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## Review Article

## Vaccine equity and access: A comparative assessment of Covaxin, Covishield, and Sputnik V.

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## ABSTRACT

The RNA virus known as SARS-CoV-2, which causes severe acute respiratory syndrome, was discovered for the first time in Wuhan, China, in December 2019. The World Health Organization (WHO) declared the outbreak a global pandemic on March 11, 2020, as a result of the virus's subsequent spread throughout the planet. The urgent creation of safe and effective vaccines has elevated to a top priority in the global healthcare industry because of the terrible effects of the COVID-19 outbreak. The Covaxin and Covishield vaccines were administered as part of the start of the SARS-CoV-2 vaccination campaign in India on January 13, 2021. Covaxin is made up of adjuvant-inactivated viral particles, whereas Covishield is an adenovirus vector-based vaccine. The utility and effectiveness of each vaccine are significantly influenced by its formulation, adjuvants, and mode of action. Vaccine efficacy depends on various factors, including the creation of memory cells, cell-mediated immunity, and antibodies. Results from third-phase trials have shown that Covishield exhibits an effectiveness of approximately 90%, while Covaxin demonstrates an effectiveness of around 80%. Both vaccines have demonstrated satisfactory efficacy against several mutant variants of SARS-CoV-2. The effectiveness of Covishield, however, should be noted as compromised if there are significant changes in the spike (S) protein structure in future variants. In contrast, Covaxin may remain effective against such variants due to its ability to elicit multiple antibodies targeting different epitopes. The objective of this study is to evaluate and contrast Covaxin, Covishield & Sputnik v immunogenic and therapeutic efficacy. Additionally, potential vaccination challenges in the coming days will be discussed. Understanding the relative strengths and limitations of these vaccines can inform decision-making and strategies related to vaccine deployment, public health interventions, and future vaccine development efforts."

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## 1. Introduction

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the virus that causes the highly contagious disease coronavirus disease-19 (COVID-19).<sup>1</sup> In Wuhan, China, suddenly in December 2019, there were 54 cases of viral pneumonia caused by an unidentified microorganism.<sup>2</sup> It was discovered that a new coronavirus from the family

Corona viridae was the cause of these pneumonia infections. Since then, the illness has spread globally, causing a pandemic that is still going on.<sup>3</sup> After the outbreak, the SARS-CoV-2 virus spread quickly throughout China in a month.<sup>4</sup> The COVID-19 pandemic has affected every country on Earth and has caused an international catastrophe of unimaginable proportions. When people breathe in droplets and tiny airborne particles (an aerosol form) that infected people exhale as they breathe, talk, cough,

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and sneeze, the disease is primarily spread through the respiratory route.<sup>5,6</sup> People who are physically close to one another are more likely to breathe in aerosols, which makes it easier for viruses to spread,<sup>7</sup> however, airborne transmission can happen over greater distances, especially in poorly ventilated areas,<sup>8</sup> If those conditions hold, tiny particles may float in the air for a few minutes to several hours.<sup>8</sup> It frequently spreads in groups, and infections can be linked to a single case or specific area.<sup>9</sup> In these situations, super-spreading events frequently take place, where a single person infects a large number of people.<sup>10</sup> According to recent research, individuals with mild to moderate COVID-19, including people with compromised immune systems, may shed the virus for up to 10 days after the onset of symptoms, and individuals with severe COVID-19 may be infectious for up to 20 days.<sup>11</sup>

## 2. Vaccine Development

### 2.1. Covaxin (BBV152)

The Central Licensing Authority (CDSCO) authorized the sale or distribution of Covaxin for limited use in urgent situations in the interest of the public as a preventative measure while in clinical trial mode (35). The ability of Covaxin to generate COVID-19-specific antibodies has been shown in phase 1 and phase 2 clinical trials. Data from completed Phase 1 to 3 trials were examined by a Subject Expert Committee (SEC) at each stage. After reviewing the Phase 3 data, the SEC advised the Drugs Controller General of India (DCGI) to grant the vaccine a marketing and manufacturing license.<sup>12–14</sup>

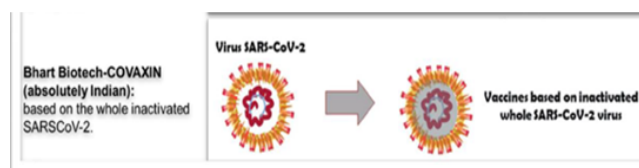


Fig. 1: Mechanism of Covaxin

### 2.2. Study

AEFI Covaxin and Covishield - In this study, a total of 217 participants (67.4%) reported experiencing adverse events following immunization (AEFI). A total of 18.3% (59) and 10.2% (32) of participants, after the first and second doses, respectively, reported experiencing immediate reactions within 30 minutes of receiving the vaccine. The most commonly reported immediate Extreme fatigue and pain at the injection site were the first symptoms. Immediate allergic reactions were observed in 0.9% (3) of the participants. Local reactions were reported by 63.6% (204) of participants after the first dose and 46.3% (144) after the second. The most common local reaction was pain

at the injection site, which was then followed by arm swell and weakness, fever, headache, chills, dizziness, somnolence, and appetite loss.<sup>15</sup> Additional categories of disorders were also included in AEFIs. There have been reports of gastrointestinal disorders like nausea, vomiting, decreased appetite, and abdominal pain. There were also symptoms of nervous system disorders, such as headaches, wooziness, somnolence, and insomnia. There are known cases of urticaria, hair loss, and rash, among other skin and subcutaneous tissue disorders. In addition, reports of musculoskeletal and connective tissue conditions that cause body aches and pain in the extremities were made. Disorders of the general and administration sites, such as tingling, heaviness, swelling, and pain at the injection site, were also noted. Overall, these findings provide valuable insights into the adverse events associated with Covaxin and Covishield vaccines. Understanding and monitoring these AEFIs are crucial for ensuring vaccine safety and addressing any potential concerns.<sup>15</sup>

### 2.3. Covishield development

Nearly 88% of all doses administered in the nation to date have been of the Covishield vaccine, which is identical to the Oxford-AstraZeneca (ChAdOx1 nCoV-19) vaccine in composition and immunogenicity. In some regions, Covishield has also been the only vaccine used.<sup>16</sup>

### 2.4. Mode of action

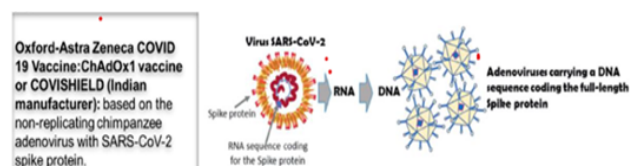


Fig. 2: 9

The Oxford AstraZeneca vaccine is based on a chimpanzee adenovirus that doesn't replicate and has SARS-CoV-2 spike protein. After being administered intramuscularly, these spike proteins are locally expressed, enabling the immune system to mount a neutralizing antibody/cellular immune response. Protection against subsequent infections is then provided by the initial exposure and immune system priming. Contrarily, the Bharat Biotech-COVAXIN response is based on the entire inactivated SARSCoV-2.<sup>17,18</sup>

### 2.5. Sputnik V

The first licensed vaccine was created in Russia. Ad5 and the vesicular stomatitis virus served as the carrier viruses in the earlier Ebola virus vaccine, which was also created at the Gamaleya National Research Centre for Epidemiology and

Microbiology (Moscow, Russia). and the general principle of prime-boost with two different vectors has been widely used experimentally Denis Logunov and colleagues report their interim results from a phase 3 trial of the Sputnik V COVID-19 vaccine in *The Lancet* publishes interim findings from a phase 3 trial of the Sputnik V COVID-19 vaccine by Denis Logunov and colleagues. The trial's findings indicate a strong protective effect that is constant across all participant age groups.<sup>18,19</sup>

### 2.5.1. Clinical trial

Phase I and II results, on 76 participants of an open, non-randomized trial, were published in the *Lancet* in September. The study found that every participant produced SARS-CoV-2 antibodies. No significant adverse events were found. The majority of side effects were minor; for instance, just over half of patients reported experiencing pain at the injection site.<sup>20</sup>

Phase III interim data were released in early February 2021. Nearly 22 000 adults who were 18 years of age or older were enrolled in the randomized, double-blind, placebo-controlled trial between September 7 and November 24, 2020, through 25 hospitals and clinics in Moscow. The vaccine was given twice to each participant, 21 days apart, either as the vaccine or a placebo.<sup>20</sup>

### 2.5.2. Study

20000 participants, of whom 75% were given the vaccine assignment, and the monitoring for infection and unfavorable events. With a planned study power of 85%, those recruited were over the age of 18, about 60% of them were men, and almost all of them were white. About 25% of those who enrolled in the trial had comorbidities, a known risk factor for COVID-19 severity. The primary outcome was that starting on day 21 following the first dose of the vaccine, 62 (1%) of 4902 participants in the placebo group and 16 (0%) of 14 964 participants in the vaccine group had confirmed SARS-CoV-2 or covid-19 infection.<sup>21</sup> The immunity needed to ward off disease appeared within 18 days of the first dose, according to a time-resolved plot of the incidence rates in the two groups. All age groups, including those over 60, were protected, and anecdotal case histories of people who were immunized but infected indicate that the severity of the disease decreases as immunity grows. Three deaths in the vaccine group occurred in people with severe co-morbidities, and they weren't thought to be related to the vaccine. Although no serious adverse events deemed to be related to the vaccine were noted, 45 participants in the vaccine group and 23 participants in the placebo group both reported experiencing serious adverse events. The reported vaccine efficacy of 91.6% (95% CI 85.6-95.2) is based on the number of confirmed COVID-19 cases from 21 days after the first dose of the vaccine, and the suggested reduction in

disease severity after one dose is especially encouraging for current dose sparing strategies.<sup>22</sup> The Sputnik V vaccine's development has come under fire for its rashness, cost-cutting, and lack of transparency<sup>11</sup> A new vaccine can now be added to the effort to lower the incidence of COVID-19 because the outcome reported here is clear and the scientific principle of vaccination is demonstrated.<sup>11</sup> As of January 2021, some countries will start using three licensed vaccines with an efficacy rate of more than 90%.<sup>23</sup>

### 2.6. Side effects

The most frequent adverse reactions were injection site pain (56.9%), fatigue (50.9%), body pain (43.9%), headache (35.7%), fever (32.9%), joint pain (30.3%), chills (29.8%), and sleepiness (20.3%). Younger people and females were significantly more likely to experience vaccine side effects. After receiving the first and second doses of the vaccine, more than 90% of the 238 participants had detectable levels of SARS-CoV-2 RBD antibody and SARS-CoV-2 neutralizing antibody.<sup>24</sup>

## 3. Result

The pharmacology, indications, and side effects of the Covaxin/Covishield and Sputnik V vaccines are contrasted in Table I. The Covaxin/Covishield and Sputnik V vaccines now receive emergency permission from the US Food and Drug Administration (FDA). Those 16 years of age and above have been advised to get the Covaxin/Covishield vaccine, which costs Rs 225 and comes in a dose of (0.5 ml). It offers immunogenicity for at least 90 days following the initial vaccine and is 91% successful in preventing SARSCOV-2 infection. To counter this, those 18 years of age and older have been advised to receive the Sputnik V Vaccination, which costs Rs 995 for a dosage of (0.5 mL). It is 91.6% effective in preventing SARS-CoV-2 infection and provides immunogenicity for at least 90 days following the first vaccine (Table I). A SARS-CoV-2 infection can be prevented with both vaccines, according to the literature that is currently available. A few allergic reactions have been documented, though. After receiving either the first or second dose of the COVID-19 vaccine, moderate side effects, such as discomfort, redness, or swelling where the vaccine was injected, fever, exhaustion, headache, muscle soreness, nausea, vomiting, itching, chills, in rare cases, anaphylactic shock, may occur. Table 1 compares the Covaxin/Covishield and Sputnik V vaccines in terms of their pharmacology, indications, and side effects. Covaxin/Covishield and Sputnik V vaccines were compared for immunogenicity, side effects, and contraindications.

**Table 1:** Comparison between characteristics of covaxin, covishield, and sputnik V.

| <b>Characteristics</b>       | <b>Covaxin</b>   | <b>Covishield</b>   | <b>Sputnik V</b>  |
|------------------------------|--|---|---|
| General name                 | Covaxin  | Covishield  | Sputnik V   |
| Generic name                 | BBV152   | ChAdOx1nCoV-19  | Gam-COVID-Vac   |
| Manufacturer                 | The National Institute of Virology (NIV), the Indian Council of Medical Research, and Bharat Biotech developed India's <sup>25</sup>               | The World's largest vaccine manufacturer, Serum Institute of India (SII), is based in Pune. <sup>26</sup>                                 | National Research Center for Gamaleya for Microbiology and Epidemiology (Russian city of Moscow). <sup>26</sup>                           |
| Types of vaccines            | Inactivated whole-virus <sup>26</sup>  | Nonreplicating viral vector <sup>26</sup>   | Nonreplicating viral vector <sup>26</sup>   |
| FDA Approval                 | Jan 3, 2021 <sup>27</sup>  | Jan 1, 2021 <sup>27</sup>   | April 12, 2021 <sup>27</sup>  |
| Mode of action               | Variants of the SARS-CoV2 virus that are grown in Vero cell lines are subsequently adsorbed on, inactivated by beta-propiolactone <sup>26,27</sup> | Adenoviruses are rendered nonreplicating and are used to introduce the gene for the spike protein antigen into human cells. <sup>28</sup> | Adenoviruses are rendered nonreplicating and are used to introduce the gene for the spike protein antigen into human cells. <sup>29</sup> |
| Mode of administration       | Intramuscular (deltoid muscle) <sup>30</sup>   | Intramuscular (deltoid muscle) <sup>31</sup>  | Intramuscular <sup>20</sup>   |
| Dose                         | 0.5 mL each  | 0.5ml each  | 0.5ml each  |
| Gap b/w the dosage & Storage | two doses, spaced 28 days apart, are stable from 2 to 8 degrees Celsius. <sup>25</sup>   | two doses and 0.5 ml, with the second dose being administered 12 weeks following the first dose. <sup>31</sup>                            | Separate administration with a break of 21 days, and storage at about -18°C. <sup>31</sup>  |
| Approximate cost per dose    | Rs. 225 retail price for each dose   | Rs. 225 retail price for each dose  | Rs. 995 retail price for each dose  |
| Effectiveness                | It has been determined that Covaxin is 78–81% effective. <sup>32</sup>   | Up to 90% of people can benefit from Covishield. <sup>32</sup>  | It is 91.6 % effective. <sup>32</sup>   |

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Table 1 continued

|          |  |  |  |
|----------|--|--|--|
| Efficacy | <p>COVAXIN is shown to be 93.4% effective against severe COVID-19 disease and 77.8% effective against COVID-19 disease with symptoms<sup>33</sup> Against mild, moderate, and severe diseases, the covaxin vaccination is 78% effective against COVID-19 infection. After 14 days of treatment, the first dose of the vaccine has a 76.7% effectiveness rate. An efficacy of 66.9% was observed after 14 days and 66.1% after 28 days in a phase 3 trial, however. After 14 days, the effectiveness of preventing a serious infection was 76.7%, and after 28 days, it was 85.4%.<sup>33</sup></p> | <p>Considering that 90.0% of subjects received both doses, the vaccine's total effectiveness was 62.1%. Throughout the 21 days, both groups' vaccination effectiveness was 70.4%. The effectiveness was discovered to be 90% when participants received the first dose followed by the second dose. compared to those who had a low dosage vaccine at the first dose and the standard booster dose (90%), who received two standard doses, had a lower efficacy (70.4%). Less effectiveness is achieved with the second dose given within six weeks of the initial dose (53.4%) than with the second dose given more than six weeks later (65.4%).<sup>20,34</sup></p> | <p>The vaccine, the overall efficacy is 91.6% Based on the analysis, The Russian Direct Investment Fund (RDIF) reported 97.6% efficacy of the Sputnik V vaccine. Based on the number of confirmed COVID-19 cases from 21 days following the first dose of the vaccine, vaccination effectiveness is reported to be 91.6%. An important finding from the phase 3 trial of the Sputnik vaccine is that older persons over the age of 60 had an effectiveness of 91.8% (confidence interval (CI) = 95%). Nonetheless, the initial efficacy was 73.6% for the first 21 days following the first dose. Delaying the second dosage can be followed to boost neutralizing antibodies. According to another trial, where the vaccine was given to older people after the first dose, it was effective in preventing 78.6% of laboratory-confirmed SARS-CoV-2 infections, 94% of hospitalizations, and 93% of deaths.<sup>35,36</sup></p> |
|----------|--|--|--|

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Table 1 continued

|                 |   |  |   |
|-----------------|---|--|---|
| Adverse effects | An excellent safety profile was reported, with the most frequent adverse events being headache, fever, weariness, and soreness at the injection site. <sup>15</sup> weariness, headache, muscle discomfort, and fever, as well as pain at the injection site Compared to Ella's trial, where side effects were observed at a rate of 10% overall arm swelling and numbness, loss of appetite, fever, headache, chills, dizziness, and chills. diseases of the gastrointestinal tract, the neurological system, the skin, and the subcutaneous tissues After the vaccination was given, people experienced injection site pain, swelling, redness, itching, stiffness in the upper arm, weakness in the injection arm, body aches, headaches, fever, malaise, weakness, rashes, nausea, and vomiting. A serious allergic reaction could result, with symptoms including trouble breathing, swelling of the face and throat, a rapid heartbeat, a rash all over your body, weakness, and disorientation <sup>15</sup> | With the second dose of AZD1222 compared to the first, adverse effects were usually mild or moderate and occurred less often (98) The most frequent adverse effects of AZD1222, according to the study of Folegatti, were fatigue, headaches, and pain at the injection site, muscle pain, and fever. Fever, headache, chills, dizziness, somnolence, swelling, and weakening of the arm, as well as a loss of appetite. diseases of the digestive system, nervous system, nervous system, skin, and subcutaneous tissues <sup>37</sup> . The most typical vaccination adverse effects were discomfort, fever, chills, muscle pain, headaches, and exhaustion. nausea, diarrhea, edema, redness at the injection site, low blood platelet counts, stomach pain, itching, rash, swollen lymph nodes, decreased appetite, drowsiness, disorientation, and tiredness. <sup>35</sup> | Only a few subjects reported experiencing severe AEFIs (grades 3 and 4); AEFIs were defined as mild, moderate, and severe (grades 1 and 2). headache, weariness, cold, discomfort at the injection site, and pain in the muscles Chills, fever, arthralgia, myalgia, asthenia, general malaise, headache) and local (soreness at the injection site, hyperemia, swelling responses) symptoms may manifest. In addition, there is a chance that these symptoms will become severe. Less often reported symptoms include indigestion, decreased appetite, and occasionally an expansion of the local lymph nodes. <sup>36</sup> |
| Advantages      | Mature technology and simple preparation. Good safety profile and stability <sup>38</sup>   | Effective induction of humoral and cellular immunity <sup>39</sup>   | Effective induction of humoral and cellular immunity <sup>39</sup>  |
| Disadvantages   | Requires multiple vaccinations due to weak immunogenicity. Short and feeble immunity; the need for adjuvants Better safety in populations with weakened immune systems, ease of production, and low cost are benefits of inactivated vaccines. <sup>40</sup>  | High standards for the virus's activity and purity; potential pre-existing immunity <sup>39</sup>  | High standards for the virus's activity and purity; potential pre-existing immunity. <sup>39</sup>  |

**Table 2:** Adverse reactions after receiving the COVID-19 vaccine in research studies and pharmacovigilance programs

| Vaccines | Adverse effects   | Number of participants or doses studied | Study duration               | Age/ Gender                     | Country/ Region     |
|----------|---|---|------------------------------|---------------------------------|---------------------|
| Covaxin  | (21%) pain following an injection, Tenderness/soreness, redness, swelling, itching, pain, fever, nausea, and vomiting. In addition, there may be joint pain, muscular pain, exhaustion, a rash, or myalgia <sup>41,42</sup> .   | 1826                                    | June 28 to September 6, 2021 | 18-88years/Both male and female | India               |
| 2        | (5.33%) discomfort and swelling where the injection was made, Fever, nausea, body aches, rashes, vomiting, and symptoms of arthralgia such as pain, myalgia, tenderness, and redness. Severe Adverse Events, or SAEs, had not been documented throughout this survey. <sup>42</sup>   | 75                                      | January 2021                 | Both                            | India               |
| 3        | (20%) Eighty-six percent of people reported pain at the injection site, followed by fever (76 percent), joint pain (40 percent), headache (30 percent), chills (22%), tachycardia (10 percent), motor weakness (6 percent), and four percent reported numbness, four percent urticaria, and four percent rashes, respectively. However, there were no reports of serious adverse reactions after vaccination. <sup>43</sup> | 400 MBBS Students                       | January 2021 to March 2021   | Both male and female            | Chhattisgarh, India |
| 4        | (8.7%) Fever, generalized body pain, headache, chills, dizziness, cough, chest pain, itching, burning sensation of eye, nausea, sore throat, drowsiness, diarrhea, running nose, heartburn, joint pain, dehydration, rashes, sleeplessness, bp change. <sup>44</sup>  | 540                                     | January 16 to March 31, 2021 | 18-75years/ both                | Tirupati, India,    |
| 5        | Injection site pain, muscle pain, exhaustion, fever and chills, headache, joint pain, flu-like symptoms, and digestive issues were all experienced by 85% of subjects <sup>45</sup>   | 503                                     | February 7 to March 7, 2021. | 20-67years/ both                | Iran                |

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| <i>Table 2 continued</i> |  |   |                                   |                      |                     |
|--------------------------|--|---|-----------------------------------|----------------------|---------------------|
| 6                        | (39%) Common symptoms of the flu, such as a high body temperature, a sore throat, a running nose, a cough, and chills, are a lump at the injection site, a fever, feeling unwell (vomiting), and flu-like symptoms. - rare (affecting 1 in 100 people): dizziness, loss of appetite, stomach pain, enlargement of the lymph nodes, excessive perspiration, itchy skin, or a rash <sup>46</sup> | 1145  | February 25th to March 30th, 2021 | 18-50 years/ Both    | Maharashtra, India, |
| 7                        | (More than 80%) Injection site pain, headache, fever, general aches, fatigue, chills and generally feeling unwell, body ache, tiredness, decrease appetite, feeling dizziness <sup>37</sup>  | Out of 914 respondents, 121 (13.2%) received Covaxin. | February to April 2021            | 18 years above/ both | Tamil Nadu, India.  |
| 8                        | (50%) The local pain at injection, site (28.72%), fever 12.76%, Myalgia (12.77%), tiredness (8.51%) and Headache (5.32%). Tiredness as most common symptom in 45%, it followed by Myalgia (44%), Fever (34%) and headache (28%) and local pain at injection site <sup>47</sup> .   | Total population 94 covaxin 10.64%                    | March 10 to March 26 2021         | 18 years above/both  | Nagpur, India       |
| Covishield               | (20%) After fever (76%), pain at the injection site (86%), joint ache (40%), Headache (30%), chills (22%), tachycardia (10%), motor weakness (6%) and 4% of people experienced numbness, 4% urticaria, 4% rashes respectively, and others 4% including congested eyes and fatigue <sup>43</sup>  | 400 MBBS Students                                     | January 2021 to March 2021        | Both male and female | Chhattisgarh, India |
| 2                        | At the injection site, there is pain, swelling, itching, and redness. Fever, chills, and rigidity were considered to be general adverse effects. body soreness, exhaustion, malaise, somnolence, drowsiness, inability to sleep, headache, nausea, vomiting, diarrhea, dizziness, joint pain, runny nose, and redness of the eyes <sup>48</sup>  | 350 Adult population                                  | 30-35 days                        | Both                 | Bangladesh          |

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Table 2 continued

|   |   |        |                                      |                                  |               |
|---|---|--------|--------------------------------------|----------------------------------|---------------|
| 3 | Pain at the injection site, fever, and headache were frequent findings. AEFIs. In comparison to men, participants with normotension, and those with no history of allergies, it was discovered that women, those with hypertension, and those with any history of allergies all had odds of having AEFIs that were two times higher. <sup>33</sup>              | 804    | 5th February to May 2021             | 18-65 Years/both                 | India         |
| 4 | (13.5%) Chill/fever, skeletal pain, local reaction, headache and fatigue, and arthralgia <sup>42</sup>  | 1460   | December 8 2020<br>March 2021        | Above 18 years                   | Iran          |
| 5 | (48%) Local or systemic response, soreness at the injection site, myalgia, fever, headache, chills, disorientation, and sleepiness are all possible side effects. Symptoms included moodiness, irritability, and nausea/vomiting. The injection site swelled. There were very few cases of diarrhea, rashes, and breathing difficulties. Symptoms <sup>49</sup> | 1006   | Before 26 January 2021               | 30 years above/Both              | Nepal         |
| 6 | (less than 1%) The majority of adverse events were immune system-related (55.2%). The most often reported side effects included body aches, tiredness, headaches, vomiting, and pain/swelling/tenderness at the injection site <sup>50</sup>  | 21,115 | 16 January 2021 to 31 December 2021  | 18-75years                       | North India   |
| 7 | (34%) On the first day, symptoms such as a headache, fever, lightheadedness, body aches, pain at the injection site, and muscular spasms were seen. Lethargy, fever, dizziness, pain following an injection, muscle spasms, body aches, redness of the eye, tiredness, and low blood pressure are among the symptoms. <sup>51</sup>                             | 91     | 29 <sup>th</sup> and 30 January 2021 | 35-74years/ Both male and female | Nepal         |
| 8 | (11.1%) Fever, generalized body pain, headache, chills, dizziness, cough, chest pain, itching, burning sensation of eye, nausea, sore throat, drowsiness, diarrhea, running nose, heartburn, joint pain, dehydration, rashes, sleeplessness, bp change, difficulty in breathing <sup>51</sup>   | 5253   | January 16 to March 31, 2021         | Less than 45years/both           | Trupti, India |

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| <i>Table 2 continued</i> |   |             |                                  |                  |                     |
|--------------------------|---|-------------|----------------------------------|------------------|---------------------|
| 9                        | (66%) Fatigue, myalgia, fever, and headache, The most frequent symptoms included joint discomfort, nausea, diarrhea, and localized pain at the injection site <sup>46</sup>   | 5128        | February 25th to March 30th,2021 | 18-50years/ Both | Maharashtra, India, |
| Sputnik V                | Hyperthermia, headaches, asthenia, and aches in the muscles and joints were the only grade 3 adverse events not reported in this trial. The majority of side effects were minor, and none of the trials recorded any substantial side effects <sup>20</sup>   | 76          | between December 2019 and 2020   | 18-60 years      | India               |
| 2                        | tiredness, musculoskeletal pain, chills, fever, and adverse injection site reactions <sup>52</sup>  | 1751        | March to August 2021             | Above 18 years   | Iran                |
| 3                        | (85% at least one adverse effect) Pain at the injection site, chills and fever, headache, exhaustion, and aching muscles and joints <sup>53</sup>   | 76          | February 7 to March 7, 2021.     | 20-67year/ both  | Iran                |
| 4                        | (84%) Fiber, exhaustion, myalgia, and headache. Moreover, several studies noted elevated bilirubin, reduced hemoglobin, and changed liver enzymes <sup>3</sup> Redness/erythema, itching, urticarial rash, morbilliform eruptions, pityriasis rose, swelling, and burning were the most frequent skin reactions <sup>54,55</sup> .  | 743         | 3months                          | 18-59years/both  | Iran                |
| 5                        | (35.71%) Injection site discomfort, including pain and swelling, as well as headache, palpitations, exhaustion, fever redness, nausea, feeling unwell, lymphadenopathy, myalgia, and Sputnik V caused the highest side Effect. Thankfully, the vaccine that causes the majority of side effects is no longer offered at the vaccination center in Libya, and the government was ordered to establish vaccination facilities <sup>53</sup> | 28 students | September1 to september25 2021   | 18-65years/ both | Libya               |
| 6                        | Pain at the injection site, fever, headache, myalgia, nausea, cough, and weariness (37%) The Sputnik vaccine might cause mild to severe adverse effects, although they often go away after three days <sup>56</sup> .   | 311         | April10 to May15 2021            | 18-45years/both  | Bahrain             |

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*Table 2 continued*

|   |   |     |                           |              |              |
|---|---|-----|---------------------------|--------------|--------------|
| 7 | Similar to local site responses, which include erythematous and morbilliform rashes, urticaria, and angioedema, focal site induration, local site erythema, exanthematous rash, urticaria, and petechiae have been documented in 23.5% of cases[[59-60] | 761 | June 1, to June 21, 2021. | 18above/both | Tehran, Iran |
|---|---|-----|---------------------------|--------------|--------------|

Covishield is reported to have the lowest percentage of side effects among the three. It must be kept in mind that because all clinical trials are performed under varying conditions, the adverse reaction rates of one clinical trial cannot be compared to another.

#### 4. Conclusion

The study discovered that due to the virus's extensive infectivity pattern, the development and distribution of COVID-19 vaccines have been deemed a global priority. As part of India's immunization drive, Covaxin, Covishield, and Sputnik V were recognized as essential vaccinations. Promoting equitable vaccination distribution requires an understanding of the distribution methods, availability, pricing, and access hurdles for these vaccines. According to the investigation, Covaxin and Covishield both showed acceptable efficacy against several mutant versions of SARS-CoV-2.

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None.

#### 6. Conflict of Interest

None.


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