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Data-Driven Management of Vaccination and Its Consequences

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Abstract: 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. However, despite the proven benefits, there is hesitation and skepticism in some areas due to side effects and lack of knowledge. Developing a data collection and processing system to analyze vaccination is critical in today's world. Vaccines are necessary to minimize morbidity and mortality, but success depends on analyzing data on vaccine use and efficacy. This system can identify potential side effects and adverse reactions, ensuring vaccine safety and building public confidence. This research focuses on IT support for analyzing vaccination side effects. The aim of this work is to develop an architecture model of the system to collect and process data on the health status of vaccinated patients. The research methodology consists of analyzing sources on the consequences and side effects of vaccination. On the basis of this knowledge, the key attributes (stakeholders, sources of information, input data, data analysis processes) of the data collection and analysis system were analyzed using an enterprise architecture approach. As a result, a general model of the architecture of the data collection and analysis system was proposed.

Keywords: digitalization; enterprise architecture; information technology; vaccination

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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:

1. 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.
2. 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.
3. 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.

The first two objectives are quite actively solved by governmental and medical authorities. The authors of this paper have also previously written about such solutions in their works [3,4]. The third of the listed objectives in the "development of a vaccination management system-integrated solution for collecting and analyzing data on vaccination outcomes" has received less attention in both the practice and research communities. Analyses of selected solutions in this area are presented in the literature review section.

The research objective of this paper is to develop an IT solution architecture (platform) for data collection and processing, integrated into a vaccination management system (national and/or regional) and aimed at effective monitoring and management of vaccination outcomes.

The article follows certain steps to achieve the objective:

Step 1. Analyze the effects of vaccination using COVID-19. In this article, the COVID-19 vaccination is used only as an example, in order to demonstrate the wide range of possible outcomes from just one vaccine and to justify the need to implement an automated (digital) solution to collect and process vaccination outcome data.

Step 2. Analyze existing solutions (organizational and IT) for collecting and analyzing vaccination outcome data.

Step 3. Formulate models of processes for managing the effectiveness of vaccination and the consequences of vaccination.

Step 4. Establish data requirements for vaccine effectiveness and vaccination outcomes management processes and information exchange between process participants.

Step 5. Propose a model architecture for a collection and analysis system (platform) for managing vaccination effectiveness and vaccination outcomes.

The paper is structured as follows: after the Methodology section, previous research on the research on the effects and side effects of vaccination and the potentials of data collection in the process of vaccination will be reviewed. In the Results and Discussion section, the motivational extension model for vaccination data collection and analysis system will be presented and discussed. The paper closes with the Conclusions.

2. Methodology

In the following, the contextualization (unless otherwise specified) refers to vaccination against COVID-19, the most recent large-scale viral infection, which, among other things, has intensified research in the field of virology itself, as well as related management, economic and IT mechanisms of vaccination management. The proposed research method-

ology, as well as the results and conclusions obtained, with certain adaptations, are also valid for cases of mass vaccination against other diseases.

The research methodology implemented to fulfill the formulated research steps is detailed below.

Step 1. Analyze the effects of vaccination using COVID-19 vaccines.

In order to develop a comprehensive solution for monitoring the effects of vaccination, it is important to understand the data structure that comprehensively describes these effects, which requires the review of the existing research. A search for scientific papers in PubMed was conducted using the terms ("BNT162b2" OR "mRNA COVID-19 Vaccine" OR "ChAdOx1 nCoV-19" OR "adenovirus-vectored COVID-19 vaccine") AND ("effectiveness" OR "reinfection" OR "side-effects" OR "adverse effects" OR "reactogenicity" OR "phase IV"). The search was not limited by language or publication type.

During the analysis phase, relevant sources were selected to analyze the effects of vaccination, identify side effects and describe fatalities. The analysis results are summarized in the literature review.

Step 2. Analyze existing solutions (organizational and IT) for collecting and analyzing vaccination outcome data.

The development of the authors' solution for monitoring the effectiveness of population vaccination should certainly be based on the best existing practices of different countries. Many countries monitor side effects after vaccination in order to quickly identify any problems and take the necessary actions [5–14]. An internet search was conducted for the query "vaccination support information systems". The following most relevant solutions were identified: the national vaccine registry in Finland; the Vaccine Tracking System (VTrckS), Immunization Information Systems (IIS), Vaccines.gov, IZ Gateway and Vaccine Administration Management System (VAMS) in the USA and the vaccination registry in Russia.

The results of this analysis are also reported in literature review.

Step 3. Formulate models of processes for managing the effectiveness of vaccination and the consequences of vaccination.

The systemic cybernetic approach to the analysis of socio-economic systems implies considering any phenomenon in context first—as part of the upper-level system of which it is an element. The top-level system for the process of vaccination and monitoring of its consequences is the entire life cycle of the vaccine. In implementing this stage of research, the authors relied on their previous results in this direction [3,4].

Step 4. Establish data requirements for vaccine effectiveness and vaccination outcome management processes and information exchange between process participants.

This step includes identification of the concerns and requirements for the data collection and processing system from all the stakeholders. In the enterprise architecture terminology, it can be presented in the form of the motivation extension model.

Step 5. Propose an architecture model for a collection and analysis system (platform) for managing vaccination effectiveness and vaccination outcomes.

The upper-level architecture model of the vaccination data platform should describe the following elements: data sources, input data, data processes, data analysis tools, data recipients, and data processing results.

The architecture of a data collection and analysis system relies on the interconnectedness of elements under the principle of "service requirements—service in response to requirements". To create an effective IT support system for analyzing the impact of vaccination, it is important to understand the underlying processes and build the system based on their requirements. Designing an architectural model involves identifying key stakeholders, understanding their goals, and defining their requirements. By taking these elements into account, a comprehensive and well-designed IT support system can be developed to facilitate vaccination impact analysis [15–18].

3. Literature Review

3.1. 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 [19]. 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 [20–22]. Furthermore, highly immunogenic vaccines tend to cause more side effects than low-immunogenic vaccines [23]. 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 [24].

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 [19]. 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 [25]. 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 [26].

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) [27].

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 [28–31], 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) [30].

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

	Children and Teenagers		Adults 18 Years of Age and Older
	From 6 Months to 3 Years Old	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 [31], 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
	COVID-19 patients with existing diseases	1
Lung disease	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
	COVID-19 patients with existing diseases	1
Heart disease	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 [31], it can be concluded that stroke was most frequently diagnosed, while liver disease was diagnosed in the lowest number of cases.

Researchers [29] 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 [28] 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 ($\geq$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.

PubMed was used to search for the relevant articles for specific terms: ("BNT162b2" OR "mRNA COVID-19 Vaccine" OR "ChAdOx1 nCoV-19" OR "adenovirus-vectored COVID-19 vaccine") AND ("effectiveness" OR "reinfection" OR "side-effects" OR "adverse effects" OR "reactogenicity" OR "phase IV"). The search was not limited by language or type of publication.

Along with the original studies, we found one published article and two preprints on data from Israel that examined the efficacy of the Pfizer-BioNTech (BNT162b2) vaccine, a preprint from the U.K., which examined the efficacy of the BNT162b2 and Oxford-AstraZeneca (ChAdOx1 nCoV-19) vaccines in people aged 70 years and older, and a study linking the medical records of all vaccinated people in Scotland to examine hospitalizations and mortality after COVID-19 vaccination.

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. The present study does not aim to analyze the severity and magnitude of vaccine effects, but to develop a system that allows data to be collected and analyzed for such purposes.

3.2. 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.

We must consider the systems in place in various countries to monitor the effectiveness of vaccination of the population.

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 [11].

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 [6].

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 [9].

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.

4. Results

4.1. Requirement to the Vaccination Data Collection and Analysis System

The system–cybernetic approach to analyzing complex systems and the Continuous Acquisition and Lifecycle Support (CALS) approach emphasizes the importance of considering any element of the system in the context of other elements—parts of the upper-level system. The same is true for processes: it is useful to consider each individual process in the context of the entire life cycle (or company) or value chain. Therefore, it is useful to begin modeling the process of vaccine effectiveness and outcome management processes by understanding its place in the overall vaccine cycle. It helps to identify its interfaces with related processes, inputs and outputs as well as stakeholders (providers and recipients of data and results).

Product life cycle models [32–34] or CALS model [35] can be considered as a reference life cycle model. In the present study, the model is based on the Deming cycle (PDCA-cycle) [36]. This framework speaks about the cycle of continuous improvement when working with the selected object: planning of activities, their implementation, collection and analysis of data during the implementation, development of corrective actions based on the analysis, and entering a new cycle with new inputs. Ilin et al. have explored this issue in detail in their previous articles [3,4]. The life cycle proposed in Figure 1 involves the sequential execution of a series of steps.

The data collection and processing system should interact directly with the following processes:

1. Monitoring of the epidemiological situation;
2. Vaccine development;
3. Vaccination;
4. Vaccine planning and monitoring.

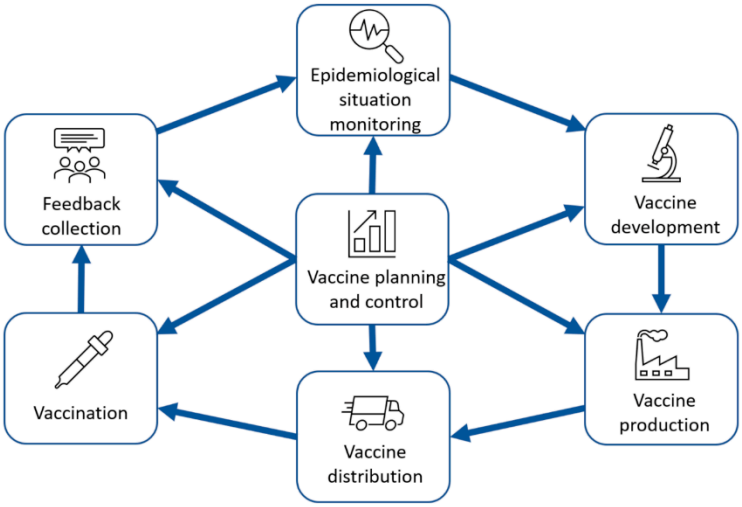

Figure 1. Life cycle of vaccines [4].

Stakeholders in the development of a data collection and processing system to analyze vaccination effectiveness are the ministry of health, medical organizations, patients, and vaccine developers and manufacturers (hereinafter referred to as developers). Each of the stakeholders has different goals in developing a system that will help them operate more efficiently. Increased efficiency for each stakeholder manifests itself in a variety of ways—from reducing the time spent analyzing the public health situation to increasing accuracy in vaccine selection while reducing the risk of adverse events. A model of key goal-setting attitudes (related in the architectural approach to the so-called motivational extension of the system architecture) is presented in Figure 2.

Effective monitoring of health status, trends, progress and performance of the health system requires the collection and analysis of data from a variety of sources on various health issues. Strengthening the capacity of the Ministry of Health to collect, collate, analyze, and use health data is critical. This primarily involves obtaining data from demographic sources, such as household surveys and civil registration systems, as well as institutional sources, such as administrative and operational activities of health facilities.

Regular, reliable data from health facilities and the resource systems that support them are needed to ensure access to and improve the quality of health services. Data from health facilities enables clinical management, disease monitoring, facility management, health sector planning, and monitoring of service coverage and effectiveness. After COVID–19, such data will become critical for assessing the impact on health workforce capacity and essential services to improve future preparedness.

Ministry of Health addresses five global vaccination challenges:

1. Monitoring and analysis of the effectiveness of vaccine-preventive measures, including impact analysis and effectiveness of individual vaccines;
2. Planning, provision and distribution of vaccines to the population;
3. Development and updating of the national vaccination calendar;
4. Support for research and development in the field of vaccine prophylaxis;
5. Developing and monitoring the implementation of national vaccine prevention programs, including programs for certain categories of the population.

The solution of these tasks creates an opportunity to adjust health care activities, which, in turn, will allow for the most effective implementation of vaccination policy in the population.

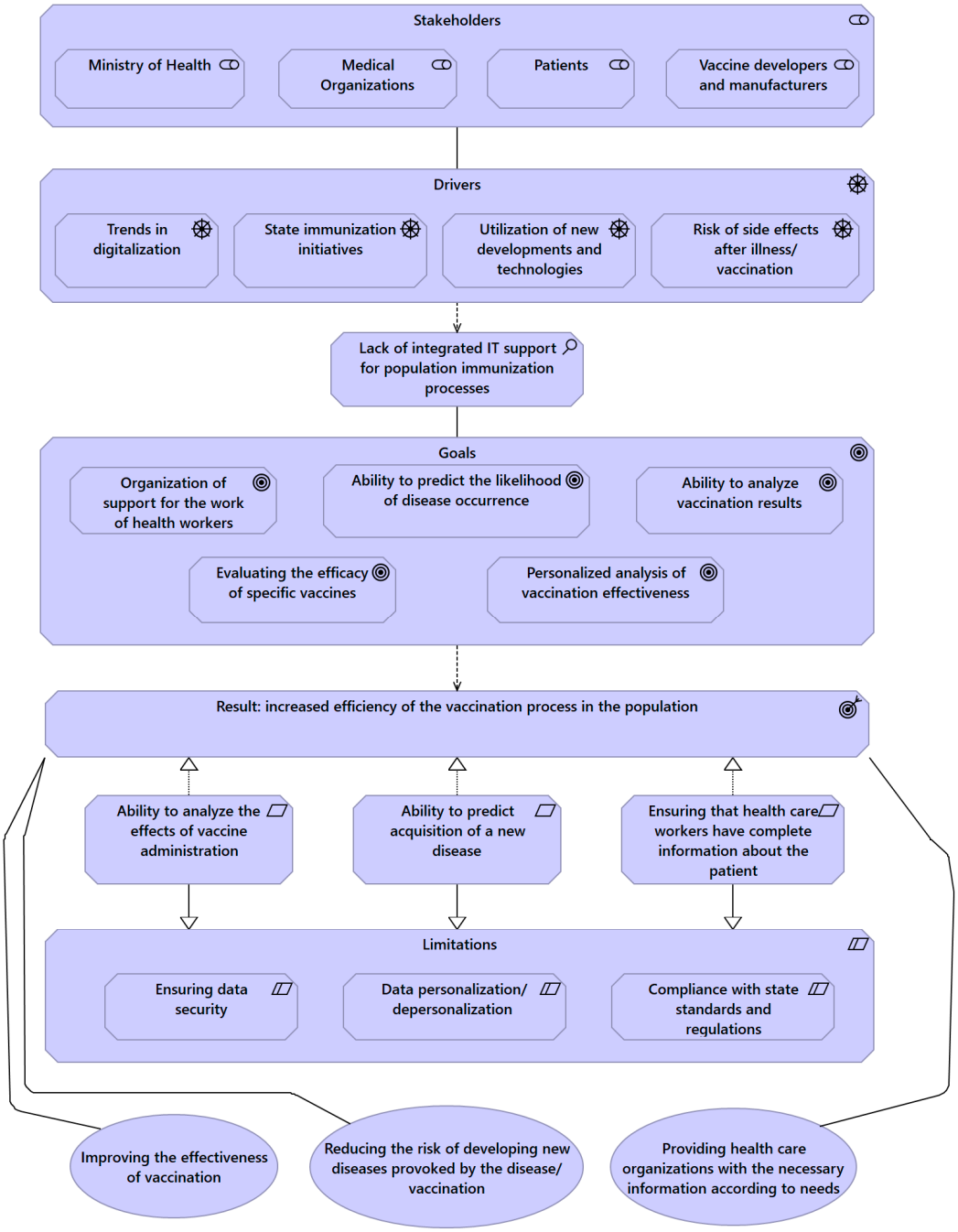

Figure 2. Motivational Extension Model for Vaccination Data Collection and Analysis System (compiled by the authors).

Vaccine development and production is a long, complex process that often lasts 10–15 years and involves a combination of public and private involvement. The modern system of vaccine development, testing and regulation evolved in the 20th century as interest groups standardized their procedures and regulations. Vaccine development, testing and production follow a standard set of steps. The first stages are exploratory in nature. Regulation and oversight increase as the candidate vaccine moves through the process. Vaccine developers have the following objectives during vaccination:

- Analyzing the efficacy of the developed vaccine;
- Vaccine market share and structural market share analysis;
- Analyzing the effects of vaccination.

Medical organizations and vaccination centers are directly involved in the provision of vaccination services to the patient. When going to a hospital or vaccination center for a pre-vaccination check-up, it is important to determine whether the patient has any contraindications to a particular medication. Therefore, the medical organization has the following objectives:

- Reducing the risks of postvaccine complications;
- Providing personalized help with vaccine selection;
- Getting comprehensive information about a patient's immunizations.

The patient, in turn, needs to be immunized in a timely manner with the vaccine that is most effective for him or her.

In order to solve a particular problem, each stakeholder needs to have information that will help them make the right decision. For example, in order to monitor and analyze the effectiveness of vaccine preventive measures, including impact analysis and the effectiveness of individual vaccines, the Ministry of Health needs to have data that will allow it to generate aggregated data on the following population groups:

1. successfully completed vaccination,
2. completed vaccination with disease acquisition,
3. incomplete vaccination,
4. fatalities.

Such data are vaccination/revaccination coverage (by vaccine type, by population group, by region, etc.), complication statistics, fatality statistics, etc.

To address the vaccination objectives of each stakeholder, the following data must be made available (see Table 3).

Table 3. Vaccination data, required by stakeholders.

Input Data	Analytical Data
1. Personal and depersonalized patient data; 2. Nomenclature of vaccines used; 3. Data on vaccine suppliers and manufacturers; 4. Vaccination and revaccination coverage by various criteria (i.e., age; gender; place of actual residence; vaccine manufacturer; number of revaccinations; previous illness); 5. Complication statistics; 6. Mortality statistics; 7. Statistics on preferred vaccines.	1. Types of complications depending on the vaccine; 2. Types of complications according to age, sex of patient; 3. Types of complications depending on the number of revaccinations; 4. Types of complications depending on chronic diseases; 5. Recommendations from a medical decision support system for vaccine selection

At the moment, it is difficult to obtain all the data discussed above as they are all stored in different systems, registries, hard copies, etc. For example, the following data can be obtained from a patient's electronic health record (EHR) and Vaccination Registry (see Table 4).

All of the above data can be obtained from the Medical Information System (MIS), specifically the EHR and the immunization registry. MISs are digital systems that use open data from a variety of sources, ethically applying effective ICT tools to create strategic information for public health. An EHR, as part of an MIS, is an electronic record of a patient's medical data maintained by a physician. It includes administrative and clinical information such as demographics, progress reports, medications, vital signs, medical histories, immunizations, laboratory data and radiology reports.

However, with incomplete information, it is possible to make mistakes that will reduce the effectiveness of vaccination activities. In order to increase the efficiency of vaccination activities, reduce the number of errors in vaccine selection and generally improve IT support of the health care system, it is necessary to develop a system of data collection and processing, which will allow solving all the tasks of stakeholders described above.

Table 4. Patient data stored in EHR and Vaccination Registry.

EHR	Vaccination Registry
1. Surname, first name of the patient; 2. Date of birth of the patient; 3. Data of the patient's identity document; 4. Patient's address; 5. Patient's phone number; 6. Health insurance policy number; 7. Patient's EHR identification number; 8. Age of the patient; 9. Presence of harmful and/or hazardous production factors at work; 10. Patient's health group; 11. Smoking; alcoholism; drug addiction/medication dependence; 12. Allergic history; 13. Presence of disability in the patient; 14. Chronic diseases; 15. Code of the medical worker who conducted medical examinations; 16. Date of medical examination; 17. Symptoms and (or) complaints detected during medical examination; 18. Diagnosis established by medical examination; 19. Attending physician comments.	1. Presence of COVID-19 disease; 2. Contact with sick persons within 2 weeks; 3. Influenza vaccination; 4. Vaccination against pneumococcal infection; 5. Reactions to previous vaccines; 6. COVID-19 vaccine preparation; 7. Vaccine serial number; 8. Reaction immediately after injection; 9. General reactions; 10. Local reactions (at the site of vaccine administration).

Each task, which is set by a stakeholder, entails requirements to the services of the developed system. Thus, it is possible to define the following requirements for the services of the data collection and processing system of the Ministry of Health. The system should:

1. allow for analysis of the effects of vaccination;
2. allow monitoring of vaccination progress;
3. be able to generate aggregated reports on vaccination, including on post-vaccine complications;
4. allow access to data on outcomes following the administration of a particular vaccine;
5. allow the formation of population groups according to postvaccine complications that have occurred.

All three challenges for vaccine developers concentrate on the need to have data on the current status of the vaccination process and on emerging new diseases. This fact forms the following requirements for data collection and processing system services. The system should:

1. allow generating aggregated reports on vaccination, including on post-vaccination complications;
2. provide access to data on outcomes following administration of a particular vaccine;
3. allow the formation of population groups according to postvaccine complications that have occurred.

Vaccine developers and manufacturers do not need to obtain data containing a patient's full name; however, it is important to obtain data with age, chronic diseases, vaccine delivered, etc.

Medical organizations and vaccination centers are directly involved in the provision of vaccination services to the patient. When going to a hospital or vaccination center, it is important to determine whether the patient has contraindications to a particular drug during the pre-vaccination examination. The tasks of medical organizations entail the following requirements to the system of information collection and processing. The system should:

1. generate data for the Physician Decision Support System (PDSS) to make recommendations for vaccine selection;
2. provide access to personalized vaccination data.

The patient, in turn, needs to receive data on the vaccine delivered in order to track vaccination information and to provide this information to government agencies and organizations that do not have access to the system.

Thus, the patient should only be able to view their own data, access to other patients' data should be restricted, and they should receive notifications when they need to be vaccinated.

All the above requirements are combined into seven general requirements for the data collection and processing system, covering the needs of all stakeholders (Figure 3). The system should:

1. allow for analysis of the effects of vaccination;
2. allow monitoring of vaccination progress;
3. be able to generate aggregated reports on vaccination, including on post-vaccine complications;
4. allow access to data on outcomes following the administration of a particular vaccine;
5. allow the formation of population groups according to postvaccine complications that have occurred.
6. provide recommendations for vaccine selection;
7. provide access to personalized vaccination data.

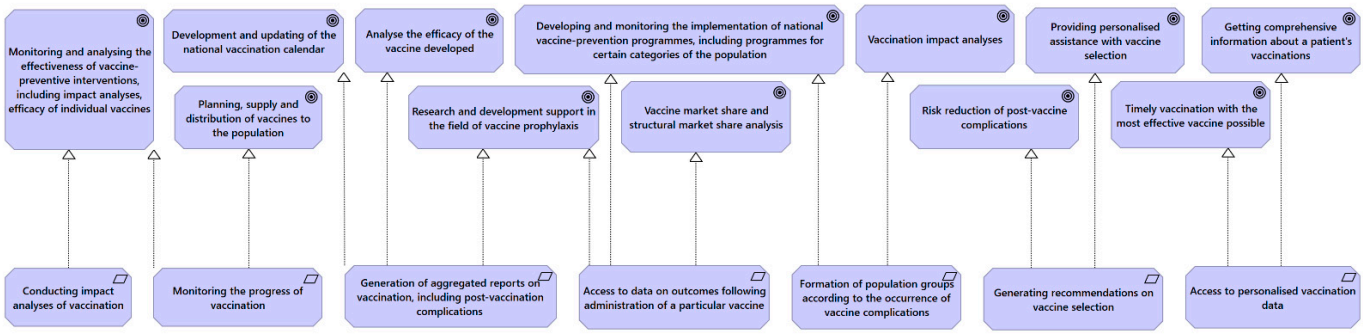

Figure 3. Requirements view for the data collection and processing system (compiled by the authors).

4.2. Architecture of the Vaccination Data Collection and Analysis System

The architectural model of a data collection and analysis system is based on the description of the following components:

1. Data sources: the system should identify all data sources. According to all the materials discussed above, we identify the following key data sources: EHR in MIS, vaccination registry, state health platform.

The State Healthcare Platform is the main, supporting element of the country's unified digital healthcare circuit. Its main goal is to ensure that key participants of the healthcare system are connected and work together seamlessly.

MIS is a software platform designed to manage and store patient data and other health information within medical organizations (hospitals). The system is used by health care providers to track patient medical records, treatment plans, medications, and other important information. The system is designed to provide easy access to information for authorized users.

The EHR is a digital version of a patient's medical history and health information. This record contains a wide range of data, including the patient's allergies, medications, current and past illnesses, and any treatments or procedures the patient has undergone. EHRs are often used by health care providers to make informed decisions about a patient's

care, and they can be shared among different providers to ensure that everyone involved in a patient's care has access to the same information.

The vaccination registry covers data on vaccinations given in public primary health care facilities. In addition, data are collected on vaccines given in specialized health care facilities and private health care facilities.

2. *Input data* are data from the data sources needed to make the right management decision.

3. *Data processes:* a mechanism to collect data from the EHR and vaccination registry in a standardized format. This will require the development of data collection tools and processes that comply with regulatory standards. In this sense, nowadays data storage systems traditionally appeal to ETL (Extract, Transform, Load) processes, as it affords to use a wide variety of information sources. Among the ETL tasks in this process are filtering, cleaning, merging, splitting, separating and sorting data.

4. *Data analysis tools:* generate reports and visualizations that help stakeholders make informed decisions.

The system can transmit data to PDSS to generate recommendations for physicians to reduce the risk of postvaccine complications, reports on vaccination progress, and reports on the occurrence of new diseases after vaccination. PDSS is a tool designed to help health care providers make clinical decisions. The system uses patient data, medical knowledge, and decision-making algorithms to help clinicians diagnose and treat a variety of conditions. It is important to note that PDSS does not replace the clinical expertise of health care providers, but rather serves as a valuable tool to help make decisions and improve the quality of health care services provided.

The system formed on the basis of the described logic meets all the requirements that are put forward to it by the selected groups of stakeholders (Figure 4).

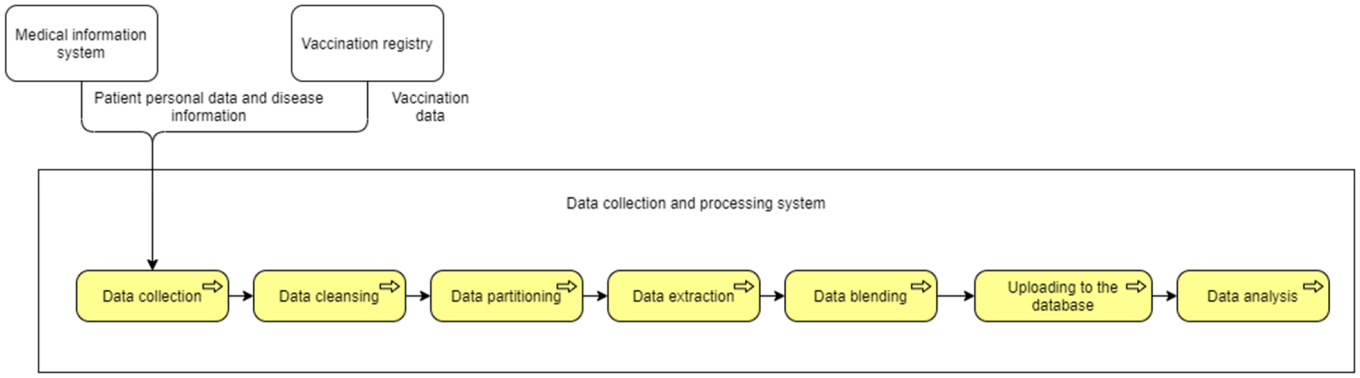

Figure 4. Transfer of data from MIS and vaccination registry to data collection and processing system (compiled by the authors).

5. *Data recipients:* those who get the results of data processing, who are much the same as data sources.

6. *Data processing results*: each stakeholder has access to data that are available to them and that meets their requirements for the system. In turn, the data obtained by stakeholders helps to achieve the vaccination objectives.

A mechanism for moving data from a EHR and vaccination registry to a data collection and processing system that analyzes vaccination outcomes is essential to ensure that patients receive appropriate vaccines and to monitor vaccine safety and efficacy. The use of EHRs and vaccination registries will simplify the collection and storage of patient vaccination information. However, the challenge is to ensure that the information is easily accessible and can be used for analysis. To this end, architectural models of the data collection and processing system need to be developed.

To access the required data, it is necessary to consider the access interfaces for each of the stakeholders. For the Ministry of Health, it is available to obtain the necessary

information through the unified state health platform. Medical organizations can obtain information from the MIS. The patient can view the data in the Electronic Immunization Certificate. With a personal account, patients can track their interactions with government agencies and receive alerts and updates on important changes that may affect them, such as being notified when vaccinations are due. Moreover, with the increased emphasis on digital services, having a personal account is more important than ever, as it allows for transactions and communication with government agencies remotely, saving the patient time and effort.

An electronic immunization certificate is a digital document that proves that a person has been vaccinated against a particular disease. This certificate contains information about a person's immunization history, including the type of vaccine administered, the date of administration, and where it was administered. The electronic vaccination certificate is becoming increasingly popular because it eliminates the need for physical copies of vaccination records and can be easily accessed from anywhere via a mobile device or computer. This certificate can also be used as a travel document, allowing people to demonstrate their vaccination status and enter countries that require proof of vaccination. Overall, an electronic vaccination certificate is a convenient and secure way to keep track of immunization records and facilitate travel.

Using the interfaces described above, each stakeholder has access to data that are available to them and that meets their requirements for the system. In turn, the data obtained by stakeholders helps to achieve the vaccination objectives. The data flow model is presented in Figure 5.

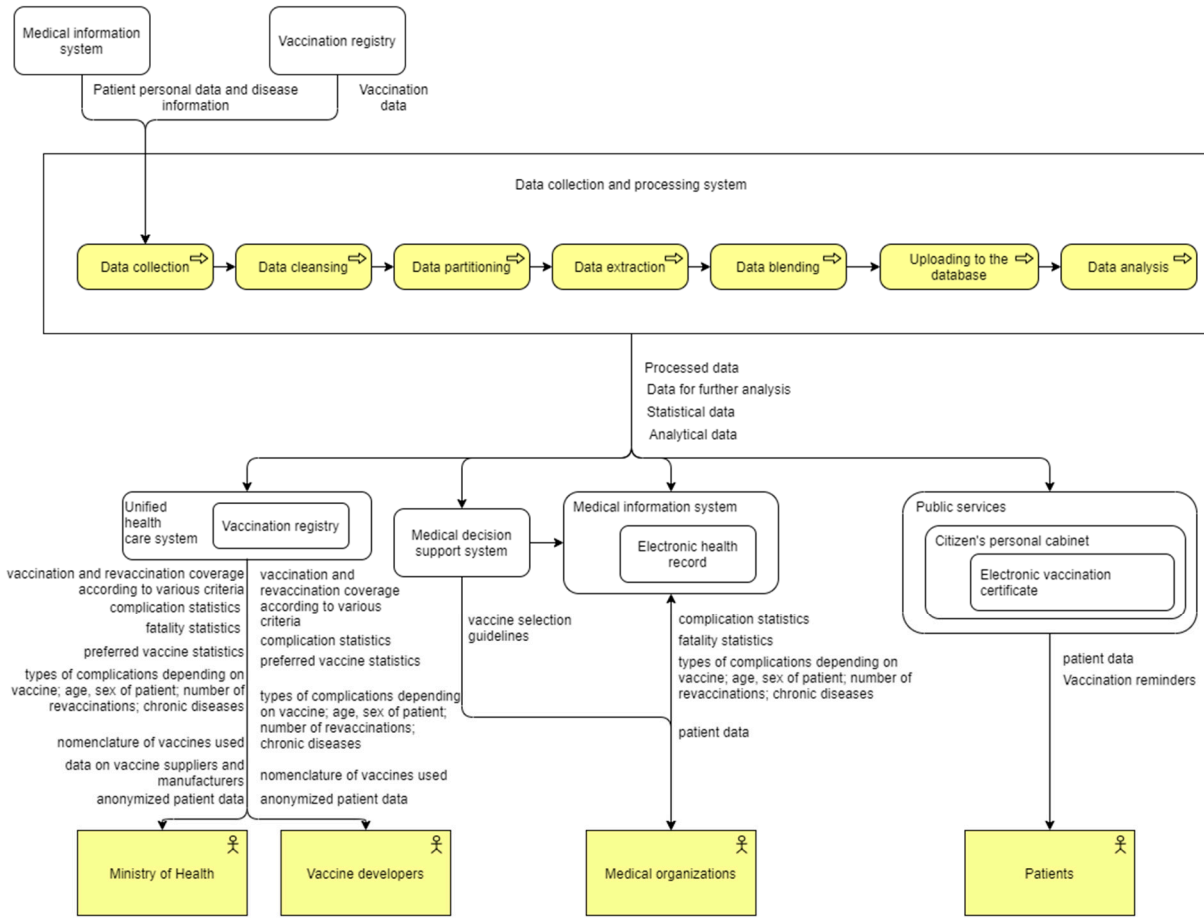

Figure 5. Data flow model (compiled by the authors).

Patient personal and disease data, as well as vaccination data from the MIS and vaccination registry, are transferred to a data collection and processing system. This system collects, cleanses, distributes, extracts and blends data as part of the ETL process, followed by loading the data into a database and initial analysis. After the data are analyzed, the processed data, data requiring further analysis, statistical and analytical data are available for stakeholders through different interfaces—the Unified state healthcare information system, PDSS, MIS (namely the electronic medical card), electronic vaccination certificate in the personal cabinet of the citizen. The data obtained from the systems allow stakeholders to solve the tasks outlined above, which leads to an increase in the effectiveness of vaccination activities in the country. Let us take a closer look at the effects of the project implementation.

5. Discussion

The collection and analysis of vaccination data are essential to ensure the success of vaccination programs. A data collection and processing system appears to be a necessary tool for monitoring vaccination programs, assessing the effectiveness of vaccines and minimizing the risks of disease and, even more so, fatalities caused by infectious diseases, as well as minimizing the risk of complications from vaccine administration. The present study focuses specifically on the development of requirements for such a system and the formation of architectural models based on them. The model proposed in this article is built as the extension of the existing solutions in this area in different countries. It allows improving the existing models in the vaccine industry and introducing new ways to analyze the effectiveness of vaccination and adverse reactions to vaccines. The proposed model is limited by the national level. But definitely such a solution can also be interesting in a cross-border format as vaccination consequences and side effects can be a matter of global healthcare community. This can be the task for future study. Among others, such a study requires a great focus on standards and interoperability issues.

According to the authors, the solution proposed in the article is intended to improve the quality of vaccine life cycle management and provide prerequisites for the introduction of personalized medicine principles in the field of vaccination. In particular, stakeholders will benefit from the realization of such a platform in the following ways:

- Patients: maintenance of vaccination history and the possibility to take into account the specifics of the medical history when choosing a vaccine;
- Medical organizations/physicians: awareness of the patient's vaccination history and the ability to predict complications and side effects based on the patient's medical history;
- Vaccine developers: information on complications and side effects of the vaccine (including for certain populations) for further refinement of the vaccine and development of new vaccines;
- State health authorities: understanding the results of vaccine campaigns (including by population groups), bottlenecks and areas of development of vaccination systems.

It is obvious that the authors have considered only the initially necessary block of functions of such a system. In the future, it will be possible to develop the functionality of such a platform and integrate it with other IT solutions in health care, pharmaceutical industry, R&D systems, medical education, public procurement systems, etc. In previous works [3,4,37,38], the authors elaborated on the context in which vaccination should be viewed from a systems–cybernetics approach.

Contextually, in this paper, the requirements for a vaccination data collection and processing system largely address the needs of health care organizations and patients/citizens, while the needs of vaccine developers are presented in less detail. This is due to firstly, with the priority of the tasks to be solved, since it is important, to create a kind of MVP for qualitative monitoring of the situation; and secondly, due to the specificity of the tasks faced by vaccine developers. The problems associated with in-depth assessment of the risks of individual complications seem to be a promising subject for a separate study in cooperation with specialists in the field of biotechnology and genomics [39–42].

The issues of cybersecurity of the developed solution have been left out of the scope of this article, which will be the subject of a separate detailed study, since personal data security is a very subtle, multidimensional issue of modern healthcare. There are a relatively large number of publications devoted to this problem [43–49].

We emphasize again that this study focuses on the outcomes and consequences of vaccination, specifically against COVID-19 as a prime example of a recent epidemic. For the study, it was necessary to focus on a specific example so that the solution would not be too generalized and undetailed. However, the use of the proposed reasoning algorithm to collect requirements in a similar system for the analysis of consequences after vaccination against other diseases is also possible, after consideration of additional factors characterizing a particular disease and the specifics of its course and consequences. In practice, it seems reasonable to create a unified system for collecting and processing data on vaccination against a selected list of critical diseases.

6. Conclusions

By collecting and analyzing data on vaccine consumption, adverse events and vaccine efficacy, the government and public health authorities can monitor the reality of the situation and improve the effectiveness of vaccination programs based on real data. This information can help develop public health policies, ensure vaccine safety and efficacy, and build public confidence in vaccination programs. Therefore, it is important to invest in the development of robust data collection and processing systems to support ongoing infectious disease control.

The main effects of the project are the development of the health care sector by the implementation of principles of continuous improvement and personalized medicine into the vaccine development and use; the possibility of predicting the acquisition of a new disease after vaccination; providing medical professionals with complete information about the patient; improving the quality of medical services; reducing the risk of new diseases provoked by the disease and/or vaccination; the possibility of analyzing the effects of vaccines; and adjusting vaccination policies in connection with the development of new ways of vaccination of the population with the use of vaccines and vaccination programs.

The authors in the article proposed their vision of the architecture of a national (regional) platform for the collection and processing of data on the effectiveness of vaccination. The proposed solution is developed using the architectural approach—a recognized systematic method of designing human–IT systems. By identifying rare side effects, patterns and trends of side effects, strengthening public trust in vaccines and improving vaccine safety monitoring, this system can help ensure that vaccines remain a safe and effective means of disease prevention.

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