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| **I. Is there strong evidence for other causes?** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 |
| 1. In this patient, does the medical history, clinical examination and/or investigations, confirm another cause for the event? | N | N | N | Y | N | N | Y | N | N | Y | N | N | N | N | N | N | N | N | Y | N | Y | N | Y | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| **II. Is there a known causal association with the vaccine or vaccination?** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Vaccine product** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Is there evidence in published peer reviewed literature that this vaccine may cause such an event if administered correctly? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 2. Is there a biological plausibility that this vaccine could cause such an event? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 3. In this patient, did a specific test demonstrate the causal role of the vaccine? | Y | Y | N | Y | Y | N | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | Y | Y | Y | Y | Y | Y | Y | Y | N | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| **Vaccine quality** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 4. Could the vaccine given to this patient have a quality defect or is substandard or falsified? | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK |
| **Immunization error** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 5. In this patient, was there an error in prescribing or non-adherence to recommendations for use of the vaccine (e.g. use beyond the expiry date, wrong recipient etc.)? | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK |
| 6. In this patient, was the vaccine (or diluent) administered in an unsterile manner? | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK |
| 7. In this patient, was the vaccine’s physical condition (e.g. colour, turbidity, presence of foreign substances etc.) abnormal when administered? | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK |
| 8. When this patient was vaccinated, was there an error in vaccine constitution/preparation by the vaccinator (e.g. wrong product, wrong diluent, improper mixing, improper syringe filling etc.)? | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| 9. In this patient, was there an error in vaccine handling (e.g. a break in the cold chain during transport, storage and/or immunization session etc.)? | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK |
| 10. In this patient, was the vaccine administered incorrectly (e.g. wrong dose, site or route of administration; wrong needle size etc.)? | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK |
| **Immunization anxiety (Immunization stress related responses - ISRR)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 11. In this patient, could this event be a stress response triggered by immunization (e.g. acute stress response, vasovagal reaction, hyperventilation, dissociative neurological symptom reaction etc)? | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK |
| **II (time): Was the event in section II within the time window of increased risk (i.e. ‘Yes” response to questions from II 1 to II 11 above)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 12. In this patient, did the event occur within a plausible time window after vaccine administration? |  | Y | Y | N | Y | Y | Y | Y | Y | N | Y | Y | Y | Y | N | N | Y | Y | Y | Y | N | Y | N | N | N | Y | N | N | Y | Y | Y | N | Y | Y | Y | Y | Y |
| **III. Is there strong evidence against a causal association?** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Is there a body of published evidence (systematic reviews, GACVS reviews, Cochrane reviews etc.) against a causal association between the vaccine and the event? | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| **IV. Other qualifying factors for classification** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. In this patient, did such an event occur in the past after administration of a similar vaccine? | N | N | UK | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| 2. In this patient, did such an event occur in the past independent of vaccination? | N | N | UK | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| 3. Could the current event have occurred in this patient without vaccination (background rate)? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 4. Did this patient have an illness, pre-existing condition or risk factor that could have contributed to the event? | UK | Y | N | Y | Y | N | N | Y | Y | Y | UK | Y | Y | Y | Y | Y | N | Y | Y | Y | UK | N | Y | Y | Y | Y | N | Y | Y | Y | N | Y | N | N | N | N | N |
| 5. Was this patient taking any medication prior to the vaccination? | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK |
| 6. Was this patient exposed to a potential factor (other than vaccine) prior to the event (e.g. allergen, drug, herbal product etc.)? | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK | UK |
| **Causality assessment classification** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| A. Consistent with causal association to immunization |  |  | A1 |  | A1 | A1 | A1 | A1 | A1 |  | A1 | A1 | A1 | A1 |  | A1 | A1 | A1 |  | A1 |  | A1 |  | A1 | A1 |  | A1 | A1 | A1 |  | A1 | A1 | A1 | A1 | A1 | A1 | A1 |
| B. Indeterminate | B2 | B2 |  |  |  |  |  |  |  | B2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | B2 |  |  |  | B2 |  |  |  |  |  |  |  |
| C. Inconsistent with causal association to immunization |  |  |  | C |  |  |  |  |  |  |  |  |  |  | C |  |  |  | C |  | C |  | C |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| D. Unclassifiable |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |