TABLE 1-2 Conclusions Based on the Evidence Bearing on Causality

DT/Td/T	Measles [a]	Mumps [a]	OPV/IPV [b]	Hepatitis B	*H. influenzae* type [b]
Category, 1: No Evidence Bearing on a Causal Relation					
		Neuropathy	Transverse myelitis (IPV)		
		Residual seizure disorder	Thrombocytopenia (IPV)		
			Anaphylaxis (IPV)		
Category, 2: The Evidence Is Inadequate to Accept or Reject a Causal Relation					
Residual seizure disorder other than infantile spasms	Encephalopathy	Encephalopathy	Transverse myelitis (OPV)	Guillain-Barré syndrome	Guillain-Barré syndrome
	Subacute sclerosing panencephalitis	Aseptic meningitis			
			Guillain-Barré syndrome (IPV)	Demyelinating diseases of the central nervous system	Transverse myelitis
Demyelinating discases of the central nervous system	Residual seizure	Sensorineural deafness (MMR)	Death from SIDS [e]		Thrombocytopenia
		Insulin-dependent diabetes mellitus			Anaphylaxis
Mononeuropathy	Sensorineural deafness (MMR)			Arthritis	
					Death from SIDS [c]
Arthritis		Sterility		Death from SIDS [c]	
	Optic neuritis				
Erythema multiforme	Transverse myelitis	Thrombocytopenia			
	Guillain-Barré syndrome	Anaphylaxis [d]			
	Thrombocytopenia				

	Insulin-dependent diabetes mellitus				
Category 3: The Evidence Favors Rejection of a Causal Relation					
Encephalopathy [e]					Early onset *H. influenzae* [b] disease (conjugate vaccines)
Infantile spasms (DT only) [f]					
Death from SIDS (DT only) [f, g]					
Category 4: The Evidence Favors Acceptance of a Causal Relation					
Guillain-Barré syndrome [h]	Anaphylaxis [d]		Guillain-Barré syndrome (OPV)		Early-onset *H. influenzae* [b] disease in children age 18 months or older who receive their first Hib immunization with unconjugated PRP vaccine
Brachial neuritis [h]					
Category 5: The Evidence Establishes a Causal Relation					
Anaphylaxis [h]	Thrombocytopenia (MMR)		Poliomyelitis in recipient or contact (OPV)	Anaphylaxis	
	Anaphylaxis (MMR) [d]				
	Death from measles vaccine-strain viral infection [c, i]		Death from polio vaccine-strain viral infection [c, i]		

a If the data derive from a monovalent preparation, then in the committee's judgment the causal relation extends to multivalent preparations. If the data derive exclusively from MMR, that is so indicated by (MMR). In the absence of any data on the monovalent preparation, in the committee's judgment the causal relation determined for the multivalent preparations does not extend to the monovalent components.

b For some adverse events, the committee was charged with assessing the causal relation between the adverse event and only oral polio vaccine (OPV) (paralytic and nonparalytic poliomyelitis) or only inactivated polio vaccine (IPV) (anaphylaxis and thrombocytopenia). If the conclusions are different for OPV than for IPV for the other adverse events, that is so noted.

c This table lists weight-of-evidence determinations only for deaths that are classified as SIDS and deaths that are a consequence of vaccine-strain adverse event can be fatal, then in the committee's judgment the evidence favors the acceptance of (or establishes) a causal relation between the vaccine and death from the adverse event. Direct evidence regarding death in

association with a vaccine-associated adverse event is limited to tetanus-diphtheria toxoid for adult use (Td) and Guillain-Barré syndrome, tetanus toxoid and anaphylaxis, and OPV and poliomyelitis. Direct evidence regarding death in association with a potentially fatal adverse event that itself is causally related to the vaccine is lacking for measles vaccine and anaphylaxis, MMR and anaphylaxis, OPV and Guillain-Barré syndrome, hepatitis B vaccine and anaphylaxis, and H. *influenzae* type b unconjugated PRP vaccine and early-onset H. *influenzae* type b disease in children age 18 months or older who receive their first Hib immunization with unconjugated PRP vaccine. See Chapter 10 for details.

d The evidence that establishes a causal relation for anaphylaxis derives from MMR. The evidence regarding monovalent measles vaccine favors acceptance of a causal relation, but are less convincing, mostly because of incomplete documentation of symptoms or the possible attenuation of symptoms by medical intervention.

e The evidence derives from studies of diphtheria-tetanus toxoid for pediatric use (DT). If the evidence favors rejection of a causal relation between DT and encephalopathy, then in the committee's judgment the evidence favors rejection of a causal relation between Td and tetanus toxoid and encephalopathy.

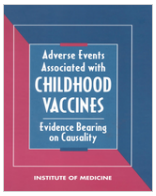
f Infantile spasms and SIDS occur only in an age group that receives DT but not Td or tetanus toxoid.

g The evidence derives mostly from DPT. Because there are supportive data favoring rejection of a causal relation between DT and SIDS as well, if the evidence favors rejection of a causal relation between DPT and SIDS, then in the committee's judgment the evidence favors rejection of a causal relation between DT and SIDS.

h The evidence derives from tetanus toxoid. If the evidence favors acceptance of (or establishes) a causal relation between tetanus toxoid and an adverse event, then in the committee's judgment the evidence favors acceptance of (or establishes) a causal relation between DT and Td and the adverse event as well.

i The data come primarily from individuals proven to be immunocompromised.

From: 1, Executive Summary



Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality.
Institute of Medicine (US) Vaccine Safety Committee; Stratton KR, Howe CJ, Johnston RB Jr., editors.
Washington (DC): National Academies Press (US); 1994.