

Neurologické komplikace očkování

Úvod, aktuální poznatky ze surveillance v USA

MUDr. J. Nečas

Rezident v oboru PLDD

Neurologické komplikace očkování

- Mohou zasáhnout všechny části nervového systému
- Vzácné
- Incidence řádově nižší než při infekci samotné proti kterému je vakcína určena

- Kauzalita x koincidence
- Zkoumáme na 2 úrovních: populační x individuální

1. Populační, epidemiologická



Vaccine Adverse Event Reporting System (VAERS)

- Systém **pasivní surveillance** pro kolekci informací o potenciálních vedlejších účincích vakcinace
- Pro monitoraci známých, detekci nových NÚ, identifikaci RF pro rozvoj NÚ, zajištění bezpečnosti nových vakcín
- **Limitace** (může nahlásit kdokoliv, informace mohou být nepřesné/chybné, jsou hlášeny především závažné komplikace)



RUTGERS
UNIVERSITY | NEWARK

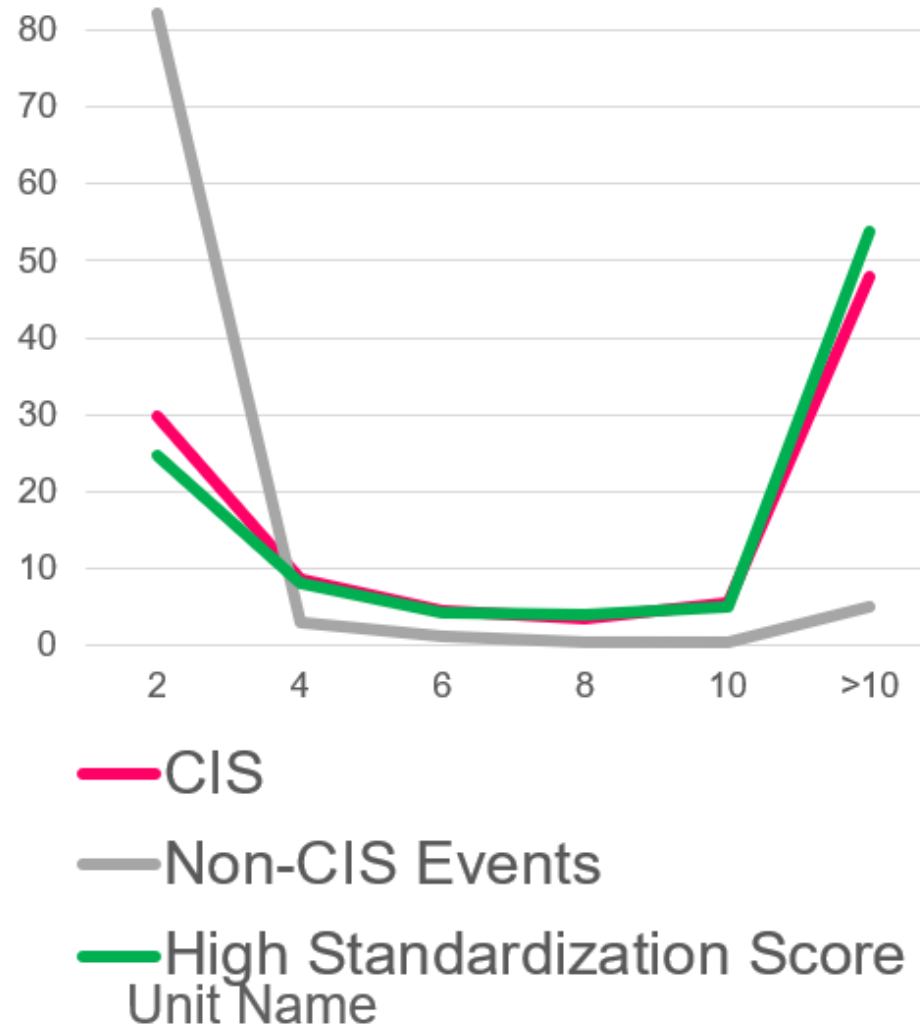
Development of Clinically Isolated Syndrome after Vaccination

Abdul Alchaki M.D., Janaki Patel B.S., Moumina Faker M.D., Nizar Souayah M.D.
New Jersey Medical School & Robert Wood Johnson

Research day 6/20/2018

Klinicky izolovaný syndrom (CIS):
izolovaný, náhlý vznik ložiskových
neurologických příznaků s možným
rozvojem roztroušené sklerózy

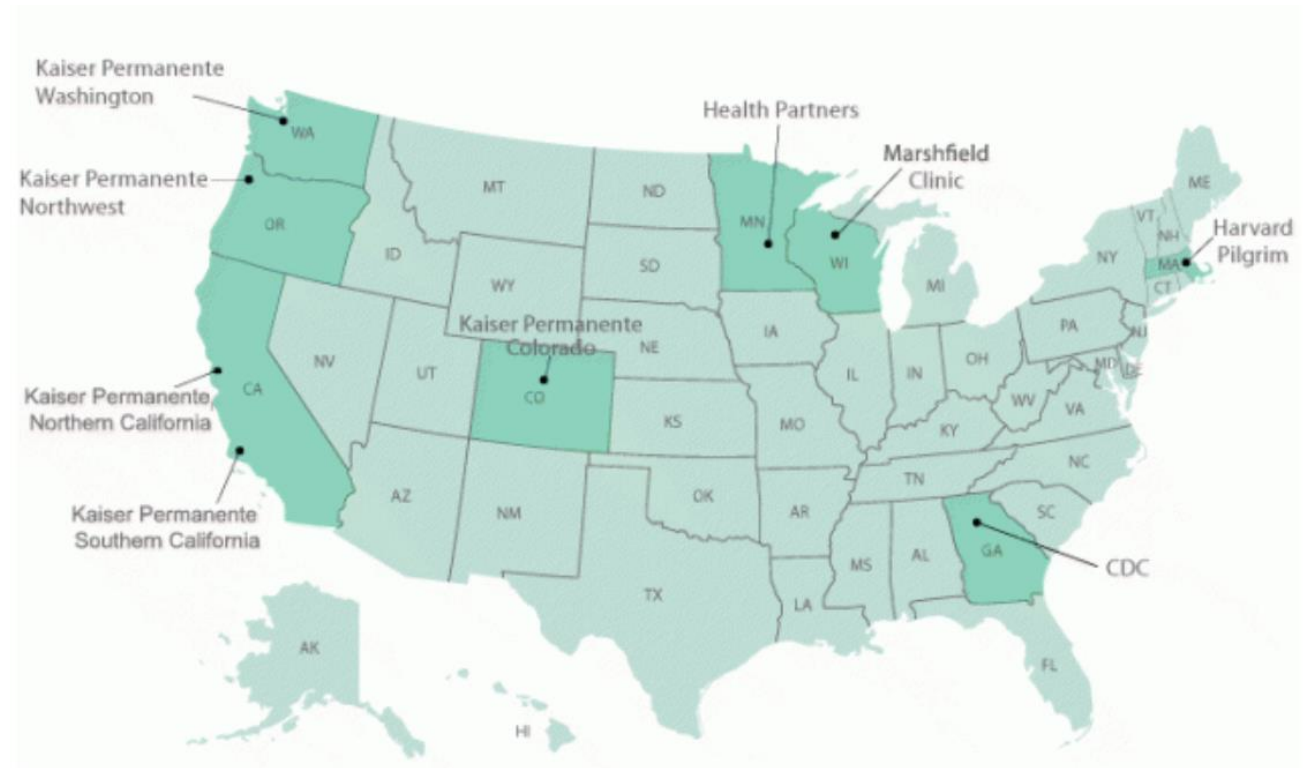
% Cases Observed





Vaccine Safety Datalink (VSD)

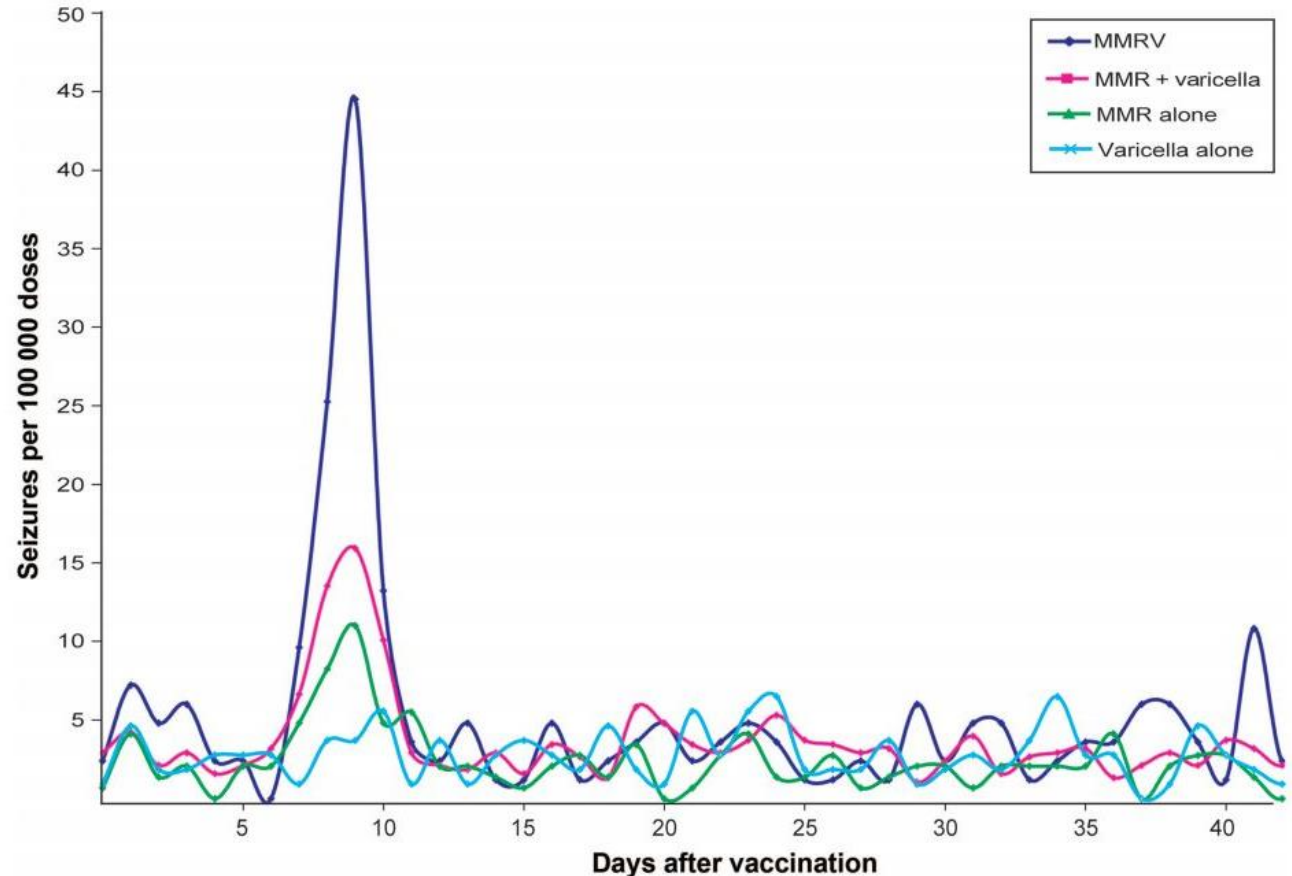
- Projekt spolupráce mezi CDC a 8 poskytovatelů zdravotní péče
- Zahrnuje data 7 mil. pacientů (500 tis.dětí ve věku 0-6 let – 2% z celého USA)
- Studie o závažných a vzácných událostech následujících po vakcinaci (založené na otázkách a obavách plynoucí z VAERS)



Measles-Mumps-Rubella-Varicella Combination Vaccine and the Risk of Febrile Seizures

AUTHORS: Nicola P. Klein, MD, PhD,^a Bruce Fireman, MS,^a W. Katherine Yih, MPH, PhD,^b Edwin Lewis, MPH,^a Martin Kulldorff, PhD,^b Paula Ray, MPH,^a Roger Baxter, MD,^a Simon Hambidge, MD, PhD,^c James Nordin, MD, MPH,^d Allison Naleway, PhD,^e Edward A. Belongia, MD,^f Tracy Lieu, MD, MPH,^b James Baggs, PhD,^g and Eric Weintraub, MPH,^g for the Vaccine Safety Datalink

^aKaiser Permanente Vaccine Study Center, Oakland, California; ^bHarvard Pilgrim Health Care Institute and Harvard Medical School, Boston, Massachusetts; ^cKaiser Permanente Colorado, Denver, Colorado; ^dHealthPartners Research Foundation, Minneapolis, Minnesota; ^eKaiser Permanente Northwest, Portland, Oregon; ^fMarshfield Clinic Research Foundation, Marshfield, Wisconsin; and ^gImmunization Safety Office, Centers for Disease Control and Prevention, Atlanta, Georgia



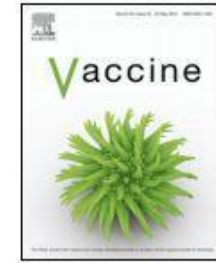


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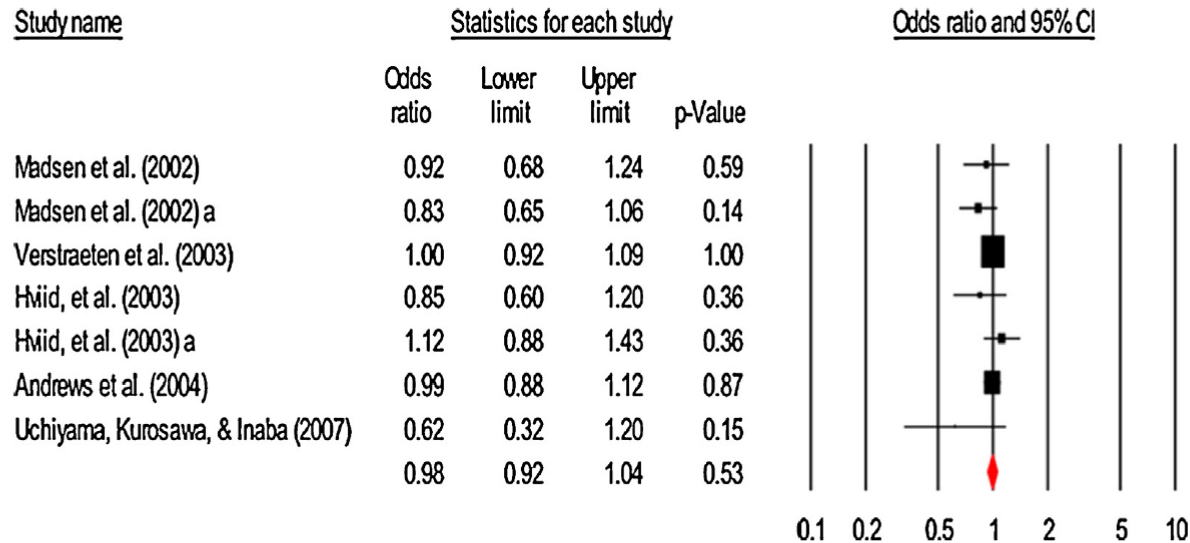


Vaccines are not associated with autism: An evidence-based meta-analysis of case-control and cohort studies



Luke E. Taylor, Amy L. Swerdfeger, Guy D. Eslick*

The Whiteley-Martin Research Centre, Discipline of Surgery, The University of Sydney, Nepean Hospital, Level 3, Clinical Building, PO Box 63, Penrith 2751, NSW, Australia



2. Individuální

- PRO: Určení potenciálně nových NÚ, jejich preventabilitu, dopad pro jedince a na důvěru k očkování
- Složitě
- Standardizované

Vaccine 30 (2012) 5791–5798



Contents lists available at SciVerse ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine



Algorithm to assess causality after individual adverse events following immunizations[☆]

Neal A. Halsey^{a,*}, Kathryn M. Edwards^b, Cornelia L. Dekker^c, Nicola P. Klein^d, Roger Baxter^d, Philip LaRussa^e, Colin Marchant^f, Barbara Slade^g, Claudia Vellozzi^g, the Causality Working Group of the Clinical Immunization Safety Assessment network¹

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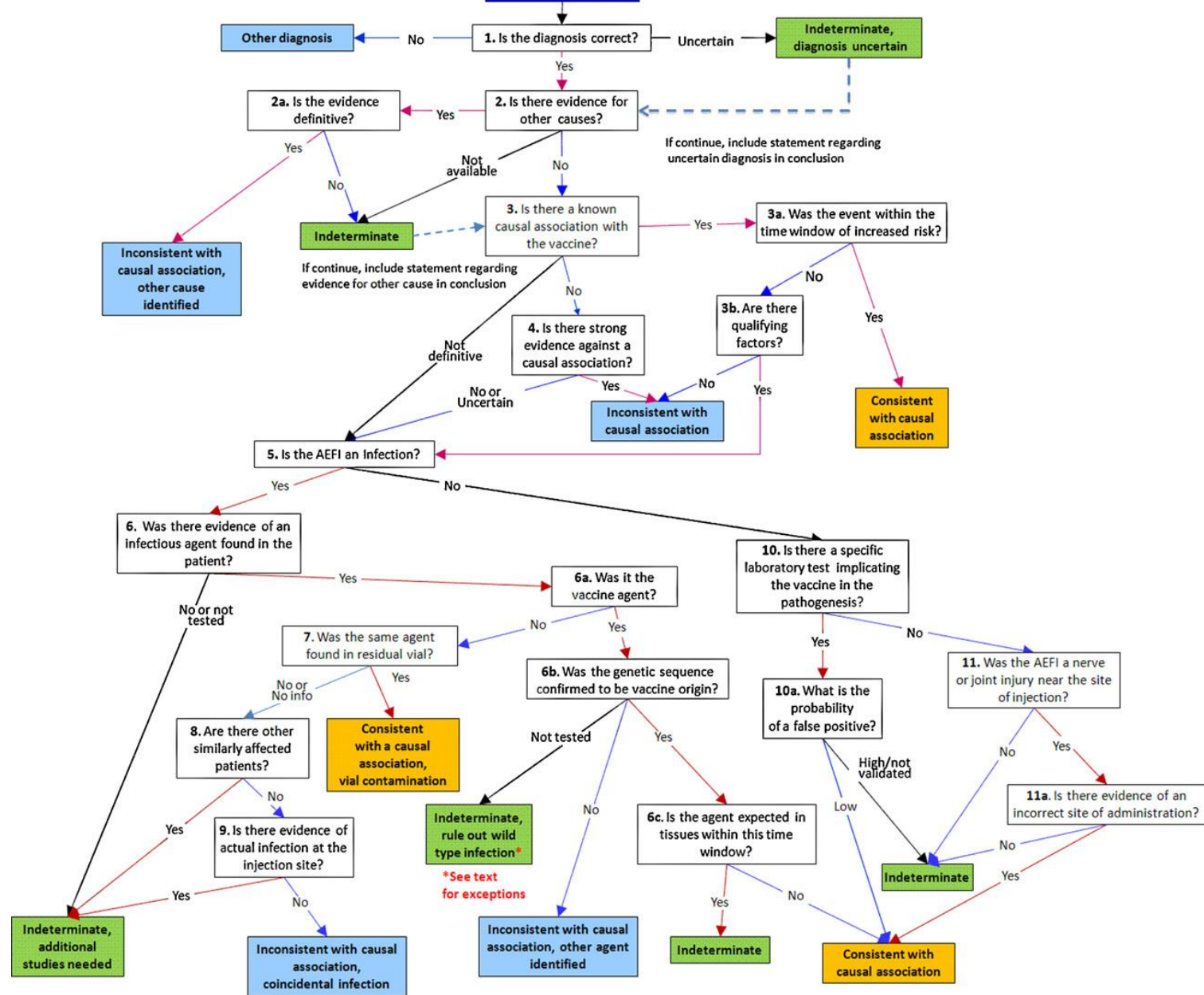
^g Immunization Safety Office, Centers for Disease Control and Prevention, United States

Review of Case Reports of Adverse Events Following Immunizations

February 28, 2012

Causality Work Group of CISA

AEFI Case Report



Post-vakcinační meningoencefalitida po aplikaci intranasální živé vakciny proti viru chřipky

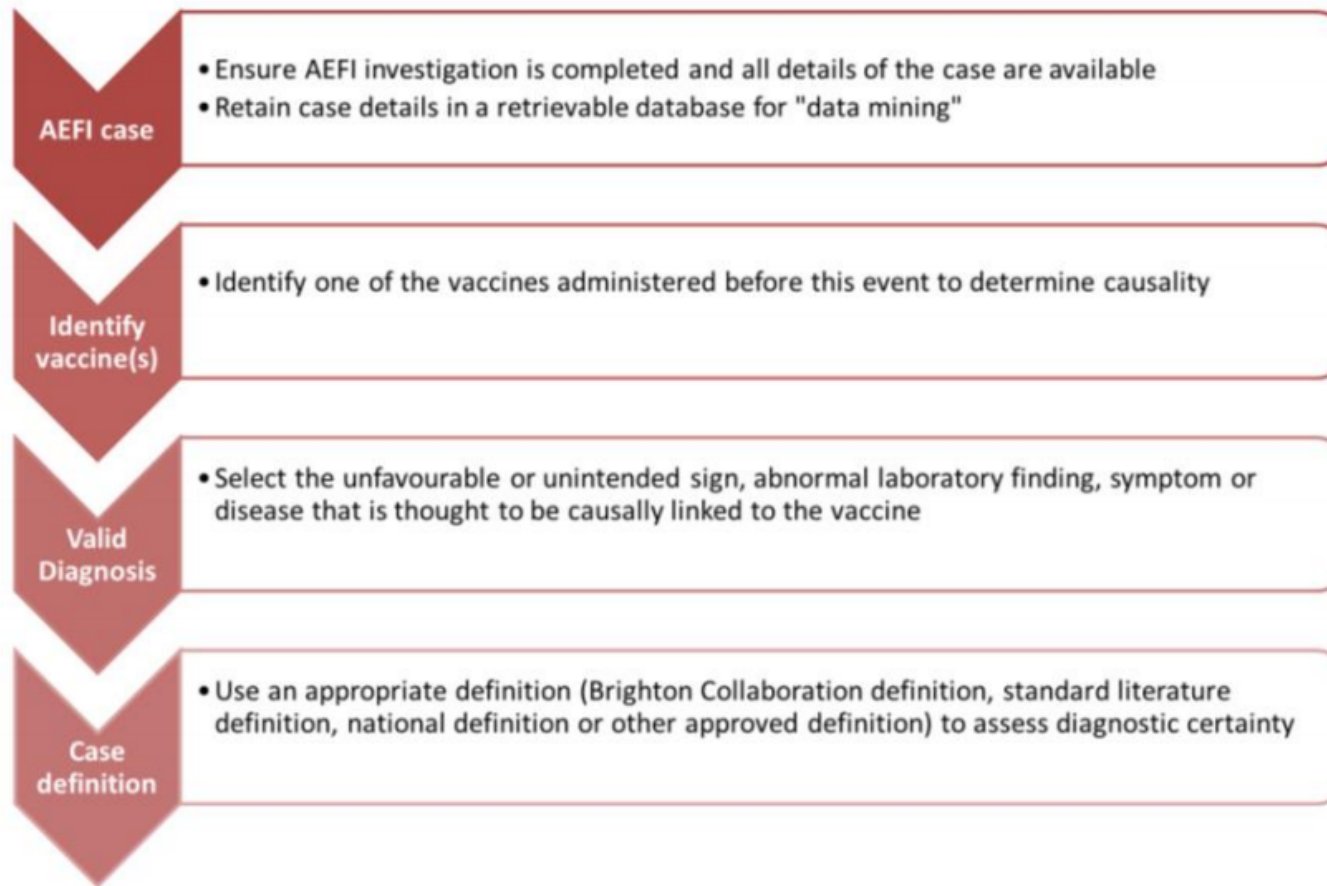


Clinical Immunization Safety Assessment (CISA) Project

Enterovirová meningoencefalitida

CAUSALITY ASSESSMENT OF AN ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI)

Fig. 1. Causality assessment – Eligibility



Vaccine risks: real, perceived and unknown[☆]

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Commentary

Neonatal encephalopathy: Case definition & guidelines for data collection, analysis, and presentation of maternal immunisation safety data



Erick Sell^{a,*}, Flor M. Munoz^b, Aung Soe^c, Max Wiznitzer^d, Paul T. Heath^e, E.D. Clarke^f, Hans Spiegel^g, Daphne Sawlwin^h, Maja Šubeljⁱ, Ilia Tikhonov^j, Khorshid Mohammad^k, Sonali Kochhar^{l,m,1}, for The Brighton Collaboration Acute Neonatal Encephalopathy Working Group²

Table 1. The causality assessment checklist

I. Is there strong evidence for other causes?	Y N UK NA	Remarks
1. In this patient, does the medical history, clinical examination and/ or investigations, confirm another cause for the event?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
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?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
2. Is there a biological plausibility that this vaccine could cause such an event?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
3. In this patient, did a specific test demonstrate the causal role of the vaccine ?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Vaccine quality		
4. Could the vaccine given to this patient have a quality defect or is substandard or falsified?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
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.)?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
6. In this patient, was the vaccine (or diluent) administered in an unsterile manner?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
7. In this patient, was the vaccine's physical condition (e.g. colour, turbidity, presence of foreign substances etc.) abnormal when administered?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
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.)?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
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.)?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
10. In this patient, was the vaccine administered incorrectly (e.g. wrong dose, site or route of administration; wrong needle size etc.)?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Immunization anxiety (Immunization Triggered Stress Response - ITSr)		
11. In this patient, could this event be a stress response triggered by immunization (e.g. acute stress response, vasovagal reaction, hyperventilation or anxiety)?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
II (time). If "yes" to any question in II, was the event within the time window of increased risk?		
12. In this patient, did the event occur within a plausible time window after vaccine administration?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
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?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
IV. Other qualifying factors for classification		
1. In this patient, did such an event occur in the past after administration of a similar vaccine?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
2. In this patient did such an event occur in the past independent of vaccination?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
3. Could the current event have occurred in this patient without vaccination (background rate)?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
4. Did this patient have an illness, pre-existing condition or risk factor that could have contributed to the event?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
5. Was this patient taking any medication prior to the vaccination?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
6. Was this patient exposed to a potential factor (other than vaccine) prior to the event (e.g. allergen, drug, herbal product etc.)?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	

Note: Y: Yes; N: No; UK: Unknown; NA: Not applicable.

Fig. 3. Causality assessment algorithm

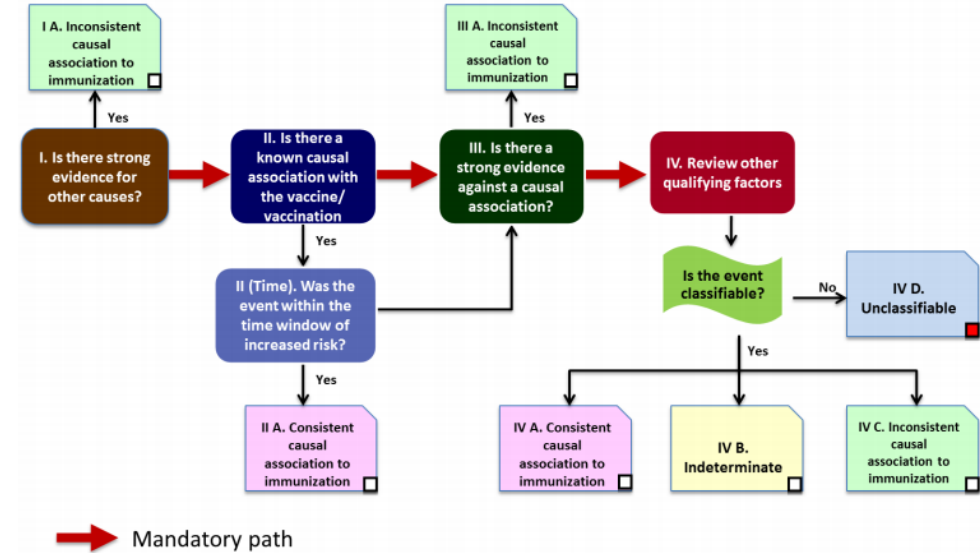
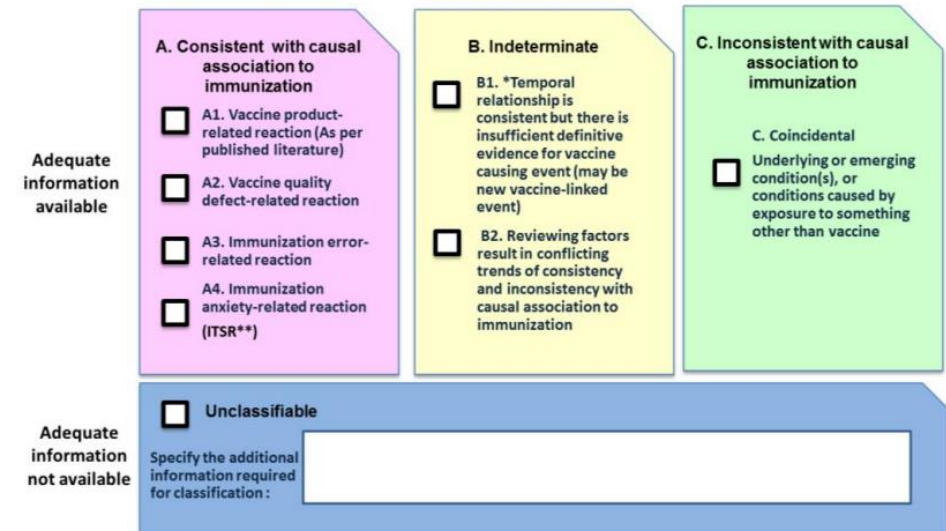


Fig 4. Causality assessment classification



Závěr

- Důkladné vyšetření, precizní stanovení diagnózy
- Snaha o nalezení jiné vysvětlující příčiny
- Provést všechny kroky pro správnou klasifikaci kauzality pro konkrétní případ
- Nebát se říct kauzalita je v daném případě neurčená, respektive NEVÍME (prozatím)

Děkuji za pozornost!