

## RISK MITIGATION OF PGA SURGICAL SUTURE DISTRIBUTION IN DISTRIBUTION COMPANIES

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### Abstract:

**Background:** The demand for PGA surgical suture is increasing, which was recorded from 2017-2019, reaching 148 million in the world and 1.2 million in Indonesia. This is in line with the increase in surgery. Currently, many foreign medical device products are supplied from imports, reaching 70%, and have high prices. PT XYZ is one of the medical device distributor companies that collaborates with companies in the European region as suppliers. The company often experiences problems in procuring product inventory because it depends on one supplier, which affects supply chain performance and creates various risks in its business processes.

**Purpose:** This research focused on risk mitigation at PT XYZ.

**Design/methodology/approach:** The HOR analysis and fishbone method.

**Findings/Result:** Based on the HOR analysis and fishbone method, 3 priority sources of risk that must be mitigated are supplier errors, fluctuating demand, and limited storage space. Furthermore, the mitigation that must be done is to encourage suppliers to build factories in Indonesia, provide quarterly order forecasting, and hold regular meetings for evaluation and strategy making.

**Conclusion:** The result of risk mitigation study at PT XYZ provides a reference for imported medical device distributor to find out the source of risk that must be mitigated immediately so that it can help the company to minimize the chance of loss in the future.

**Originality/Value (State of The Art):** There have been many studies analyzing risk mitigation, but those using the HOR approach for medical device are still rare. This study contributes to provide an overview of the application to PGA surgical suture products.

**Keywords:** fishbone, house of risk, PGA surgical suture, risk, risk mitigation

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## INTRODUCTION

Medical devices have become an important element in health services to the community. The presence of quality medical devices can not only support medical personnel in providing good services but also speed up the treatment process and increase the degree of patient safety. World Health Organization (WHO) data says that there is a significant increase in the number of surgeries in hospitals from year to year. Surgery is a treatment that uses invasive techniques, by opening the body part to be treated through an incision and ending with closure of the incision, mostly using suture. The increase in surgery was recorded from 2017; there were 140 million patients in all hospitals in the world, and it increased in 2019 to reach 148 million. It is estimated that every year there are 165 million surgical procedures performed worldwide. This increase in surgery also occurred in Indonesia, which reached 1.2 million people in 2019-2020. The number of patients continues to experience a very significant increase every year (WHO, 2020).

Based on the Indonesian Ministry of Health (2021), surgery is in 11th position out of 50 disease treatments in Indonesia, with 32% of them being elective surgery. This is followed by the need for surgical suture in Indonesia, which also continues to increase; however, according to Busthomi (2023), the need for surgical suture still depends on imported products with quite expensive prices. Currently, almost 70% of foreign medical device products are circulating in Indonesia, while domestic medical device products are only around 30%.

According to the Republic of Indonesia (RI) Minister of Health Regulation (2017), medical devices are instruments, apparatuses, machines, and/or implants that do not contain drugs used to prevent, diagnose, cure, and alleviate diseases; treat the sick; restore health in humans; and/or form structures and improve body functions. Meanwhile, a PAK (medical equipment distributor) is defined as a company in the form of a legal entity that has a permit to procure, store, and distribute medical devices in large quantities in accordance with the provisions of statutory regulations. All PAKs must be registered with the Ministry of Health and local regional government and have one person in technical responsibility who has knowledge in accordance with the product specifications to carry out the PAK functions in accordance with applicable regulations.

The government also regulates product sales services carried out by medical equipment distributors to their customers, one of which is health service facilities (fasyankes).

PT XYZ is one of the medical device distribution companies that has a Medical Device Distributor (PAK) license from the Ministry of Health, so that it can legally carry out procurement and distribution activities of medical devices as stated in the Medical Device Distribution Certificate (SDAK) for groups of sterile non-electromedical medical devices and sterile electromedical medical devices. One of the medical devices that has high demand and whose procurement must be considered is surgical suture. This medical device is a sterile electromedical medical device whose procurement is carried out by importing from a factory in the European region that acts as a supplier to PT XYZ.

In the process of implementing business activities, PT XYZ has a single supplier as well as being the sole distributor for surgical suture products, or referred to as an exclusive distributor for surgical suture products. This presents a challenge in terms of procuring product inventory because the company is highly dependent on one supplier. At the beginning of 2023, PT XYZ was unable to fulfill 81% of the surgical suture orders received by the company due to delays in delivery from the factory, resulting in a shortage of inventory. This has a further impact: consumers choose to order large quantities of products in anticipation of the recurrence of inventory shortages in the company. This problem increases the potential for companies to lose opportunities and turnover, while reducing customer confidence. Kim and Kim (2019) stated the importance of efficient supply chain management in the healthcare business to ensure product availability in health facilities.

Apart from that, companies are also faced with government regulations that strictly regulate the distribution of imported products, RI Presidential Instruction No. 2 of 2022 concerning accelerating the use of domestic products. This situation disrupts the sales pattern and procurement cycle recorded throughout 2023 and reduces the company's turnover. The government also issued Decree of the Minister of Health of the Republic of Indonesia Number HK.01.07/MENKES/1258/2022 concerning the Substitution of Imported Medical Devices with Domestic Medical

Devices in the Health Sectoral Electronic Catalog. In this decision, it is stated that the government regulates the replacement of imported medical devices with domestic medical devices by freezing imports with 2 criteria: for products that have been produced domestically and already have a distribution permit and for medical devices whose production capacity has met planned needs.

As a PGA surgical suture distributor (whose products are procured by import), the government decision mentioned in the previous paragraph risks making PT XYZ lose opportunities due to the product freeze on the e-catalog provided by the National Public Procurement Agency (LKPP). This problem creates a burden for the company and becomes a long-term risk. In response to this incident, it indicates that the problems that occurred at PT.XYZ provide a challenge for companies to be able to identify and create problem handling strategies to maintain consumer confidence in the future.

## METHODS

This research was conducted at PT XYZ headquarters in Jakarta and PT XYZ warehouse in Depok. Data collection activities using direct observation, interviews, and questionnaires began in January to February 2024. The data used in this study consisted of two sources, primary data and secondary data. Primary data was obtained through in-depth interviews, field observations, and distributing questionnaires to PT XYZ. Secondary data takes data obtained through literature studies, internet searches, journals, and other relevant supporting documents. Sample determination using purposive sampling method by selecting experts as respondents from PT XYZ from company employees who have job duties and criteria according to this research, the logistics department. Data processing is done qualitatively and quantitatively. The quantitative method begins with the Supply-Chain Operations Reference (SCOR) to identify the performance of the PGA surgical suture supply chain, but in this journal it is not included due to page limitations. Furthermore, risk sources and risk mitigation of the PGA surgical suture supply chain were identified using the House of Risk (HOR) method, which is a modified result of Failure Mode and Error Analysis (FMEA) and House of Quality (HOQ) by Pujawan and Geraldin (2009).

Risk is the probability or chance of an event that results in a loss during a certain period (Badariah et al. 2012). Mitigation is a series of actions to minimize the potential for risk and/or the impact of the risk (Nur and Septiarini, 2019). The risk mitigation analysis will use the House of Risk (HOR) method. The HOR model consists of two stages, HOR 1 is used to determine the sources of risk that are prioritized for further mitigation actions. Meanwhile, HOR 2 is used to determine mitigation actions that must be taken first as an effort to prevent risk sources so that risk events can be reduced or eliminated by considering different effectiveness as well as the resources involved and the level of difficulty. These two stages of HOR are used throughout the supply chain flow based on the observed business processes, namely plan, source, make, deliver, and return. HOR 1 calculations are based on risk events and sources, with their respective severity and occurrence values, then the correlation is seen and calculated using Microsoft Excel software. The same is done for HOR 2 which prioritizes risk mitigation actions based on the results of HOR 1. The following formula is used (Pertiwi and Susanti, 2017):

HOR 1 Formula

$$ARP_j = O_j \cdot (\sum S_i \cdot R_{ij})$$

HOR 2 Formula

$$1. TE_k = \sum (ARP_j \cdot E_{jk}) \quad 2. ETD_k = TE_k \cdot D_k$$

Information:  $ARP_j$  (Aggregate Risk Priority);  $O_j$  (Occurrence);  $S_i$ =Severity;  $R_{ij}$  (Relationship);  $TE_k$  (Total Effectiveness);  $ARP$  (Aggregate Risk Potentials);  $R_{jk}$  (Relationship);  $TE_k$  (Total Effectiveness);  $ETD_k$  (Effectiveness to Difficulty);  $D_k$  (Degree of Difficulties (0,3,6,9)).

In this research, a fishbone diagram model is added which aims to identify the root risk agent in a specific and easy-to-design mitigation strategy that will be prioritized by the company (Tague, 2005). Located between HOR 1 and HOR 2. Fishbone diagram also known as cause and effect diagram or Ishikawa diagram is one of the seven basic quality tools. Originally introduced by Dr. Kaoru Ishikawa, a quality control expert from Japan (Emmanuel & Basuki, 2019). According to Aristriyana and Fauzi (2022) and Thahira (2023), fishbone diagrams can help find out the root causes of problems that arise in an industry. This is in line with Aziz and Yunus (2023) who revealed that the application of fishbone diagrams for companies is very

important, by understanding the causes of problems, it will help companies understand the actual conditions in the field.

Aspects that can be analyzed are manpower, method, machine/material, and environment (Iqbal, 2022). Meanwhile, according to Scarvada (2004), the causes of problems can be grouped into six groups, materials, machines and equipment, manpower, methods, mother nature/environment, and measurement. The six causes of this problem are often abbreviated as 6M. In this research, the fishbone diagram analysis uses 5 aspects, namely man, method, material, measurement, environment. The fishbone diagram will be used after HOR 1 to be combined at the HOR 2 stage.

## RESULTS

### Risk Identification

Identification of risks or sources of risk is carried out through field observations, interviews with company management, questionnaire data, and brainstorming with relevant managers. Identification of the company's business processes/supply chain activities is based

on the SCOR model which is divided into business subprocesses or dimensions, plan, source, make, deliver and return. This division of business processes aims to find out where risks can arise. Identification of risk events for each business process that has been identified are all events that may arise and can cause disruption in the company's supply chain activities in achieving company goals. Meanwhile, to identify the degree of impact (severity) of a risk event on the company's business processes, it is based on how much disruption the risk event causes to the company's business processes. The scale used to assess severity is a scale of 1-10 with a value of 1 (no effect of failure) and a value of 10 (definitely an impact of failure). The results of identifying risk events and their severity degree are listed in Table 1.

Based on the identification of risk events that arise from each business process in company XYZ, the risk agent is then identified which is the reason a risk can occur. Then the risk sources that have been identified will be assessed for their probability of occurrence using a scale of 1-10 with explanation, value 1 (never occurs) and value 10 (always occurs). The results of identifying risk sources and assessing the probability of occurrence are listed in Table 2.

Table 1. Risk occurrence and risk sources

Process	Activity	Code	Risk Event (Ei)
Source	Receiving products from suppliers	E1	Product received late
		E2	The product received does not match the quantity requested
		E3	The type/item of product received does not match the request
		E4	There are products that are low in quality
		E5	There is no receipt for receiving the product from the supplier / company
		E6	There is a violation of the contractual agreement by the supplier.
	Supplier evaluation	E7	Complaints from the company to suppliers have not been resolved
	Payment to suppliers	E8	There is no receipt of payment from the supplier/company
		E9	The company is late in making payments to suppliers
	Scheduling product deliveries from suppliers	E10	Product delivery schedule error
Plans	Product procurement planning	E11	Error in stock planning quantities for products
		E12	Incompatibility of product purchase planning with financial planning
		E13	Product delivery scheduling plan errors
	Forecasting product demand	E14	Mistakes in forecasting product demand
Distribution planning	E15	Incompatibility of distribution planning with product procurement planning	
Make	Product quality checking	E16	Errors in product storage
		E17	Nonconformity of items/products produced with customer orders

Table 1. Risk occurrence and risk sources (continue)

Process	Activity	Code	Risk Event (Ei)
Deliver	Packaging	E18	No quality checking of production results is carried out
		E19	Packaging damaged
		E20	The packaging is not labeled expired
	Product quality checking	E21	The packaging was not checked for cleanliness/suitability
		E22	Product quality checks are not carried out (before delivery/sale)
	Sales process	E23	Delayed sales process
		E24	Bad sales process
E25		The number of products in the center is inadequate	
Deliver	Delivery process	E26	Complaints from customers
		E27	There was an error in the delivery process that damaged the product
		E28	There was contamination of the product and product packaging during the shipping process
		E29	Error in items/products sent to customers
		E30	Error in product delivery schedule to customers
Return	Return of goods to supplier	E32	Delay in product delivery to customers
		E33	Goods/products are returned to the supplier for certain reasons
	Return of goods from customers	E34	The number of products returned by customers to the company
		E35	The number of products returned by distributors to the company
		E36	Complaints from customers
	Return of goods to customers	E37	Delay in the process of exchanging goods from the company to the customer
		E38	No exchange of goods to customers for certain reasons
	Handling returned/unsold products	E39	Management/handling of waste from unsold/returned products is not yet carried out routinely
E40		Handling for the process and results of returned products is placed on the quarantine shelf	

Table 2. Sources of risk and degree of occurrence

Code	Risk Agent (Ai)	Event Rate Scale
A1	Human resources are not thorough	3
A2	The number of requests fluctuates from the plan/target	6
A3	Limited knowledge of human resources	2
A4	Incorrect scheduling/planning of product purchases from suppliers	2
A5	Incorrect scheduling/planning of delivery preparations to customers	2
A6	Error from supplier	4
A7	Limited storage space	9
A8	The applicable warehouse SOP has not been implemented properly	2
A9	Limited time in preparing delivery to customers	2

### Identify the Correlation

The process of identifying the correlation between a risk event and the source of the risk cause is based on a brainstorming process with management to determine how big the relationship between each risk event degree characteristic is on the SCOR dimension and the chance of the risk source appearing. This correlation

assessment is identified by giving a value of 0, 1, 3, or 9 as a sign of each relationship or correlation. A value of 0 indicates no correlation, 1, 3, and 9 indicate low, medium, and high correlation, respectively. If a risk source is assessed as causing a risk, then it can be said that there is a correlation. The higher the correlation value indicates the greater the relationship between the risk event and the risk source that causes it. The priority

of risk sources is analyzed with the aim of categorizing risk sources that really need to be sought for mitigation actions. Aggregate Risk Potential (ARP) calculations are carried out with the resulting numerical value of the magnitude of risk for each risk source using data on severity, occurrence, and correlation values between risk sources and risk events. The ARP calculation is used as consideration in determining the priority ranking of risk agents that need more attention (Makarim et al. 2024). The results of identifying priority risk sources are listed in Table 3.

### Identify the Root Cause of the Problem Using the Fishbone Method

The fishbone method is used to identify the root causes of priority risk causes selected. According to Hanta et al. (2018), this method can help find the root causes for alternative options. The fishbone method has the advantage of being able to help identify the root causes of risk by looking at 5 aspects, man, method, material, measurement and environment. Identification

of the root risk agents using a fishbone diagram is carried out by brainstorming with managerial parties. The results of identifying the root causes of problems using this fishbone diagram will then be used to design risk mitigation strategies for HOR 2. The results of identifying the root risk agents are shown in Figure 1.

### Identify the Risk Mitigation Actions

Based on the prioritized risk sources, it was found that there were 12 risk mitigation actions in the PGAPXYZ surgical suture supply chain. There are 6 mitigation actions with a score of 3, 3 mitigation actions with a score of 4, and 3 mitigation actions with a score of 5. Mitigation actions that are easy to implement or with a score of 5 are having more than one communication channel (PA4), communicating and collaborating with related agencies (PA7), and provides a backup storage warehouse (PA12). The results of expert assessment and identification of each mitigation action are presented in Table 4.

Table 3 Results of identifying priority sources of risk

Risk Agent Priority			
Code (A <sub>j</sub> )	Risk Agent	ARP <sub>j</sub>	%ARP
A6	Error from supplier	6288	54.7%
A2	The number of requests fluctuates from the plan/target	1500	13.0%
A7	Limited storage space	1215	10.6%

Description: % ARP=(ARP<sub>j</sub>/∑ ARP<sub>j</sub>)\*100%

Table 4 Results of identification and assessment of risk mitigation actions

Code	Preventive Action (PA <sub>i</sub> )	Score
PA1	Communicate more intensively according to order targets	3
PA2	Provide order forecasting for quarterly periods	3
PA3	Conduct reviews to evaluate service degrees per quarter period	3
PA4	Have more than one communication channel	5
PA5	Encourage suppliers to set up factories in Indonesia	3
PA6	Always pay attention to the latest changes in government regulations	3
PA7	Communicate and collaborate with related agencies	5
PA8	Have foreign currency reserves for purchase transactions	4
PA9	Hold training to improve the quality of forecasting regularly	4
PA10	Hold regular meetings for evaluation and strategy determination	3
PA11	Hold regular stock and warehouse management training	4
PA12	Provide backup storage warehouse	5

### Mitigation Action Priorities

The priority order of risk mitigation actions is obtained through calculating the ETDk value (Effectiveness to Difficulty) each mitigation action. The ETDk value is obtained from the degree of difficulty of identified risk mitigation actions as well as the correlation value between risk sources and risk mitigation actions. The higher the ETDk value, the closer the priority of mitigation actions to be implemented first as an effort to reduce and/or eliminate sources of risk. The results of the ETDk value and risk mitigation action classification PA5 occupy the highest position for risk mitigation actions with a value of 134,829. Meanwhile, the second value (PA2) was 42,539, followed by PA10 of 33,009. These results led to the selection of three priority risk mitigation actions presented in Table 5 which must be implemented at PT XYZ.

### Managerial Implications

This research is expected to provide various benefits for XYZ company to find out the source of risk that must be mitigated immediately so that it can help the company minimize the chance of loss in the long run. XYZ Company can consider the results of the risk mitigation priority assessment, including: (1) The company convinces suppliers to establish a factory in Indonesia which is strategically located to facilitate distribution to PT XYZ, and (2) The company provides order forecasting and service level evaluation per quarterly period.

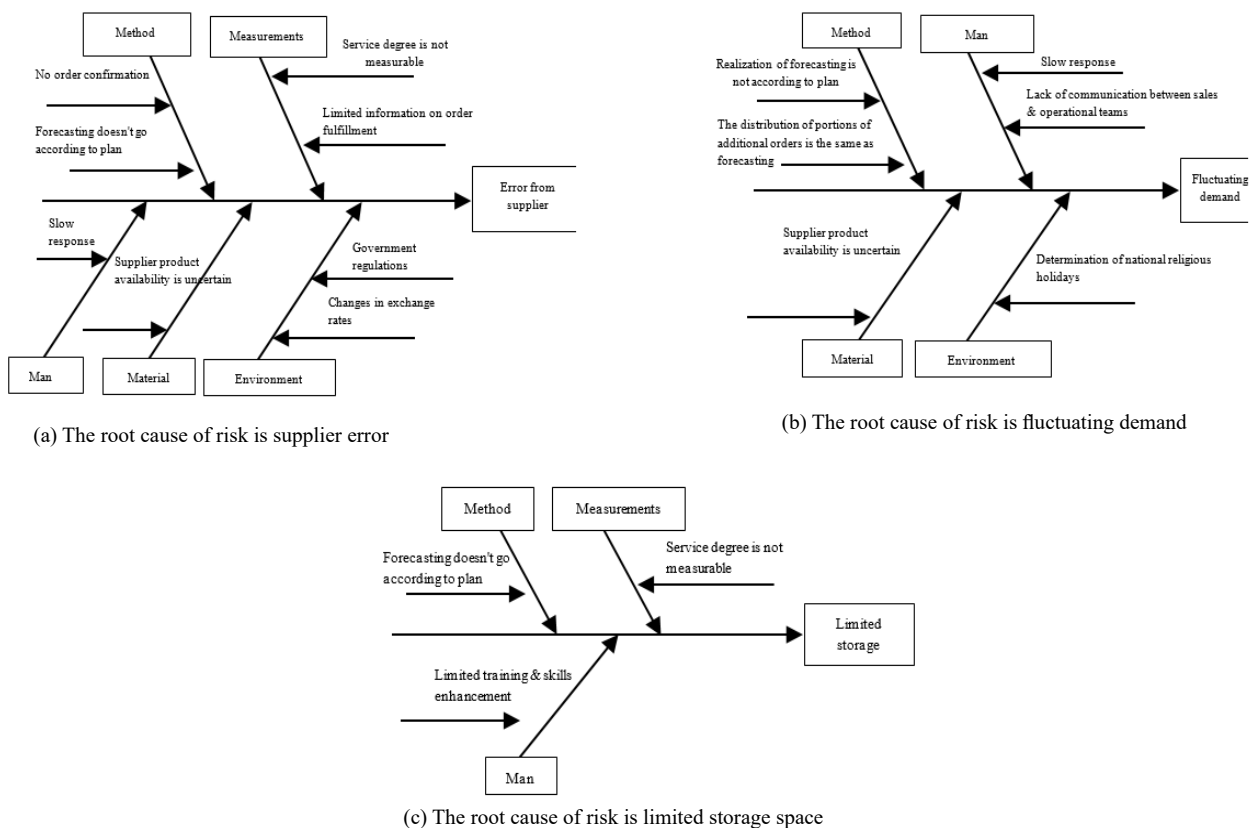


Figure 1 Results of root risk agent identification

Table 5. Priority of risk mitigation actions

Code	Preventive Action/ Mitigation Action (PAi)	ETDk Score
PA5	Encourage suppliers to set up factories in Indonesia	134,829
PA2	Provide forecasting orders for quarterly periods	42,539
PA10	Hold regular meetings for evaluation and strategy determination	33,009

## CONCLUSIONS AND RECOMMENDATIONS

### Conclusion

Risk assessment in PT XYZ's business processes through HOR 1 analysis found 40 risk events. Then three priority risks were found that needed to be taken as mitigation actions, errors from suppliers, fluctuating demand from plans or targets, and limited product storage space. Through fishbone diagram analysis, 12 root causes of problems were found which can help analyze risk mitigation actions. The results of the mitigation analysis through HOR 2 showed 3 priority mitigation actions, which include encouraging suppliers to build factories in Indonesia, providing quarterly order forecasting, and holding regular meetings to discuss evaluations and future company strategies.

### Recommendations

Based on the findings in this research, the following are the managerial implications for PT (2) The company provides order forecasting and evaluation of service degrees per quarter to suppliers. Suggestions for further research are (1) looking for other root risk agents that are not a priority for analyzing risk mitigation actions; (2) adding analysis from the company's supplier and customer side; and (3) using other methods with the aim of expanding references, for risk analysis, for example based on ISO 31000.

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