Various Views on Adverse Events: a collection of definitions.

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ID	Term	Definition	Src.	Ref.
D1	***adverse drug event*** (adverse drug error)	Any incident in which the use of a medication (drug or biologic) at any dose, a medical device, or a special nutritional product (for example, dietary supplement, infant formula, medical food) may have resulted in an adverse outcome in a patient.	JTC	[1]
D2	***adverse drug experience***	any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: • an adverse event occurring in the course of the use of a drug product in professional practice; • an adverse event occurring from drug overdose whether accidental or intentional; • an adverse event occurring from drug abuse; • an adverse event occurring from drug withdrawal; and • any failure of expected pharmacological action.	FDA	[2]
D3	***adverse drug reaction***	an undesirable response associated with use of a drug that either compromises therapeutic efficacy, enhances toxicity, or both.	JTC	[1]
D4	***adverse event***	an ***observation*** of a change in the state of a subject ***assessed*** as being untoward by one or more ***interested parties*** within the ***context*** of a protocol-driven research or public health.	BRIDG	[3]
D5	***adverse event***	an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient	IOM	[4]
D6	***adverse event***	any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure	NCI	[5]
D7	***adverse event***	any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a	CDISC	[6]

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		causal relationship with this treatment		
D8	***adverse event***	an untoward, undesirable, and usually unanticipated event, such as death of a patient, an employee, or a visitor in a health care organization. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no permanent effect on the patient.	JTC	[1]
D9	***adverse event***	an injury that was caused by medical management and that results in measurable disability.	QUIC	[7]
D10	***adverse event trigger***	Clinical data related to patient care indicating a reasonable probability that an adverse event has occurred or is occurring. An example of trigger data for an adverse drug event is a physician order for an antidote, a medication stop, or a dose decrease.	IOM	[4]
D11	***adverse outcome***	an unintended and unwanted event or state occurring during or following medical care, that is so harmful to a patient's health that (adjustment of) treatment is required or that permanent damage results. The adverse outcome may be noted during treatment or in a predefined period after discharge or transferral to another department. The intended result of treatment, the likelihood of the adverse outcome occurring, and the presence or absence of a medical error causing it are irrelevant in identifying an adverse outcome.	-	[8]
D12	***adverse outcome***	a non-trivial adverse consequence (or potential risk) of health care treatment not solely related to the course of the condition being treated but resulted at least in part from the health care treatment itself or from the manner in which the health care was delivered.	CPSNL	[9] (modi-fied)
D13	***assessment***	a process in which interested parties arrive at a judgment as to whether an observation is relevant based on asserting a temporal, spatial, or causal relationship between the observation and some other factor.	BRIDG	[3]
D14	***associated with the use of the drug***	There is a reasonable possibility that the experience may have been caused by the drug.	FDA	[2]
D15	***context***	a set of principles, processes, constraints, rules, and data structures organized to achieve some goals.	BRIDG	[3]
D16	***disability***	A substantial disruption of a person's ability to conduct normal life functions.	FDA	[2] [10]
D17	***error***	the failure of a planned action to be completed as intended (i.e., error of execution), and the use of a wrong plan to achieve an aim (i.e., error of planning) (Institute of Medicine, 2000). It also includes failure of an unplanned action that should have been completed (omission).	IOM	[11] [4]
D18	***error***	the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems	QUIC	[12]
D19	***error of commission***	An error which occurs as a result of an action taken.	JTC	[1]
D20	***error of omission***	An error which occurs as a result of an action not taken. Errors of omission may or may not lead to adverse outcomes.	JTC	[1]
D21	***interested party***	an individual or a group with the authority and/or expertise ***to assess*** the ***observation*** within the ***context***. It may be the subject of the occurrence. It could be PI, Subject, providers, etc.	BRIDG	[3]
D22	***latent failure***	An error which is precipitated by a consequence of	JTC	[1]

		management and organizational processes and poses the greatest danger to complex systems. Latent failures cannot be foreseen but, if detected, they can be corrected before they contribute to mishaps.		
D23	***life-threatening adverse drug experience***	any adverse drug experience that places the patient or subject, in the view of the (investigator/initial reporter), at immediate risk of death from the (reaction/adverse drug experience) as it occurred, i.e., it does not include a (reaction/adverse drug experience) that, had it occurred in a more severe form, might have caused death.	FDA	[2] [10]
D24	***medical error***	an adverse event or near miss that is preventable with the current state of medical knowledge.	QUIC	[7]
D25	***near miss (close call)***	an event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention.	QUIC	[7]
D26	***near miss***	an error of commission or omission that could have harmed the patient, but serious harm did not occur as a result of chance, prevention, or mitigation.	IOM	[4]
D27	***observation***	an act of recognizing and noting a fact or an occurrence of an event of interest. An observation may involve examination, interviews, or measurement with devices. Observations are not intended to alter the state of the subject.	BRIDG	[3]
D28	***sentinel event***	an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response.	JTC	[1]
D29	***serious adverse drug experience***	Any adverse drug experience occurring at any dose that results in any of the following outcomes: • death, • a life-threatening adverse drug experience, • inpatient hospitalization • prolongation of existing hospitalization, • a persistent or significant disability/incapacity, • a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.	FDA	[2] [10]
D30	***signal*** (in pharmaco-vigilance)	any reported information on a possible causal relationship between a drug and an adverse drug reaction (ADR), the relationship being unknown or incompletely documented previously	WHO	[13]
D31	***unexpected adverse drug experience***	Any adverse drug experience, the specificity or severity of which is not consistent with the current (investigator brochure/labeling for the drug product); or, (if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended/This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event	FDA	[2] [10]

		because of greater severity or specificity). "Unexpected," as used in this definition, refers to an adverse drug experience that has not been previously observed rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product.		
D32	***unpreventable adverse event***	an adverse event resulting from a complication that cannot be prevented given the current state of knowledge.	QUIC	[7]

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