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Review Article

Adverse events following immunization (AEFI) for Covid vaccines approved by WHO- A short review

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ABSTRACT

The world was suffering and People are in great grief due to COVID 19 Pandemic 2020 and 2021 due loss of life, jobs and other related socio-economic issues and now it has been in subsiding mode due to the great weapon COVID vaccine. However omicron is now threatening due to high transmissibility compare to other variants of Corona virus. All of us aware corona Vaccines have been permitted by the regulatory authorities of different countries under emergency situation for restricted use. However by considering Risk-Benefit almost >18 age group most of the people have received the vaccine in few countries but yet to reach out all people in the world. The vaccine has reached the market with exemption category and without detailed exploration of all safety parameters. In the current situation it was learned that most of the corona vaccines are safe and Adverse Events Following Immunization (AEFI) associated with all other vaccines are reported except few serious adverse effects. Corona vaccines are in the verge for administration for all age groups. Hence our health care scientist in the globe needs to study and closely to monitor the Safety parameters of all approved vaccines. This short review highlighted the ADRs reported by WHO approved vaccines during clinical trials and in treatment Adverse Events Following Immunization (AEFI).

1. Introduction

Corona Virus Disease 19 (COVID-19) SARS–CoV-2, 11^{th}March 2020 WHO declared COVID-19 pandemic. In the history of world an infectious disease disaster happened in the late 2019 and still contagious as on date Total no of cases in the world as of 07^{th} Jan 2022- 298,915,721, Total Mortality in the world 5,469,303. But the number of reporting cases and mortality has come down due to many reasons. One of the main reasons is COVID Vaccine. As of 4^{th} Jan 2022, a total of 9,118,223,397 vaccine doses have been administered.[1]

1.1. Types of vaccines[3]

1.1.1. Types of component viral vaccines

1. Protein sub unit: Contains isolated and purified viral proteins
2. Virus Like Particles (VLP): Contains viral proteins that mimic the structure of the virus, but no genetic material
3. DNA/RNA Based: Contains viral genetic material (such as mRNA) which provides instruction for making viral proteins
4. Non-replicating viral vector: Contains viral genetic material packaged inside another harmless virus that cannot copy itself
5. Replicating viral vectors: Contains viral genetic material packaged inside another harmless virus that can copy itself

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Table 1: ADRs reported in WHO approved vaccines during clinical tvrial[2]

Vaccine Name	Manufacturer	Adverse Events
BNT162b2	Pfizer	**Common**: fever, fatigue, headache, injection site pain **Serious**: shoulder injury related to vaccine administration, right axillary lymphadenopathy, paroxysmal ventricular arrhythmia, myocarditis and right leg paresthesia, fatigue and headache **Rare**: not reported
mRNA-1273	Moderna	**Common**: fever, headache, fatigue, myalgia, chills, and injection-site pain **Serious**: no serious adverse reaction **Rare**: not reported
AZD1222	Oxford/ AstraZeneca	**Common**: headache, nausea, myalgia, arthralgia, injection-site tenderness, injection-site pain, injection-site warmth, injection-site pruritus, fatigue, malaise, feverishness, chills **Serious**: pyrexia, transverse myelitis, hemolytic anemia **Rare**: not reported
Covaxin	Bharat Biotech	**Common**: fever, headache, fatigue, nausea, vomiting **Serious**: not reported **Rare**: not reported
Covishield	Serum Institute of India	**Common**: fever or chills, cough, shortness of breath, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea **Serious**: not reported **Rare**: not reported
Ad26.COV2. S	Janssen	**Common**: injection-site pain, headache, myalgia, fatigue, fever **Serious**: hypotension, bilateral nephrolithiasis in a patient with a history of kidney stones, legionella pneumonia, worsening of multiple sclerosis, fever leading to hospitalization **Rare**: not reported
CoronaVac	Sinovac	**Common**: injection-site pain **Severe**: urticaria **Rare**: not reported

1.2. Types of whole virus vaccines

1. In activated: Contains copies of the virus that have been killed(Inactivated)
2. Live attenuated: Contains copies of the virus that have been weakened (attenuated)

1.3. WHO approved vaccines for Covid-19

1. **NVX-CoV2373-** Novavax: Vaccine Type - Protein subunit approved by WHO for emergency use in 30 countries.
2. **Covovax (Novavax formulation)-** By Serum Institute of India, Type –Protein Sub Unit, approved in 2 countries
3. **mRNA1273-** Moderna- Type –RNA, approved for 83 countries
4. **BNT162b2-** Pfizer/BioN Tech **–**Type-RNA, approved in 123 countries
5. **Ad26.COV2.S-** Janssen (Johnson & Johnson) Type - Non replicating viral vector, approved in 95 countries
6. **AZD1222-** Oxford/AstraZeneca Type-Non replicating viral vector approved in 134 countries
7. **Covishield-** Serum Institute of India (Oxford/AstraZeneca formulation), Type-Non replicating viral vector approved in 47 countries
8. **Covaxin**- Bharat Biotech Type-Inactivated, approved in 12 countries
9. **BBIBP-CorV (Vero Cells)-** Sinopharm (Beijing), Type-Inactivated, approved in 80 countries
10. **CoronaVac-** Sinovac, Type-Inactivated, approved in 48 countries

1.4. Adverse events following immunization (AEFI) for Covid vaccines

The common adverse event following immunization (AEFI) with COVID vaccines includes swelling at the site of injection, pain, fever chills are the common one. Fatigue, muscle soreness, headache and joint pain have been reported in most of the receivers.[4]

1.5. Covaxin

A recent study revealed the AEFI reported for Covaxin during 1st does was 77.27% and with 2nd dose 72.72% respectively. Fever was the most common AEFI experienced in Covaxin.[4]

1.6. Covishield

AEFI reported for Covishield during 1st does was 92.45% and with 2nd dose 86.79%. Fever was the most common AEFI experienced.[5] In India through Cowin platform, more than 2300 cases were reported and only 700 Adverse events were reported to be severe (MoHFW, 2021) AEFI Committee has done a deep review of all these reports, of which only 26 cases were reported to be potential thromboembolic events following the administration of the Covishield vaccine.[5]

In a Pharmacovigilence study for Covishield conducted at Primary Health care workers in Punjab, it was revealed Covishield vaccination in subjects is associated with only minor AEs, and mostly they are manageable with simple measures.

The AEFI Committee has completed an in-depth case review of 498 serious and severe events, of which 26 cases have been reported to be potential thromboembolic (formation of a clot in a blood vessel that might also break loose and carried by the blood stream to plug another vessel) events — following the administration of Covishield vaccine — with a reporting rate of 0.61 cases/ million doses. In a descriptive study of all the AEFI reported to NCC, PvPI between 16^{th} January 2021 and 31^{st} March 2021 in a tertiary care hospital in India AEFI were observed after first dose of Covishield compared to second dose.[6] In a Adverse Events Following Immunization (AEFIs) for COVID-19 in Ontario, 21 reports of thrombosis with thrombocytopenia syndrome (TTS) after receipt of AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine, of which 16 are vaccine-induced immune thrombotic thrombocytopenia (VITT).

Adverse events study of Covishield on health care workers of 1912 nos performed in a tertiary care hospital at Tigray, Ethiopia. 72hrs post vaccination report analysis shown no serious adverse events.[7]

1.7. BNT162b2

Norway investigates 23 deaths in frail elderly patients after vaccination of BNT162b2 (Pfizer/BioNTech).[8] During the pivotal phase 3 clinical trials of mRNA COVID-19 vaccines, several cases of facial paralysis were observed in the vaccine groups (7 of 35 654) compared with 1 case among people who received placebo (1 of 35 611).[9] Myocarditis and pericarditis after COVID-19 vaccination are rare. CDC and FDA have verified 1,124 reports of myocarditis or pericarditis

1.8. CoronaVac

In a study in medical clerkship students in Indonesia for Corona Vac the most common AEFI of SARS-CoV-2 vaccinations was localized pain in the injection site during the first dose with 25 (45%) reports and the booster dose with 34 (67%) reports. Then followed by malaise, the first dose with 20 (36%) reports and the booster dose with 21 (41%) reports. Other symptoms like headache, fever, shivering, sleepiness, nausea, dysphagia, and cold were also reported.[10]

1.9. Ad26.COV2. S

Thrombosis with thrombocytopenia syndrome (TTS) after Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccination is rare. CDC and FDA identified 57 confirmed reports of people who got the J&J/Janssen COVID-19 vaccine and later developed TTS. CDC has also identified nine deaths that have been caused by or were directly attributed to TTS following J&J/Janssen COVID-19 vaccination. Guillain-Barré Syndrome (GBS) in people who have received the J&J/Janssen COVID-19 vaccine is rare. After more than 17.2 million J&J/Janssen COVID-19 vaccine doses administered, there have been around 283 preliminary reports of GBS identified. By April 12, 2021, approximately 7 million Ad26.COV2.S vaccine doses had been given in the US, and 6 cases of CVST (cerebral venous sinus thrombosis) with thrombocytopenia had been identified among the recipients.[11]

1.10. mRNA-1273

Three confirmed cases of TTS following mRNA COVID-19 vaccination (Moderna) have been reported to Vaccine Adverse Events Reporting System (VAERS) VAERS after more than 470 million doses.[8] Myocarditis and pericarditis have been reported rarely.

2. Conclusion

The current review has indicated Adverse Events Following Immunization (AEFI) of WHO approved Vaccines. The review put forward the evidences of published research articles in different journals and platforms. It was quite interesting that most of the COVID vaccines have not reported with serious adverse events in the selected population. But it was rarest and rare reported Thromboembolic events with Covishield, Myocarditis and pericarditis with BNT162b2, Thrombosis with thrombocytopenia syndrome (TTS) after Ad26.COV2. S and mRNA-1273. Hence on Risk/Benefit analysis Covid vaccines are Lifesaving medicine for millions of people during this pandemic. However a detailed study of AEFI required for extensive use of these vaccines.

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None.

4. Conflict of Interest

The author declares that there is no Conflict of interest.

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