Results of Literature Review and Survey of COVID-19 Vaccine Safety Assessment Activities

Maps

Updated May 5, 2023

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Background

In 2021, there was an urgent need to support the COVAX Vaccine Safety Working Group (VSWG), the Coalition for Epidemic Preparedness Innovations (CEPI), and the WHO-Pharmacovigilance team (WHO-PV) in collating the studies evaluating the safety of COVID-19 vaccines globally to inform strategy and policy. A landscape assessment of COVID-19 vaccine safety surveillance activities, including a literature review and a survey, was conducted to inform on potential sources of evidence and to identify gaps.

Methods for Identifying Published Studies on COVID-19 Vaccine Safety Presented on VIEW-hub

A search of the published literature for COVID-19 vaccine safety studies assessing adverse events following immunization (AEFI) was conducted January 27, 2023. Studies that evaluated active vaccine safety surveillance (AVSS) or cohort event monitoring studies of routine use of COVID-19 vaccines were included. Complete literature review methods can be found on VIEW-hub.org here.

Methods for Survey Assessing Planned and Ongoing Vaccine Safety Assessment Activities Globally

A survey to identify planned or ongoing surveillance activities (including studies) assessing AEFIs following COVID-19 vaccination was conducted December 2021 to February 2022. The survey was sent to hundreds of individuals at various institutions worldwide, including WHO regional offices, national pharmacovigilance centers, universities known to be evaluating COVID-19 vaccines, government public health institutions, vaccine manufacturers, among others. The survey collected information on planned, current and previous active surveillance activities, including the type of AVSS activity and study design, where it was to be conducted, which populations were being targeted, which COVID-19 vaccine products were being assessed, the surveillance setting and which AEFIs were to be monitored. Complete survey methods can be found on VIEW-hub.org here.

Full data from the literature review and survey are available on the COVID-19 vaccine safety studies module on <u>VIEW-hub.org</u>. This document can be found in <u>the Resources section at the bottom of the VIEW-hub safety module</u>.

Results

We identified 59 countries with AVSS publications (Figure 1a and Table). Some studies spanning multiple countries in a region did not detail the countries in which they took place. Every region of the world had at least one AVSS publication, but there were fewest in Africa. Institutions who responded to the survey reported activities in 46 countries (Figure 1b). A total of 82 countries had AVSS activities identified either through the literature review or the survey (Figure 1c); the survey did not capture activities in at lest 36 countries (Figure 1c purple). More AVSS activities are planned or ongoing in Africa than conveyed by the published data (Figure 1c yellow).





Figure 1. Countries in which COVID-19 vaccine safety studies were identified

a. Published studies



b. Survey response



c. Published literature and survey



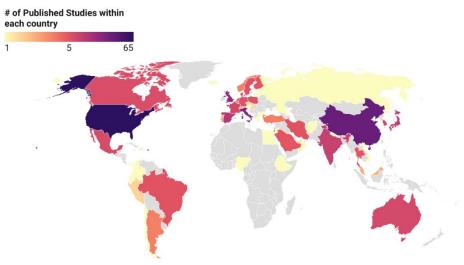
Footnote: Some may be part of multi-country studies. Maps created with Datawrapper.





The number of publications per country ranged from 1 (23 countries) to 65 (United States; Figure 2, Table).

Figure 2. Number of published COVID-19 vaccine safety studies identified within each country



Footnote: Some may be part of multi-country studies. Maps created with Datawrapper.





Table. Countries with published COVID-19 vaccine safety studies identified

Country	# of Studies
United States	65
China	46
Italy	38
United Kingdom	34
Israel	33
Multiple Countries	22
Spain	21
Japan	17
India	16
France	12
Australia	11
South Korea	11
Netherlands	11
Mexico	10
Canada	9
Denmark	9
Poland	7
Germany	7
Singapore	6
Iran	6
Brazil	6
Sweden	6
Saudi Arabia	5
Thailand	5
Finland	5
San Marino	4
Turkey	4
Argentina	4
Belgium	4
Norway	4

Country	# of Studies
Malaysia	3
Switzerland	3
Portugal	3
United Arab Emirates	2
Hungary	2
Peru	2
Czech Republic	2
Ecuador	1
Kuwait	1
Russia	1
Vietnam	1
Chile	1
Nigeria	1
Jordan	1
Nepal	1
Egypt	1
Oman	1
Afghanistan	1
Ethiopia	1
Colombia	1
Dominican Republic	1
Panama	1
Austria	1
Bulgaria	1
Estonia	1
Greece	1
Iceland	1
Latvia	1
Lithuania	1
Slovenia	1

If you are conducting an AVSS study that you do not see represented here, please contact Marley Jurgensmeyer at mjurgen4@jhu.edu.