Proceedings of the International Conference on Industrial Engineering and Operations Management
Rabat, Morocco, April 11-13, 2017

Lean based Approach for Identifying Risks and Improving Safety of Healthcare Delivery Systems: A Novel Application of FMEA and FTA in Blood Transfusion Unit at a Local Public Hospital in Jordan

Mohammed Ali Almomani
Associate Professor, Department of Industrial Engineering
Jordan University of Science and Technology
Irbid 22110, Jordan
maalmomani7@just.edu.jo

Mohammed Aladeemy
Department of Systems Science and Industrial Engineering
State University of New York at Binghamton
Binghamton, NY 13902, USA
maladee1@binghamton.edu

Ruba Zaqeba
Department of Industrial Engineering
Jordan University of Science and Technology
Irbid 22110, Jordan
rubazaqeba@hotmail.com

Thanaa Rabbaa
Department of Industrial Engineering
Jordan University of Science and Technology
Irbid 22110, Jordan
thanaa_2007@hotmail.com

Abstract

This paper aims to use the theme of lean philosophy of eliminating the waste and non-value added activities in the healthcare delivery industry by utilizing Failure Modes and Effects Analysis (FMEA) and Fault Tree Analysis (FTA). FMEA is used as a diagnostic tool to identify the failures and risks in the blood transfusion process, whereas FTA is used as a deductive failure analysis tool, to identify the root cause of these failures. Initially, the steps of blood transfusion process are determined and then the potential failure modes are identified. The risk of each failure is represented in terms of three aspects: degree of severity, occurrence, and chance of detection. Therefore, critical failures are highlighted, which help in proposing improvement strategies. Then, FTA is utilized to find the root causes of each one of the critical failures. A blood transfusion unit at local public hospital was studied to show the advantages of the proposed approach in preventing errors, and improving safety. The study shows that 35% of the potential failures in the blood transfusion process are related to workers' skills and knowledge. Therefore, increasing the awareness of workers, and providing suitable training courses can significantly reduce risks and problems in the blood transfusion process.

Keywords
Lean; Risk Identification; Blood Transfusion; FMEA

1. Introduction

Healthcare sector is an important sector responsible of maintaining people's physical and mental health. However, healthcare delivery system encounters problems that reduce the quality of the provided service, and encompasses some risks on both service provider and recipient; including: poor technologies interfaces, miscommunications, and the use of expensive tools. Thus, healthcare delivery system has to be improved in order to provide safe and efficient healthcare services utilizing the lean principals of eliminating wastes and non-value added activities (Gupta & Sharda, 2012). Governmental statistics reported the presence of large number of patient-safety incidents that have severe impacts on patient's health and sometimes cause death (Cure, Zayas-Castro & Fabri, 2011). Furthermore, the costs related to these incidents in USA were estimated to be $8.9 billion (Shapiro, 2010). Risks are not limited to service recipient (i.e., patient) only, also the service provider is subjected to risks, such as infections that cause substantial illness or death (Maclntyre, et. al, 2014; Eriksen, Iversen, & Aavitsland, 2005; Decker & Schaffner, 1996). Blood transfusion process is one of the processes in healthcare that can include such risks. Therefore, several studies in the literature aim to improve the quality of the blood transfusion process. The focus of many previous studies was on improving the goodness and quality of conducting the laboratory tests involved in the blood transfusion process, and automating the process. Moreover, some of these studies have been directed toward improving the safety and quality of blood transfusion process based on informal description, in which a description of the algorithm used on performing the standard process, is presented using flowcharts. However, ignoring the exceptional situations by which a process can be conducted represents the main drawback of this informal description of the studies. Therefore, recent studies addressed this shortcoming using formal definitions which take into account all potential errors that reduce the efficiency of the process (Henneman, et. al, 2007). Other researchers studied transfusion errors by implementing the principles of a just culture and cause mapping method in order to eliminate these errors. Aulbach et al., (2010) reported zero cases of transfusing mismatched blood at St. Luke's Episcopal Hospital in Houston, TX, USA, after 27 months following the implementation of the wireless technology of Pyxis Transfusion Verification by CareFusion..

This paper proposes a framework for implementing powerful tools in safety and reliability engineering in a blood transfusion unit at a local public hospital in Jordan. More specifically, the framework is composed of the following two major components. First, FMEA is used to identify potential failure modes in blood transfusion process. Then, FTA is used to identify the root cause of the identified failures. FMEA is a powerful technique that is commonly used in industry and services sectors to identify, analyze, classify and eliminate potential failures or errors in existing systems in order to eliminate or decrease the effect of these failures on the overall system performance (Rhee & Ishii, 2003). Due to its effectiveness in eliminating the failures, it has been applied in healthcare systems where the nature of the work is subjected to many daily potential risks or failures. FTA is an important tool that is used to dig deeply at the root causes of failures through deductive analysis of the system (Max & Slonim, 2003), which is used in this paper to identify the root cause of potential failures of blood transfusion process. The remaining of this paper is organized as follows: Section 2 presents the blood transfusion process flow and Section 3 presents the identified potential failures. Section 4 demonstrates the failures risks and their effects evaluation and Section 5 presents the classification of the identified failures.

2. Blood transfusion process flow

In this section, the steps of the blood transfusion process at the public hospital where the study was carried out are described in details, and listed in Table 1. The flowchart that demonstrates these steps is shown in Figure 1.

A. Medical history review

A1. Donor information: the donor fills specific health questionnaire and blood safety form (paperwork) includes information such as, name, date of birth, gender, etc.

A2. Auditing donor information: the blood bank technologist inspects the information in the questionnaire that was filled by the donor.

A3. Screening test: after inspecting information, screening test are used to check the donors' suitability for donation by measuring donors' weight, pulse, blood pressure, blood glucose and packed cell volume (PCV). After the screening test, a serial number is given for the donor.

B. Performing phlebotomy from the donor

B1. Blood bags checking and labeling: the phlebotomist (phlebotomy technician) checks and identifies the suitable blood bags for the specimen and add labels of blood group, name, and serial number of donor.
B2. Vein selection: the phlebotomist selects the appropriate vein to insert the needle to start withdrawing the blood from the donor into the plastic bag.
B3. Withdrawing blood: the blood is withdrawn into the bag. After withdrawing the specified quantity of blood, the phlebotomist stop blood withdrawing and removes the needle, then blood bag is prepared to be sent to the next stage. Post-phlebotomy instructions are given to the donor by the phlebotomist as well.

C. Separating the blood into its components
In this stage, the separation of blood components is performed using a centrifugal machine, and then each component is labeled in order to store them in its dedicated storage.

D. Storing separated components
The separated blood components: main blood, plasma and platelets are stored in refrigerator, freezer and agitator, respectively.

E. Infection disease testing
E1. Infectious diseases examinations: laboratory examinations are applied on the blood to separate samples with a positive result from the others with negative result to ensure safe blood transfusion.
E2. Samples stamping: the samples with negative result are stamped to indicate to their validity for transfusion.

F. Compatibility testing
F1. Donor samples collection: the samples are collected from the donor to be used in cross-match test.
F2. Recipient samples collection: recipient blood samples are collected to be used in cross-match test.
F3. Cross-match test: samples of the recipient serum are mixed with another of the donor blood and incubating them for 30 minutes to check if there is error in ABO grouping and inspecting any potential irregular antibodies in recipient serum
F4. Results documentation: results are recorded to validate donor blood unit based on cross-match test results.

G. Preparing the appropriate unit of blood to the patient
G1. Stamping names on validated blood units: the blood unit is stamped by the recipient name after it is validated by the compatibility test.
G2. Storing validated blood units: the validated blood units are stored in an appropriate storage to be retrieved once transfusion to the recipient is needed.

Retrieval blood unit: the validated blood units stored in blood storage is retrieved when it is needed for transfusion.

Table 1: List of the main stages of the blood transfusion process, and the steps included in each stage

Stage No.	Main stage	Step(s) included in the main stage	Step designation
A	Medical history review	Donor information	A1
		Auditing donor information	A2
		Screening test	A3
B	Performing phlebotomy from the donor	Blood bags checking and labeling	B1
		Vein selection	B2
		Completing the phlebotomy	B3
C	Separating the blood into its components		
D	Storing the separated components		
E	Infection disease testing	Infectious diseases examinations	E1
		Samples stamping	E2
F	Compatibility testing	Donor samples collection	F1
		Recipient samples collection	F2
		Cross-match test	F3
		Results documentation	F4
G	Preparing the appropriate unit of blood to the patient	Stamping names on validated blood units	G1
		Storing validated blood units	G2
H	Retrieval blood unit		

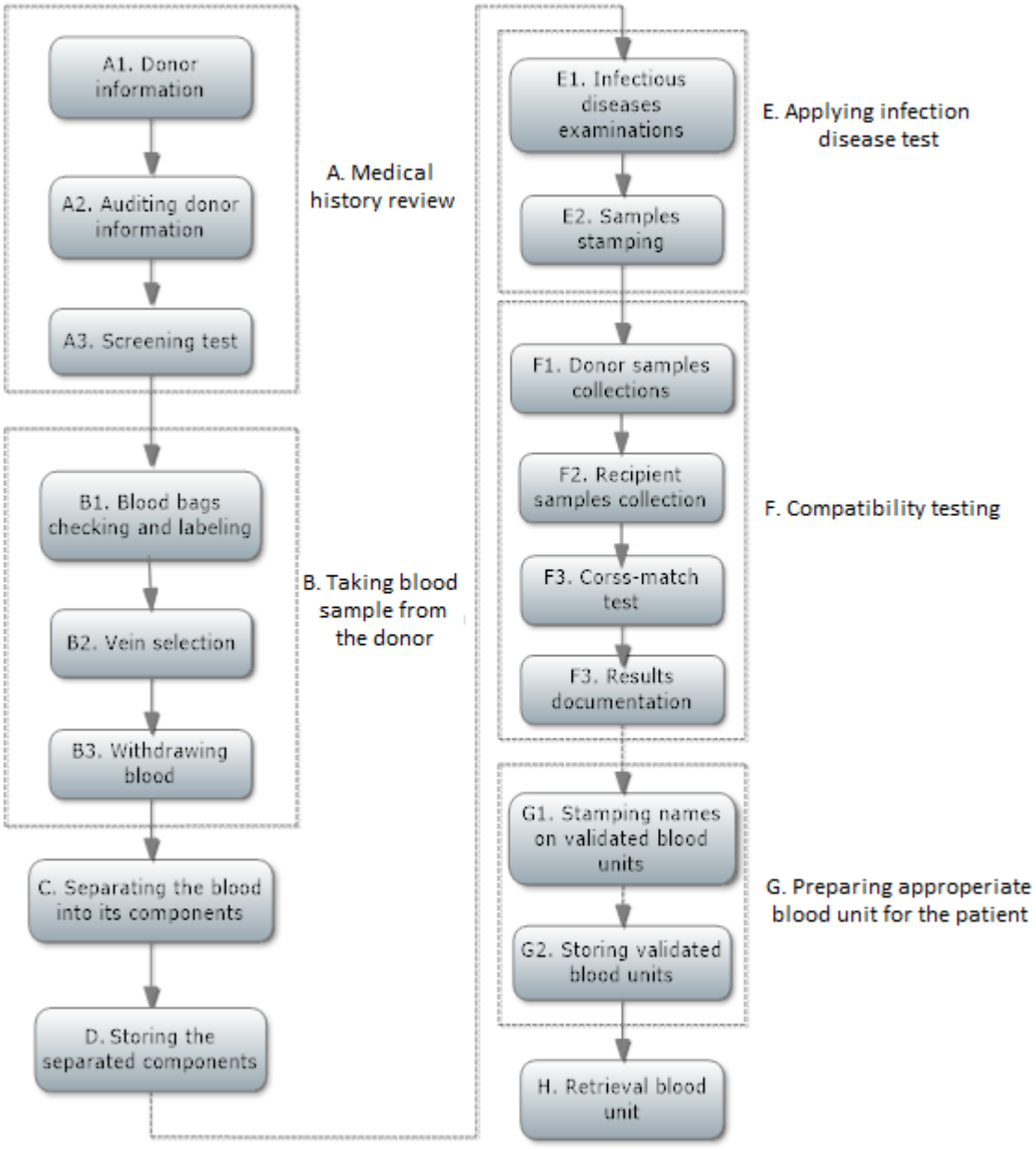

Figure 1. Flowchart that demonstrates the steps followed at the blood transfusion unit

3. Potential failure identification

For each stage of the blood transfusion process that described in the previous section, the potential failure modes, causes and effects are identified and listed in Table 2.

Table 2: Potential failure modes, causes and effects of the blood transfusion stages

No.	Code	Potential failure mode description	Cause of failure	Effect
A1	A11	Donor Files paper form in a wrong way	Misunderstanding of some form inquiries	Donor misidentification
	A12	Donor age is out of the standard age range (18-65) years	Unawareness of the donor	Dizziness for the donors and might have some complications
	A13	Medications were taken by the donor within 72 hours before donation	Unawareness of the donor	Effects on the quality of the blood
	A14	Donor has diseases not mentioned in the form	Unknown to the donor	Recipient infected with donor's disease
	A15	Previous donation was in less than three months before the current donation	Ignored or forgotten by the donor	May cause anemia to the donor
	A16	Donor had a surgery in a less than six months before the donation	Ignored or forgotten by the donor	Donors may have disease while its symptoms still unapparent which will be transferred to the recipient
A2		Technician does not inspect information donor information accurately	Questionnaire form not organized or misunderstanding donor information	Failure mode not inspected
A3		Incorrect serial number documentation		
B1	B11	Use of expired blood bags	Poorly stored or contains manufacturing errors	The elements contained in the bags may cause blood clumping or degrading it faster
	B12	Labeling error	Unsystematic labeling process and totally dependence on manual labeling	May cause death to the recipient
B2		Inappropriate vein is selected	Poor trained phlebotomist	Cause pain to the donor
B3		Blood contamination during blood withdrawing	Due to germs in air or not using well sterilized tools	Cause infections to the recipient and sometimes to the donor
C	C1	Centrifuge excessive speed	Poor calibration	Degrade blood quality
	C2	Centrifuge poorly balanced	Unbalanced position of the machine or inadequate maintenance	Hazardous effects on the machine and blood quality degradation
	C3	Centrifuge disruption	Operating machine improperly or inadequate maintenance	Blood quality degradation
D		Improper storages	Labeling errors	Spoil components and may cause serious health problems to the

E1		Infectious diseases not inspected	Use of inaccurate examination tools	Causing infections to the recipient and transferring diseases from donor to recipients
E2		Stamping error	Carrying out stamping procedure in an inadequate or incorrect way	May cause serious health problems to the recipient or even death
F1		Donor name and samples mismatch	Labeling errors	May cause serious health problems to the recipient or even death
F2		Recipient name and samples mismatch	Labeling errors	May cause serious health problems to the recipient or even death
F3		Error in cross-match test	Use of inaccurate examination tools or human Error	Causing death to the recipient
F4		Error in results documentation	Error in F1	May cause serious health problems to the recipient or even death
G1		Error in stamping names on the validated blood units	Error in F1 or F2	
G2		Quality of validated blood unit degradation	Poor maintained storage or storing validated blood units in inappropriate storage	Spoil components and may cause serious health problems to the recipient
H		Error in blood unit retrieval	Technician does not follow instructions in an inadequate way	May cause serious health problems to the recipient or even death

4. Failure risks and effects evaluation

In FMEA, the risk of each failure mode and its effect is represented in terms of three aspects, which are:

- Degree of severity: it relates to the consequence of the potential failure.
- Occurrence: it expresses the probability of the potential failure to occur.
- Chance of detection: it refers to the rate of detecting the potential failure.

Traditional FEMA uses ordinal scale for assigning scores to the potential failures, and they are illustrated in Table 3.

Table 3: Scales for score assignments for severity, occurrence, and chance of detection of traditional FMEA

Degree of severity		**Occurrence**		**Chance of detection**	
Score	**Description**	**Score**	**Description**	**Score**	**Description**
10	Death or permanent loss of major functions	10	Every time occur	1 2	Almost every time detected
9 8	Very dangerous injury	9 8	Periodically occur	3	Very high detected
7	Major injury that may cause serious problems to the recipient	7 6	Frequently occur (occur 1 out of 100 observed episodes)	4 5	Highly detected
6 5	Moderate injury requires additional medical intervention that may delay recipient discharge	5 4	Occasionally occur (occur 1 out of 200 observed episodes)	6 7	Moderately detected
4 3	Minor injury and failure might delay the transfusion process and dissatisfy the donor or degrade blood quality	3 2	Unlikely to occur	8 9	Rarely detected
2 1	No injury	1	Never occur	10	No chance to be detected

For each one of the potential failures listed in Table 2, these scores are used to compute the Risk Priority Number (RPN) by multiplying the degree of severity, occurrence, and chance of detection. The assigned score for each potential failure and its RPN is shown in Table 4. A bar chart showing RPN for all potential failures is presented in Figure 2. It can be see that the use of inaccurate examination tools (E1) has the highest score, as it may cause infection and transferring diseases from donor to recipient. The blood contamination (B3), and mistakes during labeling samples are high risk failures, and efforts have to be directed toward eliminating or reducing them in order to improve safety of the blood transfusion process, as we will discuss in the next section.

Table 4: Assigned score for potential failures of blood transfusion process and their corresponding RPN

Failure code	Degree of severity (1-10)	Occurrence (1-10)	Chance of detection (1-10)	Risk priority Number (RPN) (1-1000)
A1	2	9	4	72
A2	2	2	6	24
A3	4	8	6	192
B1	8	4	8	256
B2	4	6	8	192
B3	4	8	8	256
C	7	2	1	14
D	10	1	2	20
E1	4	8	10	320
E2	6	4	2	48
F1	2	4	10	80
F2	4	6	10	240
F3	3	3	8	72
F4	7	3	7	147
G1	9	2	2	32
G2	10	2	3	60
H	10	2	2	40

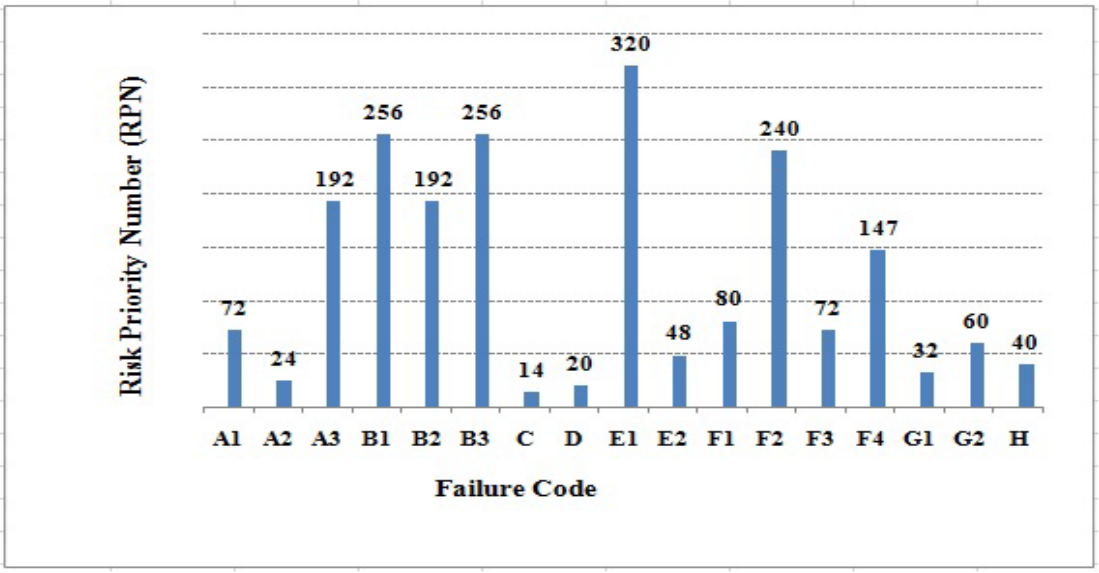

Figure 2. Risk priority number for different potential failures of the blood transfusion process

5. Potential failure error classifications

In order to utilize the proactive characteristics of FMEA analysis, potential failures assessment is very crucial as it can be used to propose improvement strategies. As it can be seen in Table 2, the potential failure modes can be categorized into five groups; which are:

Care process: This group encompasses all potential failures that may result from the low awareness of blood bank clerk or technician.

Donors' awareness and knowledge: This group includes all potential failures that can occur as a result of inaccurate filing of the forms by the donor.

Administrations and process management: This group is concerned with all technical and operational aspects of executing the blood transfusion process and inspection.

Workers' knowledge and skill: This group covers all failures that appear in the situations where the level of available skills and knowledge does not meet the standard level necessary for accomplishing the jobs perfectly.

Communications: This group deals with the potential failures that take place due to poor communication between the donor and blood bank employee.

The overall contribution of each category, w_i, is computed using;

$$W_i = \frac{\sum_{j=1}^{n} X_{ij} f_j}{\sum_{i=1}^{m} w_i}$$, where

X_{ij}: risk priority number for failure mode "j" in category i
f_j: frequency of occurrence of failure "j"
n: number of failure modes within the category
m: number of categories, 5

The distribution of the potential failures into the proposed categories, and the overall contribution of each category are presented in Table 5.

Table 5. The distribution of the potential failure modes into categories with overall weight of each category

Potential failure mode category	Failure modes	Overall contribution %
Care process	A2, A3, B11, B3, D, F1, F2, F3, F4, G2	30.71
Donors' awareness and knowledge	A12, A13, A14, A15, A16	12.93
Administrations and process management	B12, F1, F2, F3, F4, G1, G2	18.56
Workers' knowledge and skill	B12, B2, B3, C1, C2, C3, E1, E2, F3, F4, H	35.21
Communications	A11	2.56

According to the results obtained in Table 5, 35.21% of the potential failure modes are related to workers' knowledge and skills, and 30.71% of them are related to the level of awareness of blood bank clerk or technician. Therefore, improvement strategies that focus on training the staff, and educating technicians and clerks for raising their awareness will be effective tool in reducing failures occurrence, and minimizing their effects, and thus provide ground for blood transfusion quality improvements, and reducing risks. Simplifying and updating the procedures with the commitment of managers will also contribute in improving process.

The occurrence of problems during the blood transfusion process will impact on donor health, patient (bloods' recipient) health, or it may affect the quality of the blood. The distribution of failures consequences into three groups is shown in Table 6. The blood transfusion process risks and safety can be improved by digging deep at the root causes of each one of the failures or problems. One way to do this is by using Fault Tree Analysis (FTA) tool. As an example, an upper level of FTA for the blood quality degradation is shown in Figure 3.

Table 6. Distribution of failures consequences into groups

Failures affect donors' health	A11, A12, A15, B2, B3
Failures affect patients' (blood recipient) health	A11, A13, A14, A16, A2, A3, B12, B3, D, E1, E2, F1, F2, F3, F4, G1, H
Failures affect the quality of blood	A13, A14, B11, B3, C1, C2, C3, G2

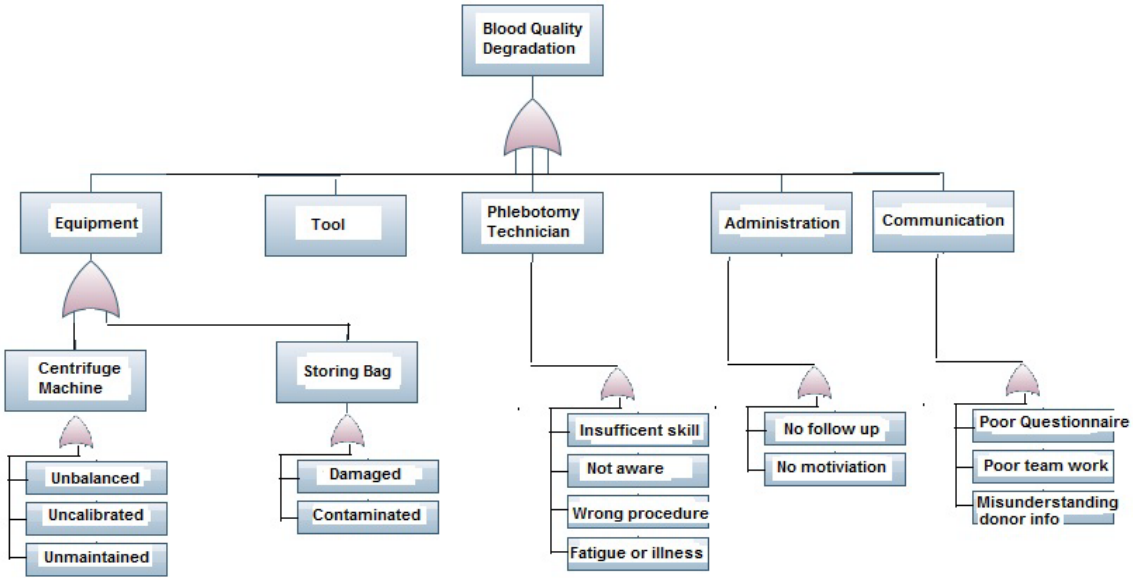

Figure 3. Upper level of the fault tree analysis for blood quality degradation within the blood transfusion process.

Therefore, FMEA can be integrated with FTA in order to reduce risks, and improve safety of healthcare delivery system, i.e., blood transfusion. In the first stage, FMEA is used to identify the potential failures, and highlight the critical ones. In the second stage, FTA is used to find the root causes of each one of the critical failures. Thus, both FMEA and FTA altogether will help to propose improvement solutions for the considered healthcare delivery system.

Conclusions

In this paper, a novel application of FMEA and FTA in Blood Transfusion Unit at a local public hospital in Jordan was presented. FMEA was found to be an effective tool in identifying potential failures in the blood transfusion process. FTA was used to identify the root causes of each critical failure determined by FMEA. It was found that 35.21% of the potential failures of the blood transfusion process are related to the workers' skills and knowledge. Therefore, increasing the awareness of workers, and providing suitable training courses will significantly help reducing risks and problems in the blood transfusion process. The major conclusion of this paper is that integrating FMEA and FTA can be very beneficial to reduce risks, improve quality and safety of any healthcare delivery system including blood transfusion process. As a recommendation, the applied framework is worthy implemented in other units of healthcare delivery system.

Acknowledgements

The authors would like to thank the hospital general manager, and the blood bank manager and all its staff members and technicians for helping accomplishing this research, and providing us with useful technical information.

References

Aulbach, R., Brient, K., Clark, M., Custard, K., Davis, C., Gecomo, J., and JO, H., Blood transfusions in critical care: improving safety through technology and process analysis, *Critical Care Nursing Clinics of North America*, vol. 22, no. 2, pp. 179-190, 2010.

Cure, L., Zayas-Castro, J., and Fabri, P., Clustering based methodology for analyzing near-miss reports and identifying risks in healthcare delivery, *Journal of Biomedical Informatics*, vol. 44, no.5, pp. 738-748, 2011.

Decker, M., Schaffner, W., Nosocomial diseases in healthcare workers spread by the airborne or contact routes (other than tuberculosis). In: Mayhall, C.G. (Ed.), *Hospitals Epidemiology and Infection Control*. Williams and Wilkins, Baltimore, pp. 859-882, 1996.

Eriksen, H., Iversen, B., and Aavitsland, P., Prevalence of nosocomial infections in hospitals in Norway, 2002 and 2003, *Journal of Hospital Infection*, vol. 60, no.1, pp. 40-45, 2005.

Gupta, A., Sharda, R., Improving the science of healthcare delivery and informatics using modeling approaches, *Decision Support Systems*, vol. 55, no. 2, pp. 423-427, 2012.

Henneman, E., Avrunin, G., Clarke, L., Osterweil, L., Andrzejewski, C., Merrigan, K., Cobleigh, R., Frederick, K., Katz-Bassett, E., and Henneman, P., Increasing patient safety and effcinecy in transfusion therapy using formal process definitions, *Transfusion Medicine Reviews*, vol. 21, no.,1, pp. 49-57, 2007.

Maclntyre, C., Wang, Q., Rahman, B., Seale, H., Ridda, I., Gao, Z., Yang, P., Shi, W., Pang, X., Zhang, Y., Moa, A., and Dwyer, D., Efficacy of face masks and respirators in preventing upper respiratory tract bacterial colonization and co-infection in hospital healthcare workers, *Preventive Medicine*, vol. 62, pp. 1-7, 2014.

Max, D., Slonim, A., Assessing patient safety risk before the injury occurs: an introduction to sociotechnical probabilistic risk modeling in health care, *Quality Safety Health Care*, vol. 12, no. 2, pp. 33-38, 2003.

Shapiro, S., Study: patient safety incidents at U.S. hospitals show no decline, cost $9 Billion, Article ID: 562793, 2010.

Rhee, S., Ishii, K., Using cost based FMEA to enhance reliability and serviceability, *Advanced Engineering Informatics*, vol. 17, pp. 179-188, 2003.

Biography

Mohammed Almomani is an Associate Professor of Materials and Industrial Engineering in the Department of Industrial Engineering at the Jordan University of Science and Technology (J.U.S.T.), Irbid, Jordan. He earned B.S. degree in Mechanical Engineering from J.U.S.T, Jordan, Masters in Industrial Engineering from University of Jordan, Jordan and PhD in Materials Engineering from University of Wisconsin-Milwaukee, U.S.A. His research interests include lean manufacturing, corrosion and electrochemistry, composite materials, metal matrix nanocomposite, coatings, manufacturing, and friction stir welding.

Mohammed Aladeemy is currently a Ph.D. candidate in the department of Systems Science and Industrial Engineering (SSIE) at State University of New York at Binghamton (SUNY Binghamton), USA. He is also a graduate research associate in Watson Institute for Systems Excellence (WISE) at SUNY Binghamton. He holds B.Sc. degree in Communication Engineering from Taiz University, Yemen and M.Sc. degree in Mechatronics from Jordan University of Science and Technology (JUST), Jordan. His research activities include the application of data mining techniques and mathematical optimization in healthcare systems including patient no-show prediction, patient volume forecasting at walk-in clinics and outpatient appointment scheduling.

Ruba Zageba was undergraduate student at the Industrial Engineering department at Jordan University of Science and Technology. She earned her bachelor degree at 2013.

Thanaa Rabbaa was undergraduate student at Industrial Engineering department at Jordan University of Science and Technology. She earned her bachelor degree at 2013.