Data-Driven Management of Vaccination

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Vaccination is critical to preventing the spread of diseases. It stimulates the immune system to produce antibodies that fight specific diseases, eradicating and reducing their incidence.

enterprise architecture information technology vaccination digitalization

1. Introduction

Vaccination is an important tool for preventing the spread of infectious diseases and to minimize the risks of serious illness and death in modern healthcare. It is a safe and effective way to protect individuals and entire communities from serious diseases such as measles, polio, influenza and others. Vaccines work by stimulating the immune system to produce antibodies that fight specific diseases. They have helped eradicate diseases that were once widespread and greatly reduced the incidence of others. For example, the mortality rate from smallpox in the late 1800s ranged from 20% to 60%, with the vast majority of survivors left with disfiguring scars [1]. Lethality among infants was even higher: it was as high as 80% in London and 98% in Berlin. As a result of a number of smallpox control measures (including vaccination), the World Health Assembly declared the world population free of smallpox on 8 May 1980 and recommended that all countries stop vaccination [1]. Similarly, according to the United Nations and WHO, as a result of the planned vaccination most countries of the world were announced polio free (wild type of polio is fixed in Afghanistan and Pakistan, and there are cases of vaccine-derived polio in some countries of Africa) [2].

The success of vaccination programs has always depended not only on the quality of the vaccine itself, but also on the quality of the planning and organization of vaccination. Nowadays, an additional factor in the success of such public health interventions is the power of technology, namely data collection and analysis.

Monitoring the vaccination process through data collection and analysis has a range of objectives:

- Monitoring the progress of the vaccination campaign. This task involves providing a clear understanding of the size and structure of the population that has received a dose of vaccine. These actions make it possible to assess the progress of the campaign and the extent to which the vaccination plan has been fulfilled.

- Obtaining data for planning the next stages of the vaccination campaign. Understanding the current progress of the campaign and the structure of the vaccinated population allows planning the next stages of the campaign in

terms of timing, vaccine volumes, required medical personnel, orders to vaccination manufacturers, vaccine logistics by region and vaccination sites, and other parameters for future stages of the campaign.

- Monitoring the effects of vaccination. Monitoring the possible effects and side effects of vaccines is essential, both in terms of predicting their occurrence in certain groups of patients and in terms of refining vaccines for the next cycle of administration. Despite the proven benefits of vaccination, vaccines can cause complications in certain groups of patients with certain combinations of health factors. Despite this background, there is still a certain amount of hesitancy and skepticism about vaccination in some communities—such patients are not in favor of vaccination because of the lack of knowledge of all the consequences. However, it is important for developers to be aware of the actual side effects and possible complications of their product in order to create the safest vaccine possible.

2. Analyzing Research on the Effects and Side Effects of Vaccination

As the most cost-effective intervention in preventive medicine and an essential element of any public health program, vaccination is widely used with coverage of over 90% in many countries [3]. Vaccines can provide protection against infectious diseases by preparing the immune system to elicit an antibody- and/or cell-mediated response specific to the pathogen. Vaccine efficacy refers to the degree of protection that vaccination provides against health problems such as symptomatic illness, hospitalization, infection, and death. It is usually determined by comparing the occurrence of these health effects in vaccinated and unvaccinated persons.

Vaccines can also cause adverse and unintended effects. Manufacturing problems, improper handling, route of administration, genetic factors (e.g., race, gender, hormones, body mass index) and other factors have been linked to vaccine side effects [4][5][6]. Furthermore, highly immunogenic vaccines tend to cause more side effects than low-immunogenic vaccines [7]. These effects range from mild manifestations (e.g., itching, swelling, redness, fever, headache and/or pain at the injection site) to more serious physiologic changes that may even end in the death of the vaccinated person [8].

There are about 5–8% of people in developed countries who have autoimmune diseases. Those with these diseases may receive vaccines before or after the onset of the disease [3]. Some vaccines are associated with inflammatory diseases of the central nervous system.

As with any medication, there is a very small chance that the vaccine will cause a severe allergic reaction, other serious injury or death [9]. However, the issue of the occurrence of side effects and/or disease after COVID-19 vaccination has gained the most publicity in the last few years.

Researchers from Germany conducted a study of numerous cases of deaths occurring within a few days to a few months after COVID-19 vaccination. In each of these cases, the cause of death was found to be “natural” or “unknown.” Burkhardt became involved in the study only because the families of the deceased doubted these verdicts and sought counseling. In this regard, it is noteworthy that Burkhardt found that vaccination was the cause

of not a few, but most of these deaths. Although all four major gene-based vaccine manufacturers were represented in the sample of patients studied by Burkhardt and Lang, most patients received mRNA vaccine from Pfizer or Moderna [10].

The COVID-19 pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has resulted in an unprecedented global economic and public health downturn. Vaccination is one of the most effective interventions to significantly reduce severe morbidity and mortality from SARS-CoV-2 infection. Vaccination programs have been deployed all around the world, but most of these vaccines have been approved without comprehensive studies on their side effects and efficacy. Side effects are caused by the body's immune response and are common after vaccination. They may be a sign that the immune system is working and building a defense against COVID-19. Recently, new autoimmune events have been increasingly reported after COVID-19 vaccination (e.g., immune thrombotic thrombocytopenia, autoimmune liver disease, Guillain–Barré syndrome, IgA nephropathy, rheumatoid arthritis and systemic lupus erythematosus) [11].

The action of vaccines causes the immune system to produce antibodies, just as it does when you contract a disease. However, because vaccines contain only dead or weakened forms of germs, such as viruses or bacteria, they do not cause disease or risk complications of disease. Studying side effects after vaccination and COVID-19 disease is an important aspect of medical research. It makes it possible to evaluate the safety and effectiveness of vaccines and medicines and to improve prevention and treatment strategies. Summarizing the information from [12][13][14][15], several patients may experience long-term effects after recovery, such as fatigue, shortness of breath, cardiovascular abnormalities and others. Overall, studying side effects after vaccination and COVID-19 disease is a necessary step to ensure the safety and effectiveness of medical drugs and treatment strategies. In general, side effects after COVID-19 vaccination are mild, temporary, and similar to those that occur after routine vaccinations. They may vary between age groups (**Table 1**) [14].

Table 1. First side effects after COVID-19 vaccination by age group (compiled by authors).

	Children and Teenagers	Adults	
	From 6 Months to 3 Years Old	18 Years of Age and Older	From 4 Years Old to 17 Years Old
At the injection site	Pain in the leg or arm where the injection was given	Pain, swelling and redness in the arm where the injection was given	
All over the body	Swollen lymph nodes Irritability or tearfulness Drowsiness Loss of appetite	Swollen lymph nodes Fatigue Headache Muscle pain Chills	Fatigue Headache Muscle pain Chills Fever Nausea

Delayed effects after COVID-19 vaccination are also the subject of research. There are reports of more serious side effects, such as thrombosis and thrombocytopenia, that have caused some vaccines to be stopped.

Studying delayed effects after vaccination is an important aspect of monitoring vaccine safety. Medical organizations and states continue to collect data and conduct studies to identify any new side effects and take appropriate action. According to researchers [15], 8 groups of side effects can be distinguished that occur as new diseases in patients (**Table 2**).

Table 2. Delayed side effects (compiled by authors).

Groups of Side Effects	Patient Category	Number of Studies
Neurological diseases	Hospitalized patients	1
	Patients with an established diagnosis of COVID-19	15
Lung disease	COVID-19 patients with existing diseases	1
	Hospitalized patients	6
	Patients with an established diagnosis of COVID-19	14
	Patients recently recovered from COVID-19	1
Liver disease	Patients with an established diagnosis of COVID-19	5
Heart disease	COVID-19 patients with existing diseases	1
	Hospitalized patients	3
	Patients with an established diagnosis of COVID-19	14
	Patients recently recovered from COVID-19	1
Thrombosis	Hospitalized patients	4
	Patients with an established diagnosis of COVID-19	13
	Patients recently recovered from COVID-19	1
Kidney disease	Patients with an established diagnosis of COVID-19	8
	Hospitalized patients	1
Stroke	Patients with an established diagnosis of COVID-19	23
	Hospitalized patients	14
Other	All population groups	37

Based on this specific study [15], it can be concluded that stroke was most frequently diagnosed, while liver disease was diagnosed in the lowest number of cases.

Researchers [13] collected data from adult patients hospitalized in the internal medicine department of a French university hospital until May 2022, all who developed or had recurring immune-mediated diseases (IMDs) less than 3 weeks after COVID-19 vaccination, without other provoking factors. The hospital coverage roughly corresponds to the population of the Limousin region, namely 723,784 people, of whom 436,360 were older than 40 years. A total of 27 cases, 24 of them new, of IMD after vaccination with the COVID-19 vaccine were reported. IMDs had a protracted course in all but three patients and usually required high-dose glucocorticoids, combined with immunomodulators in 13 patients. One patient died of intractable rhabdomyolysis, while IMDs resulted in irreversible consequences in five patients. Eleven patients with well-controlled IMD completed their COVID-19 vaccination schedule and two suffered mild recurrences of IMD.

The study [12] set out that between 8 December 2020, and 4 July 2021, 1,240,009 users of the Covid Symptom Study app received their first dose of vaccine, out of these, 6030 (0.5%) later tested positive for SARS-CoV-2. In addition, 971,504 users reported receiving a second dose, of which 2370 (0.2%) tested positive for SARS-CoV-2. The study identified frailty as a risk factor for postvaccine infection in the elderly (≥60 years) after the first dose. Infected vaccinated individuals were less likely to have symptoms than infected unvaccinated individuals, and vaccinated participants, especially those aged 60 years or older, were more likely to be completely asymptomatic.

Currently, there is insufficient research on the incidence of vaccine-related side effects. Extensive research is needed to comprehensively evaluate the safety profile of vaccines. It is important to note that vaccines undergo rigorous testing and regulatory approval procedures to ensure their safety and efficacy before they are made available to the public. Although no studies have been conducted specifically on the incidence of side effects, vaccine safety is carefully monitored and evaluated throughout the vaccine development and distribution process.

3. Decision Analysis of Data Collection and Analysis of Vaccination Outcome Data

Unified state healthcare platforms refer to integrated systems that aim to streamline healthcare services and increase efficiency. An example of such a platform is the Unified State Health Information System (USHIS) in Russia. Such platforms integrate various aspects of healthcare, such as electronic medical records, patient management and telemedicine, into a single integrated system. By bringing together healthcare providers, patients and administrators, unified platforms facilitate communication and collaboration, leading to improved patient outcomes. They provide centralized data management, providing real-time access to patient information and improving care coordination. In addition, these platforms often include advanced analytics and artificial intelligence capabilities to identify trends, predict health risks and optimize resource allocation. Ultimately, unified public health platforms can revolutionize healthcare delivery and improve the overall quality and accessibility of healthcare services.

The Finnish Institute of Health and Welfare maintains Finland’s national vaccine register. Vaccination information is collected directly from patient record systems. The vaccine register covers data on vaccinations given in public

primary health care facilities. In addition, data on vaccines given in specialized health care facilities and private health care facilities are collected. The vaccine registry cannot check the vaccination records of an individual [16].

In the United States, the vaccination process is managed through a variety of solutions. VTrckS is the CDC's vaccine order management system, which processes approximately 80 million vaccine doses annually. IIS, formerly known as "immunization registries", allow vaccine recipients and providers to access immunization records. Vaccines.gov helps people find providers offering specific vaccines and allows providers to list vaccination locations and track inventory. IZ Gateway facilitates data sharing between ISI, other provider systems, and the IZ data lake. VAMS is a convenient online tool for managing vaccinations at clinics, ensuring safe processing from arrival to administration [17].

The Russian Federation Vaccination Registry is a single database containing information about all Russian citizens who have received the COVID-19 vaccine. Registration in the registry occurs automatically when vaccination is performed in a medical institution. The registry contains information about the citizen, including full name, date of birth, gender, personal identification number, social security number, and data about the vaccination—the name of the vaccine, date and place of vaccination, series and dose number. The Russian Federation Vaccination Registry allows for control of the vaccination process at the country level, and also provides an opportunity to promptly notify citizens about the need for re-vaccination [18].

In summary, the lack of universal architectures makes it difficult to collect and analyze comprehensive data on the impact of vaccination in a country and/or region. Without such systems, it becomes difficult to collect, consolidate and interpret vast amounts of information. This hinders the ability to understand the overall impact of vaccination on a population. The development and implementation of universal architectures will greatly enhance data collection efforts, providing valuable information on the effects of vaccination and informing decisions regarding public health policies and interventions.

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