

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.

contributed to its appe	earance should be identified	d so that risk mitigation measu	res can be adopted.	
1. Indicate the sources	of information consulted to o	obtain the information for the foll	owing investigation:	
	erview of the person vaccinal autopsy report Commun	ted □ Interview of health worker nity investigation report	s □ Vaccination records □	
Other □ 1.1 Indicate:				
Section A. Basic informa	ation.			
2. Identification number	r of the AEFI indicated on the	e 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 wa	s administered during a camp	paign, indicate where:		
☐ Residence ☐ Fixed si	te □ Mobile unit □ Institutio	nal □ Other 3.2.1 Indicate:		
4. Complete address of t	the vaccination site:			
City:		Department/province/state/distr	ict:	
5. Information on the in	vestigation 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/	[/] уууу	

8. Hospitalization date: dd/mm/yyyy	9. This report is: ☐ Pre	reliminary □ Interim □ Final		
10. Status of the individual at the time of the investiga	ation:			
☐ Deceased ☐ Not recovered ☐ Recovering ☐ Fully	recovered □ Recovered	with sequelae		
□ Unknown				
10.1 If the person is deceased, indicate the date of de	eath: dd/mm/yyyy	10.2 Time of death:		
(0.01)		a.m./p.m.		
10.3 Was an autopsy performed? ☐ Yes ☐ No ☐ Scl	heduled. Expected autops	sy date: dd/mm/yyyy		
10.3.1 Reason why an autopsy was not performed:				
☐ Family refused ☐ The person who reported the external forensic autopsy services were not available ☐ There ☐ Other 10.3.1.1 Indicate:	•	•		
Enclose the autopsy report, if available.				
	times of the remort hours	over did the infection become according		
11. If the patient had the SARS-CoV-2 infection at the to the clinical record? (use the classification in Clinical Management)	•			
☐ Mild disease.				
☐ Moderate disease.				
☐ Severe disease.				
☐ Critical disease.				
From here on: DK = doesn't know NA = not applical	ble			
Section B. Relevant information about the vaccinate	d person prior to immuni	zation.		
Criteria	Findings	Comments		
12. History of a similar event.	☐ Yes ☐ No ☐ DK			
13. Adverse events after previous vaccinations.	☐ Yes ☐No ☐ DK			
14. History of allergy to a vaccine, food, or medication.	☐ Yes ☐ No ☐ DK			
modification.				
15. Acute disease diagnosed in the 15 days prior to vaccination.	☐ Yes ☐ No ☐ DK			
16. Preexisting disease (diagnosed earlier than 15 days prior to vaccination) or birth defect.	☐ Yes ☐ No ☐ DK			
17. History of hospitalization in the 30 days prior to the current vaccination.	on in the 30 days prior to ☐ Yes ☐ No ☐ 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 disea AEFI) or allergy.	Y	∕es □ No	□ DK			
PERINATAL HISTORY (complete to	e case	of childre	n under 5,	or ov	er 5 when relevant).	
19. Delivery was: ☐ Normal ☐ Indicate:	Caesarean section □	By f	orceps 🗆	l With com	plicat	ions 19.1
20. The birth was: ☐ At term ☐	erm		21. Birth	weigh	t:	
22. Was any medical problem or pathology diagnosed?	al	□ Yes □	No □ DK		22.1 Explain:	
QUESTIONS FOR WOMEN (mainly	y aged 15 to 49 or whe	en pre	egnancy is	suspected) .	
23. Determine whether the woman was pregnant when she received the vaccine.			☐ Yes, gestational week:		23.1 Indicate how the pregnancy was diagnosed:	
			No □ DK			
24. Was a risk factor for a seriou complications identified? Explain section.		□ Y	∕es □ No	□ DK		
25. If the pregnancy has ended,	mark the respective of	obstet	tric-neona	tal outcom	ie:	
26. Delivery was: ☐ Normal ☐	Cesarean section	By fo	rceps 🗆	With comp	olicatio	ons 26.1 Indicate:
27. The birth was: ☐ At term ☐	☐ Preterm		2	28. Birthwe	eight:	
□ Post-term						
29. What was the pregnancy outcome?	☐ Healthy live birth	١.	•			
outcome:	☐ Live birth with medical problem at birth.					
	☐ Fetal death.					
	☐ Early neonatal de	eath.				
	☐ Late neonatal de	ath.				
	☐ Miscarriage.					
	29.1 Describe the n	iewbo	rn's medi	cal probler	n:	
30. Was the mother breast-	☐ Yes					
feeding at the time of vaccination?	□ No					
	☐ Does not recall o	or DK				

Section C. Details of the first review of the AEFI.	
Section 6. Details of the first review of the AEF1.	
31. Source of information (mark all that apply).	
☐ Review conducted by the investigator ☐ Documents ☐ Verbal autopsy ☐	☐ Other 31.1 Indicate:
Managed and an extensive Scattering and an extensive the annual	
If a verbal autopsy, indicate the source and enclose the report:	
32. Name of the individual who first examined or treated the person:	
22.4 E mail address of that individuals	
32.1 E-mail address of that individual:	
33. Names of the professionals who treated the person:	
34. Other sources of information (specify):	
35. Signs and symptoms since vaccination, in chronological order:	
36. If the AEFI occurred in a child, is child abuse suspected?	☐ Yes 36.1 Explain:
	į,
	□ No □ DK
37. If the AEFI occurred in an adolescent or adult, is there evidence of family	☐ Yes 37.1 Explain:
violence?	
	□ No □ DK
38. Other social background relevant to the case:	
30. Other Social Dackground relevant to the case.	

39. Name and contact information of the person or pe	ersons familiar with the clinical details:	
40. Position or post:	41. Date/time: dd/mm/yyyy a.m./p.m.	
41. Has the person received medical attention for the AEFI?	☐ Yes ☐ No ☐ DK	
	ents (including the clinical history, discharge summary, case notes, criptions, vaccination record). In addition, include information	
 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 available.	vaccinate	ed with each	antigen at	the vaccinat	ion site on	the da	ay of th	e event . Ir	nclude	the records, if
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	e vaccinat	ted with the	same lot o	of vaccine in	other location	ons.				
44.5.1 Indicate the loc	ations:									
45. When was the per		•	•	s) vaccinated	?					
☐ Early in the day ☐	J Late in ti	he day ⊔ l	Jnknown							
46. In the case of mult				stered was: \square	Among th	e first	doses	of the vial	admi	nistered 🗆
Among the last doses	of the via	I □ Unkno	wn							
							Expl	anation an	d com	ments
47. Was there a prescrithe vaccine's recomme	endations	for use?		□ Yes [
48. Based on your inve	-		lieve that	☐ Yes [⊐ No					
contaminated?	ea coula	nave been		☐ Not ass	essable					
49. Based on your inve	-			□ Yes [□ No					
turbidity, extraneous s	ubstance	s, etc.) was		☐ Not ass	essable					
50. Based on your inve	estigation	, do you be	lieve		7.1.					
there was an error in t			~ 4	☐ Yes [J No │					
reconstitution of the vaccine or diluent, mix filling of the syringe, e	kture, syri	nge, or imp	roper	□ Non-ass	essable					
51. Based on your inve	estigation	, do you be		☐ Yes [□ No					
there was an error in h	•									
(interruption in the col storage, the vaccination		• .	טטונ,	☐ Not ass	essable					
52. Based on your inve	estigation	, do you be		☐ Yes [□ No					
vaccine was improperl										
site or route of admini failure to follow good i		_		☐ Not ass	SSADIE					

53. Is this case part of a cluster?	☐ Yes ☐ No ☐ 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?	☐ Yes ☐ No ☐ Unknown	
53.3.1 If not, number the vials used for the case cluster.		
Provide an individual explanation for all affirmative res	sponses.	
Section E. Immunization practices at the locations w observation of practices at the vaccination site).	here the vaccine in q	uestion was used (through interviews or
Syringes and needles used:		
54. Were auto-disable (AD) syringes used?		☐ Yes ☐ No ☐ DK
54.1 If not, indicate the type of syringes used: ☐ Glas	s 🗆 Disposable 🗆 Re	ecycled disposable
☐ Other 54.1.1 Which?		
State the key findings, additional observations, or com-	nments:	
Reconstitution procedure:		
55. Was the same syringe used to reconstitute multip	le vials of the same	☐ Yes ☐ No ☐ DK ☐ NA
vaccine?		
56. Was the same syringe used to reconstitute differe	nt vaccines?	☐ Yes ☐ No ☐ DK ☐ NA
		LITES LINO LIDIK LINA
57. Was a different syringe used to reconstitute of each	ch vial of vaccine?	☐ Yes ☐ No ☐ DK ☐ NA
58. Was a different syringe used for reconstitution in	each vaccination?	☐ Yes ☐ No ☐ DK ☐ NA
59. Were the diluents and vaccines used the ones rec manufacturer?	ommended by the	☐ Yes ☐ No ☐ DK ☐ NA

CO Chata the less findings additional about the second	
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.	□ Yes □ No
and p.m. temperature record maintained?	L 163 L 110
61.1 If yes, were there any deviations from the 2°C-8°C range after the vaccine was	☐ Yes ☐ No
placed in the refrigerator?	
61.1.1 If yes, separately attach the monitoring data.	
62. Was the proper procedure for storing the vaccines, diluents, and syringes followed?	☐ Yes ☐ No ☐ DK
63. Did the refrigerator or freezer contain anything other than NIP vaccines and	☐ Yes ☐ No ☐ DK
diluents?	
64. Was any partially reconstituted vaccine in the refrigerator?	☐ Yes ☐ No ☐ DK
65. Were there any vaccines that were unusable (expired, lacking a label, or frozen) in the refrigerator?	☐ Yes ☐ No ☐ DK
66. Did the warehouse have any diluent that was unusable (expired, not	☐ Yes ☐ No ☐ DK
recommended by the manufacture, broken or dirty)? 67. State the key findings, additional observations, or comments:	
or. State the key initings, additional observations, or comments.	
Vaccine transport.	
vaccine transport.	
68. Type of thermos or cold box used.	
69. Was the thermos or cold box sent the day of the vaccination?	☐ Yes ☐ No ☐ DK
70. Was the thermos or cold box returned the day of the vaccination?	☐ Yes ☐ No ☐ DK
71. Was an insulated cold pack used?	☐ Yes ☐ No ☐ DK
72. State the key findings, additional observations, or comments (indicate the departure	e 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	e 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, how many are:	
Vaccinated:	
 Unvaccinated: 	
Status unknown: Make a list of the related cases and, if necessary, report the unreported vaccinated cases to the in	formation system
	Tormation 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 review	ved 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).	
A2. Event related to a defect in vaccine quality.	
A3. Event related to a program error.	
A4. Stress-related event occurring immediately prior to, during, or after vaccination.	
B. Undetermined.	
B1. The temporal relationship is consistent, but sufficient definitive evidence to assign the causality to the vaccine is lacking.	
B2. The factors for determining the classification show conflicting tendencies and are not uniformly favorable to a causal relationship with vaccination.	
C. Inconsistent causal relationship with the vaccine or vaccination (coincidental event).	
D. Unclassifiable according to WHO criteria.	
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 Clinical management of COVID-19: interim guidance, 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 vaccinate	d person prior to immunization.

This section is for all medically important backgro	und 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	er 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.	
	those of reproductive age (15 to 49 years), but bearing in mind that there is a egnancy is suspected during the investigation, the following questions should
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?	· ·
	fetus, or neonate.
What was the pregnancy outcome? Was the woman breast-feeding at the time of	fetus, or neonate. Mark the most appropriate pregnancy outcome.
What was the pregnancy outcome? Was the woman breast-feeding at the time of vaccination?	fetus, or neonate. Mark the most appropriate pregnancy outcome.

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 cause of the event.	in this section. This is for the identification of patterns that can shed light on the
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 v	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.

	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.