STRENGTHENING THE DOWNSTREAM SUPPLY CHAIN MANAGEMENT FOR VACCINES IN THE PHILIPPINES: FOOD AND DRUG ADMINISTRATION PERSPECTIVE

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ABSTRACT

The case study examines the framework established by the Food and Drug Administration Philippines to facilitate the Vaccine Supply Chain in the Philippines. During the pandemic, the said regulatory body must ensure its efficiency and safety. AnyLogistix, a system software employed in Post Market Surveillance for vaccines in Norway, was discovered during the research process. This software has facilitated the efficient assessment and monitoring of vaccines in Norway. Consequently, this case study explores the potential benefits of implementing anyLogistix in the Philippines to enhance drug and vaccine cold chain management. The Grounded Theory was used to assess the readiness and acceptance of local companies and organizations responsible for managing cold chain facilities and vaccines in the Philippines to pave the way for future advancements in the field. Ultimately, the acceptability of the comparative study validates the approval of stakeholders, cold chain facilities, and government regulatory agencies in using anyLogistix as an automated system to efficiently monitor the post-market surveillance in the downstream stages of the supply chain for vaccines spearheaded by the Food and Drug Administration-Philippines. This study surveyed 14 expert panelists, both male and female, in which 8 out of 14 panelists expressed. Dissatisfaction with the current system of how the government responds to pandemic outbreaks, 10 out of 14 panelists were not familiar with anyLogistix, and 11 out of 14 panelists showed interest in using this Norwegian software to improve the efficiency in responding to vaccine supply management issues; therefore, anyLogistix could be a good development that the Food and Drug Administration could utilize.

Keywords: Supply Chain Management, Downstream, Vaccines, Policy shifts, Mixed Methods Research

INTRODUCTION

Strengthening the downstream supply chain of vaccines through post-market surveillance is a critical aspect of ensuring patient safety and maintaining the quality of vaccines (World Health Organization, 2020). In recent years, the importance of securing downstream supply chain management for vaccines has gained significant attention. The efficient and safe distribution of vaccines plays a crucial role in ensuring public health, especially in a country like the Philippines, with a large population and diverse

geographical challenges (Development Academy of the Philippines, 2021). With the ever-increasing demand for vaccines, it becomes imperative to strengthen regulatory frameworks and implement robust post-marketing surveillance activities to monitor the safety, quality, and efficacy of vaccines throughout the supply chain (Department of Health Philippines, 2021). Supply chains consist of all the steps involved in getting a product from the raw material into the hands of the customer. It normally begins with the vendors or suppliers, next to the manufacturer converting the raw materials to finished products for distribution. The final stage is distribution which involves multiple intermediaries, these could be distributors, importers, wholesalers, and retailers. Often, different stages within the supply chain are referred to as upstream or downstream. The study will focus on the downstream part of the supply chain which refers to the process of getting the finished products from the manufacturer to the end-user or customer (Administrator & Administrator, 2019). The Philippines has no manufacturer of vaccines, and instead, relies mostly on the importation of finished vaccine products. With imported vaccines, adherence to stringent regulatory requirements is of utmost importance. Close collaboration between the government agencies such as the Food and Drug Administration which is responsible for the issuance of specific authorization and registration of the imported vaccine in the Philippines, and the Bureau of Customs responsible for the issuance of clearance relative to the imported vaccines to ensure compliance with the customs laws and regulations. The Bureau of Customs supervises and controls the entrance and clearance of vessels and aircraft engaged in foreign commerce in the classroom. When students are motivated, then learning will easily take place. With this, teachers must recognize the diversity and complexity in the classroom, be it ethnicity, gender, culture, language abilities, and interests.

OBJECTIVES OF THE STUDY

The Food and Drug Administration (FDA) has implemented regulations on cold chain management for vaccines, but compliance monitoring remains a challenge. Specifically, it focuses on post-marketing surveillance activities, including pharmacovigilance, supply chain inspection, market surveillance and monitoring, rapid response and enforcement, communication, collaboration and information sharing, and lastly, education and training (Center for Disease Control and Prevention, 2023).

Whereas the specific objectives of the study are the following:

1. To assess the current state of the downstream supply chain management for vaccines in the Philippines in terms of pharmacovigilance, supply chain inspection, market surveillance and monitoring, rapid response, and enforcement, communication, collaboration, and information sharing, and lastly, education and training
2. Compare the effectiveness of existing FDA regulation in supply chain inspection for downstream and the new anyLogistix system through a survey among the local cold chain facilities, logistics, and companies.
3. Identify the key players or intermediaries in the vaccine supply chain, with regulatory compliance, implementation, and monitoring of the special storage condition requirements of the warehouse.

METHODOLOGY

Population and Sample. The study participants were 14 expert participants male and female Filipinos aged 15 years old to 64 years old who were working with logistics of vaccines, regulatory agencies, and healthcare providers at the time of the survey. The said age bracket was based on the PSA

Board Resolution No 01, Series of 2017 - 99 age range (Philippine Statistics Authority, 2016). The sample size was determined based on the study conducted by Alam et al.,(2021). The online survey was conducted between June 19 to July 3, for a total of 14 days.

Sampling Technique. Participants had the choice of answering either an English or a Filipino version of the online survey using Google Forms. Most questions were provided with a drop-down menu of a nominal scale (YES OR NO) for a timely selection of appropriate answers. For answers not included in the choices, an open option was available. The credibility of the survey form was determined based on the insights from published COVID-19 vaccine studies focusing on knowledge, attitude, and practice (Sun et al.,2021, Ivanov and Dolgui,(2021), Choi E. M. (2021) &Alam et al.,2021). The survey proper had two sections: (1) information about the participants and (2) questions regarding the participant's awareness of Vaccine Post Market Surveillance and the anyLogistix system. Research Instrument

Data Analysis. Descriptive data were sorted and analyzed using Google Sheets. As for the quantitative data, the study utilized a Simple Comparative Experimental Design (Table 1). The two independent variables were FDA Standard Operating Procedures and FDA Standard Operating Procedures with the utilization of anyLogistix, which were the two different supply chain management parameters that will be compared through a pie graph and the acceptance will be based on the majority of votes per question with a standard of 54% or higher of the total population and will be interpreted using Grounded Theory approach (Koleva, 2023).

RESULTS AND DISCUSSION

1. Current state of the downstream supply chain management for vaccines in the Philippines

The majority of institutions and specialists, 9 out of 14 panelists, are aware of the Philippine Standard procedure in Supply Chain Management for vaccines. This can be attributed to the protocols and regulations set by the Food and Drug Administration, which require companies, manufacturers, and cold chain facilities to be familiar with the requirements and procedures for Post Marketing Surveillance of Vaccines. Furthermore, many companies and experts, 8 out of 14 panelists, expressed dissatisfaction with the Philippine Standard procedure in Supply Chain Management for vaccines. This may be influenced by the accumulation of COVID-19 cases in the Philippines and other vaccine controversies.

Regarding familiarity with anyLogistix, the majority of panelists, 10 out of 14, were not knowledgeable about the system, indicating that it is still relatively new in the field. However, 11 out of 14 panelists expressed interest in using the system once it is accredited and approved by the Food and Drug Administration for its efficiency.

One panelist raised concerns that anyLogistix may not be suitable for their specific system and could be costly. However, a Norwegian study conducted by Dr. Sun disproved this notion by demonstrating that the effectiveness of a cold chain vaccine logistics system is influenced by various factors, such as fleet size, composition, vehicle types, and route optimization. Therefore, when designing an efficient vaccine allocation system, it is crucial to consider all these factors.

2. Risk and Challenges in Post-Market Surveillance in the Philippines

The Philippines encounters barriers in vaccine manufacturing due to limited funding and lower priority. In contrast, higher-income countries have the means to secure vaccines through bilateral agreements with private manufacturers. Addressing

these disparities requires collaborative efforts and financial support to ensure equitable access to vaccines for all countries, regardless of their economic status. Also, the lack of updated post-market surveillance in vaccine cold chain management in the Philippines has resulted in confusion and non-compliance among manufacturers, importers, and companies involved in the vaccine supply chain. The absence of timely surveillance updates can lead to variations in the vaccine database, making it difficult to maintain accurate and consistent information across different communities. Post-market surveillance plays a crucial role in monitoring the safety, efficacy, and quality of vaccines after they have been approved and released into the market. It involves the continuous collection, analysis, and reporting of data on adverse events and other factors related to vaccine performance.

However, if updates to the surveillance system are not implemented promptly, it can create discrepancies and inconsistencies in the vaccine database. Secondly, non-compliance with updated surveillance requirements can result in violations by manufacturers, importers, and companies, compromising the overall integrity of the vaccine supply chain. Thirdly, variations in the vaccine database can impact the accuracy of immunization records and the ability to track vaccine distribution and utilization effectively. To address these challenges, the Philippines must prioritize and implement regular updates to the post-market surveillance system for vaccine cold chain management. This includes ensuring that manufacturers, importers, and companies are aware of and comply with the latest surveillance requirements.

Additionally, clear communication channels and guidelines should be established to promote consistency and accuracy in the vaccine database across different communities. By strengthening post-market surveillance and ensuring regular updates, the Philippines can enhance the efficiency and effectiveness of vaccine cold chain management, leading to improved public health outcomes and better protection for communities. Thus, the establishment of a comprehensive and accessible database or online portal is imperative to support effective post-market surveillance efforts. This enables real-time monitoring and response to emerging safety issues, aligning with the evolving landscape of public health and regulatory requirements.

3. Assessing the risks and challenges within the downstream supply chain management of vaccines in the Philippines Lack of Philippine-based Vaccine Manufacturers

According to Roldan-Gan et al., (2022), the Philippines, being classified as a middle to low-income country, faces significant challenges in vaccine manufacturing due to limited funding and lower priority given by the government. Unlike higher-income countries like the United States and the United Kingdom, which have the financial means to enter into bilateral agreements with private vaccine manufacturers, the Philippines encounters difficulties in accessing vaccines promptly when the need arises. The financial constraints in a middle to low-income country like the Philippines can pose obstacles to establishing local vaccine manufacturing facilities. Vaccine production requires substantial investments in research and development, infrastructure, technology, and quality control measures. Limited funding and competing priorities within the government's budget allocation can make it challenging to allocate sufficient resources to develop and maintain vaccine manufacturing capabilities.

In contrast, higher-income countries have more significant financial resources and can engage in direct negotiations and agreements with private vaccine manufacturers. This enables them to secure

vaccine supplies in a timelier manner, even during times of high demand or global supply shortages. These countries have the financial capacity to invest in advanced purchasing agreements and stockpile vaccines for future use, enhancing their ability to respond effectively to public health crises(Choi, 2021).

4. Pending Post-Market Surveillance Updates

Based on the FDA Circular 2020-003 (Food and Drug Administration, 2021), certain requirements should be adopted by organizations, companies, and cold chain facilities to have a properly conducive post-market surveillance plan. To ensure the ongoing monitoring of the safety and effectiveness of drug products, the issuance of Administrative Order No. 2011-0009 established the National Policy and Program on Pharmacovigilance.

Following this, guidelines about pharmacovigilance were subsequently released, including FDA Circular No. 2013-003: Post Market Surveillance and Periodic Safety Update Report, FDA Circular No. 2013-004: Post Market Surveillance of Authorized Drug Products, and FDA Circular No.2018-012: Rescinding FDA Circular No. 2013-004 and Instituting Post-Marketing Surveillance (PMS) Requirements for New Drugs under Monitored Release.

However, the said circular was still pending in the case of the Food and Drug Administration for almost five years therefore the said protocols were considered a challenge for both parties on how they would continue the vaccine system.

Robust Database for Faster Information Flow

The creation of a strong database or an online portal is essential in both the public and private sectors (Alomar et al.,2020), in addition to the limitations imposed by rules and regulations in response to the advent of new viruses and illnesses (Madhav et al., 2017). According to the National Academies Press (US), 2007: "Such a database or portal plays a vital role in ensuring that information can be quickly and timely disseminated, aligning post-market surveillance activities with a real-time basis." Stakeholders who are involved can effectively collect and evaluate data on adverse events, product safety, and other pertinent elements relating to vaccine and medicine products by creating a consolidated, easily available database or online portal. This makes it possible to quickly identify and evaluate any potential dangers or issues related to these products.

A strong database or online portal also makes it easier for regulatory agencies, healthcare providers, and manufacturers—all parties involved in post-market surveillance—to communicate and coordinate with one another. Such a system's ability to operate in real time makes it possible to respond quickly to new safety issues or unfavorable circumstances. This can involve sending out safety alerts, carrying out recall procedures, or when needed changing product labels and instructions (Alomar et al.,2020).

Using a systematic database anyLogistix, this software solution enables companies to design, optimize, and analyze their supply chain operations using advanced analytics. By integrating analytical optimization techniques with simulation technologies, anyLogistix offers a comprehensive suite of tools for end-to-end supply chain analysis. This software provides the flexibility to leverage both simulation and optimization methods, ensuring that users are not limited by modeling capabilities when addressing supply chain challenges. By utilizing anyLogistix, companies can gain deeper insights into their supply chain, going beyond what traditional solutions can offer (anyLogistix, n.d.). Therefore, this could be a potential strategy and recommendation for strengthening the downstream supply chain management of vaccines in the Philippines. Considering the findings from the research, 10 out of 14 stakeholders would like to use this system, thus,

anyLogistix may be launched for accreditation and bidding.

CONCLUSION

The global impact of different viruses has generated vast harm to healthcare systems, economies, and people's well-being. In response, administrations have enforced infection control standards such as lockdowns, travel restrictions, and online education. These measures have significantly disrupted people's lifestyles and posed challenges to logistics systems and global supply chains. To regain normalcy, mass vaccination has been recognized as a crucial strategy.

However, the distribution of vaccines presents a complex problem due to factors like imported supplies, strict temperature requirements, policy changes, and the associated costs of facilities and transportation. Therefore, effective and timely transportation planning is essential. This article suggests the use of anyLogistix, a modern cold chain logistics system, for efficient vaccine allocation in the Philippines. The database considers various fleet designs and aims to support decision-makers, particularly the Food and Drug Administration, in their transportation planning efforts for nationwide vaccine distribution. By leveraging anyLogistix, valuable insights can be gained to optimize the allocation of resources and ensure timely and reliable transportation of vaccines.

In summary, this paper highlights the importance of efficient Post Market Surveillance downstream and proposes the use of anyLogistix as a modern cold chain logistics system to aid decision-makers in the transportation planning process. By utilizing this system, decision-makers, particularly the Food and Drug Administration, can enhance their efforts in ensuring timely and reliable vaccine distribution, contributing to the restoration of normal life, mitigating the impacts of global health crises, and enhancing FDA's services and establishing partnerships with other companies and communities, thereby contributing to the promotion of Sustainable Development Goal 17 (SDG 17) - Partnerships for the Goals. This study holds significant implications for the health and wellness of Filipinos.

RECOMMENDATIONS

Throughout the research it was evident that the downstream supply chain for vaccines in the Philippines faces significant challenges, hence, to ensure and maintain the efficiency and safety of the vaccines to be administered to the intended individual the following recommendations were identified:

1. To enhance regulatory oversight by strengthening the post-market surveillance activities of the Food and Drug Administration Philippines.

2. To simplify and streamline documentation processes related to vaccine distribution, storage, and administration through digitizing records and implementing a centralized information system that allows real-time tracking and tracing of vaccine shipments, inventory management, and adverse event reporting.

3. To improve Cold Chain Infrastructure by investing and improving the cold chain infrastructure enables to maintaining the temperature integrity of vaccines throughout the supply chain. This includes upgrading storage facilities, refrigeration equipment, and transportation systems to meet the specific requirements of different vaccine types.

4. To continuously educate the stakeholders dealing in the vaccine supply chain through regular conduct of a comprehensive training program including FDA staff, healthcare workers, logistics personnel, and distributors. The training with emphasis on proper

handling, storage, and transportation procedures, vaccine supply as well as emergency response protocols.

5. To consider anyLogistix as a reliable and efficient system software for post-market surveillance of vaccines, showcasing its benefits, capabilities, and potential to enhance the monitoring and assessment of vaccine safety and efficacy.

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