

Investigating Information Integration and Health Regulation in Immunisation Supply Chain Visibility

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ABSTRACT

Global immunisation supply chains have faced difficulties in achieving vaccine coverage. Since the COVID-19 pandemic, some countries encountered a lack of implementation of information system integration to cope with this disease because of challenges in managing information within each unique supply chain process in the vaccination program and complying with the new healthcare regulations and standards in medical supply chains. One of the major challenges lies in the integration of data within the supply chain system. This integration is vital for establishing an information network that enhances visibility into the immunisation supply chain and ensures that vaccines reach individuals promptly and with quality. This study aims to identify the factors influencing information system integration and its effects on the visibility of the immunisation supply chain. This study employs a mixed-methods approach and aims to investigate how the factors impact the visibility of the immunisation supply chain through structural equation modelling (SEM) analysis tools and semi-structured interviews using open-ended questions with experts in the field of health vaccination programs to get insight into opinions, experiences, and suggestions. This research is expected to contribute to both theoretical and managerial understanding.

Keywords: Information system, system integration, supply chain visibility, immunisation supply chains, regulatory compliance, interorganizational collaboration.

INTRODUCTION

The World Health Organization (WHO) and the Vaccine Alliance (GAVI) both stress the importance of having immunisation supply chains to achieve global vaccination coverage because the trend of immunisation has decreased. Many countries face challenges such as outdated equipment, inefficient distribution networks, and lack of data integration within their immunisation supply chains. The WHO emphasises the need for supply chain and logistic systems to ensure vaccine storage, distribution, and management. These systems are critical for maintaining quality standards and utilising information systems to enhance performance. The goal is to ensure a supply of high-quality vaccines from production to delivery reducing the risk of missed vaccination opportunities due to shortages (World Health Organization, 2014). GAVI highlights how robust immunisation supply chains can improve vaccination coverage and equity leading to a decrease in child mortality rates. Given their investment of over one billion in vaccines each year, it is imperative to enhance supply chain practices to safeguard these resources. In the changing world of health, the effectiveness and durability of supply chain systems play a crucial role in determining the success of vaccination programs worldwide. Supply chain visibility (SCV) refers to a stakeholder's ability to access or see data throughout the supply chain in time or near real-time from manufacturing to end-user delivery. Improving visibility within supply chains helps ensure vaccines are delivered promptly and efficiently maintains the integrity and quality of vaccination products through cold chain management and allows for responses to changes, in demand and potential disruptions (Kartoglu & Ames 2022). In addition, recent worldwide health crises, like COVID-19, have emphasised the significance of SCV. Being able to track and control vaccine distribution in time has been crucial for the response efforts during such emergencies. The absence of integrated data information systems hinders the ability of health supply chains to respond quickly to changes in vaccine demand manage inventory efficiently and maintain the chain's integrity. Gunasekaran and Ngai (2004) presented the effect of information systems in supply chain integration on supply chain management performance. However, they also suggested that a new form of information systems configuration should be developed for supply chain management. This study seeks to address this knowledge gap by exploring ways to enhance information system integration for improved visibility within immunisation supply chains. In summary, these research objectives are (i) to discover the aspects that affect the integration of information systems, (ii) to understand the impact of information system integration on the visibility of the immunisation supply chain, and (iii) to improve the integration of information systems in immunisation supply chains. The proposed research questions are how can information system integration be strengthened to increase the immunisation supply visibility and what insight these aspects enhance the immunisation program? The proposed sub-research questions are (i) What factors influence the supply chain visibility for vaccination products? (ii) How do these factors

contribute to the visibility of vaccination products in the supply chain? (iii) What are the insights of supply chain visibility factors in immunisation and their implications?

LITERATURE REVIEW

Immunisation Supply Chain

The immunisation supply chain includes all the individuals, tasks, facilities, tools, and preparation required to guarantee that vaccines remain secure and efficient and are administered to the end-user who requires them. Strong supply chains can lower people's mortality and are necessary for increasing immunisation coverage and equity (GAVI, 2019). The immunisation supply chain is an important part of the public health system. It can be truly considered reliable because it keeps vaccines safe and delivers to those who need them, but the supply chain still faces many challenges such as insufficient funding and often poor coordination. Yadav et al. (2014) studied the potential of the vaccine supply chain that should be integrated with other health commodity supply chains. The design of the supply chain has a large impact on its efficiency as well as its cost-effectiveness. Shamsi and Torabi (2018) also mentioned that optimization and reinforcement of the vaccine supply chain are vital for enhancing immunisation coverage as well as controlling diseases. However, there is a need for further study to tackle logistical problems (Duijzer et al., 2018). Most of the studies on vaccine supply chain management have only dealt with the logistics of vaccine distribution considering the challenges of low- and middle-income countries (Duijzer et al., 2018). Some studies raised the importance of vaccine cold chain management information systems enhancing cold chain management vaccine (Anderson et al., 2014), but there is no mention of a need for further research into supply chain information systems integrated with the broader vaccine. A modification to the supply chain's architecture such as multiple data sources, and data processing has led to improved performance, but their study did not focus on how the information system is integrated. Furthermore, fewer studies have examined the role of regulatory compliance and standards in medical supply chains and interorganizational collaboration, which impact the readiness of information systems integration of immunisation supply chains.

Supply Chain Visibility

Effective supply chain management relies heavily on supply chain visibility (SCV), which establishes a foundation for overseeing all procurement to delivery processes. SCV goes beyond tracking goods movement. Involves real-time access to crucial data like product status orders, shipments, and overall service levels throughout the entire supply network. Cutting-edge technologies such as GPS, RFID and IoT devices enable real-time tracking and monitoring of goods from their source to end customer delivery. SCV emphasises data transparency and sharing among supply chain players like suppliers, manufacturers, distributors, and customers fostering collaboration and enhancing accuracy in demand forecasting, for inventory management and production planning efficiency (McIntire, 2014). Caridi et al. (2014) studied the advantages of supply chain visibility and created a model to assess its value. They applied this concept to an aerospace company as a case study and found the results effective. The researchers suggest extending the benefits of enhancing supply chain visibility in other business sectors.

Immunisation Supply Chain Visibility

The immunisation supply chain plays a role in health by ensuring the safe and reliable delivery of vaccines from production sites to end users. The design of this chain can significantly influence its efficiency and cost-effectiveness while employing a framework, like a supply chain system can enhance its ability to withstand risks and disruptions (Srinivasan, 2017). The need, for vaccine supply and logistic systems remains significant focusing on storage capacity, system efficiency and environmental impact. Achieving the goal of an immunisation supply chain requires ensuring visibility throughout the supply chain process. Information visibility is a factor in supply chain management. Studies by Caridi et al. (2010) have underscored how enhanced visibility can boost efficiency, and productivity and aid in planning efforts. Disparities in information access can give disadvantages to parties within the supply chain network, impacting operations and increasing vulnerability.

The Knowledge Gap

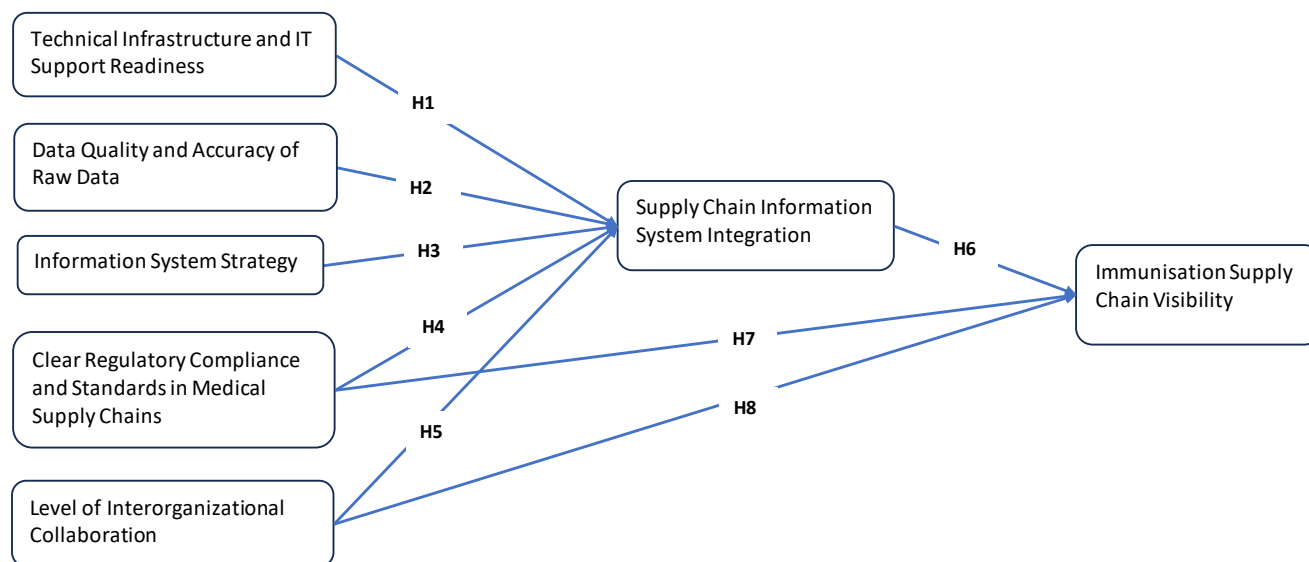
The literature review shows three domains of knowledge in this research – health management and immunisation, supply chain management (SCM), and information systems integration. First, the health management and immunisation domain, where the WHO and GAVI are the main players who drive initiatives and strategies, mainly focuses on the practice and management to deliver the immunisation product to individuals. It ensures that vaccination coverage is highest and equal. The second domain is SCM, in the context of immunisation, SCM involves the logistics challenges where the planning, control, and implementation of vaccination products from raw material procurement to a final delivery product to end-users and maintaining the quality of vaccines overall throughout the supply chain processes. Third, the information Systems Integration domain contains the technology deployment to support the sharing and exchanging the information across the supply chain process from the different components to track and monitor real-time data. This provides a solution to plan based on the information data. There is a gap in that recent studies have not integrated the three domains within the immunisation supply chain visibility. However, the role of information systems is critical for enhancing supply chain management and health management, particularly during the COVID-19 outbreak, when many countries especially developing countries such as Bangladesh, Thailand, and the Philippines encountered a lack of implementation of information systems integration to cope with this disease and to manage the vaccination program to comply with the new healthcare regulation and standards in medical supply chains (Rahman & Islam, 2024). Hence, this research will focus on the following factors - technical infrastructure and information technology (IT) support readiness, data quality and accuracy of raw data, information system strategy, clear regulatory compliance and standards in medical supply chains, and the level of interorganizational collaboration that can enhance the information systems integration and improve immunisation supply chain visibility.

The utilisation of two theoretical frameworks - Tornatzky and Fleischer's Technology-Organization-Environment (TOE) theory and the Relational View (RV) theory provides a solid theoretical framework for investigating the factors that influence information system integration. TOE theory highlights the significance of technical infrastructure and IT support readiness, data quality and accuracy of raw Data, and information system strategy (Chang et al., 2020). Data quality and accuracy are vital for the reliability of system integration and advocate decision-making. This is supported by Sharma et al. (2014) studies, yet there is a lack of comprehensive models that integrate data quality with performance outcomes. The strategic alignment of information systems is one of the TOE frameworks as noted by Qrunfleh and Tarafdar (2014) strategy of information systems (IS) enhances flexibility and performance. However, further study is essential for IS strategies which impact immunisation outcomes. Additionally, regulatory compliance and standards in medical supply chain factors are crucial for ensuring vaccine quality and safety (Martin, 2005). Still, more research is required to understand the dynamic of regulations and compliance that impact immunisation supply chain visibility. RV theory emphasises the importance of collaboration and relationships between organisations to achieve the organisation's goal (Ekanayake et al., 2017). Interorganizational collaboration increases information sharing and problem-solving (Williams, 1997), but further detailed research is needed to study collaboration mechanisms. Investigating all these variables in a conceptual model can provide insights for improving immunisation vaccine supply chain visibility.

CONCEPTUAL MODEL AND HYPOTHESES DEVELOPMENT

Conceptual Model

This study proposes a conceptual model with eight hypotheses as shown in figure 1.



Source: This study.

Figure 1: Conceptual Model.

Technical Infrastructure and IT Support Readiness

Technical infrastructure comprises a variety of hardware, software, networks, and services that aid IT operations by establishing a foundation, for system functionality, application execution and data management. The capacity and scalability of this infrastructure play roles in ensuring seamless system integration. Moreover, challenges arise during the integration phase due to the nature of infrastructures leading to compatibility issues stemming from differing data formats, communication protocols and software platforms. Overcoming these obstacles necessitates embracing industry standards and interoperable technologies to ensure system compatibility and consistency. This strategy simplifies integration processes as exemplified by used enterprise architecture frameworks like TOGAF and the Zachman Framework. Adequate preparation for IT support is essential for managing integrated systems from setup through maintenance to issue resolution. IT support teams need expertise in understanding system components and integration techniques (Cater-Steel, 2008). This knowledge is critical not during system integration but for ongoing maintenance to prevent downtime and uphold system reliability. Furthermore, robust incident management problem-solving skills and effective change management processes are indispensable for IT support readiness (Galup et al., 2009). In the field of healthcare, studies have demonstrated the need for IT systems to facilitate connectivity between health record systems across healthcare providers. This connectivity plays a role in enhancing care coordination. As a result, the hypothesis (H1) is formulated.

H1 - Technical Infrastructure and IT support Readiness positively affects Supply chain System Integration.

Data Quality and Accuracy of Raw Data

The significance of data quality and precision, in system integration is crucial on levels. Reliable and precise data play a role in ensuring the consistency and dependability of systems, which greatly impacts the quality of decision-making, particularly in

fields like operations research where data-based optimisation models are essential (Sharma et al., 2014). The integration process itself becomes more intricate and expensive when dealing with data standards and inaccuracies. Poor quality data could lead to inaccurate forecasts and subpar decisions. Inaccurate data not only increases costs by necessitating rework and additional checks but also brings about significant compliance and legal risks, especially in regulated industries highlighting the crucial role of precise data in risk management and regulatory compliance. The empirical evidence underscores the significance of data quality and accuracy, in system integration demonstrating real-world benefits and challenges across healthcare, retail, banking and manufacturing. In the field of healthcare, the adoption of electronic health records has led to enhancements in operational efficiency. This underscores the importance of maintaining high-quality data standards to ensure safety and lessen the workload on healthcare professionals (Menachemi & Collum, 2011). Therefore, the hypothesis (H2) is developed as follows.

H2 - Data Quality and Accuracy of Raw data have a positive effect on Supply chain System integration.

Information System Strategy

The relationship, between information system (IS) Strategy and system integration (SI) plays a role in the strategic capabilities of organisations. It involves an interconnection that enhances business strategies and goals by merging various computing systems. Recent progress in the strategic alignment model (SAM) emphasises the importance of aligning business and IS strategies to enhance performance and promote flexibility (Luftman et al. 1999). IS strategies focusing on adaptability and scalability have been proven to support SI processes enabling organisations to react to market changes and opportunities. Integrated systems supported by a defined IS strategy provide a perspective of organisational data, essential, for making informed strategic decisions (Pavlou & El Sawy 2006). Furthermore, an IS strategy that promotes innovation can steer system integration (SI) efforts towards embracing technologies and systems fostering an environment for ongoing enhancement and securing a competitive advantage. Therefore, the hypothesis (H3) is developed as follows.

H3 - Information System Strategy has a positive effect on Supply chain System integration.

Clear Regulatory Compliance and Standards in Medical Supply Chains

Regulatory compliance and adhering to standards in medical supply chains impact how systems are integrated. International standards play a crucial role in ensuring smooth interoperability and effective process management (Martin, 2005). However, differences in the scope of these standards can sometimes create challenges for integration. In software-driven systems, careful integration planning is essential with a focus on standardization activities as recommended by Stavridou (1997). Data and process standards coupled with shared architectures are vital for promoting information transparency within supply chains. Robertson et al. (2017) note the World Health Organization (WHO) as being influential in introducing cold chain equipment technologies standards into the market. However, Kartoglu and Ames (2022) said that the best regulatory oversight is mostly important in the public sector. Furthermore, Hazelton et al. (2002) investigate maintaining storage standards within the cold chain system and address challenges to improve. Therefore, the hypothesis H4 and H7 are developed as follows.

H4 - Clear Regulatory Compliance and Standards in Medical Supply Chains have a positive effect on Supply Chain System Integration.

H7 - Immunisation Supply Chain Visibility is positively influenced by Clear Regulatory Compliance and Standards in Medical Supply Chains.

Level of Interorganizational Collaboration

Interorganizational collaboration affects system integration by various factors. Chueh-An et al. (2022) stresses the importance of compromise and mutual adjustment to enhance organisational system integration. Williams (1997) emphasises the roles of trust and cooperation in the success of interorganizational information systems (IOS). The potential for conflicts within IOS is acknowledged, with suggested strategies for management presented by Kumar and Van Dissel (1996). Sharma and Kearins (2011) highlight the significance of collaboration in promoting sustainability and developing new products. The significant aspect of immunisation supply chain visibility also links to the level of interorganizational collaboration interactions, between organisations that play a role in shaping the visibility of immunisation supply chains, where sharing information is key. The coordination of private resources for vaccination by governments can be strengthened through information exchange and subsidies as suggested by Pan et al. (2023). Kaufmann et al. (2011) emphasised the importance of enhancing global vaccine supply chains through enhanced collaboration among organisations and better training for supply chain managers. Additionally, the technical and organisational environment surrounding immunisation reports the importance of improved interoperability. Therefore, the hypothesis H5 and H8 are developed as follows.

H5 - level of Interorganizational collaboration is a positive effect on Supply chain System integration.

H8 - Immunisation Supply Chain Visibility is positively influenced by Interorganizational collaboration.

Supply Chain Information System Integration

The process of linking systems within a supply chain to ensure coordination and collaboration among all involved parties is known as system integration (Yu Y. et al., 2021). Supply chain integration has become a distinguishing factor, for businesses in today's competitive market helping them improve customer satisfaction reduce costs and enhance overall efficiency. According to the study conducted by Yu Y. et al. (2021) achieving efficiency, agility and responsiveness is crucial for supply chain management (SCM). The importance of supply chain information system integration amongst different businesses was emphasised in Wang and Chan, (2010) studies on virtual organisations for supply chain integration with two case studies from textile and fashion companies. According to Wang et al., (2004) research, a company's increased size is associated with a

higher demand for information system integration to get operational visibility. Implementing system integration plays a role for companies striving for excellence, in their supply chains. There are advantages, to integrating supply chain systems, such as improved visibility, increased collaboration among stakeholders enhanced agility and flexibility and reduced lead times and inventory costs. This leads to the development of the hypothesis (H6).

H6 - Immunisation Supply Chain Visibility is positively influenced by Supply Chain Information System Integration.

The conceptual model identifies the key variables and the proposed hypothesis that these factors positively impact the supply chain system integration, which enhances immunisation supply chain visibility. The model draws on TOE and RV theoretical frameworks, highlighting the technology, organisation, and environment readiness and collaboration between organisations.

RESEARCH METHODOLOGY

This research will adopt a mixed methods strategy outlined by Denscombe (2008). Mixed methods aim to improve accuracy following principles while aiding in the development reducing bias and gaining comprehensive insights into phenomena.

Quantitative Research Design

The study will delve into existing literature to thoroughly examine the factors influencing immunisation supply chain visibility. A review of the literature has identified 31 indicator items that will be used to assess constructs as outlined in Table 1. The next step is the data collection from the questionnaire developed. The target demographic includes healthcare professionals such as healthcare logistics specialists, IT specialists in healthcare institutions, public health authorities, and pharmaceutical industry members, who will respond to the survey. Then, structural equation modelling (SEM) will be used to validate the relationship between independent and dependent variables. This advanced statistical method provides an understanding of how information system integration activity relates to immunisation supply chain visibility.

Table 1: The variable items and indicators

Variables	Definition	Indicators	References
Technical Infrastructure and IT Support Readiness (TSR)	The physical of hardware-based resources including software applications and the organisational capacity to provide technical support and maintenance for its information systems	TSR1-Availability of IT Resources TSR2-System Reliability TSR3-IT Support Efficiency TSR4-IT infrastructure's capacity for expanding	(Gunasekaran & Ngai, 2004)
Data Quality and Accuracy of Raw Data (DAR)	The collected and used data by the organisation are correct, reliable, and applicable to the purposes.	DAR1-Data Accuracy DAR2-Data Completeness DAR3-Timeliness of data update DAR4-Data Consistency	(Bosch-Capblanch et al., 2009; Ronveaux et al., 2005)
Information System Strategy (ISS)	The outlines plan how an organisation's information systems will support and align with its business strategies and objectives.	ISS1-Alignment with Supply Chain Goals ISS2-Investment in IT ISS3-Adoption of Advanced Technologies ISS4-Flexibility in Strategy for IT Investing	(Qrunfleh & Tarafdar, 2014; Deepu & Ravi, 2021)
Clear Regulatory Compliance and Standards in Medical Supply Chains (RCS)	The legal requirements, guidelines, and quality standards established by governmental and or international regulatory bodies, governing the development, production, delivery, storage, and management of vaccines.	RCS1-Compliance Rate RCS2-Audit Findings and issues RCS3-Training and Awareness RCS4-Efficiency of Systems for Monitoring Compliance RCS5-Flexibility in Response to Changing Standards and Regulations	(Anderson et al., 2014; Gardner et al., 2002)
Level of Interorganizational Collaboration (LIC)	The strategic alliance or partnership between two or more organisations that combine their resources, capabilities, and information to achieve common objectives.	LIC1-Collaborative Activities LIC2-Information Sharing LIC3-Collaborative Problem Solving LIC4-The scope of collaborative innovation	(Lee et al., 2014; Majchrzak et al., 2015)
Supply Chain Information System Integration (SSI)	The degree of different information systems, software applications, and digital tools are connected and operate as a whole immunisation supply chain process.	SSI1-Process Integration SSI2-Visibility to track information SSI3-Integrated Decision-Making SSI4- Information System Compatibility SSI5- Effectiveness of Data Exchange Systems	(Jiang et al., 2023; Yu Y. et al., 2021)
Immunisation Supply Chain Visibility (ISC)	The scope stakeholders can access real-time data and information on the movement, status, and condition of immunisation products from manufacturers to the point of administration.	ISC1-Inventory Accuracy ISC2-Order Tracking Capability ISC3-Demand Forecast Accuracy ISC4-Cold Chain Integrity ISC5- Supply Chain Visibility Integration from Start to Finish	(Hunaid et al., 2022; Kartoglu & Ames, 2022)

Source: This study

Qualitative Research Design

This study will conduct semi-structured interviews with key stakeholders in the immunisation supply chain to gain insights that quantitative data may not fully capture. The qualitative method will validate the variables used in the SEM analysis and provide a more contextualised understanding of the immunisation supply chain visibility challenges. The qualitative method in this phase is essential to gain deep insights into the immunisation supply chain visibility field, which is influenced by those factors. Conducting interviews will encourage the researcher to seek experiences, perceptions, and complex interactions within the supply chain that could not be found through quantitative methods. The advantages of the qualitative approach will improve comprehension of the quantitative findings. First, the SEM results highlight a crucial element for the immunisation supply chain visibility, and interviews can illustrate how those elements function in actual situations. Second, interviews can reveal aspects of supply chain management, such as company culture, that the quantitative method is unable to capture. Thirdly, by guaranteeing feedback from stakeholders' experiences in the field, interviews help validate the variables from the quantitative method - SEM.

EXPECTED CONTRIBUTIONS

Theoretical Contributions

The main goal of this study is to contribute knowledge in the field of information systems within the context of immunisation supply chains. This study aims to address a question identified in the literature on SCM and IT. Drawing from theories such as TOE theory and RV theory, this study explains how technological infrastructure organisational aspects and external factors impact supply chain visibility. Incorporating these theories in the context of immunisation supply chains will broaden the theoretical landscape of SCM and IT. This approach sheds light on how interorganizational collaboration contributes to enhancing efficiency and effectiveness within supply chains.

Managerial Contributions

From this research perspective, the research will provide insights that can be utilised by decision-makers, supply chain professionals and technology experts. By explaining how enhanced technical systems, data accuracy, compliance, regulations, and collaboration between organisations play a vital role, this study becomes a resource for improving vaccination product distribution networks. This could speed up the delivery process and increase vaccine availability, contributing to better global health logistics. The practical implications of this paper go beyond discussions in terms of supporting real changes that address the urgent needs of the international health community.

CONCLUSION

This research proposes a model of information system integration to overcome the challenge of immunisation supply chain visibility by examining a factor that will influence the effective delivery of immunisation products. This research aims to fill the gap by proposing a supply chain system integration framework to improve the visibility of the immunisation supply chain. This ongoing research is expected to advance our knowledge of supply chain information system integration and provide important insights from real-world stakeholders on the aspects of organisational and managerial practices.

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