rest of risks as scenario 2. The three most highly impacted risks are R12 (0.9083), R13 (0.8249) and R3 (0.8045). This shows that service risks highly affect the Supplier's delivery ratio, Management level and Product qualification ratio. The most highly affected risk category was long-term cooperation risks (mean= 0.8068) as scenario 2.

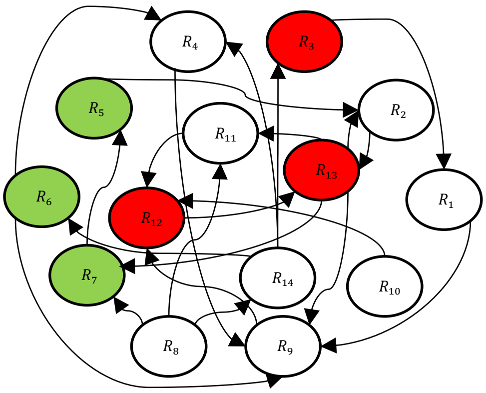

Figure 4. 7 Activating service risks (R5-R7) and their impact on R12, R13, and R3.

Scenario 4, activating supplier's profile risks

In the fourth scenario, we assess the impact of activating "supplier's profile risks" set on the other risks. In this scenario, at the initial time only supplier's profile risks (R8, R9, R10, and R11) are activated. The steady state vector C^* reveals that these impacts were from 0.4929 to 0.9047. The average influence was 0.7243. This indicates that the activated risks have a high and positive influence on the rest of risks. The three most highly impacted risks were R12(0.9047), R13 (0.8575) and R11 (0.8148). This shows that supplier's profile risks highly affect the Supplier's delivery ratio, Management level and Production facility and capacity. As scenarios 2 and 3, long-term cooperation risk set was the most highly affected risk category (mean = 0.8216). Simulation 4 also reveals that the one of the most affected risks were the same activated risk R11 (0.8148).

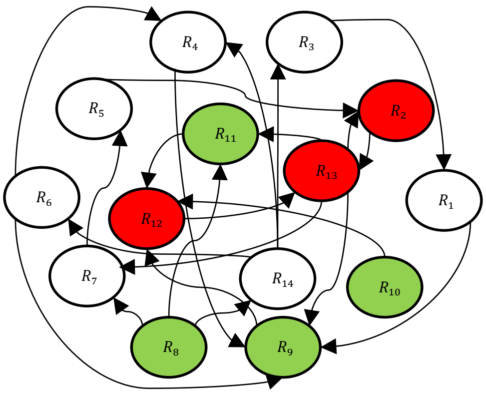

Figure 4. 8 Activating supplier's profile risks (R8-R11) and their impact on R12, R13, and R2.

Scenario 5, activating long-term cooperation risks

In this scenario, we assess the impact of activating "long-term cooperation risks" set on the other risks. In this scenario, at the initial time only long-term cooperation (R12, R13, and R14) are activated. The results of this simulation reveal that the impacts of the activated risks were from 0.4934 to 0.9027. The average influence was 0.6983. This indicates that the activated risks have a slightly high and positive influence on the rest of risks. The three most highly impacted risks were R9 (0.80494), R11 (0.80491) and R3 (0.8074). This shows that long-term cooperation risks moderately affect the customer base, production facility and capacity and product qualification ratio risks. The most highly affected risk category was again long-term cooperation risks (mean = 0.8171). The result of simulation 5 also shows that the most strongly affected risk factors were the same activated risks, with the exception of R14.

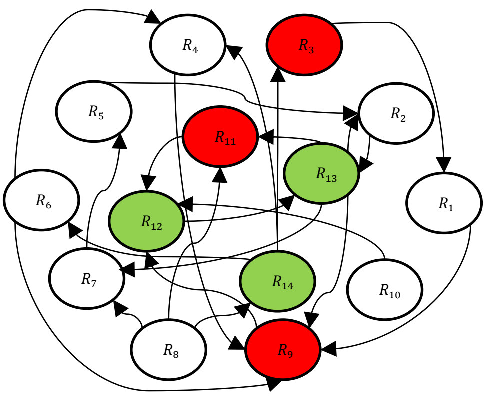

Figure 4. 9 Activating long-term cooperation risks (R12-R14) and their impact on R9, R11, and R3.

Scenarios 6.1-6.4, marginal analysis of Scenario 1

In the last scenario, based on scenario 1, we defined four new scenarios in order to verify the impact of increasing/decreasing the initial risks of each set of risks for 20%, while holding others equal as RS_j^*. Then, we compared the results to that of scenario 1. Unlike scenario 2 to scenario 5, these scenarios have all starting risk scores greater than zero as scenario 1. But, the sum of values in $\mathrm{C}^{\mathrm{Initial}}$ matrices are not equal to one as scenario 1. This is because we increased/decreased the initial values of each set of risks for 20% while holding others equal as RS_j^*. The results of these scenarios (6.1-6.4), as indicated in Table 7, reveal that although the risk values have been slightly changed by increasing/decreasing the initial risks of any set of risks for 20%, it has no significant influence on the final ranking of risk factors. In all cases, the risk factors R12 and R13 have the highest values which belong to the long-term cooperation risk set. This analysis certifies the robustness and effectiveness of the proposed framework.

As it is clear from the above nine scenarios, the proposed tool is able to prioritize risk factors by calculating their probability of occurrence and consequences and also more importantly, by considering all complex interactions among risk factors. In addition, it is able to predict the impact of each risk or set of risks on the other risks more accurately since it takes into account the multiple connections between risks and the uncertainties in decision making process. Therefore, decision makers and managers could manage the risks more properly and accurately and offer better risk mitigation strategies. Nevertheless, the main limitation of FCM-based models is their dependency to the experts' knowledge and experience. Special attention should be paid to the selection of right panel since their opinions could significantly affect the final results and could lead to wrong decisions (Lopez & Salmeron, Dynamic risks modelling in ERP maintenance projects with FCM, 2012; Bevilacqua, Emanuele Ciarapica, & Mazzuto, 2012; Lakovidis & Papageorgiou, 2011; Subramanian, Karmegam, Papageorgiou, Papandrianos, & Vasukie, 2015). To the best of our knowledge, no research has been carried out for sensitivity analysis of the impact of experts' opinions in final results in FCM-based models. Therefore, research that answers this question is required.

6. Conclusion

Today's advanced and complex systems require an advanced risk assessment tool in order to take into account all aspects of risks in risk analysis process. The conventional risk analysis tools such as FMEA, FTA, AHP/ANP and their modified versions are not able to predict the behaviour of complex risks accurately and analysis them in a dynamic way. FCM is a useful graphical tool which represents and analyzes the dynamic behavior of complex systems composed of interrelated variables. Due to its simplicity, FCM has gained increasing attention as an advanced decision support tool in recent years. This tool has also been successfully applied for evaluating risks in complex and critical environments such as healthcare. In this paper, we focus on this feature of FCM and propose an integrated approach to generalize and enhance its application as an advanced decision support system for dynamic risk analysis of complex systems. Some features makes our proposed tool distinguished form other risk assessment tools such as FMEA. First of all, all the interactions among variety of risk factors are considered by handling incomplete data and based on the opinions of several experts. In addition, the importance of risk factors is considered by calculating the probability of occurrence and consequences of risks. To our best knowledge, this is the first time in the literature that the dependencies among risk factors are included in the risk assessment process. In addition, in the existing FCM-based risk assessment models, the values of initial concept vectors (risks) have been always considered as 1 for the activated risks and 0 for the other risks. But, in this research as a new contribution, we consider the value of activated risks as RS_j^* values. The proposed approach provides valuable information to practitioners for predicting impact of risks on the other risks or on the system performance by developing what-if analyses. In other words, practitioners are able to understand how any change in a risk factor could affect the other risks or outcomes of the project. By transforming decision problems into causal graphs, decision makers with no technical background can easily understand all of the risk factors in a given problem and their relationships. The above features could lead to a more precise and accurate risk analysis and practitioners will have a strong support for identifying critical risks/failures and mitigating them. In future works, we will evaluate the performance of the proposed tool in a large-scale practical environment. As a future research topic, this study could be extended in different directions. For example, application of other learning algorithms such as particle swarm optimization (PSO) could be considered for improving the training process of FCMs. In addition, other risk analysis methods such as FMEA or Probabilistic risk assessment (PRA) could be applied for calculating the risk scores in the second step of the proposed method. Moreover, considering the impact of risks on the system performance or organizational goals could be an interesting future research topic. Finally, development of a user-friendly software based on the proposed framework in this study would be very useful in order to streamline the implementation of the proposed approach in practice.

Acknowledgements

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4.2 Dynamic risk modeling and assessing in maintenance outsourcing with FCM

Résumé: L'externalisation de maintenance est une pratique courante dans de nombreuses industries, comme l'aviation et la fabrication de matériel médical. Cependant, il existe toujours des risques dynamiques associés à l'externalisation. L'analyse des risques des projets d'externalisation de maintenance est une tâche complexe en raison de la présence de nombreux facteurs de risque avec des dépendances entre eux. Bien qu'il existe quelques études sur les risques de sous-traitance de la maintenance, aucune attention n'a été accordée à l'analyse des risques de l'externalisation de la maintenance en considérant les dépendances entre les facteurs de risque. Considérant les dépendances entre les facteurs de risque pourrait conduire à une analyse plus précise des risques et augmenter le taux de réussite des projets d'externalisation. Pour y remédier, nous proposons un outil avancé d'aide à la décision appelé «Fuzzy Cognitive Maps» (FCM) qui peut traiter les risques de tels systèmes complexes. La FCM représente le comportement de systèmes complexes avec précision et peut tenir compte des incertitudes, de l'information imprécise, des interactions entre les facteurs de risque, de la pénurie d'information et des opinions de plusieurs décideurs. En outre, il pourrait être appliqué dans différents problèmes décisionnels liés à des projets d'externalisation tels que le problème de sélection du fournisseur. Par conséquent, l'outil proposé aidera les praticiens à gérer les risques de sous-traitance de maintenance d'une manière plus efficace et proactive et offrirait de meilleures solutions d'atténuation des risques.

Keywords: Risks analysis; Maintenance outsourcing; Fuzzy cognitive maps; Aviation; Medical equipment.

4.2 Dynamic risk modeling and assessing in maintenance outsourcing with FCM

Abstract: Maintenance outsourcing is a common practice in many industries, such as aviation and medical equipment manufacturing. However, there is always some dynamic risks associated with outsourcing. Risk analysis of maintenance outsourcing projects is a complex task due to consisting of many risk factors with dependencies among them. Although there are some studies on maintenance outsourcing risks, no attention has been paid to the risk analysis of maintenance outsourcing by considering the dependencies among risk factors. Considering the dependencies among risk factors could lead to more precise risks analysis and increase the success rate of outsourcing projects. To address this, we are proposing an advanced decision support tool called "Fuzzy Cognitive Maps" (FCM) which can deal with risks of such complicated systems. FCM represents the behavior of complex systems accurately and is able to consider uncertainties, imprecise information, the interactions between risk factors, information scarcity, and several decision maker's opinions. In addition, it could be applied in different decision makings problems related to outsourcing projects such as provider selection problem. Therefore, the proposed tool would help practitioners to manage maintenance outsourcing risks in a more effective and proactive way and offer better risk mitigation solutions.

Keywords: Risks analysis; Maintenance outsourcing; Fuzzy cognitive maps; Aviation; Medical equipment.

1. INTRODUCTION

Outsourcing is comprehensively used by many U.S. companies. Two common examples of the practice are outsourcing IT jobs to India and outsourcing product manufacturing to China (Welborn, 2007). However, outsourcing does not guarantee business success. While outsourcing is a powerful tool to cut costs, improve performance, and refocus on the core business, it is associated with some major risks including; (1) outsourcing activities that should not be outsourced; (2) selecting the wrong vendor: (3) writing a poor contract; (4) overlooking personnel issues; (5) losing control over (he outsourced activity; (6) overlooking the hidden costs of outsourcing: and (7) failing to plan an exit strategy (i.e., vendor switch or reintegration of an outsourced activity). Outsourcing failures are rarely reported because firms are reluctant to publicize them (Baitheiemy, 2003). Maintenance outsourcing is one of the best solutions or strategies available for each company that can lead to greater competitiveness and it has a major part to play in the design, installation and commissioning of an asset, and is instrumental in driving post commissioning improvements. In terms of maintenance outsourcing, a set of potential and attractive benefits can be reached such as to increase labour productivity, to reduce maintenance costs, to focus in-ho use personnel on "core" activities, to improve environmental performances, to obtain specialist skills not available in house , to improve work quality, etc. (Bertolini, Bevilacqua, Braglia, & Frosolini, 2004).

However, maintenance outsourcing is a complex arrangement associated with uncertainties in dynamic business environments. This uncertainty and complexity could lead to critical risks that can impact on the enterprises' performance. Risk evaluation of maintenance outsourcing is a complex and critical task since several tangible and intangible risk factors should be considered in this process. In addition, there are always some dependencies among risks that can influence each other mutually and these dependencies make the evaluation process more complex and challenging. Therefore, an effective method for evaluating the risks is fundamental and essential. Many papers related to outsourcing exist in the literature (Baitheiemy, 2003) (Jimmy Gandhi, Gorod, & Sauser, 2012) (Welborn, 2007). However, research about the risk assessment of maintenance outsourcing by considering the interrelationships among risks factors and forecasting the impact of each risk on the other risks is lacking in the literature and further research in this field is required. Considering the interdependencies among risks could lead to more accurate risk assessment to organizations.

Therefore, this paper deals with risk assessment of maintenance outsourcing arrangements as the most important phase of risk management, and proposes an advanced decision support tool called "FCM" to overcome the shortcomings of current risk evaluation tools applied in maintenance outsourcing such as failure mode and effect analysis (FMEA) (Welborn, 2007). FCM is a useful artificial intelligence technique which represents and analyzes the dynamic behavior of complex systems composed of interrelated variables (Kosko B. , 1986; Jamshidi, Abbasgholizadeh Rahimi, Ait-Kadi, & Ruiz, 2015). This tool recently has been applied successfully in evaluating risks in complex and critical environments such as Enterprise Resource Planning (ERP) maintenance (Lopez & Salmeron, 2014) (Ahmad & Kumar, 2012) and IT projects (Salmeron, 2010), and therefore we think it has a good potential to be applied in complex maintenance outsourcing projects for evaluating risks and forecasting the impact of each risk by considering interdependencies. The reminder of this paper is organized as follows. Section 3 and 4 explain the proposed tool with an example related to outsourcing risk evolution. Conclusions are drawn in Section 5.

2. The proposed method

In order to illustrate the proposed tool, we adopted the related risks to outsourcing identified in Jimmy et al. (Jimmy Gandhi, Gorod, & Sauser, 2012) study. The identified risks and their definitions are shown in Table 4.1 and the related FCM graph is depicted in Fig. 4.1. Besides, four risk consequences (Effects) are imagined as C1, C2, C3, and C4 to show how the proposed tool could consider all the interrelationships among risks and their effects on the project performance.

Table 4. 8 Risk factors in outsourcing.

Risks	Index	Definitions
Schedule	R1	The inability to deliver the end product within the originally specified period of time
Technical	R2	The inability of the technology to provide the expected performance
Financial	R3	The inability to complete the project within a given budget
Vendor	R4	The possibility of choosing an inappropriate vendor that could impact project performance
Culture	R5	Occurrence of shared values and assumptions that govern acceptable behavior and thought patterns which could result in widely differing work ethics and quality standards
Reputation	R6	Negative opinion of the stakeholders towards an organization
Intellectual property	R7	The threat of the vendor using your ideas to produce a competing product or service
Flexibility	R8	The inability of an organization to respond to potential internal or external changes in a timely and cost effective manner
Compliance	R9	The inability of an organization to comply with appropriate regulations (local and global)
Quality	R10	The inability of the end deliverable (product or service) to meet customer requirements

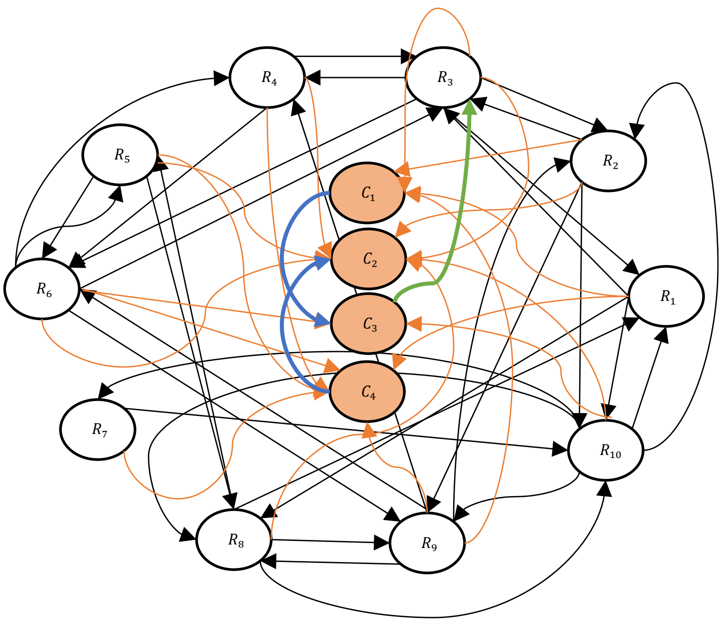

Figure 4. 10 FCM for risk analysis on maintenance.

The FCM graph in Figure 4.1 is depicted based on experts' opinions in order to show the dependencies and feedbacks among factors. In this numerical example, the interrelationships among ten risk factors are identified through Jimmy et al. (Jimmy Gandhi, Gorod, & Sauser, 2012) study (black lines in Fig. 4.1). In addition, some interrelationships are depicted among risks & consequences and vice versa (orange and green lines in Fig. 4.1). Moreover, two possible dependencies among consequences C1 & C3 and C4 & C2 are depicted with blue bolded lines in Fig. 4.1. To make the initial weight matrix (W_{ij}), each expert individually determines the dependencies between concepts, using fuzzy linguistic terms such as Very High (VH), Low (L), etc. Then, the linguistic variables are aggregated and defuzzified to numerical values (Elpiniki I. Papageorgiou, 2005). The initial weight matrix, is shown in Table 4.2.

Table 4. 9 Initial weight matrix.

W^{Aug}	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10	C1	C2	C3	C4
R1	0	0	0.5	0	0	0	0	0.5	0	0.3	0.1	0	0	0.2
R2	0	0	0.6	0	0	0	0	0	0	0	0.1	0.7	0	0
R3	1	0	0	0	0	0.1	0	0.5	0.9	0	0.1	0.88	0	0
R4	0.8	0.9	0	0	0.2	0	0.14	0.5	0	0.68	0	-0.2	0	0.2
R5	0.7	0	0.8	0.4	0	0.6	0	0	0.1	0	0	0.7	0	0.77
R6	0.8	1	0	0	0.2	0	0	0.47	0	0	0	0.66	0.6	0.2
R7	0.8	0	0	0.6	0.6	1	0	0.5	0.8	0.5	0	0	0	0.2
R8	0	0.2	0	0.5	0	0	0.1	0	0.9	0	0	0	0.6	0
R9	0.7	0.3	0.8	0.8	0.5	0.11	0	0	0	0	0.1	0	0	0.2
R10	0.1	0.35	0.2	0.1	0.9	0.13	0.2	0	0	0	0	0.44	0.69	0
C1	0	0	0	0	0	0	0	0	0	0	0	0	0.9	0
C2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
C3	0	0	1	0	0	0	0	0	1	0	0	0	0	0
C4	0	0	0	0	0	0	0	0	0	0	0	0.78	0	0

3. FCM building process

Two types of FCM model could be developed for evaluating risks. The first type is scenario-based which is used in this paper and the second type is based on initial concept values obtained from multi criteria decision making tools such as AHP/ANP (Abbasgholizadeh Rahimi & Jamshidi, Prioritization of Organ Transplant Patients using

Analytic Network Process, 2014) or eigenvalue approach. In order to evaluate the impact of risks in a scenario-based FCM model, several what-if analysis scenarios should be developed using different initial concept values (c). In each scenario, a risk or a set of risks are activated and using Eq. 3.1 and learning algorithms the initial vector (c) is updated in order to show the impact of activated risks on the other risks.

In second type of FCM modeling, the initial concept values (c) is updated by using initial weight matrix (W_{ij}) and Eq. 3.1 until it converges to the steady state condition. The updated concept values C^* shows the importance of each risk. Since this type of FCM is unable to assess the impact of each risk on the other risks, we propose to apply the first type in evaluating the risk of maintenance outsourcing. To illustrate the risk evaluation process, in this paper we only assess the impact of "Schedule" risk on other risks.

In this scenario, none of the risks in the initial vector are activated at the initial time, but schedule risk (R1):

c = [**1**, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0];

Using W_{ij} matrix, Initial concept vector c, Eq. 3.1 and learning algorithm, the training process starts. In this paper we applied NHL-DE algorithm for training FCM which is combined of differential evolution (DE) and nonlinear Hebbian learning (NHL) algorithms. We imported the data into Matlab code and we used MATLAB version R2012a software to obtain the updated concept matrix (C^*). For this specific problem, the suggested value of learning rate parameter (η), mutation constant (μ), crossover constant (CR), and weight decay learning parameter (γ) have been selected 0.04, 0.5, 0.5, 0.98 respectively. The population size is equal to 50. For the algorithm, 100 independent experiments have been performed, to enforce the reliability of the results, and the algorithm was allowed to perform 1000 iterations (generations) per experiment.

C^* = [0.66, 0.7, **0.95**, 0.87, **0.99**, 0.4, 0.8, **0.94**, 0, **0.97**, 0.2, 0.49, 0.78, **0.96**];

The steady state vector C^* shows that activating "Schedule" risk have a strong influence over the risks R3, R5, R8, R10 and also it has a strong effect over the consequence C4. The same procedure should be done for all other risks by activating their risk or related sub-risks each time. The results reveal that which risks are critical and which have a greater impact on the other risks. In addition, it reveals that each risk factor on which consequence(s) has strong effect. Therefore, decision makers will be able to manage the risks properly and accurately.

4. Conclusion

This paper proposes an effective decision support tool called "Fuzzy Cognitive Maps" (FCM) which can deal with risks of maintenance outsourcing (or other type of outsourcing) by taking into account the interrelationships among risk factors and consequences. The main features of FCM in contrast with those of other existing methods such as FMEA are; 1) the dependence and the feedback effects among variety of risk factors, their effects and also importance of factors could be considered , 2) uncertainties on the decision-making process are taken into account, 3) several experts can state their opinions, 4) it has capabilities to handle both qualitative and quantitative factors, 5) several risk factors and effects can be considered in risk analysis process and 6) by transforming decision problems into causal graphs, decision makers with no technical background can easily understand all of the components in a given problem and their relationships.

Apart from the application of this tool in risk analysis, FCM is sufficiently general and it could be adapted to a wide range of complex and critical multi criteria decision making problems in outsourcing such as service provider selection, simulation and forecasting with application to predict behaviors in outsourcing, etc. The major contribution of this paper is considering the possible interrelationships in risk analysis of maintenance outsourcing including interrelationships among risks & consequences and vice versa, relationships among risks and finally possible dependencies among consequences. To the best of our knowledge, this is the first time in the literature of outsourcing that such interrelationships are taken into account through an advance decision support tool. Considering the dependencies among risk factors and consequences could lead to a more precise and accurate risk analysis and decision makers and managers will have a strong support to better mitigate associated risks. As a future research topic, application of other hybrid algorithms for training FCM could be considered.

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4.3 A new decision support tool for dynamic risks analysis in collaborative networks

Résumé: Les réseaux collaboratifs sont des systèmes complexes et se composent de nombreux facteurs avec des dépendances parmi eux. Bien que le nombre de réseaux collaboratifs tels que les chaînes d'approvisionnement avancées ou les organisations virtuelles / laboratoires / cyber sciences ne cessent de croître et leur importance augmente dans le monde, bon nombre d'entre elles ne réussissent pas. En outre, on a accordé très peu d'attention à l'analyse des risques des réseaux collaboratifs en tenant compte des dépendances entre les facteurs de risque. Ainsi, l'analyse précise des risques associés aux projets de réseaux collaboratifs est cruciale pour atteindre une performance satisfaisante. Pour y remédier, nous proposons un outil avancé d'aide à la décision appelé «Fuzzy Cognitive Maps» (FCM) qui peut traiter les risques de tels systèmes compliqués en tenant compte des interrelations entre les facteurs. La FCM considère le comportement de systèmes complexes avec précision et illustre tout environnement complexe basé sur les perceptions des experts et par des représentations graphiques. Elle peut tenir compte des incertitudes, des informations imprécises, des interactions entre les facteurs de risque, de la rareté de l'information et des opinions de plusieurs décideurs. La FCM n'est pas seulement en mesure d'évaluer les risques plus précisément dans les réseaux de collaboration, mais elle pourrait également être appliquée dans différents processus décisionnels liés à des réseaux collaboratifs tels que la sélection des partenaires et les comportements de prévision, l'analyse des politiques, la modélisation de l'évaluation de la collaboration. L'outil proposé, aiderait les praticiens à gérer les risques collaboratifs et les problèmes de prise de décision de manière efficace et proactive.

Mots-clés: Analyse des risques, Réseaux collaboratifs, Cartes cognitives floues, Entreprises virtuelles, Connaissances approfondies.

4.3 A new decision support tool for dynamic risks analysis in collaborative networks

Abstract. Collaborative networks are complex systems and consist of many factors with dependencies among them. Although the number of collaborative networks such as advanced supply chains or virtual organizations/laboratories/e-science is growing and their significance is increasing in the world, many of them are unsuccessful. In addition, very little attention has been paid to the risk analysis of collaborative networks by considering the dependencies among risk factors. So, the precise risks analysis associated with collaborative networks projects is crucial to attain a satisfactory performance. To address this, we are proposing an advanced decision support tool called "Fuzzy Cognitive Maps" (FCM) which can deal with risks of such complicated systems by considering the interrelationships between factors. FCM states the behaviour of complex systems accurately and illustrate any complex environment based on the experts' perceptions and by graphical representations. It is able to consider uncertainties, imprecise information, the interactions between risk factors, Information scarcity, and several decision maker's opinions. FCM is not only able to evaluate risks more precisely in collaborative networks, but also it could be applied in different decision makings problems related to collaborative networks such as partner selection and forecasting behaviors, policy analysis, modeling collaboration preparedness assessment, etc. Hence, the proposed tool would help practitioners to manage collaborative network risks and decision making problems effectively and proactively.

Keywords: Risks analysis, Collaborative networks, Fuzzy cognitive maps, virtual enterprises, Expert knowledge.

1. Introduction

Collaborative networks (CNs) such as virtual organizations, dynamic supply chains, professional virtual communities, collaborative virtual laboratories, etc. are complex systems associated with uncertainties in dynamic business environments. This uncertainty and complexity could lead to critical risks which could influence on the enterprises' performance. According to Munyon & Perryman (2011), failure rate of alliances are estimated between 60% and 70%. Risk evaluation of CNs is a complex and critical task since several tangible and intangible risk factors should be considered in this process. In addition, there are always some dependencies among risks that can influence each other mutually and these dependencies make the evaluation process more complex and challenging. Therefore, an effective method for evaluating the risks is fundamental and essential. In recent decade, many problems related to CNs such as partner selection (Hexin & Jim, 2005) (H.Shah & Nathan, 2008) (Jarimo & Salo, 2007), modeling collaboration preparedness assessment (Rosas & Camarinha-Matos, 2008), etc. have been investigated. However, very little attention has been paid to the risk analysis of collaborative networks by considering the dependencies among risk factors (LI & Liao, 2007) (Zhou & Lu, 2012).

Li & Liao (LI & Liao, 2007) identified all possible risks which could influence on the operation of alliance and measured their priority numbers using three criteria; probability of risk, severity of risk and risk detection number. Das and Teng (Das & Teng, 2001) developed a risk perception model. The model consists of the following components: the antecedents of risk perception, relational risk and performance risk, risk perception and structural preference, and the resolution of preferences. Ip et al. (Ip, Huang, Yung, & Wang, 2003) described and modeled a risk-based partner selection method by taking into account risk of failure, due date and the precedence of sub-project. In addition, a rule-based genetic algorithm with embedded project scheduling was proposed to solve the problem. Huang et al. (Huang, Ip, Yang, Wang, & Lau, 2008) developed a risk management model for virtual enterprises (VE) and presented a tabu search algorithm by considering uncertainties in experts' opinions. Huang et al. (Huang, Lu, Ching, & Siu, 2011) proposed a two level Distributed Decision Making (DDM) model for the risk management of dynamic alliance. A Particle Swarm Optimization (PSO) algorithm is used to solve the resulting optimization problem. Their proposed model improves the description of the relationship between the owner and the partners.

However, research about the risk assessment of CNs by considering the interrelationships among risks factors and forecasting the impact of each risk on the other risks don't exist in the literature of CNs and further research in this field is required. Considering the interdependencies among risks could lead to more accurate risk assessment to enterprises. In addition, during the risk assessment process, there are lots of uncertainties and imprecise information associated with experts opinions that should be taken into account. Recently, Zhou and Lu (Zhou & Lu, 2012) presented a methodology for choosing a coalition partner using Fuzzy Analytic Network Process (FANP) and by considering the interaction and feedback relationships between risk factors. Although ANP is able to consider interdependencies among factors, it has some disadvantages. Sometimes it is not easy even for experts to compare the importance of a factor to another (R. Yu, 2006). In addition, different structures could lead to the different rankings and it is usually difficult for experts to provide the true relationship structure by taking into account several factors. Moreover, ANP is time-consuming due to the large number of pair-wise comparisons needed for comparing the risk factors.

Therefore, this paper deals with risk assessment of CNs as the most important phase of risk management, and proposes an advanced decision support tool called "FCM" to overcome the shortcomings of current risk evaluation tools applied in CNs. FCM is a useful tool that states and evaluates the dynamic behaviour of complex systems by considering the interrelationships among factors (Kosko B. , 1986). It considers the uncertainties and imprecise information by using linguistic variables. Hence, expert perception is considered in the model more precisely. Moreover, FCM can even be used when the information is scarce. This tool recently has been applied successfully in evaluating risks in complex and critical environments such as Enterprise Resource Planning (ERP) maintenance (Lopez & Salmeron, 2014) (Ahmad & Kumar, 2012) and IT projects (Salmeron, 2010), and therefore we think it has a good potential to be applied in complex CNs for evaluating risks and forecasting the impact of each risk.

The reminder of this paper is organized as follows. Section 2 explains the proposed tool with an example related to risk evolution in dynamic alliance and conclusions are drawn in Section 3.

2. The proposed method

In order to illustrate the proposed tool, we adopted the risks identified in Li & Liau (LI & Liao, 2007) study regarding dynamic alliance. Dynamic alliance or VE is a temporary network of specialised individuals and independent institutes who work together and share skills and costs in order to better respond to fast changing market opportunities (LI & Liao, 2007). The identified risks are shown in Table 4.3 and the related FCM graph is depicted in Fig. 4.2. The definitions of these risks are available in study (LI & Liao, 2007).

The FCM graph is depicted based on experts' opinions in order to show the dependencies and feedbacks among factors. To make the initial weight matrix (W_{ij}), each expert individually determines the dependencies between concepts, using fuzzy linguistic terms such as Very High (VH), Low (L), etc. Then, the linguistic variables are aggregated and defuzzified to numerical values (Elpiniki I. Papageorgiou, Fuzzy Cognitive Maps Learning Using Particle Swarm Optimization, 2005). The initial weight matrix, is shown in Table 4.4.

In order to deffuzify a triangular fuzzy number (l, m, u) the following Equation is usually applied:

$$t = \frac{l+m+m+u}{4} \tag{1}$$

Table 4. 10 Risk factors in dynamic alliance.

Risk	Sub-risks	Index
Market risk	Demand fluctuation risk	C1
	Competition risk	C2
	Spillover effect risk	C3
Financial risk	Interest rate risk	C4
	Exchange rate risk	C5
Natural risk	Natural risk	C6
Relational risk	Trust risk	C7
	Moral risk	C8
	Motivation risk	C9
	Communication risk	C10
	Organization risk	C11
Operational risk	Information sharing risk	C12
	Information integration risk	C13
	Information conveyance risk	C14
Political risk	Social risk	C15
	Policy risk	C16
Competency risk	Quality risk	C17
	Cost risk	C18
	Time risk	C19
	Technologic risk	C20
Investment risk	Investment recovery risk	C21
	Investment implementation risk	C22

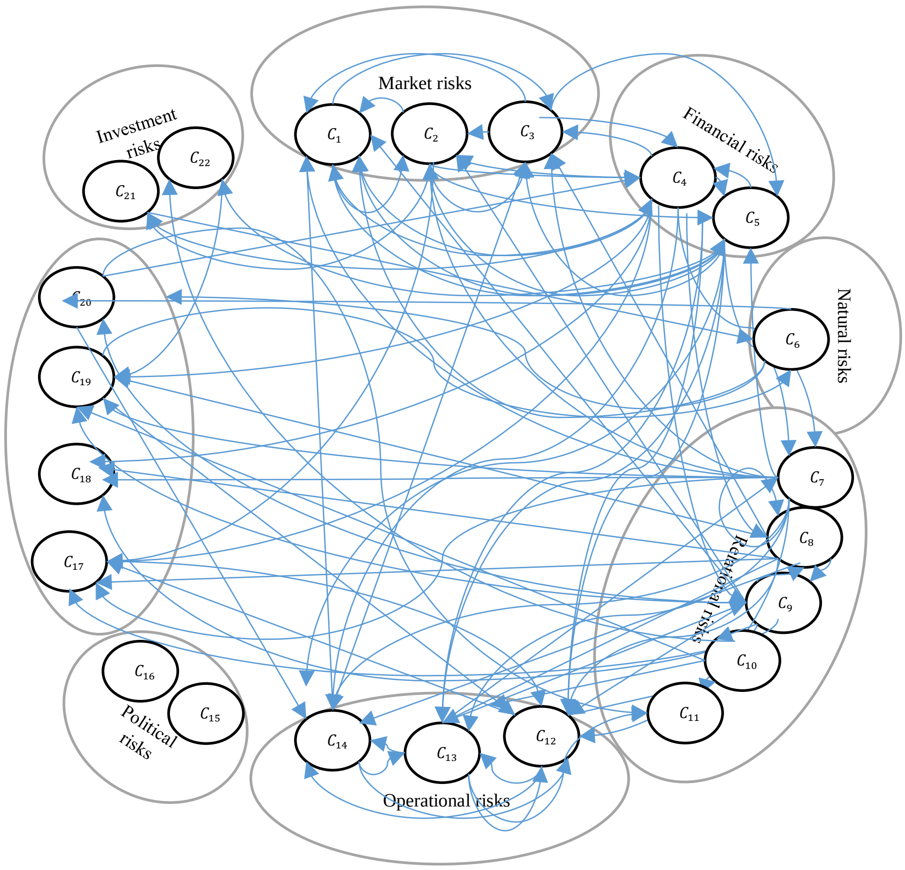

Figure 4. 11 FCM for risk analysis on dynamic alliance.

Table 4. 11 Initial weight matrix.

W^{Aug}	C1	C2	C3	C4	C5	.	.	C18	C19	C20	C21	C22
C1	0	0.2	0.5	0	1	.	.	0	0	1	0	0.3
C2	0.2	0	0.6	0.5	0	.	.	0.26	0	0	0.1	0.3
C3	1	0	0	0	0	.	.	0	0	0.8	0	0.3
C4	0.8	0.9	0	0	0.2	.	.	0.12	0	0	0.1	0
C5	0.7	0	0.8	0.4	0	.	.	0	0	0.4	0	0
C6	0.8	1	0	0	0.2	.	.	0	0.1	0	0	0
C7	0.8	0	0	0.6	0.6	.	.	0.78	0	0	1	0.38
C8	0	0.2	0	0.5	0	.	.	0	0	0.5	0.1	0.1
C9	0.7	0.3	0.8	0.8	0.5	.	.	0	0.78	0	0.99	0
C10	0.1	0.35	0.2	0.1	0.9	.	.	0	0	0	0	0
C11	0.4	0	0.2	0	0	.	.	0	0	0.1	0.1	0
C12	0	1	0.1	0	0	.	.	0.5	0.3	0	0	0.9
C13	0	0.3	1	0.2	0	.	.	0	0	0.2	0.1	-1
C14	0	0	0.5	0.5	0	.	.	0	0.6	0	0	0.8
C15	0.7	0.3	0.3	0	0.9	.	.	0	0	0	0.6	0.9
C16	0.2	0	0.1	0	0	.	.	1	0.67	0	0	0
C17	0.65	0.3	0	0.8	0.5	.	.	0	0	0.3	0.1	0
C18	0.7	0	0	0	0.1	.	.	0	0.6	0	0.5	0
C19	0.2	0.5	0	0.8	0	.	.	0.3	0	0	0.1	0
C20	0.6	0	0.3	0	0	.	.	0.9	0.7	0	0.1	0.56
C21	0	0.6	0.7	0	0	.	.	0.3	0.2	0.1	0	0.8
C22	0	0	1	0.5	0	.	.	0	0.7	0.1	0.5	0

2.1. FCM building process

Two types of FCM model could be developed for evaluating risks. The first type is scenario-based which is used in this paper and the second type is based on initial concept values obtained from multi criteria decision making tools such as AHP/ANP or eigenvalue approach. Scenario-based FCM is a new method recently presented by different authors and it is becoming popular in complex and fast-changing domains such as business environment, therefore it is critical to predict the impact of potential risks that could be happened in the future. In order to evaluate the impact of risks in a scenario-based FCM model, several what-if analysis scenarios should be developed using different initial concept values (c). In each scenario, a risk or a set of risks are activated and using learning algorithms the initial vector (c) is updated in order to show the impact of activated risks on the other risks. Note that when a risk is activated, its value in the initial vector (c) is considered 1. This number is 0 for the rest of the risk factors which are not activated.

In second type of FCM modeling, the initial concept values (c) is updated by using initial weight matrix (W_{ij}) and Eq. 1 until it converges to the steady state condition. The updated concept values C^* shows the importance of each risk. Since this type of FCM is unable to assess the impact of each risk on the other risks, we propose to apply the first type in evaluating the risk of CNs. To illustrate the risk evaluation process, in this paper we only assess the impact of "Market risks" on other risks.

In this scenario, at the initial time only risks related to market risks including "Demand fluctuation risk (C1)", "Competition risk (C2)", and "Spillover effect risk (C3)" are activated.

c = [**1, 1, 1**, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0];

Using W_{ij} matrix, Initial concept vector c, Equation (1) and learning algorithm, the training process starts. In this paper we applied NHL-DE algorithm for training FCM which is a combination of nonlinear Hebbian learning (NHL) and differential evolution (DE) algorithms. According to Papageorgiou (Papageorgiou E. , 2014), the hybrid training approaches such as NHL-DE emerge less limitations as they combine two training algorithms and inherit the benefits and shortcomings of both of them. The training process in NHL-DE has two steps. The first step starts with NHL algorithm and in the second step, the result of first step is used to seed the DE algorithm. We imported the data into Matlab code and we used MATLAB version R2012a software to obtain the updated concept matrix (C^*). In this paper, the values of learning rate parameter (η), mutation constant (μ), crossover constant (CR), and weight decay learning parameter (γ) have been selected 0.04, 0.5, 0.5, 0.98 respectively. The population size is considered 50. It should be noted we performed 1000 iterations for the algorithm per experiment and 100 independent experiments were performed.

C^* = [0.7, 0.47, 0.85, 0.7, **0.98**, 0.4, 0, **0.94**, 0, **0.97**, 0.2, 0.49, 0.78, 0.21, **0.93**, 0.7, **0.91**, 0.1, 0.78, **0.99**, 0, 0.37];

The steady state vector C^* shows that activating C1, C2, and C3 risks have a strong influence over the remainder risks in particular risks C5, C8, C10, C15, C17, and C20.

The same procedure should be done for all other risks by activating their sub-risks each time. The results reveals that which risks are critical. In addition, the proposed tool is able to predict the impact of each risk on the other risks more accurately because it take into account the multiple connections between risks. Therefore, decision makers will be able to manage the risks of CNs properly and accurately. It should be noted that the process for developing a FCM is strongly dependent on the experts' opinions. Then, special attention should be paid to matters such as the selection of experts' team and the feedback with them.

3. Conclusion

This paper proposes an advanced decision support tool called "Fuzzy Cognitive Maps" (FCM) which can deal with risks of collaborative networks by taking into account the interrelationships among factors. This tool can be adapted to a wide range of multi criteria decision making problems such as predicting behaviors in CNs, partner selection, policy analysis, modeling collaboration preparedness assessment, etc.

The main features of FCM in contrast with those of other existing methods are; 1) the relationships among variety of factors and also importance of factors could be considered , 2) uncertainties and imprecise information are taken into account on the decision-making process, 3) several experts can state their opinions, 4) it has capabilities to handle both qualitative and quantitative factors, 5) several alternatives can be considered in decision making about best partner and 6) by using the casual graphs in FCM, it is easier for decision makers and experts to understand the factors and their dependencies. Moreover, by relying on FCM models, the decision makers have a strong support, and therefore are able to decide more precisely and accurately when evaluating risks or choosing the partner. As a future research topic, application of other hybrid algorithms for training FCM could be considered. Currently, we are working on developing a comprehensive framework for partner selection problem in dynamic alliance by using an integrated FCM-based method.

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Chapter 5. A new framework for risk assessment in ERP maintenance

The fifth chapter is dedicated to the following article:

[1] "A new framework for risk assessment in ERP maintenance", Afshin Jamshidi, Samira Abbasgholizadeh Rahimi, Angel Ruiz, Daoud Ait Kadi. IEEE Xplore, PP: 1-6, 2014, The annual reliability and maintainability symposium, DOI:10.1109/RAMS.2014.6798515.

5.1 A new framework for risk assessment in ERP maintenance

Résumé: Au cours des dernières décennies, des entreprises du monde entier ont mis en place des systèmes de Progiciel de Gestion Intégré (PGI). Une mise en œuvre correcte des PGI a été une question plus explorée. Plus précisément, de nombreux articles ont présenté les facteurs critiques de succès de ces projets. Mais même lorsque l'implémentation s'est terminée de manière satisfaisante, le succès de l'adoption de PGI n'est pas garanti. Cela dépend aussi du processus d'efficacité dans les systèmes PGI post-implémentation. La maintenance de l'PGI est nécessaire pour corriger et prévenir les risques des systèmes ainsi que pour améliorer ses performances et s'adapter en permanence au système. Néanmoins, cela est souvent géré intuitivement et sans tenir compte des risques existants. En ce sens, les gestionnaires de maintenance doivent connaître l'importance de tous les risques identifiés.

Compte tenu de cette lacune existant dans la littérature et des besoins professionnels, l'objectif de cette recherche est d'analyser les facteurs de risque (RF) qui menacent la performance de maintenance PGI. Dans cet esprit, nous présentons d'abord les principaux risques relevés lors de la revue de la littérature, affectant la performance de la maintenance PGI. En outre, nous proposons une approche systématique pour l'identification et l'évaluation des risques potentiels à l'aide d'une Analyse de mode de défaillance et leurs effets flou (FFMEA) et d'une Analyse Relationnelle Grise (ARG). L'approche proposée comporte deux étapes: la construction du FFMEA et l'application du ARG. La première étape vise à incorporer les caractéristiques spécifiques à la maintenance PGI au nouveau modèle FFMEA, en fournissant différentes dimensions et sous-dimensions, englobant les caractéristiques d'entretien PGI. À la deuxième étape, le GRA est appliqué pour calculer la priorité de risque de chaque mode de défaillance pour traiter les nécessités d'un cadre d'évaluation flexible sous ces multi-dimensions interdépendantes. Enfin, tous les risques présentés dans la taxonomie générale des risques sont classés des plus critiques au moins critiques en fonction de leur importance pour le risque.

Les résultats soulignent quels sont les risques les plus importants dans la maintenance PGI. Ce cadre aide les gestionnaires, les fournisseurs, les consultants, les auditeurs, les utilisateurs et le personnel informatique à mieux gérer la maintenance PGI dans le cadre systématique.

Mots clés: Maintenance de PGI, évaluation des risques, Analyse de mode de défaillance et leurs effets, Analyse Relationnelle Grise

5.1 A new framework for risk assessment in ERP maintenance

Abstract: In recent decades, companies across the world have implemented enterprise recourse planning (ERP) systems. Proper ERP implementation has been a more explored issue. Specifically, numerous papers have presented the critical success factors in these projects. But even when the implementation finished satisfactorily, success in ERP adoption is not guaranteed. It also depends on the effectiveness process in the post-implementation ERP systems. The maintenance of the ERP is necessary to correct and prevent systems risks as well as to enhance its performance and adapt continuously to the system. Nevertheless, this is often managed intuitively and without taking into account the existing risks. In this sense, the maintenance managers need to know the importance of all risks identified.

Given this gap existing in the literature and the professional needs, the aim of this research is to analyze the risk factors (RFs) that threaten ERP maintenance performance. With this in mind, at first we introduce the main risks retrieved from literature review, affecting the performance of ERP maintenance. Moreover, we propose a systematic approach for identifying and evaluating potential risks using a Fuzzy Failure Mode and Effect Analysis (FFMEA) and Grey Relational Analysis (GRA). The proposed approach consists of two stages: construction of FFMEA and application of GRA. The first stage, aims at incorporating the ERP Maintenance-specific characteristics to the new FFMEA model, providing different dimensions and sub-dimensions, encompassing the ERP Maintenance characteristics. At the second stage, GRA is applied to calculate the risk priority of each failure mode to deal with the necessities of a flexible evaluation framework under these interrelated multi-dimensions. Finally, all risks presented in the general risks taxonomy are ranked from more to less critical according to their risk importance.

The results highlight which risks are most important in ERP maintenance. This framework helps managers, vendors, consultants, auditors, users and IT staff to manage ERP maintenance better and within the systematic framework.

Key Words: ERP Maintenance, Risk Assessment, FMEA, GRA

1. INTRODUCTION

Enterprise resource planning (ERP) systems are defined as a single software system allowing the complete integration of information flow from all functional areas in companies by means of a single database and accessible through a unified interface and channel of communication . Companies have spent billions of dollars in ERP implementation. However, ERP projects are never finished: after the implementation process, the maintenance starts. The ERP system's maintenance is a critical issue, because if it is not fit, the system will soon not be useful.

A survey about ERP systems shows a growing activity in ERP maintenance. This trend has continued in recent years. However, ERP risks studies represent about only 12% of the ERP research [1]. According to advanced market research (AMR) , 67% of companies spent more than $1 million on ERP, and 13% of them spent more than 20 million dollars in 2006. This report also expects budgets to grow 12.3%. ERP maintenance costs can exceed initial acquisition, with average annual ERP maintenance costs estimated at 25% of original implementation. Despite this, a model unaware of risk has been developed [1].

The successful maintenance of ERP systems has shown itself to be a complex and difficult activity [2]. Indeed, the progress and outcomes of the final projects are usually uncertain and this requires facing many unforeseen events. Moreover, it has been proved that planning and control risks negatively affect the success of ERP projects [2]. To avoid undesired outcomes, practitioners have to proactively manage real ERP maintenance risks. A large number of models, methods and techniques have been developed to address the need for a structured Risk Management (RM) approach as a core activity of ERP projects for identifying, evaluating and prioritizing ERP implementation projects risks [3-5,8-10]. These studies have applied techniques such as analysis of variance (ANOVA), the fuzzy variables set method, the Analytic Hierarchy Process (AHP), neural networks, and decision trees [4,6,7]. However, these tools lack certain characteristics necessary to fairly and accurately model ERP projects risks. In fact, these methods are not capable of representing all possible interactions between risks. In addition, none of these methods considers different opinions of experts and assigns different weights to each idea. In a specific review on ERP ‘‘risk management’’, Aloini et al. [3] stated that most of the contributions were focused on the risk identification and risk analysis in a rather descriptive way, while only a few of them suggested working models or techniques for the risk quantification or for defining the appropriate treatment strategies. Moreover, even in case of structured approaches, works do not include the complex system of internal relationships (among the risk factors and between risk factors and effects) in the quantification step. To our best knowledge, this is still a major gap in literature. The most common shortcomings in terms of potential cause of failure in RM are often about a superficial risk analysis which misses risk interdependence analysis; this is also valid within the ERP case. The complex structure of an ERP project and the high number of risk factors indeed increase the magnitude of risks not only in relation to each single factor, but also to the interconnections between them. More recently, Aloini & Lopez [2,11] applied Petri Net and fuzzy cognitive maps (FCM) approaches respectively.

In this paper, we deal with the Risk Assessment (RA) stage of RM in an attempt to contribute to the development of an effective methodology for its application and to provide a support tool for the formulation of risk treatment strategies and actions for ERP maintenance. Specifically, our aim is to provide a quantitative RM methodology to include risk interdependence in the risk analysis process as well as considering the different experts' opinions. Then we rank and prioritize ERP maintenance risk factors to establish the relative importance of each one. To do this, we introduce an integrated multi-criteria decision making (MCDM) methodology. For the numerical example, we refer to the General ERP maintenance risks taxonomy defined in [1]. The results indicate where the maintenance team must focus on treating and mitigating the risks and threats. The main objective of this work is to develop a quantitative framework using fuzzy FMEA& GRA to model ERP project risks and rank each risk factor including their interdependencies.

2. ERP MAINTENANCE

The ERP maintenance project is made up of activities undertaken from the time the ERP goes live until it is retired from production. ERP maintenance management is different from the classical one. This is not only due to the size, scope and organizational impact of the ERP project. ERP is a standard software that is adjusted to the specific needs of the firm. As such, ERP kept in line with continuous changes and improvements but it is conditioned by the generation of further versions. Moreover, the ERP maintenance project's complexity is greater than that of the classical software maintenance project due to the amount of modifications applied to the ERP during the implementation and post-implementation stage. In spite of this, there is not an ERP maintenance standard which indicates just one way to manage the process better.

ERP's nature requires a more ongoing process of improvement and fine-tuning than classical maintenance because the ERP scope is wider than other applications and its impact on companies is larger. However, many companies have not maintained their ERPs successfully. In this sense, the ERP maintenance risks need to be managed. Otherwise, ERP will not attain its whole potential benefits and ERP might even become useless. Despite this, the maintenance team usually treats these risks intuitively. Moreover, little effort to analyze ERP maintenance risks has been made in the literature. As a result, the authors consider that a formal study about ERP maintenance risks is valuable.

3. ERP MAINTENANCE RISK FACTORS

Identifying the risks factors to include in the analysis can be quite challenging for managers, especially because there are different ways in which they can be described and categorized [11]. Factors affecting an ERP implementation project spread around all the project phases [12]. Many empirical researches have focused the attention on risk identification and classification [5,8]. Aloini et al. [3] especially reviewed a large number of articles about ERP system implementation from a RM perspective. They identified 19 risk factors and 10 project effects. The general risks taxonomy summarizes the threats that affect the ERP maintenance. However, if the maintenance team wants to correctly manage the risk existing in the process, this is not enough. The managers need to know which risks are critical, moderate and marginal. To do so, the maintenance team has to have a structured framework. Most of authors [1,2,12] have estimated both the probability of occurrence and the impact on the ERP maintenance performance while, this is not enough criteria for risks estimation and their ranking. To rank and prioritize risks factors in ERP Maintenance, we need to take into account some other dimensions/sub-dimensions. In addition, we should be capable of representing all possible interactions between risks [11]. Then, in this paper we address these gaps and propose a new framework to improve current risk assessment processes in ERP maintenance. Specifically, we develop a new version of FMEA called ERP-specific FMEA and consider three dimensions and eight sub-dimensions in this method.

4. CONSTRUCTING ERP-SPECIFIC FMEA FRAMEWORK

FMEA is a reliability analysis tool widely used in the manufacturing sectors, to identify, prioritize, and eliminate known potential risks from systems [14,15]. Much debate has taken place regarding risk prioritization by traditional FMEA [16] which is related to the appropriateness of the relation, consideration of different impacts of "S" (severity), "O" (occurrence), and "D"(detection) in risk implication, and the appropriateness of multiplication [12].

In the traditional FMEA, the risks are assessed by the Risk Priority Number (RPN).

$$RPN = D \times O \times S \tag{1}$$

The severity, occurrence, and detection of the RFs are scaled from 1 to 10.

where: S is an assessment of the seriousness of the effect of the risk to system if it occurs, O is the likelihood that a specific risk will occur, and D is an assessment of the ability of the current experts to detect a potential risk. A larger RPN represents a higher risk.

To consider accurately all of three dimensions of FMEA method, in this paper we have considered eight sub-dimensions (3, 3, and 2 for S ,O , and D dimensions respectively). The explanation of these sub-dimensions is as follows:

S1: Impact (How much the impact of risk is)
S2: Affected range (How broad the affected range is)
S3: Interdependency (How closely the risk is linked with other risks)
O1: Frequency (How frequently the failure happens)
O2: Repeatability (Does the failure happen repeatedly)
O3: Failure visibility (Is the failure visible to the customer or not)
D1: Chance of detection (How severe is the detection of risk)
D2: Method of systematic detection (Does the periodical and systematic method exist for detection)

FMEA is normally a team effort in which several experts are involved. Thus, different opinions will arise in ranking. In order to consider all of experts' opinion, we present a fuzzy FMEA. In fuzzy FMEA, the values are expressed by membership functions instead of real numbers. The application of fuzzy membership functions better represents the team opinions. We define fuzzy membership functions for S, O, and D values of RPN as follows:

$$\mu_S = \frac{s_{ij}}{\sum_{i=1}^{n} s_{ij}} \quad \mu_O = \frac{o_{ij}}{\sum_{i=1}^{n} o_{ij}} \quad \mu_D = \frac{d_{ij}}{\sum_{i=1}^{n} d_{ij}} \quad (2)$$

The value for level *i* given by expert *j* for severity dimension is denoted as s_{ij} , *i* = 1…m, *j* =1…*n*, where *n* is the number of experts and m is the number of risks factors. After this transformation, values are between 0 and 1. In this paper, triangular membership functions is used.

The complete ERP-specific FMEA framework is shown in Figure 5.1. It should be mentioned that, we can determine particular weights (W_{ij}) for experts based on their experience and knowledge. Weights should be between zero and one and total weights for all experts, should be one. In addition, in our previous article [14] we did a pair wise comparison among S, O, and D to obtain the comparison matrix (0.3538, 0.1652, 0.4809). After assigning weights for each expert (W_{ij}) and each dimension, we present the new fuzzy membership function called RPI, as follows:

$$\mu(RPI) = \sqrt[3]{W_{ij}(0.3538\mu_S + 0.1652\mu_O + 0.4809\mu_D)} \quad (3)$$

The membership function for the RPI needs to be defuzzified to obtain the RPI value. In this paper, we used Center of Maximum (COM) method. In the COM method, the average of the minimum value and the maximum value is considered to be the expected RPI.

Finally, after obtaining the RPI values we use grey analysis relational theory to obtain risk score for each dimension. The application of our framework is demonstrated through a numerical example.

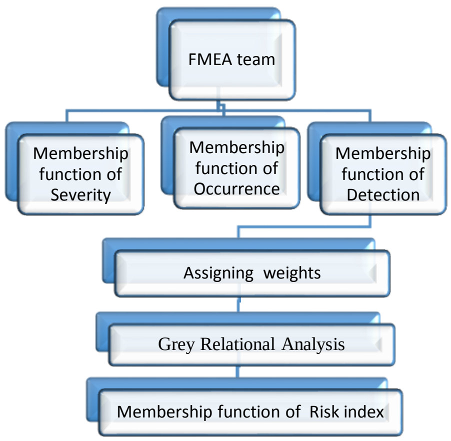

Figure 5. 1 ERP-specific FMEA framework

4.1 Grey relational analysis as a tool for risk prioritization

In this section, a new integrated method for risk prioritization is introduced with the help of GRA and our proposed new membership function. Contrary to the traditional FMEA which consists of only three dimensions, ERP specific-FMEA has some sub-dimensions describing each dimension, showing the complicated relationships between themselves. Therefore, a GRA characterized by the multiple criteria decision making in a complicated interrelated situation, is proposed as a resolution of this problem. GRA is a method for decision making, which is suitable for solving problems with complicated interrelationships between multiple factors and variables [16]. It is a simple and data-driven method useful for making decisions by analyzing various relationships.

Contrary to the previous studies, application of GRA in this paper consists of a two-phase application in order to highlight the multilateral perspective of ERP specific-FMEA. The first phase deals with the calculation of risk score for each dimension, and the second phase covers the calculation of overall risk priority by using Equation 3. In the first phase, the risk score for each dimension is calculated and referred to S, O, and D score respectively. These calculated scores are then used as the inputs of the second phase, calculating the final risk priority. Section 4.1.1 illustrates the calculation of risk scores.

4.1.1 The calculation of risk scores

Step 1. Calculating the comparative series for RFs for each dimension.

As the first stag e, all values for each RF are processed into a comparability sequence. If there are m RFs and n attributes in a dimension, the ith RF can be expressed as a comparative series $x_i = (x_{i1}, x_{i2}, \ldots, x_{in})$ as below[16].

$$x_{ij} = \frac{y_{ij} - Min\{y_{ij}, i = 1,2,\ldots,m\}}{Max\{y_{ij}, i = 1,2,\ldots,m\} - Min\{y_{ij}, i = 1,2,\ldots,m\}} \tag{4}$$

Where i = 1, 2, . . . , m, j = 1, 2, .., n, yij is the value of attribute j of alternative i.

Step 2. Setting the reference sequence (standard series) definition.

Since the RFs with high value should be selected, the reference set should be set as $x_o = (x_{o1}, x_{o2}, \ldots, x_{on}) = (1, 1, 1, \ldots, 1)$.

Step 3. Calculating the grey relational coefficient for each dimension. This step is used for determining how close x_{ij} is to x_{oj} .The larger the coefficients, the closer x_{ij} and x_{oj} . The relational coefficient can be expressed as:

$$\gamma(x_{0j}, x_{ij}) = \frac{\Delta_{\min} + \zeta\Delta_{\max}}{\Delta_{ij} + \zeta\Delta \max} \tag{5}$$

(ζ : the distinguishing coefficient, $\zeta \in (0, 1)$)

Generally, ζ can be 0.5 [16]. where i = 1, . . . ,m, j = 1, . . . , n, $x_{o(k)}$ is the standard series, and $x_{i(k)}$ is the comparative series.

$$\Delta_{ij} = |x_{oj} - x_{ij}|$$

$$\Delta_{\max} = Max\{\Delta_{ij}, i = 1,\ldots,m,\ j = 1,\ldots,n\}\ \Delta_{\min} = Min\{\Delta_{ij}, i = 1,\ldots,m,\ j = 1,\ldots,n\}$$

Grey relational coefficient for each dimension $\gamma(x_{0j}, x_{ij}) = \frac{\Delta_{\min} + \zeta\Delta_{\max}}{\Delta_{ij} + \zeta\Delta \max}$ Where i = 1, . . . ,m, j = 1, . . . , pd, (pd = total number of attributes for each dimension).

Step 4. Calculating the grey relational grade: (The risk score). Using the weighting coefficient of the decision factors, the final grey relational grade is calculated according to the following formula:

$$\Gamma(X_0, X_i) = \sum_{j=1}^{n} w_{j\gamma}(x_{0j}, x_{ij}) \tag{6}$$

for i = 1,..., m where w_j is the weighting coefficient of factors, and $\sum_{j=1}^{n} w_j = 1$.

Therefore, scores for each dimension can be calculated under the framework of calculating grey relational grade, as shown in Table 5.1.

Dimension	Grey relational grade (Risk score)
S score	$\Gamma(X_o, X_i) = \sum_{j=1}^{n_s} w_j\, \gamma(x_{oj}, x_{ij})$ for i = 1, 2, . . . ,m (n_s : Total number of attributes for S dimension)
O score	$\Gamma(X_o, X_i) = \sum_{j=1}^{n_o} w_j\, \gamma(x_{oj}, x_{ij})$ for i = 1, 2, . . . ,m (n_o : Total number of attributes for O dimension)
D score	$\Gamma(X_o, X_i) = \sum_{j=1}^{n_r} w_j\, \gamma(x_{oj}, x_{ij})$ for i = 1, 2, . . . ,m (n_r : Total number of attributes for D dimension)

Table 5. 1 Risk scores for each dimension

Here, $\Gamma(X_o, X_i)$ is the grey relational grade between x_o and x_i, representing the level of correlation between the reference sequence and the comparability sequence. It means that if the degree of relation is stronger, this RF is more risky, and is thus prioritized as the urgent one. Until now, the risk score of each dimension is evaluated. After calculating scores for each dimension, the overall risk score can be calculated.

5. Numerical Example

In this section, a numerical example is used to illustrate the proposed approach. Firstly, RFs are identified and listed based on the article of Salmeron et al. [1]. They identified 30 RFs in their paper. Assigned ranks for each RPI factor, according to the opinions of five engineers, is shown in Table 5.2. The value in parentheses refers to the weight of each dimension. The value W refers to the weight of experts' opinion (which was assigned based on their experience and knowledge).

RF	Eng	W	S1(5)	S2(5)	S3(3)	O1(5)	O2(3)	O3(4)	D1(5)	D2(3)
R2	1	0.25	1	5	1	9	9	8	1	7
	2	0.1	2	10	6	10	10	4	3	8
	3	0.15	10	1	1	3	4	3	10	10
	4	0.35	3	6	6	8	8	5	5	4
	5	0.15	9	3	7	4	2	5	1	2
R5	1	0.25	1	3	3	5	5	3	7	7
	2	0.1	10	2	3	9	10	8	9	1
	3	0.15	4	3	5	9	6	3	10	4
	4	0.35	8	2	4	4	7	4	7	3
	5	0.15	6	2	2	10	5	1	3	10
		. .				. .				
R30	1	0.25	10	3	5	2	9	8	2	2
	2	0.1	10	9	10	4	10	8	5	2
	3	0.15	5	6	3	8	1	6	4	10
	4	0.35	4	2	10	8	7	10	10	3
	5	0.15	7	2	6	4	9	3	4	2

Table 5. 2 Assigning ranks for each RPI factor

In Table 5.3, we assign different weights for each experts' opinion.

RF	Eng	W	S1	S2	S3	O1	O2	O3	D1	D2
R2	1	0.25	0.01	0.25	0.011	0.595	0.613	0.64	0.012	0.395
	2	0.1	0.016	0.4	0.171	0.294	0.303	0.064	0.045	0.206
	3	0.15	0.6	0.006	0.007	0.039	0.072	0.054	0.75	0.483
	4	0.35	0.126	0.504	0.599	0.658	0.678	0.35	0.437	0.180
	5	0.15	0.486	0.054	0.35	0.070	0.018	0.15	0.007	0.019
R5	1	0.25	0.008	0.187	0.132	0.168	0.189	0.118	0.340	0.49
	2	0.1	0.344	0.033	0.052	0.218	0.303	0.336	0.225	0.004
	3	0.15	0.082	0.112	0.220	0.328	0.163	0.071	0.416	0.096
	4	0.35	0.772	0.116	0.329	0.151	0.519	0.294	0.476	0.126
	5	0.15	0.186	0.05	0.035	0.405	0.113	0.007	0.037	0.6
.			.		.		.		.	
R30	1	0.25	0.694	0.102	0.183	0.038	0.675	0.457	0.04	0.052
	2	0.1	0.277	0.368	0.294	0.061	0.333	0.182	0.1	0.021
	3	0.15	0.104	0.245	0.039	0.369	0.005	0.154	0.096	0.789
	4	0.35	0.155	0.063	1.029	0.861	0.571	1	1.4	0.165
	5	0.15	0.204	0.027	0.158	0.092	0.045	0.038	0.096	0.031

Table 5. 3 Assigning W to each sub - dimension

Now we have to convert the fuzzy membership functions numbers into numerical values. Then, we use COM defuzzification method. After defuzzification of Table 5.3, the ERP- specific FMEA is constructed, as shown in Table 5.4.

Risks	S1	S2	S3	O1	O2	O3	D1	D2
R2	7.115	6.131	5.771	7.944	8.007	5.878	6.341	6.930
R5	7.288	2.5	3.742	7.359	6.700	4.436	7.638	6.58
.		.		.		.		.
R30	7.716	4.999	8.169	6.727	7.761	8.385	7.596	5.676

5.1 Application of grey relational analysis

Step1. Based on Table 5.4 and Equation 4, the first step of GRA is applied. Table 5.5 shows the comparative series for S, O, and D dimensions.

Risks	S1	S2	S3	O1	O2	O3	D1	D2
R2	0.667	0.525	0.473	0.845	0.857	0.437	0.593	0.686
R5	0.693	0.723	0.179	0.729	0.599	0.152	0.799	0.631
.		.		.		.		.
R30	0.755	0.361	0.820	0.604	0.809	0.932	0.792	0.487

Table 5. 4 Comparative series for S, O, and D

Step 2. Working with the reference set and using Equation 5, the grey relational coefficients for each dimension are calculated as Table 5.6. In this case, we set $\zeta = 0.5$.

Step 3. After calculating the grey relational coefficients, grey relational grade for each dimension is calculated using the weighted average of each grey relational grade. Table 5.7 shows the weight vector for S dimension.

Risks	S1	S2	S3	O1	O2	O3	D1	D2
R2	0.582	0.494	0.468	0.763	0.778	0.470	0.551	0.614
R5	0.601	0.626	0.361	0.649	0.555	0.370	0.713	0.575
.		.		.		.		.
R30	0.654	0.420	0.720	0.558	0.724	0.881	0.706	0.493

Table 5. 5 Grey coefficients for S, O, D dimensions

S1	S2	S3	O1	O2	O3	D1	D2
0.3846	0.3846	0.2307	0.416	0.25	0.333	0.625	0.375

Table 5. 6 Weight vector for each sub-dimension

Step 4. Using the weighting coefficient of the decision factors in Table 5.7, Equation 6 and Table 5.1, the final grey relational grade is calculated for S, O, and D dimensions. The result of the grey relational grade for each dimension is illustrated in Table 5.8.

Risks	S	O	D
R2	0.1741	0.2230	0.2876
R5	0.1853	0.1775	0.3308
R30	0.1933	0.2356	0.3134

Table 5. 7 Grey relational grades for each dimension

By using Equation 3, the overall grey relational grades can be calculated, as shown in Table 5.9.

Risks	S*W1	O*W2	D*W3	SUM	SUM^1/3=RPN
R2	0.0616	0.0368	0.1383	0.2367	0.6186
R5	0.0655	0.0293	0.1591	0.2539	0.6332
.		.		.	
R30	0.0684	0.0389	0.1507	0.2581	0.6366

Table 5. 8 Overall grey relational grade

Table 5.10 presents the final risks ranking. The findings suggest which risks are more critical in the ERP maintenance and this indicates in which order the risks should be treated. As shown in Table 5.10, the most important and critical RFs are RF12, RF6,and RF10 respectively.

Risks	Rank	Risk	Rank
R2	17	R28	6
R5	13	R1	16
R6	2	R12	1
R8	21	R13	23
R15	26	R14	24
R23	18	R17	5
R7	22	R19	28
R9	14	R20	27
R18	20	R25	15
R27	9	R21	10
R4	19	R3	25
R10	3	R22	8
R11	4	R24	12
R16	29	R30	11
R26	7	R29	30

Table 5. 9 Final risks ranking

6. Conclusion & Future Works

The aim of this research was to introduce a new framework to identify and prioritize the risks factors that threaten ERP maintenance performance. Our new framework is an integrated approach based on combining ERP-specific FMEA, and GRA. The results indicate which risks are more likely to occur in ERP maintenance. The major contributions and attributes of this framework are:

- A systematic way to consider interdependence in the risk analysis process,
- Considering different experts' ideas,
- Assigning weights for each experts' idea and also each dimension and sub-dimension,
- It provides a rapid response, as well as the ability to modify or expand the model. Our model has the flexibility for defining different Criteria/ sub-criteria or removing some of them in order to adapt best framework for prioritization of risks factors.

For the future works it is worthwhile to consider cost and profitability dimensions in ERP maintenance risks prioritization. The findings of this research will help the maintenance managers to decide which risk treatment to carryout in order to minimize unacceptable risks. But they should obtain more information about the risks factors for this purpose. In addition, the professionals also need to know how the risks arise. In this sense, we believe that studies about the ERP maintenance risks dimensions are also necessary.

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Chapter 6 .
Risk-based maintenance of Medical Devices

This chapter is dedicated to the following articles:

[1] “Medical devices Inspection and Maintenance; A Literature Review”, A. Jamshidi, S. A. Rahimi, D. Ait-kadi, A. Ruiz. 2014 IIE Annual Conference (ISERC) Proceedings, May 31-June 3. Montreal, Canada.

[2] “A risk-based Maintenance Strategy using Fuzzy HFMEA for Critical Medical Equipment” A. Jamshidi, S. A. Rahimi, D. Ait-kadi, A. Ruiz. Industrial and systems engineering world conference September 16-18, 2012, Washington, DC, USA.

[3] “A comprehensive fuzzy risk-based maintenance framework for prioritization of medical devices”, Afshin Jamshidi, Samira Abbasgholizadeh Rahimi, Daoud Ait-kadi, Angel Ruiz, Applied Soft Computing, Volume 32, 2015, Pages 322-334.

[4] A comprehensive fuzzy risk-based framework for replacement of medical devices, A. Jamshidi, S. A. Rahimi, D. Ait-kadi, A. Ruiz. 11th International Industrial Engineering Conference- CIGI 2015, Quebec, Canada, October 2015.

6.1. Medical devices Inspection and Maintenance; A Literature Review

Résumé: Les dispositifs et équipements médicaux modernes sont devenus très complexes et sophistiqués, et devraient fonctionner dans des environnements stricts. Les hôpitaux doivent s'assurer que leurs dispositifs médicaux critiques sont sûrs, précis, fiables et fonctionnent au niveau de performance requis. Même si l'importance, l'application de tous les modèles d'inspection, de maintenance et d'optimisation aux dispositifs médicaux est assez nouvelle. Au Canada, la plupart, sinon tous les organismes de santé, incluent tout leur matériel médical dans leur programme d'entretien et suivent simplement les recommandations des fabricants pour l'entretien préventif. Ensuite, les stratégies actuelles d'entretien utilisées dans les hôpitaux et les organismes de santé ont des difficultés à identifier les risques spécifiques et à appliquer des activités optimales de réduction des risques. Ce document aborde ces lacunes dans la littérature pour l'inspection et l'entretien des équipements médicaux et examine divers aspects importants, y compris les politiques actuelles appliquées dans les hôpitaux. Enfin, nous proposons des recherches futures qui seront le point de départ pour développer des outils et des politiques pour une meilleure gestion des dispositifs médicaux à l'avenir.

Mots-clés: Dispositifs médicaux, Maintenance, Fiabilité, externalisation, prioritisation

6.1. Medical devices Inspection and Maintenance; A Literature Review

Abstract: Modern medical devices and equipment have become very complex and sophisticated and are expected to operate under stringent environments. Hospitals must ensure that their critical medical devices are safe, accurate, reliable and operating at the required level of performance. Even though the importance, the application of all inspection, maintenance and optimization models to medical devices is fairly new. In Canada, most, if not all healthcare organizations include all their medical equipment in their maintenance program and just follow manufacturers' recommendations for preventative maintenance. Then, current maintenance strategies employed in hospitals and healthcare organizations have difficulty in identifying specific risks and applying optimal risk reduction activities. This paper addresses these gaps found in literature for medical equipment inspection and maintenance and reviews various important aspects including current policies applied in hospitals. Finally, we suggest future research which will be the starting point to develop tools and policies for better medical devices management in the future.

Keywords: Medical devices, Maintenance, Reliability, outsourcing, prioritization

6.1.1. Introduction

The maintenance of medical equipment is as important as its design and development. Usually, much more money is spent on maintaining a piece of equipment over its life span than on its procurement [1]. Medical equipment is extensively (from 5,000 to more than 10,000 different type) used in all aspects of health services, ranging from prevention, screening, diagnosis, monitoring, and therapeutics to rehabilitation. Nowadays, it is virtually impossible to provide health services without them. Unlike other types of healthcare technologies (i.e., drugs, implants, and disposable products), medical equipment requires maintenance (both scheduled and unscheduled) during its useful life. As the sophistication and cost of medical equipment continue to escalate, the complexity and cost of its maintenance have also risen sharply in the last few decades. Studies conducted using data collected from hundreds of acute-care hospitals indicate that on average, each hospital acquired about 15–20 pieces of medical equipment for each staffed bed, which translates into a capital investment of around US$200–400,000/staffed bed. Thus, it is common for a 500-bed hospital to own more than US$100–200 million worth of medical equipment and considerably more if it is affiliated with a medical school. The same studies have indicated that annual medical equipment maintenance and management cost is approximately 1% of the total hospital budget, so a 500-bed hospital spends typically around $5 million/year. In addition to its high maintenance costs, medical equipment is often involved in patient incidents that resulted in serious injuries or deaths. In fact, statistics accumulated by The Joint Commission (TJC) show medical equipment-related "sentinel events1" is typically among the top ten types every year [2]. Therefore, Hospitals and healthcare organizations must ensure that their critical medical devices are safe, accurate, reliable and operating at the required level of performance.

Maintenance strategies and reliability engineering techniques have been significantly improved in the last two decades, and they have been successfully applied in many industries to improve the performance of equipment maintenance management. Numerous inspection and optimization models are developed and widely used to achieve maintenance excellence, i.e. the balance of performance, risk, resources and cost to reach to an optimal solution. However, most of hospitals and healthcare organizations do not benefit from maintenance excellence as much as other industries [3]. Unnecessary and excessive preventive maintenance could be also loss-making likewise inadequate level of maintenance. The time, which is spent doing the unnecessary preventive maintenance, is robbing an organization of a fraction of one of its most vital resources [4].Since 2004, when Joint Commission on Accreditation of Healthcare Organizations(JCAHO) introduced standard EC.6.10 [5], hospitals in US have started adopting their maintenance programs to put their maintenance resources where most needed. This standard allows hospitals to not have schedule inspection or maintenance tasks for certain pieces or types of medical equipment, if these tasks are not needed for safe and reliable operation [6].

However, in Canada, most, if not all healthcare organizations include all their medical equipment in their maintenance program and just follow manufacturers' recommendations for preventative maintenance [3]. Current maintenance strategies employed in hospitals and healthcare organizations have difficulty in identifying specific risks and applying optimal risk reduction activities [7]. Moreover, even though the use of reliability engineering tools is well established, their application to the medical industry is new. Most research in this area merely suggests how to assess or improve the reliability of devices in their design or manufacturing stages. To this point, best maintenance strategies for medical equipment in their operating context have not been considered. Hospitals, due to possessing a large number of difference devices, can benefit significantly if the optimization techniques are used properly in the equipment management processes. In this paper we address these gaps and review the research literature regarding medical device inspection and maintenance. We consider various important aspects, concerned with MEIM including prioritization of medical equipment, maintenance optimization models applied for medical devices, maintenance outsourcing, and current MEIM policies applied in hospitals for improving medical equipment maintenance. Finally, in the discussion and conclusion section, we present the main research gaps found and suggestions for future research which will be the starting point to develop tools suitable for better medical devices management.

6.1.2. Review of the existing literature

In this section, we assess the status of research on maintenance of medical devices. We consulted a range of academic archives including books, research papers and theses to identify relevant research for medical device maintenance. The source used for our study was academic journal articles published between 1985 and 2014. Publications in languages other than English were not included. The archives consulted included, Proquest, ScienceDirect, Emerald, Google scholar, and JSTOR. Moreover, a search for additional papers in the reference lists of all papers is carried out. Clinical engineering departments have struggled to optimize medical device risk management using various Medical Equipment Management Programs (MEMPs) for more than 25 years. Many risk based MEMPs, including the seminal Fennigkoh and Smith method and its variations, have been proposed and are currently in use. A common theme in these methods is that a single measure of a number of different risks is defined and used to guide safety and performance inspection and preventive maintenance activities. These methods, although simple to use, present a number of problems including difficulty in identifying specific risks and applying optimal, specific risk reduction activities. It is widely recognized that although current medical equipment management methods do reduce risks, they are not near optimal in minimizing risks [7].

A serious debate on preventive maintenance (PM) intervals is taking place among clinical engineering (CE) practitioners on various levels and in professional journals. The debate is focused on the standard requirements by regulating authorities and accreditation organisation in many countries that (PM) intervals should follow the equipment manufacturer's recommendations [8]. Some devices that appear to be very similar in their function and design have manufacturer-recommended intervals that vary by a factor of two or more. The question has been raised about the credibility of these recommended intervals and whether it is based on meaningful test data. Debating the PM intervals with equipment manufacturers does not seem to be a practical approach because manufacturers may be reluctant to share that information with end-users if there are any documented data. Judging maintenance outcomes based on PM or safety and performance inspection (SPI) is not possible and the same applies to periodic replacement of parts or calibrations [6].

Clinical and biomedical engineering professionals are still holding on to process measures rather than analysing the outcome of maintenance in spite of the experience from other industries, which shows that traditional PM is often unnecessary, if not counterproductive [9]. In 1984, the Emergency Care Research Institute (ECRI) [10] published a recommendation to use risk as the primary criteria for deciding which piece of equipment should be subject to SM as well as the frequency of the SM and risk was categorised as high-medium-low. ECRI has developed scheduled (planned) maintenance (SM) for most of medical equipment which is known as health device inspection and preventive maintenance (IPM). The IPM includes guidelines on PM and SPI. Fennigkoh and Smith [11] introduced another approach, which classifies equipment using three parameters, i.e. function, physical risk, maintenance requirements. This approach was known later as the risk-based inclusion criteria and allowed CE professionals to focus their PM on a limited portion of medical devices (life support).

Ridgway [12] noted that PM does have some impact on the reliability of some items and therefore it does have some beneficial impact on equipment uptime. However, the discussion about what value properly executed PM brings to the facility's maintenance program requires considering the impact of eliminating or increasing the intervals for some or all of the PM-related tests and results achieved: increased safety, reduced downtime and fewer expensive repairs. Ridgway [13] further noted that PM is an issue of declining importance-relative to several other equipment issues. Yet, US$300 million per year is still allocated to this in the USA hospitals. Ridgway further indicated that there is still no good consensus on the definition of PM or even why it is done, no rational process for defining a non-critical device and no good method for justifying PM intervals. PM does not prevent all types of equipment failure and only addresses failures that result from the degeneration of a device's non-durable parts and hidden failure.

In this review, we divide the studies used in the literature into three main categories, which are prioritization of medical devices, empirical researches, and mathematical modeling. The three categories, each with their own related approaches and references, are reported in Table 6.1 In what follows, we more specifically go into the references and show what has been done.

6.1.3 Development of maintenance philosophies

Maintenance management techniques have been through a major process of metamorphosis over recent years. Today, the maintenance progress has been provoked by the increase in complexity in manufacturing processes and variety of products, growing awareness of the impact of maintenance on the environment and safety of personnel, the profitability of the business and quality of products. There is a paradigm shift in implementing maintenance strategies like condition-based maintenance (CBM) and reliability-centered maintenance (RCM). Then the risk-based maintenance (RBM) has been emphasized. The development of maintenance philosophies is shown in Figure 6.1 This figure reveals that maintenance policies are evolved over time and can be categorized as first, second, third and recent generations.

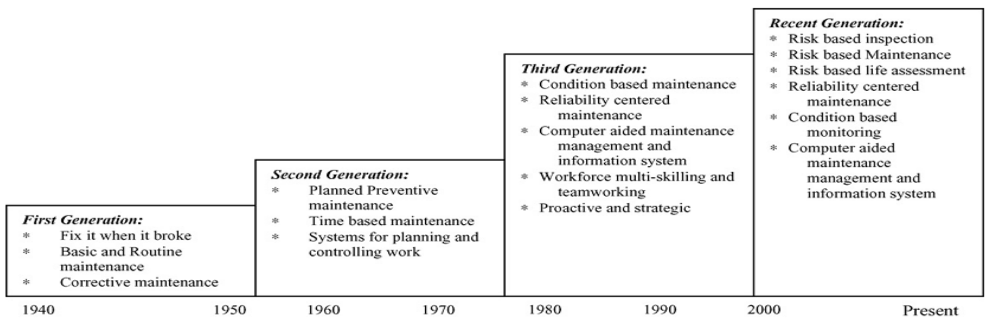

Figure 6. 1 Development of maintenance philosophies [14]

6.1.4. Empirical approaches versus mathematical models

Today, medical equipment maintenance suffers from the same ailments that traditional medicine was suffering from before. Rapid advance of medical technologies has proven that traditional maintenance is no longer enough to ensure that equipment is getting the best possible maintenance. Medical equipment industry has been following empirical approaches and very little was done on mathematical modelling. Preliminary data collected from some hospitals in USA and analysed show that current maintenance strategies might be effective but there is no clear evidence whether they are efficient. However, incorporating mission-criticality concept with patient risk might produce much higher impact on reduction of risk. Refocusing resources from scheduled maintenance to higher impact tasks, e.g., use error tracking, self-identified failures and repairs, user training and working with facilities and purchasing should lead to a balanced mix between needs and resources [15].

Literature review has shown that very little research has been done to measure the availability of medical equipment in relation to maintenance using mathematical modelling. The empirical approach is widely used in other sectors of industry and various mathematical models were developed to measure availability and reliability of equipment and systems. Evidence in literature shows that maintenance policies based on mathematical models are much more flexible than heuristic policies and the great advantage of the mathematical approach is that the outcomes can be optimised and maximum reliability or minimal cost can be achieved [16].

The empirical approach is based on experience and manufacturer's recommendations. One method is called reliability centred maintenance (RCM), introduced about 30 years ago and considered to be empirical. RCM is based on condition monitoring, analysis of failure causes and investigation of operating needs and priorities. According to Endrenyi [16] RCM selects the critical components in equipment, which contribute to equipment failure or financial loss and initiates stringent maintenance programs for these components. Endrenyi further concluded that RCM helps to decide where to put the next dollar budget for maintenance and is good for comparing policies but not for true optimisation. In RCM, six basic patterns of failure have been identified based on industrial experience (very little data is available for medical equipment). A study done 1982, which analysed maintenance data from the USA Navy industry using six patterns, found the following information in Figure 6.2 [17].

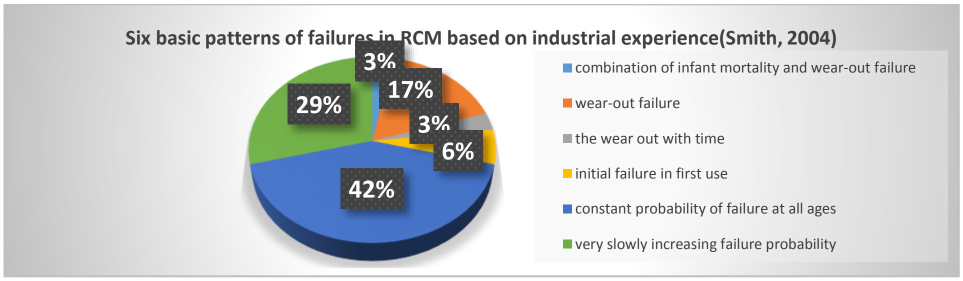

Figure 6. 2 Six basic patterns of failures in RCM [17]

Hall [18] noted that there are two keys to RCM method, the first is having a good maintenance history of medical equipment and the second key is the age. Hall further indicated that RCM might be a better strategy for younger equipment. To balance both sides of maintenance (preventive, corrective), condition based maintenance (CBM) was introduced, which observes and forecasts real time health of machines where RCM studies the failure causes over a period of time and initiates maintenance programmes to increase the up time of these equipment. Recent development in CBM revealed promising technologies for advanced fault detection and forecasting. In addition, CBM increases productivity, availability and safety of the machinery systems [19]. In CBM, machines are continuously monitored by various sensors to detect failures in real-time and therefore CBM is useful in estimating the time of a future failure and remaining useful life.

6.1.5. Classification and Prioritization of medical devices for maintenance activities

The ever-increasing number and complexity of medical devices demands that hospitals establish and regulate a Medical Equipment Management Program (MEMP) to ensure that critical devices are safe and reliable and that they operate at the required level of performance. As fundamental aspects of this program [20] inspection, preventive maintenance, and testing of medical equipment should be reviewed continuously to keep up with today's technological improvements and the increasing expectations of healthcare organizations. No longer content to merely follow manufacturers' recommendations, hospital clinical engineering departments all around the world including Canada, Australia, and United States have begun to employ more efficient and cost-effective maintenance strategies. Gentles et al [21] have begun to develop a unique database to collect comparative data on inventory and maintenance of the most critical devices used in hospitals across Canada and the United States. This project will provide a large statistical failure data set which could be used to establish optimum intervals for routine maintenance scheduling. Ridgway et al. [12] provide concise guidelines for maintenance management of medical equipment and address methods, which have been used for a long time in other industry segments, such as RCM. Significant and critical assets should be identified and prioritized, and many techniques have been developed for criticality assessment of devices. Most use some variation of the probability risk number or PRN, a product of the probability of failure of an asset, severity of the consequence of the failure, and detectability of the failure:

PRN =Probability of failure* Severity* Detectability*

In hospitals, risk is a criterion in criticality assessment of medical devices, but the definition of risk differs from that used in RCM. After running an evaluation on medical devices, clinical engineers decide which should be included in the MEMP of the hospital based on their risk scores.

Fennigkoh and Smith [11] proposed a risk assessment method to group medical devices on the basis of their Equipment Management (EM) numbers, or the sum of the numbers assigned to the device's critical function, physical risk, and required maintenance:

EM= Critical Function + Physical Risk + Required Maintenance

Devices with an EM number above a critical value 12 are considered to have critical risk and thus are included in inspection and maintenance plans. In 1989, JCAHO recognized importance of this method and eventually in 2004 approved it as the standard (EC6.10) [5]. This standard allows hospitals not to perform scheduled inspection or maintenance tasks for certain pieces or types of medical equipment, if these tasks are not needed for safe and reliable operation [6]. Since then, Fennigkoh and Smith's method or its many variations have been used by clinical engineers [7]. Ridgway [12] in his recent paper emphasizes that preventive maintenance can provide a benefit for just a relatively few devices, and a significant number of repair calls are made due to random failures of device's components. Wang and Rice [22] propose simplified version of gradient risk sampling and attribute sampling to select a portion of equipment for inclusion. Clinical engineers believe that risk is not the only inclusion criterion, however, even though it is the most important one [23]. Other criteria which reflect the needs and reality of a hospital should be considered, including mission criticality, availability of backup, hazard notice, and recall history (24,25]). Taghipour et al. [26] presented a multi-criteria decision-making model to prioritize medical devices according to their criticality. Devices with lower criticality scores can be assigned a lower priority in a maintenance management program. However, those with higher scores should be investigated in detail to find the reasons for their higher criticality, and appropriate actions, such as 'preventive maintenance', 'user training', 'redesigning the device', etc. should be taken. In this paper, the authors also describe how individual score values obtained for each criterion can be used to establish guidelines for appropriate maintenance strategies for different classes of devices. Recently, Jamshidi et al [27] developed a fuzzy healthcare failure modes and effects analysis (HFMEA) method for prioritization of medical devices. The authors calculated the risk based on conditional probability of failures and consequence analysis.

6.1.6. Inspection and maintenance optimization models

Wang and Levenson [24] proposed a new interpretation of the function parameter and called it mission criticality, which they defined as the "equipment role or importance within the organisation's mission". Later Wang et al. 6] proposed a more explicit maintenance approach that uses patient risk-mission criticality as a classification method and a maintenance-strategy selection. According to Wang [9] ideally PM should be performed at time intervals just below the mean-time-between-failure (MTBF), as this would allow one to minimise resources while preventing the majority of failures. Wang further proposed that the theoretical ideal interval for SPIs is (SPI period =2*(1- uptime)*MTBF). Uptime or availability of equipment for use is measured as a percentage of the planned operational time. Baker [28] assessed validity of some widely-used models of age-related failure rate, such as the power-law and loglinear Poisson process, using large database of failures of many types of medical equipment. According to his research the power-law process is the best proposed model to study the dependence of failure rate on equipment age and on time since repair, which demonstrated a complete methodology for deriving optimum equipment replacement policies. The above study was limited to the use of mathematical models to assess failure rate and excluded the effect of PM on failure rate. Khalaf [29] suggested a maintenance model for minimizing the risk and optimizing the cost-effectiveness of medical equipment. The elements of both risk management and cost-effectiveness were evaluated together with the role of medical equipment suppliers. The results showed a poor overall performance and lack of effective procedures regarding risk and costs of maintenance programs. Therefore, Khalaf revised the model to suit clinical engineering departments in Palestinian hospitals. Khalaf et al [15] developed a mathematical model using a mixed integer based approach for maintenance operations schedules for medical equipment. In addition, they proposed a greedy algorithm to give an initial solution for the model. Tentative conclusions from preliminary analysis done by ARAMARK Healthcare's Clinical Technology Services show that current maintenance strategies are effective.

Taghipour et al. [26] considered a repairable system with components subject to hard and soft failures; soft failures are only rectified at periodic inspections and are fixed with minimal repairs. They propose a model to find the optimal periodic inspection interval on a finite time horizon. Taghipour and Banjevic [30] further present two inspection optimization models over finite and infinite time horizon for a multi-component repairable system subject to hidden failures. Recently, Zhang [31] demonstrated how a Condition Based Maintenance (CBM) program can be used to utilize field data and usage data, to minimize unnecessary maintenance, and to reduce service costs. In the case study, the service order data, local dispensing station logs, and install asset data on medicine dispensing products were analyzed. The case study shows that a significant cost saving can be achieved by utilizing the existing field and usage data to establish the CBM program in medicine dispensing product service. In addition, Khalaf et al. 32] proposed a global model to measure the probability of equipment being available using real data extracted from maintenance history of infusion pumps and ventilators and analysed using Matlab. To confirm the validity of the developed model, the survival analysis approach was used to develop a model that measures the survival of equipment as a function of maintenance and age of equipment. The method was first tested using simulated data and the findings confirm the validity of the proposed approach.

6.1.7. Maintenance outsourcing

When a health care institution lacks the technical skills or specialized assets needed for the maintenance of its medical technology, maintenance should be outsourced. Yet while outsourcing has grown in popularity, research on maintenance outsourcing for medical devices in academic literature remains scarce. Research into the outsourcing of medical device maintenance services and its associated risks in hospitals is still in its infancy stages, and that further progress in this field would benefit from additional empirical study grounded in management theory. In the healthcare environment this problem is worthy of study, as healthcare institutions lacking the capacity to deal with these issues may face significantly higher costs [33].

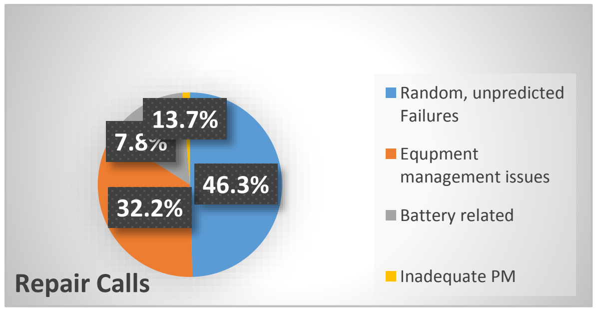

Figure 6. 3 Results of Ridgway's 2009 study [34]

6.1.8. Medical device-related facts and figures

6.1.8.1 Repair calls

A recent study conducted by Ridgway et al. [34] in which the authors used nine categories of codes to analyse ongoing repair calls cause coding and applied that to data captured from Master plan's database. They studied three different groups of facilities, one of which consists of 14 hospitals and analysed 2,598 repair calls made over three months during 2009. Some of the interesting findings are (Fig. 6.3):

I. 46.3 percent of repair calls are due to random, unpredicted failures associated with the device inherent reliability.
II. 32.2 percent of repair calls are due to equipment management issues such as accessories, physical stress, environmental stress and user related.
III. 7.8 percent of repair calls are battery related.
IV. 13.7 per cent is related to inadequate PM, set-up and uncategorised repair calls.

Another study was conducted by Wang et al. [35] in which the authors used maintenance data collected from 40,496 equipment records in various hospitals and applied specific failure codes developed by the team to measure maintenance effectiveness. The codes are assigned by CE professionals when completing SM and CM activities for all kinds of medical equipment. The summary of the preliminary findings of the above study is:

- Current maintenance strategies are effective but it is not clear whether they are efficient.
- It would be preferable to drop SPI on some equipment and use the time saved to help user. The time saved is estimated to be 25 per cent.
- Refocus resources from SM (SPI+PM) to higher impact tasks, e.g. use error tracking, self-identified failures, and repairs.

6.1.8.2 Observations

We looked at scholarly papers tackling the maintenance problems, scrutinizing three major branches of papers, including: mathematical models, empirical research on the maintenance of medical devices, and prioritization of medical devices for maintenance activities. Table 6.1 shows the existing literature on maintenance of medical devices between 1989 and 2014.

Table 6. 1 Studies related to maintenance of medical devices between 1989 and 2014

Author(Year)	Optimization/ Prioritization/ Empirical	Book/ Paper/ Thesis	Description
Fennigkoh and Smith (1989) [11]	Prioritization	Paper	Classification of medical equipment using three parameters
Wang and Levenson (2000) [24]	Empirical	Paper	Proposed mission criticality
Dhillon, 2000 [36]	Empirical	Book	Medical device Reliability
Ridgway, (2001)[25]	Prioritization	Paper	Classifying medical devices
Baker, (2001) [28]	Optimization	Paper	Data-based modeling of the failure rate of repairable equipment
Wang and Rice (2003) [22]	Empirical	Paper	proposed simplified version of gradient risk sampling and attribute sampling
Ridgway, M, 2003 [37]	Prioritization	Paper	Analysing PM data by FMEA
Hyman, 2003 [23]	Empirical	Paper	The Theory and Practice of Preventive Maintenance
Abdelbaset Khalaf, 2004 [29]	Optimization	Paper	Maintenance model for minimizing risk of medical equipment
Wang et al. (2006a) [6]	Empirical	Paper	Interview with Larry Fennigkoh
Wang et al. (2006b) [38]	Empirical	Paper	An strategy for incorporating multiple criteria
Hall (2006) [18]	Empirical	Paper	Evaluation of RCM method
Rice (2007) [7]	Empirical	Paper	Building an effective MEMP using FTA
Wang (2008) [9]	Empirical	Book	A Practicum for Biomedical Engineering
Ridgway (2008) [13]	Empirical	Paper	Decoding the PM puzzle
Ridgway (2009a) [8]	Empirical	Paper	Manufacturer-recommendation PM intervals
Ridgway (2009b) [12]	Empirical	Paper	Optimizing PM programs
Ridgway et al.(2009c) [34]	Empirical	Paper	Reducing Equipment Downtime
Stiefel, 2009 [20]	Empirical	Book	Medical Equipment Management Manual
Wang et al. (2010) [35]	Empirical	Paper	Evidence-based maintenance – part II
Khalaf et al. (2010) [15]	Empirical	Paper	Evidence-based mathematical maintenance model for medical equipment
Gentles et al. 2010 [21]	Empirical	Paper	Collecting comparative data on inventory and maintenance of the most critical devices used in hospitals
Wang et al. (2011) [39]	Empirical	Paper	Enhancing Patient Safety Using Failure Code Analysis
Taghipour (2008-12) [3,26,30]	Optimization& Prioritization	Thesis	Reliability and Maintenance of Medical devices
Cruz and Rincon (2012) [33]	Empirical	mapping review	Medical device maintenance outsourcing
Jamshidi et al. (2012) [27]	Prioritization	Paper	A risk-based Maintenance Strategy for prioritization of Medical Equipment
Wang, 2012 [2]	Empirical	Book	Medical Equipment Maintenance: Management and Oversight
Afshin Jamshidi(2012-16) [40]	Optimization& Prioritization	Thesis	Risk-based Inspection& Maintenance of Medical Devices
Khalaf et al. (2013) [32]	Optimization	Paper	The effect of maintenance on the survival of medical equipment
Wang et al. (2013a) [41]	Empirical	Paper	An estimate of patient incidents caused by medical equipment maintenance omissions
Wang et al. (2013b) [42]	Empirical	Paper	Evidence-Based Maintenance
Bassel et al (2013) [43]	Prioritization	Paper	Revisiting and Reassessing the major factors that affect device risk scores.
Richard C. Fries (2013) [44]	Empirical	Book	Reliable design of Medical Devices
Qian Zhang (2013) [31]	Optimization	Paper	Condition Based Maintenance Used in Medical Devices

6.1.8.3. Patient incidents caused by medical equipment maintenance omissions

Patient incidents involving medical equipment are fairly common, but it is unclear how many of them are actually caused by maintenance omissions, i.e., improper or lack of scheduled and unscheduled maintenance. This question is important because hospitals have been allowed by The Joint Commission (TJC) to develop their own maintenance practice instead of following manufacturers' recommended frequencies and procedures. Wang et al. [42] reported an attempt to estimate the magnitude of such incidents using the sentinel events database collected by TJC. Using worst-case assumptions, the estimates ranged 0.14-0.74 in 2011, which translates into .00011-.0006 per million equipment uses. These extremely low values were confirmed by a survey conducted by AAMI in which 1,526 participants reported no known patient incidents traceable to maintenance practice. Wang states that it seems unwise to mandate clinical engineering (CE) professionals to refocus their attention to manufacturers' maintenance recommendations versus active involvement in technology management and, especially, user training and assistance, to address the most frequent root causes of sentinel events.

Figure 6.4 shows the classification of 2011 sentinel events reviewed by TJC as a percentage of the 1,242 events reported that year. Medical equipment-related events totaled 39 (3.1%) and represented the 10th highest category. These values are consistent with prior years 'data, as there were 176 events related to medical equipment in the period of 2004-2011, representing 2.9% of the grand total of 6,093 events and the11th highest category. Healthcare organizations that

report sentinel events to TJC are required to share its RCA results and TJC reviews them and assign one or more root causes to each event' Multiple causes are often assigned for each event because the outcome is typically the consequence of the failure or inefficiency of one or more processes instead of a single cause. Figure 6.5 shows the root causes of the medical equipment-related events as determined by TJC for the medical equipment-related events for the period of 2004-2011as a percentage of the 620 causes identified. Since TJC did not provide the root causes of the39 medical equipment-related events reported in2011, it was not possible to assess if these causes differ significantly from those of prior years [42].

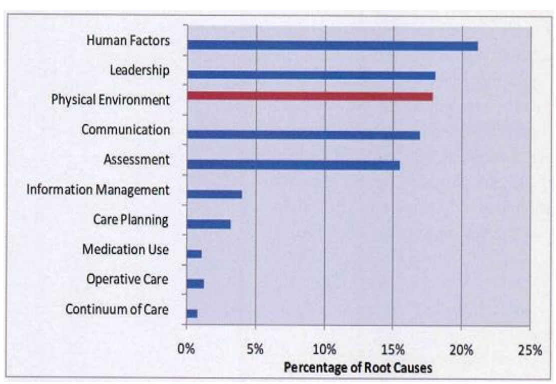

Figure 6. 4 Number of sentinel events reported to TJC in 2011

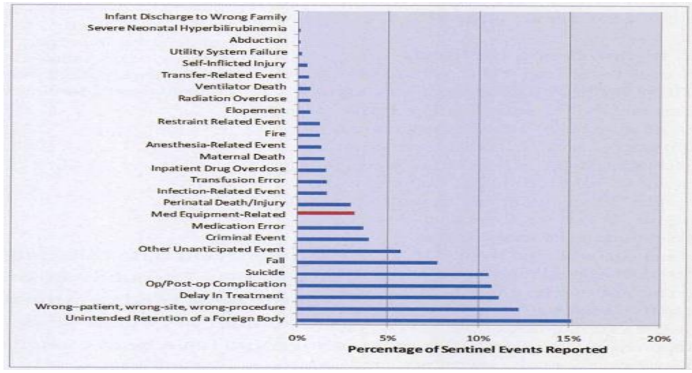

Figure 6. 5 Number of root causes of sentinel events

6.1.8.4. The effect of maintenance on the survival of medical equipment

The recent analysis using survival approach reveals that conducting preventive maintenance (PM) on the selected medical equipment had an impact on survival of equipment. However, the manufacturer's recommended PM intervals do not correlate to the failure rate encountered. This will contribute to the debate on PM manufacturer's recommended intervals and might lead to the revision of maintenance strategies implemented by hospitals and clinical engineering (CE) practitioners [32].

6.1.9. Conclusion and directions for future works

This paper has attempted to provide a literature review and assessment of the status of research dealing with the maintenance of medical devices. To the best of our knowledge, this is the first paper that has tackled this issue in a review. Based on literature published so for, totally 34 studies exist. These studies include 27 papers, 2 theses and 5 books regarding maintenance of medical devices. As Fig. 6.6 shows, majority of papers are empirical. According to this figure, out of 34 research studies, 64% are empirical, 19% are prioritization and 17% are optimization models.
In addition, Fig 6.7 shows the distribution of the reviewed articles. This figure depicts increasing status of research papers during 1989 till 2014. However it reveals that not much research has been presented in the literature during 25 years to address proper strategies and the methods for implementing them, while maintenance optimization models are widely developed and applied in other industries. In addition, this review shows that most of researches have been done in US, while research status on maintenance strategies in other developed countries such as Canada remain scare. The most significant finding of this review is the need for further research in the field of maintenance of medical devices, as indicated by the gaps in existing research detailed above. The main suggestions for future work are as follows:

1- Although there are several research works on maintenance strategy selection in different industries, there is still a need to use a systematic mathematical approach to help the decision maker in taking an appropriate decision for selecting the maintenance strategy in healthcare industries. There is no study done in healthcare area for selecting best maintenance strategy. There are a large number of tangible and intangible criteria, which often are in conflict with each other, that should be considered in selection of the best maintenance strategy. For these reasons, it is particularly difficult to equipment managers choose the best maintenance strategy for each piece of equipment from a set of feasible alternatives. As a result, using multi attribute decision making methods can be useful.

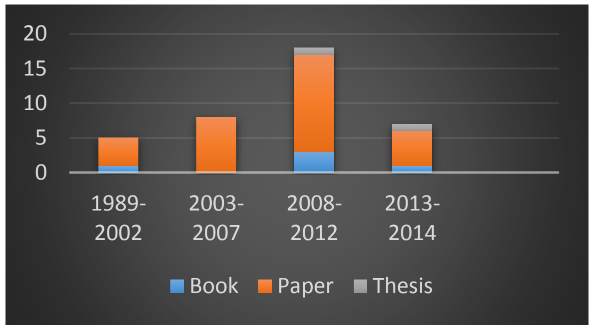

Figure 6. 6 Classification of papers from 1989 to 2014

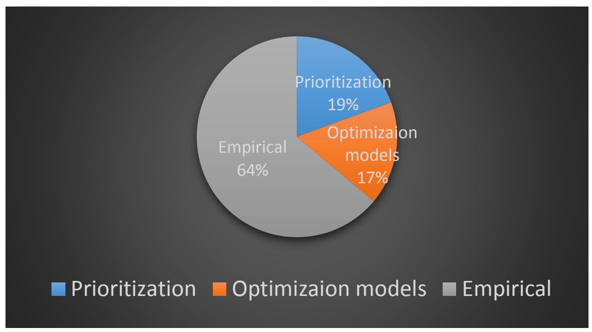

Figure 6. 7 Distribution of the reviewed articles

2- Although there are a number of research works on maintenance strategy selection in healthcare industries, there is still a need to use a comprehensive framework for prioritizing critical medical devices.

3- Research into the outsourcing of medical device maintenance services in hospitals is still in its infancy stages, and that further progress in this field would benefit from additional empirical study grounded in management theory.

4- Researcher need to measure outcomes such as uptimes and failure rates as part of their PM.

5- The use of suitable techniques and methodologies, careful investigation during the risk analysis phase, and its detailed and structured results are necessary to make proper risk-based maintenance decisions.

6- Last but not least, authors working in this area should apply new integrated risk-based maintenance models rather than traditional methods to consider different uncertainties in hospital environment, expert's opinion, and etc.

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6.2 A risk-based Maintenance Strategy using Fuzzy HFMEA for prioritization of Critical Medical Equipment

Résumé: Les équipements médicaux tels que les machines d'anesthésie nécessitent une maintenance essentielle pour assurer un haut niveau de fiabilité dans les services de santé. Une stratégie de maintenance basée sur les risques (RBP) est un outil utile pour concevoir un programme d'entretien rentable; Son objectif est de réduire le risque global. Dans l'évaluation des risques d'un scénario d'échec dans les organisations de soins de santé, les conséquences ont souvent trois caractéristiques clés: l'effet de la sécurité des patients, l'effet des ressources de maintenance et des pertes économiques. Dans cet article, pour quantifier la gravité des lésions du patient et des ressources de maintenance, une méthode d'analyse de mode de défaillance et leurs effets floue (FFMEA) est développée à partir de données provenant de cinq experts. En fonction de la probabilité conditionnelle de défaillances et de l'analyse des conséquences, le risque est calculé et priorisé. Pour faciliter la comparaison des échecs, un nouvel indice de risque est introduit. Un exemple numérique illustre la faisabilité de l'approche proposée pour l'équipement médical critique. Les résultats indiquent que cette méthode serait apte à identifier les défaillances critiques dans le processus d'entretien des équipements médicaux complexes en tenant compte des avis de cinq experts et la méthode proposée peut augmenter la fiabilité des machines à haut risque dans les industries de la santé.

Mots-clés: Maintenance axée sur le risque, Analyse de mode de défaillance et leurs effets floue, Logique floue, Sécurité des patients, Appareils d'anesthésie.

6.2 A risk-based Maintenance Strategy using Fuzzy HFMEA for prioritization of Critical Medical Equipment

Abstract: Medical equipment such as anaesthesia machines require essential maintenance to ensure high levels of reliability in healthcare services. A risk-based maintenance (RBP) strategy is a useful tool to design a cost-effective maintenance schedule; its objective is to reduce overall risk. In risk assessment of a failure scenario in healthcare organizations, consequences often have three key features: patient safety effect, maintenance resources effect and economic loss. In this paper, to quantify the severity of patient injury and maintenance resources, a fuzzy healthcare failure modes and effects analysis (HFMEA) method is developed using data derived from five experts. Based on conditional probability of failures and consequence analysis, the risk is calculated and prioritized. To facilitate the comparison of failures, a new risk index is introduced. A numerical example illustrates the feasibility of proposed approach in critical medical equipment. The results indicate that this method would be fit for identifying critical failures in complex medical equipment maintenance process by considering different ideas of five experts and the proposed method can increase the reliability of high risk machines in healthcare industries.

Keywords: Risk-based maintenance (RBM), Healthcare Failure modes and effects analysis (HFMEA), Fuzzy Logic, Patient safety, Anaesthesia machines.

6.2.1. Introduction

Maintenance of medical equipment is not just a question of repairing broken things. It is an integral part of managing the whole lifecycle of equipment. Medical equipment brings along with it associated benefits and problems. The problem that draws the most attention is maintenance. Lack of a maintenance policy can result in no advance planning for maintenance budgets and thus no availability of spares and accessories. Many laboratories and healthcare programmes suffer because the installation and maintenance requirements are not planned in advance. This renders much equipment unusable and many devices lie idle because of lack of spares or funds. There are two types of maintenance of Medical Equipment; Corrective Maintenance (or Repair) and Preventive Maintenance (Planned or Scheduled) (Ministry of Health and Family Welfare, 2010).

Risk-based maintenance (RBM) methodology provides a tool for maintenance planning and decision making to reduce the probability of failure of equipment and the consequences of failure. The concept of risk-based maintenance was developed to inspect the high-risk components usually with greater frequency and thoroughness and to maintain in a greater manner, to achieve tolerable risk criteria. In an RBM strategy in healthcare areas, the risk of a particular failure scenario can defined as the product of likelihood and consequences. These consequences have three key features: patient safety effect, maintenance resources effect and economic loss. With regard to the problem of how to use available resources in the most effective way, cost-effective maintenance strategies are both vital and necessary.

Over the past few decades, maintenance strategies have been through a major metamorphosis from primitive breakdown maintenance to the more sophisticated strategies like condition-based maintenance and reliability-centered maintenance (Patton, 1983; Rao, 1996; Rausand, 1998). The risk-based maintenance (RBM) strategy, which emerged in the 1990s, provides a new vision for asset integrity management (Harnly, 1998; Kumar, 1998; Montgomery, & Berratella, 2002; Backlund, & Hannu, 2002; Farquharson, & Choquette, 2002; Kjellen, Motet, & Hale, 2009). The RBM strategy uses the risk level as a criterion to plan maintenance tasks and has received increasing attention from researchers in recent years. Apeland and Aven (2000) presented a Bayesian method for RBM optimization as an alternative to the probabilistic framework. Jovanovic (2003) reviewed practices and trends in the area of risk-based inspection and maintenance in power and process plants by comparing European and US studies. Arunraj and Maiti (2007) reviewed research on RBM and risk assessment technologies. Khan and Haddara (2003) proposed a complete framework for the RBM strategy, in which the probability of the unexpected event was determined using fault tree analysis and the consequences involved the estimation of system performance loss, financial loss, human health loss and environmental and/or ecological loss. Arunraj and Maiti (2010) used risk as a criterion to select the appropriate maintenance policy and the results showed that condition-based maintenance was suitable for high-risk equipment and corrective maintenance for low-risk equipment. Capuano and Koritko (1996) and Ridgway (2001) have used the risk-based policy in the maintenance of medical devices. Taghipour (2010) proposed prioritization of medical equipment for maintenance decisions.

However these researches indicate that there is few researches related to using risk based maintenance for critical medical devices and these researches don’t cover all aspects of prioritization of critical medical equipment. For example there is no attention to several experts' opinion or all of the experts have the same weights while they have different knowledge and experience and so on. In response, in the present paper, after finding the possible potential failures of medical devices, to judge the severity of the patient safety effect and maintenance resources effect, at the first step the failure probability of a medical device is calculated using a Weibull distribution model. Then, a fuzzy HFMEA (Healthcare Failure modes and effects analysis) is developed based on information derived from five experts. In the second step, for risk evaluation, a new risk index is introduced to facilitate the comparison between the calculated risks. To integrate the three risk indices into a single index, weight factors that represent the relative importance of the three consequence features are determined using an analytic hierarchy process (AHP). The remainder of this paper is organized as follows: section 2 proposes the framework of the improved RBM strategy; a numerical example is presented in section 3 to demonstrate the detailed procedures of the methodology; and finally, conclusion and future research are presented in the last section.

6.2.2. Risk-based maintenance (RBM) strategy

The RBM strategy is a quantitative approach integrating reliability analysis and risk assessment to develop a cost-effective maintenance policy. Generally the RBM strategy consists of the following four modules: identification of a system scope, risk assessment, risk evaluation and maintenance planning. Risk can be seen as a natural consequence of medical devices activities. It is impossible to eliminate all risks, so risks are reduced to an acceptable level. Risk assessment requires the application of the appropriate techniques to analyze the risk of an unexpected failure scenario, which involves the estimation of the likelihood (failure probability) and consequences (severity of the undesired failure scenario) (Wang, Cheng, Hu and Wu 2012). When a failure scenario occurs in healthcare organizations, the consequences often have three key features: patient safety effect, maintenance resources effect and economic loss. Economic loss can be evaluated directly in terms of money. It should be noted that a medical device is prone to several failure modes, and each failure mode may lead to different consequences.

Therefore, FMEA is an appropriate method to analyze different failure modes and their consequences. The FMEA methodology is one of the risk analysis techniques recommended by international standards such as Society of Automotive Engineers, US Military of Defense (Wang, Cheng, Hu and Wu 2012), and Joint Commission on Accreditation of Healthcare Organizations (JACAHO). FMEA is organized around failure modes, which link the cause and effect of failures. FMEA takes three parameters into consideration; Severity (S), Occurrence (O), and Detection (D) which are usually evaluated through easily interpreted linguistic expressions, each has a score rage (minimum of 1 to a maximum of 10) but, traditional FMEA considers opinion of only one expert while, FMEA is a team work and all of the different opinions should be considered in order to gain better and accurate results. Hence, in the presented method, the purpose of performing fuzzy HFMEA is to identify every device's failure modes and their effects (Severity) concerning patient safety effect and maintenance resources effect based on information derived from all relevant experts. In addition, the opinions of all experts by assigning their knowledge and experience as a weight is considered. It should mentioned that sum of weights for experts should be one. In this paper weights for five experts are considered 0.1, 0.25, 0.15, 0.2, 0.3, respectively.

In this case, it is reasonable to assume that a failure mode is almost certain to be detected once it occurs under current inspections, which corresponds to a Detection score of "1"; thus the RPN would be in accordance with the concept of risk in RBM which is defined as the product of likelihood and consequences (Wang, Cheng, Hu and Wu 2012). According to domain experts, severity of patient safety can be divided into five levels: minor, low, moderate, high and very high; each level is described by linguistic terms in detail (Table 6.2). In addition severity of maintenance resources can be divided into three levels as mentioned in Table 6.3 (Li, Ma, Gong and Wang 2011). The FMEA is performed to identify failure modes of each device; then the experts give individual judgments on the severity level of the patient safety effect and maintenance resources effect for each failure mode based on their own knowledge and experience, which are expressed as scores in Table 6.2 and Table 6.3 However, this may not be realistic in real applications. Therefore, in this paper we treat the severity factors as fuzzy variables and evaluate them using fuzzy linguistic terms. Then, after assigning certain numbers to each failure, we have normalized them to get the fuzzy numbers.

Table 6. 2 Description of patient safety effect

Consequence	Level	Score	Description
patient safety effect	Minor	1-2	Less or no effect
	Low	3-4	Minor injury or illness
	Moderate	5-6	Moderate injury or illness(can recovery)
	High	7-8	Debilitating injury or serious long-term illness
	Very high	9-10	Death

Table 6. 3 Rating guidelines of impact on the level of maintenance resources (M) (Li, Ma, Gong and Wang 2011)

Maintenance tools	Score	Maintenance materials	Score	Maintenance skills	Score
General tools (multiple alternatives)	1	No special requirements	1	No special requirements	1

General tools (no alternatives)	2	Special requirements	2	Level requirements	2
Special tools	3			High requirements	3

To obtain the defuzzified values, the membership function for the severity factor needs to be defuzzified. We have used center of maximum (COM) method for defuzzification in Table 6.2.5. In the COM method, the average of the minimum defuzzified value and the maximum defuzzified value is considered to be the expected R_1 (P risk) and R_2(M risk) (Jamshidi 2010).

$$R_1 = \text{dP} \times F_i(\text{t}) \quad (1)$$
$$R_2 = \text{dM} \times F_i(\text{t}) \quad (2)$$

Where, dP is defuzzified patient safety risk (P risk), dM is defuzzified maintenance resources risk (M risk), and F_i(t) is the probability of failure mode i.

Economic loss (R_3) is a combination of the maintenance cost (MC) and delayed treatment loss (DL). In healthcare organizations, maintenance costs typically consists of both fixed costs and variable costs.

$$MC = C_f + DT.C_v \quad (3)$$

Where MC is the maintenance cost, C_f is the fixed cost of the failure scenario ($US), C_v is the variable cost per hour of downtime ($$h^{-1}$), DT is the downtime, which includes the total time the device would be out of service as a result of the failure scenario (hours). The delayed treatment loss (DL) can be estimated by multiplying downtime (DT) and delayed treatment loss per hour (DLPH, $$h^{-1}$).

$$\text{DL} = \text{DT. DLPH} \quad (4)$$
$$R_3 = \text{DL+MC} \quad (5)$$

The possible risk in a failure scenario involves three risk parts: patient safety effect (R_1), maintenance resources effect (R_2) and economic loss (R_3); each can be calculated by multiplying the failure probability and the corresponding consequences (normalized numbers).

6.2.3. New proposed risk index for risk evaluation

The purpose of risk evaluation is to judge whether the calculated risk is acceptable. In order to facilitate the comparison risk indices of failure modes, a new risk index (RI) is introduced. The risk index of the three risk parts should be integrated into a single index. Thus, weight factors that respectively represent the relative importance of the three consequence features are required. The AHP is a popular multiple criteria decision-making tool, and has been used in almost all applications related to decision making (Vaidya, & Kumar, 2006; Ho, 2008). Its basic principal is that the weight factors are derived from comparing the importance of factors two at a time. In the present paper, AHP is used to determine the values of three weight factors: patient safety effect and economic loss are ranked as being more important than maintenance resources effect. On the basis of the three weight factors, the risk index can be calculated as follows:

$$RI = \sqrt[3]{w_1 \times R_1 + w_2 \times R_2 + w_3 \times R_3} = \sqrt[3]{RI_1 + RI_2 + RI_3} \tag{6}$$

Where w_1 , w_2 and w_3 are weight factors of patient safety effect, maintenance resources effect and economic loss, respectively; RI is the risk index of a failure scenario. Now we can prioritize our medical devices by using the new RI. Devices with higher scores should be investigated in detail to find the reasons for their higher criticality, and appropriate actions, such as ‘preventive maintenance’, ‘user training’, ‘redesigning the device’, etc. should be taken.

6.2.4. Numerical example

We present a simplified example to illustrate the model’s application in the prioritization of critical medical devices for maintenance activities. We extracted information of 4 different medical devices from Taghipour's paper (Taghipour, 2010). As Table 6.4 shows, we have multiple failure modes for device A and one failure mode for the rest.

Table 6. 4 Risk assessment of the failure modes in four different devices (Taghipour, 2010)

Device No.	Device name	Failure mode	Failure effect
A	Infant incubator	Audio alarms are not working	Injury
		Motor is stuck	Death
B	ECG physiological telemetry unit	Telemetry does not detect lead off	Inappropriate therapy
C	CT scanner	Wire harness for CT dislodged	Delayed treatment
D	External pacemaker	Pulse generator failure	Death

6.2.4.1 Risk assessment

6.2.4.1.1. Failure probability of basic event

It is assumed that the device failure process follows the two-parameter Weibull distribution. The failure probability at a given time t can be determined from the cumulative distribution probability of the facility, Eq.7 (Wang, 2012).

$$F(t) = 1 - exp\left[-\{\frac{t}{\beta}\}^{\alpha}\right] \tag{7}$$

The values of the two parameters α (Shape parameter) and β (Scale parameter) can be obtained from failure and maintenance records using maximum likelihood estimations (Shin, Lim and Lie, 1996). We assume that α and β data are given as table 6.5. Then, cumulative distribution probability during 1 year can be calculated; the results are listed in Table 6.5.

Table 6. 5 Parameters of the probability distribution function

Device	Failure mode	α	β	F(t)
A	Failure mode 1	1.7765	12.8924	0.5854
	Failure mode 2	2.8897	14.1356	0.4636
B	Failure mode 3	2.2255	10.3058	0.2592
C	Failure mode 4	1.7411	11.343	0.2888
D	Failure mode 5	1.9425	16.6722	0.4102

6.2.4.1.2. Identifying risk factors and consequence analysis

In this step at first, five experts are selected from the operation, maintenance and management departments of the healthcare organization. Then FMEA is used to identify the failure modes of each device as listed in Table 6.6; these five experts are asked to make their own judgments on the severity of the patient safety effect and maintenance resources effect for each failure mode. The experts give score values for patient safety effect (P effect) and maintenance resources effect (M effect) for each failure mode. In third column of Table 6.6, the numbers inside the parenthesis refer to weights of each expert based on their knowledge and experience. In fifth column of Table 6.6, we have normalized the P effect scores to reach fuzzy numbers (N-P). We do the same approach for M effect to get the normalized numbers of M (N-M). In the next step we have used COM method to calculate the defuzzified numbers for N-P and N-M. Finally, the patient safety risk (P risk) and maintenance resources risk (M risk) is calculated as the product of the failure probability and consequence scores by using Eq.1 &2. The results are listed in Table 6.6.

Table 6. 6 Risk of patient safety effect and maintenance resources effect

Device	Failure mode	Expert(Weight)	Severity of consequences											P risk	M risk
			P effect	N-P	N-M*W	Defuzzified P	M effect				N-M	N-M*W	Defuzzified M	R_1	R_2
							M_1	M_2	M_3	M total					
A	FM 1	Exp1(0.1)	8	0.190	0.019	0.038	1	2	1	2	0.049	0.005	0.068	0.022	0.04
		Exp2 (0.25)	7	0.167	0.042		2	2	3	12	0.293	0.073			
		Exp3 (0.15)	9	0.214	0.032		3	1	1	3	0.073	0.011			
		Exp4(0.2)	10	0.238	0.048		3	2	1	6	0.146	0.029			
		Exp5(0.3)	8	0.190	0.057		3	2	3	18	0.439	0.132			
	FM 2	Exp1(0.1)	6	0.214	0.021	0.051	1	2	2	4	0.114	0.011	0.070	0.024	0.032
		Exp2 (0.25)	5	0.179	0.045		3	2	3	18	0.514	0.129			
		Exp3 (0.15)	1	0.036	0.005		3	1	1	3	0.086	0.013			
		Exp4(0.2)	7	0.250	0.050		2	1	2	4	0.114	0.023			
		Exp5(0.3)	9	0.321	0.096		1	2	3	6	0.171	0.051			
B	FM 3	Exp1(0.1)	8	0.235	0.024	0.055	2	2	3	12	0.353	0.035	0.035	0.014	0.009
		Exp2 (0.25)	7	0.206	0.051		3	1	2	6	0.176	0.044			
		Exp3 (0.15)	5	0.147	0.022		2	1	3	6	0.176	0.026			
		Exp4(0.2)	4	0.118	0.024		3	2	1	6	0.176	0.035			
		Exp5(0.3)	10	0.294	0.088		1	2	2	4	0.118	0.035			
C	FM 4	Exp1(0.1)	5	0.200	0.020	0.170	1	1	3	3	0.073	0.007	0.037	0.049	0.011
		Exp2 (0.25)	3	0.120	0.030		2	2	2	8	0.195	0.049			
		Exp3 (0.15)	7	0.280	0.042		3	2	3	18	0.439	0.066			
		Exp4(0.2)	8	0.320	0.064		3	2	1	6	0.146	0.029			
		Exp5(0.3)	2	0.080	0.024		2	1	3	6	0.146	0.044			
D	FM 5	Exp1(0.1)	6	0.188	0.019	0.150	2	1	3	6	0.222	0.022	0.044	0.062	0.018
		Exp2 (0.25)	5	0.156	0.039		2	2	2	8	0.296	0.074			
		Exp3 (0.15)	4	0.125	0.019		3	1	3	9	0.333	0.050			
		Exp4(0.2)	8	0.250	0.050		1	1	2	2	0.074	0.015			
		Exp5(0.3)	9	0.281	0.084		1	2	1	2	0.074	0.022			

The fixed costs, variable costs and downtimes of the device are obtained from maintenance records. In this paper we assume that the results of fixed costs, variable costs and downtimes for each device's failure are as Table 6.7. We used equation 3, 4 and 5 to obtain economic loss in Table 6.7. Finally, we normalized R_3 numbers because they are not adjusted with R_1 and R_2 numbers.

Table 6. 7 Risk of economic loss

Device	Failure mode	C_f/$	C_v/$$h^{-1}$	DT /hours	DLPH/$$h^{-1}$	Economic loss/$	R_3 /$	Normalized R_3
A	FM 1	2152	158	24.000	1968.000	53176	31129.230	0.165
	FM 2	7874	316	48.000	1969.000	117506	54475.781	0.288
B	FM 3	1575	158	24.000	984.000	28983	7512.393	0.040
C	FM 4	3850	316	60.000	1968.000	140890	40689.032	0.215
D	FM 5	3937	316	72.000	1968.000	168385	69071.527	0.365

6.2.4.1.3. Using new risk index for risk evaluation

In this paper, AHP was used to determine the three weight factors as follows: patient safety effect (w_1= 0.5958), environmental threat (w_2 =0.1958) and economic loss (w_3 =0.2084). The detailed calculation procedures of AHP are not presented here. The risk index calculations for each device are shown in Table 6.8 using Eq.6.

Table 6. 8 Risk evaluation results

Device	Failure mode	RI_1	RI_2	RI_3	RI	Rank
A	FM 1	0.01203	0.00783	0.03429	0.37833	4
	FM 2	0.01273	0.00635	0.06001	0.42925	2
B	FM 3	0.00771	0.00179	0.00828	0.26100	5
C	FM 4	0.02649	0.00207	0.04482	0.41866	3
D	FM 5	0.03320	0.00357	0.07609	0.48325	1

6.2.4.1.4. Ranking medical devices

Our model is now ready to rank critical medical devices. Based on the last column in the table 6.8, the prioritization of devices is: FM5, FM2, FM4, FM1 and FM3. Devices with lower criticality scores can be assigned a lower priority in a maintenance management program. However, those with higher scores should be investigated in detail to find the reasons for their higher criticality, and appropriate actions, such as ‘preventive maintenance’, ‘user training’, ‘redesigning the device’, etc, should be taken.

6.2.5. Conclusion and Future research

This paper presents a methodology by using an improved RBM strategy and fuzzy HFMEA for prioritization of critical medical devices. When quantifying the risk of a failure scenario in healthcare sectors, a consequence analysis involves three features: patient safety effect, maintenance resources effect and economic loss. However, it should be noted that it is a sensitive matter to measure patient injury and maintenance resources in monetary terms; thus a fuzzy HFMEA method was developed to determine the severity of the patient safety effect and maintenance resources effect, according to the opinions of five experts and by assigning different weights to their opinions. Maintenance process is the research object of FMEA that defects of maintenance procedures can be found; therefore, the problems that may exist in the maintenance process of critical medical devices could be predicted by adopting the technology of HFMEA. The results show that the new integrated fuzzy HFMEA and RBM strategy is a simple tool to prioritize critical medical devices. In addition, this method introduce new risk index which consider all opinions of experts team and assign weights to them based on their knowledge and experience. Future research should focus on the design of maintenance strategies for better scheduling of inspections and maintenance besides, other features such as age of a device, failure frequency, cost of repair and etc. can be added to new risk index for considering all aspects in critical medical devices.

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6.3. A comprehensive Fuzzy Risk-based Maintenance Framework for Prioritization of Medical Devices

Résumé: Les équipements médicaux tels que l'incubateur pour nourrissons, la pompe à perfusion, le scanner CT, etc. doivent être maintenus correctement pour répondre aux normes de fiabilité adéquates dans les services de santé. Cet article propose un nouveau cadre de priorisation exhaustif axé sur les risques pour la sélection de la meilleure stratégie de maintenance. Le cadre comprend trois étapes. Dans la première étape, on applique une méthode d'analyse des modes de défaillance et des effets floue (FFMEA) en considérant plusieurs facteurs d'évaluation des risques. Dans la deuxième étape, sept dimensions diverses, telles que les risques liés à l'utilisation, l'âge et l'utilisation, sont appliquées pour tenir compte de tous les aspects des dangers et des risques inhérents à la hiérarchisation des dispositifs médicaux. Enfin, on introduit une méthode simple dans la troisième étape pour trouver la stratégie de maintenance la plus appropriée pour chaque dispositif en fonction des scores produits par les étapes précédentes. Un exemple numérique illustre l'approche proposée et montre que, grâce à la méthode présentée dans ce document, les gestionnaires peuvent facilement classer les dispositifs médicaux pour les activités d'entretien en fonction de leurs scores de criticité. La mise en œuvre de ce cadre pourrait accroître la disponibilité des machines à haut risque dans les industries de la santé. En outre, ce cadre peut être appliqué dans d'autres industries essentielles telles que l'aviation en modifiant certains critères et dimensions.

Mots-clés: Dispositifs médicaux, FMEA, Priorité à la criticité, Maintenance axée sur le risque, Hôpitaux, Prise de décision multi-critères

6.3. A comprehensive Fuzzy Risk-based Maintenance Framework for Prioritization of Medical Devices

Abstract: Medical equipment such as Infant incubator, Infusion pump, CT scanner, and etc. should be maintained properly to meet adequate standards of reliability in healthcare services. This paper proposes a new comprehensive risk - based prioritization framework for selecting the best maintenance strategy. The framework encompasses three steps. In the first step, a fuzzy failure modes and effects analysis (FFMEA) method is applied by considering several risk assessment factors. In the second step, seven miscellaneous dimensions such as use-related hazards, age, and utilization are applied to consider all aspects of hazards and risks in prioritization of medical devices. Finally, a simple method is introduced in the third step in order to find the most suitable maintenance strategy for each device according to the scores produced by the previous steps. A numerical example illustrates the proposed approach and shows that, through the method introduced in this paper, managers can easily classify medical devices for maintenance activities according to their criticality scores. Implementation of this framework could increase the availability of high risk machines in healthcare industries. Moreover, this framework can be applied in other critical industries such as aviation by modifying some criteria and dimensions.

Keywords: Medical devices, FMEA, Criticality prioritization, Risk-based maintenance, Hospitals, Multi criteria decision making

6.3.1. Introduction

Nowadays, safety of medical device and the hazards associated with utilization of them is one of the critical issues for healthcare organizations across the world [1]. Medical devices are instruments or machines that are used to diagnosis, monitor, treat, or prevent disease or other conditions. Degradation in the performance of critical medical devices and inadequately maintained medical equipment create an unacceptable risk of patient injury. In addition, there are risks of injury to clinical staff from simple, direct hazards, such as accidental contact with electrified parts or from mechanical failures within the device [3], for example defects in ultrasound machines, defective artificial cardiac valves, leakage of insulin pumps [4], and high number of errors in CT scans which leads to patients receiving 10 times the intended dose of radiation in some cases. Thus, the maintenance of medical devices is fundamental and it calls for an effective and efficient framework to prioritize medical devices for maintenance activities based on key criteria and choose the best maintenance policy for each device.

Clinical engineering departments in hospitals have been developing programs such as Medical Equipment Management Program (MEMP) to reduce risks associated to medical devices and to promote the safety of medical devices in support of patient care. Some risk based MEMP methods have been presented for assessment of devices and are currently in use. These models consider risk in terms of maintenance requirements of medical device, function of medical device, and physical harm/risk. However, other important criteria such as the number of patients served, economic loss, mean time to repair (MTTR), and use-related hazards, among others are overlooked. Rice [5] in his paper mentions that, “although these methods do reduce risks, they are not near optimal”. Besides, in most of the proposed models equal risk levels are assigned to similar devices and the operational and environmental conditions and independently of the hospital's mission statement are overlooked. This could lead to misclassifying devices, such as steam sterilizers, as low risk [6].

This paper presents a novel fuzzy multi-criteria decision making (FMCDM) approach to the medical device prioritization problem within a Risk-based Maintenance (RBM) framework. This comprehensive approach first prioritizes medical devices based on their criticality and then propose a diagram for selecting appropriate maintenance strategy in healthcare organizations. The two objectives of this research are (1) to revisit and reassess the major criteria and sub criteria that can affect medical devices risk scores, and (2) to propose a three steps approach for clinical engineers to prioritize medical devices and select the best maintenance strategy for them. The first step consists in applying FFMEA method to calculate the Risk Priority Index (RPI_D) for each device. In the proposed FFMEA model, three criteria – Severity (S), Occurrence (O) and Detection (D) – and eight sub-criteria have been considered. In the second step, seven miscellaneous dimensions are applied and Total Intensity (TI) score is calculated based on weighted sum of seven miscellaneous dimensions in order to take into account other aspects of hazards as well as S, O and D. Finally, in the third step, a maintenance planning diagram is proposed according to the scores produced by the previous steps. The proposed approach is illustrated by an academic example including five medical equipment.

The rest of this paper is organized as follows. Section 2 draws a literature review on the existing approaches to the medical device prioritization problem. Section 3 describes the proposed approach, while Section 4 illustrates its application on an academic numerical example. Conclusions and directions for future research are presented in Section 5.

6.3.2. Literature review

The prioritization of medical devices into risk management programs based on risk scores has become a capital task for healthcare organizations. The medical equipment standards presented by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have forced hospitals in US to use their own risk management tools in order to decide which equipment must be involved in the MEMP [2]. In 1989, Fennigkoh and Smith [10] proposed a device classification scheme based on three criteria: maintenance requirements, physical harm/risk and equipment function. They classified medical equipment by assigning scores to the three criteria and calculating equipment management (EM) number using the summation of values assigned to the three criteria. Their approach includes any device with EM number greater than or equal 12 in the MEMP. In 2004, JCAHO approved the Fennigkoh and Smith method and introduced the standard EC6.10 [11]. This method has been widely used after publication in The Joint Commission. However, this method is not appropriate for risk management because it merely computes an arithmetic average over three factors, and it is rather insensible to changes on the estimated risk of medical equipment. In addition, all of three criteria have the same weight and different experts' opinions are ignored and so on. As Tawfik et al. [7] has mentioned in their recent paper, these shortcoming could causes some critical equipment (such as blood gases analyzers, hematology analyzers, and steam sterilizers) to be classified as low risk because they have low scores in two criteria (physical harm and equipment function).

In 1996, the American Society for Healthcare Engineering (ASHE) [12] presented a Classification Scheme for ranking medical equipment according to the five criteria; equipment function (E), clinical application (A), preventive maintenance requirements (P), probability of equipment failure (F), and environmental use (U). A total score (T) is calculated for each component using the following Equation.

$$T = E + A + [(P + F + U) /3] \quad (1)$$

Wang and Levenson [6] proposed a new interpretation for the equipment function criterion proposed in [10], and they suggested that it should be replaced with 'mission criticality' criterion as the equipment's importance. In addition, they added another criterion called 'equipment utilization rate (UR)' to the Fennigkoh and Smith's Equation. Finally, they proposed the following equation for calculating Equipment Management Rating (EMR).

$$EMR= [UR \times (\text{Mission Critical} + 2\times \text{Maintenance})] + 2\times \text{Risk} \quad (2)$$

where 'risk' scores are obtained from the Emergency Care Research Institute (ECRI) risk classification [13] by assigning score 5 to high risk (H) with 5, score 4 to medium risk (M), and score 1to low risk (L). Maintenance scores are the same with Fennigkoh and Smith [10] maintenance criterion. Wang and Rice [14] proposed two sampling methods for inclusion of a portion of medical equipment in maintenance activities; a simplified version of gradient risk sampling (GRS) and Attributes Sampling.

Ridgway [3] discusses that although preventive maintenance (PM) prevents some devices failures, the fact is that it is useful for a relatively few devices and it cannot be used for all of devices failures. He also provides guidelines for MEMP and introduces some tools which successfully have been used in different industries, such as Reliability Centered Maintenance (RCM). Youssef et al [15] proposed a medical device classification model based on their complexity. Their model consists of two steps: technical complexity and use complexity. Technical complexity includes four criteria about technical perspective such as Equipment Maintainability, while use complexity consists of nine criteria regarding difficulty at the operation level of medical equipment such as data entry, setup process.

Some authors (Wang and Levenson [6], Hyman [16], Ridgway [17] and Taghipour [18]) have debated that although risk is an important criterion in medical equipment classification, other criteria also should be taken into account such as, equipment utilization rate, availability of identical devices, mission criticality, hazard notice, and recall history. To overcome this problem, Taghipour et al. [18] presented a multi-criteria decision-making (MCDM) method using Analytical Hierarchy Process (AHP) for prioritization of medical equipment based on their criticality. Their proposed AHP method consists of six criteria 'Risk', 'Age', 'Equipment Function', 'Mission criticality', 'Recalls', and 'Maintenance requirements'. However, the AHP method has been criticized by many authors for some certain issues such as the need for large number of subjective pairwise comparisons, uncertainties in experts' ideas because of subjectivities in comparison process and etc..

Recently, Corciovă et al. [19] provided some guidelines to establish and manage a medical equipment quality assurance program, and presented some procedures for inspection, maintenance, evaluation, and performance testing for medical devices. They considered five risk criteria in their scoring system in relation to patient and staff members. Tawfik et al. [7] developed a fuzzy logic model for classification of medical equipment. They used four criteria (Mission criticality status, equipment function, maintenance requirements, and physical risks) in order to calculate the risk scores for each device. Their results show that, in certain cases, the same equipment type may attain different risk scores. In addition, they made a comparison between their classification scheme versus other schemes. This comparison illustrates that in some cases medical equipment may obtain different risk scores.

Despite all these efforts some important points are overlooked and, in our opinion, need to be improved. Among them, special attention should be devoted to the followings aspects.

1) Since prioritization and classification of medical equipment is a MCDM problem, different expert's evaluations should be considered rather than prioritizing based on a sole expert's assessment;
2) Some criteria applied in the literature need to be reassessed and revisited;
3) Some new criteria should be added to the reassessed criteria;
4) The criteria and the tables used in prioritization process should be defined in a more simple and realistic way in order to be understandable for all of clinical experts, because most of experts in hospitals are not familiar with fuzzy logic principles and maintenance technical vocabulary.
5) Most of the existing studies don't consider the uncertainties associated to experts' opinions;
6) Last but not least, there is no systematic and comprehensive framework for Prioritization of Medical devices and classification of them for maintenance activities.

Then, inspired by some of reliability and maintenance tools and equations successfully applied in manufacturing and other critical industries (such as Aviation, Oil & Gas, etc.), the main goal of this study is to first cover all of the above mentioned weaknesses in current prioritization systems in healthcare and then propose a comprehensive risk-based maintenance framework for prioritization of medical devices. To do so, first the existing criteria in the literature for prioritization of medical devices are reassessed and for some of criteria, new or modified equations have been introduced. Besides, some new criteria are defined and added to the existing criteria in order to consider all aspects in prioritization of devices. Then, a new comprehensive fuzzy multi criteria and multi dimensions decision making approach is proposed in order to prioritize medical devices based on different expert's ideas and by considering their experience and knowledge. In addition, the third step of the approach contributes a new method to select appropriate maintenance strategies for each device.

6.3.3. A Fuzzy FMEA based approach to the medical device prioritization

In agreement with traditional FMEA and RBM principles, the aim of the proposed approach is to assure high availability for critical medical devices. In brief, this approach is able to prioritize medical devices based on their criticality, taking into account the different criteria and dimensions. In addition, the proposed model is able to choose the best maintenance strategy for each medical device. The proposed approach is comprised of the three following steps.

6.3.3.1. First Step

This step is based on a FFMEA model which integrates three criteria (D, O, and S) and eight sub criteria. In traditional FMEA method, the risk priorities of failure modes are obtained by using the Risk Priority Number (RPN), which is the product of three factors (RPN = O × S × D). This method is simple but it has been criticized by several authors. Some of these criticisms include:

A. Various sets of O, S and D may produce an identical RPN [8],
B. The relative importance among O, S and D is overlooked [8],
C. The method used by the traditional FMEA for calculating the risk scores of failures [9],
D. Cost and profitability factors are ignored,
E. Different experts opinions are ignored,
F. The scales for S, O and D are ordinal.

In order to overcome the traditional FMEA weaknesses, we use a fuzzy approach for computing RPN. Doing so, we apply a modified version of FFMEA at the first step of our model by assigning linguistic variables to RPN factors in order to consider uncertainties in experts' ideas. In addition, particular weights have been assigned to experts' ideas and also RPN factors. Moreover, we have added eight sub criteria to the main criteria (S, O, and D) of RPN method in order to consider different aspects of failures in each medical device. It should be highlighted that our proposed FFMEA model has the ability to consider multiple failures. All of the new/modified criteria and sub-criteria are defined in the sections 3.1.1, 3.1.2 and 3.1.3.

Detectability (D)

This criterion refers to the probability of detection of a potential failure before it occurs. In this study, detectability includes two following sub criteria; the chance of non-detection and Method of failure detection.

Probability of non-detection (D_1)

This sub-criterion estimates the rate of detection of the device failures by applying the Table 6.9. According to Sharma [20], "the probability of non-detection is related to different factors including the ability of maintenance personnel to detect failure through periodical inspection or naked eye or with the help of machine diagnostic aids such as automatic controls, alarms and sensors".

Table 6. 9 Fuzzy ratings for detection assessment of a failure

Visibility			Detection via automatic diagnostic aids			Detection after an inspection		Scheduled inspection		Rating	Fuzzy number
Yes	Partially	No	Directly	Indirectly	No	Yes	No	Yes	No	Probability of detection	
☑										Almost certain (AC)	(1, 1, 2)
	☑		☑			☑				Very high (VH)	(1, 2, 3)
		☑		☑		☑		☑		High (H)	(2, 3, 4)
		☑		☑		☑			☑	Moderately high (MH)	(3, 4, 5)
		☑		☑			☑	☑		Moderate (M)	(4, 5, 6)
	☑			☑			☑		☑	Low (L)	(5, 6, 7)
		☑			☑	☑		☑		Very low (VL)	(6, 7, 8)
		☑			☑	☑			☑	Remote (R)	(7, 8, 9)

		☑			☑		☑	☑		Very remote (VR)	(8, 9, 10)
		☑			☑		☑		☑	Absolute uncertainty (AU)	(9, 10, 10)

Table 6.9 shows the four elements and fuzzy ratings used for evaluating the D_1. The fuzzy ratings in this table are defined in accordance with the experience of authors, the opinions of maintenance staff, and by using Braglia's study [21]. Note that the ratings for this criterion have been considered in reverse scale, because we are dealing with the chance of 'non-detection'. It is evident from Table 6.9 that the less a device failure is visible the less its probability of non- detecting grows. The second element *Detection via automatic diagnostic aids* refers to the auto-analysis programs or installed sensors to detect some defects in the device. Each expert should consider all of these four elements in order to be able to rate the D_1 sub criterion. Fig. 6.8 shows the fuzzy membership function of this sub criterion. It should be noted that Figures 6.8 and 6.9 were drawn using Fuzzy Tech Software (http://www.fuzzytech.com/).

All failure modes and their associated frequency, consequence, and detectability could be estimated using the device maintenance history [18].

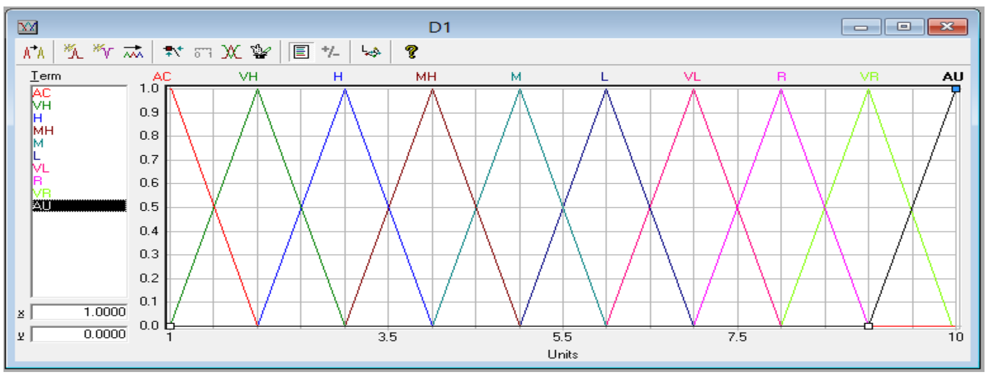

Figure 6. 8 Fuzzy membership function for D1

Method of failure detection (D_2)

The kind of method which is used for detecting the failures is another important indicator of detection ability for repairable devices. In particular, this sub criterion measures the degree of automation in inspection process of medical device. Table 6.10 shows the linguistic terms and their fuzzy numbers used for evaluating the method of failure detection and Fig. 6.9 shows the membership functions of this sub criterion.

Table 6. 10 Fuzzy ratings for Systematic method of failure detection

Rating	Description	Fuzzy rating
Remote/unreliable (R)	The device is 100% inspected and the inspection process is automatic (for example, automatic sensors has been installed in the device).	(0, 0, 1.5)
Low (L)	There is complete inspection, but it is not automated.	(1, 2.5, 4)
Moderate (M)	There is a process for manual inspection and it is applied only to some components in the device.	(3.5, 5, 6.5)
High (H)	There is no inspection process for the device and the failure has been allowed to occur.	(6, 7.5, 9)
Very high (VH)	There is no known inspection process for detecting the device failures and the failures can hardly be detected even with a complete inspection.	(8.5, 10, 10)

It should be noted that fuzzy membership functions for the rest of sub criteria ($O_1, O_2, O_3, C_1, C_2, C_3$ and C_4) are similar to the one in Figure 6.10 and therefore they will not be shown.

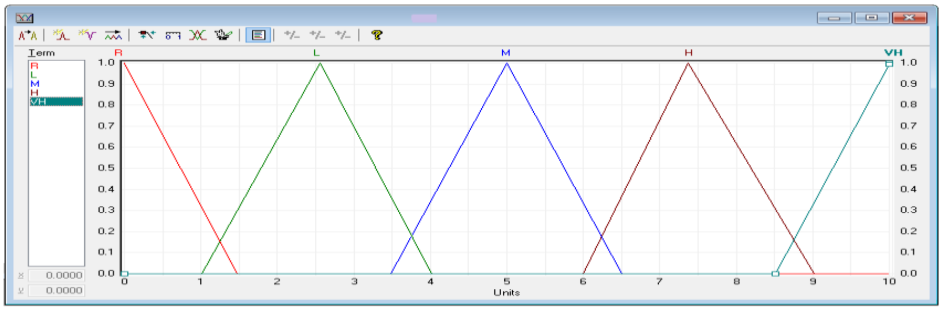

Figure 6. 9 Fuzzy membership functions for D2

Occurrence (O)

The frequency of failures or probability of occurrence estimates the frequency of potential failure(s) or risk(s) for a given device. In order to calculate this probability more precisely, it is required that some sub criteria be added to the occurrence criterion depending on the device or system. Then, in this paper, we propose three following sub-criteria to be added to the occurrence criterion; Frequency or mean time between failures (O_1), Repeatability (O_2) and Visibility (O_3). These sub criteria are presented in the following.

Mean time between failures (O_1)

Mean time between failures ($MTBF$) is one of frequently used basic measures in reliability engineering of repairable devices or components [22]. MTBF reports the expected time between two failures for a repairable system. Required data related to $MTBF$ can be obtained from computerized Maintenance Management Systems (CMMS) of firms/ organizations, and they should be integrated with the experience of maintenance experts. In this study, $MTBF$ is defined as a chance of failure in a period of time as shown in Table 6.11.

Repeatability (O_2)

Repeatability is another important factor in terms of occurrence that should be considered in estimating the probability of occurrence. Geum et al. [23] define "Repeatability" as "a concept differentiated from the frequency, representing the frequency of occurrence of failure due to the same source within a specified time". In this paper, repeatability is defined as a "same failure occurring in a period of time for a device or component" as shown in Table 6.11. It is evident from Table 6.11 that when a same failure occurs in a short period, (e.g. 3 months), its repeatability rating is very high, while when a same failure occurs in a long period of time (e.g. ten years), the repeatability rating is very low.

Visibility (O_3)

Visibility of failures is the third important factor in measuring the probability of occurrence of failures specially hidden failures. It shows whether the failure is visible to the maintenance experts or not.

Table 6. 11 Fuzzy rating and scales for measurement of occurrence sub-criteria

Rating	(O_1)		(O_2)	(O_3)	Fuzzy number
	Chance of failures	Corresponding $MTBF$	Corresponding time	Corresponding time	
Very high (VH)	Failure is almost inevitable	< 3 months	same failures in 3 months	It is not visible at all.	(8.5,10,10)
High (H)	Repeated failures	3-6 months	same failures in 3-6 months	Visible while using the device	(6,7.5,9)
Moderate (M)	Occasional failures	6 months-2 years	same failures in 6-24 months	Visible between two inspection intervals	(3.5,5,6.5)
Low (L)	Relatively few failures	2-10 years	same failures in 2-10 years	Visible while inspecting	(1,2.5,4)
Remote (R)	Failure is unlikely	>10 years	failure is unlikely>10 years	Visible before an inspection	(0,0,1.5)

Table 6.11 presents our proposal of scales for descriptive assessment of probability of failure occurrence or frequency of occurrence for the three sub criteria $MTBF$, Repeatability, and Visibility. It also indicates the fuzzy triangular numbers associated to each statement.

Failure's consequences (S)

When a device failure occurs in healthcare organizations, the consequences often show three major impacts: impact on patient's safety, impact on the maintenance resources, and economic loss. Then, to consider the total consequences of each failure mode, all its potential impacts need to be assessed.

Patient safety (S_1)

According to LD.5.2 JCAHO's patient safety standard, "leaders must ensure that an ongoing, proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented" [24]. In addition, possible effects of each failure mode should be identified. To do so, JCAHO proposed Health Care Failure Mode and Effect Analysis (HFMEA) in 2002 [25]. HFMEA is a valuable tool that focuses on patient safety. Hence, in this paper we considered patient safety as a first sub criterion of severity criterion in our FFMEA model. The levels of patient safety and the other sub-criteria of Consequences (S_2, S_3, S_4) and their associated fuzzy rating are described in Table 6.12.

Potential Risk for the Device Operator and Maintenance Personnel (S_2)

A potential failure or malfunction in a component or device can result in injury, permanent impairment, or even death to the device users or maintenance personnel as well as the patient. Then, in this paper, the potential risks for the device operator is considered as a second major sub criteria.

Mean time to repair (S_3)

Mean time to repair ($MTTR$) is one of the widely used technical measures of the maintainability for repairable devices or components [26]. It is the average time required to perform corrective maintenance in a device or system [22]. *MTTR* in a system is computed as "the total corrective maintenance time divided by the total number of corrective maintenance actions during a given period of time" [27]. $MTTR$ is expressed by:

$$MTTR = (\sum_{i=1}^{n} MTTR_i * \lambda_i) / (\sum_{i=1}^{n} \lambda_i) \quad (4)$$

where $i = \{1, \dots, n\}$ is the index for the set of units or medical devices considered, $MTTR_i$ is the time required to repair item or unit *i*, and λ_i is the number of corrective maintenance actions of item or unit *i* during the considered period. In this paper, *MTTR* levels and its fuzzy ratings are defined according to the experience of authors and maintenance staff as shown in Table 6.12.

Economic Loss (S_4)

Wang et al. [28] define "Economic Loss" in industrial petrochemical plants as "a combination of the maintenance cost and production loss". Inspired by their definition, we define economic loss in healthcare organizations as a combination of maintenance cost (*MC*) and the hourly loss associated to delaying treatment (*DL*). Maintenance costs (due to a malfunction or failure in a component or medical device) contains fixed costs (e.g., the costs of spare part(s)) and variable costs (e.g., maintenance experts' costs). Therefore *MC* for a given medical device is expressed as:

$$MC = C_f + DT.C_v \quad (5)$$

where C_f and C_v refer to the fixed and variable costs of the failure *f*, and *DT* is the downtime or repair time of the device (hr.).

The delayed loss *DL* can be estimated as a product of downtime *DT* and hourly loss associated to delaying treatment $DLPH$($/hr.)

$$DL = DT.\,DLPH \quad (6)$$
$$C_4(for\ each\ failure) = DL + MC \quad (7)$$
$$C_4(for\ each\ device) = \sum_{i=1}^{n}(DL + MC) \quad (8)$$

where *n* represents the number of failures that could happen for each medical device.
Economic loss levels and their related linguistic levels and fuzzy ratings are described in Table 6.12.

Table 6. 12 Consequences sub-criteria levels and their associated fuzzy rating

Level	S_1 and S_2	S_3	S_4	Fuzzy rating
Very high (VH)	Death	Order a new device	Economic Loss ≥ $5000	(8.5,10,10)
High (H)	Debilitating long-term injury	External intervention for repairs	$2000≤ Economic Loss < $5000	(6,7.5,9)
Moderate (M)	Moderate injury	1 day ≤MTTR <4 days	$500≤ Economic Loss < $2000	(3.5,5,6.5)
Low (L)	Minor injury or illness	1 Hour ≤MTTR<1 day	$250≤ Economic Loss < $500	(1,2.5,4)

Remote (R)	Less or no effect	MTTR<1 Hour	\$0≤ Economic Loss <\$250	(0,0,1.5)

Fuzzification and defuzzification

All of criteria and sub criteria are fuzzified using the proposed membership functions in the previous sections. The fuzzy conclusion is then defuzzified to get crisp RPI_D (index D refers to the device number). The higher the value of RPI_D, the more critical the failure. The following paragraphs discuss the fuzzification and defuzzification operations.

Let O_{jkl}^n, S_{jkl}^n, and D_{jkl}^n be respectively the occurrence, severity, and detection values for medical device j, failure mode k and sub criteria l evaluated by expert n. Let us also consider the triangular fuzzy membership function:

$$O_{jkl}^n = (LO_{jkl}^n, MO_{jkl}^n, UO_{jkl}^n), \quad \text{where } 0 \le LO_{jkl}^n \le MO_{jkl}^n \le UO_{jkl}^n \le 10 \tag{9}$$

$$S_{jkl}^n = \left(LS_{jkl}^n, MS_{jkl}^n, US_{jkl}^n\right), \quad \text{where } 0 \le LS_{jkl}^n \le MS_{jkl}^n \le US_{jkl}^n \le 10 \tag{10}$$

$$D_{jkl}^n = \left(LD_{jkl}^n, MD_{jkl}^n, UD_{jkl}^n\right), \quad \text{where } 0 \le LD_{jkl}^n \le MD_{jkl}^n \le UD_{jkl}^n \le 10 \tag{11}$$

It should be noted that weighting values w_i are determined for each expert $i \in \{1, \ldots, n\}$ according to their experience and knowledge. These values are in the $[0,1]$ interval, and sum of them for all experts must be one. Besides, a pairwise comparison among, O, S and D parameters should be done in order to determine the weights of importance for each criterion (W_O, W_S, and W_D). Equations (12) to (14) are used to aggregate the experts' opinions (w_i).

$$O_{jkl} = \sum_{i=1}^{n} O_{jkl}^i w_i \tag{12}$$

$$S_{jkl} = \sum_{i=1}^{n} S_{jkl}^i w_i \tag{13}$$

$$D_{jkl} = \sum_{i=1}^{n} SD_{jkl}^i w_i \tag{14}$$

After assigning weights W_O, W_S, and W_D to reflect the relative importance of each criterion, we obtain the fuzzy membership function called μ(RPI):

$$\mu(RPI) = W_O \mu\left(O_{jkl}\right) + W_S \mu\left(S_{jkl}\right) + W_D \mu(D_{jkl}) \tag{15}$$

In order to obtain crisp numbers from the above fuzzy set, (μ(RPI)) should be defuzzified. There are many different defuzzification methods available in literature. Center-of-area (COA) method [29] is one of simple and practical methods for defuzzification which can be used to defuzzify the fuzzy membership functions of O, S and D ($O_{jkl}^n, S_{jkl}^n, D_{jkl}^n$) and also $\mu(RPI)$. Eqs. 16-18 represent DO, DS, and, the defuzzified values of fuzzy O, S and D for a given device, respectively.

$$DO = \frac{1}{3}[(UO - LO) + (MO - LO)] + LO \tag{16}$$

$$DS = \frac{1}{3}[(US - LS) + (MS - LS)] + LS \tag{17}$$

$$DD = \frac{1}{3}[(UD - LD) + (MD - LD)] + LD \tag{18}$$

Finally, defuzzified RPI for a given device is calculated using $DO, DS,$ and DD in Equation (19).

$$RPI_D = DO \times DS \times DD \quad (19)$$

Tables 2.9 to 2.12 and Figures 6.9 and 6.10 represent the linguistic variables and their fuzzy ratings developed for calculating the O, S, D criteria and sub criteria proposed in this paper for the sake of visualization.

6.3.3.2. Second step

In the second step, seven important miscellaneous dimensions (that could not be considered as FFMEA factors) are considered in order to take into account other factors and aspects strongly related to risks in prioritization of medical devices for maintenance works. Most of these dimensions are probabilistic (rated between 0% and 100%) and they are assessed by using device history and based on experts' opinions. For each dimension *d*, several grades or levels are proposed and for each grade, an Intensity (I_d) is associated. Intensities obtained for the seven dimensions need also to be weighted according to their relative importance in order to obtain the total intensity (TI) for the incumbent device. The seven dimensions, the computation of the Intensity score for each dimension and the medical device's TI are detailed in the next subsections.

Age

Reliability of a medical device is a function of the age of a component or system. The failure rate of components and systems depends on time and it is calculated as the number of malfunctions occurring during a period of time. Bathtub curve describes the different rates of failures for a component or system in three distinct regions (Fig. 6.10). The first region, is the beginning of the life of an electronic device and it is called the "*Infant Mortality* region". As shown in Fig. 6.10, this period is characterized by decreasing high rate of failures. According to Fries [4], "early failures occur usually within the first 1000 h of operation". Generally, failures occurring in this period are because of poor component quality. In the second region, referred to as the "*Useful Life* region", the failure rate is constant. During this period chance or random failures occur. These failures usually stem from weaknesses in the design, hidden component failures, or improper use of device. The rightmost part of the bathtub curve, known as the "*Wear-out"* region, exhibits an increasing failure rate due to long-term usage of the product or fatigue. In order to consider the life cycle of medical devices for failures, we propose Table 6.13 for assessing sub dimension age. According to Taylor [30], the average life span of medical devices is 10 years. It should be highlighted that the life of equipment and failure rate relation is not the same for all devices.

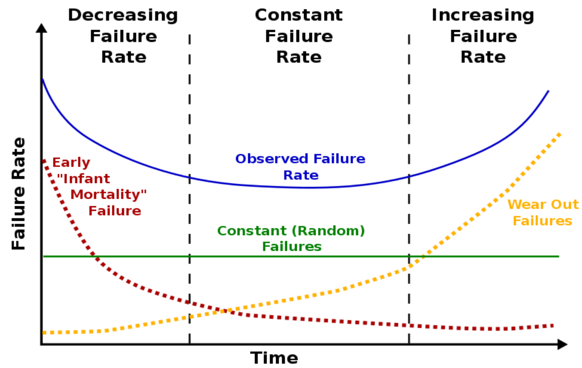

Figure 6. 10 Typical Life Cycle Bathtub Curve for devices' failures

Table 6. 13 Assessing intensity for Age sub dimension

Age	Description	Intensity
Age < 1 000 hours of operation	Infant mortality region	0 – 15%
1000hr. ≤ Age < 90000hr.	Useful life	15 – 70%
Age ≥ 90 000 hr. of operation	Wear-out region	70 – 100%

Usage-related Hazards (URH)

According to FDA [31], "hazards associated with device usage are a common and serious problem". Generally, these hazards derive from the complexity of medical device and also user training issues. The FDA's evidences show that the manner in which a device is used determines significantly its overall safety and effectiveness. In addition, evidence from research works indicate that the frequency and consequence of hazards due to medical device misuse might far exceed the device failures. Therefore, usage-related hazards should be identified, assessed and prioritized by experts in order to perform risk management efforts based on their severity. The device's manual helps the analyst to identify use-related hazards. Our model includes use-related hazards as an important dimension in order to capture all the medical device- related hazards. To do so, we have proposed in Table 6.14 linguistic levels and description of each linguistic level to assess the potential consequences of device- related hazards.

Table 6. 14 Intensities and their descriptions for assessing of use-related hazards

Level	Description	Intensity
Very high	Death	100%
High	long-term injury	70 – 90%
Moderate	Moderate injury	40 – 70%
Low	Minor injury	10 – 40%
Remote	Less or no effect	< 10%

In order to assess precisely the linguistic levels in Table 6.14, the experts must answer some or all of the following questions described by FDA based on the device complexity level [31].

1. *"What are the critical steps in setting-up and operating the device? Can they be performed adequately by the normal users? Is it likely that the user sets up the device incorrectly? If yes, what kind of effects would this have?*

2. *Is the user likely to operate the device differently than the manner indicated by the instructions?*
3. *How might the physical and mental capabilities of users affect their use of the device?*
4. *Are users likely to be affected by clinical or age-related conditions that impact their physical or mental abilities? Could these conditions affect their ability to use the device?*
5. *How might safety-critical tasks be performed incorrectly and what effects would this have?*
6. *How important is user training, and will users be able to operate the device safely and effectively if they don't have it?*
7. *Do any aspects of device use seem complex, and how can the operator become "confused" when using the device?*
8. *Can touching or handling the device harm the user or patient?*
9. *If the device fails, does it "fail safe" or give the user sufficient indication of the failure?*
10. *Could device use be affected if power is lost or disconnected (inadvertently or purposefully), or if its battery is damaged, missing or discharged?"*

Utilization (U)

Calculating medical device utilization rate can vary depending on the device, what it is used for, and how often among others. Utilization is a compound measure based on the weighted sum of two indicators. The first indicator is the average daily utilization rate of the device, and the second indicator, is calculated as "the proportion between the number of patients served per day and the maximum number of patients that the device may treat". After proposing these indicators to a group of experts in the field of healthcare devices maintenance, they suggested to assign weights of 0.4 and 0.6 to these indicators, respectively, in order to calculate U, the medical device utilization sub dimension. As in the previous paragraphs, we suggest in Table 26.15 several Utilization levels and the corresponding Intensity allowing experts estimating Utilization intensity for each medical device.

Table 6. 15 Assessing intensity for sub dimension utilization

Daily utilization rate of device *i*	Intensity
$0 \leq U < 0.4$	0 - 40%
$0.4 \leq U < 0.7$	40 – 70%
$0.7 \leq U$	70 – 100%

Number of available identical devices

As pointed out by Taghipour [18], having several identical medical devices does not always guarantee higher availability. In fact, the number of patients served each day by these devices is the major aspect impacting the availability of these devices. For example, if five similar MRI devices are available in a hospital and all of them are used at the same time, if either fails, none of the others can be substituted with the failed device. Availability of identical devices' can be computed as a function of the number of identical devices and their demand per unit of time. Therefore, we propose a modified version of the *Overall Equipment Effectiveness* (OEE) indicator to compute the availability of identical devices. OEE is a major key performance indicator defined as the product of three constituent aspects [32]:

$$OEE = Availability \times Performance \times Quality \tag{20}$$

Availability is defined as the expected proportion of time that a device is in a functioning condition. Given n as identical devices, we compute its Availability during a period of length t as:

$$Availability = 1 - \frac{\sum_{i=1}^{n} Down_i}{n \times 24h} \tag{21}$$

where $Down_i$ is the sum of downtimes incurred by the n concerned devices during period t.

$$Performance = \frac{Avrage\ number\ of\ patients\ served\ by\ the\ n\ devices \times Ideal\ cycle\ time\ per\ patient}{Average\ Operation\ Time\ of\ n\ devices} \tag{22}$$

where "Ideal cycle time per patient" I the number of minutes that each patient is served by medical device i.

Finally, we assume that the Quality of treatment is the same for all the patients and we set its value to 100%.
Hence, once the modified OEE indicator for measurement of availability of identical medical devices has been computed, Table 6.16 allows obtaining intensity values.

Table 6. 16 Intensity associated to Modified OEE values

Modified OEE	Intensity
0 ≤ OEE < 0.5	70 - 100%
0.5 ≤ OEE < 0.7	20 – 70%
0.7 ≤ OEE	10 – 20%

Recalls and hazard alerts

Recalls are issued by manufacturers or the FDA to address problems in equipment that can pose risks to health or violate FDA regulations. Recalls should be considered as an important dimension in ranking medical devices for maintenance activities. This dimension could be considered as the function of the number and levels of recalls for a device. FDA has categorized recalls into three classes according to the level of hazard involved [32].

- *"Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death".*
- *"Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote".*
- *"Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences[2]".*

Based on these categories, Table 6.17 proposes intensity values for the sub dimension Recalls and hazard alerts.

Table 6. 17 Intensity values of sub dimension Recalls

[2] U.S.A. Department of Health and Human Services, U.S. Food and Drug Administration (http://www.fda.gov/safety/recalls/ucm165546.htm) accessed on line 2014/06/06.

Recalls numbers & classes	Intensity
Total number of Class I recalls (per year)≥1	100%
3≤Total number of Class II & III recalls(per year)<5	20 – 60%
1≤Total number of Class II & III recalls(per year)<3	10 – 20%

Function

The classification of medical devices is a 'risk based' system linking the vulnerability of the human body to the potential risks associated with the devices. The Medical Devices Bureau (MDB) of Health Canada has classified medical devices into four classes based on the safety and effectiveness; Devices placed in Class I, have the lowest potential risk, while Class IV devices present the highest risk. In addition, the Association for the Advancement of Medical Instrumentation (AAMI) classified equipment into six categories [33]. Recently, Taghipour [18] proposed five classes as function categories in order to describe more explicitly the function of medical devices. In this study we elected to use Taghipour's classification to support the functional risk and proposed related intensities for each class as shown in Table 6.18.

Table 6. 18 Intensity values of sub dimension Function

Class	Intensity
Life support	100%
Therapeutic	40 – 50%
Diagnosis	30 – 40%
Analysis	20 – 30%
Others	10%

Maintenance requirements

Each medical device has its own maintenance requirements. According to [33], a device's maintenance task involves resources of three different natures: tools, materials, and skills. In [12], authors classified maintenance requirements for medical devices into three grades (high, medium and low). In this paper, we adopt the maintenance's resources categories proposed by [33], and assign to each kind of resource potential grades and scores as shown in Table 6.19.

Table 6. 19 Assessing maintenance resources and the proposed scores [33]

Maintenance tools	Score
General tools (multiple alternatives)	1
General tools (no alternatives)	2
Special tools	3

Maintenance materials	Score
No special requirements	1
Special requirements	2

Maintenance skills	Score
No special requirements	1
Level requirements	2
High requirements	3

Total Maintenance requirements intensity is computed as the product of maintenance tools, maintenance materials, and maintenance skills scores. Since the intensities achieved by this dimension are not probabilistic, they are not adjusted to the other dimensions intensities. Then, we normalize the intensity values of the dimension *Maintenance requirement* by dividing the *Total Maintenance requirement* intensity (assigned by each expert) by the sum of all intensities assigned by different experts for each device. This step is illustrated in Table 6.28 in the numerical example section.

Intensity scores and medical device's TI computation

After acknowledging the dimensions, grades and intensities of each of the dimensions, each expert should assess each device with respect to every dimension $d \in \{1, \ldots, 7\}$. Assuming that *n* experts are consulted, the *Intensity score for each dimension*, I_d is computed as:

$$I_d = \sum_{i=1}^{n} w_i I_{di} \tag{23}$$

where I_d is the intensity score obtained for dimension d based on the judgement of expert *i*, and w_i are the weights assigned to the experts according to their experience and knowledge.

After finding the intensity score for each dimension, the TI of a medical device can be calculated using a weighted sum of dimensions. To do so, an analytical hierarchy process (AHP) method has been employed to determine the set of weights W_d reflecting the relative importance of each dimension. Weights must be in the [0,1] interval and total weights for all dimensions should be equal to one. Applying this process led to the weights given in Table 6.20.

Table 6. 20 Weights assigned to the seven dimensions

Dimension	Weight
Age	0.06
Usage-related Hazards	0.16
Utilization	0.07
Number of available identical devices	0.03
Recalls	0.16
Function	0.43
Maintenance requirements	0.48

It should be pointed out that the different weights might be assigned to the above dimensions by participation of different experts from other departments, because their opinions generally differ [34].

Finally, the TI of a medical device is calculated as:

$$TI = \sum_{j=1}^{d} W_d I_d \tag{24}$$

6.3.4 Third step (Maintenance Planning)

After prioritization of all medical devices, the final step is to design an appropriate maintenance strategy. Generally, maintenance strategies are categorized based on their required resources such as labor and equipment and also their effect on maintenance of equipment [34]. Improper selection of the maintenance strategy may adversely affect the patient safety and even user's safety, as well as affecting the available operating budget due to unplanned costs. Unfortunately, little research has been devoted to maintenance strategy selection in the particular case of medical equipment. Only, Taghipour [18] suggested a 'Transformed score value' (TSV) in order to determine appropriate maintenance policies for medical devices.

In this paper we propose a Maintenance Planning Diagram (see Fig. 6.11) to identify the optimal maintenance strategy for each medical device. This Diagram uses the RPI_D and TI scores which are achieved from the first and second steps of our approach. The abscissa reports the risk priority index numbers, valued by RPI_D , while the ordinate reports the TI scores achieved by the second step of the proposed method.

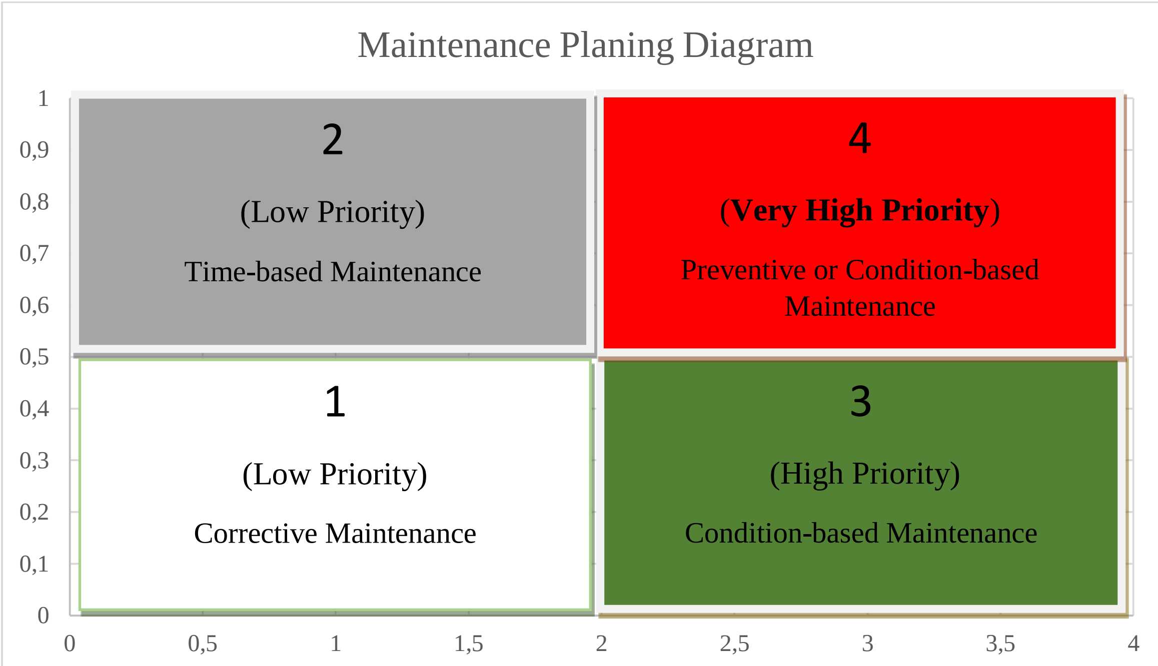

Figure 6. 11 The TI-RPI diagram

To make a classification, the position of each medical device should be first determined on the TI-RPI diagram (by using RPI_D and TI scores). The points (coordinates) placed on the diagram display medical devices and their disposition on each of four quarters presents information regarding the criticality of each medical device and maintenance actions to undertake. Figure 6.11 shows 4 zones; Zone 1 comprises a 'Low Priority' area where both TI and RPI have low scores. Zone 2 shows a second 'Low Priority' zone, including high TI scores and low RPI scores. Zone 3 is a 'High Priority' area including high RPI and low TI scores. Last, zone 4 is a 'Very High Priority' area. Devices within this zone have very high RPI and TI scores, and therefore they are critical. According to criticality of the devices determined on this diagram, four different maintenance strategies described in the following, are proposed in Figure 6.11 to reduce the risks of the devices.

1. Corrective Maintenance: This maintenance policy is carried out after detection of failure and it restores the component or device to an operational condition. We recommend this maintenance strategy for the devices placed in the first zone [35].
2. Time-based preventive maintenance: In this policy, the maintenance tasks are performed periodically in order to reduce the rate of failures. In this paper, this strategy is suggested for the devices placed in the second zone [36].
3. Condition-based maintenance (CBM): This maintenance policy is carried out according to data gathered from a set of system's sensors and some indicators such as vibration monitoring, lubricating analysis, and ultrasonic testing. CBM uses real-time data for prioritization and optimization of maintenance resources. We propose this strategy for the devices located in the third zone [36].

4. Predictive maintenance: This policy is designed to predict device failures by evaluating the observed data and determine when maintenance should be performed. In this paper, this strategy is suggested for the devices placed in the fourth zone [37].

In order to obtain reliable and safe medical devices, there should be a periodic inspection of all devices, and their maintenance strategies should be adjusted accordingly. Note that the proposed framework should be performed for each new device which is added to the inventory. Since there is no maintenance history of new devices, their maintenance data should be monitored and recorded in order to analysis the effectiveness of the proposed maintenance policy for the new device.

6.3.5. Numerical example and discussion

In order to illustrate the proposed framework, this section presents an academic numerical example. We extracted multiple failure modes of five medical devices from the literature and assessed them, following the three proposed steps. The judgement of three different experts were considered.

Step 1. Construct RPI assessment table for each device: Tables 2.21 to 2.25 illustrate the first step of the framework. Table 6.21 presents the five medical devices, their considered failure modes and the scores assigned by three experts. The first step of the proposed framework uses FFMEA model to calculate the RPI numbers. Each RPI factor is computed based on linguistic scales as described in the first step (Tables 6.9-12). Values under header 'W' in Table 6.21 represents the weights assigned to each of the experts based on their experience and knowledge. The same weights are applied in step 2 for the experts (Table 6.26). In addition, relative AHP is employed to determine criteria weighting values (w_O, w_S, and w_D) [38] and the numbers ''0.4809, 0.1652, and 0.3538'' are achieved for O, S, and D criteria, respectively.

Table 6.22 shows how linguistic variables are assigned to sub criterion C_4 in Table 6.21. The fixed costs (C_f), variable costs (C_v) and downtimes of the device (DT) are obtained from maintenance records. To achieve the related linguistic variables for sub criterion C_4, first economic loss values are calculated by using Equations 5 to 8 and then these values are converted to linguistic variables by using Table 6.12.

Table 6. 21 Numerical example Fuzzy FMEA starting values

Equipment	Failure	Exp (W)	Fuzzy Risk Priority Index								
			Detection		Occurrence			Consequences			
			D_1	D_2	O_1	O_2	O_3	C_1	C_2	C_3	C_4
Infant Incubator	1	1(0.50)	M	M	VH	H	VH	H	M	H	H
		2(0.15)	M	H	H	H	H	H	M	M	M
		3(035)	MH	M	VH	H	H	VH	L	M	M
	2	1(0.50)	VL	R	H	VH	VH	L	H	M	VH
		2(0.15)	VL	L	H	VH	VH	L	M	L	H
		3(035)	L	R	H	H	VH	R	VH	R	M
	3	1(0.50)	M	L	L	L	L	VH	M	VH	M
		2(0.15)	MH	M	L	R	R	VH	R	VH	M
		3(035)	M	H	L	L	R	VH	L	VH	M
	1	1(0.50)	L	R	M	H	M	L	L	L	L
		2(0.15)	M	L	H	M	H	L	M	L	M
		3(035)	M	M	M	H	M	L	VH	M	M

Defibrillator	2	1(0.50)	M	M	H	VH	H	M	VH	M	L
		2(0.15)	L	M	VH	H	H	L	H	M	L
		3(035)	M	M	VH	VH	VH	L	M	H	L
	3	1(0.50)	VL	R	H	H	M	VH	M	H	VH
		2(0.15)	L	L	M	H	H	VH	M	H	H
		3(035)	VL	L	M	M	H	H	M	M	VH
Surgical Lights	1	1(0.50)	AC	VH	H	H	H	H	L	M	L
		2(0.15)	AC	VH	H	VH	VH	M	L	M	L
		3(035)	VH	VH	M	H	H	M	L	M	M
	2	1(0.50)	H	H	M	L	M	M	L	L	M
		2(0.15)	VH	VH	M	L	M	M	M	L	M
		3(035)	H	H	M	M	L	H	L	R	L
Automatic X-ray processor	1	1(0.50)	AC	VH	H	H	H	L	VH	M	R
		2(0.15)	VH	H	H	VH	VH	L	VH	L	L
		3(035)	VH	VH	H	H	VH	L	VH	L	R
Infusion Pump	1	1(0.50)	VL	L	L	M	L	VH	H	VH	M
		2(0.15)	L	L	L	L	L	H	H	H	VH
		3(035)	R	R	M	L	L	H	M	H	H
	2	1(0.50)	R	R	H	H	H	L	M	M	L
		2(0.15)	VL	R	VH	VH	H	R	M	H	L
		3(035)	VL	L	H	H	H	R	H	H	M

Table 6. 22 The economic loss assessment of failure modes

Device	Failure mode	C_f/\$	C_v/\$$h^{-1}$	DT /hours	MC	DLPH/\$$h^{-1}$	DL	Economic loss/\$
Infant Incubator	FM 1	180	40	28	1300	25	700	2000
	FM 2	30	20	10	230	25	250	480
	FM3	500	60	95	6200	25	2375	8575
Defibrillator	FM 1	100	18	12	316	22	264	580
	FM 2	200	30	34	1220	22	748	1968
	FM 3	200	30	80	2600	22	1760	4360
Surgical Lights	FM 1	200	56	24	1544	19	456	2000
	FM 2	400	15	2	430	14	28	458
Automatic X-ray	FM 1	100	12	18	316	10	180	496
Infusion Pump	FM 1	78	57	68	3954	15	1020	4974
	FM 2	50	25	12	350	12	144	494

Table 6. 23 Assignment of expert's weights (wi) and fuzzy triangular numbers

Equipment	Failure	Fuzzy Risk Priority Index												
		Detection				Occurrence			Consequences					
		D_1			D_2	O_1	O_2	O_3	C_1	C_2	C_3	C_4		
Infant Incubator	1	2	2.5	3	.	.	.	.	.	.	.	3	3.75	4.5
		0.6	0.75	0.9	.	.	.	.	.	.	.	0.525	0.75	0.975
		1.05	1.4	1.75	.	.	.	.	.	.	.	1.225	1.75	2.275
	2	3	3.5	4	.	.	.	.	.	.	.	4.25	5	5
		0.9	1.05	1.2	.	.	.	.	.	.	.	0.9	1.125	1.35
		1.75	2.1	2.45	.	.	.	.	.	.	.	1.225	1.75	2.275
	3	2	2.5	3	.	.	.	.	.	.	.	1.75	2.5	3.25
		0.45	0.6	0.75	.	.	.	.	.	.	.	0.525	0.75	0.975
		1.4	1.75	2.1	.	.	.	.	.	.	.	1.225	1.75	2.275
Defibrillator	1	2.5	3	3.5	.	.	.	.	.	.	.	0.5	1.25	2
		0.6	0.75	0.9	.	.	.	.	.	.	.	0.525	0.75	0.975
		1.4	1.75	2.1	.	.	.	.	.	.	.	1.225	1.75	2.275
	2	2	2.5	3	.	.	.	.	.	.	.	0.5	1.25	2
		0.75	0.9	1.05	.	.	.	.	.	.	.	0.15	0.375	0.6
		1.4	1.75	2.1	.	.	.	.	.	.	.	0.35	0.875	1.4
	3	3	3.5	4	.	.	.	.	.	.	.	4.25	5	5
		0.75	0.9	1.05	.	.	.	.	.	.	.	0.9	1.125	1.35
		2.1	2.45	2.8	.	.	.	.	.	.	.	2.975	3.5	3.5
		0.5	0.5	1	.	.	.	.	.	.	.	0.5	1.25	2

Surgical Lights	1	0.15	0.15	0.3	.	.	.	.	.	.	.	0.15	0.375	0.6
		0.35	0.7	1.05	.	.	.	.	.	.	.	1.225	1.75	2.275
	2	1	1.5	2	.	.	.	.	.	.	.	1.75	2.5	3.25
		0.15	0.3	0.45	.	.	.	.	.	.	.	0.525	0.75	0.975
		0.7	1.05	1.4	.	.	.	.	.	.	.	0.35	0.875	1.4
Automatic X-ray processor	1	0.5	0.5	1	.	.	.	.	.	.	.	0	0	0.75
		0.15	0.3	0.45	.	.	.	.	.	.	.	0	0	0.225
		0.35	0.7	1.05	.	.	.	.	.	.	.	0	0	0.525
Infusion Pump	1	3	3.5	4	.	.	.	.	.	.	.	1.75	2.5	3.25
		0.75	0.9	1.05	.	.	.	.	.	.	.	1.275	1.5	1.5
		2.45	2.8	3.15	.	.	.	.	.	.	.	2.1	2.625	3.15
	2	3.5	4	4.5	.	.	.	.	.	.	.	0.5	1.25	2
		0.9	1.05	1.2	.	.	.	.	.	.	.	0.15	0.375	0.6
		2.1	2.45	2.8	.	.	.	.	.	.	.	1.225	1.75	2.275

Using tables 2.9 to 2.12 and equations 9 to 11, linguistic variables for each dimension (in Table 6.21) are converted into fuzzy triangular numbers (see Table 6.23). The values in Table 6.23, are obtained by multiplying experts' weights (w_i) by fuzzy triangular numbers for each linguistic variable. It should be mentioned that Table 6.23 contains 27 columns; however because of lack of space some columns are not shown.

Table 6. 24 Aggregation of all sub criteria and failure modes

Equipment	Fuzzy Risk Priority Index								
	Detection			Occurrence			Consequences		
	Lower	M	Upper	Lower	M	Upper	Lower	M	Upper
Infant Incubator	1.510	1.911	2.244	0.415	0.580	0.810	1.594	2.142	2.770
Defibrillator	1.689	2.090	2.411	0.280	0.481	0.729	1.592	2.211	2.868
Surgical Lights	0.296	0.506	0.907	0.456	0.691	0.939	1.850	2.557	3.234
Automatic X-ray processor	0.092	0.150	0.350	0.0647	0.161	0.285	0.633	0.810	1.164
Infusion Pump	2.180	2.560	2.821	0.511	0.746	0.994	1.297	1.916	2.566

Using Equations 12 to 14, the fuzzy triangular numbers for each sub criterion in Table 6.23 are aggregated in order to achieve one fuzzy triangular number for each main criteria of FFMEA model (D, O and S). Results of this aggregation are given in Table 6.24 Finally, by using Equations 16 to 19, the defuzzified numbers for D, O and S and also final RPI_D scores are shown in Table 6.25. This table shows the final ranking of five medical devices.

Table 6. 25 RPI value of each medical device

Equipment	Risk Priority Index				
	Detection	Occurrence	Consequences	RPI_D	RANK
Infant Incubator	1.888	0.602	2.168	2.466	2
Defibrillator	2.063	0.497	2.224	2.283	3
Surgical Lights	0.570	0.695	2.547	1.011	4
Automatic X-ray processor	0.197	0.170	0.869	0.029	5
Infusion Pump	2.520	0.750	1.926	3.647	1

As shown in Table 6.25, Infusion Pump and Automatic X-ray processor have the highest and lowest rankings among other medical devices, respectively.

Table 6. 26 Numerical values for the calculation of miscellaneous dimensions' Intensities

Device	Exp(W)		Age (0.06)	Use-related Hazards (0.16)	Utilization (0.07)	Availability (0.03)	Recalls (0.16)	Function (0.45)	Maintenance Requirements(0.07)			M Total	Normalized M
									Tools	Materials	Skills		
Infant Incubator	1(0.50)		60%	90%	100%	98%	30%	100%	3	3	3	27	0.375
	2(0.15)		55%	100%	95%	90%	30%	100%	3	3	3	27	0.375
	3(035)		55%	95%	98%	95%	30%	100%	2	3	3	18	0.25
Defibrillator	1(0.50)		45%	85%	95%	10%	0%	100%	3	3	2	18	0.285
	2(0.15)		50%	85%	90%	15%	0%	100%	2	3	3	18	0.285
	3(035)		40%	70%	90%	15%	0%	100%	3	3	3	27	0.428
Surgical Lights Automatic X-ray processor	1(0.50)		50%	5%	20%	50%	0%	40%	1	1	1	1	0.25
	2(0.15)		40%	7%	23%	40%	0%	45%	1	1	1	1	0.25
	3(035)		50%	10%	25%	30%	0%	40%	2	1	1	2	0.05
Surgical Lights Automatic X-ray processor	1(0.50)		90%	45%	50%	15%	0%	30%	2	2	2	8	0.15
	2(0.15)		95%	20%	55%	12%	0%	35%	3	3	3	27	0.509
	3(035)		100%	20%	50%	14%	0%	30%	3	2	3	18	0.339
Surgical Lights	1(0.50)		85%	90%	60%	20%	0%	50%	2	1	2	4	0.444
	2(0.15)		90%	70%	65%	20%	0%	50%	2	1	2	4	0.444
	3(035)		90%	60%	55%	18%	0%	50%	1	1	1	1	0.111

Step 2. Construct assessment table: Table 6.26 reports the values produced by the second step of the proposed framework. All the dimensions except *Maintenance requirement* are estimated based on probabilistic intensities (presented in Tables 2.13-19). Dimension *Maintenance requirement* is computed as the product of *Maintenance tools*, *Maintenance materials* and *Maintenance skills*. Since the total score M isn't probabilistic, the values of total *M* are normalized (last column of Table 6.26).

After assigning the intensity values for each dimension, we calculate the TI score for each medical device by using Equations 23 and 24. Table 6.27 shows the TI scores and rankings of five medical devices. According to this table, Infant Incubator and Surgical Lights have the highest and lowest rankings, respectively.

Step 3. After prioritization of all medical devices by steps 1 and 2, the final step is to elect an appropriate maintenance strategy using the TI-RPI diagram. Studying the location of each medical device in the TI-RPI diagram provides useful information about their criticality as well as their maintenance actions to undertake. As shown by Fig. 6.12, Infant Incubator and Defibrillator are in the very high priority zone (Zone 4 in Fig. 6.11). According to Fig. 6.11, predictive or preventive maintenance strategy can be applied for devices located in this zone. In addition, condition-based maintenance should be applied for Infusion Pump. Automatic X-ray processor is placed in the second zone and according to Fig. 6.11 Time-based maintenance is proposed for devices placed in this zone. Finally, Surgical Lights should be maintained by corrective maintenance.

Table 6. 27 Total Intensity scores and ranking for each medical device

Equipment	6%	16%	7%	3%	16%	45%	7%	TI	RANK
Infant Incubator	0.011	0.049	0.022	0.009	0.016	0.15	0.087	0.347	1
Defibrillator	0.008	0.042	0.021	0.001	0	0.15	0.121	0.345	2
Surgical Lights	0.009	0.003	0.005	0.004	0	0.061	0.046	0.130	5
Automatic X-ray processor	0.018	0.017	0.011	0.001	0	0.0461	0.103	0.199	3
Infusion Pump	0.017	0.040	0.0137	0.001	0	0.075	0.029	0.178	4

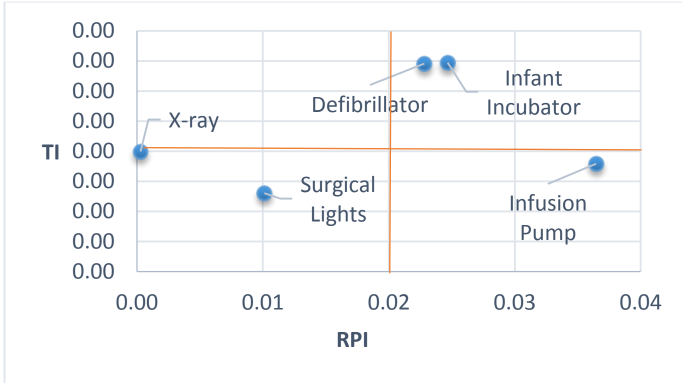

Figure 6. 12 TI-RPI diagram

6.3.6. Conclusion and Future work

The two main contributions of this study are: (i) development of a comprehensive framework for prioritization of critical medical devices, and (ii) proposing a method to select the best maintenance strategy for each device. The risk based prioritization of medical devices is valuable to healthcare organizations in prioritizing maintenance activities and in budget allocation to maintenance works. In addition, the findings of this research are very beneficial both academically and to other critical industry such as aviation, petroleum and etc. by modifying some criteria and dimensions.

In contrast with other existing methods, the proposed approach offers the following strengths and main features:

- The possibility of converting traditional factors of the FMEA into quantitative and objective factors, based on economic aspects. In our new FFMEA approach, the RPI_D number is based on experts' fuzzy linguistic assessment. Prioritization of medical devices contains different qualitative criteria and dimensions. Therefore, the expert's judgement using linguistic terms and assigning weights to their knowledge and experience is an efficient way to obtain more precise results.
- Easiness: we propose a classification for maintenance activities of medical devices through the graphic solution proposed in Fig. 6.3.4.
- Considering cost aspects by attributing the economic loss to consequences of each medical device failure, through the maintenance costs (MC), delayed treatment losses (DL) and linguistic terms proposed in Table 6.12.
- In the proposed framework, several multidisciplinary experts can scale on both importance of criteria and evaluation of alternatives. In fact, a multidisciplinary team ensures that various opinions are taken into consideration.
- The proposed framework is able to consider both qualitative and quantitative criteria/ sub criteria.

This is an original and innovative framework and the above features, distinguish it from other methods. This framework produces precise and reliable prioritization results and not only a simple ordering. In addition, it is able to select the best maintenance policy for each medical device based on its criticality. In future works, we will develop a risk-based maintenance software based on this framework in order to facilitate implementing the proposed framework in healthcare organizations.

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6.4 A comprehensive fuzzy risk-based framework for replacement of medical devices

Résumé: L'analyse de remplacement est l'un des défis de la gestion hospitalière. La gestion de milliers de dispositifs médicaux prend du temps et coûte chère, et dans certains cas, cela peut entraîner des erreurs qui conduisent à des accidents avec des conséquences potentiellement mortelles pour les patients. Par conséquent, une méthode robuste pour évaluer le remplacement du matériel médical est nécessaire pour éviter tout risque pour le patient. Cependant, peu de recherches dans ce domaine existent et les méthodes proposées comportent quelques lacunes majeures. Par exemple, aucun d'entre elles ne considère les incertitudes et les informations imprécises associées aux opinions des experts lors de l'évaluation des critères de remplacement et les critères proposés ne tiennent pas compte de tous les aspects du risque. Ensuite, nous proposons un cadre exhaustif axé sur le risque pour le remplacement des dispositifs médicaux en tenant compte des incertitudes et de plusieurs facteurs qualitatifs / quantitatifs. Dans un premier temps, une méthode fondée sur le risque est appliquée en fonction de la probabilité et de la gravité des échecs et en tenant compte de plusieurs facteurs. Ensuite, sept dimensions diverses telles que les risques liés à l'utilisation, l'âge et l'utilisation sont appliquées pour tenir compte de tous les aspects des dangers et des risques. Enfin, un diagramme est proposé pour identifier la priorité des dispositifs de remplacement. Grâce au cadre proposé, les gestionnaires peuvent facilement et plus précisément classer les dispositifs médicaux pour le remplacement en fonction de leurs scores de criticité. Ce cadre peut être adopté dans d'autres industries essentielles telles que l'aviation en modifiant certains critères et dimensions.

Mots-clés: Logique floue, Appareils médicaux, Maintenance à risque, Remplacement, MCDM.

6.4 A comprehensive fuzzy risk-based framework for replacement of medical devices

Abstract: Replacement analysis is one of the challenging issues in hospital management. Managing thousands of medical devices is time and cost consuming and in some cases this may result in errors which lead to accidents with potentially fatal consequence for patients. Therefore, a robust method for appraising medical equipment replacement is needed to avoid any risk for patient. However, little research in this area exists and proposed methods have some major shortcomings. For example, none of them consider uncertainties and imprecise information associated with experts' opinions when assessing the replacement criteria and the proposed criteria don't consider all risk aspects. Then, this paper proposes a comprehensive risk-based framework for replacement of medical devices by considering uncertainties and several qualitative/quantitative factors. At first, a risk-based method is applied based on probability and severity of failures and by considering several factors. Then, seven miscellaneous dimensions such as use-related hazards, age, and utilization are applied to consider all aspects of hazards and risks. Finally, a diagram is proposed to identify the priority of devices for replacement. Through the proposed framework, managers can easily and more accurately classify medical devices for replacement according to their criticality scores. This framework can be adopted in other critical industries such as aviation by modifying some criteria and dimensions.

Keywords: Fuzzy logic, Medical devices, Risk-based Maintenance, Replacement, MCDM.

6.4.1. Introduction

Given the limited funding of hospitals, decisions regarding the replacement or maintenance of medical devices is a challenge. If these decisions are not carefully structured, ad hoc judgment can lead to a premature replacement of one piece of equipment while failing to replace other equipment that should have been a higher priority [Dreiss, 2008]. This may increase costs and also risks to patients and/or hospital personnel and visitors. Variety of criteria are proposed for medical devices replacement decisions in the literature and some techniques are developed for evaluating these criteria. However, no attention has been paid to the uncertainties and imprecise information associated with experts' opinions when assessing the replacement criteria. In addition, the proposed methods are either qualitative or quantitative and some influential risk-based criteria such as mean time between failures (MTBF), probability of occurrence of failures, potential risk for the device operator, etc. are not taken into account. One of qualitative approaches compiles a list of medical equipment with its basic data to calculate the cumulative cost of replacement then determine "cut off" line that depends upon the available budget [Yeo, 2005]. Rajasekaran [Rajasekaran, 2005] developed an automated equipment replacement planning system (ERPS) to identify equipment most in need of replacement in order to optimize the utilization of capital budget resources. Taylor and Jackson [Taylor and Jackson, 2005] developed another automated technique called "medical equipment replacement score system (MERS)" based on technical, safety and mission critical rules, where higher scores propose higher priorities to replace. In another effort, Yatsenko and Hritonenko [Yatsenko and Hritonenko, 2008] developed a new approach to model the optimal policies of machine replacement under technological change. They considered a single-machine replacement problem in continuous time and reduced it to a nonlinear integral equation for the variable optimal service life of machine. However, this technique is complicated for medical equipment and lacks for other important factors such as safety and vendor support [Ouda et al., 2010]. A mathematical model using event tree theory for the removal of medical devices from hospital inventory was published by Miguel [Miguel, 2002]. This model guarantees a warning when a piece of medical equipment needs to be replaced. Despite a significant percentage of success between real-world situation and the mathematical model proposed, the model could not predict certain cases [Cruz and Denis, 2006]. To solve these cases, a so-called α factor was introduced in the model. Although interval values of α were obtained, more comprehensive studies were needed to obtain more generalized α values. To overcome this shortcoming, Cruz and Denis [Cruz and Denis, 2006] used artificial neural network (ANN) to classify the medical equipment life into three zones, depending on its service costs and age factors using software program; zone I: remove equipment, zone II: surveillance, zone III: maintain equipment.

This paper proposes several risk-based criteria and seven miscellaneous dimensions for assessing the replacement of medical devices and presents a comprehensive risk-based framework for replacement of medical devices by considering uncertainties and imprecise information. The proposed framework considers the level of experience and knowledge of experts and it is able to assign different weights to the proposed criteria and dimensions. This framework is explained in section 2.

6.4.2. Methodology

In this paper, we propose a novel integrated framework for prioritizing medical devices for replacement based on several risk-based criteria and dimensions which are introduced in the previous section (section. 6.1). This comprehensive approach first prioritizes medical devices based on their criticality and then propose a diagram for selecting appropriate replacement strategy for medical devices in healthcare organizations. The aim of the proposed approach is to assure high patient and personnel safety for medical devices. The proposed approach is comprised of the three following steps.

6.4.2.1. First Step

In first step, we calculate the risk score for each medical device using the Eq. 1 and by considering uncertainties in experts' ideas. In addition, particular weights have been assigned to experts' opinions. Moreover, we have added seven sub criteria to the main criteria in order to consider different aspects of failures in each medical device. It should be highlighted that our proposed model has the ability to consider multiple failures. In this paper, risk score for each medical device is calculated using the following Equation:

$$Risk = probability\ of\ occurence \times consequences \tag{1}$$

Probability of occurrence (O)

The probability of occurrence estimates the frequency of potential failure(s) or risk(s) for a given device. In this paper, we propose two following sub-criteria to be added to the occurrence criterion in order to calculate this probability more precisely; Frequency or mean time between failures (O_1) and Repeatability (O_2). These sub-criteria are already introduced in sub-section 2.3.3.

Consequences of failures (S)

In order to consider the consequences of failures, we use the four criteria that we already proposed in sub section 2.3.3. These criteria are; Patient safety, Personnel safety, Mean time to repair, and Economic loss.

Fuzzification and defuzzification

All of criteria and sub criteria are fuzzified using the proposed membership functions in the previous sections (2.3.3). The fuzzy conclusion is then defuzzified to get crisp RPI_D (index D refers to the device number). The higher the value of RPI_D, the more critical the failure. The following paragraphs discuss the fuzzification and defuzzification operations.

Let O_{jkl}^{n} and S_{jkl}^{n} be respectively the occurrence and severity values for medical device j, failure mode k and sub criteria l evaluated by expert n. Let us also consider the triangular fuzzy membership function:

$$O_{jkl}^{n} = (LO_{jkl}^{n}, MO_{jkl}^{n}, UO_{jkl}^{n}), \tag{7}$$

where $0 \le LO_{jkl}^{n} \le MO_{jkl}^{n} \le UO_{jkl}^{n} \le 10$

$$S_{jkl}^{n} = (LS_{jkl}^{n}, MS_{jkl}^{n}, US_{jkl}^{n}), \tag{8}$$

where $0 \le LS_{jkl}^{n} \le MS_{jkl}^{n} \le US_{jkl}^{n} \le 10$

It should be noted that weighting values w_i are determined for each expert $i \in \{1, ...,n\}$ according to their experience and knowledge. These values are in the $[0,1]$ interval, and sum of them for all experts must be one. Besides, a pairwise comparison among O and S parameters should be done in order to determine the weights of importance for each criterion (W_O and W_S). Equations 9 and 10 are used to aggregate the experts' opinions (w_i).

$$O_{jkl} = \sum\nolimits_{i=1}^{n} O_{jkl}^{i} w_i \tag{9}$$

$$S_{jkl} = \sum\nolimits_{i=1}^{n} S_{jkl}^{i} w_i \tag{10}$$

After assigning weights W_O and W_S to reflect the relative importance of each criterion, we obtain the fuzzy membership function called μ(RPI):

$$\mu(Risk) = W_O \mu(O_{jkl}) + W_S \mu(S_{jkl}) \tag{11}$$

In order to obtain crisp numbers from the above fuzzy set, (μ(Risk)) should be defuzzified. In this study, Center-of-area (COA) method [Lin, 2014] is used to defuzzify the fuzzy membership functions of O and S (O_{jkl}^{n}, S_{jkl}^{n}) and also $\mu(Risk)$. Eqs. 12-13 represent $DO\ and\ DS$.

$$DO = \frac{1}{3}[(UO - LO) + (MO - LO)] + LO \tag{12}$$

$$DS = \frac{1}{3}[(US - LS) + (MS - LS)] + LS \tag{13}$$

Finally, defuzzified RPI for a given device is calculated using $DO\ and\ DS$ in Equation (14).

$$Risk_D = DO \times DS \tag{14}$$

6.4.2.2. Second step

In the second step, seven important miscellaneous dimensions are considered as previous paper in order to take into account other factors and aspects strongly related to replacement of medical devices. After acknowledging the dimensions, grades and intensities of each of the dimensions, each expert should assess each device with respect to every dimension $d \in \{1, \dots, 7\}$. Assuming that n experts are consulted, the *Intensity score for each dimension*, I_d is computed using equation 2.18 presented in sub section 2.3.3. In addition, the Total Intensity of each medical device is calculated using Eq. 19.

6.4.3. Third step

After ranking all of considered medical devices, the final step is to identify which device should be replaced. In this paper we propose a Replacement Planning Diagram (see Fig. 6.13) to identify the critical medical devices in need for replacement. This Diagram uses the $Risk_D$ and TI scores which are achieved from the first and second steps of our approach. The abscissa reports the risk scores, valued by $Risk_D$, while the ordinate reports the TI scores achieved by the second step of the proposed method.

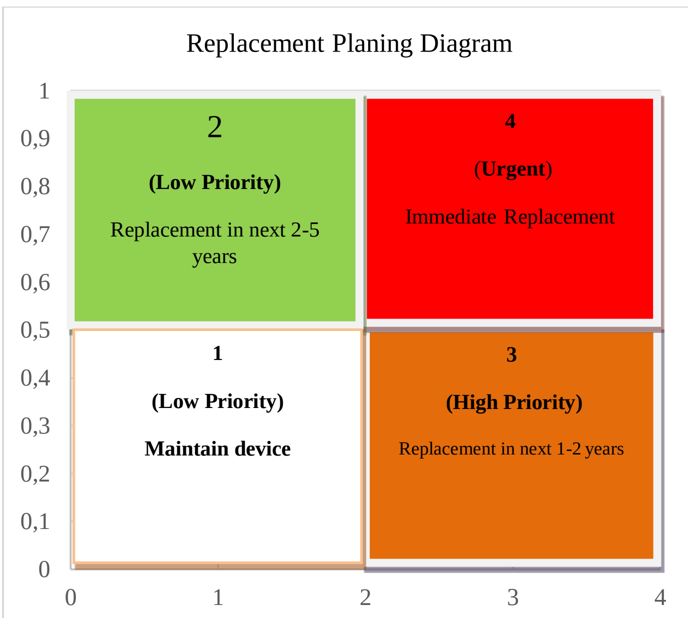

Figure 6. 13 The TI-Risk diagram

To make a classification, the position of each medical device should be first determined on the TI-Risk diagram (by using $Risk_D$ and TI scores). The points (coordinates) placed on the diagram display medical devices and their disposition on each of four quarters presents information regarding the criticality of each medical device for replacement. Figure 6.13 shows 4 zones; Zone 1 comprises a 'Low Priority' area where both TI and $Risk_D$ have low scores. Zone 2 shows a second 'Low Priority' zone, including high TI scores and low $Risk_D$ scores. Zone 3 is a 'High Priority' area including high $Risk_D$ and low TI scores. Zone 4 shows 'Urgent' area. Devices within this zone have very high RPI and TI scores, and therefore they are critical and need to be replaced as soon as possible. Devices located in zone 3 are less critical than zone 4, but they are close to the replacement and therefore they should be considered in the next 1-2 years. Since devices within zone 2 have low priority, they could be considered for replacement in the next 2-5 years. Devices within zone 1 very low priority for replacement and they could be maintained periodically. Note that the limited budget of organization should be considered when planning for replacement.

6.4.4. Conclusion

Although the concept of capital equipment planning and replacement are well established in different industries, replacement planning of medical devices has received the least attention. According to the literature, very few hospitals have any formal process for evaluating medical devices replacement. In addition, there are some major shortcomings in currently used tools in hospitals, while this may result in errors which lead to accidents with potentially fatal consequence for patients and even device operator or maintenance personnel.

Considering the patient safety and limited budget of healthcare organizations, the risk-based prioritization of medical devices for maintenance activities or replacement is valuable and essential. Therefore, this paper proposes a comprehensive fuzzy risk-based framework for replacement planning of medical devices. In contrast with other existing methods, the proposed framework offers the following strengths and main features; 1) it contains several qualitative and quantitative risk-based criteria and dimensions in order to consider all possible aspects of risks in replacement of devices, 2) the expert's judgement using linguistic terms and assigning weights to their knowledge and experience is an efficient way to obtain more precise results, 3) several experts can scale on both importance of criteria and evaluation of devices, 4) the proposed framework is able to consider both qualitative and quantitative criteria/ sub criteria, and 5) to the best of our knowledge this is the first paper that consider uncertainties in replacement of medical devices.

This is an original and innovative framework and the above features, distinguish it from other methods. This framework produces more precise and reliable prioritization results and not only a simple ordering. The findings of this research are very beneficial both academically and to other critical industry such as aviation, petroleum and etc. by modifying some criteria and dimensions.

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Chapter 7. Case study

Updating clinical practice guidelines: A new priority-based quantitative framework for updating existing guidelines

The seventh chapter is dedicated to the following articles:

[1] "Influential criteria in updating clinical practice guidelines", Afshin Jamshidi, Samira Abbasgholizadeh Rahimi, Daoud Ait-kadi, Angel Ruiz, Marie-eve Lamontagne, Froncoia Routhier (Submitted in Journal of Health Services Research).

[2] "A comprehensive prioritization framework for updating Clinical Practice Guidelines", Afshin Jamshidi, Angel Ruiz, Daoud Ait-kadi, Marie-eve Lamontagne, Froncoia Routhier (Submitted in International Journal of Medical Informatics).

Collaborators:

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7.1 Influential criteria in updating clinical practice guidelines

Objectifs: Identifier, valider et pondérer les critères potentiellement influents dans la mise à jour des GPC.
Méthodes: Nous avons effectué des recherches dans les bases de données MEDLINE, EMBASE, CINAHL et dans la bibliothèque du Réseau international de recommandations (G-I-N) pour trouver des articles, des manuels méthodologiques et des manuels qui donnent des conseils sur la mise à jour des GPC. Ensuite, nous avons réalisé un sondage en ligne entre février et juillet 2015. L'enquête a été envoyée par courrier électronique à 83 organismes publics et privés du monde entier et à 16 auteurs qui ont publié des articles pertinents sur la mise à jour des GPC.
Résultats: Nous avons inclus un total de treize documents dans l'examen systématique et nous avons identifié 18 critères potentiels. Trois articles, un manuel méthodologique et deux manuels décrivent 15 critères explicitement pour évaluer les GPC à mettre à jour. Nous avons identifié le reste des critères en fonction de la perception par les experts de certaines phrases ou paragraphes dans les articles inclus et un consensus a été atteint sur tous les critères potentiels. Trente institutions et 5 auteurs ont répondu au questionnaire (taux de réponse de 36%). En dernière analyse, 24 questionnaires remplis (24%) ont été inclus.
Conclusions: C'est la première fois que les critères de hiérarchisation utilisés pour la mise à jour des GPC ont été identifiés et validés. L'évaluation et la priorisation des GPC existants sur la base des critères validés peuvent favoriser la canalisation des ressources limitées dans la mise à jour des GPC les plus sensibles au changement, améliorant ainsi la qualité et la fiabilité des décisions prises en matière de santé fondées sur les GPC actuels.
Mots-clés: Mise à jour, Guides de pratique clinique, Priorité, Critères, Prise de décision multicritères.

7.1 Influential criteria in updating clinical practice guidelines

Objectives: To identify, validate and weigh the potential influential criteria in updating CPGs.

Methods: We searched the MEDLINE, EMBASE, CINAHL databases and the Guideline International Network (G-I-N) library for articles, methodological handbooks, and manuals that provide guidance on updating time/process of CPGs. Then, based on the review's results, we conducted an online survey between February and July 2015. The survey was sent by email to 83 public and private organizations across the world and 16 authors who have published relevant articles on the subject of updating CPGs.

Results: We included a total of thirteen documents in the systematic review and we identified 18 potential criteria. Three articles, one methodological handbook, and two manuals describe 15 criteria explicitly for assessing CPGs for updating. We identified the rest of the criteria based on experts' perception of some sentences or paragraphs in the included articles and a consensus was reached on all potential criteria. Thirty institutions and 5 authors answered the questionnaire (36% response rate). In the final analysis, 24 completed questionnaires (24%) were included.

Conclusions: This is the first time that criteria for prioritization used in updating CPGs were identified and validated. Evaluation and prioritization of existing CPGs based on the validated criteria can promote channelling limited resources into updating CPGs that are most sensitive to change, thus improving the quality and reliability of healthcare decisions made based on current CPGs.

Keywords: Updating, Clinical Practice Guidelines, Prioritization, Criteria, Multi-Criteria Decision Making.

BACKGROUND

A clinical practice guideline (CPG) is a document that includes recommendations to assist physicians, healthcare practitioners, and patients in making decisions about diagnosis, management, and treatment for specific clinical conditions [1]. The lifespan of CPGs is limited since new evidences emerge continuously [2,3]. New information needs to be assessed frequently and CPGs should be updated regularly based on the new evidence in order to remain valid [4]. Many organizations recommend a full update every 3-5 years [5]. This could be a waste of the limited resources of organizations since the rate of new evidence for different fields is variable [6]. Currently, there is not robust evidence about differences between lifespan of CPGs by topic [6,7]. Updating CPGs is a crucial and complex process in the lifecycle of CPGs for ensuring their validity and quality [8,9]. Substantial human and financial resources are being expended internationally for updating existing CPGs [5,8,10,11]. According to Shekelle [11], conducting a systematic review in the US Agency for Healthcare Research and Quality (AHRQ) costs approximately $250,000 USD for each CPG. Considering the limited resources of organizations, dynamic and fluid environment of CPGs, and substantial cost and time needed for updating, it is obvious that updating all CPGs regularly is not feasible. Therefore, there must be some criteria in order to prioritize the existing CPGs for updating. Prioritization of existing CPGs for updating is an effective way of ensuring that resources are spent in an efficient and effective manner towards the upkeep of the CPGs that are the most relevant and of the highest priority [10]. Although there are some criteria and methods for prioritization of recommendations for CPG development, there is no validated criteria, standardized method or comprehensive process for prioritizing CPGs and assessing when each CPG should be updated, and very few research has been done into this prioritization process [4,5,8,10-15]. According to the recent systematic review of methodological handbooks conducted by Vernooij et al. [5], “Crucial elements in identifying new evidence, the assessment for the need for an update and the updating strategy itself, are generally lacking or include solely a reference to the development process”. Considering the above-mentioned shortcomings in updating CPGs, the main objectives of this study were: 1) to identify and describe the potential priority criteria in updating CPGs, and 2) to validate, and weigh the identified criteria.

METHODS

Systematic Review

Information sources and search strategy

To identify and describe the potential priority criteria in updating CPGs, we performed the primary systematic search in September 2014 in three databases (MEDLINE, EMBASE, and CINAHL) as well as the Guideline International Network (G-I-N) Library (from 1990 onwards). We included studies published in English, regardless of their publication status and by using a combination of free text terms (Updating, Clinical Practice Guidelines, Clinical Guidelines, Guidelines, Criteria, elements, factors, and Prioritization). Additionally, a secondary search was performed by checking the reference lists of the included studies. Moreover, we used the Google search engine to search the grey literature in order to find additional relevant sources. The Research Ethic Board’s approval was not required for this systematic review.

Eligibility criteria

- Articles, manuals, and methodological handbooks that provide guidance on updating methods including evaluating, or comparing strategies or methods and assessing the need for an update;
- Published in English after 1990;
- Full-text version available.

Exclusion criteria

- Handbooks which focus mainly on developing CPGs;
- Reports on CPGs;
- Updated systematic reviews or meta-analyses;
- Health technology assessments.

Study selection

Two authors (AJ, SAR) independently selected potential articles by reviewing titles and abstracts, and finally full text for a more detailed evaluation. Disagreements were initially resolved by discussion and consensus, and if necessary, with the help of a third author (MEL). Since updating issue of clinical practice guidelines is common among all guideline developers, we opted not to target any specific population/patients or health condition in this study and we considered updating issue for all topics.

Data Extraction Strategy

An initial extraction was performed (AJ) on 5 articles to pilot the designed form in order to obtain a reliable data extraction form. The results of this pilot extraction were examined to refine the data extraction form. The final extraction form included the following information:

1) Characteristics of articles, manuals, and methodological handbooks including the institution/organization/author name, country, and publication year,
2) Study characteristics including health topic, sample size and type of analysis,
3) The proposed criteria/factors and their descriptions by indicating their exact address in the article (including page, column and paragraph), and;
4) Limitations of the proposed model/criteria.

The above data was systematically extracted from each study by two authors (AJ, SAR) and was double-checked by a third author (MEL).

Survey

To validate and weight the criteria identified in the previous step, an international web survey was conducted. It was approved by the Research Ethic Board of the *Institut de réadaptation en déficience physique de Québec* (IRDPQ) (Project # 2014-396). The survey consisted of four sections. The first section included questions about the organization (three questions), the second was related to the updating process of CPGs (eight questions), the third section was dedicated to participants' characteristics (five questions), and the last section focused specifically on the expert's perceived importance of the identified criteria which were divided into two different steps with regards to relevance for updating CPGs (see Supplementary file 1). At the end of each step's questions, we included two open-ended comment sections in order to gather comments or additional information. In particular, we asked the participants whether a criterion should be eliminated from, or added to, the identified criteria for each step. The questionnaire was first tested with two individuals for clarity and burden. Their feedback was used to refine the final version of the survey for optimal understanding. We sent personalized invitation emails to each organization as well as each author, providing them with brief information about the study and survey. We sent three reminders at intervals of two weeks (1^{st}, 3^{rd}, 5^{th} week) to all the participants. In addition, we extended the survey's deadline by three months and we contacted all the institutions and authors who didn't complete the survey.

Study population

Our study population includes: 1) experts involved in CPG development in institutions which are members of the G-I-N and the U.S. National Guideline Clearinghouse (NGC), and: 2) the authors of relevant articles on the subject of updating CPGs.

Study sample

We selected participant institutions based on the following criteria: 1) institutions included in NGC that published more than 20 CPGs, 2) members of G-I-N, and 3) institutions additionally selected by an expert committee based on relevance. In addition, we contacted the authors of the relevant articles found in the systematic review and invited them to participate in our survey. We sent an email to each organization and author through the address identified via the internet and the author information in the manuscripts, respectively. In addition, we asked them if they knew some other experts within their organization or university who could answer the survey and, if so, distribute the survey link to them.

Analysis

We used descriptive statistics to analyze the data in sections A, B, and C of the questionnaire. For questions in section D, we applied a multi-attribute decision making (MADM) tool called “Fuzzy Simple Additive Weighting (FSAW)” [16] to weight the importance of each criterion based on the experts’ opinions. This tool is explained in the following.

Simple Additive Weighting (SAW) is the most popular and applicable MADM method [17]. The basic concept of SAW method is to find the weighted sum of ratings for some alternatives by some decision makers. Due to its simplicity, SAW method has been used in several healthcare decision making problems [16-19]. In this method, each criterion is assessed independently with respect to its importance in the updating process of CPGs and is given the most descriptive rank. Since the traditional SAW method is not able to handle the uncertainties existing in the expert’s opinions, in this study a Fuzzy SAW model (FSAW) was employed [16]. Parameter uncertainty refers to the uncertainty in decision-makers’ opinions, for example when a group of experts assign linguistic terms to a criterion [20]. In this study, the criteria are evaluated by adapting a nine-scale linguistic terms [21] to handle the uncertainties in the experts’ opinions (See Table 1). The linguistic terms are used to convert the subjective perception of experts into numerical values to obtain the importance weight of criteria.

The steps of FSAW method are presented as follows:

Step 1: form a committee of experts ($j = 1, 2 \ldots n$) for rating the criteria ($i = 1, \ldots, m$).

Step 2. Determine the weights of importance for each expert (W_j) by considering the level of knowledge and experience. In this study, we assigned scores 2, 6, 8, and 10 to the highest level of education (less than BSc, BSc, MSc, and PhD, respectively) and also scores between 0 and 10 to the expert level of experience in CPG development and updating. Then, we aggregated them using Microsoft Excel 2013 average function. Finally, in order to obtain the weights of experts in the zero to one interval, $W_j \in [0,1]$, we defined the following Equation.

$$W_j = \frac{A_j}{\sum_{j=1}^{n} A_j} \quad (1)$$

where A_j indicates the average value of scores assigned to expert j. Note that the sum of total weights for all experts should be equal to one ($\sum_{n=1}^{j} W_j = 1$).

Step 2: Assign suitable linguistic term for each criterion using Table 1.

Table 7. 1 Linguistic terms and fuzzy triangular numbers for rating the criteria step 1 & 2.

	Linguistic terms	Fuzzy triangular numbers
1	Absolutely Low	(1, 1, 2)
2	Very Low	(1, 2, 3)
3	Low	(2, 3, 4)
4	Medium Low	(3, 4, 5)
5	Fair	(4, 5, 6)
6	Medium High	(5, 6, 7)
7	High	(6, 7, 8)
8	Very High	(7, 8, 9)
9	Absolutely High	(8, 9, 10)

Step 3: Translate the assigned linguistic terms to fuzzy triangular numbers $F_{ij} = (a_{ij}, b_{ij}, c_{ij})$ using Table 1. Figure 1 shows a simple fuzzy triangular number. The values $a, b,$ and c indicate the lower, medium and upper bound for the assigned linguistic term. The aim of considering lower and upper bounds for each linguistic term is to take into account the uncertainties in experts' opinions.

Definition 1. A fuzzy set is built from a reference set called universe of discourse. The reference set is never fuzzy. Assume that $U = \{x1, x2, \dots, xn\}$ is the universe of discourse, then a fuzzy set $\tilde{T}$ in U ($\tilde{T} \subset U$) is defined as a set of ordered pairs $\{(xi, \mu_A(x_i))\}$ where $x_i \in U, \mu_{\tilde{T}}: U \to [0,1]$ is the membership function of $\tilde{T}$ and $\mu_{\tilde{T}}(x) \in [0,1]$ is the degree of membership of x in $\tilde{T}$ [22].

Definition 2. A fuzzy variable determined by the triplet $\tilde{T}$=$[a, b, c]$ of crisp number with ($a < b < c$) is called a triangular fuzzy linguistic variable, which is characterized by the following member function:

$$\mu_{\tilde{T}}(x) = \begin{cases} \frac{x-a}{b-a}, & if\ l \le x \le m \\ \frac{c-x}{c-b}, & if\ m \le x \le u \\ 0, & otherwise \end{cases}$$

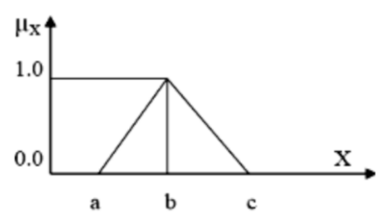


Fig 7. 1 A fuzzy triangular number.

Step 4: Multiply the experts' weights in the fuzzy triangular numbers and obtain the weighted fuzzy numbers (WF_{ij}).

$$WF_{ij} = Wj \times (a_{ij}, b_{ij}, c_{ij}) \tag{2}$$

Step 5: Aggregate the weighted fuzzy numbers of all experts (by calculating the average value of lower, medium, and upper bounds for each criterion) and obtain the aggregated fuzzy number AF_i=(a_i, b_i, c_i).

$$AF_i = \frac{(WF_{1i} + WF_{2i} + \dots + WF_{ni})}{n}; \qquad j = 1, 2 \dots n; i = 1, \dots, m \tag{3}$$

Step 6: Defuzzify the aggregated values (AF_i) using the following Equation [23]:

$$d = \frac{(a_i + 2b_i + c_i)}{4} \quad (4)$$

Step 7: Normalize the defuzzified values for each criterion by dividing the diffuzzified value of each criterion into the sum of diffuzified values of all criteria.

RESULTS

Systematic review

Study selection

We initially identified 160 publications from the literature search that met the eligibility criteria and excluded 15 duplicates and 106 references after examining the title and abstract (Figure 2). We selected 39 articles for full-text review and excluded 26 references. We finally included thirteen studies [4,6,10-13,24-30]. The screening process is summarized in Figure 2.

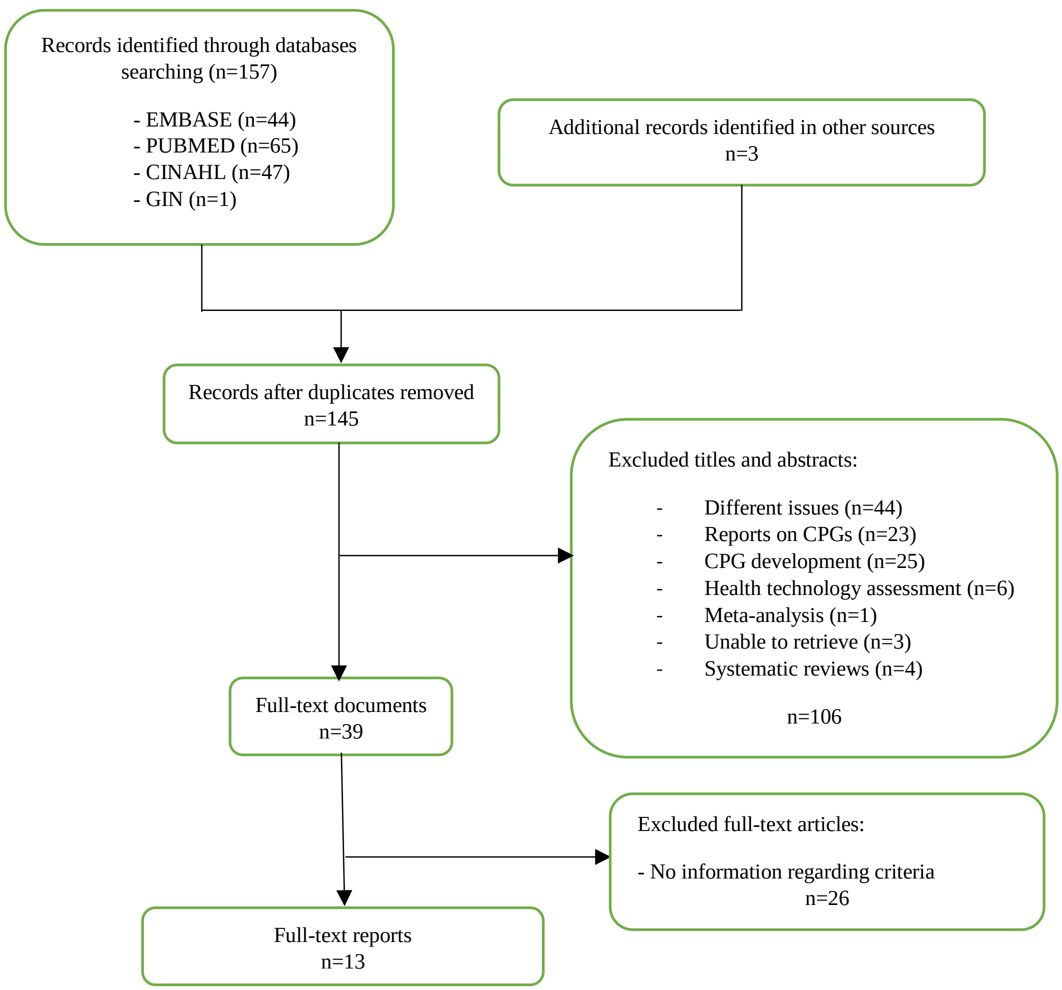


Fig 7. 2 Flow diagram for the identification of studies.

Criteria for assessing the importance of each CPG (Criteria-Step 1)

As Table 4 shows, the first step includes 10 criteria. The purpose of the identified criteria for this step is to rank the updating importance of each CPG for without assessing new evidence and only based on the following criteria in order to identify which CPG has a high priority for updating. In this study, we use parameter C_{ki} to call the criteria step 1 and 2, where index $k = 1{,}2$ refers to the step of criterion and index $i = 1, \dots, m$ indicates the number of each criterion. 8 out of 10 criteria were explicitly introduced by two articles [10,28] and two manuals [26,30]. Only two criteria (C11 and C12) were identified based on the experts' perception of some sentences or paragraphs in the included articles. The exact reference/s of each identified criterion is mentioned in Table 4. The complete description of each first step's criterion is described in the following. Note that in some cases, we have applied different references than Table 4 in order to find more suitable description of the following criteria.

1- The Scope of the guidelines (C_{11})

The scope of the CPG represents the clinical condition, patients' population, target audience, the type of care providers, guidelines' consumers, the interventions and the types of settings in which the guidelines will be employed [31].

2- Fast-changing fields and rate of new evidence (C_{12})

Some fields are fast-changing such as AIDS, breast cancer, and cardiovascular risk management. Other guidelines may need less frequent updating [12].

3- The required resources (C_{13})

The required resources (including human resources and material) for updating each CPG should be considered according to the topic/scope of CPG [30]. This information could be estimated by experts based on the update history of the CPGs and by assigning linguistic variables to this criterion.

4- Potential benefits of updating a guideline for public health (C_{14})

Some topics have a high public health burden such as infectious diseases, while the burden of other topics is low (e.g. counseling for dental disease) [26].

5- Performance evaluations and feedback on guideline use (C_{15})

Availability of feedback on guideline use from CPG users could improve the implementability and acceptance of the recommendations in subsequent versions of the CPG [28].

6- The appropriateness of the questions and search criteria (C_{16})

The questions and search criteria as they are in the CPG should address current needs, such that an updated literature search would be useful and identify relevant evidence [10].

7- The last review date of CPG (C_{17})

The last review date indicates how old the existing guideline is [10].

8- The current relevance of the CPG (C_{18})

This criterion indicates that how current and relevant the recommendations still are for decision making [10].

9- The impact of the CPG on access to care (C_{19})

Sometimes some decisions are made about access or payment for care by the Ministry or other organizations based on the recommendations in the CPG such as funding, case-by-case review or out of country requests [10].

10- The risk of leaving the CPG publicly available, the risk of being outdated (C_{110})

The recommendations have the potential to cause harm to patients if they are outdated. Then, the risk of leaving the guideline publicly available should be assessed by experts [10].

Criteria for assessing the new evidences (Criteria-Step 2)

The purpose of the identified criteria for this step is to determine the influence of the new evidence on the CPGs categorized as high priority (in step 1) and the actions such as full/partial update or defer to the next year that should be taken. This step includes 8 criteria which 7 of them were explicitly introduced by Shekelle [6,29]. The one other criterion (C_{27}) was identified based on the experts' perception from a methodological handbook [27]. The 8 identified criteria for assessing the new evidences are described in the following.

1- Changes in the available interventions (C_{21})

"Since the development of a guideline, new preventive, diagnostic, or treatment interventions may have emerged to complement or supersede other interventions" [6].

2- Changes in the evidence on the benefits and harms of existing interventions (C_{22})

"New evidence regarding the benefits and harms may invalidate the existing CPG. for example, the surgical risk of carotid endarterectomy has fallen substantially over the past 30 years, altering the risk-benefit ratio in favour of performing the operation for selected patients with symptomatic, high grade carotid stenosis" [6].

3- Changes in outcomes that are considered important (C_{23})

"New evidence may identify important outcomes that were previously unappreciated or wholly unrecognized" [6].

4- Changes in the evidence that current practice is optimal (C_{24})

"Guidelines are developed to help narrow the gap between ideal and current clinical practice. This gap could narrow over time to the point that a guideline is no longer needed" [6].

5- Changes in the values placed on outcomes (C_{25})

"The values that individuals or society place on different outcomes may change over time. For example, economic issues have received little attention in most guidelines but will be considered explicitly in guidelines developed by the UK National Institute for Clinical Excellence" [6].

6- Changes in the resources available for healthcare (C_{26})

"Guidelines may need to be updated to permit increased delivery of services if the level of available resources increases over time" [6].

7- The quality of the evidence (C_{27})

The quality of evidence indicates the level of confidence or certainty in the estimates of effects related to an outcome [12].

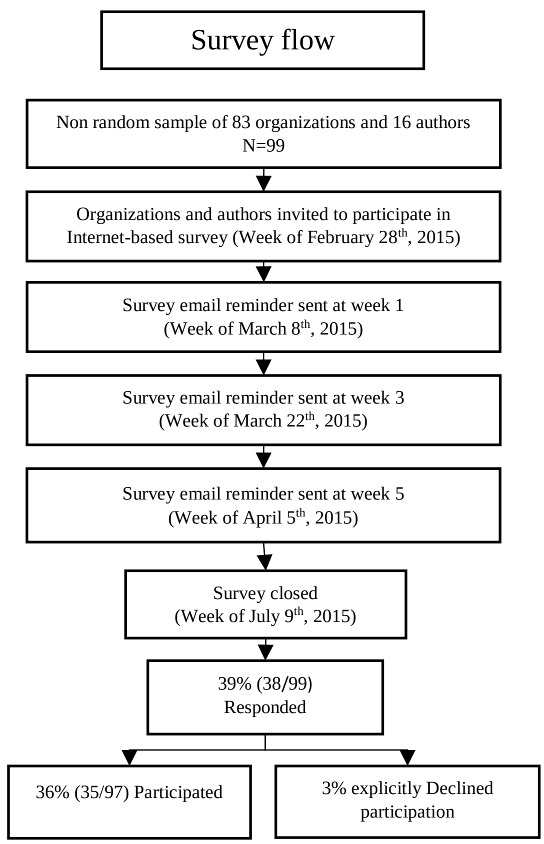
8- The strength of the evidence (C_{28})

This criterion indicates the level of confidence that adherence to the recommendation will do more good than harm [32]. It may influence the durability of guideline recommendations, with recommendations based on stronger evidence lasting longer [29].

Survey

We contacted 83 organization including 52 members of G-I-N, 30 institutions included in NGC that published more than 20 CPGs, and one organization, which was not a member of G-I-N or NGC and 16 authors. After three reminders, we received a reply from 9 participants (9% response rate). Due to the low response rate, we extended the deadline of the survey until the end of June 2015 and contacted all the institutions and authors who started to complete the survey and didn't complete it. Finally, we received 35 completed questionnaires. We excluded eleven questionnaires because more than 30% of questions were not answered. In the final analysis, we included 24 questionnaires (see Figure 2).

Fig 7. 3 Survey flow diagram.



The information obtained from participants is described in the following sub sections. It should be mentioned that the number of respondents for each questionnaire's section varied between 21 and 24.

Organizational Characteristics

23 organizations answered the questions related to the organizational characteristics. The majority reported that they do update their guidelines (92%). Most of the respondents were from North America and Europe (87%). Around 50% of organizations reported that they publish fewer than 5 new CPGs per year. 56% of participating organizations were public institutions.

Characteristics of the Updating Process of CPGs

21 organizations answered the questions related to the updating process of CPGs (Section B of questionnaire). The information regarding the CPGs' updating process of these organizations is indicated in Table 2. The time frame to check for the need of updating was variable between 2 to 5 years. Only one institution mentioned that they assess all their CPGs annually. Over 90% of the institutions reported that they review the CPGs every 3-5 years. Only one organization mentioned that they review "*Every 2 years from publication date - with a less intensive procedure at 2, 6, 10 years etc., and a more thorough look at 4, 8, 12 years etc.*".

In section B of the survey, we also asked the participants whether they prioritize their CPGs based on some criteria. One organization reported that they usually consider *a 1st come - 1st served process* for minor/discrete updates. Some organizations reported criteria such as the topics of guidelines, policy issues, number of patients affected by CPG, nature of any clinical changes, new evidences, consensus from other relevant guidelines and the program's capacity to make changes. One organization reported that "*The prioritization is done according to the epidemiology of major pathologies of the country, according to mortality and morbidity among others. Also in response to priority health programs in the country.*" Only one organization mentioned that they have a quantitative method for the prioritization of CPGs' updating as follows: *"All CPGs that are identified as needing updates are given a priority score (between 1&5) based on five questions including the guidelines relevance to neurologists, prevalence of the disease, the amount of practice variation or controversy, feasibility, and patient care and outcomes."*

By considering and evaluating the above criteria with our expert team, we came to the conclusion that most of these criteria are already identified through our systematic review and introduced in our questionnaire. Additionally, some of them could not be considered as a criterion such as the *first come - first served process*. Moreover, none of the participant organizations suggested that we add any of the above criteria to our identified criteria.

Table 7. 2 Characteristics of the responding institutions & the process of updating CPGs.

The guideline updating process (participants number=21)	Number of guidelines assessed per year	0≪N< 5	6	28
		5≪N< 10	3	15
		10≪N≪15	3	15
		N>15	9	42
	Number of guidelines updated per year (Partially or fully)	0≪N< 5	10	46
		5≪N< 10	3	15
		10≪N≪15	5	24
		N>15	3	15
	Part of the guidelines checked	Clinical questions	13	62
		Recommendations	2	9
		Methodologies	0	0
		The whole CPG	5	24
		Unknown	1	5
	Reliability of the updating process	Not very reliable	2	10
		Could be more reliable	2	10
		Moderately reliable	9	42
		Very reliable	8	38
	Time frame to check for the need of updating	Yes	16	76
		No.	5	24
	Time frame to decide when to update	Yes	14	67
		No.	7	33
	Prioritizing CPGs according to their urgency	Yes	15	72
		No.	6	28
	Prioritizing CPGs based on some standardized criteria	Yes	13	62
		No.	8	38

Participants' characteristics

In section C of the survey, we asked some questions regarding the level of experience and knowledge of participants in order to consider their experience and knowledge in scaling the criteria to achieve more precise and rigorous rankings. Table 3 shows the calculated weights of 24 experts based on the obtained data in section C of survey.

Table 7. 3 Assigned values to experts' level of education and experience.

Experts	Highest level of education	Level of experience	Exp. Weights
EXP.1	10	3	0.045
EXP.2	2	2	0.026
EXP.3	1	1	0.026
EXP.4	5	5	0.026
EXP.5	10	10	0.055
EXP.6	7	6	0.045
EXP.7	4	1	0.028
EXP.8	5	3	0.038
EXP.9	10	10	0.064
EXP.10	10	8	0.055

EXP.11	5	3	0.034
EXP.12	10	1	0.045
EXP.13	10	7	0.058
EXP.14	10	1	0.041
EXP.15	5	5	0.043
EXP.16	8	8	0.051
EXP.17	7	5	0.030
EXP.18	4	4	0.034
EXP.19	4	4	0.030
EXP.20	10	10	0.060
EXP.21	7	5	0.043
EXP.22	10	10	0.064
EXP.23	4	1	0.028
EXP.24	5	5	0.034

Criteria Importance

Although few organizations reported few criteria for considering the urgency of CPGs in section B of the survey, no criterion was added or eliminated by them in section D of the questionnaire. Table 5 and 6 indicate the assigned linguistic values for criteria step 1 and 2 by 24 and 22 participants, respectively. Tables 7 and 8 show the fuzzification and defuzzification process for obtaining the weights of criteria step 1 and 2. Note that the fuzzy numbers in Tables 7 and 8 are multiplied by the weights of experts in Table 3. Due to lack of space some columns are not shown in Tables 7 and 8. Since the criteria for steps 1 and 2 are not related to each other, we calculated the weights for steps 1 and 2 based on 24 and 22 responses, respectively.

Table 7. 4 Validated and weighted criteria for first and second step of CPG prioritization.

Step	**Author, year**	**Criteria**	**Health Topic**	**Criterion explicitly Proposed**
Step 1	Eccles, 2002	The Scope of the guidelines (C_{11})	Angina and asthma in adults	No
	Van der Wees, 2007		Physical therapy	
	Alonso, 2011	Fast-changing fields and rate of new evidence (C_{12})	All topics	No
	Alonso, 2011	The required resources (C_{13})	All topics	Yes
	Laura, 2012			
	AAOS, 2011		Orthopedic Surgeons	
	AHRQ, 2008		All topics	
	AHRQ, 2008	Potential benefits of updating a guideline for public health (C_{14})	All topics	Yes
	AAOS, 2011		Orthopedic Surgeons	
	Burgers, 2012	Performance evaluations and feedback on guideline use (C_{15})	Chronic obstructive pulmonary disease (COPD)	Yes
	Agbassi, 2014	Changes in the resources available for healthcare (C_{26})	Cancer	Yes
		The last review date of CPG (C_{17})		Yes
		The current relevance of the CPG (C_{18})		Yes
		The impact of the CPG on access to care (C_{19})		Yes
		The risk of leaving the CPG publicly available (C_{110})		Yes

Step 2	Shekelle, 2001__BMJ	Changes in the available interventions (C_{21})	All topics	Yes
		Changes in the evidence on the benefits and harms of existing interventions (C_{22})		Yes
		Changes in outcomes that are considered important (C_{23})		Yes
		Changes in the evidence that current practice is optimal (C_{24})		Yes
		Changes in the values placed on outcomes (C_{25})		Yes
		Changes in the resources available for healthcare (C_{26})		Yes
	Alonso et al., 2009	The quality of the evidence (C_{27})		No
	Shekelle, 2014	The strength of the evidence (C_{28})		No

Table 7. 5 Assigned values for criteria-step 1 by 24 experts.

Criteria	**Experts**																							
	E1	**E2**	**E3**	**E4**	**E5**	**E6**	**E7**	**E8**	**E9**	**E10**	**E11**	**E12**	**E13**	**E14**	**E15**	**E16**	**E17**	**E18**	**E19**	**E20**	**E21**	**E22**	**E23**	**E24**
C_{11}	8	6	7	9	3	3	3	6	6	5	7	9	2	9	3	9	7	6	9	7	7	2	9	9
C_{12}	7	7	7	9	7	7	9	7	7	6	9	8	8	9	7	9	8	7	9	7	9	8	9	9
C_{13}	4	6	6	9	3	6	8	9	7	8	9	9	7	5	8	9	7	6	3	8	8	8	9	7
C_{14}	8	5	6	7	9	2	8	8	5	7	9	8	7	7	1	9	7	7	2	7	4	3	7	7
C_{15}	3	8	8	9	9	7	7	6	7	5	9	7	3	3	6	9	5	5	9	8	5	8	9	7
C_{16}	7	8	5	7	6	9	8	8	5	3	9	8	7	8	9	9	8	8	8	6	7	7	9	7
C_{17}	9	7	5	9	7	8	7	6	6	2	8	9	6	9	2	9	5	6	7	6	7	7	7	7
C_{18}	3	8	6	9	7	9	8	9	4	9	9	9	6	8	8	9	8	6	8	6	6	5	8	7
C_{19}	2	5	4	9	7	8	6	6	6	9	8	7	7	1	8	9	5	5	2	7	8	7	9	4
C_{110}	3	5	8	9	4	4	8	8	8	8	9	9	5	9	7	9	6	8	2	7	7	8	9	7

Table 7. 6 Assigned values for each criteria-step 2 by 22 experts.

Criteria	**Experts**																					
	E1	**E2**	**E3**	**E4**	**E5**	**E6**	**E7**	**E8**	**E9**	**E10**	**E11**	**E12**	**E13**	**E14**	**E15**	**E16**	**E17**	**E18**	**E19**	**E20**	**E21**	**E22**
C_{21}	8	8	9	9	8	7	9	8	9	7	9	9	9	9	9	9	8	7	8	7	9	8
C_{22}	9	9	8	9	9	9	9	8	9	8	9	9	9	7	9	9	8	9	8	7	9	8
C_{23}	6	9	6	7	6	7	8	8	9	3	9	8	8	8	9	9	6	9	8	7	8	8
C_{24}	7	7	7	7	7	9	7	7	6	6	9	8	8	6	9	9	6	9	2	7	4	7
C_{25}	9	7	5	7	9	5	6	6	6	3	9	7	8	4	6	9	5	5	3	7	5	7
C_{26}	4	7	5	7	8	4	6	5	7	2	9	8	7	3	2	9	4	5	2	7	6	8
C_{27}	9	7	9	9	9	6	9	6	9	5	9	8	7	8	8	9	7	9	7	8	7	7
C_{28}	9	7	8	9	9	6	8	6	9	5	9	7	8	9	8	9	7	9	7	8	7	8

Table 7. 7 Fuzzification and defuzzification process for obtaining the weights of criteria-step 1.

Criteria	WF_{i1}			…			WF_{i24}			Aggregation (AF_i)			**Defuz.**	**Normalized**
	a_{i1}	b_{i1}	c_{i1}	a_{ij}	b_{ij}	c_{ij}	a_{i24}	b_{i24}	c_{i24}	a_i	b_i	c_i	(d)	**Weights**
C_{11}	0.324	0.370	0.416	.	.	.	0.285	0.320	0.356	0.206	0.247	0.289	0.247	0.088
C_{12}	0.278	0.324	0.370	.	.	.	0.285	0.320	0.356	0.281	0.323	0.365	0.323	0.115
C_{13}	0.139	0.185	0.231	.	.	.	0.214	0.249	0.285	0.250	0.292	0.333	0.292	0.103
C_{14}	0.324	0.370	0.416	.	.	.	0.214	0.249	0.285	0.221	0.261	0.303	0.261	0.093
C_{15}	0.093	0.139	0.185	.	.	.	0.214	0.249	0.285	0.235	0.277	0.318	0.277	0.098
C_{16}	0.278	0.324	0.370	.	.	.	0.214	0.249	0.285	0.252	0.294	0.336	0.294	0.104

C_{17}	0.370	0.416	0.463	.	.	.	0.214	0.249	0.285	0.235	0.277	0.319	0.277	0.098
C_{18}	0.093	0.139	0.185	.	.	.	0.214	0.249	0.285	0.252	0.293	0.335	0.293	0.104
C_{19}	0.046	0.093	0.139	.	.	.	0.107	0.142	0.178	0.230	0.270	0.312	0.270	0.096
C_{110}	0.093	0.139	0.185	.	.	.	0.214	0.249	0.285	0.244	0.285	0.327	0.285	0.101

Table 7. 8 Fuzzification and defuzzification process for obtaining the weights of criteria-step 2.

Criteria	WF_{i1}			…			WF_{i22}			Aggregation (AF_i)			Defuz. (d)	Normalized Weights
	a_{i1}	b_{i1}	c_{i1}	a_{ij}	b_{ij}	c_{ij}	a_{i22}	b_{i22}	c_{i22}	a_i	b_i	c_i		
C_{21}	0.342	0.391	0.440	.	.	.	0.526	0.602	0.677	0.329	0.374	0.420	0.374	0.139
C_{22}	0.391	0.440	0.489	.	.	.	0.526	0.602	0.677	0.341	0.387	0.432	0.387	0.144
C_{23}	0.244	0.293	0.342	.	.	.	0.526	0.602	0.677	0.291	0.336	0.382	0.336	0.125
C_{24}	0.293	0.342	0.391	.	.	.	0.451	0.526	0.602	0.273	0.318	0.364	0.318	0.118
C_{25}	0.391	0.440	0.489	.	.	.	0.451	0.526	0.602	0.248	0.294	0.339	0.294	0.109
C_{26}	0.147	0.195	0.244	.	.	.	0.526	0.602	0.677	0.223	0.268	0.314	0.268	0.100
C_{27}	0.391	0.440	0.489	.	.	.	0.451	0.526	0.602	0.307	0.352	0.398	0.352	0.131
C_{28}	0.391	0.440	0.489	.	.	.	0.526	0.602	0.677	0.312	0.357	0.403	0.357	0.133

Comparing the importance weights of criteria for the prioritization's first and second steps

As shown in the last column of Table 7, according to the experts' opinions, the importance weights of the 10 criteria for the first step are very close which means that all of identified criteria are almost equally important in the CPGs' prioritization for the updating process. Regarding the 8 criteria for the second step, their importance weights are close as the first step (See Table 8). However, the "Changes in the evidence on the benefits and harms of existing interventions" (C_{22}) criterion has obtained the highest importance weight in comparison with other criteria. In addition, the criteria "Changes in the available interventions (C_{21})" and "The strength of evidence (C_{28})" have the second and third highest importance weights. Another criterion worth emphasizing is that "Changes in the resources available for healthcare" (C_{26}) was the less important criterion in assessing the new evidence.

DISCUSSION

Major Findings

The prioritization of CPGs for the updating process is a complex task since a variety of subjective and objective criteria should be taken into account. This is the first systematic review and international survey dedicated to the identification of priority criteria for prioritization of CPGs' updating. We identified most of the articles and manuals that were identified by Alonso-Coello et al. [12] and Becker et al. [13] in their systematic reviews. Very few documents have introduced some criteria or algorithms for the prioritization of CPGs' updating. We identified most of the criteria from four articles [10,6,28,29], one methodological handbook [27] and two manuals [26,30]. Most of the included documents offer general information regarding the need for systematic methods for updating CPGs such as prioritization or propose a scheduled review date.

The Need for a Systematic and Comprehensive Prioritization Tool

In this study, the priority criteria for prioritization used in updating CPGs were identified, validated, and weighed. They now need to be integrated into a priority-based algorithm in order to be more effective. Currently, we are in the process of developing such an algorithm based on the validated criteria and by using some engineering tools such as Multi-Criteria Decision Making (MCDM) methods. The main features of the proposed algorithm will be the ability to consider: 1) the uncertainties and imprecise information, 2) multiple experts' opinions in all stages of the algorithm; 3) the level of experience and knowledge of experts, 4) variety of subjective and objective criteria, 5) the dynamic environment of CPGs; and 6) the required resources and limited budget parameters. The proposed algorithm will aggregate and normalize the data obtained from experts to annually prioritize CPGs in order to identify the CPGs in need of updating.

Methodology Limitations

Our project presents some weaknesses that should be discussed. One potential weakness of our systematic review is that, because we only included English manuscript, we may have missed relevant literature that is only available in other languages. In addition, given the nature of the documents reviewed, most of them are not empirically derived and are more related to general wisdom than to actual evidences. Thus, it was not possible to comment on the overall quality of the selected studies. Moreover, the survey used a convenience sample, inferring with the generalizability of the results. It is possible that other existing individuals or authors were reached with our strategy. We evaluated the face validity of our survey, however, it was not possible to explore further the metrological qualities of our questionnaire. Thus, it may affect the reliability or the validity of the answers provided. Finally, we acknowledge the small number of potential participants due to the small number of existing experts in the field. However, we included the responses of most prominent guideline organizations such as Cochrane, GRADE, NICE, SIGN, CCO, the United States Preventive Services Task Force, and the New Zealand Guidelines Group.

CONCLUSION

Due to limited healthcare resources for updating CPGs, the substantial cost of updating, and on-going advances and new evidences in healthcare, every institution faces the challenge of CPGs' prioritization for updating. However, there is no validated criteria or comprehensive process for prioritization of updating CPGs in literature. Therefore, the aim of this research was to identify, validate, and weight the priority criteria in updating CPGs through a systematic review and international survey which can be used for prioritizing CPGs. Our study is the first systematic review and international survey dedicated to the identification and validation of these criteria. This study enables a prioritization process to be followed based on the transparent weighted criteria and, as are validated through an international survey, are likely to be acceptable to the public. In addition, by considering these validated criteria the organizations can assign their limited resources to updating only the CPGs that are the most sensitive to change, thus improving the quality and reliability of healthcare decisions made based on current CPGs. An obvious area for further research is the application of the validated criteria in practice.

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7.2 A Comprehensive Prioritization Framework for Updating Clinical Practice Guidelines (CPGs)

Article 2 in integrating efforts in guidelines' updating

Résumé: Les guides de pratique clinique (GPC) devraient être mises à jour régulièrement en fonction des nouvelles données probantes afin de rester valides. La mise à jour des GPC est une tâche cruciale et complexe car une variété de critères subjectifs et objectifs doit être envisagée. De plus, les ressources pour l'évaluation des GPC sont inférieures à celles nécessaires pour évaluer tous les GPC en vue de leur mise à jour. Par conséquent, des priorités doivent être établies afin de déterminer les GPC dont la mise à jour est urgente. Dans cette étude, on propose pour la première fois un algorithme de priorisation dynamique pour la mise à jour des GPC s sur la base des 18 critères que nous avons validés et pondérés dans notre étude précédente. En outre, des échelles catégoriques pour la notation des critères ont été élaborées sur la base de la littérature. Une méthode Fuzzy TOPSIS est appliquée pour hiérarchiser les GPCs en deux étapes différentes de l'algorithme proposé. Enfin, un règlement de classification est proposé afin de classer les GPC dans différentes catégories sur la base des valeurs de score transformées (TSV). Les principales caractéristiques de l'algorithme proposé sont la capacité à considérer; Les incertitudes et les informations imprécises; Des avis d'experts multiples à tous les stades de l'algorithme; Le niveau d'expérience et de connaissances des experts; Une variété de critères subjectifs et objectifs; L'environnement dynamique des GPC; Et les ressources requises et les paramètres budgétaires limités. En appliquant le cadre proposé, les organisations auront un processus formel et plus précis pour hiérarchiser les mises à jour des GPC.

Mots-clés: Guides de pratique clinique, Mise à jour, Priorisation, TOPSIS floue, Analyse de sensibilité.

7.2 A Comprehensive Prioritization Framework for Updating Clinical Practice Guidelines (CPGs)

Article 2 in integrating efforts in guidelines' updating

Abstract: Clinical Practice Guidelines (CPGs) should be updated regularly based on the new evidence in order to remain valid. Updating CPGs is a crucial and complex task since variety of subjective and objective criteria should be considered. In addition, the resources for CPGs' assessment fall short of that needed to evaluate all CPGs for updating. Therefore, priorities have to be set in order to determine the CPGs which are in urgent need for updating. In this study, for the first time, a dynamic prioritization algorithm is proposed for updating CPGs based on the 18 criteria that we validated and weighted in our previous study. In addition, categorical scales for scoring the criteria were devised based on the literature. A Fuzzy TOPSIS method is applied for prioritizing the CPGs in two different steps of the proposed algorithm. Finally, a classification regulation is proposed in order to classify the CPGs in different categories based on the Transformed Score Values (TSV). The main features of the proposed algorithm are the ability to consider; the uncertainties and imprecise information; multiple experts' opinions in all stages of the algorithm; the level of experience and knowledge of experts; variety of subjective and objective criteria; the dynamic environment of CPGs; and the required resources and limited budget parameters. By applying the proposed framework, the organizations will have a formal and more accurate process for prioritizing the updates of CPGs.

Keywords: Clinical Practice Guidelines, Updating, Prioritization, Fuzzy TOPSIS, Sensitivity Analysis.

Background

Clinical Practice Guidelines (CPGs) have a limited lifespan and need to be assessed for updating regularly in order to ensure their validity and quality [1]. This is due to the rapid and continues emergence of new evidence. Considering the finite resources of organizations, dynamic and fluid environment of CPGs, and substantial cost and time needed for updating, it is obvious that updating all CPGs regularly is not feasible. Many authors and organizations around the world, have recognized the need to use more rigorous processes such as setting priorities for updating CPGs [1-10]. According to our recent survey [2], 72% of participant reported that they prioritize their CPGs based on their urgency, however, only 38% of them believe that their updating process is very reliable. Without some attempts to set relative priorities, organizations can not appropriately manage the limited resources for the retrieval of evidence, assessment of evidence, or updating CPGs. Although there are few methods for prioritization of recommendations for CPG development, there is no standardized method or comprehensive process to prioritize CPGs for updating process. Recently, a new CPG-updating procedure called DAR (Document Assessment and Review) process [3] was developed and tested by a research team of the Program in Evidence-based Care (PEBC) for cancer CPGs in Ontario, Canada. This process has encountered some major and minor challenges at every step of the process, as mentioned by the authors [3]. The first major challenge is that the volume of documents requiring reviews exceeds the availability of research methodologists and clinical experts to commit to completing the review. From engineering point of view, we think this is due to the fact that the DAR process is not based on mathematical modeling and it is not able to rank the CPGs based on their importance or new evidence. Therefore, the CPGs that fall into the review category, have all the same urgency for updating and experts will not be able to distinguish between them. Second, this process doesn't consider the uncertainties associated with experts' opinions while there is a lot of uncertainties due to incomplete data or imprecise information in prioritization of CPGs. Third, several influential criteria such as the scope of guidelines, fast-changing fields, the required resources, etc. are not considered in this priority-based process. In addition, the two questionnaires used in conducting the document assessment and review are not validated. Last but not least, all the questions have the same level of importance, while some questions (criteria) are much more important than the others in prioritization of CPGs.

To overcome the above-mentioned shortcomings, in our first article we performed a systematic review and international survey to identify and validate influential criteria that could be considered for prioritization of CPGs' updating. Through this study, we validated and weighted 18 influential criteria and inspired from DAR process, we divided them into two different steps; the CPGs assessment and the new evidence review. In this article, based on the results of our first work, we first propose a two-step dynamic and general prioritization algorithm that could be applied by all organizations for updating CPGs. Then, we categorize and score our validated criteria in order to illustrate how they could be scored by experts in our prioritization model. Afterwards, we propose a Fuzzy TOPSIS approach for prioritization of CPGs. Finally, we propose a classification regulation for both prioritization steps based on the Transformed Score Values (TSV) in order to classify the CPGs in different categories. The proposed formulized approach is not only able to consider subjective and objective criteria, but also takes into account the uncertainties associated with several experts' opinions. Moreover, this approach is able to consider the importance weights of criteria. This is the first time that a mathematical-based prioritization framework is proposed for updating the existing CPGs by considering the finite resources. By applying the proposed framework, the organizations will have a formal process for prioritizing the updates of CPGs.

The rest of this paper is organized as follows. In section 2, the methodology including the proposed prioritization algorithm, categorisation and scoring of criteria, Fuzzy TOPSIS technique, and classification regulation is described. Section 3 deals with comparison of our prioritization framework with DAR process and also discusses about the validation process and limitations of this study. Finally, conclusions are explained in Section 4.

Methods

Proposed prioritization algorithm

Inspired from DAR process [3], our proposed prioritization algorithm consists of two steps; "The CPGs Assessment" Step and "The New Evidence Review" Step as shown in Figure 7.3. These steps are explained in the following.

First step (The CPGs Assessment)

The purpose of first step is to assess the importance of each CPG among other CPGs based on criteria-step 1 and without assessing the new evidence. The ten criteria for this step were identified and validated in our first study [2] (see Table 7.4). In this step, we first prioritize all CPGs and then categorize them in one of the following three priority levels: (1) High Priority, (2) Medium Priority, and (3) Low Priority. The CPGs which are categorized as "High

Priority" move to the next step of our process for assessing the new evidence and the other CPGs with medium and low priority values are evaluated in the next annual assessment. The prioritization and categorization process are described in sections 2.5 and 2.6, respectively.

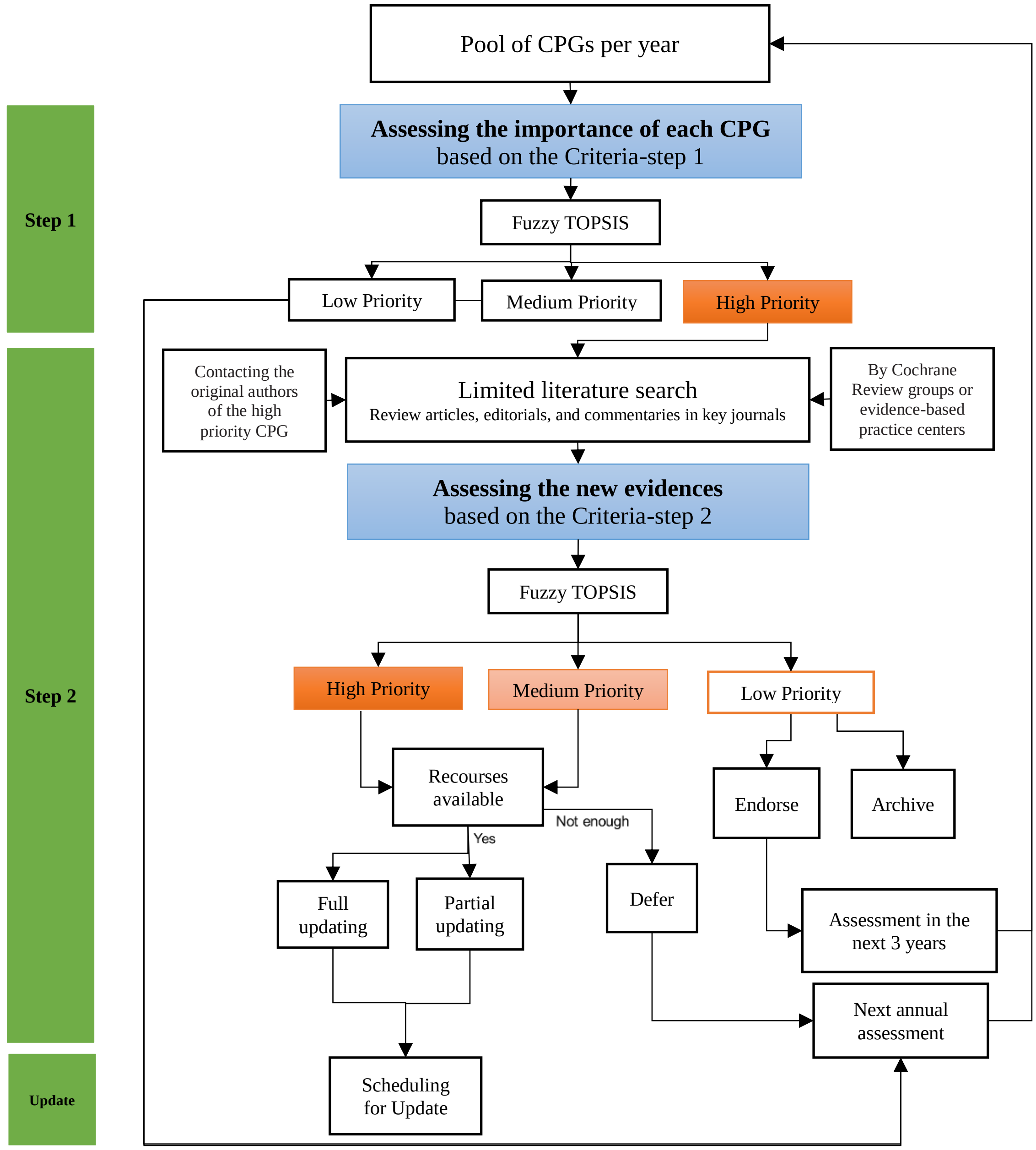

Fig 7. 4 The proposed prioritization algorithm for updating CPGs.

Second step (The New Evidence Review)

The purpose of second step is to assess the new evidence published since the CPG was completed or last reviewed based on the criteria-step 2. As criteria-step 1, the eight criteria for step 2 were identified and validated through our first study (see Table 7.5). Note that only the CPGs categorized as "High Priority" from step 1 are eligible for step 2. In order of their priority determined in first step, a clinical expert and a methodologist should conduct a limited search of the literature for significant new evidence that may have an effect on the validity of the guideline statements. Having the limited literature searches conducted by groups already familiar with the topic, such as relevant Cochrane Review groups or evidence-based practice centers, is likely to be more efficient in this step [4]. As suggested by Shekelle [4], the limited literature searches could be restricted using the "document type" Medical Subject Heading terms to retrieve only review articles, editorials, and commentaries published since the last search on the particular guideline topic. In addition, the limited literature search could be restricted to key journals, ie, those most likely to have published evidence of sufficient magnitude to warrant the revision of an existing CPG. Titles, abstracts, and articles should be reviewed sequentially, seeking new evidence regarding the guideline statements. New evidence (principally randomized clinical trials) referenced in the review articles, editorials, or commentaries should be retrieved and reviewed for relevance. Relevant articles should then be distributed to the entire panel for scoring of the impact of new evidence on the validity of the existing CPG, using the criteria-step 2 that we have validated for new evidence assessment.

Based on the clinical experts' responses to the criteria-step 2, the CPGs are first categorized in one of the following categories: (1) High Priority, (2) Medium Priority, and (3) Low Priority. Then, in order of their priority, we classify each CPG into one of the following five categories: 1) Full Update, 2) Partial Update, 3) Defer[3] to the next year, 4) Endorse[4], and 5) Archive[5].

1. **CPGs with high priority score** fall into either "Full Update" or "Partial Updating" classes. This decision should be made based on the experts' opinions and by considering the required resources and limited budget of organization. In general, partial updates are preferable to full updating of CPGs in terms of costs and efforts [6] and they should be given priority. If available recourses are enough for full/partial updating of CPGs, they will be updated in the current period and the approximate time for updating the CPG will be estimated and scheduled. If not, they have to be postponed to the next annual assessment and they should be assessed along with other existing CPGs.
2. **CPGs with medium priority score** could also be considered for full/partial update if there is still some budget available after assigning for the CPGs with high priority. Otherwise, they are determined as "Defer" and should be evaluated in the next annual assessment.
3. **CPGs with low priority score** will be either endorsed or archived depending on the characteristics of the CPG and based on the opinions of the experts. The CPGs which are determined as "Endorse" will be assessed in 3 years. If there is sufficient and significant scientific evidence that motivates a review before that date, the review process may be accelerated for a more rapid update of some recommendations. In addition, occasionally a request for an exceptional surveillance review decision (decision to update) is received from a stakeholder and this (after consideration from the director) might warrant a more expeditious surveillance review than the standard three yearly pattern. The archiving may happen because the recommendations are no longer clinically relevant and applicable to current practice. Or, it may be because the developing group

[3] Defer means that the CPG is still valid enough and could be used until the next assessment [3].

[4] Endorsement means that the recommendations are still current and relevant and there is no need for updating [3].

[5] Archive means that the CPG cannot be endorsed or deferred, and the recommendations will no longer be maintained [3].

has little or no interest in maintaining them; for example, the topic areas may have changed so much that developing a new document is a more practical option than updating the existing one [3].

Categorisation and scoring of criteria

Key to any prioritization process are the criteria. The 18 validated and weighted criteria in Tables 7.4 and 7.5 should be categorized and scored in order to be measurable by experts. Then, in this paper, categorical scales for scoring these criteria were devised. The choice for these categorical scales was partly based on the Oortwijn et al. and Agbasi et al. studies [11, 3]. Specifically, scores for most of criteria-step 1 (Table 7.4) are constrained within a linguistic scale from Very Low to Very High or Low to High. Only, scores for the criterion "The last review date of CPG" is constrained within a numerical scale from 1 to 5. Regarding the criteria-step 2 (Table 7.5), we barley found indications for scaling or categorizing in the literature, except the "*quality and strength of the evidence*" criteria that were explicitly categorized and scored by GRADE [12] and AHRQ [13], respectively. According to Shekelle [5], measuring these subjective criteria (criteria 1-6) is complex and there is high degree of uncertainty and imprecise information. However, we devised some classes and scoring based on few existing studies [5, 14-16] and also perception of our experts from these criteria.

It is evident that some concerns will be raised about the different scales and categorizations that we devised for quantitative and qualitative criteria in Tables 7.4 and 7.5. It should be mentioned that our aim of devising the scales and categorizations in this study was to only demonstrate how these criteria should be categorized and scaled by experts in order to be applicable in our proposed prioritization tool (Fuzzy TOPSIS). Each organization could adjust the proposed scales and scores based on its CPGs and the opinions of its own experts.

Table 7. 9 Categorization and scoring of criteria-step 1.

Criterion (*Sub-criterion*)	Criterion weight	Measured with	Intensity Score	Source of Data
The Scope of guideline - *Patient population (Incidence rate)* [11]	0.088	Absolute numbers (per year) 0-5000 5001-10000 10001-15000 15001-20000 >20000	Very Low Low Moderate High Very High	National data; review articles
- *Broadness of scope*		Broad Moderate More narrowly defined (very focused)	Low Medium High	Expert's opinion and stakeholder input
Fast-changing fields	0.097	1- (Rate of new evidence) Slowly-changing fields such as venous ulcer, sinusitis, etc. • Fast-changing fields such as AIDS, cardiovascular risk management, breast cancer, etc.	Very slow slow Moderate rapid Very rapid	Review articles, expert's opinion, surveys
The required resources [11]	0.103	• US $ >200000 US $ $ 150000-200000 US $ 100000-150000 US $ 50000-100000 US 0-50000 US $	Very Low Low Moderate High Very High	National data; review articles, CPG developer
Potential benefits for public health (Disease Burden)	0.105	• Disease/Condition incidence or prevalence, • High risk impact of disease/condition in the health system,	Very Low Low Moderate	Experts' opinion,

[17]		• High frequency of risk factors associated with the disease/condition, • High frequency of avoidable risk factors associated with the disease/condition.	High Very High	surveys
Feedback on guideline use	0.097	- No important feedback available, - Some performance evaluation is reported, - High-quality effective reviews are available,	Low Moderate High	Review articles, contacting with other CPG developers active in the same disease area, surveys
The appropriateness of the questions and search criteria [3]	0.114	1- The standard of care has shifted significantly since the last version of the document, such that the questions only address the topic in part, • There are new, significant options (for treatment, diagnosis, etc.) available that are not covered by the current questions, such that new questions would need to be added to the document, • For the document to still be useful it will have to substantially be rewritten.	Very Low Low Moderate High Very High	Experts' opinion, surveys
The last review date of CPG	0.091	≤1 year ago 2 years ago 3 years ago 4 years ago ≥ 5 years ago	1 2 3 4 5	Update history of the CPG
The current relevance of the CPG	0.104	81%-100% 61%-80% 41%-60% 21%-40% 0%-20%	Very Low Low Moderate High Very High	Experts' opinion, surveys
The impact of the CPG on access to care [3]	0.094	• Ministry funding decisions have been, are, or will be made on the basis of this document, • Case by case review or out of country requests are known to be decided based on the document, • Funding for some screening, diagnostic, staging or treatment procedure was or is determined.	Very Low Low Moderate High Very High	Meetings, policymakers,
The risk of being outdated	0.102	0%-20% 20%-40% 40%-60% 60%-80% 80%-100%	Very Low Low Moderate High Very High	Experts' opinion Review articles, The last review date of CPG, surveys

Table 7. 10 Categorization and scoring of criteria-step 2.

Criterion	Weight	Measured with	Intensity Score	Source of Data
Changes in the available interventions [5]	0.139	-Weak intervention available -Some effective interventions available -The recommended interventions are inappropriate, ineffective, or superseded by new significant interventions	Low Moderate High	Existing reviews; Literature search; Expert judgment
Changes in the evidence on the benefits and harms of existing interventions [15, 16]	0.144	• Risk-Benefit Balance -The desirable and undesirable consequences are closely balanced, -Uncertain risk-benefit balance, -The benefits outweigh the risks,	Low Moderate High	Existing reviews; Literature search; Expert judgment
Changes in outcomes that are considered important [14]	0.126	-No significant outcomes/ Further research is likely to change the outcomes, -Some outcomes available/ Further research is likely to have an important impact on the outcomes, -Significant outcomes available,	Low Moderate High	Existing reviews; Literature search; Expert judgment
Changes in the evidence that current practice is optimal	0.119	- Evidence does not permit a conclusion - Some considerable evidences available - Large clinical trials show that current practice is optimal	Low Moderate High	Existing reviews; Literature search; Expert judgment

Changes in the values placed on outcomes	0.108	-No significant change in the values -Considerable changes in the values -Significant change in the values	Low Moderate High	Policymakers
Changes in the resources available for healthcare	0.098	-No significant change in the resources -Considerable changes in the resources -Significant change in the resources	Low Moderate High	Policymakers
The quality of the evidence [12]	0.131	- Further research is very unlikely to change our confidence in the estimate of effect. *Example: Randomized trials without serious limitations, Well-performed observational studies with very large effects* - Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. *Example: Randomized trials with serious Limitations, Well-performed observational studies yielding large effects* - Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. *Example: Randomized trials with very serious limitations, Observational studies without special strengths or important limitations* - Any estimate of effect is very uncertain. *Example: Randomized trials with very serious limitations and inconsistent results, Observational studies with serious limitations Unsystematic clinical observations*	High Moderate Low Very low	Quality measurement based on the GRADE's eleven factors [12]; experts' opinion
The strength of the evidence [13]	0.132	• Risk of bias, consistency, directness, precision -High confidence that the evidence reflects the true effect (randomized trials). Further research is very unlikely to change our confidence in the estimate of effect. - Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate. -Low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate. -Evidence either is unavailable or does not permit a conclusion.	High Moderate Low Insufficient	Strength measurement; experts' opinion

Availability of Data and uncertainties

The data used to score most of the above-mentioned criteria will often be incomplete or imprecise, either because data are not available or because they are too expensive to collect. Therefore, they should be scored based on the experience and knowledge of experts and by using linguistic terms. To limit the distortions that may arise from reliance on obviously incomplete data or imprecise information in prioritization of CPGs, in this study we developed our prioritization tool based on fuzzy logic approach which is explained briefly in the next section.

Fuzzy Logic

Fuzzy set theory was proposed by Zadeh in 1965 for handling the uncertainties and imprecise information in decision-making. Fuzzy numbers stand for a specific range between zero and one for a specific value. Due to this specific range, it is easier for the expert to indicate his/her preference [22]. Experts are asked to express their opinions using linguistic terms. Then, these terms are translated into a Fuzzy number consisting of multiple numbers. This way, the linguistic rating is reflected as a range. Both triangular and trapezoidal Fuzzy numbers parametrized by a triplet (l, m, u) (Fig. 7.4) or a quadruplet (p, q, r, s) (Fig. 7.5) can be used for Fuzzy soft sets. In this article, we use triangular Fuzzy numbers (TFNs) because of the ease of computation.

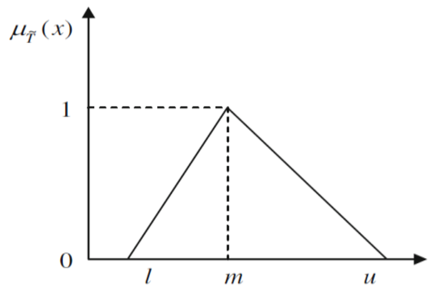

Fig 7. 5 A triangular fuzzy number.

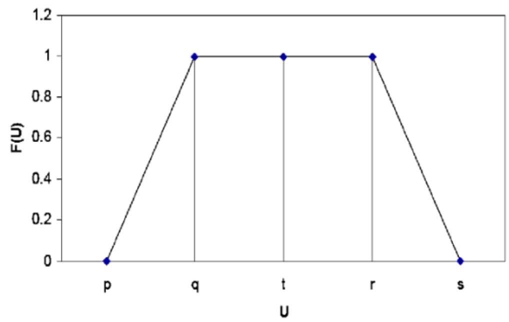

Fig 7. 6 A trapezoidal fuzzy number.

The Fuzzy TOPSIS method

The Technique for Order Preference by Similarity to Ideal Solution (TOPSIS) was first proposed by Hwang and Yoon [18] and a Fuzzy TOPSIS method was later introduced by Chen and Hwang [19]. There are many real-life situations where decision makers' opinions are uncertain and they are not able to assign precise crisp values to their judgments [20]. The Fuzzy TOPSIS approach is capable of dealing with multi-criteria decision-making (MCDM) by translating the linguistic values into Fuzzy numbers and thereby allowing decision-makers to incorporate incomplete or unavailable information into the decision model. This method has been widely applied in the literature to support MCDM problems [20-22]. Among the techniques based on fuzzy set theory, fuzzy TOPSIS is usually preferred since it doesn't have the limitation of criteria and alternatives' numbers. In addition, it does not cause the ranking reversal problem and null weights as in fuzzy AHP; and in relation to comparative approaches, it requires a lower number of judgments by decision makers [21] .This method comprises the following steps:

The steps of the Fuzzy TOPSIS method for prioritizing CPGs

Step 1: Form a committee of expert to evaluate the CPGs.

Step 2: Determine the weighting of evaluation criteria. We already performed this step using Fuzzy AHP method in our first article [2] and determined the weights of criteria step 1 and 2 based on the opinions of 24 participants through an online survey (See second column of Table 7.4 and 7.5).

Step 3: Apply the linguistic variables devised in Tables 7.4 and 7.5 for each criterion in order to prioritize the CPGs.

Step 4: Determine the aggregated weight of CPGs with respect to each criterion. If the Fuzzy rating of the decision-maker k is described as TFNs $\tilde{R}_k = (a_k, b_k, c_k), k = 1,2,3, \dots, K$, then the aggregated Fuzzy rating can be determined as $R = (a, b, c), k = 1,2,3, \dots, K$. Here, $a = \min(a_{ijk})$; $b = \frac{1}{K}\sum_{k=1}^{K} b_{ijk}$; $c = \max(c_{ijk})$ [22].

Step 5: Construct the Fuzzy decision matrix [21].

$$\tilde{D} = \begin{array}{c} \\ A_1 \\ A_2 \\ \vdots \\ \\ A_m \end{array} \begin{array}{c} \begin{array}{ccccc} C_1 & C_2 & . & . & C_n \end{array} \\ \begin{bmatrix} \tilde{X}_{12} & \tilde{X}_{12} & . & . & \tilde{X}_{12} \\ \tilde{X}_{21} & \tilde{X}_{22} & . & . & \tilde{X}_{2n} \\ . & . & . & . & . \\ . & . & . & . & . \\ \tilde{X}_{m1} & \tilde{X}_{m2} & . & . & \tilde{X}_{mn} \end{bmatrix} \end{array}$$

Step 6: Normalize the Fuzzy decision matrix. For normalization, the linear-scale transformation can be used to transform the various criteria scales into a comparable scale. The normalized Fuzzy decision matrix $\tilde{R}$ through the following Equation [22].

$$\tilde{R} = \left[r_{ij}\right]_{m\times n} \quad i = 1,2,3, \dots, m; \quad j = 1,2,3, \dots, n$$

where $\tilde{r}_{ij}= (\frac{a^*_{ij}}{c_j}, \frac{b^*_{ij}}{c_j}, \frac{c_{ij}}{c^*_j})$ and $C^*_j = \max C_{ij}$

Step 7: Construct weighted normalized Fuzzy decision matrix.

Considering the different weight of each criterion, the weighted normalized decision matrix is computed by multiplying the important weight of evaluation criteria in the normalized Fuzzy decision matrix. The weighted normalized decision matrix V is defined as

$$\tilde{V} = \left[\tilde{v}_{ij}\right]_{m\times n} \qquad i = 1,2,3, \dots, m; j = 1,2,3, \dots, n$$

$\tilde{v}_{ij}=\tilde{r}_{ij}W$ where W is the weighted vector of evaluating criteria.

Step 8: Determine the Fuzzy positive ideal solution (FPIS) and Fuzzy negative ideal solution (FNIS) as:

$FPIS(P *) = (\widetilde{V_1^*}, \widetilde{V_2^*}, \widetilde{V_3^*}, \dots, \widetilde{V_n^*})$ and $FPIS(P^-) = (\widetilde{V_1^-}, \widetilde{V_2^-}, \widetilde{V_3^-}, \dots, \widetilde{V_n^-})$

where $\tilde{V}_j^* = max_i\{v_{ijk}\}$ and $\tilde{V}_j^- = min_i\{v_{ijk}\}$; $i = 1,2,3, \dots, m$; $j = 1,2,3, \dots, n$

Step 9: Calculate the distance of each alternative from FPIS and FNIS as

$d_i^* = \sum_{j=1}^{n} d_v\,(\tilde{v}_{ij} v_j^*)$; $\quad i = 1,2,3, \dots, m$ and $d_i^- = \sum_{j=1}^{n} d_v\,(\tilde{v}_{ij} v_j^-)$; $i = 1,2,3, \dots, m$

where d_v is the distance measurement between two Fuzzy numbers.

Step 10: Calculate the Closeness Coefficient (CC_i) for each CPG. The closeness coefficient represents the distance to the FPIS (P^*) and Fuzzy negative ideal solution (P^-). The closeness coefficient for each alternative is calculated as:

$$CC_i = \frac{d_i^-}{d_i^- + d_i^*}, \quad i = 1,2,3, \dots, m$$

Classification of CPGs

To judge the importance level of CPGs, the CC_i scores have to be transformed into categories. Then, we suggest to classify the CPGs in each prioritization process according to "Transformed score value (TSV)" and based on the corresponding thresholds which are given in Table 7.6. The TSV can be mapped to 0, 100% using the following equation:

$$TSV = \frac{CC_i - \min CC_i}{\max CC_i - \min CC_i} \%$$

where "$\min CC_i$" shows the lowest CC_i score which is obtained when the CPG gets the lowest intensity from all criteria, and "$\max CC_i$" shows the highest CC_i score which is obtained when the CPG gets the highest intensity from all criteria.

Table 7. 11 The proposed classification regulation.

TSV	Classification of CPGs in 1st step of prioritization	Classification of CPGs in 2nd step of prioritization
$70\% \leq TSV \leq 100\%$	High Priority	- Full/Partial Update by considering budget
$40\% \leq TSV \leq 100\%$	Medium Priority	- Full/Partial Update by considering budget - Defer to the next year
$0\% \leq TSV \leq 40\%$	Low Priority	- Endorse - Archive

In general, the suggested thresholds for TSV can be adjusted after applying the model and investigating the obtained CC_i values. Thresholds should always be established according to both the characteristics of CPGs and their estimated score values. Moreover, the number of classes and updating strategies (full/ partial update) depend on available resources (budget, personnel, etc.) in the organization.

Discussion

Our proposed prioritization algorithm is based on the DAR process [2]. However, there are some major differences that makes our algorithm unique. In the first step of DAR process, 6 questions are asked in order to classify each candidate CPG into one of the following groups: endorse, review, defer, and archive. The CPGs categorized as review from step 1 are assessed based on 4 questions in step 2 in order to determine the effect of new evidence. In order to response these question a streamlined systematic review of new evidence is conducted by a methodologist. Finally, based on the experts' responses to the 4 question in step 2, each CPG is classified into one of the following outcomes: endorse, archive, or update. Comparing this process with our prioritization algorithm explained in section 2.1 illustrates the main differences as followings: 1) we consider 18 validated and weighted criteria for prioritization of CPGs, while DAR process prioritizes CPGs based on 10 non-validated questions; 2) the responses of questions in DAR process are Yes or No, while in our prioritization method different levels and linguistic terms for each criterion is devised out in order to prioritize the CPGs more accurately and precisely; 3) different categorizations are defined in each step of our proposed algorithm; 4) we consider uncertainty in experts' opinions when assigning values for each criterion; 5) our proposed framework is able to consider both qualitative and quantitative criteria/sub criteria, and last but not least 6) we consider the required resources and limited budget of organizations in our prioritization process.

We have applied the same approaches successfully in solving many prioritization problems in critical industries. Although we have not implemented our prioritization process in practice and we don't have sufficient data to make meaningful comparisons between our algorithm and DAR process, we believe that the proposed algorithm and the validated criteria are more systematic, meaningful, and cost-effective. Since the proposed framework is generally sufficient, it could be tested by other institutes in order to verify its universality and identify any shortcomings with this prioritization process. Another important point which should be highlighted is that this process is flexible and some criteria could be added or eliminated depending on the objectives of organizations. Moreover, the calculated weights for the 18 criteria could be recalculated by each organization based on their experts' opinions and for their specific guidelines. It is evident that these weights could be different for any organization.

Conclusions

In this paper, a dynamic prioritization algorithm and a MCDM model has been developed and presented in a fuzzy environment for prioritization of CPGs for updating process. This is the first time that such a quantitative method has been proposed in the literature of guidelines. The main contributions of this research are; 1) developing a comprehensive prioritization algorithm for updating CPGs, 2) categorizing and scoring the validated criteria, 3) developing a fuzzy TOPSIS model for prioritization of CPGs in two different steps, and 4) proposing a classification regulation based on the Transformed Score Values. Using Fuzzy TOPSIS, uncertainty and vagueness can be effectively handled and reached to a more effective decision. The proposed process provides a more accurate, effective, and systematic decision support tool for updating CPGs. The present process can be adopted in any organization. In addition, it could be applied to other MCDM problems related to guidelines such as setting priorities for recommendations for CPG development, and updating Systematic Reviews. In the future, we will implement the proposed prioritization process in practice and compare it to the results of other methods to improve and socialize our findings with a wider audience. In addition, we will provide an easy to use online software to be applied by practitioners as a systematic prioritization tool. As a future research, we will extend the proposed prioritization algorithm to new CPG topic that are in progress as well as the existing CPGs in need for updating in order to better manage the CPGs' development and updating process.

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Chapter 8. General Conclusion

This chapter summarizes the main research topics of this dissertation. It summarizes the essential learnings and resulting from the research. This chapter also provides opportunities for future research.

This thesis proposed several comprehensive frameworks related to risk-based maintenance planning and advanced risk analysis of complex systems. In addition, as a case study, a comprehensive priority-based framework was developed for updating CPGs by validating the influential criteria in updating process. Twelve publications have been produced, which present contributions of this thesis.

In the first contribution, we addressed the shortcomings of current MSS methods in different industries and developed an integrated dynamic risk-based framework using AHP, FCM, and FSS for selecting the best maintenance policy by considering uncertainties and dependencies among criteria. By performing a sensitivity analysis, it was revealed that the final priority of maintenance policies remained stable in all cases when the weights of the main criteria were increased/decreased for 25 percent. In addition, we demonstrated that considering the complex dependencies among criteria has an impact on priority of maintenance policies.

The second paper aimed to address the shortcomings of traditional failure mode and effect analysis (FMEA) method and enhance it using FCM. FMEA is one of well-known methods for assessing potential failures and has been widely used in the literature. However, traditional FMEA has been criticised for some major shortcomings. In this study, we proposed an innovative framework for analysis of failure modes in complex systems by considering the complex interactions among failures and cause of failures. The proposed framework is able to predict the impact of each failure or cause of failure on the other failure modes or on the system performance. In addition, it is able to take into account the level of experience and knowledge of experts, the uncertainties on failure analysis process, and multiple causes of failures and components.

In papers 3 and 4, we proposed a dynamic risk modeling and assessment tool using FCM for dealing with risks of maintenance outsourcing and collaborative networks. Then, in paper 5, we extended the developed tool and proposed an advanced decision support tool using FCM for predicting the impact of each risk on the other risks or on the performance of system. The main feature of this tool is the ability to consider all the possible interdependencies among risk factors. This tool could help practitioners in critical industries to manage the risks of complex systems in a more effective and precise way and offer better risk mitigation solutions. In the sixth paper, we addressed the associated risks in ERP maintenance and proposed another integrated approach using fuzzy FMEA method for prioritizing the risks. The maintenance of the ERP is necessary to correct and prevent systems risks as well as to enhance its performance and adapt continuously to the system. Nevertheless, this is often managed intuitively and without taking into account the existing risks. In this sense, the maintenance managers need to know the importance of all risks identified.

The contributions 7-10 are related to maintenance and replacement of medical devices, since these devices have become very complex and sophisticated and the application of maintenance and optimization models to them is fairly new. In the seventh paper, we performed a literature review regarding the maintenance planning of medical devices.

Then, based on the results of this review, we developed three integrated frameworks (papers 8-10) for risk-based maintenance and replacement planning of medical devices.

As a case study, we performed a project titled “Updating Clinical Practice Guidelines; a priority-based framework for updating existing guidelines” in collaboration with CIRRIS which led to two important contributions. In the first contribution (paper 11), we performed a systematic literature review to identify potential criteria in updating CPGs. Then, based on the review’s results, we conducted an online survey. We validated and weighed all the identified criteria through an international survey. In the second contribution (paper 12), we developed and validated a comprehensive priority-based framework for updating CPGs based on the approaches that we had already developed and applied successfully in other industries. This is the first time that such a comprehensive framework has been proposed in the literature of guidelines. Evaluation and prioritization of existing CPGs based on the validated criteria and proposed quantitative framework can promote channelling limited resources into updating CPGs that are most sensitive to change, thus improving the quality and reliability of healthcare decisions made based on current CPGs. By implementation of this framework in healthcare, institutes will have a formal and rigorous process for deciding which guideline is in urgent need for updating and when a guideline should be updated. We can expect that the proposed frameworks result more realistic and more robust plans compared with the traditional models.

Future work

Several perspectives can be developed in the future research which are suggested as follows:

1. Applying the proposed frameworks and decision tools in this thesis in a real case study as a pilot study and comparing them with current methods
2. Extending the proposed framework for replacement of medical devices in order to taking into account new technologies
3. Research into the outsourcing of medical device maintenance services in hospitals is still in its infancy stages, and that further progress in this field would benefit from additional empirical study grounded in management theory.
4. Applying other learning algorithms for training FCM in the developed frameworks and comparing with our proposed NHL-DE learning algorithm
5. Applying the proposed priority-based framework for updating CPGs in other similar cases such as setting priorities for updating systematic reviews or development of CPGS.