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Research Article

Revolution of Medical Device Distribution Structure by Expanding UDI Code: A Case Study of Edwards Lifesciences in South Korea

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Abstract: The South Korean medical device market is rapidly growing, necessitating a more efficient and reliable system for managing the supply and distribution of medical devices. (1) Background/Purpose: The current 'Medical Device Supply Reporting' system, which utilizes the Unique Device Identifier (UDI) code, provides a foundation for tracking medical device supplies but remains limited in scope, covering only certain classes of medical devices. Hospitals, Group Purchasing Organizations (GPOs), and government agencies operate in silos without effective communication, forcing suppliers to adapt to each system separately and imposing substantial manpower burdens. This study aims to analyze the current distribution structure, evaluate the effectiveness of the existing UDI system, and propose a comprehensive framework for expanding and optimizing the UDI code system to revolutionize medical device distribution in South Korea. (2) Study Design/Methodology/Approach: The study employs a combination of qualitative and quantitative methods, including literature review, case analysis of Edwards Lifesciences Korea using ERP system data and customer service interview insights, comparison against international UDI standards (U.S. FDA, EU MDR/IVDR), and stakeholder analysis. (3) Findings: Based on four years of order data (2020–2023), approximately 38% of consignment replenishment orders were received through cold calling and 47% via GPO-operated sites, with CSRs required to manually monitor 71 separate GPO sites daily. The UDI supply reporting system has increased administrative workload without addressing root-cause inefficiencies in the distribution structure. (4) Originality/Value: This paper strongly proposes the introduction of an Electronic Data Interchange (EDI) system integrated with UDI codes to create an automated, unified solution that maximizes supply chain efficiency, enhances medical device management reliability, and ultimately improves patient safety.

Keywords: UDI code; medical device distribution; Electronic Data Interchange (EDI); South Korea; supply chain management; consignment inventory management; Group Purchasing Organization (GPO); patient safety; Medical Device Act

1. Introduction

1.1. Background of the Study

In order to modernize the distribution of pharmaceuticals and reduce distribution costs, South Korea introduced the pharmaceutical barcode labeling system in 2000. This system aimed to efficiently manage distribution history by establishing a foundation for the informatization of pharmaceutical distribution. However, six years after the system's implementation, a sample survey conducted by the Ministry of Health and Welfare and the

Korea Health Industry Development Institute in 2006 revealed that approximately 19.5% of barcodes had labeling errors, indicating that the system had not been properly established and operated.

As a result, the informatization of ordering, delivery, inventory management, and stock management of pharmaceuticals was not activated, posing obstacles to the operation of large pharmaceutical logistics centers equipped with modern logistics management systems. To promote the use of barcodes, the government introduced the Korea Drug Code (KD Code), an international standard for pharmaceutical barcodes, which has been in effect since January 15, 2008. As of the end of March 2008, the Health Insurance Review and Assessment Service (HIRA) announced 98,175 standard codes for 42,210 pharmaceutical items from 394 manufacturers and importers, and continues to assign standard codes based on the submission of product information by companies.

The pharmaceutical standard code is assigned to all pharmaceuticals distributed in South Korea by item and packaging unit, and is used for pharmaceutical supply reporting and barcode labeling. It is also systematized to be used as an EDI code for managing pharmaceutical benefits in health insurance, thereby informatizing the entire pharmaceutical distribution process. (Source: Kim Bo-yeon, Director of the Pharmaceutical Management Information Center, Health Insurance Review and Assessment Service, Policy and Issues)

The Unique Device Identifier (UDI) is a standardized code displayed on the packaging or container of medical devices to systematically and efficiently manage and identify them. With the development of advanced medical technologies, including AI, and the increasing demand for medical devices due to an aging population, the need for efficient management of medical devices has become more critical. Medical devices are produced, distributed, and supplied to an unspecified number of people, and their long durability necessitates tracking their distribution and supply information even after sale. Until recently, the lack of mandatory UDI labeling made it challenging to quickly identify recall targets, distribution volumes, supply quantities, and similar cases from other companies when adverse effects or issues arose from the use of medical devices.

At a time when a standardized code-based medical device safety management and distribution system is needed to manage the entire lifecycle of medical devices from production to distribution, supply, and use, the United States introduced the UDI system in 2013. Internationally, there is a trend towards integrating information at each stage of the medical device lifecycle based on standardized codes. The U.S. FDA announced UDI regulations on September 24, 2013, aiming to integrate UDI into the entire healthcare system, including electronic health information, medical device distribution, patient registry research, and electronic health records (EHR), establishing it as a national standard identification method for medical devices. Europe announced the MDR/IVD regulations in 2016 and revised the Medical Device Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR) in 2017 to include UDI regulations, setting guidelines for the rapid identification and tracking of medical devices in case of issues.

Existing studies have argued that national-level leadership is needed for the introduction of the UDI system and that a state-led data integration system should be established (Jacobson, 2018; Da Silva & Figueira, 2015; Drozda Jr., 2018; Tcheng, 2014; Sorenson & Drummond, 2014). Furthermore, the need for international institutional coordination, evolution, and data standardization was also suggested (Tcheng, 2014; Jiang, 2019; Sorenson & Drummond, 2014). Through this, existing studies have emphasized that the UDI system has been effective in inventory management of medical devices in medical device companies or hospitals, and has improved patient safety by enabling tracking of adverse reactions in patients (Drozda Jr., 2016; Muhlestein et al., 2020). In order to further improve the effectiveness of the UDI system, it is said that medical device suppliers, distributors, medical institutions, and insurance companies should create an agreed model and evolve based on it (Karas, 2016; Tcheng, 2014; Da Silva & Figueira, 2015).

South Korea also established legal grounds in the Medical Device Act in 2016 to systematically manage and identify medical devices by labeling standardized codes on the packaging or container of medical devices. The mandatory labeling of standardized codes on medical device packaging is being implemented in phases from July 2019 to July 2022, starting with Class IV devices and progressing to Class I devices. The mandatory reporting of medical device supply details is also being phased in from July 1, 2020, for Class IV devices to July 1, 2023, for Class I devices. Additionally, an integrated information system for medical devices has been established to register and manage standardized codes, product information, and manufacturer and importer

information. Through this system, the government and medical device manufacturers and importers can manage safety by reporting adverse events, tracking and recalling hazardous medical devices, and ensuring that users have accurate information about the products they use. (Source: Kang Min-ho, Shin Kwang-soo, Yeon Ju-han, Innovations in Regulations and Safety Management in the Medical Device Industry)

The 9-digit EDI code is currently used only as an insurance benefit code for medical devices, and the integrated information system using UDI codes is limited to medical device supply reporting. This study aims to first examine the theoretical background and domestic and international operational status of the medical device standard code system, investigate and analyze the issues faced by South Korean medical device suppliers, and propose a new solution based on UDI codes for the distribution and industry of medical devices.

1.2. Problem Statement

The distribution of medical devices in South Korea faces significant challenges due to the lack of a fully integrated and standardized identification system. Despite the introduction of the Unique Device Identifier (UDI) system in 2016, its implementation has been limited, resulting in inefficiencies in traceability, safety, and regulatory compliance. The current use of the 9-digit EDI code is restricted to insurance benefit coding, and the integrated information system using UDI codes is confined to medical device supply reporting.

With top-tier major hospitals in South Korea, there are separate logistics systems for each hospital, GPO company, and the government's medical device management system. These systems exist in silos without communication, and hospital logistics systems, in particular, oppose external information sharing. Consequently, customer service teams and departments handling customer interactions at medical device suppliers must access and process information from the government, hospitals, and GPO companies' systems separately.

Additionally, hospitals still place replenishment orders for consignment inventory by phone immediately after surgeries. These orders are often made through cold calling, where the supplier is contacted unexpectedly, often without prior notice or a clear intention to purchase, leading to inefficiencies.

The significance of this problem is underscored by the growing demand for medical devices driven by advancements in medical technology and an aging population. Efficient management of medical devices is critical to ensuring their safe and timely delivery to healthcare providers and patients. However, the existing system's limitations prevent the full realization of these benefits, necessitating a comprehensive solution.

1.3. Objectives

The primary objective of this study is to revolutionize the distribution structure of medical devices in South Korea by expanding and optimizing the implementation of the Unique Device Identifier (UDI) code system. This study aims to achieve the following specific goals:

1. Analyzing the current distribution structure of medical devices in South Korea. This involves identifying key challenges and inefficiencies within the existing system, such as the fragmented logistics systems of hospitals, consignment companies, and government agencies, which operate in silos without effective communication. The study will highlight how these inefficiencies hinder order management, recall identification, distribution tracking, and supply management.
2. Evaluating the effectiveness of the current UDI code system in South Korea. This objective focuses on assessing the impact of the UDI system on traceability, safety, and regulatory compliance. The study will identify both the strengths and limitations of the current UDI implementation, including the restricted use of the 9-digit EDI code for insurance benefit coding and the limited scope of the integrated information system for medical device supply reporting.
3. Investigating the benefits and limitations of the UDI code system by comparing it with international standards and practices. By benchmarking against the UDI systems implemented in the United States and Europe, the study will extract best practices and lessons that can be applied to the South Korean context. This comparison will provide valuable insights into how South Korea can enhance its UDI system by learning from the experiences of other countries.

4. Proposing a comprehensive framework for expanding and optimizing the UDI code system in South Korea. This involves developing strategies for effective implementation and integration into the existing healthcare infrastructure. The proposed framework will outline the steps needed to expand the UDI system, ensuring that it addresses the identified challenges and leverages best practices from international standards.
5. Assessing the potential impact of the expanded UDI code system on various stakeholders. This objective focuses on evaluating how the expanded UDI system will affect manufacturers, distributors, healthcare providers, and patients. By considering the perspectives and needs of different stakeholders, the study aims to ensure a comprehensive approach to improving the medical device distribution process.
6. Developing strategic recommendations for policymakers, manufacturers, and healthcare providers. The study will formulate actionable insights to effectively implement and optimize the expanded UDI code system. These recommendations will aim to enhance distribution efficiency, reduce costs, and improve patient safety, providing a clear roadmap for stakeholders to follow.

1.4. Significance of the Study

The significance of this study lies in its potential to revolutionize the distribution structure of medical devices in South Korea by expanding and optimizing the implementation of the Unique Device Identifier (UDI) code system. The current fragmented approach to medical device distribution poses significant challenges, including inefficiencies in order management, recall identification, distribution tracking, and supply management. These issues not only increase distribution costs but also pose risks to patient safety and add to the workload and stress of customer service teams at medical device suppliers.

By conducting a comprehensive analysis of the existing distribution structure and evaluating the effectiveness of the current UDI system, this study aims to identify key challenges and areas for improvement. Benchmarking against international standards and practices will provide valuable insights into best practices that can be applied to the South Korean context. The proposed framework for expanding the UDI system will offer strategic recommendations for effective implementation and integration into the existing healthcare infrastructure.

The practical implications of this study are significant. An optimized UDI system will enhance traceability, safety, and regulatory compliance, leading to more efficient and effective management of medical devices. This will benefit manufacturers, distributors, healthcare providers, and patients by ensuring the safe and timely delivery of medical devices. Additionally, the study's findings will provide actionable insights for policymakers, helping to shape regulations and policies that support the advancement of medical device distribution.

Ultimately, this study has the potential to contribute to broader goals of improving public health and patient safety, reducing healthcare costs, and fostering technological innovation in the medical device industry. By addressing the identified gaps and challenges, this study will pave the way for a more efficient and effective medical device distribution system in South Korea.

1.5. Scope

This study focuses on revolutionizing the distribution structure of medical devices in South Korea by expanding and optimizing the implementation of the Unique Device Identifier (UDI) code system. The scope of the study includes the following:

- **Geographical Area:** The study is limited to South Korea, with a specific focus on top-tier hospitals, GPO companies, and government agencies involved in medical device distribution.
- **Time Frame:** The study will cover the period from the introduction of the UDI system in 2016 to the present, with an emphasis on recent developments and current practices.
- **Population:** The study will involve key stakeholders in the medical device distribution process, including manufacturers, distributors, healthcare providers, and regulatory bodies.
- **Methodologies:** The study will employ a combination of qualitative and quantitative methods, including literature review, case studies, surveys, and interviews with industry experts and stakeholders.

- **Aspects Covered:** The study will analyze the current distribution structure, evaluate the effectiveness of the UDI system, compare international standards, propose a framework for UDI expansion, assess stakeholder impact, and develop strategic recommendations.

2. Literature Review and Environment Analysis

2.1. Introduction to UDI

The Unique Device Identification (UDI) system is a standardized coding system designed to systematically and efficiently manage and identify medical devices. The UDI code is displayed on the packaging or container of medical devices and is essential for tracking the distribution and supply of these devices. The implementation of the UDI code is becoming increasingly important due to the advancement of medical technology and the growing demand for medical devices in an aging population.

The UDI system mainly consists of two key components:

- **Device Identifier (DI):** A fixed part that identifies a specific medical device model.
- **Production Identifier (PI):** A variable part that includes information such as the manufacturing date, serial number, batch number, and expiration date.

These components are displayed in barcode form on the packaging or label of medical devices, making it easier to track and manage the devices.

2.2. Benefits of UDI Implementation

The implementation of the UDI system has had a notable impact on the medical device industry in South Korea:

- **Enhanced Traceability:** The UDI system has improved the ability to track medical devices throughout their lifecycle, from manufacturing to patient use. This has enhanced the ability to quickly identify and recall defective devices, reducing the risk of patient harm.
- **Improved Safety Management:** By providing a standardized method for identifying medical devices, the UDI system has enhanced the accuracy of adverse event reporting and facilitated better post-market surveillance. The survey results indicated that 64% of companies reported improvements in the efficiency of their distribution management.
- **Efficient Inventory Management:** The UDI system has helped healthcare providers and distributors manage their inventory more efficiently, reducing waste and ensuring that devices are available when needed.

2.3. Prior Research

The Unique Device Identification (UDI) system has been widely studied and implemented across various countries to enhance the traceability, safety, and management of medical devices. This section reviews key studies, regulations, and case studies that have contributed to the development and implementation of the UDI system.

The Mercy Unique Device Identifier Demonstration Project

Drozda Jr. et al. (2016) conducted a significant study titled “The Mercy unique device identifier demonstration Project: implementing point of use product identification in the cardiac catheterization laboratories of regional health system.” This project demonstrated the practical application of UDI codes in a clinical setting, specifically in cardiac catheterization laboratories. The study highlighted the benefits of UDI implementation, including improved inventory management, enhanced patient safety, and better tracking of device usage and outcomes.

European Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR)

The European Commission (2017) introduced the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) to establish a robust regulatory framework for medical devices in Europe. These regulations mandate the use of UDI codes to ensure the traceability and safety of medical devices. The

MDR/IVDR regulations have set a high standard for the identification and tracking of medical devices, contributing to improved patient safety and transparency in the medical device supply chain.

South Korean Medical Device Act

The Ministry of Food and Drug Safety (MFDS) in South Korea implemented the Medical Device Act in 2019, which mandates the registration of UDI codes and integrated information. This law aims to enhance the safety and transparency of medical device management by requiring all medical device manufacturers and suppliers to register UDI codes. The phased implementation of this act has laid the foundation for a more efficient and reliable system for managing medical devices in South Korea.

The Portuguese Experience with UDI

Da Silva and Figueira (2015) explored the impact of the UDI system in Portugal in their study "Unique Device Identifier System: The Impact Of The Portuguese Experience." The study found that the integration of UDI codes with the national health system's electronic records significantly improved the management of medical devices. The UDI system enabled better tracking of device usage and outcomes, leading to enhanced patient safety and more efficient inventory management.

Australian Unique Device Identification (UDI) System

The Therapeutic Goods Administration (TGA) in Australia adopted the UDI system in 2020 to improve the traceability and safety of medical devices. The integration of UDI codes with the national health information system facilitated better monitoring of device performance and adverse events. This regulatory approach has contributed to improved patient outcomes and more efficient management of medical devices in Australia.

Summary of International UDI Implementations

- **United States:** The U.S. FDA's UDI regulations have been instrumental in improving the traceability and management of medical devices. The integration of UDI codes with electronic health records (EHR) has facilitated better tracking of device performance and patient outcomes. For example, the Mercy Health System implemented UDI codes in their cardiac catheterization laboratories, which significantly improved inventory management and patient safety by enabling precise tracking of devices used in procedures.
- **Europe:** The MDR/IVD regulations in Europe have set a high standard for the identification and tracking of medical devices. The use of UDI codes has enhanced the transparency and efficiency of the medical device supply chain, contributing to improved patient safety. The European Union's EUDAMED database integrates UDI codes to provide comprehensive information on medical devices, including their distribution and usage, which helps in monitoring and managing device-related incidents.
- **South Korea:** The phased implementation of UDI codes in South Korea, starting with Class IV devices and progressing to Class I devices, has laid the foundation for a more efficient and reliable system for managing medical devices. The introduction of UDI codes has improved the ability to quickly identify and recall defective devices, reducing the risk of patient harm.
- **Portugal:** The Portuguese experience with the UDI system has shown significant improvements in the management of medical devices. The integration of UDI codes with the national health system's electronic records has enabled better tracking of device usage and outcomes. This has led to enhanced patient safety and more efficient inventory management.
- **Australia:** In Australia, the Therapeutic Goods Administration (TGA) has adopted UDI regulations to improve the traceability and safety of medical devices. The integration of UDI codes with the national health information system has facilitated better monitoring of device performance and adverse events, contributing to improved patient outcomes.

3. Case Study of Edwards Lifesciences

3.1. Case Analysis of Edwards Lifesciences

Company Overview

Edwards Lifesciences is a leading global medical technology company specializing in innovative solutions for structural heart disease and critical care monitoring. Founded in 1958 by engineer Miles "Lowell" Edwards, the company is headquartered in Irvine, California. Edwards Lifesciences is renowned for developing the SAPIEN transcatheter aortic heart valve, a groundbreaking technology that allows for minimally invasive heart valve replacement.

The company's product portfolio includes surgical valve technologies, transcatheter heart valves, transcatheter mitral and tricuspid therapies, and critical care technologies. Edwards Lifesciences is dedicated to improving patient outcomes through advanced medical technologies, world-class clinical evidence, and strong partnerships with healthcare professionals. With a mission to enhance the quality of life for patients worldwide, Edwards Lifesciences continues to innovate and lead in the field of cardiovascular care. The company operates globally, with manufacturing facilities and offices in multiple countries, and remains committed to delivering life-changing medical solutions.

This case analysis utilizes data from Edwards Lifesciences ERP system, contents from its customer service (CS) interviews and voices of its Regulatory Affairs (RA) team. Edwards Lifesciences Korea has a customer service (CS) team with two customer service representatives (CSRs) handling Class 3 and Class 4 medical devices. The company operates under two business models: the Direct business model and the Indirect business model.

- **Direct Business Model:** In this model, Edwards Lifesciences directly delivers consignment inventory to each hospital, with billing provided to the Group Purchasing Organization (GPO).
- **Indirect Business Model:** In this model, delivery is made to a distributor instead of directly to the hospital, with billing provided to the distributor.

This case analysis focuses solely on the Direct business model for Class 4 medical devices. Orders from the Transcatheter Aortic Valve Replacement (TAVR) business unit were excluded from this study, as TAVR orders are processed through the Salesforce (SFDC) system, with sales representatives directly entering orders into SFDC. Therefore, TAVR was considered out of scope for this topic, even though it involves Class 4 devices and the Direct business model.

Stakeholders

- **Group Purchasing Organization (GPO):** An entity that helps healthcare providers, such as hospitals and clinics, to achieve cost savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors, and other vendors. GPOs negotiate contracts for a wide range of products and services, including medical devices, pharmaceuticals, and office supplies.
- **Healthcare Professional (HCP):** Refers to any individual who provides health care treatment and advice based on formal training and experience. This includes a wide range of professionals such as doctors, nurses, pharmacists, dentists, and other allied health professionals. HCPs are responsible for diagnosing, treating, and managing patient care, and they often work in various healthcare settings, including hospitals, clinics, and private practices (including Physicians, Nurses and Allied Health Professionals).
- **Ministry of Food and Drug Safety (MFDS):** Formerly known as the Korea Food & Drug Administration (KFDA), is a government agency in South Korea responsible for promoting public health by ensuring the safety and effectiveness of foods, pharmaceuticals, medical devices, and cosmetics. The MFDS oversees the regulation, approval, and monitoring of these products to protect consumers and support the food and pharmaceutical industries.

UDI System of Edwards Lifesciences

Impact of the UDI Supply Reporting System

In July 2019, the Korea Food and Drug Administration (KFDA) conducted a policy briefing aimed at introducing the new supply reporting requirements to medical device suppliers. This initiative, however, highlighted a significant gap in the detailed analysis of the medical device market and the realities faced by

suppliers, leading to criticism regarding the unilateral approach of the KFDA in policy implementation.

The initial briefing session was followed by a question-and-answer segment, which was quickly overwhelmed by numerous inquiries, causing a temporary disruption. Subsequently, the session was restructured to allow individual interactions where officials addressed specific queries from attendees. The majority of these attendees were small to medium-sized importers and distributors who supply directly to hospitals.

The primary concerns raised during the session included:

- The appropriate level of packaging for the application of the UDI DI barcode.
- The criteria for defining the extent of supply.
- The rationale behind requesting the supply price.

As a Supply Chain Management (SCM) manager, a question was posed to the policy chairperson: "According to the policy, we are to report using the UDI DI code based on the product's distribution flow. If the final billing entity is a Group Purchasing Organization (GPO), should medical device suppliers consider their supply complete upon reaching the GPO?" Unfortunately, an immediate response was not provided. At that time, the KFDA was unable to involve the GPO in the policy, so they announced an alternative at the next policy briefing, creating a feature called 'different supplier' that made medical device suppliers take on the GPO's tasks. This was inefficient and increased the workload for suppliers, and it was implemented in 2020.

Figure 1. *Supply Reporting Flow Chart from MFDS website.*

With the implementation of supply reporting through the KFDA portal site, the RA completed the registration of UDI codes for Class 3 and 4 on the site. The SCM manager had to register all hospitals, distributors, and consignment companies that Edwards Korea was dealing with at the time in the master system. From the company's perspective, the management targets included the hospital logistics system, the GPO logistics system, and the medical device supply reporting portal added to the ERP. Particularly, since the GPO could not be made a reporting target by the KFDA, the SCM manager had to access the logistics systems of over 41 GPOs and perform additional tasks of entering UDI information into the material codes for each hospital in those logistics systems.

There are two methods for reporting to the medical device supply reporting portal: accessing the portal and scanning each item individually at the time of shipment, or using an Excel file created by the portal for bulk uploads. Initially, the policy suggested reporting via barcode scanning at the time of shipment, but it was impossible to proceed with bulk shipments while entering all the necessary information one by one on the portal. Other companies also raised objections, leading to the addition of the bulk upload method using Excel. However, the code system used by the portal was not unified with the company's ERP, resulting in the initial reporting taking 8 hours of resource.

Reducing Reporting Time for Medical Device Supply

To reduce the time required for reporting medical device supply, a master file was created to quickly prepare the Excel file format specified by the portal site. This master file integrated the company's ERP codes with the portal site codes and supplier information. Additionally, the necessary report formats were developed through BI report development. Consequently, the time required to complete the final stage of medical device supply reporting was reduced to a maximum of approximately 2 hours, depending on proficiency. In summary, the key points are:

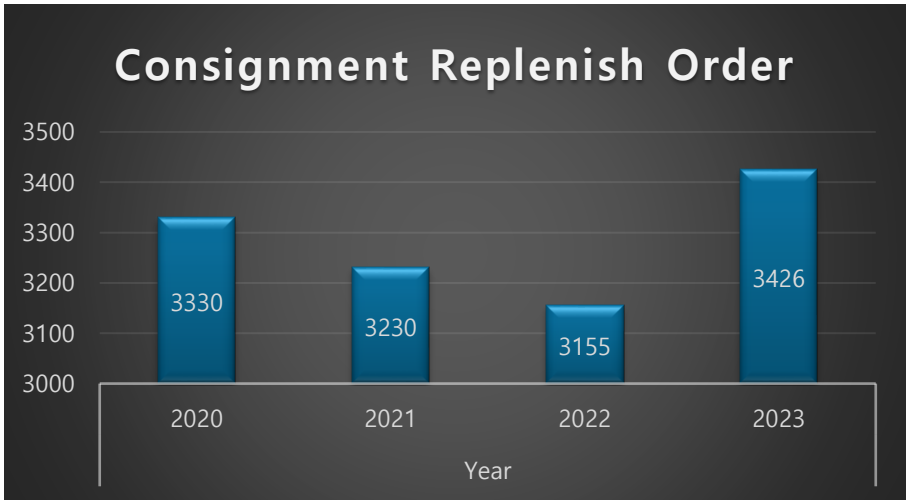
- Creation of a master file integrating the medical device supply reporting codes with the company's ERP.
- Development of BI reports to output data in the format required by the portal's Excel file.

These efforts are generally similar across medical device suppliers, though they may vary depending on the environment. However, these methods cannot be considered fundamental solutions. The primary purpose of implementing medical device supply reporting is to manage the entire lifecycle of medical devices and to track and manage the final usage information for patient safety. Yet, the reporting still only covers the supply up to the hospital. In other words, it has become another reporting system that fails to perform its core function, merely imposing a resource impact on the suppliers.

Pain Point in the Ordering Process

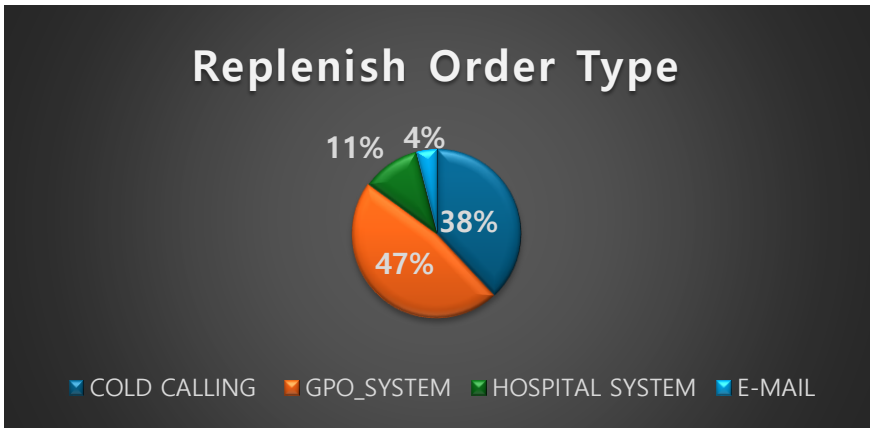
From 2020 to 2023, Edwards Lifesciences CSRs processed a total of 13,141 consignment replenishment orders, averaging 3,285 orders annually. Despite the decline in 2021 and 2022 due to the impact of COVID-19 on thoracic surgery, this is a significant number of orders. In 2023, the situation returned to normal.

Figure 2. *EW Consignment Replenish Order per year (2020–2023).*



An analysis of the accumulated order data from Edwards Lifesciences over the past four years reveals that approximately 38% of orders were received through cold calling, 47% from sites operated by GPOs, 4% via email, and the remaining 11% through separate logistics systems directly managed by hospitals. Based on this data, it can be inferred that small and medium-sized suppliers providing Class IV medical devices through the Direct business model face significant challenges due to the lack of a unified order reception method. In the case of large companies, firms that have contracts with these large companies provide Direct business services on their behalf.

Figure 3. *EW Replenish Order Type distribution.*



38% of orders are received through cold calling and another 47% involve Customer Service Representatives (CSRs) checking the day-to-day usage of consignment inventory on separate sites operated by GPOs and entering replenishment orders. Another issue is the frequent emergence of new GPOs and the frequent changes in GPOs for each hospital. Based on Edwards' data, these changes occur approximately every two years. 19 GPOs are listed in Table 1 below. However, each GPO has a different site per hospital, and there are 71 sites that must be checked on a daily basis.

Table 1.. GPO List and Corresponding Weight in Edwards Lifesciences Korea Order Volume.

GPO	Weight
E* Medi*om	12%
B*S Partner	8%
A*ison C*re	6%
C*re C*mp	5%
O*ERA *ALU	5%
Sm*rt-m**re	3%
He*lth *sse	1%
JE**G-J*N	1%
E**th A	1%
Da**	1%
W**HUSM*DI	1%
R*no M*dic	1%
Sh**s*ng P**rm	1%
T*t*l Medi**l	1%
J**l I*ves	0.4%
In**	0.3%
Vi**on Medi**l	0.1%
V*lue*ro	0.1%
Jise***	0.0%

This analysis of the order data revealed the following distribution of order reception methods:

- **38%**of orders were received through cold calling.
- **47%**were received from sites operated by Group Purchasing Organizations (GPOs).
- **4%**were received via email.
- **11%**were received through separate logistics systems directly managed by hospitals.

This data indicates significant challenges for small and medium-sized suppliers providing Class IV medical devices through the Direct business model due to the lack of a unified order reception method. Large companies often have contracts with other firms to provide Direct business services on their behalf.

Additional issues include:

- Frequent emergence of new GPOs and changes in GPOs for each hospital, occurring approximately every two years.

- The need for CSRs to check the day-to-day usage of consignment inventory on separate sites operated by GPOs and enter replenishment orders.

These challenges highlight the inefficiencies and resource burdens faced by suppliers due to the fragmented and manual order reception processes.

3.2. Summary and Implications

The government's medical device supply reporting through the UDI code has failed to meet its initial purpose and has only resulted in adding workload to the relevant companies and stakeholders. Despite investing significant resources and costs to establish this integrated information system, the government has not provided the necessary solutions to improve the medical device distribution structure. If the current structure continues to maintain silos without integration points between the operating systems of hospitals, GPOs, and suppliers, it is impossible for suppliers and the market to accept the UDI code and achieve a revolution in the distribution structure.

4. Conclusions

4.1. Summary and Conclusion

The current implementation of the Unique Device Identifier (UDI) code system in South Korea has brought significant improvements in the traceability and management of medical devices. However, several limitations hinder its full potential. Based on the analysis of the current UDI code systems, the following key conclusions can be drawn:

- **Enhanced Traceability:** The UDI system has improved the ability to track medical devices throughout their lifecycle, from manufacturing to patient use. This has enhanced the ability to quickly identify and recall defective devices, reducing the risk of patient harm. However, the system's effectiveness is limited by its partial implementation, which excludes certain classes of medical devices from mandatory reporting.
- **Improved Safety Management:** By providing a standardized method for identifying medical devices, the UDI system has enhanced the accuracy of adverse event reporting and facilitated better post-market surveillance. Despite these improvements, the current system's limited scope and fragmented implementation reduce its overall effectiveness in ensuring comprehensive safety management.
- **Operational Inefficiencies:** The current UDI system faces operational inefficiencies due to non-integrated operating systems among hospitals, suppliers, and government agencies. This fragmentation leads to redundant data entry, increased administrative burden, and potential errors. The lack of a unified system for order management and reporting further exacerbates these inefficiencies.
- **Limited Scope and Coverage:** The phased implementation of the UDI system has left some classes of medical devices exempt from mandatory reporting. This limited scope reduces the overall effectiveness of the system in ensuring comprehensive traceability and safety management. The exclusion of certain devices from the UDI requirements creates gaps in the tracking and management of medical devices.

4.2. Implications

- **Patient Safety and Public Health:** While the UDI system has improved traceability, the gaps in coverage and operational inefficiencies pose risks to patient safety and public health. Comprehensive traceability and quick recall capabilities are essential for mitigating risks and ensuring safe device usage. The current system's limitations may delay the identification and recall of defective devices, potentially compromising patient safety.
- **Operational Burden:** The fragmentation and lack of integration among different stakeholders' systems increase the administrative burden on manufacturers, suppliers, and healthcare providers. This inefficiency can lead to higher operational costs and reduced focus on core activities. The need for manual data entry and reconciliation across multiple systems consumes valuable resources and time.

- **Market Competitiveness:** The limited scope and regulatory misalignment of the current UDI system can hinder the competitiveness of the South Korean medical device market. Aligning with international standards and expanding the system's coverage are crucial for enhancing market access and fostering innovation. The current system's limitations may deter foreign investment and collaboration, affecting the market's growth and development.
- **Need for Integration:** The current system's limitations highlight the need for a more integrated and automated solution. Integrating the UDI system with an Electronic Data Interchange (EDI) system can address these inefficiencies and improve overall supply chain management. A unified system can streamline processes, reduce errors, and enhance data accuracy and accessibility.

4.3. Strategic Suggestions

To address the limitations of the current UDI code system and achieve its full potential, the following strategic suggestions are strongly proposed:

- **Implementing an Integrated EDI System:** To address the inefficiencies caused by non-integrated operating systems, it is critical to implement an integrated EDI system that connects manufacturers, suppliers, GPOs, hospitals, and government agencies. This system should automate the exchange of business documents such as purchase orders, invoices, and shipping information, reducing manual errors and increasing data accuracy. The implementation process should involve a phased approach, starting with a pilot program to test the system's functionality and identify any potential issues. Training programs for all stakeholders should be conducted to ensure smooth adoption and effective use of the EDI system. Additionally, continuous monitoring and evaluation should be carried out to assess the system's performance and make necessary adjustments.
- **Aligning with International Standards:** Adopting best practices from international standards such as the U.S. FDA's UDI regulations and Europe's MDR/IVDR regulations will ensure regulatory compliance and enhance the competitiveness of the South Korean medical device market. This alignment will facilitate global market access and collaboration. By harmonizing the UDI system with international standards, South Korea can attract foreign investment and foster international partnerships.
- **Enhancing Data Integration and Reporting:** Linking the UDI system with an integrated EDI system will automate the process of registering UDI codes and reporting integrated information. A centralized data repository should be established to facilitate data sharing and access among stakeholders. Advanced analytics and reporting tools can be integrated into the system to provide real-time insights and support decision-making. Additionally, data security measures should be implemented to protect sensitive information and prevent unauthorized access. Enhanced data integration will improve the accuracy and reliability of information, supporting better decision-making and regulatory compliance.
- **Streamlining Order Reception Methods:** Standardizing and centralizing the order reception process through the EDI system will reduce reliance on manual and error-prone methods such as phone calls and emails. Stakeholders should collaborate to develop standardized order templates and workflows that can be easily integrated into the EDI system. Training and support should be provided to ensure that all users are familiar with the new processes and can effectively utilize the system. Regular feedback and performance reviews should be conducted to identify areas for improvement and optimize the order reception process. Streamlined order management will enhance efficiency, reduce errors, and improve overall supply chain performance.

4.4. Limitations

Despite the significant findings and strategic suggestions presented in this study, several limitations must be acknowledged. First, the availability and quality of data on medical device distribution and UDI implementation may vary, potentially affecting the accuracy and completeness of the analysis. Second, the willingness and availability of stakeholders to participate in surveys and interviews may impact the depth and breadth of insights gathered. Third, the findings and recommendations of this study are specific to the South Korean context and may not be directly applicable to other countries with different regulatory environments and healthcare systems.

Finally, the study's reliance on qualitative methods, such as case studies and interviews, may introduce subjective biases. Efforts were made to triangulate findings with quantitative data to enhance validity.

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