

Article Evaluating the Performance of a Safe Insulin Supply Chain Using the AHP-TOPSIS Approach

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Abstract: People with type 1 diabetes require insulin, a lifesaving and essential medication, to maintain their blood sugar levels below dangerous levels. Unfortunately, the insulin industry faces supply and affordability issues, and patients and their families face an enormous burden. As a result of high prices and lack of availability, individuals are turning to other options for purchasing insulin, such as online pharmacies, which may or may not be legitimate. Despite the necessity of safe insulin for diabetics in the legitimate Pharmaceutical Supply Chain (PSC), few researchers have considered implementing strategies to maximize patient safety for purchasing insulin. Therefore, the current research seeks to bridge this gap and provide cohesive information on overcoming this challenge and maximizing insulin safety. This study employs a Multi-Criteria Decision-Making (MCDM) model that combines Supply Chain Operations Reference (SCOR) metrics, Analytic Hierarchy Process (AHP), and Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS) to develop a model that can prioritize and select the best criteria for maximizing insulin safety and achieving the study objective. A comparison of two insulin supply chain scenarios was performed. As a result of this research, adding a traceability technology to the insulin supply chain, specifically blockchain (T42) in scenario 2 provides the best results to the supply chain for maximizing and ensuring the safety of insulin, as compared to scenario 1, where the final score achieved almost 71%. This research provides a useful tool for assessing the safety of other critical goods that customers value in strategic and complex decision-making. Academics, professionals, and decision-makers can benefit from this research using a rigorous scientific decision-support system.

Keywords: pharmaceutical supply chain; insulin safety; drug counterfeit; traceability technology

1. Introduction

Pharmaceutical counterfeiting has been detected since about 1990 and has become a serious issue in developed and developing countries [1]. The World Health Organization (WHO) defines counterfeit medications as those which are "intentionally and fraudulently mislabeled with respect to identification and/or source" [2]. Counterfeit products, in general, generate problems for numerous manufacturing industries and pose severe issues to the Pharmaceutical Supply Chain (PSC) if drugs fall under fake products. Both branded and generic drugs can be counterfeited, and counterfeit drugs can include those formulated with the right ingredients, have incorrect ingredients, formulated without active ingredients, formulated insufficiently, or packaged in fake packaging [3]. Therefore, counterfeiting drugs endanger the public's health, causes potential customers to lose faith in the medications' brands, and have a detrimental influence on pharmaceutical companies' legality, and profitability suffers as a result [4].

According to some estimates, one of every 10 drugs available on legal markets, particularly in middle- to low-income or developing nations, is fake. Despite the lack of accurate data, it is estimated that not less than 10% of pharmaceuticals are falsified each year, 50% of which are purchased online due to weak regulatory systems [5]. Antibiotics and diabetes



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Copyright: © 2022 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https:// creativecommons.org/licenses/by/ 4.0/). medications, for example, are frequently counterfeited pharmaceuticals [3]. The most important reasons for counterfeited insulin are the lack of availability and affordability of insulin among different segments of patients. A lack of insulin has been identified as a major problem in the legitimate PSC. Konrad [6] reported counterfeit insulin as a main public health concern that needs more attention in the coming years.

Background

Banting and Best's discovery of insulin at the University of Toronto (ON, Canada) in 1921 changed type 1 diabetes from a life-threatening to a manageable chronic condition. Canadian Leonard Thompson was the first patient to receive insulin for type 1 diabetes treatment in 1922 [7]. Insulin is a chemical substance delivered by the pancreas and is important for people with chronic diseases, such as pancreatic insufficiency and diabetes [8]. Its main function is to regulate the amount of glucose and fat in the blood according to the body's reasonable reserves. Moreover, it helps regulate the digestion of sugar and fat. The body cannot process these components properly when insulin is lacking, leading to worse glucose control, impaired vision, liver and kidney failure, and even death.

The demand for insulin is rising due to the number of diabetics in various countries, as diabetes is becoming more common worldwide, with an estimated 1 billion individuals affected [9]. It is estimated that one out of two people do not have access to insulin. According to estimates, one-fourth of the 7 million Americans who use insulin have difficulty paying for the medication. They have reported injecting expired insulin and using insulin less frequently than prescribed to cope, which resulted in worse glucose control, hospitalization for diabetic ketoacidosis, and death in many cases [10]. Although efforts are being made to slow down the growth of diabetes, the continuous supply and transportation of safe insulin under optimal conditions are essential for the well-being of patients with diabetes, which is a progressive disease [11].

Figure 1 illustrates that there were 537 million diabetics in the world in 2021, projected to increase to 643 and 783 million by 2030 and 2045, respectively [12]. Increasing numbers of diabetic patients correspond to the increasing demand for insulin. However, according to BBC [13], pharmaceutical companies cannot fulfil patients' demands due to supply level issues. The same article mentions that the availability and supply of insulin have been very low in Sri Lanka, Pakistan, Nepal, Malawi, Brazil, and Bangladesh due to inefficient distribution channels and poor management.

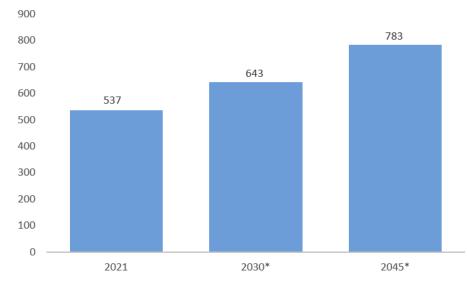


Figure 1. Estimated number of diabetics worldwide in 2021, 2030, and 2045 (in millions). (*) Forecasts. Source: Statista [12].

According to Vanhee et al. [14], insulin demand is crucially increasing, which has led to finding alternative ways to meet it illegally, such as having counterfeit insulin obtained

from illegal markets. Other reasons for counterfeiting insulin are the increasing number of diabetic patients in an uncontrollable manner, which has resulted in a lower supply and higher demand, as well as the growth in the market revenue for insulin in the last few years, which has incentivized counterfeiters seeking illegal profits. As illustrated in Figure 2, data from Statista [15] show that revenue from the human insulin market grew from 2015 to 2021. In turn, higher market revenue attracts fraudulent groups to counterfeit insulin to yield higher profits.

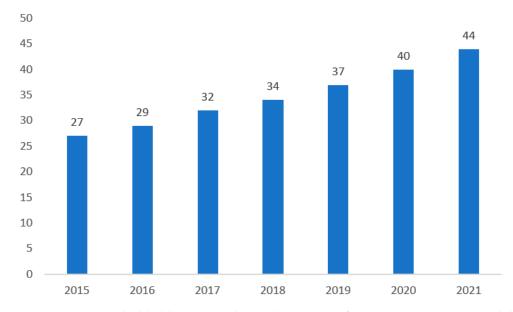


Figure 2. Estimated global human insulin market revenue from 2015 to 2021 (in USD billion). Source: Statista [15].

Considering the evidence above, the conclusion can be reached that the high cost of insulin, the high market revenue, scarcity, and the inability to align the supply with patient demand have contributed to its lack of availability and thereby increased the probability of counterfeiting insulin to meet patient demands. Despite the necessity of safe insulin for diabetics in the legitimate PSC, few researchers have investigated this subject. The majority of authors, such as Chow et al. [9] and Luo et al. [10], were concerned and discussed the importance of the availability and affordability of insulin for diabetes across high-income, middle-income, and low-income countries. In their study, Beran et al. [7] discussed the complex challenges of access to insulin and the need for a wide range of solutions to make sure all individuals living with diabetes can benefit from insulin and innovations in diabetes care. Another study by Beran et al. [8] examined the value, affordability, and availability of insulin for diabetes treatments and concluded that, when purchased appropriately, diabetes medications can be made affordable for many individuals and systems by reducing costs. Considering time restrictions, operational warehousing, and transportation costs, Jacobo-Cabrera et al. [11] proposed a model for creating a more efficient insulin distribution.

On the other hand, Vanhee et al. [14] proposed a model in their study that could identify and quantify the method currently used by their official medicines control laboratory to analyze insulins retrieved from the illegal market. They demonstrated that the combined label-free full scan approach could achieve more than distinguish between the different versions of insulin and the insulins originating from different species and could chromatographically separate human insulin and insulin lispro in conditions compatible with Mass Spectrometry (MS). Therefore, the authors of the current research have identified a gap in the literature in this regard; namely, there are no studies that provide cohesive information and data on how to overcome the concerns and challenges that exist in the insulin supply chain to ensure its safety. Therefore, the aim and objectives of this study are to identify and evaluate the key performance indicators and develop a model capable of selecting the best criteria that maximize the safety of the insulin supply chain and eliminate counterfeits. Different tools, including Supply Chain Operations Reference (SCOR) metrics, Analytic Hierarchy Process (AHP) model, Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS), and ranking and comparing the two scenarios were used to select the best traceability technology.

The steps that will help in achieving the aim of this study include the following:

- Identifying the significance and issues related to insulin in the PSC;
- Identifying the criteria that will be used to measure the performance of the insulin supply chain to maximize its safety; and
- Assessing the priorities and importance of each criterion to maximize safety.

2. Literature Review

In this section, we overview insulin as a crucial medication used for people with type 1 diabetes and explore the common issues affecting the PSC and public health at large. A description of the Supply Chain Operation Reference (SCOR) metric used for the performance measures of insulin follows, along with the selection of the specific criteria from the literature.

2.1. Significance of Insulin as a Medication

Insulin is a hormone produced by the pancreas responsible for regulating blood sugar levels in the body. Diabetes occurs when the body produces insufficient insulin or cannot appropriately utilize insulin. There are two types of diabetes: Type 1 and type 2. Type 1 diabetes is an autoimmune response where the body's immune system mistakenly attacks the pancreatic cells that produce insulin. Type 2 diabetes is the most common type and is caused by a combination of factors, including genetics, lifestyle, and obesity [16].

Diabetes is a progressive disease growing rapidly; therefore, the need for insulin products is also growing. People with diabetes need insulin injections to regulate their blood sugar levels. Various insulin products are available, each with its strengths and weaknesses, but insulin's supply chain is rife with problems. Since insulin prices are expected to rise, new players are entering the marketplace [17]. Therefore, the effective management of the insulin supply chain is a pressing concern for pharmaceutical companies to sustain their business operations at the same expected level. Successful companies will offer high-quality products and manage the insulin supply chains effectively.

2.2. Common Issues of Insulin in the PSC

A Sustainable Development Goal (SDG) for guaranteeing healthy lifestyles and improving individual well-being includes increasing access to genuine pharmaceuticals. According to estimates, most of the world's population does not have guaranteed access to the authorized medicines they require [18]. There has been notable success in improving access to medicines, such as vaccinations, antiretroviral medicines, contraceptives, and malaria and tuberculosis medicines. On the other hand, access to treatments for non-communicable diseases, such as diabetes continues to be a major issue [19].

Despite being discovered 100 years ago, insulin is not widely available, and one in two people worldwide does not have access [20]. As noted by Greene and Riggs [21], access to insulin has substantial limitations and is difficult to obtain by a large segment of patients. High efficiency and effectiveness are important aspects when dealing with insulin in the PSCs. Numerous factors affect accessibility to insulin in supply chains, including high prices, issues in manufacturing, delays in distribution, lack of patents for insulin, process complexity of the insulin, and the dominance of three big companies that manufacture insulin in this field: Eli Lilly, Novo Nordisk, and Sanofi. These companies compete for a share of the USD 24 billion global insulin market [22]. The key to success in this market is to have a strong product portfolio, well-developed sales history, and a strong marketing strategy. In addition, this demand provides opportunities for new insulin manufacturers to prosper and flourish. Figure 3 illustrates the complexity of the insulin supply chain in

real life. In this case study, we focused on sketching the process map of an insulin drug and how that drug is managed by Distributor X. In the same market, this distributor has several authorized pharmacies. The insulin needs are calculated based on the feedback they receive from their retailers from 6 months to 1 year.

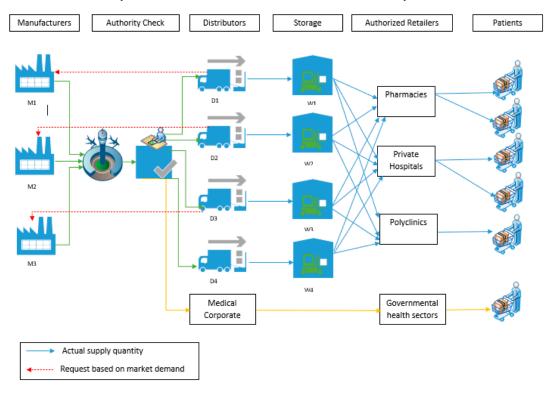


Figure 3. Insulin supply chain complexity in real life.

As with any drug supply chain, the insulin supply chain generally starts with raw materials suppliers, manufacturers, packagers, distributors, wholesalers, authorized retailers (hospitals and pharmacists), and end-users. The WHO reports that one main barrier to easy access to insulin is the monopoly of producers on the insulin market [23]. As a result, patients may miss doses, use fewer doses than prescribed, or look for alternative unknown and cheaper sources that supply insulin for survival to save money for running their domestic affairs, despite the danger of counterfeit insulin. These cheap sources are readily available and are often deadly or, in worse cases, impose negative impacts on the health of individuals. The non-availability of insulin can also result in a loss of profit for healthcare providers, as they must purchase insulin at higher prices to meet their patients' needs.

Detecting counterfeit medications merely by examining their labels, packaging, and country of origin has always been challenging. Indeed, technology has made it possible to produce counterfeit packaging and labels that are difficult to detect. One study stated that almost 1 million counterfeit glucose test strips were sold in the United States in 2006 [24], and real cases of patients who use counterfeit are counted in the millions in the United States alone [25].

There are two types of insulin that diabetics can take: Analogue and human insulins. Analogue insulin is more modern and engineered to mimic the body's insulin, while human insulin has been used for many years and is extracted from cows and pigs. Analogue insulin is more expensive than human insulin. There are a few reasons for the increased cost of analogue insulin. One reason is that Sanofi, the producer of Lantus (analogue insulin), has a virtual monopoly on the market. This virtual monopoly indicates that Sanofi can set the price for Lantus at any point it desires. Additionally, Sanofi has been able to delay generic competition for Lantus using multiple patents, allowing Sanofi to maintain high profits on this product [26].

Another reason for the high cost of analogue insulin is the complexity of the manufacturing process. These insulins are made in Escherichia coli bacteria, Saccharomyces cerevisiae (baker's yeast), or a hybrid of the two methods. Each organism requires different conditions for optimal growth, and Bioreactors are used to provide these specific conditions. The organisms must be checked for quality and purity before the insulin is extracted [7]. The entire process is expensive and time-consuming. The high cost of analogue insulin has caused some people to switch to human insulin. This type of insulin is significantly less expensive and is available in generic form. However, human insulin is not as effective as analogue insulin and can be more difficult to dose correctly. Some people with diabetes may also experience more severe side effects with human insulin.

2.3. SCOR for Performance Measures

The evaluation and measurement of a supply chain are essential to identify problems and improve business performance. The SCOR tool allows firms to conduct an in-depth fact-based analysis of all aspects of their supply chain by providing a complete set of process details, performance metrics, and industry best practices [27]. The SCOR framework is an ideal method to identify performance measures and can be used to determine a product's performance for an organization. These identified attributes (main criteria) allow companies to have a systematic approach to describe, analyze, and improve the performance of their complex supply in a simple and easy-to-apply manner.

Theodore Pittiglio, Robert Rabin, Robert Todd, and Michael McGrath proposed SCOR in 1996 [28,29], which is one of the most popular methods used by numerous companies to evaluate their efficiency and effectiveness. A SCOR model is implied to integrate business process re-engineering, benchmarking, and procedure measurement into a cross-functional framework. Using the framework of SCOR, firms can assess the maturity and level of advancement of their supply chain processes. Additionally, SCOR helps align results with business objectives [30].

Supply Chain Management (SCM) is a complex process and can be quite challenging to implement in complex fields, such as PSCs for selecting the appropriate performance attributes and criteria. When SCOR captures an effective management procedure, it can be used effectively to attain a competitive edge and be tailored and aligned to the specific objective [31]. Implementing SCOR frameworks allows procedures to be standardized and outcomes to be measured and tracked.

Different studies have been conducted on measuring the performance of the supply chain using the SCOR model. Ikasari et al. [32] used the SCOR model to evaluate the effectiveness and performance of the supply chain at the UNS Lithium Battery Factory. Based on the monitoring system of the performance indicators, reliability and cost performance were classified as good, whereas responsiveness, agility, and asset management efficiency were classified as average. This has led to the identification of improvement areas for the organization. Several other researchers have suggested using the SCOR model to evaluate supply chain performance and supplier selection [33–35]. The results show that the SCOR model can be effectively used to evaluate a supply chain's effectiveness and efficiency and identify the appropriate suppliers for various supply chain businesses, and improvement areas can also be identified. Wibowo and Sholeh [36] implied that the SCOR model could be used to define and evaluate the performance of the supply chain in construction.

Ayyildiz and Taskin Gumu [37] stated that the SCOR model includes five main performance attributes in two categories: Customer-facing metrics that include reliability, responsiveness, and flexibility, and internal-facing attributes that include cost and assets, as shown in Table 1. Moreover, the authors explained that these attributes could be modified based on the problem and proposed solution. The same authors extended the SCOR with new metrics related to Industry 4.0 and digitalization to understand and evaluate the performance measures of supply chains.

Model	Section	Performance Attributes	Definition
		Reliability	Efficiency of the process. Distributing supplies to the right clients at the right time, place, and quantity, and with the expected packaging and quality.
	Customer	Responsiveness	The speed at which tasks are accomplished. Providing products to customers as quickly as possible.
SCOR performance attributes		Flexibility	A flexible approach to change ensures that a supply chain remains competitive by responding to market changes.
	Internal	Cost	Expenses associated with the supply chain operations. Controlling and reducing all costs of the supply chain processes.
		Assets	Utilizing assets efficiently. Managing and optimizing assets to meet demand.

Table 1. SCOR performance attributes (main criteria) [37].

Bukhori et al. [38] used SCOR to evaluate the performance measures of a slaughterhouse's chicken supply chain, which selected the four more suitable attributes for their studies: Reliability, responsiveness, flexibility, and cost.

Based on Pundarika [39], this current study addresses only reliability, responsiveness, and flexibility as the main criteria of the SCOR model, the three more customer-centric attributes. In addition, these attributes are closely related to the scope of the issue of insulin availability and enhancing its safety, which we are addressing. Therefore, to ensure that the insulin supply chain is as safe as possible, we focused solely on the three customer-facing criteria of SCOR. The first part of the study evaluated these attributes using a normal scenario of an insulin supply chain, highlighted in red; the second scenario was highlighted in green. Figure 4 depicts the main criteria that will be measured to ensure a safe supply of insulin in the PSCs.

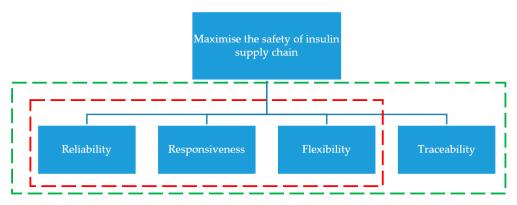


Figure 4. Selected SCOR performance attributes.

The following detail explains each attribute (main criteria and sub-criteria) from the literature and its importance in achieving the goal of maximizing insulin in the supply chain. Below, we discuss each criterion selected from the relevant literature.

2.3.1. Reliability

"Reliability" refers to the supply chain's capacity to deliver the correct product to the right client at the right time, in the appropriate form and package, in the right quantity, and with the right papers. In the SCOR model, reliability is integral and primarily used to determine a product's credibility in the marketplace. In addition, it directly influences the volume of sales and the frequency with which customers use a specific product [40].

Counterfeit insulin can be prevented by focusing on reliability with its sub-criteria and using the key determinants to ensure the product's dependability. The reliability attribute will automatically enhance and maximize insulin safety in authentic supply chains. Numerous studies have shown that reliability is critical when dealing with customers as end-users, often leading to a greater sense of trust. The need for reliability is also a major concern for customers [41].

Reliability consists of four sub-criteria or level 2 key performance indicators (KPIs). The first is "Maximize timely delivery," related to the least lead time the supply chain requires to deliver the product to customers [42]. The second is "Maximize quantity delivery," which refers to the maximum number of products that can be delivered to the end customer [43]. The third is "Maximize accuracy of documentation," which is also important for the supply chain authenticity and the products. Any difference between the document and real physical goods may cause harm to the end-user of the product, especially when dealing with pharmaceuticals [44]. The fourth is "Maximizing quality," which refers to the accuracy of the subsequent qualities of the product: Flawless orders. This can be expressed as the ratio of the number of orders received without damage against the total number of orders processed in a given period [45].

2.3.2. Responsiveness

"Responsiveness" can be defined as the speed at which customer services are provided. Similarly, responsiveness is a key factor in ensuring the timely availability of insulin and its safety. Ntabe et al. [46] suggested that the supply chain's responsiveness could be improved by minimizing order fulfilment cycle times, maximizing supplier cooperation, shortening delivery lead times, and reducing the time it takes to resolve complaints. Therefore, this ensures that the required drugs are easily accessible and available on the market promptly.

"Minimize time for order fulfilment cycle" evaluates the time it takes for a customer to receive a product or service after placing an order [47]. The second is "maximizing supplier assistance rate," which can be achieved by implementing consistent communication channels, assisting them with clarifications, and responding to their queries as quickly as possible. Any productive relationship relies on effective communication, which is even more important when dealing with suppliers [48]. Staying connected with suppliers and building good relationships will enable a company to build strong partnerships with different suppliers and companies to receive continuous feedback, thus improving the company's processes, including lead times. In addition, implementing technological solutions can also achieve transparency with suppliers.

The third is "Minimizing delivery lead time," which includes a process used to prepare, produce, and deliver the vehicles efficiently. Several ways are used to reduce delivery lead times, which according to Hall et al. [49], is particularly important in the pharmaceutical industry. Reduced delivery lead times are essential for safe insulin to be available in PSCs. In this situation, insulin must always be available when demand is high. The availability of insulin will reduce the need to seek out other unknown sources, thereby increasing its safety. Castle et al. [50] stated that many companies prefer to source their products from domestic suppliers, reducing lead time. As the frequency of orders increases, the lead time will decrease by 2 weeks or more and help manage lead times more effectively. Moreover, proper inventory management reduces lead time, allowing pharmaceutical companies to manage their inventory more efficiently. Forecasting insulin sales is important to the inventory and warehouse manager as it reduces lead time and enables Total Quality Management (TQM) and Kaizen methods to be implemented efficiently [51].

2.3.3. Flexibility

Flexibility refers to the ability to adapt to market changes to remain competitive. Bauer and Gobl [52] suggested that one essential metric for a secure supply chain is flexibility, which helps maximize a supply chain's safety and ensure that products are accessible to consumers on time. Furthermore, a study by Sellitto et al. [53] indicated that flexibility is guaranteed through volume change flexibility, item change flexibility, and custom order flexibility. These products will be readily available and accessible on the market at all times; therefore, insulin will be readily available when needed.

On this basis, there are three level 2 KPIs that determine flexibility. "Volume change flexibility" refers to the ability to alter production volume. Therefore, when the amount of demand changes, a provider's ability to meet the demand also changes [54]. "Item change flexibility" refers to a manufacturing system's ability to adapt to changes in product variety in order that the supply chain system is more efficient [27]. "Custom order flexibility" refers to the ability to commission, customize, personalize, or manufacture products based on specific needs [55]. As stated by Plozczuk and Nolan [56], a company's supply chain process can be more efficient if order flexibility exists with its customers.

2.3.4. Traceability Technologies

The concept of traceability has many facets and can be viewed from various perspectives. ISO 9000:2005 defines product traceability as the ability to identify products throughout the entire supply chain [57]. Tracking a product and its constituents up and down a supply chain is one way of protecting consumers from unsafe products and ensuring product quality, safety, and sustainability [58,59]. Growing complexity in the supply and distribution of drugs has led to the need for innovative technology-based solutions to protect patients overseas through traceability systems [60]. Tracking and identifying drugs that do not contain the intended active ingredients are crucial to enhance their effectiveness and avoid patient harm or death [61].

Through advanced technological implementation solutions, inter-organizational networks can be configured to facilitate real-time data exchange, enabling the creation of various controls, such as tracking products in the supply chain to detect fake products [62]. In most industries, traceability has been recognized as a competitive advantage since consumers prefer companies that provide information about the traceability of their products. Several studies have shown that consumers with access to a company's products and subsequent information preferred that company five times more than its competitors [20]. According to Kim et al. [63], preferences vary depending on a product's criticality. Several scholars are more interested in the pharmaceutical sector than any other sector due to government interests, stringent regulations designed to protect public health and end-consumers, and broad interest from international organizations. Similarly, in the pharmaceutical industry around the world, safety and quality have captured significant attention [64].

Multiple techniques and approaches are being used in the pharmaceutical industry to trace counterfeit drugs. Kumar and Tripathi [65] proposed the use of a smart track with RFID or the bar code on medicine bottles to verify legality and originality. Rehman et al. [66] proposed a data matrix tracking system in which each medicine includes a data matrix for tracking information. This matrix includes product identification codes, manufacturer names, unique package numbers, and optional Metadata. A further extension of this concept would be the Central Verification Register (CVR) that would be capable of storing the hash value of the description contained in the data matrix. A manufacturer uses a CVR to verify the data scanned during purchase, including the hash value.

Wazid et al. [67] suggested that Near Field Communication tags could be used to verify drug authenticity. The three stages include product registration, product authentication by key-value, and NFC tag. Bansal et al. [68] explained that pedigree is a technique for counteracting counterfeits. A drug pedigree is a document that traces the history of a drug, from its manufacture to its distribution through the wholesale transaction, to the point at which a dispenser, such as a pharmacy or a physician, receives it. Upon receiving the pedigree with the shipment, someone must ensure that all distributions are recorded and that the specific information is accurate. In this way, the prescribed drugs cannot be easily diverted or replaced with counterfeits. When preventing the entry of counterfeit drugs into the supply chain, a blockchain has been recognized as a key technology since it ensures an immutable chain of every transaction and tracks each drug's progress at every stage of the PSC [69].

A company's credibility is enhanced if its products can be traced precisely. For example, keeping track of a drug's performance in real time is crucial to its safety. Additionally, it allows PSC members to communicate directly and be transparent with other stakeholders. A company must identify the critical success factors to implement an effective drug traceability system. As a result, it must be determined if incorporating traceability technology will enhance its supply chain. Traceability can be a key performance indicator for pharmaceutical companies. The traceability of insulin is a reliable, consistent indicator of safety across supply chains and an important key performance indicator for ensuring continuous availability and safety in the insulin supply chain. For this reason, traceability has been selected as a critical KPI and added to the supply chain of the second scenario to analyze and compare the results.

In view of the discussion above, all scientists and professionals agree that insulin is a lifesaving and essential medication. Diabetes patients, especially those with type 1 diabetes, require insulin injections to regulate and maintain their blood sugar levels. Numerous factors affect the availability and accessibility to safe insulin in supply chains, including high prices, issues in manufacturing, delays in distribution, lack of patents for insulin, process complexity of the insulin, and the dominance of three main companies that manufacture insulin. As a result of high prices and lack of availability, individuals are turning to other options for purchasing insulin, such as online pharmacies, which may or may not be legitimate.

Several studies have highlighted the challenges in PSC management for critical medications, such as lack of availability and affordability [7,70–72], the existence of cheap and alternative counterfeits [73–75], and their negative effects on public health and patients with chronic disease [3,76–79]. Ozsahin et al. [80] used the TOPSIS methodology to compare 24 alternative migraine drugs that can help clinicians manage productive migraine medication in general and/or in a specific patient situation and to understand their various characteristics. Hien and Thanh [81] focused on evaluating and selecting logistics suppliers that manage special medications and vaccines requiring cold handling and low-temperature storage, considering many factors to reduce the potential waste of products resulting from poor storage practices. In this paper, the author presents an integrated approach to solving Fuzzy Multiple Criteria Decision-Making (FMCDM) problems using the Fuzzy Analytical Hierarchy Process (FAHP) model and the Interactive and Multi-Criteria Decision-Making in Portuguese (TODIM) method.

Numerous studies have discussed insulin's importance to type 1 chronic diabetes, methods of delivering insulin safely to patients, and its use for patients, such as young children, pregnant women, and pilots. Despite the necessity of safe insulin for diabetics in the legitimate PSCs, few researchers seem to have considered implementing strategies and models to maximize patient safety for purchasing insulin. Therefore, the current research seeks to bridge this gap and provide cohesive information on overcoming this challenge and maximizing insulin safety.

3. Methodology

Considering the study's goal to develop criteria for ensuring safe insulin supply chains, the authors employ a hybrid Multi-Criteria Decision-Making (MCDM) model that combines SCOR metrics, the AHP model, and the TOPSIS technique to prioritize the criteria and maximize insulin safety, while ensuring its availability in the PSC and eliminating the counterfeit. This integrated use of SCOR metrics, the AHP model, and the TOPSIS technique was well suited for the task as this can be addressed through quantitative and qualitative analysis. As part of this study, we have developed two scenarios where we will look at the normal insulin supply chain in scenario 1, highlighted in red and then consider the inclusion of traceability technology in scenario 2, highlighted in green, as a critical factor to assist in maximizing the safety of the insulin in the supply chain, as exemplified in Figure 5 [3,37]. A list of KPIs is presented here for both scenarios, along with a discussion of the steps needed to achieve the study's objectives.

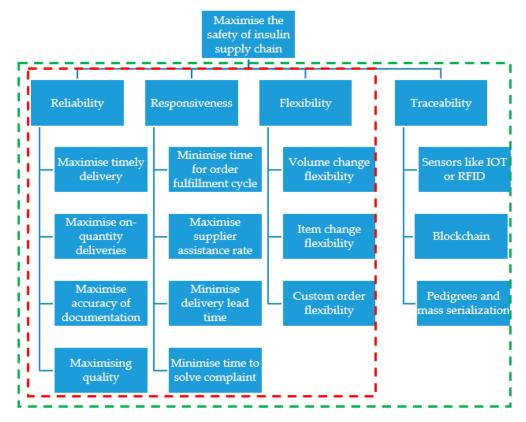


Figure 5. Scenarios 1 and 2 for the insulin supply chain.

3.1. Model Outline

SCOR was employed to develop the criteria used for this study, and this model was compiled and validated at a later stage to finalize and form the hierarchy of criteria. The identified KPIs are used to measure the performance of the insulin and determine how efficiently and effectively it can accomplish its goals. Based on comparisons among criteria, the weight of each KPI is determined by AHP in the second stage. Ratio scales are derived from paired comparisons. TOPSIS compares the KPIs based on the Positive Ideal Solution (PIS) and the longest distance from the Negative Ideal Solution (NIS). Finally, we compare the results of two supply chain scenarios for insulin. Similarly, Hanugrani et al. [82] tested tobacco products with SCOR and AHP. For a construction project, Marzouk and Sabbah [83] used a combination of AHP and TOPSIS to identify criteria with relative importance weights, then assessed 17 different suppliers and prioritized the best. Wang et al. [33] used a hybrid model of all three MCDMs, as well as SCOR, AHP, and TOPSIS, to determine the best supplier for the gas and oil sector.

Table 2 contains the level 1 KPIs (main criteria) and level 2 KPIs (sub-criteria) for both scenarios and their generated codes for this study, which can be distinguished by the same colors represented in Figure 4.

Level 1 KPIs	Level 2 KPIs	Codes	Scenario 1	Scenario 2
	Maximize timely delivery	RL11	Ō	$\overline{\bullet}$
Reliability (RL)	Maximize documentation accuracy	RL12	Ō	\bigcirc
	Maximize quality	RL13	•	\bigcirc
	Maximize supplier assistance rate	RS21	Ō	\bigcirc
Responsiveness (RS)	Minimize delivery lead time	RS22	Ō	$\overline{\bullet}$
	Minimize time to solve a complaint	RS23	•	\bigcirc
	Volume change flexibility	F31	•	\bigcirc
Flexibility (F)	Item change flexibility	F32	Ō	\bigcirc
	Custom order flexibility	F33	Ō	$\overline{\bullet}$
	Sensors, such as IOT or RFID	T41		\bigcirc
Traceability (T)	Blockchain	T42		$\overline{\bullet}$
	Pedigrees and mass serialization	T43		•

Table 2. List of the KPIs and identification codes.

3.2. Proposed Stages

As illustrated in the flowchart in Figure 6, this study achieved its objectives using the following steps:

- Stage 1:
- Define a research problem

Locating the issue to be addressed with insulin and building the next steps around the issue. Establishing goals and brainstorming initial attributes (criteria and sub-criteria) to resolve the issue.

Data Collection

There are two types of data collection: Primary and secondary. This study used a combination of semi-structured interviews, literature searches, and a survey questionnaire.

The questionnaire was developed to validate the selection of the SCOR KPIs and to get professionals' help in weighing these criteria using the AHP model to determine the efficiency of the insulin and ensure its safety. This study intended to determine what the authors prefer regarding the proposed solution and what decision-makers prefer to achieve a predetermined objective. A survey was administered to supply chain professionals and PSC stakeholders based on what the pharmaceutical industry deems more important to maximize safety and protect the PSC from counterfeit insulin. Participants were recruited via emails, phone calls, and virtual and physical interviews. Due to the social distancing mandates as a result of the coronavirus pandemic, most participants could only conduct interviews virtually on Zoom or Google Meet. The surveys, created on a word document and Google forms, were distributed via a link through e-mails or SMS, especially for those working in pharmaceutical manufacturers; some people were handed a hard copy of the survey. Surveys were collected from 94 experts from November 2021 to January 2022. Appendix A presents the participants' demographics and profiles with pseudonyms to keep their identities anonymous.

The diverse opinions developed a more comprehensive and clearer picture of possible solutions.

Conduct unstructured interviews

This study utilized unstructured, open-ended interviews for preliminary understanding and initial data collection. Performing preliminary unstructured interviews with different drug supply chain stakeholders can help in better understanding how the downstream and upstream phases of the supply chain function in terms of general mechanisms to ensure the medication is received and distributed safely. These initial interview sessions were also structured to get to know the participants and establish trust. The researchers explained the purpose of the study to the participants. Participants were informed that participation was voluntary and that they could discontinue their participation if, during the process, they found that they were no longer interested in completing the process. Participants were promised anonymity. They were assured that all interview notes and transcripts would remain secure, and only the research team would have access to the records. Verbal consent was obtained from the participants. Meetings were conducted virtually, face-to-face, or via phone. The questions used during the meeting are shown in Appendix B. They were open-ended, and depending on the conversation, some questions were changed depending on different cases. The literature review criteria were also compared with the criteria generated by the interviews, which were also checked during the interview process to verify validity. The steps were to:

Identify the criteria from the literature review

Conducting an extensive literature review in this step to identify the criteria for maximizing the safety of the insulin supply chain and assist in understanding the study's goal in general.

Determine the criteria based on SCOR metrics

At this point, the main objective was to select criteria for maximizing and ensuring safe insulin since international markets lack availability. A preliminary breakdown structure based on the SCOR framework was used to obtain and classify these criteria for levels 1 and 2 KPIs.

Design a questionnaire for SCOR and AHP

Compilation of all previous steps and preparation of a questionnaire to verify the selected KPIs by domain experts and stakeholders. Moreover, the questionnaire contains pairwise comparisons, which are presented as matrices. With the AHP questionnaire, elements are rated on a scale of 1–9 according to their relative importance to each other. Stage 2:

• Validate the SCOR criteria and update

After identification of the criteria and KPIs, the next step was for experts and stakeholders in the domain to verify these KPIs. Part of the same survey questionnaire was used to verify these KPIs. The survey used a 5-point Likert scale to determine whether a selected KPI should be included or excluded from the final framework. Potential answers ranged from 1 = strongly agree, 2 = somewhat agree, 3 = neither agree nor disagree, 4 = somewhat disagree, and 5 = strongly disagree.

Weight the criteria according to the AHP model

The same sample-distributed questionnaire also included pairwise comparisons to calculate criteria weights. As matrices with scales 1–9, pairwise comparisons were used to measure the relative importance of elements, as shown in Table 3. An objective or decision factor analysis was based on comparing and evaluating criteria and sub-criteria.

• Assigning weights to each criterion and sub-criterion

After confirmation that consistency was within acceptable ranges (less than 0.1 or 10%), weights were assigned, and preparations were made for the final calculations. See Section 4.2 for details.

Stage 3:

This last stage included the calculation and the final ranking based on the AHP model and verifying it. If it seems reasonable, then TOPSIS was applied to rank the alternatives based on measuring the distance between the PIS and NIS.

Table 3. The fundamental scale for pairwise comparisons.

Intensity of Importance	Definition	Explanation
1	Equal importance	Two elements contribute equally to the objective.
3	Moderate importance	Experience and judgement favor moderately one element over another.
5	Strong importance	One element is favored strongly over another; its dominance is practically demonstrated.
7	Very strong importance	The evidence favoring one element over another has the highest possibility of affirmation.
9	Extreme importance	One element is favored against another at the highest possibility of the order of affirmation.
2, 4, 6,	and 8 were used for expres	sing immediate values.

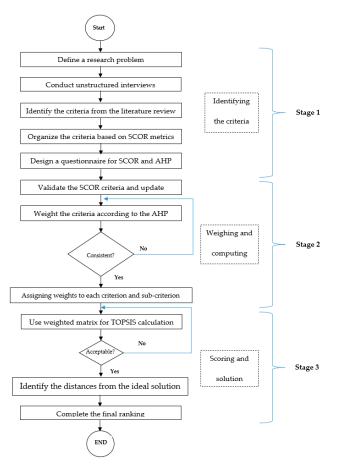


Figure 6. Research design flowchart.

3.3. Equations

Using the well-known AHP and TOPSIS methods, a model can be developed to prioritize and select the best criteria to maximize insulin safety and fulfill the study objectives. This is achieved using the equations presented in the following sections.

3.3.1. AHP Method

Thomas L. Saaty developed the AHP method in the 1970s, which is commonly used for decision-making [84]. Criteria and sub-criteria are arranged in a hierarchical structure using pairwise comparison metrics to decompose complex and ill-structured issues [85]. According to Saaty [86], the main advantage of AHP is its ability to rank options according to their effectiveness in resolving conflicting goals.

The steps used to achieve the results from the AHP process are as follows:

1. Calculate the geometric means

This is the value used to calculate the Logarithmic Least Squares Method [87] for all responses from the survey.

- 2. Performing a pairwise comparison of elements.
- 3. Calculating weights and Consistency Ratio (CR).

$$r_{ij} = \frac{x_{ij}}{\sum_{1-i}^{m} x_{ij}^2}$$
(1)

Net weights w_{ij} = Average f (normalized weights of rows) (2)

Consistency Ratio Matrix (CRM) = Average weight matrix \times Net weight matrix (3)

Consistency Vector Matrix (CVM) =
$$\frac{CRM}{Net weight matrix}$$
 (4)

$$Lambdamax(\lambda_{max}) = \frac{Sum \, of \, \text{CVM}}{n} \tag{5}$$

Consistency Index (CI) =
$$\frac{\lambda_{max} - n}{n - 1}$$
 (6)

Random Consistency Index (RCI) = chosen in accordance with the indicators order (n) in the comparison matrix with the Saati table, where for n = 3, it equals 0.58, and for n = 4, it equals 0.90.

Consistency Ratio (CR)
$$=\frac{CI}{RCI}$$
 (7)

3.3.2. TOPSIS Method

TOPSIS is another type of MCDM that is practical and useful in ranking and selecting alternatives based on Euclidean distance. Hwang and Yoon developed TOPSIS in 1981 [88]. The TOPSIS has been applied and tested in many fields, including medicine, marketing, economics, financial planning, public policy, education, and resource management in military defense [89]. Even though TOPSIS has a weakness where it does not provide a good alternative, it does provide a decision-maker with the closest alternative, which is believed to be the best choice based on the scores [90]. This approach assumes that the chosen alternative should be closest to the Positive Ideal Solution (PIS), the solution that maximizes the benefit criterion and minimizes the cost criterion. At the same time, it is furthest from the Negative Ideal Solution (NIS), the solution that maximizes the cost criterion and minimizes the benefit criterion [91]. Therefore, TOPSIS can provide each decision-maker with the optimal solution.

This study used a TOPSIS approach to identify and evaluate the characteristics of an effective insulin supply chain and ensure maximum safety; the main steps used to achieve the results from the TOPSIS technique process are as follows [92]:

- 1. Normalized decision matrix (r_{ij}) ;
- 2. Net weights (w_{ij}) ;
- 3. Weighted normalized decision matrix (v_{ij}) .

Using the equation below, we can calculate the normalized weighted value:

$$v_{ij} = w_{ij}r_{ij} \tag{8}$$

where,

 w_{ij} is the net weight from AHP;

 r_{ij} is the AHP normalized decision matrix;

 v_{ij} is the weighted normalized decision matrix.

4. Identify the ideal best A⁺ and ideal worst A⁻

In this stage, we decide which attributes are beneficial and which are not. In beneficial attributes, the maximum value is desired and called the ideal best (A^+) and the lowest is the ideal worst (A^-) , while in non-beneficial or cost attributes, the lowest value is the desired one and called the ideal best, whereas the highest value is the ideal worst.

$$A^{+} = \{ v_{1}^{+}, v_{2}^{+}, \dots, v_{n}^{+} \} \text{ where } v_{j}^{*} = max_{i}v_{ij} \text{ for benefit and } v_{j}^{*} = min_{i}v_{ij} \text{ forcost}$$
(9)
$$A^{-} = \{ v_{1}^{-}, v_{2}^{-}, \dots, v_{n}^{-} \} \text{ where } v_{i}^{-} = min_{i}v_{i}^{-} \text{ for benefit and } v_{i}^{-} = max_{i}v_{ij} \text{ forcost}$$
(10)

A = {
$$v_1, v_2, ..., v_n$$
 } where $v_j = min_i v_j$ for benefit and $v_j = max_i v_{ij}$ forcost (10)

5. Separation measure for each row calculation

The Euclidean distance S_i^+ describes the distance between every alternative and the PIS. The Euclidean distance S_i^- measures the separation distance between each alternative from the NIS using the following equations.

Positive ideal separation formula:

$$S_{i}^{+} = \sqrt{\sum_{j=1}^{n} \left(v_{ij} - v_{j}^{*} \right)^{2}}$$
(11)

Negative ideal separation formula:

$$S_{i}^{-} = \sqrt{\sum_{j=1}^{n} \left(v_{ij} - v_{j}^{-} \right)^{2}}$$
(12)

6. Calculate the relative closeness of each alternative to the ideal solution, as follows:

$$C_{i} = \frac{S_{i}^{-}}{S_{i}^{+} + S_{i}^{-}} \text{ and } 0 \le C_{i}^{+} \le 1$$
(13)

where Ci % is the TOPSIS performance score.

7. Rank the attributes based on Ci values

4. Results and Discussion

4.1. SCOR Model Implementation

Based on the aggregate responses from the experts, a descriptive analysis was performed using Statistical Package for the Social Sciences (SPSS) to validate the sub-criteria selected for SCOR to achieve the main objective. Among the 14 KPIs identified, 12 are deemed valid and measurable to measure insulin supply chain performance; a final form of the framework has been finalized for scenarios 1 and 2 of the updated hierarchy for criteria and sub-criteria. People did not respond correctly to the level 2 KPIs, maximized quantity delivery, and minimized order fulfilment cycle, and in many cases, that option was left empty. Possibly a respondent did not understand the question or thought it was a repeat of the KPI to maximize the timely delivery. Therefore, the two KPIs were dropped. Figure 7 illustrates the updated frameworks for scenarios 1 and 2.

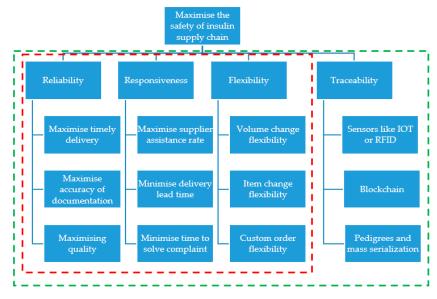


Figure 7. Finalized SCOR metrics for scenarios 1 and 2.

4.2. AHP

As a result of using the AHP Equations (1) to (7), the consistency ratio is 0.3597794 and 0.5860326 for levels 1 and 2, respectively, for scenario 1. In addition, the consistency ratio is 0.5562699 and 0.5327051 for levels 1 and 2, respectively, for scenario 2. Therefore, this result shows that all ratios are less than 10%, thus all weights are consistent. Appendix C provides a step-by-step example calculation to achieve the final CR for both scenarios. Therefore, we can use the AHP net weights based on levels 1 and 2 KPIs for both scenarios to calculate TOPSIS and determine the most important criteria to prioritize and ensure a safe insulin supply chain. Tables 4 and 5 show the calculations for the net weights for each level of the KPIs in scenarios 1 and 2.

L 1 KPIs	L 2 KPIs	L 1 KPIs Weights	L 2 KPIs Weights
Reliability (RL)	RL11	0.2886445	0.0921203
	RL12		0.1019035
	RL13		0.1034720
Responsiveness (RS)	RS21	0.3881160	0.1025291
	RS22		0.1082195
	RS23		0.1165034
Flexibility (F)	F31	0.3232395	0.1219434
	F32		0.1242532
	F33		0.1290556
Sum			1

Table 4. Net weights for levels 1 and 2 KPIs for scenario 1.

L 1 KPIs	L 2 KPIs	L 1 KPIs Weights	L 2 KPIs Weights
Reliability (RL)	RL11	0.2190725	0.0684206
	RL12		0.0735677
	RL13		0.0747803
Responsiveness (RS)	RS21	0.2698025	0.0744026
	RS22		0.0774349
	RS23		0.0799297
Flexibility (F)	F31	0.2288229	0.0824567
	F32		0.0846041
	F33		0.0865902
Traceability (T)	T41	0.2823022	0.1018253
	T42		0.1032666
	T43		0.0927213
Sum			1

Table 5. Net weights for levels 1 and 2 KPIs for scenario 2.

4.3. TOPSIS

As part of this study, we developed two scenarios where TOPSIS was used to prioritize and compare the KPIs based on the PIS and NIS. The following section presents the results of the two scenarios, along with an overall comparison of two insulin supply chains that maximize insulin safety while ensuring its availability in a PSC and eliminating counterfeits.

4.3.1. Scenario 1

The normalized decision matrix (r_{ij}) and net weights (w_{ij}) were used from AHP to initiate the calculations of TOPSIS for all the KPIs. Following the step-by-step Equations from (9) to (13) for TOPSIS presented in the previous section, we can arrive at the following calculations, as shown in Table 6.

Table 6. Final results of TOPSIS for scenario 1 KPIs.

L2 KPIs	A ⁺	\mathbf{A}^{-}	S_i^+	S_i^-	$S_i^+ + S_i^-$	C _i	%	Rank
RL11	0.0123	0.0085	0.0133	0.0109	0.0242	0.4500	45.00	8
RL12	0.0134	0.0079	0.0139	0.0069	0.0207	0.3320	33.20	9
RL13	0.0133	0.0082	0.0108	0.0120	0.0228	0.5259	52.59	4
RS21	0.0150	0.0088	0.0106	0.0124	0.0230	0.5388	53.88	2
RS22	0.0096	0.0147	0.0099	0.0114	0.0213	0.5344	53.44	3
RS23	0.0091	0.0185	0.0125	0.0107	0.0232	0.4618	46.18	7
F31	0.0182	0.0112	0.0111	0.0099	0.0210	0.4698	46.98	6
F32	0.0186	0.0109	0.0116	0.0108	0.0224	0.4836	48.36	5
F33	0.0167	0.0128	0.0092	0.0136	0.0228	0.5956	59.56	1

The calculations show that, under the normal condition of the insulin supply chain, the level 2 criterion F33 is reaching the highest point compared to other attributes. Even though sub-criteria are important to ensure the safety and availability of safe insulin in the supply chain, the F33 criterion should be prioritized, emphasizing the importance of having the ability to customize the amount of insulin being manufactured based on market requirements to meet the continuous demand and individual patient needs. The practice of seeking insulin in other places will decrease, leading to a decrease in selling

counterfeit insulin. A situation similar to this illustrates how important it is to ensure that diabetes patients have access to insulin immediately and that it is available to them promptly. Therefore, they will not be compelled to look elsewhere for their needs.

Figure 8 illustrates the spider diagram for the separation distance of each attribute from the positive and negative ideal solutions, which are distinguished by different colors on the diagram. As per TOPSIS, the best alternative should have the shortest Euclidean distance from the ideal solution. The KPI F33 has the maximum value score of 0.5956 and rated 1 in performance.

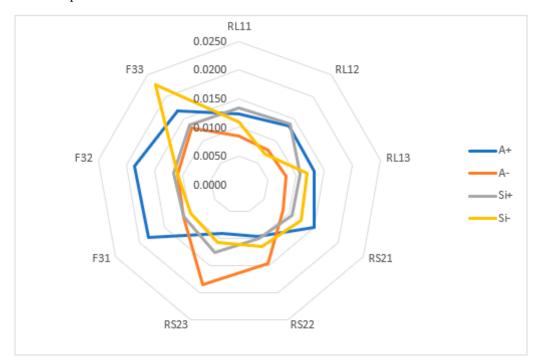


Figure 8. Separation from positive and negative ideal solutions for scenario 1 KPIs.

4.3.2. Scenario 2

The SCOR criteria in scenario 2 are similar to those in scenario 1, but a traceability technology factor was included as an intervention in evaluating the performance of the insulin supply chain and comparing the results. To rank the KPIs-based TOPSIS technique, we used the normalized decision matrix (r_{ij}) and net weights (w_{ij}) from AHP. The results are shown in Table 7.

The calculations show that, with the addition of traceability technology into the insulin supply chain, the preference score has been shifted to level 2 criterion blockchain (T42). Therefore, this leads to the conclusion that traceability technologies should be prioritized and implemented in the PSC to ensure maximum safety in the insulin supply chain. The great advantage of blockchain technology is that information can be secured and immutable among authorized individuals. For example, since all stakeholders and organizations in PSC have access to the same information, blockchain technology is structured to make changes difficult without being noticed. In addition, blockchain can ensure the transparency and immutability of the information. Moreover, it ensures consistency and reliability. The ability to access information from anywhere in the world is another crucial aspect of blockchain. All authorized stakeholders will be in control, eliminating the control of the central authority. However, it does not indicate that everyone can easily access the information. The security of a blockchain is robust enough in order that only authorized stakeholders can access it. Blockchain technology has the potential to prevent the spread of counterfeit medicines, ensure that adequate amounts of APIs in raw materials are sourced from reliable suppliers, and improve clinical trials [93].

L2 KPIs	A^+	\mathbf{A}^{-}	S_i^+	S_i^-	$S_i^+ + S_i^-$	C_i	%	Rank
RL11	0.0068	0.0047	0.0202	0.0099	0.0301	0.3291	32.91	6
RL12	0.0070	0.0041	0.0205	0.0089	0.0294	0.3019	30.19	9
RL13	0.0070	0.0043	0.0198	0.0103	0.0300	0.3414	34.14	4
RS21	0.0079	0.0047	0.0199	0.0104	0.0303	0.3427	34.27	3
RS22	0.0049	0.0076	0.0196	0.0101	0.0297	0.3404	34.04	5
RS23	0.0043	0.0091	0.0216	0.0088	0.0304	0.2893	28.93	10
F31	0.0096	0.0050	0.0213	0.0085	0.0298	0.2839	28.39	11
F32	0.0094	0.0050	0.0204	0.0092	0.0297	0.3110	31.10	8
F33	0.0105	0.0057	0.0204	0.0097	0.0301	0.3226	32.26	7
T41	0.0130	0.0051	0.0159	0.0158	0.0317	0.4988	49.88	2
T42	0.0236	0.0017	0.0103	0.0251	0.0354	0.7097	70.97	1
T43	0.0170	0.0061	0.0254	0.0093	0.0347	0.2685	26.85	12

Table 7. Final results of TOPSIS for scenario 2 attributes.

Figure 9 illustrates the separation distance for each attribute from the positive and negative ideal solutions on a spider diagram for scenario 2. The KPI T42 has the maximum value score of 0.7097 and rated 1 in performance.

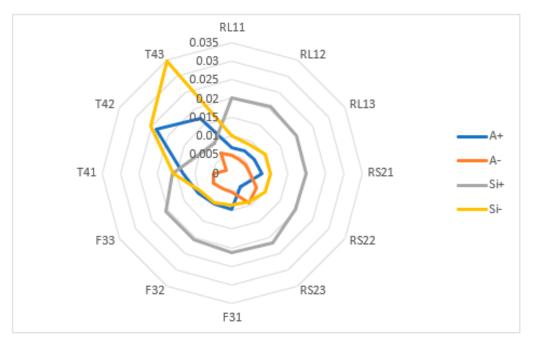


Figure 9. Separation from positive and negative ideal solutions for scenario 2 KPIs.

This situation demonstrates the need to ensure diabetes patients have access to insulin immediately, which can be achieved with criterion F33 and implementing a traceability technology, such as T42 that can be used to determine the history of products and ensure their authenticity as part of the supply chain. Therefore, the main objective of this study can be achieved by ensuring patient safety in the insulin supply chain.

4.4. Results Comparison

To select the best criteria, all stakeholders in the PSC must understand how and why safe insulin is important and how to evaluate this criterion. Consequently, the authors define the research objectives and criteria for maximizing the safety of insulin supply chains and evaluate them using SCOR metrics. Second, an AHP model is used to determine the weights of each factor, and then the TOPSIS model is used to calculate the optimal criteria. The results of this research indicate that T42 in scenario 2 provides the best results to the supply chain for maximizing and ensuring the safety of insulin, as compared to F33 in scenario 1, where the competitive alternative is close to the ideal solution by 0.7097 in comparison to the 0.5956 in scenario 1, and the final score achieved almost 71% as illustrated in Figure 10.



Figure 10. Final ranking score for scenarios 1 and 2.

4.5. Sensitivity Analysis

The sensitivity analysis is one of the essential elements of validating any model or framework and identifying how the model will perform under different conditions [94]. It is being performed to ensure that the results remain stable when attribute weights are altered [83]. It is considered that a stable decision-making process is not affected by weight changes [89]. Therefore, it examines the robustness and stability of the ranking concerning the criteria weights. Tables 8 and 9 present the sensitivity analysis results for scenarios 1 and 2. To obtain the pattern for the new weights, we used the Evaluation based on Distance from Average Solution (EDAS) method and ranked the final answers similarly to [89]. Parameter weights are adjusted according to the strategies presented in the table.

The average correlation results for each test against the original ranking for scenarios 1 and 2 are shown in Figure 11. The range is within 0.8445 and 0.9455 for scenarios 1 and 2, respectively. According to all tests, F33 ranks the highest. Clearly, the original ranking and the tests performed are in strong agreement. Therefore, our decision-making process is relatively insensitive to changes in the weight of the criteria.

 Table 8. Results of sensitivity analysis for scenario 1.

	RL11	RL12	RL13	RS21	RS22	RS23	F31	F32	F33	Ranking
Original Weights	0.09212	0.101904	0.103472	0.102529	0.108219	0.116503	0.121943	0.124253	0.129056	F33 > F32 > F31 > RS23 > RS22 > RL13 > RS21 > RL12 > RL11
Test 1	0.101904	0.09212	0.103472	0.102529	0.108219	0.116503	0.121943	0.124253	0.129056	F33 > F32 > F31 > RS23 > RS22 > RL13 > RS21 > RL12 > RL11

Test 2	0.108219	0.101904	0.103472	0.102529	0.09212	0.116503	0.121943	0.124253	0.129056	F33 > F32 > F31 > RS23 > RL11 > RL13 > RS21 > RL12 > RS22
Test 3	0.09212	0.103472	0.101904	0.102529	0.108219	0.116503	0.121943	0.124253	0.129056	F33 > F32 > F31 > RS23 > RL12 > RL13 > RS21 > RS22 > RL11
Test 4	0.09212	0.108219	0.103472	0.102529	0.101904	0.116503	0.121943	0.124253	0.129056	F33 > F32 > RL12 > RS23 > RS22 > RL13 > RS21 > F31 > RL11
Test 5	0.09212	0.121943	0.103472	0.102529	0.108219	0.116503	0.101904	0.124253	0.129056	F33 > F32 > F31 > RS23 > RS22 > RS21 > RL13 > RL12 > RL11
Test 6	0.09212	0.101904	0.102529	0.103472	0.108219	0.116503	0.121943	0.124253	0.129056	F33 > F32 > F31 > RS23 > RS22 > RL13 > RS21 > RL12 > RL11
Test 7	0.09212	0.101904	0.116503	0.102529	0.108219	0.103472	0.121943	0.124253	0.129056	F33 > F32 > F31 > RL13 > RS22 > RS23 > RS21 > RL12 > RL11
Test 8	0.09212	0.101904	0.124253	0.102529	0.108219	0.116503	0.121943	0.103472	0.129056	F33 > RL13 > F31 > RS23 > RS22 > F32 > RS21 > RL12 > RL11
Test 9	0.09212	0.101904	0.103472	0.121943	0.108219	0.116503	0.102529	0.124253	0.129056	F33 > F32 > RS21 > RS23 > RS22 > RL13 > F31 > RL12 > RL11
Test 10	0.09212	0.101904	0.103472	0.102529	0.116503	0.108219	0.121943	0.124253	0.129056	F33 > F32 > F31 > RS22 > RS23 > RL13 > RS21 > RL12 > RL11

Table 8	3. Cont.
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 Table 9. Results of sensitivity analysis for scenario 2.

	RL11	RL12	RL13	RS21	RS22	RS23	F31	F32	F33	T41	T42	T43	Rankin
Original Weights	0.068421	0.073568	0.07478	0.074403	0.077435	0.07993	0.082457	0.084604	0.08659	0.101825	0.103267	0.092721	T42 > T41 > T43 > F33 > F32 > F31 > RS23 > RS22 > RL13 > RS21 > RL12 > RL11

Test 1	0.073568	0.068421	0.07478	0.074403	0.077435	0.07993	0.082457	0.084604	0.08659	0.101825	0.103267	0.092721	$\begin{array}{l} T42 > \\ T41 > \\ T43 > \\ F33 > \\ F32 > \\ F31 > \\ R523 > \\ RS22 > \\ RL13 > \\ RS21 > \\ RL11 > \\ RL12 \end{array}$
Test 2	0.077435	0.073568	0.07478	0.074403	0.068421	0.07993	0.082457	0.084604	0.08659	0.101825	0.103267	0.092721	$\begin{array}{l} T42 > \\ T41 > \\ T43 > \\ F33 > \\ F32 > \\ F31 > \\ RS23 > \\ RL11 > \\ RL13 > \\ RS21 > \\ RL12 > \\ RS22 \end{array}$
Test 3	0.068421	0.07478	0.073568	0.074403	0.077435	0.07993	0.082457	0.084604	0.08659	0.101825	0.103267	0.092721	$\begin{array}{l} T42 > \\ T41 > \\ T43 > \\ F33 > \\ F32 > \\ F31 > \\ RS23 > \\ RS22 > \\ RL12 > \\ RS21 > \\ RL13 > \\ RL11 \end{array}$
Test 4	0.068421	0.077435	0.07478	0.074403	0.073568	0.07993	0.082457	0.084604	0.08659	0.101825	0.103267	0.092721	$\begin{array}{l} T42 > \\ T41 > \\ T43 > \\ F33 > \\ F32 > \\ F31 > \\ RS23 > \\ RL12 > \\ RL13 > \\ RS22 > \\ RL11 > \end{array}$
Test 5	0.068421	0.082457	0.07478	0.074403	0.077435	0.07993	0.073568	0.084604	0.08659	0.101825	0.103267	0.092721	$\begin{array}{l} T42 > \\ T41 > \\ T43 > \\ F33 > \\ F32 > \\ RL12 > \\ RS23 > \\ RS22 > \\ RL13 > \\ RS21 > \\ F31 > \\ RL11 \end{array}$

Test 6	0.068421	0.073568	0.074403	0.07478	0.077435	0.07993	0.082457	0.084604	0.08659	0.101825	0.103267	0.092721	T42 > T41 > T43 > F33 > F32 > F31 > RS23 > RS22 > RS21 > RL13 > RL12 > RL11
Test 7	0.068421	0.073568	0.07993	0.074403	0.077435	0.07478	0.082457	0.084604	0.08659	0.101825	0.103267	0.092721	T42 > T41 > T43 > F33 > F32 > F31 > RL13 > RS22 > RS23 > RS21 > RL12 > RL11
Test 8	0.068421	0.073568	0.084604	0.074403	0.077435	0.07993	0.082457	0.07478	0.08659	0.101825	0.103267	0.092721	T42 > T41 > T43 > F33 > RL13 > F31 > RS23 > RS22 > F32 > RS21 > RL12 > RL11
Test 9	0.068421	0.073568	0.07478	0.074403	0.077435	0.103267	0.082457	0.084604	0.08659	0.101825	0.07993	0.092721	T42 > T41 > F33 > F32 > F31 > RS23 > RS22 > RL13 > RS21 > RL12 > RL11
Test 10	0.068421	0.073568	0.07478	0.074403	0.077435	0.07993	0.082457	0.084604	0.092721	0.101825	0.103267	0.08659	T42 > T41 > F33 > T43 > F32 > F31 > RS23 > RS22 > RL13 > RS21 > RL12 > RL11

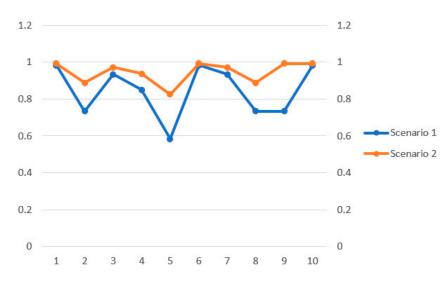


Figure 11. Correlations of each test against the original ranking for scenarios 1 and 2.

5. Conclusions

The discovery of insulin 100 years ago marks a significant milestone for the diabetes community. As a result of the discovery of insulin in 1921, type 1 diabetes is no longer a death sentence but can be managed as a chronic condition. The demand for insulin is rising due to the number of diabetics in various countries. It is estimated that one out of two people do not have access to insulin. The insulin market differs from the regular prescription drug market in many ways. In this market, several upward price pressures impact the insulin market and create an unusually complex environment. Furthermore, the high cost of insulin, the high market revenue, scarcity, and the inability to align the supply with patient demand have contributed to its lack of availability and thereby increased the probability of counterfeiting the insulin in the market to meet patient demand.

Several available studies highlight the challenges in Pharmaceutical Supply Chain (PSC) management for critical medications, such as lack of availability and affordability, the existence of cheap and alternative counterfeits, and their negative effects on public health and patients with chronic disease. Despite the necessity of safe insulin for diabetics in the legitimate PSC, few researchers have investigated this subject to the best available knowledge. However, interest has grown among pharmaceutical companies and stakeholders in developing strategies to maximize patient safety when purchasing insulin. Therefore, the authors of the current research have noticed that no studies provide cohesive information and data on how to overcome the concerns and challenges in the insulin supply chain and maximize its safety.

Several criteria must be considered in the assessment process to ensure the safety of insulin in the supply chain. Maximizing insulin safety is a case of Multi-Criteria Decision-Making (MCDM). For this reason, a hybrid MCDM model using SCOR metrics, AHP, and TOPSIS was implemented to manage this research problem. As a result, we have developed two scenarios, where we looked at the normal insulin supply chain in scenario 1 and then considered the inclusion of a section of traceability technologies in scenario 2 as an intervention and critical factor to assist in maximizing the safety of the insulin in the supply chain. Finally, we compared the results of two different supply chain scenarios for the same insulin.

This research has some limitations. Although there are many studies with respect to the importance of keeping insulin safe for diabetics, few previous studies exist on this topic, and very few researchers have considered implementing strategies to maximize patient safety for purchasing insulin. Therefore, there were issues, such as limited access to data. The other limitation was that the pharmaceutical sector's medical staff and workers were pressured and preoccupied with the crisis. Although the initial physical interview sessions are important for getting to know the participants and establishing trust, most participants

were recruited via emails, phone calls, and virtual interviews. Due to the social distancing mandates as a result of the coronavirus pandemic, the researchers preferred to conduct these interviews virtually on Zoom or Google Meet. An important contribution of this work is the formulation of a new and feasible MCDM model for evaluating and maximizing insulin safety. In addition, the research model allows practitioners and decision-makers to visualize how different criteria impact the outcome.

An important contribution of this work is the formulation of a new and feasible MCDM model for evaluating and maximizing insulin safety. In addition, the research model allows practitioners and decision-makers to visualize how different criteria impact the outcome. Considering the findings of this study, certain decisions can be made regarding insulin safety. When purchasing insulin, integrity is crucial, which is why trusted sources are important. It is the responsibility of politicians and governments to make wise decisions regarding the receival of safe insulin that patients with diabetes require. To produce insulin at a lower cost and make it affordable to patients, innovative methods must be developed to release a production method that allows patients to make their own insulin at the required time. Several previous studies concluded that the importance of integrating technologies would assure medication safety [3]. Therefore, the top management of concerned supply chain organizations is responsible for analyzing their market environment, requiring capabilities and comparing it to their needs, and investing in implementing the best traceability technology that can be used in their PSC to track individual insulin items. Additionally, these strategic initiatives can benefit PSC stakeholders.

Moreover, the current research can be applied to selecting other medications, such as vaccines, antibiotics, or medications for chronic diseases where instant availability and affordability are crucial. Future studies should consider additional selection criteria, such as political, regulatory, and institutional capacities, to ensure a thorough evaluation procedure. Furthermore, this research can be expanded to other critical products, such as foods which are critical to humans, and hypotheses can be tested based on similar quantitative methodologies. Results can then be analyzed and compared. Similarly, the model could be tested on reverse supply chains related to public health products to ascertain its feasibility. Additionally, further research can be conducted on testing the current model with other MCDM methods to ensure more comprehensive results. Therefore, this research model has many academic and practical applications.

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Appendix A

The demographic profile of the respondents shown in the table below provides an overview of their experience and expertise.

Percentage (%) Frequency Gender Male 62 66 32 Female 34 Professional Experience Professional in pharmaceutical supply chain 2 management (sourcing, procurement, warehousing, 2.1 distribution, retailing) Professional in other sectors of the healthcare industry 1 1.1 (hospitals, clinics, other medical service providers) 8 8.5 Experienced in supply chain management Professional in other sectors of the healthcare industry 51 54.3 (hospitals, clinics, other medical service providers) Professional in pharmaceutical supply chain 32 34.0 management (sourcing, procurement, warehousing, distribution, retailing) Total 94 100.0 Activity in Pharmaceutical Supply Chain Distributor/Wholesaler of drugs 15 16.0 Healthcare user 7 7.4 Hospitals/Clinics/Pharmacy 45 47.9 Manufacturer of drugs 16 17.0 3 Packager of drugs 3.2 8 8.5 Supplier of pharmaceuticals' raw materials 94 100.0 Total Years of Experience >10 years 15 16.0 1-3 years 56 59.6 12 12.8 4-6 years 7-9 years 11 11.6 Total 94 100.0

Table A1. Demographics of participants.

Appendix B

Questions for the unstructured, open-ended interviews:

- 1. Which model of the pharmaceutical supply chain does your company use?
- 2. Who are your upper and lower bounds of partners and stakeholders?
- 3. What makes your supply chain robust, and what are the success factors for safe medications?
- 4. What is your procedure for selecting a supplier of raw materials/manufacturer/ distributor/pharmacy?
- 5. What are the main barriers you face in ensuring the safety of the medication you receive?
- 6. What are the major problems your company face in transporting insulin?
- 7. What are the steps involved in recalling medications?
- 8. Is a cold supply chain method a better transportation mechanism for transporting insulin? Is it the only one ideal for insulin?
- 9. What traceability technologies do your company usually adopt for their products in general and, in particular, insulin?
- 10. We will be preparing a survey. Are you willing to help us with the required information from your side and your stakeholders?

Appendix C

To determine the relative importance of attributes or criteria, we created a pairwise comparison matrix, as shown in Table A2. Based on Table 3, the diagonal line indicates that all items are equally important and equal to 1. Using the geometric mean, we calculated the pairwise comparisons of the criteria and sub-criteria based on the consolidated questionnaire responses for scenarios 1 and 2. We calculated the reciprocal of the first pairwise comparison for the remainder of the cells.

Table A2. Pairwise comparison matrix.

	Reliability	Responsiveness	Flexibility
Reliability	1	0.793	0.837
Responsiveness	1.2610340	1	1.2811673
Flexibility	1.1947431	0.7805382	1
Sum	3.4557772	2.5735382	3.1181673

The calculations for the normalized pairwise matrix are as follows: Normalized pairwise matrix for reliability column = $\frac{x_{ij}}{\text{Sum}}$

=	$\frac{1}{3.4557772}$	=	0.2893705
=	$\frac{1.2610340}{3.4557772}$	=	0.3649061
=	$\frac{1.1947431}{3.4557772}$	=	0.3457234

Net weights

 w_{ij} = Averageof (normalized weights of rows)

The net weight for the reliability row

$$=\frac{0.2893705 + 0.3081361 + 0.2684269}{3} = 0.2886445$$

Table A3 shows the overall normalized matrix

Table A3. Normalized pairwise comparison matrix.

	Reliability	Responsiveness	Flexibility	Net Weights (w_{ij})
Reliability	0.2893705	0.3081361	0.2684269	0.2886445
Responsiveness	0.3649061	0.3885701	0.4108719	0.3881160
Flexibility	0.3457234	0.3032938	0.3207012	0.3232395
Sum	1	1	1	1

To calculate the consistency ratio, we followed the steps below:

 Consistency Ratio Matrix (CRM) = Average weight matrix (normalized weights of rows) × Net weight matrix

Table A4. Calculation of the consistency ratio matrix.

	Reliability	Responsiveness	Flexibility
Reliability	$0.2893705 \times 0.2886445$	$0.3081361 \times 0.3881160$	$0.2684269 \times 0.3232395$
Responsiveness	0.3649061 imes 0.2886445	0.3885701 imes 0.3881160	0.4108719 imes 0.3232395
Flexibility	$0.3457234 \times 0.2886445$	$0.3032938 \times 0.3881160$	$0.3207012 \times 0.3232395$

- CRM = 0.8669719
 1.1662304
 0.9710349
- Then, we need to calculate the Consistency Vector Matrix (CVM) = $\frac{CRM}{m_{cons}}$
- CVM =
 3.0035977
 3.0048500
 3.0040727

Lambda _{max} =
$$\lambda_{max} = \frac{\text{Sum of CVM}}{n} = \frac{3.0035977 + 3.0048500 + 3.0040727}{3} = 3.0041734$$

Consistency Index = CI = $\frac{\lambda_{max} - n}{n - 1} = \frac{3.0041734 - 3}{3 - 1} = 0.0020867$

Using the Saati table as a comparison matrix, we will select the Random Consistency Index (RCI) based on the indicator order(n). For n = 3, it is equal to 0.58, and for n = 4, it is equal to 0.90.

Consistency Ratio =
$$CR = \frac{CI}{RCI} = \frac{0.0020867}{0.58} = 0.0035978$$

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