COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Committee of Experts on Management of Safety and Quality in Health Care (SP-SQS)
Expert Group on Safe Medication Practices

Glossary of terms related to patient and medication safety

Terms and translations	A	R	P	B	Definitions and references	Comments and synonyms
accident French : accident Spanish : accidente German : Unfall Italiano : incidente Slovene : nesreča				X	**accident :** an unplanned, unexpected, and undesired event, usually with adverse consequences (Senders, 1994).	*"For many years safety officials and public health authorities have discouraged use of the word "accident" when it refers to injuries or the events that produce them. An accident is often understood to be unpredictable -a chance occurrence or an "act of God"- and therefore unavoidable. However, most injuries and their precipitating events are predictable and preventable. That is why the BMJ has decided to ban the word accident. (…) Purging a common term from our lexicon will not be easy. "Accident" remains entrenched in lay and medical discourse and will no doubt continue to appear in manuscripts submitted to the BMJ. We are asking our editors to be vigilant in detecting and rejecting inappropriate use of the "A" word, and we trust that our readers will keep us on our toes by alerting us to instances when "accidents" slip through."* (Davis & Pless, 2001)
active error French : erreur active Spanish : error activo German : aktiver Fehler Italiano : errore attivo Slovene : neposredna napaka see also : *error*	X		X		**active error :** an error associated with the performance of the 'front-line' operator of a complex system and whose effects are felt almost immediately. (Reason, 1990, p.173)	Synonym : *sharp-end error* This definition has been slightly modified by the Institute of Medicine : "*an error that occurs at the level of the frontline operator and whose effects are felt almost immediately.*" (Kohn, 2000)
active failure French : défaillance active Spanish : fallo activo German : aktives Versagen Italiano : fallimento attivo Slovene : aktivna napaka see also : *active error*				X	**active failures :** actions or processes during the provision of direct patient care that fail to achieve their expected aims, for example, errors of omission or commission. While some active failures may contribute to patient injury, not all do. (Wade, 2002; Davies,2003)	Since failure is a term not defined in the glossary, its use is not recommended. A different meaning exists for active failure : "*an error which is precipitated by the commission of errors and violations. These are difficult to anticipate and have an immediate adverse impact on safety by breaching, bypassing, or disabling existing defenses.*" (JCAHO, 2002)
administration error French : erreur d'admnistration Spanish : error de administración German : Anwendungsfehler Italiano : errore di somministrazione Slovene : napaka pri dajanju see also : *medication error*	X				**administration error :** whatever type of medication error, of omission or commission, that occurs in the administration stage when the medication has to be given by a nurse, or the own patient, or a caregiver.	A process error taking place in the medication use system: definition and type to be refined with the taxonomy of medication errors.
adverse drug event French : événement indésirable médicamenteux Spanish : acontecimiento adverso por medicamentos German : unerwünschtes Arzneimittelereignis Italiano : evento avverso legato all'uso di farmaci Slovene : neželeni dogodek pri uporabi zdravila see also : *adverse drug event trigger, potential adverse drug event, preventable adverse drug event, unpreventable adverse drug event*	X				**adverse drug event :** any injury occurring during the patient's drug therapy and resulting either from appropriate care, or from unsuitable or suboptimal care. Adverse drug events include: the adverse drug reactions during normal use of the medicine, and any harm secondary to a medication error, both errors of omission or commission. An adverse drug event can result in different outcomes, notably: in the worsening of an existing pathology, in the lack of any expected health status improvement, in the outbreak of a new or to be prevented pathology, in the change of an organic function, or in a noxious response due to the medicine taken.	"*Adverse drug events may have resulted from medication errors or from adverse drug reactions in which no error was involved.*" (Gurwitz, 2000) "*An injury, large or small, caused by the use (including non-use) of a drug. There are two types of adverse drug events (ADEs) : those caused by errors and those that occur despite proper usage. If an adverse drug event is caused by an error it is, by definition, preventable. Nonpreventable adverse drug events (injury, but no error) are called adverse drug reactions (ADRs)* " (Leape et al 1998).

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adverse drug reaction French : effet indésirable d'un médicament Spanish : reacción adversa a medicamentos German : unerwünschte Arzneimittelwirkung Italiano : reazioni avverse da farmaci Slovene : stranski učinek zdravila see also : *mandatory reporting, voluntary reporting*		X			**adverse drug reaction** means a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function ; **serious adverse drug reaction** means an adverse action which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congential anomaly/birth defect ; **unexpected adverse drug reaction** means an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics.	Chapter Va (Pharmacovigilance) of Directive 75/319/EEC (Article 29b) amended by Commission Directive 2000/38/EC of 5 June 2000 : similar to the WHO's definition : "*a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.*" [WHO Technical Report No 498 (1972)] To be used where there is a causal relationship with the use of the "medicinal product" (medicine) (EMEA, 2003) Synonyms (not recommended by EMEA) : *adverse effect, side effect, undesirable effect* *" Unfortunately, many have used the term ADR as synonymous with ADE, which blurs an important distinction."* (Leape et al, 1998)
adverse event French : événement indésirable Spanish : acontecimiento adverso German : unerwünschtes Ereignis Italiano : evento avverso Slovene : varnostni incident see also : *adverse event trigger, harm, iatrogenic, incident, injury*			X		**adverse event :** an unintended injury caused by medical management rather than by a disease process (Michel, 2004). **patient safety incident:** any unintended or unexpected incident(s) that could have or did lead to harm for one or more persons receiving NHS-funded healthcare. 'Patient safety incident' is an umbrella term which is used to describe a single incident or a series of incidents that occur over time. (NPSA, 2004)	"*An adverse event 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.*" (Aspden, 2004) In the UK, the terms 'patient safety incident' and 'patient safety incident (prevented)' are preferred (by patients and the public) to the terms 'adverse events', 'clinical errors' and 'near misses'. Terms such as adverse, error or mistake suggest individual causality and blame. Medical error in particular suggests the main cause is the medical profession. (NPSA Terminology)
adverse event trigger, marker French : événement traceur Spanish : señal alertante de acontecimiento adverso, marcador German : Auslöser eines unerwünschten Ereignisses Italiano : trigger di eventi avversi Slovene : kazalnik verjetnega varnostnega incidenta see also : *adverse event, adverse drug event*	X		X		**adverse event triggers :** clinical data related to patient care indicating a reasonable probability that an adverse event has occurred or is occuring. An exemple of **trigger data for an adverse drug event** is a physician order for an antidote, a medication stop, or a dose decrease. (Aspden, 2004) **adverse drug event triggers and markers :** a medication, laboratory value, or other indicator that prompts further review of patient care for the purpose of uncovering adverse drug events that may otherwise go undetected or unreported. Examples of triggers and markers include diphenhydramine, naloxone, aPTT greater than 100 seconds, serum glucose less than 50, falls, rash, and death. (AHA&HRET&ISMP, 2002)	
cause French : cause Spanish : causa German : Ursache Italiano : causa Slovene : vzrok see also : *root cause analysis*			X		**cause :** an antecedent factor that contributes to an event, effect, result or outcome. A cause may be proximate in that it immediately precedes the outcome, such as an action. A cause may also be remote, such as an underlying structural factor that influences the action, thus contributing to the outcome. Outcomes never have single causes. (Wade, 2002)	
causation French : causalité Spanish : causalidad, inferencia causal German : Kausalität Italiano : causazione Slovene : vzročnost see also : *root cause analysis*			X		**causation :** the act by which an effect is produced ; the causal relationship between the act and the effect.	Synonym: *causality*. In epidemiology, the doctrine of causation is used to relate certain factors (predisposing, enabling, precipitating, or reinforcing factors) to disease occurrence. The doctrine of causation is also important in the fields of negligence and criminal law.(JCAHO)

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computer prescribing, computer physician order entry (CPOE) French : prescription informatisée Spanish : prescripción informatizada asistida German : elektronische Verordnung Slovene : elektronsko predpisovanje	X		X		**computer physician order entry (CPOE)** : clinical systems that utilize data from pharmacy, laboratory, radiology, and patient monitoring systems to relay the physician's or nurse practitioner's diagnostic and therapeutic plans, and alert the provider to any allergy or contraindication that the patient may have so that the order may be immediately revised at the point of entry prior to being forwarded electronically for the targeted medical action. (Aspden, 2004)	
constraint French : contrainte Spanish : restricción German : Beschränkung Italiano : limitazione Slovene : omejitev see also : *forcing function*	X		X		**constraint :** a limitation of the options available to keep behavior in a "safe" zone. (Leape, 1998)	
contributing factor French : facteur contributif, facteur favorisant Spanish : factor contribuyente German : begünstigender/mitverursachender Faktor Italiano : fattori contribuenti Slovene : prispevajoči dejavnik see also : *root cause analysis*			X		**contributing factor (interchangeable with contributory factor) :** an antecedent factor to an event, effect, result or outcome similar to a cause. A contributory factor may represent an active failure or a reason an active failure occurred, such as a situational factor or a latent condition that played a role in the genesis of the outcome. (Wade, 2002)	
criticality French : criticité Spanish : criticidad German : Gefährlichkeit Italiano : indice di priorità di rischio Slovene : kritičnost see also : *failure mode and effect analysis*			X		**risk priority number (RPN) :** determines the criticality of the failure mode and helps determine whether the risk of failure should be accepted (do nothing about the potential failure), controlled (take action to enhance detection or reduce the risk of the potential failure), or eliminated (prevent the potential failure). This number plays a role in the failure mode and effects analysis process**.** (AHA&HRET&ISMP, 2002)	
culture of safety French : culture de la sécurité Spanish : cultura de seguridad German : Sicherheitskultur Italiano : cultura della sicurezza Slovene : varnostna kultura see also : *just culture*			X		**culture of safety:** an integrated pattern of individual and organizational behavior, based upon shared beliefs and values, that continuously seeks to minimize patient harm which may result from the processes of care delivery. (Aspden, 2004)	"*There isn't a universally accepted definition of a safety culture in healthcare but it is essentially a culture where staff have a constant and active awareness of the potential for things to go wrong. It is also a culture that is open and fair and one that encourages people to speak up about mistakes. In organisations with a safety culture people are able to learn about what is going wrong and then put things right.*" (NPSA, 2004)
dispensing error French : erreur de dispensation Spanish : error de dispensación German : Abgabefehler Italiano : errori legati alla distribuzione del farmaco Slovene : napaka pri izdajanju see also : *medication error*	X				**dispensing error :** a deviation from an interpretable writen prescription or medication order, including writtent modification of the prescription made by a pharmacist following contact with the prescriber or in compliance with the pharmacy policy. Any deviation from professional or regulatory references, or guidelines affecting dispensing procedures is also considered as a dispensing error. (Beso, 2005)	Whatever type of medication error, of omission or commission, that occurs in the dispensing stage in the pharmacy when distributing medications to nursing units or to patients in ambulatory settings A process error taking place in the medication use system: definition and type to be refined with the taxonomy of medication errors. Since they can be detected by this way, dispensing errors are also defined as deviations from the prescriber's order. (AHA&HRET&ISMP, 2002)

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drug-related problem French : problème lié la prise en charge médicamenteuse Spanish : problema relacionado con medicamentos German : Arzneimittelproblem Italiano : problemi legati al processo terapeutico Slovene : problem povezan z zdravili					**drug-related problem :** an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes. (PCNE, 2003)	This working definition is designed for *pharmaceutical care*, that is to mean "*the responsible provision of drug therapy for the pupose of achieving definite outcomes that improve a patient's quality of life*" (Hepler, 1989), in fact optimizing the individual benefit/risk balance for each individual patient. Even if the diagnosis of DRPs overlaps with the detection of medication errors threatening the patient, these definitions are not applicable to medication safety, focused on a system approach. For preventing any risk of confusion, the proposed recommandation is to strictly avoid the use of "medication or drug-related problems" when the matter is medication safety.
error French : erreur humaine Spanish : error German : Fehler Italiano : errore Slovene : napaka see also : *mistake, slip, lapse*	**X**		**X**		**error :** a generic term to encompass all those occaions in wich a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot attributed to the intervention of some change agency. (Reason, 1990, p.9) ; failure of planned actions to achieve their desired ends-whithout the intervention of some unforeseeable event (Reason, 1997, p.71)	"*The failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., an error of planning)*" (Kohn 2000) ; "*and also the failure of an unplanned action that should have been completed*". (Aspden, 2004) "*Errors can include problems in practice, products, procedures, and systems.*" (QuIC, 2000)
error of commission French : erreur par commission Spanish : error de comisión German : Ausführungsfehler Italiano : errore di esecuzione Slovene :napaka izvršitve see also : *error, mistake, slip, lapse*	**X**		**X**		**error of commission :** an error which occurs as a result of an action taken. (JCAHO, 2002)	Examples include when a drug is administered at the wrong time, in the wrong dosage, or using the wrong route;
error of omission French : erreur par omission Spanish : error por omisión German : Unterlassungsfehler Italiano : errore di omissione Slovene : napaka opustitve	**X**		**X**		**error of omission :** an error which occurs as a result of an action not taken (JCAHO, 2002)	For example, when a nurse omits a dose of a medication that should be administered (JCAHO, 2002) ; failing to prescribe a medication from which the patient would likely have benefited. (Aspden, 2004)
evidence-based guidelines French : recommandations fondées sur des preuves Spanish : recomendaciones basadas en la evidencia German : Evidenz-basierte Leitlinien Italiano : linee guida basate sull' evidence-based Slovene : na dokazih temelječe smernice					**evidence-based guidelines :** consensus approaches for handling recurring health management problems aimed at reducing practice variability and improving health outcomes. Guideline development emphasizes using clear evidence from the existing literature, rather than expert opinion alone, as the basis for advisory materials (Aspden, 2004)	

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failure mode and effects analysis French : analyse des modes de défaillance et de leurs effets (AMDE) Spanish : análisis modal de fallos y efectos (AMFE) German : Fehlermöglichkeits- und Wirkungsanalyse Italiano : analisi delle modalità e degli effetti del fallimento Slovene : analiza možnih napak in njihovih posledic (AMNP) see also : *error, mistake, slip, lapse, risk priority number*			X		**failure mode and effects analysis (FMEA)** : a risk assessment method based on the simultaneous analysis of failures modes, their consequences and their associated factors. This systematic method is used to identify and prevent product and process problems before they occur.	Others risk assessment methods using the failure mode (that is : "*different ways that a process or subprocess can fail to provide the anticipated result*" AHA&HRET&ISMP, 2002) exist, like: - failure mode analysis (FMA) "examining a product or system to identify all the ways in which it might fail" (AHA&HRET&ISMP, 2002) - failure mode, effect, and criticality analysis (FMECA) "a systematic way of examining a design prospectively for possible ways in which failure can occur. It assumes that no matter how knowledgeable or careful people are, errors will occur in some situations and may even be likely to occur." (JCAHO, 2002)
forcing function French : fonction de contrainte Spanish : función de restricción German : erzwingende Funktion Italiano : limitazioni al comportamento Slovene : prisilna omejitev see also : *constraint*	X		X		**forcing function :** something that prevent the behaviour from continuing until the problem has been corrected (Lewis & Norman, 1986; in Reason, 1990, p.161) ; design features that make it impossible to perform a specific erroneous act.	e.g. using oral syringes, for oral liquid doses, that will not fit with IV tubing and to which needles cannot be attached; and computer order entry which can be used to 'force' the physician to order standardized products. (AHA&HRET&ISMP, 2002)
harm French : dommage Spanish : daño German : Schaden Italiano : danno Slovene : škodlji vost see also : *adverse event, adverse drug event, iatrogenic*			X		**harm :** temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom requiring intervention. (NCC MERP, 1998)	Synonyms: *iatrogenic illness*, *iatrogenic injury*
high-alert medications French : médicaments à haut risque Spanish : medicamentos de alto riesgo German : Hochrisiko-Arzneimittel Italiano : farmaco ad alto rischio	X				**high-alert medications :** drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error with these medications are clearly more devastating to patients. (Cohen, 1999; ISMP, 2003)	ISMP's list of high-alert medications available at: http://www.ismp.org/MSAarticles/highalert.htm
human factors French : facteur humain Spanish : factores humanos German : menschliche Faktoren Italiano : fattore umano Slovene : človeški dejavniki	X		X		**human factors :** the study of the interrelationships between humans, the tools they use, the environment in which they live and work, and the design of efficient, human centred processes to improve reliability and safety. (RFM, Wade, 2002)	

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iatrogenic French : iatrogène Spanish : iatrogénico German : Iatrogen Italiano : iatrogena (malattia) Slovene : iatrogen see also : *adverse event, harm*			X		**iatrogenic 1**. any undesirable condition in a patient occurring as the result of treatment by a physician (or other health professional). **2.** Pertaining to an illness or injury resulting from a procedure, therapy, or other element of care. (JCAHO, 2002)	iatrogenic illness : "*any illness that resulted from a diagnostic procedure or from anyform of therapy.*" (Steel, 1981) iatrogenic injury : "*injury originating from or caused by a physician (ιατρος: for "physician"), including unintended or unnecessary harm or suffering araising from any form of health care management, including problems arising from acts of commission or omission.*" (Aspden, 2004)
incident French : incident Spanish : incidente German : Zwischenfall Italiano : incidente Slovene : incident see also : *adverse event*			X		**incident :** an event or circumstance which could have, or did lead to unintended and/or unnecessary harm to a person, and/or a complaint, loss or damage. (ACSQHC). In the UK, the NHS National Patient Safety Agency defines 'patient safety incident' as "*any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS funded healthcare*". (NPSA Terminology)	"*An incident includes any irregularity in the process of medication use. It might represent an ADE, potential ADE, medication error, or none of these-it is essentially a "catch all" term for what to call something before it has been classified.*" (Morimoto, 2004)
just culture French : culture de la responsabilité Spanish : cultura de responsabilidad German : Gerechtigkeitskultur Italiano : cultura giusta Slovene : kultura pravičnosti see also : *culture of safety*			X		**just culture :** is a key element of a safe culture (Aspden, 2004). A just culture reconciles professional accountability and the need to create a safe environment to report medication errors; seeks to balance the need to learn from mistakes and the need to take disciplinary action (Marx, 2001).	Reason was the first to coin the term "just culture" which provides a fair and productive alternative to the two extremes of punitive or blame-free cultures. "*Creating a just culture –it could be just as well be called a trust culture- is the critical fist step in socially engineering a safe culture. (…) A just culture hinges critically on a collectively agreed and clearly understood distinction being drawn between acceptable and unacceptable behaviour.*" (Reason, 2003) Marx has expanded the concept further and provided guidance for health care organizations.(Marx, 2001)
lapse French : raté, erreur de mémoire Spanish : lapsus, error de memoria German : Aussetzer Italiano : lapsus Slovene : lapsus see also : *error, mistake, slip*	X		X		**lapses :** errors which result from some failure in the execution and/or storage stage of an action sequence, (…) largely involving failures of memory, that do not necessarily manifest themselves in actual behaviour and may be only apparent to the person who experience them. (Reason, 1990, p.9) ; internal events [that] generally involve failures of memory. (Reason, 1997, p.71)	
latent (error, conditions) French : défaillance latente Spanish : error latente German : latente Fehler, Systemfehler Italiano : errori latenti Slovene : latentna napaka see also : *root cause analysis, human factor*	X		X		**latent errors :** errors in the design, organization, training, or maintenance that lead to operator errors. They may lie dormant in the system for lengthy periods of time. (Kohn, 2000) They represent root causes of adverse events. **latent conditions :** arise from decisions made by designers, builders, procedure writers, and top level management. Latent conditions may lie dormant within the system for many years before they combine with active failures and local triggers to create an accident opportunity. Unlike active failures, latent conditions can be identified and remedied before an adverse event occurs. Understanding this leads to proactive rather than reactive risk management. (Reason, 2000)	Synonym : *latent failures* Latent errors have been described as "*accidents waiting to happen*". (Leape, 1995a) "*Latent conditions are the inevitable "resident pathogens" within the system. They arise from decisions made by designers, builders, procedure writers, and top level management. Such decisions may be mistaken, but they need not be. All such strategic decisions have the potential for introducing pathogens into the system. Latent conditions have two kinds of adverse effect: they can translate into error provoking conditions within the local workplace (for example, time pressure, understaffing, inadequate equipment, fatigue, and inexperience) and they can create longlasting holes or weaknesses in the defences (untrustworthy alarms and indicators, unworkable procedures, design and construction deficiencies, etc). Latent conditions - as the term suggests- may lie dormant within the system for many years before they combine with active failures and local triggers to create an accident opportunity. Unlike active failures, whose specific forms are often hard to foresee, latent conditions can be identified and remedied before an adverse event occurs. Understanding this leads to proactive rather than reactive risk management.*" (Reason, 2000)

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mandatory reporting French : système de déclaration obligatoire Spanish : notificación obligatoria German : Obligatorische Meldung, Meldepflicht Italiano : reporting obbligatorio Slovene : obvezno poročanje		X			**mandatory reporting :** those patient safety reporting systems that by legislation and/or regulation require the reporting of specified adverse events. (Aspden, 2004)	
medication error French : erreur médicamenteuse Spanish : error de medicación German : Arzneimittelfehler, Medikationsfehler Italiano : errori legati ai farmaci Slovene : napaka pri ravnanju z zdravili	X				**medication error :** any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (NCC MERP, 1998)	"*Obviously, nonpreventable drug-related problems (DRPs) are not included.*" (Foppe van Mil, 2004)
medication safety French : sécurité des soins médicamenteux Spanish : seguridad en el uso de los medicamentos German : Arzneimittelsicherheit Italiano : sicurezza dei farmaci Slovene : varnost pri ravnanju z zdravili see also : *patient safety, pharmacovigilance*	X				**medication safety :** freedom from accidental injury during the course of medication use; activities to avoid, prevent, or correct adverse drug events which may result from the use of medications**.** (AHA&HRET&ISMP, 2002)	
medication use system French : circuit du médicament Spanish : sistema de utilización de los medicamentos German : Arzneimittelanwendungssystem Italiano : sistema di utilizzo dei farmaci Slovene : sistem ravnanja z zdravili see also : *process, system*	X				**medication use system :** a combination of interdependent processes that share the common goal of safe, effective, appropriate, and efficient provision of drug therapy to patients. Major processes in the medication use system are : selecting and procuring; storage; prescribing; transcribing and verifying/reviewing; preparing and dispensing; administering and monitoring. (Cohen, 1999; AHA&HRET&ISMP, 2002; JCAHO, 2003; Otero 2003).	"*Medication use within a healtcare organisation can be viewed as a system, with several components and processes, inputs (patient and drug theray information, and outputs (effective, efficient, and safe treatment). The provision of medications to patients, regardless of the setting, depends on a set of processes…*" (Nadzam, 1998) "*Each major process in the medication system- ordering, dispensing, and administration – has its own unique opportunities for error.*" (Leape 1998) For flowcharts describing the medication use system, see these references.
mistake French : erreur de jugement Spanish : equivocación German : Beurteilungsfehler, Irrtum Italiano : mistake Slovene : zmota see also : *error, slip, lapse*	X		X		**mistake :** deficiency or failure in the judgemental and/or inferential processes involved in the selection of an objective or in the specification of the means to achieve it, irrespective whether or not the actions directed by this decision-scheme run according to plan (Reason, 1990, p.9) ; errors of concious though including *rule-based errors* that occur during problem solving when a wrong rule is chosen, and *knowledge-based errors* that arise because of lack of knowledge or misinpretation of the problem (Leape, 1994).	"*The actions may conform exactly to the plan, but the plan is inadequate to achieve its intended outcome.*" (Reason, 1997, p.71)
monitoring error French : erreur de suvi thérapeutique Spanish : error de seguimiento German : Überwachungsfehler Italiano : monitoraggio degli errori Slovene : napaka pri sledenju	X				**monitoring error :** failure to review a prescribed regimen for appropriateness and detection of problems, or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy. (Leape, 1998)	A process error taking place in the medication use system: definition and type to be refined with the taxonomy of medication errors.

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negligence French : faute, négligence Spanish : negligencia German : Fahrlässigkeit, Vernachlâssigung Italiano : negligenza Slovene : malomarnost			X		**negligence :** care provided failed to meet the standard of care reasonably expected of an average practitioner qualified to care for the patient in question. (AHA&HRET&ISMP, 2002)	
nosocomial French : nosocomial Spanish : nosocomial German : nosokomial Italiano : nosognomico Slovene : nosokomialen			X		**nosocomial :** pertaining to or originating in a health care facility (ACSQHC).	Synonym : *health care acquired*
observation method French : méthode d'observation directe Spanish : método de observación German : Beobachtungsmethode Italiano : metodo di osservazione Slovene : opazovalna metoda	X				**observation method :** an active method of error surveillance in which a trained observer observes medication administration during peak workload periods and compares the observations to the original order on the patient's chart for the purpose of uncovering medication errors and clues as to why they happen. (Allan&Barker, JCAHO, 2002)	
opportunity for error French : opportunité d'erreur Spanish : oportunidad de error German : Fehlermöglichkeit Italiano : opportunità di errore Slovene : priložnost za napako	X				**opportunity for error :** any dose dose given plus any dose ordered but omitted. It is a basic unic of data in medcation error studies preventing the error rate from exceeding 100%. (Allan, 1990; Barker, 1966)	
patient safety French : sécurité des patients Spanish : seguridad clínica German : Patientensicherheit Italiano : sicurezza del paziente Slovene : varnost bolnikov see also : *medication safety*			X		**patient safety :** freedom from accidental injuries during the course of medical care; activities to avoid, prevent, or correct adverse outcomes which may result from the delivery of health care. (Kohn, 2000; AHA&HRET&ISMP, 2002) **patient safety :** the identification, analysis and management of patient-related risks and incidents, in order to make patient care safer and minimise harm to patients. (Aspden, NPSA, 2004)	"*Safety, the first domain of quality, refers to "freedom from accidental injury." This definition is stated from the patient's perspective*." (Kohn, 2000)
pharmacovigilance French : pharmacovigilance Spanish : farmacovigilancia German : Pharmakovigilanz, Artzneimittelüberwachung Italiano : farmacovigilanza Slovene : farmakovigilanca see also : *adverse drug reaction*		X			**pharmacovigilance :** the science and activities relating to the detection, assessment, understanding and prevention of the adverse effects of pharmaceutical products. (WHO, 2002)	

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Terms and translations	A	R	P	B	Definitions and references	Comments and synonyms
potential adverse drug event French : événement indésirable médicamenteux potentiel Spanish : acontecimiento adverso por medicamentos potencial German : mögliches unerwünschtes Arzneimittelereignis Italiano : eventi avversi potenziali legati ai farmaci Slovene : možen neželeni dogodek pri uporabi zdravila see also : *recovery*	X				**potential adverse drug event** : a serious medication error-one that has the potential to cause an adverse drug event, but did not, either by luck or because it was intercepted and corrected. Examining potential adverse drug events helps to identify both where the system is failing (the error) and where it is working (the interception). (Leape, 1998, Morimoto, 2004)	Synonyms : *near miss, close call, prevented patient safety incident* close call : "*an event or situation that could have resulted in an adverse event but did not, either by chance or through timely intervention*." (Aspden, 2004) near miss : "*an act of commission or omission that could have harmed the patient, but did not so as a result of chance (e.g., the patient received a contrraindicated drug, but did not experienced an adverse drug reaction), prevention (e.g., a potentially lethal overdose was prescribed, but a nurse identified the error before administering the medication), or mitigation e.g., a lethal overdose was administered but discovered early, and countered with an antidote).*" (Aspden, 2004)
potential error French : erreur potentielle Spanish : error potencial German : möglicher Fehler, beinahe Fehler Italiano : errore potenziale Slovene : možna napaka see also : *latent error*	X		X		**potential error:** circumstances or events that have the capacity (potentiality) to cause error	
preparation error French : erreur de préparation Spanish : error de preparación German : Zubereitungsfehler Italiano : errore di preparazione Slovene : napaka pri pripravi see also : *medication error*	X				**preparation error :** whatever type of medication error, of omission or commission, that occurs in the preparation stage when the medication has to be compounded or prepared by a pharmacist, a nurse, or the own patient, or a caregiver.	Synonym : *compounding error* A process error taking place in the medication use system: definition and type to be refined with the taxonomy of medication errors. For example, an IV compounding error is "*a deviation of the actual compounding process from specifications in the pharmacy's patient-specific IV label or the hospital's policies and procedures for IV Compounding*." (Allan, 1997).
prescribing error French : erreur de prescription Spanish : error de prescripción German : Verschreibungsfehler Italiano : errore di prescrizione Slovene : napaka pri predpisovanju see also : *medication error*	X		X		**prescribing error :** a medication error occurring during the prescription of a medicine that it is about writing the drug order or taking the therapeutic decision, appreciated by any non intentional deviation from standard references such as: the actual scientific knowledge, the appropriate practices usually recognized, the summary of the characteristics of the medicine product, or the mentions according to the regulations. A prescribing error notably can concern : the choice of the drug (according to the indications, the contraindications, the known allergies and patient characteristics, interactions whatever nature it is with the existing therapeutics, and the other factors), dose, concentration, drug regimen, pharmaceutical form, route of administration, duration of treatment, and instructions of use; but also the failure to prescribe a drug needed to treat an already diagnosed pathology, or to prevent the adverse effects of others drugs.	A process error taking place in the medication use system: definition and type to be refined with the taxonomy of medication errors. "*A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescribing writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice*." (Dean, 2000)
preventable adverse event French : événement indésirable évitable Spanish : acontecimiento adverso prevenible German : Vermeidbares unerwünschtes Ereignis Italiano : evento avverso prevenibile see also : *adverse drug event, unpreventable adverse drug event*	X		X		**preventable** : potentially avoidable in the relevant circumstances. (ACSQHC) **preventable adverse event :** adverse event that would not have occurred if the patient had received ordinary standards of care appropriate for the time of the study (Michel, 2004).	

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preventable adverse drug event French : événement indésirable médicamenteux évitable Spanish : acontecimiento adverso por medicamento prevenible German : Vermeidbares unerwünschtes Arzneimittelereignis Italiano : evento avverso da farmaco prevenibile Slovene : preprečeni neželeni dogodek pri uporabi zdravila see also : *adverse drug event, unpreventable adverse drug event*	X				**preventable adverse drug event :** any adverse drug event that would not have occurred if the patient had received ordinary standards of care appropriate for the time when this event occurred, so that, associated to a medication error. **preventable adverse drug event :** an adverse drug event associated with a medication error (Roswell, 2001)	"*any adverse drug event due to an error or preventable by any means currently available*" (Bates, 1995a)
preventability French : évitabilité Spanish : evitabilidad German : Vermeidbarkeit Italiano : prevenibilità Slovene : preprečevanje	X		X		**preventability** : implies that methods for averting a given injury are known and that an adverse event results from failure to apply that knowledge. (Leape, 1993) **prevention** : modification of the system or its exploitation in order to decrease the probability of arisen the dreaded event and to return to an acceptable risk level ; any measure aiming at reducing the frequency and the severity of the risks.	« *Some adverse events are unavoidable. Patients and their caregivers are sometimes forced to kowingly accept adverse secondary consequences to achieve a more important primary treatment goal. The concept of* ***preventability*** *separates care delivery errors from such recognized but unavoidable treatment consequences* » (Aspden, 2004, 195)
process French : processus Spanish : proceso German : Prozess Italiano : processo Slovene : proces see also : *medication use system, system*	X				**process :** a series of related actions to achieved a defined outcome. Prescribing medication or administering medication are processes (Leape et al, 1998)	
recklessness French : imprudence Spanish : imprudencia German : Unvorsichtigkeit, Sorglosigkeit Italiano : spericolatezza Slovene : neodgovornost see also : *just culture, violation*			X		**recklessness :** 1) The individual knows that there is a risk, is willing to take that risk, and takes it deliberately. 2) The individual performs an act that creates an obvious risk, and when performing that act has either given no thought to the possibility of such a risk, and having recognised that such a risk existed, goes on to take it. (NPSA, 2004)	NPSA'*Incident Decision Tree* (IDT), based on a model developed by Professor J Reason for the aviation industry, is an interactive web-based tool for NHS managers and organisations dealing with staff who have been involved in an incident. It helps to identify whether the action(s) of individuals were due to systems failures or whether the individual knowingly committed a *reckless*, *intentional unsafe* or *criminal act*. The tool changes the focus from asking 'Who was to blame' to 'Why did the individual act in this way?' (NPSA)
recovery French : récupération Spanish : restablecimiento German : Erholung, Genesung Italiano : recupero Slovene : poprava see also : *close call, near miss, potential adverse drug event*	X		X		**recovery :** an informal set of human factors that lead to a risky situation being detected, understood, and corrected in time, thus limiting the sequence to a near-miss outcome, instead of it developping further into possibly an adverse event. (Aspden, 2004) **mitigating factors :** some factors, whether actions or inaction such as chance or luck, may have mitigated or minimised a more serious outcome. (NPSA, 2004)	Synonym : *mitigating factors*

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Terms and translations	A	R	P	B	Definitions and references	Comments and synonyms
risk assessment French : évaluation des risques Spanish : evaluación de riesgos German : Risikobewertung Italiano : valutazione del rischio Slovene : ocena tveganja			X		**risk assessment :** the process that helps organisations understand the range or risks that they face both internally and externally, the level of ability to control those risks, the likelihood of occurrence and their potential impacts. It involves a mixture of quantifying risks and using judgement, assessing and balancing risks and benefits and weighing them for example against cost. (NPSA, 2004)	
risk management French : gestion des risques Spanish : gestión de riesgos German : Risikomanagement Italiano : gestione del rischio Slovene : upravljanje s tveganji			X		**risk management :** clinical and administrative activities undertaken to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itself. (JCAHO, 2002) **risk management :** identifying, assessing, analysing, understanding, and acting on risk issues in order to reach an optimal balance or risk.benefits and costs'. (NPSA, 2004)	
root cause analysis French : analyse des causes profondes Spanish : análisis de causas raíz German : Ursachenanalyse Slovene : analiza porekla vzrokov see also : *cause, latent conditions*	X		X		**root cause analysis :** a systematic investigation technique that looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which the incident happened. (NPSA, 2004) The analysis focuses on identifying the latent conditions that underlie variation in performance and on developing recommendations for improvements to decrease the likelihood of a recurrence. (Wade, 2002, Davies, 2003)	Typically, the analysis focuses primarily on systems and processes, not individual performance. (Aspden, 2004)
sentinel event French : événement sentinelle Spanish : acontecimiento o suceso centinela German : Sentinel-Ereignis, Signal-Ereignis Italiano : evento sentinella Slovene : opozorilni nevarni dogodek	X		X		**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. (JCAHO, 2002)	
slip French : lapsus, erreur d'attention Spanish : distracción, desliz, error de atención German : Ausrutscher Slovene : spodrsljaj see also : *error, mistake, lapse*	X				**slip :** error which result from some failure in the execution and/or storage stage of an action sequence, (…) potentially observable as actions-not-as-planned (slips of the tongue, slips of the pen, slips of action). (Reason, 1990, p.9). Slips relate to observable actions and are commonly associated with attentional or perceptual failures (Reason, 1997, p.71)	"*They are errors of execution that occurs when there is a break in the routine while attention is diverted.*" (Leape, 1994)
system French : système Spanish : sistema German : System Italiano : sistema Slovene : sistem see also : *medication use system, process*	X				**system :** a set of interdependent elements interacting to achieve a common aim. These elements may be both human and non-human (equipment, technologies, etc.). (Kohn, 2000)	

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unpreventable adverse drug event French : événement indésirable médicamenteux inévitable Spanish : acontecimiento adverso por medicamento inevitable German : unvermeidbares unerwünschtes Arzneimittelereignis Italiano : eventi avversi da farmaci non prevenibili Slovene : neželeni dogodek pri uporabi zdravila, ki ga ni moč preprečiti see also : *preventability*	X				**unpreventable adverse event:** an adverse event resulting from a complication that cannot be prevented given the current state of knowledge. (QuIC, 2000) **unpreventable adverse drug event :** an adverse drug event that do not result from an error but reflect the inherent risk of drugs and cannot be prevented given the current state of knowledge. (Otero and Dominguez-Gil,2000).	"*Nonpreventable adverse drug events (ADEs) are called adverse drug reactions (ADRs)*" (Leape et al 1998).
violation French : non respect des règles ou procédures Spanish : transgresión German : Regelverletzung Italiano : violazione Slovene : kršitev		X			**violation :** a deliberate -but not necessarily reprehensible- deviation from those practices deemed necessary (by designers, managers and regulatory agencies) to maintain the safe operation of a potentially hazardous system (Reason, 1990, p.195) ; appreciated by the individual as being required by regulation, or necessary or advisable to achieve an appropriate objective while maintaining safety and the ongoing operation of a device or system. (Runciman, 2003)	
voluntary reporting French : notification spontanée Spanish : notificación voluntaria German : freiwilliges Meldesystem Italiano : reporting volontario Slovene: prostovoljno poročanje	X		X		**voluntary reporting :** those reporting systems for which the reporting of patient safety events is voluntary (not mandatory). Generally, reports on all types of events are accepted. (Aspden, 2004)	

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