

## Commentary

# A System View to the Risks of COVID-19 Vaccination Projects

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**Abstract:** The global vaccination program provides hope for ending the present worldwide pandemic. Due to the current pandemic, COVID-19 vaccines must be delivered and administered to communities once supplies are available. However, there are significant challenges in the sourcing, allocation, distribution, and uptake of vaccinations. A successful vaccination program would necessitate adequate risk management across the vaccination supply chain. This article has collected the predictable risks of the COVID-19 vaccines considered within the vaccine delivery system framework. The risks are presented based on relevant literature. Hence, this work's framework is expected to contribute to better risk management of vaccination programs and similar future projects.

**Keywords:** COVID-19; vaccination system; vaccine supply chain; public health; project administration



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## 1. Introduction

From November 2019 until November 2021, the World Health Organization (WHO) has received reports of more than 228,807,630 confirmed cases of Coronavirus Disease (COVID-19), with more than 4,697,095 deaths [1]. Up to now, public vaccination is the most important means of controlling the COVID-19 pandemic. Within just under a year from the start of the pandemic, researchers developed vaccines against COVID-19. These vaccines, such as Pfizer, Moderna, AstraZeneca, Sputnik V, Covishield, Ad26.COV2.S, Sinopharm, Sinovac, and Bharat are still in the development process and have authorization only for emergency use. Now it is time to make these vaccinations available to individuals worldwide. To control the pandemic, individuals in all countries need to get vaccinated. However, authorities worldwide face the challenge of vaccinating the public as rapidly as possible [2]. By January 2022, 9.42 billion doses of COVID-19 vaccines had been administered globally [3]. Although vaccination policies differ, in general, by the 8th of January 2022, approximately 59.1% of the world's population had taken at least one dose of a COVID-19 vaccination [4]. However, this worldwide statistic conceals significant disparities between continents and income groups, as vaccine doses have been delivered unevenly with low-income countries lagging behind [3]; just 2% of individuals in low-income nations have received at least one dosage [4]. These statistics emphasize the need for an efficient vaccine delivery project and make it even more critical to reduce the global supply chain risks in these regions in order to save lives, prevent additional costs and minimize any potential for project failure [5].

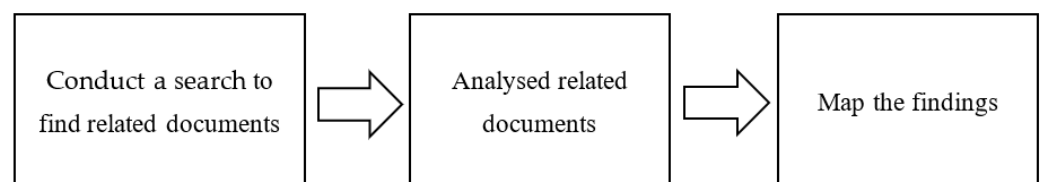
For the past 50 years, the supply chain methods for distributing vaccines have remained essentially unchanged, with only minor improvements [6]. The results are the suboptimal vaccination projects witnessed during the COVID-19 pandemic. Many countries have faced a multitude of difficulties at various stages of vaccine distribution [7]. Moreover, many regions have struggled to meet the required service level standards due to inadequate risk management and vaccine supply chain breakdowns [2]. Although vaccination is a medical intervention, successful public vaccination programs are impossible

without a reliable supply chain [8]. Lowering the risks related to vaccine delivery has never been more of a global concern than it is now [9]. The scientific community has recently shown an increasing interest in the logistical elements of vaccination, but the majority of published studies still focus on only a single logistical component [8]. Thus, the primary aim of this article is to propose a framework that conceptualizes and unites the related risks and concerns of the entire vaccine supply chain that may be beneficial to COVID-19 mass vaccination policymakers and authorities.

## 2. Methodology

In June 2021, the authors used (TITLE (“vaccination” OR “vaccine”) AND TITLE-ABS-KEY (“supply chain” OR “logistics” OR “distribution”) AND TITLE-ABS-KEY (“COVID\*”)) to search the Scopus database. From the resulted list of publications, 59 were published in 2020 and 226 in 2021. The U.S. had the highest number of publications, followed by the U.K. and China. These three countries had more than 50% of the total publications. The review results showed that not many published articles are associated with the potential risks of the COVID-19 vaccine supply failure, and almost none covered the potential risks associated with the vaccine supply network. Thus, this study is one of the first to address those issues and open the dialogue on the efficiency of the global vaccination delivery framework. For the purpose of this study, the authors relied on both their expertise and published research studies. The authors’ background in supply chain management and project operations management and the relevant material, including scientific articles, practice reports, and news items on potential risks, were all used in the analysis.

Additionally, public vaccination requires a systematic approach by which vaccines are introduced into a system that consists of managing the distribution, output, and data processing, as well as feedback and information administration [10,11]. Following the analysis of the collected material on vaccine delivery-related risks, the authors conducted a systematic mapping based on the idea that systematic mappings can be used to structure a given subject area [12]. In the social sciences, systematic mapping was developed in response to a lack of information and the need to classify the existing data by organizing and stratifying accessible evidence relevant to a given topic of interest [13]. In short, Figure 1 depicts the design used for this article.



**Figure 1.** Approach design.

### Delimitation

The majority of the COVID-19 vaccines are produced by a small number of WHO-approved COVID-19 vaccine manufacturers located in a small number of countries [14], similar to how manufacturing of many other vaccines is set up [15]. Thus, for most participants in the distribution chains, vaccines are developed and manufactured abroad and later imported into the country [2]. Vaccine development and production risks will not be addressed in this report, as those risks cannot be directly mitigated by the importing authorities working within local governments on to the macrolevel policy making. Disruptions covered in this article are those that occur during sourcing, logistics, and distribution.

## 3. Results

This section presents concerns and potential risks associated with the vaccination system, which are held into system aspects, including input, process, output, and feedback.

### 3.1. Input Concerns

- With various vaccines available on the market, authorities need to decide which should be procured [8]. This complex decision-making task involves multiple criteria such as vaccine hesitancy, price, ethical and legal issues, delivery lead times, supply uncertainties, and social and political concerns. In the market with high demand and limited supplies available, delays in making this decision often translate into the country's failure to secure early supplies [7]. In this respect, procurement leverage of the countries in terms of negotiation power, volumes, financial stability, coalitions, and relationships can have a significant impact [16].
- When securing contracts for vaccines, it is critical to ensure that all activities performed in the production of the vaccine adhere to an established set of rules and regulations and comply with the laws of the country to which the vaccine will be delivered; otherwise, the product will be returned, costing the country money and lives [17,18].
- On-time financing of the vaccine procurement is a risk. However, sponsors and donors influence the vaccination market to enhance equal access of the population to the vaccine [8,18,19]. In addition, the infrastructure modifications such as transport and storage space and capabilities, including those related to cold chains, also require governmental funding to maintain the distribution. The current pandemic revealed the insufficient capacity and readiness of the existing infrastructure to respond to such public health emergencies [7].
- The role of governments and media to encourage public vaccination should not be underestimated. Considering the vaccine resistance during and even prior to the COVID-19 pandemic, relevant authorities should identify the root of such behavior and address this problem objectively. This is a sensitive and complex issue involving public health and personal freedoms, which, in some cases, are at odds. Thus all efforts should be made to reassure the public and prepare the community to reach the level of national and global immunization required for herd immunity [20,21].
- Lack of logistics, handling skills, and training among the health workers, poor infrastructure, and the lack of technology also adversely affect public access to vaccines, resulting in waste, poor assessment and shortages, and lack of support products [22].
- Modern, data-driven technology that can help better visibility, estimations, and real-time planning, has also been missing in many distribution systems worldwide. While investments in those resources generally may be significant and the returns not always visible [23], the current pandemic has clearly demonstrated the added value such technology can bring to the distribution systems.
- Supply chains, as all other systems, need to be tested to determine their resiliency and readiness in different situations [24]. Identifying and accounting for the potential system flaws can help increase their efficiency and preparedness. Therefore, decision makers and managers should design, organize, and execute proper supply chain stress tests to identify and classify potential problems in order to address them adequately.

### 3.2. Process Concerns

- Failure to calculate the program costs is a risk, as the program objective is to reduce both the costs of infections and the expenses of the control plan [8]. Feasible plans for rapid distribution and administration of vaccines are essential [25,26].
- In logistics, when selecting where to locate vaccine stocks, inventory control considerations must be made, and they include issues concerning the location, required personnel, and structure of distribution stations. When movable facilities are deployed, routing and scheduling issues arise [2,8,20,27,28].
- Vaccine dosages can sometimes be insufficient to vaccinate the entire population, particularly during rapid outbreaks such as COVID-19. This raises the question of vaccine priority and necessitates that we discriminate between high-risk and low-risk groups within a community, as well as high-transmission and low-transmission

groups. A thorough examination is required to identify which group(s) should be vaccinated first [2,8,18,25,27,29,30].

- COVID vaccines should be kept at a regulated temperature. Thus, risk-free technologies for inventory and transportation stages are another concern [29]. When vaccine distribution venues do not have the necessary infrastructure to keep vaccines at a safe temperature, they will have little time to distribute the stock once it arrives [2,18,29].
- Logistics disruptions can occur as a result of a variety of infrastructure flaws [2]. Some of these are a lack of dependable power supply in remote regions, geographical barriers, lack of spare components for maintaining cold storage, a severe shortage of skilled personnel, and an insufficient number of delivery vehicles. In addition to frequent interruptions, these infrastructure problems are also likely to reduce the effective shelf life of the vaccines [2,17]. Supply lead time interruptions, combined with the sensitivity of shelf life, are causing massive problems manifesting in vaccine waste due to expiry and reduction in customer service [2].
- Existing local health facilities, mobile facilities, and field hospitals are all potential vaccine administration sites. Thus decisions must be made regarding sites' location [8], the number of clinics per area, proper layout of the facilities [8], and the necessary number of professional personnel [2,8]. For mobile clinics, proper project management for moving the facility to different serving nodes in an area is another challenging task [8].
- Security and safety of the developing vaccines are crucial. Fake COVID-19 vaccines exist [20,31], and failure to control the black markets risks the vaccination program's success. The potential of any bioterror attack is another concern [8].
- Unpredictable natural or human-caused disasters create many obstacles throughout the supply chain, which may result in a loss of a large number of vaccines. Thus, authorities should make an effort to try to prevent or mitigate the fallout of these circumstances [32].
- Developing and implementing nascent modern technology such as Blockchain-based systems or data-driven methodologies can provide a golden chance to trace and monitor the products throughout the supply chain [28,33,34]. However, high dependence on such technologies can also bring about irreversible outcomes, for instance, in countries with corrupt or authoritarian political systems.
- Socioeconomic status directly impacts the supply chain and vaccination of a population. Therefore, stratifying the population in vaccination administration helps keep the risk of vaccine waste and disposal at a lower level [21].
- The flow of information between different parties in the vaccine supply chain plays a key role in diminishing ambiguity and creating knowledge necessary to optimize the system operation [22]. In the conventional supply chain, the lack of proper communications between all involved parties leads to disruptions in the flow of relevant information to the consumers.

### 3.3. Output Concerns

- Proper training and licensing actions are likely to allow health providers to facilitate agile vaccinations [25]. While many countries confront enormous hurdles in their vaccination program, it is critical to identify and support their existing strengths to aid their vaccination efforts [7]. When health facilities are overcrowded or individuals' access to vaccines is difficult, existing health volunteer campaigns and external aids to facilitate vaccination would be beneficial. However, the use of these aids requires a prior adequate training program.
- Postvaccination follow-up for tracking possible side effects is crucial for assessing vaccine safety [20,35]. It is also critical to evaluate the body's response and ability to produce enough antibodies to develop COVID-19 immunity. Some people may not produce enough antibodies and may need additional vaccine doses [27,36].

- Insufficient studies on the effectiveness of COVID-19 vaccines [37] may result in additional challenges. Individuals may experience different responses to the different types of vaccines produced by different manufacturers. Therefore, studying the rate of immune system responses to different types of COVID-19 vaccines among different population groups may help assign appropriate vaccine types and dosages to all communities.

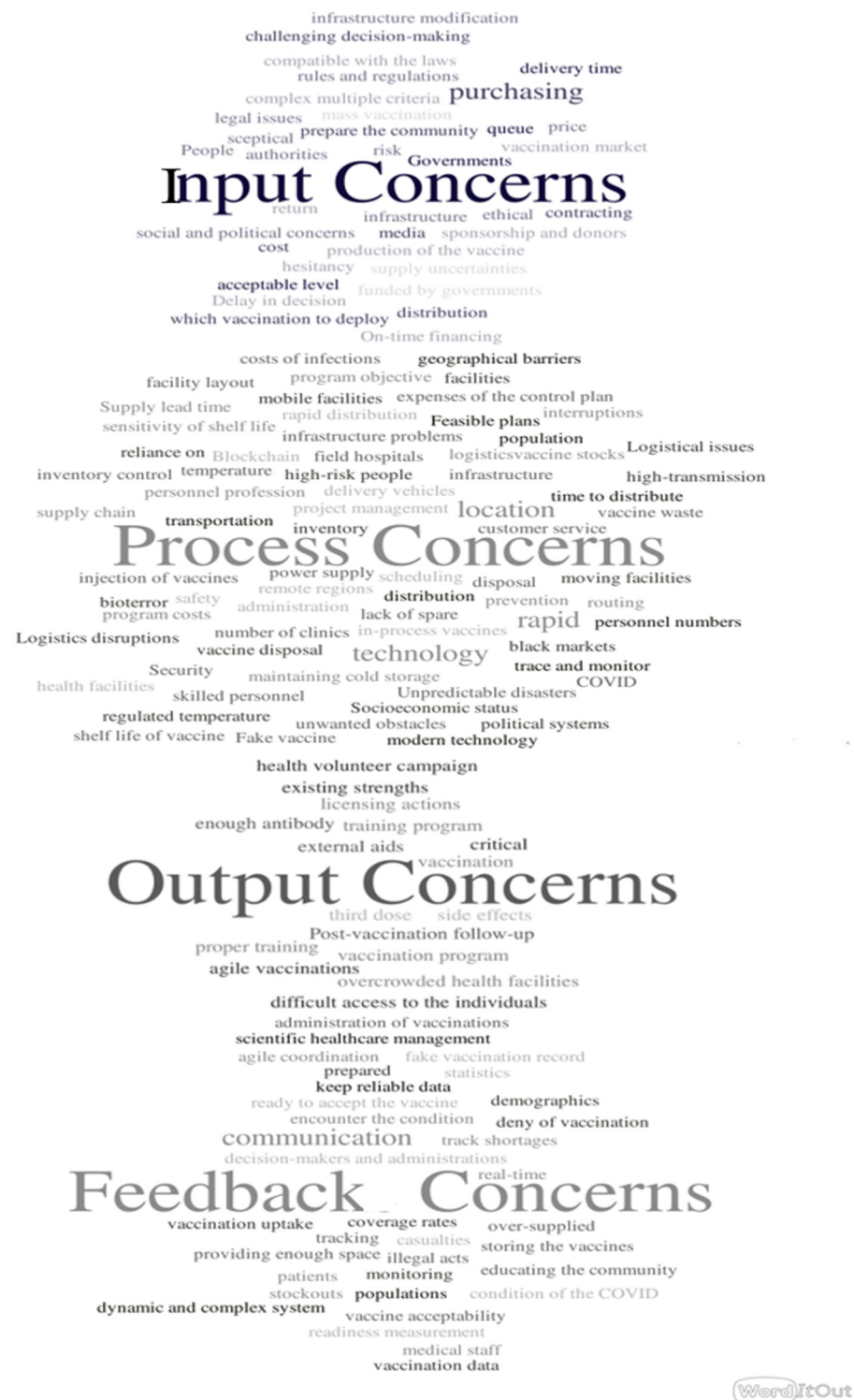
#### 3.4. Feedback Concerns

- Failing to communicate the facts about a condition, especially one that is a major public health concern such as COVID-19, leads to unpreparedness to counter the threat of the pandemic. The resulting lack of readiness to take care of patients, provide adequate vaccine storage space, and prevent casualties, directly relates to the lack of appropriate research-based healthcare management [38]. Therefore, it is strongly recommended that governments pursue homogeneous regulatory measures to secure the flow of information and public exposure to fact-based initiatives.
- Healthcare is a dynamic and complex system, requiring well-organized smooth-running procedures [11]. Some societies reported being on the lower end of the vaccine acceptability range [7,39]. Hence, falling behind in readiness, community education, and reliable communication may risk public vaccine acceptance [25,26,39] and lead to illegal acts, such as the recently reported use of fake COVID-19 vaccination record cards [40].
- After delivering the products, vaccine administration will be a Herculean effort. It will involve not just the necessity of keeping reliable data on population demographics, including rural, remote, and migrant populations, but also tracking vaccination uptake in real time to track shortages [7]. Due to poor data communication, communities may face shortages or vaccine surpluses, both of which jeopardize the success of the vaccination programs [8].
- Several concerns were expressed about vaccination data, including uptake and coverage rates, monitoring, and statistics. Thus, adequate data collection and tracking methods needed to be improved [25].
- Vaccination programs and initiatives may overlap; hence the lack of agile coordination between the authorities and decision makers may undermine their joint efforts and result in vaccination program failure [8,25].

#### 4. Conclusions

There is still a long way to go until the COVID-19 mass vaccination program is completed, and much research on the topic is required. This article serves as a springboard for additional research into this critical topic. It contributes to the ongoing study of the COVID-19 pandemic and points to management strategies to help manage the risks and tailor COVID-19 vaccination projects adequately and efficiently to avoid costly mistakes. As visualized by a word cloud in Figure 2, this paper provides a framework for public health organizations to deal with the vaccination programs in a more productive manner. To the authors' knowledge, this is the only such existing framework in the current debate. However, as already noted, vaccination program strategies and risks discussed here are largely interconnected, and this leaves many opportunities for future research on their interrelationships and preventative solutions. The authors also propose further research on drivers and impediments to a more productive vaccination supply chain, which can aid in a better understanding of supply risks.





**Figure 2.** Visualization of concerns via a system approach.

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