PAHO
Pan American Health Organization
World Health Organization Americas

FORM FOR REPORTING ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

This form contains the questions that should be answered when reporting an AEFI. Enter all information on the case during your first contact with the patient (on detection of the AEFI).

1. Case identification number:	
Identity of the vaccinated or affected person	**Identity of the reporter**
2. Full name:	**11. Full name:**
3. National identification number:	**12. Profession:**
4. Complete address:	**13. Institution and position:**
5. Subnational geographical level:	**14. Complete address:**
6. Telephone and e-mail:	**15. Subnational geographical level:**
7. Sex: M ☐ F ☐	**16. Telephone and e-mail:**
8. Date of birth: dd/mm/yyyy	
9. Age at onset of the event (using the first sign, symptom, or abnormal laboratory finding as a reference)**:** ☐☐ years ☐☐ months ☐☐ days	**17. Date of consultation:** dd/mm/yyyy
10. ** Ethnicity This applies to countries whose legislation requires the disaggregation of records by ethnicity.	**18. Date form was completed:** dd/mm/yyyy

History of the person vaccinated.	
19. Medical history (history and another relevant information, such as other AEFIs and other epidemiological information):	
Please note: DK = doesn't know NA = not applicable	
20. Does the person have a history of events similar to the current one?	☐ Yes ☐ No ☐ DK
21. Does the person have a history of allergic reactions to other vaccines?	☐ Yes ☐ No ☐ DK
22. Does the person have a history of allergic reactions to medication?	☐ Yes ☐ No ☐ DK
23. Does the person have a history of allergic reactions to previous doses of the same vaccine?	☐ Yes ☐ No ☐ DK ☐ NA
24. Did the person receive a diagnosis of SARS-CoV-2 prior to vaccination?	☐ Yes ☐ No → *skip to question 29* ☐ DK → *skip to question 29*
25. Asymptomatic? ☐ Yes → *skip to question 27* ☐ No ☐ DK	26. Date of onset of symptoms: dd/mm/yyyy
27. How was the diagnosis of the infection confirmed? ☐ By clinical manifestations only ☐ By immunoassay ☐ By molecular test ☐ Other **Explain:**	

28. Date the sample for the confirmatory test was taken: dd/mm/yyyy

Only for AEFI related to COVID-19 vaccines.

29. Was or is the vaccinated person participating in a clinical trial of COVID-19 vaccines?

☐ Yes ☐ No

30. Medication history (indicate all medications that the person was taking when vaccinated):

Medication	Presentation	Dose	Route of administration	Date first administered
				dd/mm/yyyy
				dd/mm/yyyy
				dd/mm/yyyy
				dd/mm/yyyy
				dd/mm/yyyy

If the person vaccinated is a woman aged 15 to 49 years or if pregnancy is suspected:

31. Was she pregnant at the onset of the AEFI?

☐ Yes, weeks of gestation: ☐ No ☐ Probable delivery date is unknown: dd/mm/yyyy

32. Were there any complications during pregnancy, delivery, or the puerperium, or neonatal complications or birth defects? ☐ Yes ☐ No Diagnosis of the complication:

Describe the complication:

33. Once was it determined that the woman was pregnant when she received the vaccine, did a health facility begin monitoring her?

☐ Yes ☐ No ☐ DK

34. Health institution where the person was vaccinated:

35. Address of the vaccination site:

36. Vaccines (administered immediately prior to the AEFI):							**37. Diluent (if applicable):**				
Generic name of the vaccine	Trade name or manufacturer of the vaccine	Vaccination date (dd/mm/yyyy)	Vaccination time (a.m. or p.m.)	Dose	Lot number	Expiration date (dd/mm/yyyy)	Name	Lot number	Expiration date (dd/mm/yyyy)	Reconstitution date (dd/mm/yyyy)	Reconstitution time (a.m. or p.m.)

38. Was another vaccine administered in the 30 days prior to the onset of the AEFI? ☐ Yes ☐ No ☐ DK

Which one?_____

39. How was the vaccination information verified? ☐ Card or physical record ☐ Card or e-record

☐ Verbal declaration ☐ Clinical history corroborated with card ☐ Unknown ☐ Other: Indicate _____

40. AEFI information. Select the events relevant to the case in question. The codes will be assigned by the subnational or national level, as determined by the country. When electronic data collection tools are used, the best code for the AEFI list can automatically be assigned. If the AEFI corresponds to a syndrome or defined medical condition, record it as "Other". Select as many as applicable.

40.1 AEFI		40.2 Date of onset	40.3 Time of onset	40.4 MedDRA or ICD code
Fever ≥38° C	☐			
Pain at the injection site	☐			
Erythema at the injection site	☐			
Inflammation at the injection site	☐			
Headache	☐			
Febrile seizures	☐			

Abscess	☐			
Lymphadenitis	☐			
Encephalopathy	☐			
Encephalitis	☐			
Thrombocytopenia	☐			
Anaphylaxis	☐			
Toxic shock syndrome	☐			
Sepsis	☐			
Other_____	☐			
Other_____	☐			
Other_____	☐			

41. Description of the AEFI (enter below the symptoms as the patient describes them and the clinical signs of the event, and include the results of any laboratory tests and imaging performed, if relevant):

42. Serious AEFI:

☐ Yes ➔ ☐ Death ☐ Life-threatening ☐ Significant or persistent disability ☐ Hospitalization
☐ Birth defect ☐ Miscarriage ☐ Fetal death ☐ Another major medical event. Specify:

☐ No

43. AEFI outcome:

☐ Death Date of death: dd/mm/yyyy Was an autopsy performed? ☐ Yes (enclose the autopsy report) ☐ No
☐ Unknown

☐ Not recovered ☐ Recovering ☐ Fully recovered ☐ Recovered with sequelae ☐ Unknown

To be completed by the level conducting the investigation:

44. Is an investigation warranted? ☐ No ☐ Yes ➔ Type of investigation that should be conducted: ☐ Concise ☐ Full	**45. Date the investigation is expected to begin or date it began:** dd/mm/yyyy

To be completed by the national level:

46. Date received at the national level:
dd/mm/yyyy

47. Additional comments or information you consider important that has not been entered in the previous sections:

INSTRUCTIONS FOR COMPLETING THE REPORTING FORM FOR AN ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI)

Question	Response instruction
Case identification number	Enter only the case identification number assigned at the national level. This number should not be the same as the national identification number of the person who experienced the AEFI. It should always be used as a case reference to maintain confidentiality and avoid using names or sensitive information.
Identity of the vaccinated or affected person	
National identification number	Enter only the national identification number of the vaccinated or affected person.
Subnational geographical level	Enter the name of the subnational geographical level in which the vaccinated or affected person resides. This is the level immediately below the national level – that is, the department, province, state, or region, depending on the country.
Sex	Mark M if male and F if female.
Age at onset of the event	Mark the age, in years, months, or days, of the affected person at the onset of the AEFI. Use the date of the first sign, symptom, or abnormal laboratory finding identified as a reference.
** Ethnicity	Enter the ethnicity of the vaccinated or affected person. For this question, include the list of ethnic groups officially recognized by the country in which the form is used.
Identity of the reporter	
Institution and position:	State the institution that employs the reporter and the position he/she holds or has been assigned.
Subnational geographical level:	Enter the subnational geographical level of the institution reporting the case. This is the level immediately below the national level – that is, the department, province, state, or region, depending on the country.
Date of consultation date: dd/mm/yyyy	Enter the date that the vaccinated person was first seen in the health service for the AEFI.
History of the vaccinated person.	
Medical history:	Enter previous or recent illness, relevant toxicological, exposure, surgical, and epidemiological history. State whether other people in the family or community — whether or not vaccinated — have had similar symptoms. Also indicate whether you have information on an infectious agent circulating in the community surrounding the vaccinated person or among other members of the community.
Does the person have a history of previous events similar to the current one?	Mark “Yes” if there is a history of events with the same signs, symptoms, or abnormal laboratory findings with a similar clinical presentation. Otherwise, mark “No”. If there is no information in this regard, mark “DK”.
Does the person have a history of allergic reactions to other vaccines?	Mark “Yes” if there is a history of allergic reactions to other previously administered vaccines. Otherwise, mark “No”. If there is no information in this regard, mark “DK”.
Does the person have a history of allergic reactions to medication?	Mark “Yes” if there is a history of allergic reactions to a previously administered medication. Otherwise, mark “No”. If there is no information in this regard, mark “DK”
Does the person have a history of allergic reactions to previous doses of the same vaccine?	Mark “Yes” if there is a history of allergic reactions to a dose of the same previously administered vaccine. Otherwise, mark “No”. If there is no information in this regard, mark “DK”.
Date of onset of symptoms	Enter the date when SARS CoV-2 symptoms began. If asymptomatic infection was confirmed, leave the space blank.

How was the diagnosis of the infection confirmed?	Select the method used to confirm the diagnosis of the SARS CoV-2 infection referred to in the previous question. Mark "By clinical manifestations only" if no diagnostic test was performed; "By immunoassay" if serum antibody or viral antigen tests were conducted primarily using immunologic methods; and "By molecular test" if molecular detection using nucleic acid techniques was used. If none of these tests were performed, mark "Other" and describe the confirmation method.
Date the sample for the confirmatory test was taken:	Indicate when the sample was taken for the first positive test in the course of SARS-CoV-2 disease.
Was or is the vaccinated person participating in a clinical trial of SARS-CoV-2 vaccines?	Indicate whether the vaccinated person received the vaccine in a clinical trial of a SARS-CoV-2 vaccine.
Medication history:	In this section, state the medications that were being administered to the vaccinated person at the time of vaccination or had been administered in the 48 hours prior to vaccination.
30.1 Medication	Enter the name of the active principle of the medication that was being administered.
30.2 Presentation	Indicate the presentation or dosage form of the medication administered.
30.3 Dose	Indicate the dose in free text, providing the number, unit of measure, and frequency of administration (for example, 500 mg every 6 hours
30.4 Route of administration	Indicate the route of administration, based on the following list: ° Enteric ° Buccal or sublingual ° Respiratory ° Ophthalmic or nasal ° Urogenital ° Rectal ° Dermal ° Transcutaneous injection or infusion ° Intraorgan injection or infusion ° Central nervous system injection or infusion ° Circulatory injection or infusion ° Musculoskeletal injection or infusion ° Other
30.5 Date first administered	Indicate the date that the first dose of the medication was administered in dd/mm/yyyy format.
If the vaccinated person is a woman aged 15 to 49 or if pregnancy is suspected:	This group of questions will be answered only if the vaccinated person is a woman of reproductive age. The official age range is 15 to 49 years. However, in special cases, girls younger than 15 and women older than 49 can conceive. It is recommended that you always ask about her history.
Was she pregnant at the onset of the AEFI?	Mark "Yes" if the pregnancy diagnosis was confirmed by a laboratory test or diagnostic imaging, or if a fetal heartbeat was consistently heard. If there is no certainty about the pregnancy diagnosis, mark "Unknown". If it can reliably be ensured that the woman was not pregnant, mark "No".
Probable delivery date:	The probable delivery date should be calculated using the most reliable method, in the following order: 1. Date of the first day of the reliable last menstrual period. 2. First trimester ultrasound. 3. Second or third trimester ultrasound.
Were there any complications during pregnancy, delivery, or the puerperium, or neonatal complications or birth defects?	Indicate any pathology of pregnancy, delivery, or the puerperium, or any neonatal and congenital pathology confirmed by a physician. For a list of possible complications, review the list of pathologies in perinatal clinical history at PAHO's Latin American Center for Perinatology.

32.2 Describe the complication:	Provide details on the complication, including a summary of the dates of onset, diagnoses, diagnostic tests, treatments, and outcomes.
Once it was determined that the woman was pregnant when she received the vaccine, did a health facility begin monitoring her?	Ask the patient whether, when her pregnancy was diagnosed, a health facility began monitoring her. The objective of monitoring inadvertently vaccinated pregnant women is to guarantee maternal and fetal well-being and properly document all complications.
Vaccines (administered immediately prior to the AEFI):	In this section, include all vaccines administered immediately prior to the AEFI. It is recommended that whenever an AEFI is reported, a copy of the person's most reliable complete vaccination record (that is, vaccination card, copy of the e-record, etc.) be attached.
Generic name of the vaccine	Enter the generic name of the vaccine, which usually indicates the antigens it contains or the diseases it prevents.
Trade name or manufacturer of the vaccine	Enter the name of the manufacturer of the vaccine.
Vaccination date	Enter the vaccination date, in dd/mm/yyyy format.
Vaccination time (a.m. or p.m.)	Enter the vaccination time, if known, in a.m./p.m. format
Dose	Indicate which dose of the vaccine was administered – that is, whether it is the first, second, or third dose of the same vaccination series.
Lot number	Enter the lot number of the vaccine administered as stated on the vial, the sticker on the vaccine label, or the electronic vaccination record.
Expiration date	Enter the expiration date of the vaccine indicated by the manufacturer.
Diluent (if applicable):	This is where to enter the information on the diluent of the vaccine administered.
Name	Indicate which diluent was used.
Lot number	Enter the lot number of the diluent.
Expiration date	Enter the expiration date indicated by the diluent's manufacturer, in dd/mm/yyyy format.
Reconstitution date	Enter the date the vaccine was reconstituted, in dd/mm/yyyy format.
Reconstitution time.	Enter the time the vaccine was reconstituted, in a.m./p.m. format
Was another vaccine administered in the 30 days prior to the onset of the AEFI?	Confirm whether a vaccine other than those already entered was administered in the 30 days prior to the onset of symptoms of the AEFI in question. If "Yes," enter the name of the vaccine.
How was the vaccination information verified?	Select the option corresponding to the means of vaccination verification – that is, the card or physical or e-record, the verbal declaration of the vaccinated person or his/her caregiver, or an entry in the clinical history that the physician or nurse declares to have verified with the card or immunization record. If there is no certainty about this or it was not verified, mark "Unknown". Mark "Other" if a mechanism not on the list was used and specify it under "Indicate".
AEFI information	
40.1 AEFI.	Mark all applicable AEFIs from the list of signs, symptoms, and medical problems. Select the option that best describes the problem of the affected person. If the signs and symptoms correspond to an established medical disorder, mark it and do not detail the respective signs and symptoms. For example, a person with encephalitis may have a headache and fever of ≥38°C. To answer this question, select only encephalitis, provided that the diagnosis has been confirmed. If the diagnosis is in doubt, the respective signs and symptoms should be selected. If the AEFI is not on the predetermined list, enter it as "Other".
40.2 Date of onset.	Enter the date that the signs or symptoms began, or the date of the abnormal laboratory findings that configured the AEFI.
40.3 Time of onset.	Enter the time that the signs or symptoms appeared, or the time of the anomalous laboratory findings that configured the AEFI, if known.

40.4 MedDRA or ICD code.	**This field should be completed at the national level**, indicating the MedDRA or ICD code for the AEFI you are reporting.
AEFI description:	Enter the details of the AEFI's clinical history, including those requested in the question's instructions.
Serious AEFI:	If the AEFI is serious, mark "Yes" and select the reasons why it is considered serious. When selecting "Other major medical event," indicate what you are referring to in the "Specify" space. If it is not serious, mark "No".
AEFI outcome:	Mark the option that best indicates the outcome of the AEFI. If it was death, enter the date using the dd/mm/yyyy format and indicate whether an autopsy was performed. Enclose the autopsy report if one was performed.
Is an investigation warranted?	**Indicate whether the administrative level responsible for the decision to use the form in the country determined that an investigation of the case should be launched.** If you mark "Yes," indicate what type of investigation will be conducted. "Concise" means a brief investigation that includes a review of the clinical case records and perhaps an interview with the patient or treating physician. It does not require substantial resources, and there is no need to collect a great deal of information. A "full" investigation involves a visit to the vaccination site and the community, coupled with an extensive review of the clinical records. **Moreover, additional records are created to broaden the diagnostic study.**
Date the investigation is expected to begin or date it began	Enter the date the investigation is expected to begin or when it began.
Date received at the national level.	Enter the date the national level received the report.
Additional comments or information you consider important that has not been entered in the previous sections.	Include all additional information on the case in this section, if you consider it relevant. This will depend on the case in question.

DICTIONARY OF VARIABLES AND MAP OF KEY VARIABLES

The variables in the green field are considered key for reporting to WHO. The remaining variables are considered essential for reporting to the national and regional levels.

Data element	Permissible values	Coding
Case identification number	Free text	
Full name	Free text	
National identification number	Free text	
Complete address	Free text	
Subnational geographical level	Free text	
Telephone and e-mail	Free text	
Sex	Male	1
	Female	2
Date of birth	dd/mm/yyyy	
Age at onset of the event	yy/mm/dd	
Ethnicity		
Institution of the reporter	Free text	
Profession of the reporter	Free text	
Office and position of the reporter	Free text	
Complete address of the reporter	Free text	
Subnational geographical level of the reporter	Free text	
Telephone and e-mail of the reporter	Free text	
Date of consultation	dd/mm/yyyy	
Current date	dd/mm/yyyy	
Medical history	Free text	
Does the person have a history of previous events similar to the current one?	Yes	
	No	
	DK	
Does the person have a history of allergic reactions to other vaccines?	Yes	
	No	
	DK	
Does the person have a history of allergic reactions to medications?	Yes	
	No	
	DK	
Does the person have a history of allergic reactions to previous doses of the same vaccine?	Yes	
	No	
	DK	

Did the person receive a diagnosis of SARS-CoV-2 infection prior to vaccination?	Yes No DK	
Asymptomatic	Yes No DK	
Date of onset of symptoms	dd/mm/yyyy	
How was the diagnosis of the infection confirmed?	By clinical manifestations only By immunoassay By molecular tests Other	1 2 3 0
Explain the confirmation of the diagnosis	Free text	
When was the sample for the confirmatory test taken?	dd/mm/yyyy	
Was or is the person vaccinated participating in a clinical trial of COVID-19 vaccines?	Yes No	
Medication	Free text	
Presentation	Free text	
Dose	Free text	
Route of administration	Free text	
Date first administered	dd/mm/yyyy	
Was the woman pregnant at the onset of the AEFI?	Yes No Unknown	
Weeks of gestation	Numerical	
Probable delivery date	dd/mm/yyyy	
Complications during pregnancy, delivery, or the puerperium, or neonatal complications or birth defects	Yes No	
Diagnosis of the complication	Free text	
Describe the complication	Free text	
Once it was determined that the woman was pregnant when she received the vaccine, did a health facility begin monitoring her?	Yes No DK	
Health institution where she was vaccinated	Free text	
Address of the vaccination site	Free text	
Generic name of the vaccine	Free text	

Trade name or manufacturer of the vaccine	Free text	
Vaccination date	dd/mm/yyyy	
Vaccination time	a.m. or p.m.	
Dose	Numerical	
Lot number	Free text	
Expiration date	dd/mm/yyyy	
Name of the diluent	Free text	
Diluent lot number	Free text	
Diluent expiration date	dd/mm/yyyy	
Diluent reconstitution date	dd/mm/yyyy	
Diluent reconstitution time	a.m. or p.m.	
Was another vaccine administered in the 30 days prior to the onset of the AEFI?	Yes	
	No	
	DK	
Which one?	Free text	
How was the vaccination information verified?	Card/Physical record	1
	Card/E-record	2
	Verbal declaration	3
	Clinical history corroborated with card	4
	Unknown	5
	Other	0
Indicate: (another information verification method)	Free text	
AEFI	Fever ≥ 38ºC	1
	Pain at the injection site	2
	Erythema at the injection site	3
	Inflammation at the injection site	4
	Headache	5
	Febrile seizures	6
	Abscess	7
	Lymphadenitis	8
	Encephalopathy	9
	Encephalitis	10
	Thrombocytopenia	11
	Anaphylaxis	12
	Toxic shock syndrome	13
	Sepsis	14
	Other	0

Date of AEFI onset	dd/mm/yyyy	
Time of AEFI onset	a.m. or p.m.	
AEFI MedDRA or ICD code	Numerical	
AEFI description	Free text	
Was it a serious AEFI?	Yes	1
	No	0
AEFI seriousness: Death	Yes	1
	No	0
AEFI seriousness: Life-threatening	Yes	1
	No	0
AEFI seriousness: Significant or persistent disability	Yes	1
	No	0
AEFI seriousness: Hospitalization	Yes	1
	No	0
AEFI seriousness: Birth defect	Yes	1
	No	0
AEFI seriousness: Miscarriage	Yes	1
	No	0
AEFI seriousness: Fetal death	Yes	1
	No	0
AEFI seriousness: Another major medical event	Yes	1
	No	0
AEFI outcome	Fully recovered	1
	Recovering	2
	Not recovered	3
	Recovered with sequelae	4
	Death	5
	Unknown	0
Date of death	dd/mm/yyyy	
Was an autopsy performed?	Yes	1
	No	0
	Unknown	2
Is an investigation warranted?	Yes	1
	No	0
Type of investigation that needs to be conducted	Concise	1
	Full	2
Planned date of investigation	dd/mm/yyyy	
Date received at the national level	dd/mm/yyyy	
Additional comments or information you consider important that has not been entered in the previous sections	Free text	