Risk Identification and Control Strategies of Vaccine Supply Chain Based on SCOR Model

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Abstract: From a whole-process perspective of the supply chain, this study identifies and analyses the risks existing in the vaccine supply chain (VSC) and proposes targeted risk control measures, aiming to provide directions and recommendations for building a safe VSC. Based on the Supply Chain Operations Reference model (SCOR), the risks in the operation process of the VSC are systematically identified, the risk factors in the VSC are summarized, and targeted governance countermeasures are proposed accordingly. The results show that the risks in the VSC mainly come from the processes of planning, procurement, production, distribution, and returns. Based on the SCOR model, a total of 27 specific risk factors are identified, and corresponding risk control countermeasures are proposed from the perspective of the five processes.

Keywords: SCOR model; vaccine supply chain; risk identification; risk control strategies

1 Introduction

At the onset of 2020, the COVID-19 pandemic rapidly spread worldwide, severely threatening human life and safety. In China, for example, by the end of September 2021, the country had reported a total of 96,162 confirmed COVID-19 cases and 4,636 deaths [1]. To mitigate the spread of the virus and minimize infections and fatalities, China initiated an emergency COVID-19 vaccination program. By the end of September 2021, more than 2.2 billion vaccine doses had been administered [2]. The vast demand for vaccines has not only exerted immense pressure on vaccine production but also presented significant challenges for cold chain logistics. Studies have shown that transportation is the most vulnerable part of the cold chain, and currently, China's cold chain logistics are relatively underdeveloped, with issues such as poor management. Given the current unique social context, the vaccine supply chain (VSC) is vital to the nation's well-being. A disruption in the VSC would inevitably impact the overall health of society and could even threaten public safety. Therefore, from a risk management perspective, it is essential to analyze the risks throughout the entire VSC and propose appropriate governance strategies to assist stakeholders in managing these risks comprehensively. This would help

establish a safe and effective VSC. The findings of this research are of significant importance to pandemic prevention and control, the vaccine industry, and public health and safety.

Scholars' current research on vaccine risks primarily concentrates on two areas. The first area is risk analysis in the vaccine production stage. For example, Song et al. [3] analyzed risks during vaccine production using quality risk management theory and proposed targeted regulatory strategies. Xu [4] and Jian [5] employed FMEA/FMECA models to assess the relative importance of various risk factors in biological vaccine production. Based on their risk analysis and evaluation, they developed risk control measures and enhanced the internal quality management systems of vaccine manufacturing companies. The second area of focus is risk analysis in the vaccine transportation stage. Li [6], using the fault tree analysis method, evaluated the structural and probability importance of risk events in the pharmaceutical cold chain logistics process, identifying the significance of each basic event and suggesting corresponding control measures for critical risk factors. Ying et al. [7] reviewed the current status and challenges of vaccine cold chain management in China and offered improvement suggestions from the perspective of cold chain management. Du [8] analyzed issues related to COVID-19 vaccine transportation within cold chain logistics and proposed feasible strategies concerning supply chain models, the application of new technologies, and vaccine traceability systems.

A review of existing studies reveals that most research primarily focuses on risk identification in vaccine production and transportation, with limited attention to analyzing risks throughout the entire vaccine operation process from a supply chain perspective. Therefore, this paper aims to systematically identify risks across the entire operation process of the VSC by utilizing the supply chain operations reference (SCOR) model and total quality management (TQM) theory. It also offers targeted governance strategies based on the risk identification findings, aiming to assist stakeholders in managing potential risks within the VSC.

2 Supply chain operations reference model

The SCOR model, initially introduced by the Supply Chain Council, serves as a standard reference framework and diagnostic tool applicable across various industries' supply chains. The SCOR model consolidates concepts such as business process reengineering, benchmarking, and process assessment into a comprehensive cross-functional framework that includes business processes, performance metrics, best practices, and technology features. It provides a universal language for enterprises to describe and analyze their supply chains. The SCOR model is

composed of five core management processes: Planning, Sourcing, Making, Delivering, and Returning, each of which is regarded as a critical internal function and a key inter-organizational process [9]. Commonly employed as a risk identification tool, the SCOR model facilitates systematic identification and evaluation of supply chain risks, thereby reducing them.

In this paper, building upon the general supply chain definition, the VSC is defined as a functional network focused on the vaccine as the core product. The process starts with the procurement of materials required for vaccine production, followed by manufacturing by vaccine producers, then distribution through logistics networks to vaccination centers, and finally, the administration of vaccines to individuals. This network integrates suppliers of vaccine materials, vaccine manufacturers, various levels of Centers for Disease Control (CDCs), epidemic prevention agencies, and the vaccinated individuals into a cohesive system. The structure of the VSC is clear: vaccine manufacturers are at the core, supported by upstream suppliers of vaccine materials, and downstream, various levels of CDCs and epidemic prevention departments. Logistics operations are typically managed either by the manufacturers themselves or through third-party logistics providers.

Compared to other supply chains, the VSC demands higher quality standards, is extremely time-sensitive, and involves significant costs in the event of losses. These unique characteristics of the VSC substantially increase the potential risk impacts and the complexity of risk management. If risks materialize in the VSC, they can not only compromise vaccine quality but also pose significant threats to the safety of those receiving the vaccine. The SCOR model provides a clear depiction of the VSC's structure and components while also enabling systematic identification of potential risks within the supply chain. This facilitates effective risk management by stakeholders involved in the VSC.

3 Risk factors in the VSC based on the SCOR model

3.1 Risks in the planning process

The planning process involves strategizing the entire supply chain based on forecast outcomes, ensuring a balance between demand and supply. As the initial process at the highest level of the SCOR model, it is fundamental to the efficient operation of all subsequent processes. This section identifies and analyzes activities

related to VSC risks by considering the main activities within the planning process and the unique characteristics of vaccine companies.

SCR1: Risk of Inaccurate Demand and Supply Forecasting

The presence of the bullwhip effect and information asymmetry between companies means that the accuracy of demand and supply forecasts significantly impacts the planning and decision-making processes of vaccine companies. This risk is identified as “Accuracy of Demand and Supply Forecasts”.

SCR2: Risk from Inefficient Supply Chain Structure Design

China's vaccine distribution largely follows traditional supply chain structures. However, practical experience has shown that these traditional models, characterized by multiple hierarchical levels and slow response times, fail to meet the distribution needs of various vaccines. Inefficient supply chain structure design can lead to reduced vaccine supply efficiency and risks such as delivery delays. This risk is termed “Efficiency of Supply Chain Structure Design”.

SCR3: Risk of Poor Management During Vaccine Product Decline

Vaccine companies must assess when a product is entering its decline phase using relevant indicators and data, and either innovate to meet market demands anew or decide to withdraw the product from the market. Poor management during this phase can not only harm the company’s interests but also strain its relationship with the public [10]. This risk is referred to as “Management of Product Decline Phase”.

SCR4: Risk of Weak Risk Awareness Among Employees

Given the high quality and safety requirements for vaccines, it is essential for management and production staff in vaccine companies to maintain strong risk awareness throughout the process and to foster a deep understanding of risk culture. Weak risk awareness can easily lead to quality and safety issues with vaccines. This risk is labeled “Employee Risk Awareness”.

3.2 Risks in the procurement process

The procurement process encompasses key activities such as supplier selection and raw material transportation. However, certain activities within this process overlap or are redundant. To identify the associated risks effectively, similar activities were consolidated, and the risks were analyzed based on the refined procurement process activities, resulting in the identification of the following risk factors.

SCR5: Risk from Inadequate Control Over Material Procurement Prices

For vaccine manufacturers, the cost of materials is a significant determinant of their overall production costs. Effective control over procurement prices is crucial for maintaining price stability. If procurement prices increase, it can reduce the company's profitability, impacting future production plans and material quality, potentially leading to risks within the VSC. This risk is termed "Procurement Price Management".

SCR6: Risk from Inappropriate Supplier Selection

Supplier selection criteria significantly influence the overall functioning of the supply chain. Evaluating suppliers should encompass aspects such as delivery speed, reputation, supply quality, and material costs. Poor supplier selection can impede the VSC's goals and may even introduce severe risks to the company. This risk is identified as "Supplier Selection Effectiveness".

SCR7: Risk from Non-Adherence to Material Quality Standards

Vaccine manufacturers must rigorously inspect raw materials during procurement to ensure compliance with quality standards. If the materials fail to meet these standards, the resulting vaccines will also be substandard. This risk is labeled "Quality Consistency".

SCR8: Risk from Delayed Material Supply

Without thorough assessment and continuous monitoring of suppliers, vaccine manufacturers may face increased instances of delayed material deliveries. Such delays can disrupt production schedules or result in the loss of market opportunities. This risk is referred to as "Supply Punctuality".

SCR9: Risk from Inaccurate Material Verification

During the material receipt process, if the staff does not meticulously verify the materials against procurement standards, substandard or incomplete materials may be accepted into the company. This risk is known as "Material Verification Accuracy".

SCR10: Risk from Poor Material Delivery Conditions

Once procurement is completed, materials must be transported from suppliers to the vaccine manufacturer. Mismanagement during transportation can result in significant material damage, potentially reducing the vaccine company's production capacity [11]. This risk is termed "Delivery Condition Integrity".

SCR11: Risk from Inadequate Warehouse Management

After materials are stored, improper management—such as the absence of labeling or exposure to a humid environment—can lead to issues like material mix-ups or quality degradation. This risk is called “Warehouse Management Efficiency”.

3.3 Risks in the production process

To comprehensively identify risk factors in the vaccine production process, TQM theory is applied. The potential risks are categorized based on the five key elements: personnel, equipment, materials, methods, and environment.

3.3.1 Vaccine production personnel

SCR12: Risk of Contamination by Particles and Microorganisms

During production, it is challenging to fully disinfect and sterilize personnel entering sterile areas, leading to the risk of product contamination by particles and microorganisms. This risk is termed “Particle and Microbial Contamination”.

SCR13: Risk from Non-Standard Operations

The vaccine production process requires human involvement, and improper operations by production staff can result in quality issues with vaccine products. This risk is identified as “Operational Standardization”.

3.3.2 Vaccine production equipment

SCR14: Risk of Cross-Contamination

During the use of production equipment, containers may come into direct contact with the vaccine solution, leading to the risk of microbial adhesion and cross-contamination. This risk is labeled “Cross-Contamination”.

SCR15: Risk from Improper Equipment Usage

If vaccine production equipment is not properly installed, designed, or used in accordance with specified procedures, it may adversely affect the quality of the vaccines. This risk is termed “Equipment Usage Compliance”.

3.3.3 Vaccine production materials

SCR16: Risk from Substandard Production Materials

The quality of materials used in vaccine production directly impacts the final product, and substandard materials can compromise vaccine safety and efficacy [12]. This risk is referred to as “Material Quality Compliance”.

SCR17: Risk from Material Mismanagement

Inadequate management and categorization of production materials can lead to confusion and the incorrect use of materials, resulting in significant risk events. This risk is identified as “Material Management Accuracy”.

3.3.4 Vaccine production methods

SCR18: Risk from Inaccurate Production Processes and Methods

Successful vaccine production requires meticulous adherence to manufacturing methods and complex processes. Any deviation at any stage can result in substandard vaccine quality. This risk is labeled “Process and Method Accuracy”.

SCR19: Risk from Insufficient Research Prior to Process and Method Changes

Changes in production processes and methods without thorough research can negatively impact the safety and efficacy of vaccine products. This risk is referred to as “Research Sufficiency Before Changes”.

3.3.5 Vaccine production environment

SCR20: Risk of Environmental Contamination

Production personnel, equipment, and the manufacturing environment can all contribute to the contamination of vaccine products. This risk is labeled “Environmental Contamination”.

SCR21: Risk from Improper Disinfection Methods and Low Frequency of Disinfection

If the disinfection methods used in the production environment do not meet standards or if disinfection is infrequent, the risk of environmental contamination increases. This risk is termed “Disinfection Practices and Frequency”.

3.4 Risks in the distribution process

The distribution process includes managing product inventory and transportation. Based on the primary activities of distribution and the specific characteristics of vaccine companies, the following risks are identified.

SCR22: Risk from Improper Control of Finished Products

After production, vaccines must be stored under strict conditions, including specific temperature and cleanliness requirements. Poor inventory management can lead to vaccine damage, delaying delivery times. This risk is identified as “Finished Product Management”.

SCR23: Risk from Poor Decision-Making in Distribution Methods

Temperature control during vaccine distribution is critical, especially in maintaining the cold chain. Poor decisions in transportation methods can lead to frequent changes in handling, risking improper temperature control. This risk is termed “Distribution Method Selection”.

SCR24: Risk from Equipment Malfunction

Vaccines require cold chain transportation, which involves storing them in refrigerated equipment at controlled temperatures. Equipment malfunction can lead to temperature excursions, rendering vaccines unusable. This risk is identified as “Equipment Reliability”.

SCR25: Risk from Low Employee Competence

The quality of distribution personnel is crucial in mitigating risks. Distribution staff must be skilled drivers, capable of handling emergencies, and knowledgeable about vaccine handling. This risk is labeled “Human Resource Competence”.

3.5 Risks in the return process

The return process in the supply chain represents reverse logistics, involving the return of products and materials. This includes handling product returns from customers and material returns to suppliers, requiring communication, documentation, and the physical return of items.

SCR26: Risk from Low Product Quality

In the vaccine industry, product returns often occur due to issues such as deviations in vaccine efficacy or the presence of counterfeit products [13]. This risk is termed “Product Quality Compliance”.

SCR27: Risk from Low Vaccine Distribution Satisfaction

Errors in vaccine distribution can lead to reduced customer satisfaction, prompting return requests from recipients. This risk is labeled “Distribution Satisfaction”.

Table 1 summarises the risk factors at each stage of the VSC.

Table 1. The risk factors of VSC

No.	Risk category	Risk factors
SCR1	Risks in the planning process	Risk of inaccurate demand and supply forecasting
SCR2		Risk from inefficient supply chain structure design
SCR3		Risk of poor management during vaccine product decline
SCR4		Risk of weak risk awareness among employees
SCR5	Risks in the	Risk from inadequate control over material procurement prices

SCR6	procurement process	Risk from inappropriate supplier selection
SCR7		Risk from non-adherence to material quality standards
SCR8		Risk from delayed material supply
SCR9		Risk from inaccurate material verification
SCR10		Risk from poor material delivery conditions
SCR11		Risk from inadequate warehouse management
SCR12		Risk of contamination by particles and microorganisms
SCR13	Risks in the production process	Risk from non-standard operations
SCR14		Risk of cross-contamination
SCR15		Risk from improper equipment usage
SCR16		Risk from substandard production materials
SCR17		Risk from material mismanagement
SCR18		Risk from inaccurate production processes and methods
SCR19		Risk from insufficient research prior to process and method
SCR20		Risk of environmental contamination
SCR21		Risk from improper disinfection methods and low frequency of disinfection
SCR22	Risks in the distribution process	Risk from improper control of finished products
SCR23		Risk from poor decision-making in distribution methods
SCR24		Risk from equipment malfunction
SCR25		Risk from low employee competence
SCR26	Risks in the return process	Risk from low product quality
SCR27		Risk from low vaccine distribution satisfaction

4 VSC risk management strategies

4.1 Risk control in the planning process

Risks in the planning process include the accuracy of demand and supply forecasting, the reasonableness of supply chain structure design, the management of product decline, and the level of risk awareness. To address these, companies should consider integrating demand and supply planning with supply chain structure design to propose coordinated control measures. For instance, transitioning from a CDC-centric supply chain model to a logistics-centric one could help overcome the inefficiencies of traditional models, such as excessive layers, slow information flow, and challenges in vaccine quality control. This transition could also alleviate the bullwhip effect, reducing risks associated with inaccurate demand and supply forecasts (SCR1). Furthermore, leveraging modern technologies like the Internet of Things (IoT) can enable real-time visibility and information sharing within the VSC, enhancing the accuracy of planning and ensuring the supply chain's safety and efficiency (SCR2). Additionally, establishing a dedicated risk management

department within the organization can facilitate rapid risk detection and response. Implementing safety principles, such as DuPont's top ten safety tenets, across the company can foster a culture of risk awareness, ensuring that all employees recognize safety as their responsibility (SCR4). Lastly, for vaccines entering the decline phase (SCR3), companies should develop robust product withdrawal plans, strictly adhere to regulations for recalls or market exits, and conduct thorough evaluations to provide valuable insights for future product improvements.

4.2 Risk control in the procurement process

Risks in the procurement process encompass procurement pricing (SCR5), supplier selection capability (SCR6), quality consistency (SCR7), supply punctuality (SCR8), material approval (SCR9), delivery integrity (SCR10), and warehouse management (SCR11). Vaccine companies should begin by gathering comprehensive data on suppliers, evaluating their performance in areas like delivery speed, reputation, quality, and pricing, to select the most reliable partners. Additionally, maintaining relationships with alternative qualified suppliers can serve as a safeguard against potential disruptions. When procuring materials, companies should deploy a specialized team to establish and enforce stringent quality standards while negotiating prices to ensure cost-effectiveness. Contracts should clearly define deadlines, and continuous monitoring should ensure suppliers meet their obligations until the transaction is finalized. Upon receiving materials, companies must conduct thorough inspections to verify quantities and compliance with standards. Post-delivery, enhancing warehouse management through regular inspections and strict labeling can prevent mishandling. Companies might also implement a tiered management system, categorizing materials based on their impact on vaccine quality, to ensure higher levels of control where needed.

4.3 Risk control in the production process

Managing risks in the production process is vital to the effective operation of the entire VSC, so companies should treat it as a priority in risk governance. First, because vaccine quality is foundational, substandard materials can directly undermine product quality. Risk control should therefore start at the source, with rigorous management of procurement, transportation, and storage to ensure material quality. Second, to prevent material mix-ups, companies should strengthen oversight of production materials through routine inspections and clear labeling, and verify all

materials before use to confirm they meet production requirements. Third, environmental contamination risks arise from personnel, the workshop environment, and equipment, and should be managed in an integrated manner. For personnel-related risks, firms should require pre-employment health screening and enforce strict entry protocols, including cleaning, disinfection, and appropriate clothing. For risks related to the workshop and equipment, regular disinfection and appropriate sterilization methods are needed to maintain a sterile setting, alongside routine equipment inspection and timely cleaning and disinfection after use to reduce cross-contamination and extend equipment life. Fourth, operational risks should be controlled by establishing strict standards, procedures, and change-management rules. Companies should recruit skilled staff, ensure new hires receive comprehensive training, and allow only those who pass assessments to work. Equipment should be properly designed, selected, and operated according to guidelines, and any changes to methods or processes should be supported by thorough research and validation to avoid arbitrary modifications.

4.4 Risk control in the distribution process

Risks in the distribution process involve finished-product storage (SCR22), transportation decisions (SCR23), equipment reliability (SCR24), and personnel capability (SCR25). To strengthen risk management in the VSC, companies should first ensure vaccines are stored at the required temperature and in a clean environment, supported by routine cleaning, disinfection, and continuous temperature monitoring. Second, before distribution, companies should assess conditions at both the current storage site and the destination, then select appropriate routes and transport methods to reduce temperature fluctuations caused by frequent mode changes. Third, cold chain equipment should be inspected and maintained regularly, and key devices such as temperature monitors should be checked before each shipment to lower the likelihood of in-transit failures and vaccine damage. Finally, all distribution personnel should complete training and certification before work begins, covering vaccine handling, cold chain equipment maintenance, and driving skills, so they can respond to emergencies and ensure safe, efficient delivery.

4.5 Risk control in the return process

To address the risks in the return process, which arise from poor product quality (SCR26) and low satisfaction with vaccine distribution (SCR27), companies should

give this area careful attention. By enhancing the quality control of vaccines and managing deviations during the distribution process, it is crucial to ensure that vaccines meet quality standards before they are dispatched and that the distribution process remains error-free until safe delivery to vaccination centers. Moreover, in maintaining product quality, companies should rigorously enforce vaccine release procedures, including detailed information logging and verification, to prevent basic errors in distribution. Although the risks associated with the return process are of relatively lower priority compared to other risks, any such event can still disrupt the efficiency of the VSC and lead to increased operational costs. Therefore, vaccine manufacturers should still focus on this aspect to ensure that the supply chain achieves its intended objectives.

5 Conclusion

This study systematically identifies risks within the VSC operations by applying the SCOR model and integrating TQM theory to identify risks specifically in the vaccine production phase, identifying a total of 27 distinct risk factors. The study then proposes targeted risk management strategies from the perspective of planning and other processes. By analyzing risks across the entire supply chain, this approach addresses the shortcomings of previous studies that only focused on individual stages of vaccine risk identification. This comprehensive approach enriches the theoretical framework of VSC risk management, enabling stakeholders to better manage potential risks and establish a secure and effective VSC. This has significant implications for pandemic prevention, the vaccine industry, and public health and safety.

References

1. National Health Commission, http://www.nhc.gov.cn

2. Yang, M, Qu, S, Ji, Y, et al.: Risk management of the vaccine supply chain: Interactions of risk factors and control strategies. Socio-Economic Planning Sciences. 98, 102153 (2025)

3. Song M, Huang T. Research on the Risk Supervision Strategy during Vaccine Production. China Pharmacy. 24(5), 385-387 (2013)

4. Zhang X. Risk Management in Biological Vaccine Production Process. University of Chinese Academy of Sciences. 2015

5. Zhang J. The Ouality of The Vaccine Production Process Of Risk Assessment and Control. University of Chinese Academy of Sciences. 2014

6. Li L. Research on Drug Cold Chain Logistics Process Risk Management. Beijing Jiaotong University. 2021

7. Ying X, Liu Q, Zhang M, et al.: Current Situation and Development Prospect of Vaccine Cold Chain Management in China. Chinese Journal of Modern Applied Pharmacy. 37(5), 636-640 (2020)

8. Du X. Research on COVID-19 vaccine transportation issues and countermeasures based on cold chain logistics. China storage & transport magazine, 4, 96-98 (2021)

9. Abolghasemi M, Khodakarami V, Tehranifard H. A new approach for supply chain risk management: Mapping SCOR into Bayesian network. Journal of Industrial Engineering and Management. 8(1): 280-302 (2015)

10. Sankarankutty S. Application of risk assessment in product quality lifecycle management. Rapports De Pharmacie. 1(2), 46-53 (2015)

11. Faisal Li L, Su Q, Chen X. Ensuring supply chain quality performance through applying the SCOR model. International Journal of Production Research. 49(1), 33-57 (2011)

12. Moktadir M A, Ali S M, Mangla S K, et al.: Decision modeling of risks in pharmaceutical supply chains. Industrial Management Data Systems. 118(7), 1388-1412 (2018)

13. Vishwakarma V, Prakash C, Barua M K.: A fuzzy-based multi criteria decision making approach for supply chain risk assessment in Indian pharmaceutical industry. International Journal of Logistics Systems and Management. 25(2), 245-265 (2016)