



EDITORIAL ARTICLE

Vaccine safety surveillance across the globe with a focus on the COVID-19 vaccines

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With 19 approved COVID-19 vaccines in the market across the globe and 325 under development (Vaccine Centre, London School of Hygiene & Tropical Medicine, 2021), vaccine safety surveillance remains one of the key focus areas for all Pharmacovigilance professionals worldwide today. Especially because they are being developed under extraordinarily compressed timelines.

Safety assessment of vaccines starts at the clinical development stage and continues to post-marketing approval. The word “surveillance” however is used commonly in the context of safety monitoring in the post-marketing phase. For the COVID-19 vaccines which had a shorter development phase than other vaccines, the post-marketing safety surveillance needs to be stronger to make sure that no rare adverse events are being missed. This is of paramount importance in protecting the vast population who are the recipients of the vaccine.

Traditionally, vaccine safety surveillance can be active or passive. Let's look at some of the vaccine safety surveillance initiatives across the world, especially with a focus on COVID-19 vaccine safety.

In the US, when it comes to safety surveillance of vaccines, the Centre for disease control and prevention (CDC) is invested in three key areas (Salman *et al.*, 2021):

- Active Surveillance in the form of vaccine safety research, especially for targeted monitoring of Adverse Events of Special Interest (AESIs)

- Determining causality and identifying preventable risk factors
- Public health surveillance to identify vaccine-related adverse events

Similarly, for the COVID-19 vaccines, the FDA has initiated both active and passive safety surveillance systems, in collaboration with the CDC (FDA, 2021).

Interestingly, today the world is using the best of its technologies to aid the purpose of safety surveillance. For example, one of the active safety surveillance methods used by the FDA for COVID-19 vaccines is the BEST (Biologics Effectiveness and Safety) sentinel system which heavily banks on different Artificial Intelligence (AI) tools. BEST is not a new initiative though. It commenced in October 2017 as an active surveillance program for biologics in the US. The BEST has developed a prototype for automating the detection, validation, and reporting of biologic product adverse events (AEs). The methods used include artificial intelligence, machine learning, natural language processing, and robotics. BEST can monitor the potential safety concerns of the already approved COVID 19 vaccines.

Needless to say, this is a great boon for effective safety monitoring in the face of the huge scale of mass COVID-19 vaccination efforts.

In the European Union, other than their strong active and passive surveillance systems for vaccines, one interesting



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thing to observe is their focus on public sensitization and transparency. Some examples of commitment to transparency and keeping patients and healthcare professionals fully informed to make their choices are (Arlett *et al.*, 2021):

- There is public access to EudraVigilance since 2012 through www.adrreports.eu
- Data from reports of suspected side effects to vaccines are weekly updated and published
- COVID-19 vaccine-related safety updates are made public regularly
- Risk management plans (RMPs) for COVID-19 vaccines are published
- The package leaflet includes all the established side effects

Similarly in Australia, Therapeutic Goods Administration (TGA) has come up with a COVID-19 Vaccine Safety Monitoring Plan, which aims to strengthen the existing vaccine vigilance system for early detection and investigation of suspected side effects (TGA, 2021). Enhanced reporting and enhanced signal detection activities are their key focus area. Initiating active surveillance activities, strengthening “environmental scanning” such as reviewing medical literature/overseas data, building their capacity and capability for investigating individual COVID19 AEFI reports, enhanced cumulative data reviews for each COVID-19 vaccine are some of the initiatives taken by TGA(TGA, 2021).

Looking at the developing world landscape, World Health Organisation (WHO) has been doing considerable work through the years in training all stakeholders in vaccine safety. There are e-learning modules available that give details on vaccine safety surveillance methods and mechanisms.

India follows the WHO directives for vaccine safety surveillance and it is called National AEFI (Adverse Events Following Immunisation) surveillance system. A key component of this public health program is to train health care workers at the district level to identify and report adverse events following immunization (Joshi *et al.*, 2018). For the COVID-19 vaccines, the adverse events can be submitted through the Government’s vaccination drive (COWIN) portal and also through the website of the Pharmacovigilance Program of India (PvPI). While there are downloadable forms and toll-free numbers available on these websites, the overall awareness about how to report and what to report needs to go up a notch higher.

Taking a bird's eye's view across the globe to understand the different methods to look at vaccine safety surveillance, one thing becomes clear. The commitment to monitor the safety of a vaccine does not stop at the clinical development stage. Rather, awareness, reporting, and research need to be bolstered after the vast population gets exposed to the vaccine. Global collaboration, understanding, and embracing the global best practices will go a long way to

ensure safer vaccinations. With the COVID-19 pandemic already creating havoc in minds of all, the panic or unacceptance about the vaccination side effects in the population is undesirable. Adverse events are the unfortunate yet unavoidable element in the journey of a new drug or a vaccine. But since it is a healthy population who are recipients of vaccines, the researchers and PV professionals need to be more mindful of the risk-benefit profile of the vaccine.

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