AEFI Core Variables (Revised Dec 2015)

| | Suggested Heading | Description of the Basic core variable Date when information of the AEFI case first reached the National |
|----------|---|---|
| Identity | Date AEFI report first received at National level | level |
| | Country where the AEFI occurred | Name of the country where the adverse event occurred |
| <u>8</u> | Location (address) | Geographic location of the case (address) |
| | Unique identification of the report | Unique ID number used for communicating the details of the case |
| Case | Patient identifier | Name of the patient or initials as decided by the country |
| | Date of birth (or) | Date patient was born |
| | Age at time of onset (or) | Age at time of onset |
| | Age Group at onset | Age Group (<1 year, 1-5years, >5 years) |
| | Sex | Male or Female |
| | Medical history | Free text information (e.g. allergies, concomitant medication, etc.) |
| Vaccine | Primary suspect vaccine name | Vaccine suspected to have caused the AEFI |
| | Other vaccines given just prior to AEFI | Other vaccines given prior to the AEFI |
| | Vaccine batch/lot number | Batch/lot number of all vaccines mentioned above |
| | Vaccine dose number for the vaccinee | Dose number for this particular vaccinee |
| | Diluent batch/lot number | Batch/lot number of the diluent (if applicable) |
| | | (11 / |
| | Date and Time of vaccination | Date and time the vaccine was administered |
| | Date and Time of vaccination Date and Time of AEFI onset | |
| | | Date and time the vaccine was administered |
| Event | Date and Time of AEFI onset | Date and time the vaccine was administered Date and time of the AEFI onset |
| Event | Date and Time of AEFI onset Adverse event | Date and time the vaccine was administered Date and time of the AEFI onset Case diagnosis + Signs & Symptoms Outcome of the reaction(s): Recovering/resolving; Recovered/resolved; Recovered/resolved with sequelae; Not |
| Event | Date and Time of AEFI onset Adverse event Outcome of AEFI | Date and time the vaccine was administered Date and time of the AEFI onset Case diagnosis + Signs & Symptoms Outcome of the reaction(s): Recovering/resolving; Recovered/resolved; Recovered/resolved with sequelae; Not recovered/not resolved; Fatal; Unknown If the case is serious and resulted in death, threatened the patient's life, caused persistent or significant disability, hospitalization, congenital anomaly or any other medically relevant event that may jeopardize the patient or may require intervention to prevent one of |
| Event | Date and Time of AEFI onset Adverse event Outcome of AEFI Serious case | Date and time the vaccine was administered Date and time of the AEFI onset Case diagnosis + Signs & Symptoms Outcome of the reaction(s): Recovering/resolving; Recovered/resolved; Recovered/resolved with sequelae; Not recovered/not resolved; Fatal; Unknown If the case is serious and resulted in death, threatened the patient's life, caused persistent or significant disability, hospitalization, congenital anomaly or any other medically relevant event that may jeopardize the patient or may require intervention to prevent one of the outcomes mentioned here |
| | Date and Time of AEFI onset Adverse event Outcome of AEFI Serious case Name of initial reporter of AEFI case | Date and time the vaccine was administered Date and time of the AEFI onset Case diagnosis + Signs & Symptoms Outcome of the reaction(s): Recovering/resolving; Recovered/resolved; Recovered/resolved with sequelae; Not recovered/not resolved; Fatal; Unknown If the case is serious and resulted in death, threatened the patient's life, caused persistent or significant disability, hospitalization, congenital anomaly or any other medically relevant event that may jeopardize the patient or may require intervention to prevent one of the outcomes mentioned here Name of the reporter of the AEFI case |
| Reporter | Date and Time of AEFI onset Adverse event Outcome of AEFI Serious case Name of initial reporter of AEFI case Institution/Location | Date and time the vaccine was administered Date and time of the AEFI onset Case diagnosis + Signs & Symptoms Outcome of the reaction(s): Recovering/resolving; Recovered/resolved; Recovered/resolved with sequelae; Not recovered/not resolved; Fatal; Unknown If the case is serious and resulted in death, threatened the patient's life, caused persistent or significant disability, hospitalization, congenital anomaly or any other medically relevant event that may jeopardize the patient or may require intervention to prevent one of the outcomes mentioned here Name of the reporter of the AEFI case Place (address) of the reporter (including the name of the country) |
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IMPORTANT: Critical variables in italics