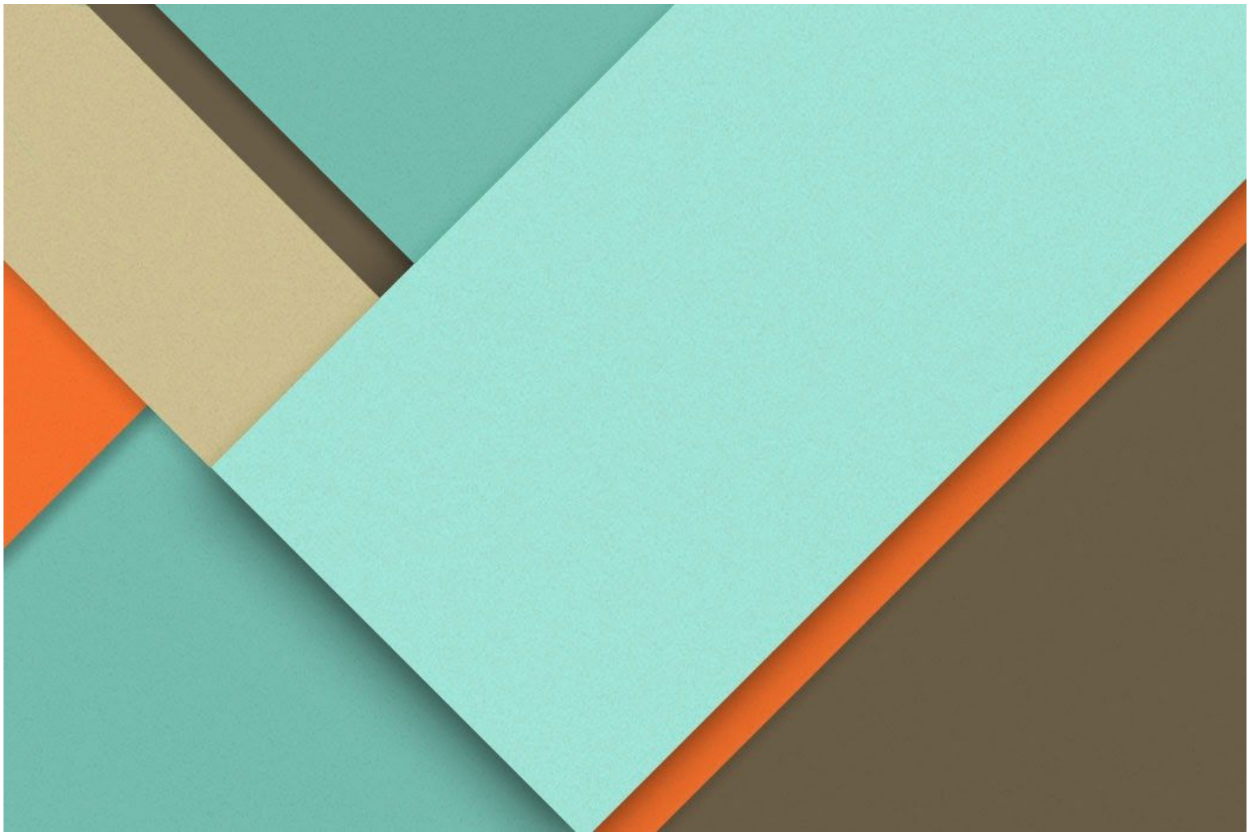

# Vaccine-Log

Documentations


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[Gitlab - Vaccine_Log [Repo link]]

# Overview

The Immunization Programme is one of the key interventions for the protection of mankind from preventable life-threatening conditions. This project helps the vaccination procedure be easier, secure, flexible and reliable. By building a DApp, we are collaborating conventional database & Blockchain technology to get a more secure and reliable vaccination procedure which ensures the quality and traceability of vaccines provided in the health centres and community centres.

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# Introduction

The Immunization Programme is one of the key interventions for the protection of children from preventable life-threatening conditions. It is one of the largest immunization programmes in the world and a major public health intervention in the country.

The Immunization Programme in India was introduced in **1978** as the **Expanded Programme of Immunization** (**EPI**). The programme gained momentum in **1985** and was expanded as **Universal Immunization Programme** (**UIP**) to be implemented in a phased manner to cover all districts in the country by 1989-90. UIP became a part of Child Survival and Safe Motherhood Programme in 1992 Since, 1997, immunization activities have been an important component of National Reproductive and Child Health Programme and is currently one of the key areas under **National Rural Health Mission** (**NRHM**) since 2005.

Under the Universal Immunization Programme, Government of India is providing vaccination to prevent seven vaccine-preventable diseases i.e.

- Diphtheria,
- Pertussis,
- Tetanus,
- Polio,
- Measles,
- The severe form of Childhood Tuberculosis and Hepatitis B,
- Haemophilus influenzae type b (Hib) and Diarrhea

When tourists do get an infection in India, often that infection could have been prevented with a vaccine. In India, children get more vaccines than in most other countries. Even though only around 60% of the Indian population is getting vaccination when other countries have above 80%. From 2012-2016 many cases were reported due to the lack of disease preventable vaccines. Pneumococcal viruses are causing many deaths in India, As per recent surveys, one in five children died in Global is in India. Community Health Centres and other Health Programmes are making small gradual progress even though they are not enough.

India is one of the top countries which exports a large number of vaccines. Even though there are many factors which hold back India to get proper health assessment.

Some of them are due to:

- The lack of proper management,
- The quality of vaccines,
- Availability of vaccines in rural areas,
- Vaccine storage,
- Lack of data  regarding the disease for further R&D,
- Less reporting and observation of problems,
- The Exploitation of private Pharmaceutical Companies

Even small countries with less capital income than India are providing more immunization vaccines. India is one of the largest countries which produce more vaccines, in that one-third of that are produced by private Pharmaceutical companies.

So to get a proper vaccination, all the details regarding the vaccination need to be recorded and traced to improve the quality and management of vaccines. To provide that this DApp is used by taking advantage of the blockchain properties like immutability and high traceability, etc...

# What is Vaccination?

Vaccination is the administration of a vaccine to help the immune system develop protection from disease. Vaccines contain a microorganism or virus in a weakened, live or killed state, or proteins or toxins from the organism. In stimulating the body's adaptive immunity, they help prevent sickness from an infectious disease. When a sufficiently large percentage of a population has been vaccinated, herd immunity results. Herd immunity protects those who may be immunocompromised and cannot get a vaccine because even a weakened version would harm them. The effectiveness of vaccination has been widely studied and verified. Vaccination is the most effective method of preventing infectious diseases widespread immunity due to vaccination is largely responsible for the worldwide eradication of smallpox and the elimination of diseases such as polio and tetanus from much of the world.

The first disease people tried to prevent by inoculation was most likely smallpox, with the first recorded cases occurring in the 16th century in China. It was also the first disease for which a vaccine was produced. Although at least six people had used the same principles years earlier, the smallpox vaccine was invented in **1796** by English physician **Edward Jenner**. He was the first to publish evidence that it was effective and to provide advice on its production. Louis Pasteur furthered the concept through his work in microbiology. The immunization was called vaccination because it was derived from a virus affecting cows (Latin: Vacca 'cow'). Smallpox was a contagious and deadly disease, causing the deaths of 20–60% of infected adults and over 80% of infected children. When smallpox was finally eradicated in 1979, it had already killed an estimated 300–500 million people in the 20th century.

## Vaccine Development and Approval

No vaccine can be 100% safe or effective for everyone because each person's body can react differently. While minor side effects, such as soreness or low-grade fever, are relatively common, serious side effects are very rare and occur in about 1 out of every 100,000 vaccinations and typically involve allergic reactions that can cause hives or difficulty breathing. However, vaccines are the safest they have ever been in history and each vaccine undergoes rigorous clinical trials to ensure their safety and efficacy before the FDA (Food and Drug Administration) approval.

Before human testing, vaccines are run through computer algorithms to model how they will interact with the immune system and are tested on cells in culture. During the next round of testing, researchers study vaccines in animals, including mice, rabbits, guinea pigs, and monkeys. Vaccines that pass each of these stages of testing are then approved by the FDA to start a three-phase series of human testing, advancing to higher phases only if they are deemed safe and effective at the previous phase. The people in these trials participate voluntarily and are required to prove they understand the purpose of the study and the potential risks.

After 3 phase trials, If a vaccine passes all of the phases of testing, the manufacturer can then apply for licensure of the vaccine through the FDA. Before the FDA approves use in the general public, they extensively review the results of the clinical trials, safety tests, purity tests, and manufacturing methods and establish that the manufacturer itself is up to government standards in many other areas.  Additionally, most vaccines also undergo phase IV trials, which monitors the safety and efficacy of vaccines in tens of thousands of people, or more, across many years. This allows for delayed or very rare reactions to be detected and evaluated.

# Side Effects

The **Centers for Disease Control and Prevention** (**CDC**) has compiled a list of vaccines and their possible side effects. The risk of side effects varies from one vaccine to the next, but below are examples of side effects and their approximate rate of occurrence with diphtheria, tetanus, and acellular pertussis (DTaP) vaccine, a common childhood vaccine.

**Mild side effects** (common)

- Mild fever (1 in 4)
- Redness, soreness, swelling at the injection site (1 in 4)
- Fatigue, poor appetite (1 in 10)
- Vomiting (1 in 50)

**Moderate side effects** (uncommon)

- Seizure (1 in 14,000)
- High fever (over 105 °F) (1 in 16,000)

**Severe side effects** (rare)

- Serious allergic reaction (1 in 1,000,000)
- Other severe problems including long-term seizure, coma, brain damage have been reported, but are so rare that it is not possible to tell if they are from the vaccine or not.

# Vaccination Policy

Vaccination policy is the health policy a government adopts concerning vaccination. Vaccination policies have been developed over approximately two centuries since the invention of vaccination to eradicate the disease from or create herd immunity for the population the government aims to protect. Vaccination advisory committees within each country are usually responsible for providing information to governments that are used to make evidence-based decisions regarding vaccine and immunization policy.

Vaccinations are voluntary in some countries and mandatory in others, with mandatory vaccination policies sometimes leading to the opposition. Some governments pay for all or part of the costs of vaccinations in a national vaccination schedule.

In India, the Vaccine Schedule or Immunization Timetable

| | | Months | | | | | | | | | | Years | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Infection | Birth | 1.5 | 2.5 | 3.5 | 6 | 9 | 9-12 | 12 | 15 | 16-18 | 18 | 2 | 4-6 | 10-12 |
| Tuberculosis | BCG | | | | | | | | | | | | | |
| Polio | OPV | | | | OPV | OPV | | | | | | | OPV | |
| Hepatitis B | HepB | HepB | | | HepB | | | | | | | | | |
| Rotavirus | | RV | RV | RV | | | | | | | | | | |
| Diphtheria | | | | | | | | | | | | | | |
| Tetanus | | DTwP | DTwP | DTwP | | | | | | DTwP | | | DTwP | Tdap |
| Pertussis | | | | | | | | | | | | | | |
| Haemophilus influenzae | | HIB | HIB | HIB | | | | | | HIB | | | | |
| Pneumococcus | | PCV | PCV | PCV | | | | | PCV | | | | | |
| Polio | | IPV | IPV | IPV | | | | | | IPV | | | | |
| Measles | | | | | | | | | | | | | | |
| Mumps | | | | | | MMR | | | MMR | | | | MMR | |
| Rubella | | | | | | | | | | | | | | |
| Typhoid | | | | | | | TCV | | | | | TCV | | |
| Hepatitis A | | | | | | | | HepA | | | HepA | | | |
| Varicella | | | | | | | | | VV | | | | VV | |
| Human papillomavirus | | | | | | | | | | | | | | HPV (girls) |

# History of Vaccination

The practice of immunisation dates back hundreds of years. Buddhist monks drank snake venom to confer immunity to snakebite and variolation (smearing of a skin tear with cowpox to confer immunity to smallpox) was practised in 17th century China. Edward Jenner is considered the founder of vaccinology in the West in 1796, after he inoculated a 13 year-old-boy with vaccinia virus (cowpox), and demonstrated immunity to smallpox. In 1798, the first smallpox vaccine was developed. Over the 18th and 19th centuries, systematic implementation of mass smallpox immunisation culminated in its global eradication in 1979.

Louis Pasteur's experiments spearheaded the development of live attenuated cholera vaccine and inactivated anthrax vaccine in humans (1897 and 1904, respectively). Plague vaccine was also invented in the late 19th Century. Between 1890 and 1950, bacterial vaccine development proliferated, including the Bacillus-Calmette-Guerin (BCG) vaccination, which is still in use today.

In 1923, Alexander Glenny perfected a method to inactivate tetanus toxin with formaldehyde. The same method was used to develop a vaccine against diphtheria in 1926. Pertussis vaccine development took considerably longer, with a whole-cell vaccine first licensed for use in the US in 1948.

Viral tissue culture methods developed from 1950-1985 and led to the advent of the Salk (inactivated) polio vaccine and the Sabin (live attenuated oral) polio vaccine. Mass polio immunisation has now eradicated the disease from many regions around the world. Attenuated strains of measles, mumps and rubella were developed for inclusion in vaccines. Measles is currently the next possible target for elimination via vaccination.

Despite the evidence of health gains from immunisation programmes, there has always been resistance to vaccines in some groups. The late 1970s and 1980s marked a period of increasing litigation and decreased profitability for vaccine manufacture, which led to a decline in the number of companies producing vaccines. The decline was arrested in part by the implementation of the National Vaccine Injury Compensation programme in the US in 1986.

**Molecular genetics** sets the scene for a bright future for vaccinology, including the development of new vaccine delivery systems (e.g. DNA vaccines, viral vectors, plant vaccines and topical formulations), new adjuvants, the development of more effective tuberculosis vaccines, and vaccines against cytomegalovirus (CMV), herpes simplex virus (HSV), respiratory syncytial virus (RSV), staphylococcal disease, streptococcal disease, pandemic influenza, shigella, HIV and schistosomiasis among others. Therapeutic vaccines may also soon be available for allergies, autoimmune diseases and addictions.

Timeline of Human development in vaccination

Some recent pandemic risks:

- Crimean Congo hemorrhagic fever
- Chikungunya
- Ebola
- Lassa fever
- Marburg virus disease
- Middle East respiratory syndrome coronavirus
- Nipah virus infection
- Rift Valley fever
- Severe acute respiratory syndrome
- Severe fever with thrombocytopenia syndrome
- Zika

## Current Scenario

Currently, India's universal immunisation programme (UIP) targets 26.7 million newborns and 29 million pregnant women every year – together making up 4% of the total population. These people receive about 390 million doses of vaccines, over nine million sessions, every year.

In this scenario, to administer 400-500 million doses of a COVID-19 vaccine by the first two quarters of 2021, India needs to ramp up its existing infrastructure significantly. This capacity-building entails strengthening the vaccine **cold-chain network**, increasing the stock of ancillary items like syringes and glass vials, and training healthcare workers. Otherwise, a COVID-19 vaccine may not be made accessible to people who need it the most, according to IndiaSpend.

Routine immunisation has already been stretched during the COVID-19 lockdown. Between January and August 2020, only 12 million children were vaccinated, coverage of 68.5%, in eight months, according to data from the Union health ministry. But 17.8 million children should have been vaccinated in these months to meet the UIP's 2019 goal of vaccinating 26.7 million infants every year. **India's routine vaccination programme has struggled to meet its goal of vaccinating 55.7 million people annually over the last five decades, according to the UIP's five-year plan in 2018.**

India does not have a universal adult vaccination programme, for example for flu shots, the human papillomavirus or pneumococcus. In a 2012-2016 survey, many deaths were reported due to pneumococcus and other vaccine-preventable diseases.

The private sector provides almost 80% of healthcare in India, as far as vaccination delivery is concerned, it is just the reverse. The private sector in India has got around 10% of the share as far as immunization delivery is concerned. The Government of India (GoI) has recently added a few new vaccines in its Universal Immunization Program (UIP).

# Challenges

## Issues plaguing the public sector:

1. **The ineffective and poorly-functioning regulatory system of licensing vaccines**

    1.1. There are great inadequacies of the regulatory system as far as the vaccination scenario of the country is concerned. First of all, there is no separate **National Regulatory Authority** (NRA) to exclusively deal with vaccines. The existing NRA called **Central Drugs Standard Control Organization** (CDSCO) is functioning on the decades-old '*Drugs and Cosmetics Act, 1940 and Rules, 1945*'.

    1.2. In India, vaccines are licenced without proper studies. In the US and other industrialized countries, the year-wise data on vaccine effectiveness are analyzed and shared publicly. No such provision is there in India. There is no published data on the safety, tolerability and effectiveness of the flu vaccines for Indian children. The existing flu vaccines are arguably one of the weakest vaccines in our armamentarium today.

2. **Prioritizing the introduction of a vaccine based on the burden**

    2.1. There is no clarity on what vaccines are needed by our children and how to prioritize them. Often, we do not have a major say in the decision-making process. There is also no transparent, scientifically-tested model that can be applied and objectively analyzed by other stakeholders. Most of the time, a new vaccine is launched under 'pressure' (dubbed as support) from international health organizations and philanthropists who dictate their terms and conditions.

3. **Monitoring vaccine introductions**

    3.1. There ought to be periodic post-marketing surveillance (PMS) studies, effectiveness studies, etc. These should be regularly supervised and corrective measures must be employed like cancellation of license given to a vaccine manufacturer.

4. **Monitoring vaccine supply**

    4.1. The frequent scarcity of EPI vaccines like BCG and IPV, and now the sudden decision by the manufacturer to stop production of a trivalent Diphtheria-Tetanus-Pertussis (DTP) vaccine are few examples of how unprepared our vaccine regulatory system is.

## The Unregulated and Unethical practices of the private sector

On the other hand, the private sector is also poorly supervised. There are no guidelines from the Ministry of Health on various critical issues like who can provide vaccines to the community? What are the prerequisites to open and run a vaccination clinic? Can a non-health professional also provide vaccines and conduct camps?

There are no guidelines and supervision of vaccine distributors and doctors who are dispensing vaccines. At most places, proper vaccine storage systems like Ice-lined Refrigerators (ILRs) are not available and vaccines are stuffed with grocery items in domestic refrigerators, hence, the proper cold chain is not maintained. There is no proper record keeping of the vaccinated children that ideally should be made available to the local immunization officer.

## Summary of current challenges in vaccination:

- Proper vaccine management
- Quality of vaccines
- Less trained people
- Vaccine storage
- Diseases observation
- New improvements in the vaccination field
- Less Data regarding the disease
- Less Research & Development centres
- Less reporting and observation of the problem
- Low vaccination in rural areas
- Risk factors  & safety are concerned by many
- People or community against vaccination
- The exploitation of private Pharmaceutical Companies
- High cost for the development of vaccines

## Benefits of implementing DApp

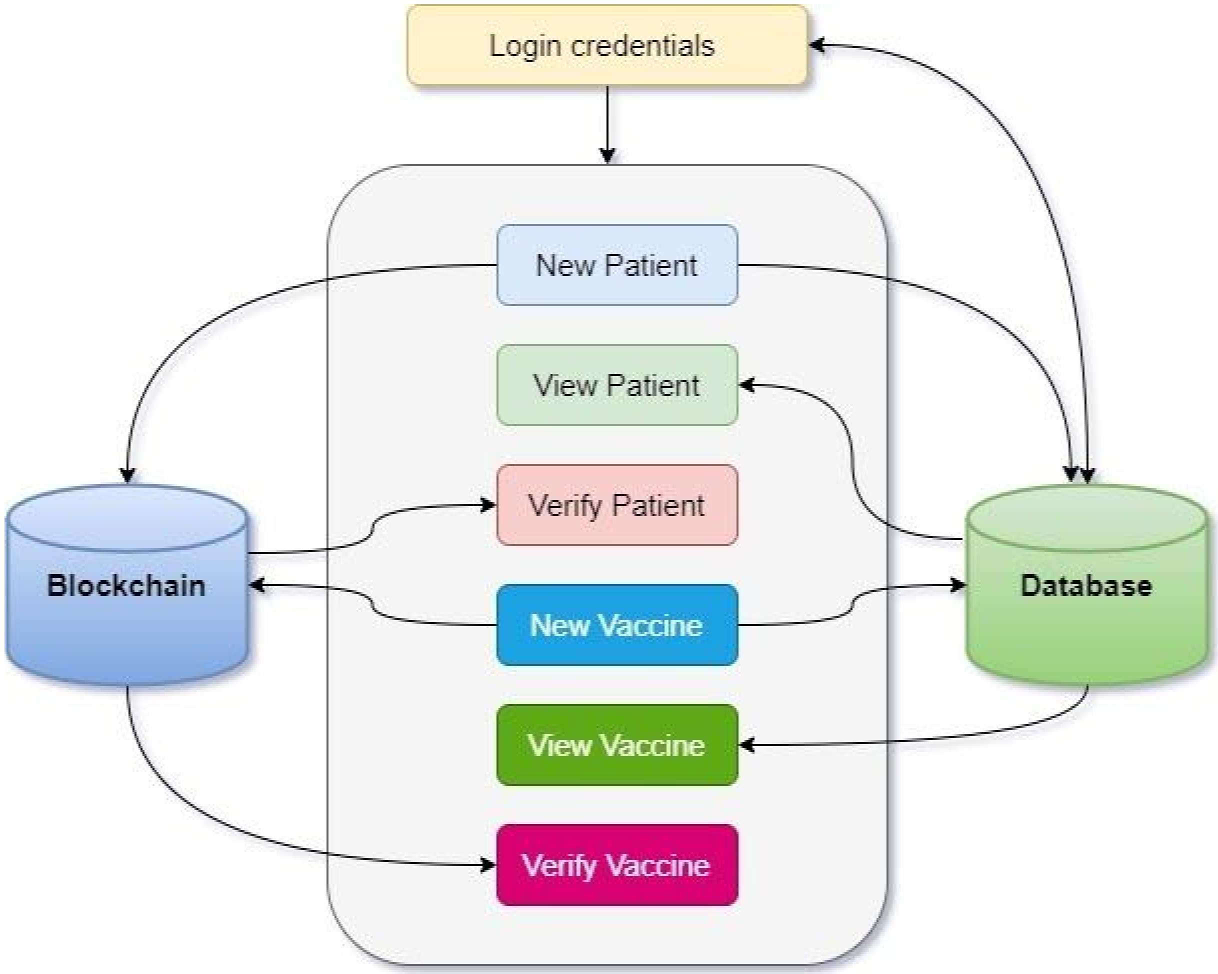
Currently, many children and people are struggling without getting proper treatments for preventable diseases. One factor is the shortage of medicines, Vaccines are one of them. In many scenarios even though governments are supplying necessary vaccines and they are not provided to rightful personals. Many vaccines are sold in the black market for higher prices.

Another reason is many vaccines are wasted because of not getting proper treatments, certain vaccines can be stored only in certain temperatures. Unfortunately, we don't have a facility now to properly track the supplements and their details.

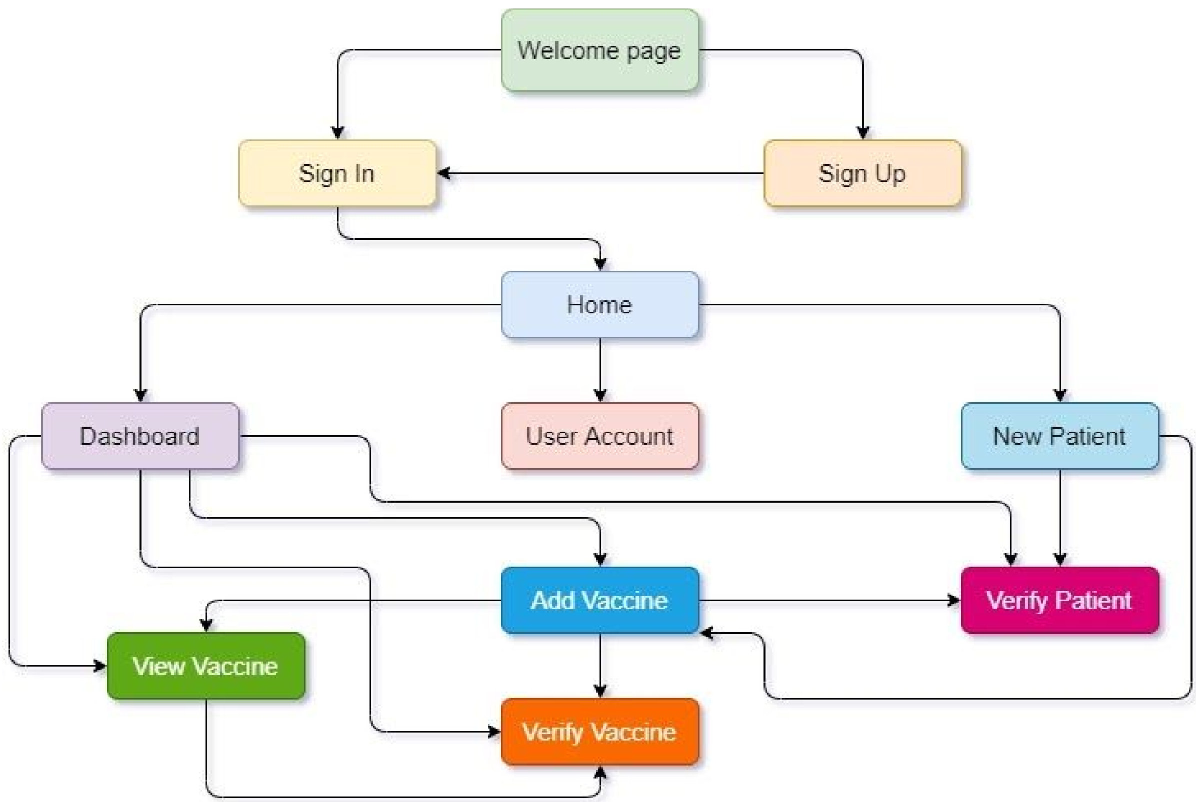
These issues can be overcome to a certain extent by making use of public blockchain properties like easier traceability, immutability, transparency etc...

By implementing a Hybrid Type DApp all personal details and private data are stored securely without compromising any above-mentioned properties. This helps the society get proper medical care, and helps the country to eradicate these preventable diseases and helps to foresee and prevent pandemic risks. Also, ensure the supply of sufficient amounts of vaccines and prevent a shortage of vaccines when a pandemic breakout.

# Block Diagram



# Workflow




After successfully signed in the Sign-out will redirect to welcome page

# Legends:

**Processes** are in Blue;

**Storing to Database or Blockchain** are in Green;

**Retrieving from Database or Blockchain** is in Yellow;

**DB - Database, BC- Blockchain**

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- ➔ Authenticating Credentials of Vaccinator
- ➔ Patient's Details
    - ◆ **New**
        - Unique Id -[DB,BC(Uint)]
        - Name -[DB,BC]
        - Age -[DB,BC]

- Gender -[DB,BC]
- Contact Details
    - Address -[DB,BC]
    - Phone Number -[DB,BC]
- Vaccine Needed -[DB, BC]
- Details of Vaccine
    - Company -[DB]
    - Serial Number -[DB]
    - Batch & MFD -[DB]
    - Unique Data includes above mentioned details [BC]
- After Vaccination, the transaction is done by paying the fee and the data are saved
- Option for Verifying the Txn Details -[BC]
- Showing the Details in Front-End

- **Revisit**
    - Fetching data using Unique Id -[DB, BC(Uint)]
    - All Details about the Patient is retrieved
    - Vaccine needed -[DB,BC]
    - Details regarding the last vaccinations
        - Option for verifying previous data with BC data using unique id
    - Details of Vaccine
        - Company -[DB]
        - Serial Number -[DB]
        - Batch & MFD -[DB]
        - Unique Data includes above mentioned details [BC]
    - After Vaccination, the transaction is done by paying the fee and the data are saved
    - Showing the Details in Front-End

# Working

1. Vaccinator needs to login into the website using his/her credentials.

2. After successfully logged in, he/she will be able to select options:

    **2.1. New Patient**

    2.1.1. When a new patient is registering for vaccination, he/she is provided with a unique Id (we can also use any gov. issued ID or any official IDs for that) which will be stored securely in Database and blockchain.

    2.1.2. Patient's details are stored (securely in the database & Blockchain).

    **2.2. View Patient**

    2.2.1. When a patient revisits the vaccination centre, he/she needs to share the unique Id which is used or provided during the registration time.

    2.2.2. The vaccinator will fetch the patient's previous vaccination records for the vaccination remarks to get a medical picture of the patient's condition.

    2.2.3. Here the patient or vaccinator has an option for verifying the previous vaccination details and records.

3. The patient will get a prescribed vaccine shot.

4. The data of the vaccine and remarks of vaccination will be stored in a database along with a combined code of vaccine details like Vaccine manufacturer, M.F.D., batch, serial number etc... This combined code will be also stored in the Blockchain for verification purposes.

5. After entering sufficient details into the system the transaction is made.

6. All details regarding that vaccination will be available in the front end as a report, which will be printed and given to the patient.

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