



ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) INVESTIGATION FORM

This form complements the reporting form and should be completed with the data from that form. It should be used only in cases where the subnational technical level has decided to conduct a thorough investigation of a serious or non-serious event that meets the following criteria:

1. Temporal or geographic case clusters (groups of two or more cases) have been identified.
2. The frequency of the event is higher than expected.
3. It is a new or previously undescribed event, or it is a known event with new or unexpected epidemiological or clinical manifestations (in terms of population groups, geographic areas, etc.).
4. Some data indicate that the event was caused by a program error or a defect in the quality of the vaccine, its diluent (if applicable), or the device used in its administration.

This form is a guide for identifying all information considered relevant to analyzing the causality of the event. The analysis should be conducted by a national or subnational committee of AEFI experts, and the factors that contributed to its appearance should be identified so that risk mitigation measures can be adopted.

1. Indicate the sources of information consulted to obtain the information for the following investigation:

- Clinical history Interview of the person vaccinated Interview of health workers Vaccination records Autopsy report Verbal autopsy report Community investigation report

Other Indicate: _____

Section A. Basic information.

2. Identification number of the AEFI indicated on the reporting form: _____

3. Vaccination site: Public hospital Private hospital Vaccination post Private physician's office

Campaign Other 3.1 Indicate: _____

3.2 If the vaccination was administered during a campaign, indicate where:

Residence Fixed site Mobile unit Institutional Other 3.2.1 Indicate: _____

4. Complete address of the vaccination site:

City:

Department/province/state/district:

5. Information on the investigation team:

5.1 Full name	5.2 Institution and position	5.3 E-mail	5.4 Mobile telephone

6. Date this form was completed: dd/mm/yyyy

7. Date of investigation: dd/mm/yyyy

8. Hospitalization date: dd/mm/yyyy		9. This report is: <input type="checkbox"/> Preliminary <input type="checkbox"/> Interim <input type="checkbox"/> Final	
10. Status of the individual at the time of the investigation:			
<input type="checkbox"/> Deceased <input type="checkbox"/> Not recovered <input type="checkbox"/> Recovering <input type="checkbox"/> Fully recovered <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Unknown			
10.1 If the person is deceased, indicate the date of death: dd/mm/yyyy		10.2 Time of death: a.m./p.m.	
10.3 Was an autopsy performed? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Scheduled. Expected autopsy date: dd/mm/yyyy			
10.3.1 Reason why an autopsy was not performed:			
<input type="checkbox"/> Family refused <input type="checkbox"/> The person who reported the event or treated the patient did not request one <input type="checkbox"/> Clinical or forensic autopsy services were not available <input type="checkbox"/> There are no regulations permitting an autopsy in cases of AEFI <input type="checkbox"/> Other			
10.3.1.1 Indicate: _____			
Enclose the autopsy report, if available.			
11. If the patient had SARS-CoV-2 infection at the time of the report, how severe did the infection become, according to the clinical record? (use the classification in Clinical Management of COVID-19. Interim Guidance, published by WHO ¹ , as a reference)			
<input type="checkbox"/> Mild disease. <input type="checkbox"/> Moderate disease. <input type="checkbox"/> Severe disease. <input type="checkbox"/> Critical disease.			
From here on: DK = doesn't know NA = not applicable			
Section B. Relevant information about the vaccinated person prior to immunization.			
Criteria	Findings	Comments	
12. History of a similar event.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK		
13. Adverse events after previous vaccinations.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK		
14. History of allergy to a vaccine, food, or medication.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK		
15. Acute disease diagnosed in the 15 days prior to vaccination.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK		
16. Preexisting disease (diagnosed earlier than 15 days prior to vaccination) or birth defect.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK		
17. History of hospitalization in the 30 days prior to the current vaccination.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK		

¹ World Health Organization. Clinical Management of COVID-19: interim guidance, 27 May 2020. Geneva: WHO; 2020. Available from: <https://apps.who.int/iris/handle/10665/332196>.

18. Family history of other disease (relevant to an AEFI) or allergy.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK	
PERINATAL HISTORY (complete this section only in the case of children under 5, or over 5 when relevant).		
19. Delivery was: <input type="checkbox"/> Normal <input type="checkbox"/> Caesarean section <input type="checkbox"/> By forceps <input type="checkbox"/> With complications 19.1 Indicate: _____		
20. The birth was: <input type="checkbox"/> At term <input type="checkbox"/> Preterm <input type="checkbox"/> Post-term	21. Birthweight:	
22. Was any medical problem or congenital or neonatal pathology diagnosed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK	22.1 Explain:
QUESTIONS FOR WOMEN (mainly aged 15 to 49 or when pregnancy is suspected).		
23. Determine whether the woman was pregnant when she received the vaccine.	<input type="checkbox"/> Yes, gestational week: _____ <input type="checkbox"/> No <input type="checkbox"/> DK	23.1 Indicate how the pregnancy was diagnosed:
24. Was a risk factor for a serious obstetric complications identified? Explain in the “comments” section.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK	Comments:
25. If the pregnancy has ended, delivery was: <input type="checkbox"/> Normal <input type="checkbox"/> Cesarean section <input type="checkbox"/> By forceps <input type="checkbox"/> With complications 25.1 If there were complications, describe them:		
26. If the pregnancy has ended, the birth was: <input type="checkbox"/> At term <input type="checkbox"/> Preterm <input type="checkbox"/> Post-term	27. Birthweight:	
28. If the pregnancy has ended, what was the outcome?	<input type="checkbox"/> Healthy live birth. <input type="checkbox"/> Live birth with medical problem at birth. <input type="checkbox"/> Fetal death. <input type="checkbox"/> Early neonatal death. <input type="checkbox"/> Late neonatal death. <input type="checkbox"/> Miscarriage. 28.1 Describe the newborn’s medical problem:	
29. Was the mother breast-feeding at the time of vaccination?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Does not recall or DK	

Section C. Details of the first review of the AEFI.

30. Source of information (mark all that apply).

Review conducted by the investigator Documents Verbal autopsy Other 30.1 Indicate:

If a verbal autopsy was conducted, indicate the source and enclose the report:

31. Name of the individual who first examined or treated the person:

31.1 E-mail address of that individual:

32. Names of the professionals who treated the person:

33. Other sources of information (specify):

34. Signs and symptoms since vaccination, in chronological order:

35. If the AEFI occurred in a child, is child abuse suspected?

Yes 35.1 Explain:

No DK

36. If the AEFI occurred in an adolescent or adult, is there evidence of family violence?

Yes 36.1 Explain:

No DK

37. Other social background relevant to the case:

38. Name and contact information of the person or persons familiar with the clinical details:

39. Position or post:

40. Date/time: dd/mm/yyyy a.m./p.m.

41. Has the person received medical attention for the AEFI?

Yes No DK

Instructions: Attach a copy of ALL available documents (including the clinical history, discharge summary, case notes, laboratory or autopsy reports, concomitant drug prescriptions, vaccination record). In addition, include information UNAVAILABLE in the existing documents.

- ***If the person received medical attention:*** include copies of all available documents and note here only the information not available in the attached documents.
- ***If the person did not receive medical attention:*** question and examine him/her and enter your comments below. Include additional pages, if necessary.

42. Definitive or preliminary diagnosis:					43. MedDRA or ICD diagnostic code:				
Section D. AEFI-related information on the people vaccinated at the vaccination site.									
44. Number of people vaccinated with each antigen at the vaccination site on the day of the event. Include the records, if available.									
44.1 Name of the vaccine									
44.2 Number of doses									
44.3 Number of people vaccinated with the vaccine vial involved.									
44.4 Number of people vaccinated with the same antigen involved on the same day or session.									
44.5 Number of people vaccinated with the same lot of vaccine in other locations.									
44.5.1 Indicate the locations:									
45. When was the person who experienced the AEFI(s) vaccinated? <input type="checkbox"/> Early in the day <input type="checkbox"/> Late in the day <input type="checkbox"/> Unknown									
46. In the case of multidose vials, the vaccine administered was: <input type="checkbox"/> Among the first doses of the vial administered <input type="checkbox"/> Among the last doses of the vial <input type="checkbox"/> Unknown									
					Explanation and comments				
47. Was there a prescribing error or failure to follow the vaccine's recommendations for use?					<input type="checkbox"/> Yes <input type="checkbox"/> No				
48. Based on your investigation, do you believe that the vaccine administered could have been contaminated?					<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not assessable				
49. Based on your investigation, do you believe that the physical condition of the vaccine (color, turbidity, extraneous substances, etc.) was abnormal at the time of administration?					<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not assessable				
50. Based on your investigation, do you believe there was an error in the preparation or reconstitution of the vaccine (wrong product, vaccine or diluent, mixture, syringe, or improper filling of the syringe, etc.) by the vaccinator?					<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Non-assessable				
51. Based on your investigation, do you believe there was an error in handling the vaccine (interruption in the cold chain during transport, storage, the vaccination period, etc.)?					<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not assessable				
52. Based on your investigation, do you believe the vaccine was improperly administered (wrong					<input type="checkbox"/> Yes <input type="checkbox"/> No				

dose, site or route of administration; wrong-size needle, failure to follow good injection practices, etc.)?	<input type="checkbox"/> Not assessable	
53. Is this case part of a cluster?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
53.1 Case cluster identification number:		
53.2 If yes, how many additional cases have been detected in the cluster?		
53.3 Did all cases in the cluster receive the vaccine from the same vial?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
53.3.1 If not, number the vials used for the case cluster.		
Provide an individual explanation for all affirmative responses.		
Section E. Immunization practices at the locations where the vaccine in question was used (through interviews or observation of practices at the vaccination site).		
Syringes and needles used:		
54. Were auto-disable syringes used?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK	
54.1 If not, indicate the type of syringes used: <input type="checkbox"/> Glass <input type="checkbox"/> Disposable <input type="checkbox"/> Recycled disposable <input type="checkbox"/> Other 54.1.1 Which? _____		
State the key findings, additional observations, or comments:		
Reconstitution procedure:		
55. Was the same syringe used to reconstitute multiple vials of the same vaccine?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> NA	
56. Was the same syringe used to reconstitute different vaccines?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> NA	
57. Was a different syringe used to reconstitute of each vial of vaccine?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> NA	

68. Was a different syringe used for reconstitution in each vaccination?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> NA
69. Were the diluents and vaccines used the ones recommended by the manufacturer?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK <input type="checkbox"/> NA
60. State the key findings, additional observations, or comments:	
Section F. Cold chain and transport.	
Last storage point.	
61. Was the temperature of the last storage refrigerator monitored, and a daily a.m. and p.m. temperature record maintained?	<input type="checkbox"/> Yes <input type="checkbox"/> No
61.1 If yes, were there any deviations from the 2°C-8°C range after the vaccine was placed in the refrigerator?	<input type="checkbox"/> Yes <input type="checkbox"/> No
61.1.1 If yes, separately attach the monitoring data.	
62. Was the proper procedure for storing the vaccines, diluents, and syringes followed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK
63. Did the refrigerator or freezer contain anything other than NIP vaccines and diluents?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK
64. Was any partially reconstituted vaccine in the refrigerator?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK
65. Were there any vaccines that were unusable (expired, lacking a label, or frozen) in the refrigerator?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK
66. Did the warehouse have any diluent that was unusable (expired, not recommended by the manufacture, broken or dirty)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK
67. State the key findings, additional observations, or comments:	
Vaccine transport.	
68. Type of thermos or cold box used.	
69. Was the thermos or cold box sent the day of the vaccination?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK
70. Was the thermos or cold box returned the day of the vaccination?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK
71. Was an insulated cold pack used?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> DK
72. State the key findings, additional observations, or comments (indicate the departure and arrival time of the vaccine thermos or cold box, if relevant):	

Section G. Community investigation (visit the locality and interview the family or neighbors of the affected person).

73. Was a similar event reported in the same locality around the time the AEFI occurred? Yes No DK

73.1 If yes, describe it:

73.2 If yes, how many events or episodes were reported?

74. Of the people affected, indicate how many are:

- **Vaccinated:** _____
- **Unvaccinated:** _____
- **Status unknown:** _____

Make a list of the related cases and, if necessary, report the unreported vaccinated cases to the information system.

75. Other comments:

Section H. Other findings, observations, and comments.

Section I. Final classification of the event.

76. What was the final classification issued by the national or subnational committee that reviewed the AEFI?

Mark the box if the subcommittee did not arrive at a final classification.

76.1 Indicate what entity assigned this causality:	
A. Causal relationship consistent with the vaccine or vaccination process.	
A1. Event related to the antigen or a component of the vaccine (as published in the specialized bibliography).	<input type="checkbox"/>
A2. Event related to a defect in vaccine quality.	<input type="checkbox"/>
A3. Event related to a program error.	<input type="checkbox"/>
A4. Stress-related event occurring immediately prior to, during, or after vaccination.	<input type="checkbox"/>
B. Undetermined.	
B1. The temporal relationship is consistent, but sufficient definitive evidence to assign the causality to the vaccine is lacking.	<input type="checkbox"/>
B2. The factors for determining the classification show conflicting tendencies and are not uniformly favorable to a causal relationship with vaccination.	<input type="checkbox"/>
C. Inconsistent causal relationship with the vaccine or vaccination (coincidental event).	<input type="checkbox"/>
D. Unclassifiable according to WHO criteria.	<input type="checkbox"/>
77. Comments on the causality classification:	

Instructions for completing the adverse events following immunization (AEFI) investigation form

The criteria for recommending a full investigation are indicated at the top of the form. Given the amount of resources required to complete all the information required on this form, selective criteria should be employed to determine the cases where it is necessary.

Detailed instructions for answering some of the questions on the form are provided below:

Question	Instruction
Indicate the sources of information consulted to GATHER the information for the following investigation.	Mark all sources used in obtaining the information provided on this form.
Section A. Basic information	
Identification number of the AEFI indicated on the reporting form.	This is the number assigned to the case on the reporting form. Make sure that the number is exactly the same as the one assigned and that it is not the same as the national identification document number of the affected person.
Vaccination site.	Mark the location where the vaccine was administered, as appropriate. If it none of the options applies, select "Other" and provide more details on the "Indicate" line. If the AEFI occurred during a vaccination campaign, leave the first part blank and respond in the section on vaccination campaigns.
Department/province/state/district:	The term for the first subnational level may differ from country to country. A list is included here, but it is suggested that the correct name of the geographic unit be used.
Information on the investigation team:	Use this box to provide complete information on the individuals who participated in the investigation. This information is important for keeping a record of responsible personnel and for long-term evaluation of the use of resources for this surveillance.
Date this form was completed.	Indicate the date the form was finally completed, using the dd/mm/yyyy format.
Date of the investigation.	Date on which AEFI investigation began, using the dd/mm/yyyy format.
Date of hospitalization.	Date of the first day of hospitalization or hospital consultation, using the dd/mm/yyyy format.
Reason why an autopsy was not performed:	In the section on the diagnosis at death, if an autopsy was not performed, mark the reason. If there is more than one, mark all that are applicable. Even though a verbal autopsy was performed, explain why a clinical or pathological autopsy was not.
If the patient had the SARS-CoV-2 infection at the time of the report, how severe did the infection become according to the clinical record?	To learn the criteria for the severity of a SARS-CoV-2 infection, WHO's <i>Clinical management of COVID-19: interim guidance</i> , dated 27 May 2020, should be used. It can be accessed at the following link: https://apps.who.int/iris/handle/10665/332196 .
Section B. Relevant information about the vaccinated person prior to immunization.	
This section is for all medically important background information on the vaccinated person.	

History of a similar event	If the affected person developed signs or symptoms, or had abnormal laboratory results that appeared to be similar to those currently observed and followed a similar course, mark "YES". Describe or explain them in detail in the "Comments" section.
Acute disease diagnosed in the 15 days prior to vaccination.	Indicate all diseases diagnosed in the 15 days prior to vaccination.
Preexisting disease (diagnosed before 15 days prior to vaccination) or birth defect.	Indicate all diseases diagnosed before 15 days prior to vaccination.
Family history of another disease (relevant for an AEFI) or allergy.	If a family member has a history of a disease that could indicate a risk that the AEFI is related to the clinical status of the affected person, mark "Yes".
PERINATAL HISTORY.	
This section applies only to AEFIs in children under 5, and the questions are about their history.	
The delivery was:	Mark how the child was delivered. If there were complications, explain.
The birth was:	Indicate the term of the pregnancy at birth. In the next question, indicate the birthweight in grams.
Were any medical problems or congenital or neonatal pathology diagnosed?	If the infant was diagnosed with a congenital medical problem at birth or in the first 30 days postpartum, mark "Yes".
QUESTIONS FOR WOMEN.	
This section is applicable to all women, principally those of reproductive age (15 to 49 years), but bearing in mind that there is a real risk of pregnancy outside that age range. If pregnancy is suspected during the investigation, the following questions should also be asked.	
Confirm whether the woman was pregnant when the vaccine was administered.	If the pregnancy diagnosis was confirmed by a laboratory or health worker, mark "Yes" and indicate the weeks of gestation at the time of the investigation. In the "Comments" space, include information on the test used to confirm the pregnancy.
Was any risk factor for serious obstetric complications identified? Explain this in the comments space.	If a risk factor for some obstetric complication was identified, mark "Yes" and explain.
If the pregnancy ended, mark the obstetric-neonatal outcome, as appropriate:	Complete this section only if the pregnancy has ended at the time of the investigation. It should refer to the maternal outcome and that of the embryo, fetus, or neonate.
What was the pregnancy outcome?	Mark the most appropriate pregnancy outcome.
Was the woman breast-feeding at the time of vaccination?	Indicate whether she was nursing when she was vaccinated.
Section C. Details of the first review of the AEFI.	
Source of information.	Indicate the source of the details on the affected person's clinical status.
Name of the individual who first examined or treated the person:	Include information on the identity of the professional who first had contact with the affected person.

Name of the professionals who treated the person:	Provide information on the identity of the other professionals who treated the affected person; this additional information may be useful in the future.
Other sources of information (specify):	If some source of information has not been included, indicate it in this field.
Signs and symptoms since vaccination, in chronological order:	In this field, create a timeline of relevant clinical events. This can guide additional investigatory measures and the final analysis.
If the AEFI occurred in a child, is child abuse suspected?	This question is relevant, as other causes of the event need to be ruled out and the effects of abuse can often be confused with diseases or medical conditions that may have been classified as AEFIs.
If the AEFI occurred in an adolescent or adult, is there evidence of family violence?	This question is relevant, as other causes of the event need to be ruled out, and the effects of abuse can often be confused with diseases or medical conditions that may have been classified as AEFIs.
Other relevant social background of the case:	This type of background is highly relevant in cases of a suspected anxiety reaction. Socioeconomic status, educational level, etc. should be considered.
Definitive or preliminary diagnosis:	The diagnosis of the case should be indicated in free text.
MedDRA or ICD diagnostic code:	Include the appropriate MedDRA or ICD for the reported AEFI.
Section D. AEFI-related information on the vaccine and people vaccinated at the vaccination site.	
Enter the results of the visit to the vaccination site in this section. This is for the identification of patterns that can shed light on the cause of the event.	
Number of people vaccinated with each antigen at the vaccination site on the day of the event.	Indicate the total number of people vaccinated with each antigen or vaccine at the place where the affected person was vaccinated, including people vaccinated during off-site activities, if appropriate.
Number of people vaccinated with the same lot of vaccine in other locations.	To obtain this information, it is necessary to have traced the lot of vaccine indicated in the report. Enter the number of people vaccinated with the same lot as the affected person in the country where the AEFI was reported.
Was there a prescribing error or failure to follow the vaccine's recommendations for use?	This and the other questions in this section require reasonable evidence to back the judgment of poor practice indicated. If sufficient evidence is lacking, "Not assessable" should be marked. Mark "No" if there is evidence that the error mentioned did NOT occur.
Is this case part of a cluster?	An association between two or more cases in time or location represents a cluster and should be studied as such. A cluster is defined as two or more cases of the same or similar event, related in time, geographical location, and/or vaccine administered (i.e., route of administration or lot). It can also be associated with the same distributor or health facility
Section E. Immunization practices at the locations where the vaccine in question was used.	
Syringes and needles used:	This section refers to the syringes used to administer the vaccine. If the vaccine is not administered parenterally, leave it blank.
Reconstitution procedure:	This section can be completed once the person who administered the vaccine has been interviewed and records of the vaccination site have been reviewed.

	The vaccination procedure can be observed and the details of the reconstitution and vaccination process can be observed.
Section F. Cold chain and transport.	
Last storage point.	This section involves inspecting the location where the vaccine and all vaccines at the vaccination site are stored. Verify temperature records at the vaccination site.
Vaccine transport.	This section refers to the transport of the vaccine in question on the day it was administered. This usually applies to cases in which the vaccination was off-site. The individual responsible for vaccine transport logistics should review the information on the transport and temperature control of the lot at every step after its arrival in the country. Enter that information in question 72.
Type of thermos or cold box used.	Describe in detail the type of vaccine carrier used to transport the vaccines on the day of administration, if applicable. If not, leave this section blank.
Section G. Community investigation.	
Was a similar event reported in the same locality around the time the AEFI occurred?	This section requires reporting of events in the community that are potentially related to the case in question. It is important to review the surveillance data and assess this situation in advance. When answering this question, it is especially important to indicate the geographic location of all cases. The ideal would be to undertake a complete epidemiologic characterization of the cases.
Section H. Other findings, observations, and comments.	
In this section, enter any additional findings that you consider relevant and essential for analyzing the case.	
Section I. Final classification of the event	
In this section, final classification of case causality is recorded, following a review by the national or subnational committee. In the comments section, add a brief summary of how the case was assessed.	