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Post Vaccine Adverse Events Reporting Systems – Comparative Chart

In the late 19th century, British Dr. Edward Jenner demonstrated that infection with a relatively mild cowpox virus conferred immunity against the deadly smallpox virus, launching the history of vaccines, which have been become critical in the protection of public health.

However, as with all medical products, vaccines are not without risks. For instance, the development of a vaccine against Dengue, launched close to 100 years ago, was hindered by the damages caused by Dengue vaccines to those not previously affected by Dengue. Similarly, despite several decades of search, there is currently no vaccine against Respiratory Syncytial Virus. Indeed, clinical trials conducted in children in the 1960s led to *enhanced* rather than *weakened* respiratory disease among those who had received the vaccine and were later exposed to the virus and developed the disease.

How, then, can vaccines be developed where the benefits, if any, outweigh the risks enough to warrant their distribution? The answer is that there must be a commitment to the safety of vaccines, as well as the safety of any medical product, as well available information to allow policymakers, health professionals and the public to monitor the effects of vaccines once they are launched into the market. It is here when "post vaccine events reporting systems" come into play.

This handout presents the most relevant and popular systems used around the world developed to report adverse events post reception of vaccines. It is organized by country or agency endorsing each system and addresses the most common questions that policymakers, health professionals, and the public need answers to in order to make collective and individual decisions.

Country/Authority	USA	Canada
Database and recommended search tools	The Vaccine Adverse Event Reporting System (VAERS, Medalerts)	Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)
When was it launched and what training resources exist?	• Established in 1990 • Tutorial on using VAERS search • Tutorial on using the Medalerts for running VAERS searches • Reporting adverse events	• Established in 1987 • AEFI Reporting Form • Guide for completing and submitting AEFI reports
When to use the reporting tool?	To report adverse events after administration of any vaccine licensed in the United States.	To report adverse events after administration of any vaccine licensed in Canada when they: 1. Have a clear temporal association with a vaccine; 2. Do not have any other clear cause at the time of reporting; 3. Meet one or more of the 'seriousness' criteria; and 4. Are unexpected regardless of seriousness.
Who can report?	Anyone can submit a report on VAERS.	Only healthcare professionals can submit a report to CAEFISS.
What is the process of submission like in terms of adequacy and legitimacy?	VAERS is co-administered by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA)-agencies of the U.S. Department of Health and Human Services (HHS). VAERS reviews all submissions. Submitting false reports is considered a criminal offense.	CAEFISS reports are submitted by public health authorities in provinces and territories, which in turn receive them from local public health units. These organizations evaluate if reports are adequate and legitimate.

What are some limitations?	VAERS is not a fully compulsory surveillance system. While health providers are required to report a limited number of serious adverse events, they are only encouraged to report others. The public can also report their experiences after vaccination, yet many do not know of the system or find it difficult to use. Therefore, there may be substantial underreporting (as high as 90%). VAERS is a passive reporting system. Reports adverse events are not automatically collected. Rather, someone who had or is aware of an adverse event following vaccination files a report. VAERS does not rely on expert reporting. Reports are error prone as they may be submitted by people untrained in the details of reporting. VAERS data alone does not determine if the vaccine caused the reported adverse event. However, data collection is critical to post-marketing studies of vaccine safety).	Only healthcare professionals can report, and reporting is complex and time consuming, so there is potential for vast underreporting. Passive surveillance for AEFIs is also subject to a lack of certainty regarding the diagnostic validity of a reported event, missing information regarding other potential causes such as underlying medical conditions, or concomitant medications and the different AEFI reporting practices by jurisdictions within Canada. These issues may lead to over/under-reporting of mild AEFIs from some FPTs (Federal/Provincial/Territory levels).

Country/Authority	UK	Europe	Vaxxtracker	Global
Database & search tools	Yellow Card	European database of suspected adverse drug reaction reports (EudraVigilance)	Vaxxtracker	VigiAccess
When was it launched & what training resources exist?	• Established in 1964 • COVID-19 reporting site • Reporting site for non-COVID-19 related issues (click on numbered hyperlinks) • Guidance on reporting • Drug analysis profiles • COVID-19 Adverse Reactions	• Established in 2001 • Understanding web reports • Information on reporting side effects • Viewing and interpreting reports	• Established in 2020 (to confirm) • Viewing COVID-19 statistics • Viewing vaccine side-effects	• VigiAccess was launched by the World Health Organization (WHO) in 2015 to provide public access to a global database of reported potential side effects of medicinal products • To view COVID-19 statistics, search "covid-19 vaccine" in tool
When to use the reporting tool?	To report suspected problems or incidents involving: 1. Side effects (adverse drug reactions or ADRs); 2. Medical device adverse incidents;	To report adverse events after administration of any vaccine licensed in the EU **Note*: submissions are sent to national medicines regulatory authorities or to the pharmaceutical company that holds market authorization for the drug.	To report adverse events after administration of any COVID-19 vaccines	To report adverse events after administration of any medicinal product **Note*: submissions are sent to the national centre for pharmacovigilance for evaluation and identification of unknown or poorly addressed risks.

	3. Defective medicines (those not of acceptable quality); 4. Counterfeit or fake medicines or medical devices; and 5. Safety concerns for e-cigarettes or refill containers (e-liquids).	These reports are then forwarded to EudraVigiliance.		The WHO PIDM (World Health Organization Program for International Drug Monitoring) members anonymise their reports, so patients, healthcare professionals, or institutions involved cannot be identified, and forward them to UMC (Uppsala Monitoring Center) to be uploaded into VigiBase.
Who can report?	Both the public and healthcare professionals are encouraged to submit reports to Yellow Card. For specific reporting on medical devices, manufacturers, marketing authorization holders, or "others" can report as well.	Reporting is usually carried out by healthcare professionals, although patients can also report, through online patient reporting forms hosted by national medicines regulatory authorities or by telephone.	Anyone can submit a report, whether health professionals or the public.	Both health providers and the public can and should report adverse effects to their respective national pharmacovigilance centres.
What is the process of submission like in terms of adequacy and legitimacy?	The Medicines and Healthcare products Regulatory Agency (MHRA) is the executive Agency of the Department of Health and Social Care. It runs the Yellow Card reporting system. Reported side effects are evaluated, along with additional information from clinical trial data, medical	The European Medicines Agency carries out quality reviews in EudraVigilance. These include identifying duplicate reports, coding reported medicines and active substances, and providing feedback on the quality of information sent by "medicines regulatory authorities" and marketing-authorisation holders in the EEA.	The organizers of Vaxxtrack go over submissions The website notes that "VaxxTracker.com was created by a group of NGO citizens concerned about potential risks associated with vaccinations."	National centres for pharmacovigilance review the data to identify unknown or poorly addressed risks before anonymizing them, and send them to the UMC to be uploaded to VigiBase UMC regularly screens the data to identify, characterize, and better

	literature, or data from international medicines regulators, to identify unknown safety issues. These reports are assessed by a team of medicine safety experts of doctors, pharmacists and scientists who study the benefits and risks of medicines. Where appropriate, the MHRA also seeks advice from the independent Commission on Human Medicines (CHM)			understand potential risks of medicinal products. UMC shares the results of its analyses with the national centres, WHO, and the general public through various channels.
What are some of the limitations?	Much like with other voluntary surveillance systems, there is generally underreporting As with VAERS, people without training may submit reports that lack helpful information or other pertinent details. Reported data does not imply causation. Further research is needed to that effect. See links to specific drugs on the Interactive Drug Analysis Profiles (iDAPs) page.	The information on this website includes suspected associations that reflect the reporter's observations and opinions. the assessment considers many other factors, such as the medical condition and the medical history of the patient The information may include known side effects already listed in the summary of product characteristics (SmPC) and the package leaflet. While cause-effect relationships cannot be determined by simple	As approximately 80% of the reports on the website come from the VAERS database, its limitations resemble those of VAERS	The information on this website relates to potential side effects; that is, symptoms and other circumstances observed after using a medicinal product, but which may or may not be related to, or caused by, that product. Information on potential side effects do not mean that the product or its active substance either caused the observed effect or is unsafe. Scientific assessment and detailed evaluation of all data is needed to confirm causality between a product and a side effect.

	Understanding limitations can help to prevent misinterpreting the data.	reporting, a scientific assessment of such relationships are a critical aspect of the continuous monitoring of the benefits and risks of drugs. The number of suspected side effects should not serve as a basis for determining the likelihood of an adverse effect occurring in the population, because these numbers need to be contextualized with other factors, such as how many people take the medicine and how long the medicine has been on the market. Each case in generally refers to a single patient; however, reports may include more than one side effect, so the total number of side effects will not match the number of cases. Side-effect reports do not represent all information on benefits and risks of a drug and should not be the sole source of decision-making regarding treatment. Other sources, including patients' unique characteristics, must be considered.		A search on a medicinal product will return a basic list of reported potential side effects and the number of times each effect has been reported. However, the database does not include other factors needed to contextualize the retrieved information, such as how many people have taken the product, how long they have taken it, how long it has been on the market, and the differing reporting practices that influence which observations are included in the reports. VigiAccess cannot be used to compare the safety profiles of different medicinal products, because it does not provide sufficient context to make such comparisons possible. Information should not be used alone for treatment decisions. Other sources should be considered, including patients' unique characteristics, product inserts, and other sources of prescribing information.