

Impact of sample size on variation of adverse events and preventable adverse events: systematic review on epidemiology and contributing factors

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ABSTRACT

Objectives To perform a systematic review of the frequency of (preventable) adverse events (AE/PAE) and to analyse contributing factors, such as sample size, settings, type of events, terminology, methods of collecting data and characteristics of study populations.

Review methods Search of Medline and Embase from 1995 to 2007. Included were original papers with data on the frequency of AE or PAE, explicit definition of study population and information about methods of assessment. Results were included with percentages of patients having one or more AE/PAE. Extracted data enclosed contributing factors. Data were abstracted and analysed by two researchers independently.

Results 156 studies in 152 publications met our inclusion criteria. 144/156 studies reported AE, 55 PAE (43 both). Sample sizes ranged from 60 to 8 493 876 patients (median: 1361 patients). The reported results for AE varied from 0.1% to 65.4%, and for PAE from 0.1% to 33.9%. Variation clearly decreased with increasing sample size. Estimates did not differ according to setting, type of event or terminology. In studies with fewer than 1000 patients, chart review prevailed, whereas surveys with more than 100 000 patients were based mainly on administrative data. No effect of patient characteristics was found.

Conclusions The funnel-shaped distribution of AE and PAE rates with sample size is a probable consequence of variation and can be taken as an indirect indicator of study validity. A contributing factor may be the method of data assessment. Further research is needed to explain the results when analysing data by types of event or terminology.

INTRODUCTION

Following the Institute of Medicine (IOM) report 'To Err is Human' in 1999, there has been much debate on the true incidence of adverse events (AE), and preventable adverse events (PAE).¹ Several studies at national level and with the Harvard Medical Practice Design (see below) have found results for AE up to 16.6%, and for PAE up to 8.4%^{2–12} of inpatients. Variations in the figures were soon considered, and several systematic reviews have covered this issue.¹³

Systematic reviews are restricted by the diversity of studies. One strategy to deal with it is to refine research so as to focus on particular healthcare settings or subgroups of endpoints such as medication-related events^{14–18} or events leading to hospital admission.^{19–24} Only loose attempts have been made in mapping AE across the total healthcare system comprehensively, however.^{25–27}

The present systematic review aims to specify the overall incidence of AE and PAE across all settings and procedures, so as to describe the influence of heterogeneity factors such as sample size, settings, type of events, terminology, methods of collecting data or characteristics of the study population. We hypothesise that variation of incidence is explained primarily by sample size.

METHODS

Search strategy

The present article is part of a broader literature research on the epidemiology of patient safety,²⁸ and looks at papers giving frequencies of AE and PAE as percentages of patients affected. We began with a search in Medline and Embase for studies published between January 1995 and October 2007. Key words (truncated) were: 'AE*', 'PAE*', 'negligent AE*', 'adverse medical device event*', 'medication error*', 'medical error*', 'near miss*', 'adverse drug event*' and 'iatrogenic illness*'. This search was limited to titles and abstracts. References cited in the studies retrieved were examined in order to identify additional publications.

Articles in English, German, Spanish, French, Portuguese, Danish and Norwegian were considered. Other languages were approved when there was an English abstract containing data essential for extraction. Articles identified were reviewed at full-text level.

Selection

To be included, studies had to meet the following five criteria: (1) original paper; (2) a specified study population; (3) data collected on AE or PAE or both; (4) explicit information given about the study method; and (5) results reported as percentages of patients affected. AE was defined as any patient-related injury caused by clinical management rather than by the underlying disease, and PAE was defined as an AE resulting from error, and therefore avoidable.^{1 2 29} Patient populations might represent all patients in an institution, patients related to a defined medical specialty, or patients in an entire sector of care such as drug therapy or nosocomial infections.

A study was considered as an article on a single study population. Papers reporting results from different study populations were regarded as two or more studies. In the case of duplicate publications, only the primary or the one reporting overall results was included. Intervention studies were included with baseline data before the implementation of risk prevention. When several assessment methods



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were used, we extracted combined results as far as possible. Studies limited to single diseases or isolated procedures were excluded.

Data abstraction

Retrieved studies were assessed independently by two reviewers and controlled twice. Discrepancies were resolved by discussion. Data on the frequency of AE and PAE were extracted. Additional variables were the number of patients included, information on healthcare settings, classification according to types of event and terminology, method of collecting data and patient characteristics. We distinguished between medication-related, procedure-related and all types of events. We also distinguished between AE terminologies used by different authors. Two main groups were discerned. The first group refers to the definition of the IOM, 'an AE is an injury resulting from a medical intervention, or in other words, it is not due to the underlying disease'.¹ The second group apply to the definition due to the WHO of adverse drug events/adverse drug reactions as 'any response to a drug which is noxious, unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease'.³⁰ All other definitions were summarised in a third definition group. Among methods of collecting data, we distinguished between chart review, computer-based alerts, direct observation, voluntary reporting, critical incident reporting systems, interviews, clinical surveillance and the analysis of administrative data, usually in the form of codes from the International Statistical Classification of Diseases and Related Health Problems (ICD).³¹ We chose to distinguish between three types of chart review: prospective, retrospective and the Harvard Medical Design. The latter was developed especially to detect AE and PAE, and consists of a retrospective structured two-staged review process.^{32 33}

Quantitative data synthesis

Abstracted data were entered into a Microsoft Access database for further analysis (Microsoft, Seattle, Washington). Frequencies of outcome measures were recorded or calculated as numbers and percentages of patients. Data were rounded to one decimal place. Patient subgroups were totalled, if we were sure that every patient was included only once.

RESULTS

Trial flow

Our primary research found a total of 241 studies in 230 publications that matched our inclusion criteria. A total of 156 studies gave results as percentages of patients affected by AE or PAE, see figure 1 (full list of references in Appendix 1, available online only).

Study characteristics

In total, the 156 studies in our review reported results on 23 696 252 patients. Sample size varied from 60 patients³⁴ to 8 493 876 patients.³⁵ The median sample size was 1361 patients, the 25th percentile was 379 patients, and the 75th percentile was 14 766 patients.

AE as a single outcome measure was observed in 101/156 (64.7%) of studies, 12 (7.8%) observed PAE, and 43 (27.6%) observed both. Studies were performed in 27 countries, primarily in highly developed industrial countries, headed by the USA (51 surveys). Most studies were short-term; 55.1% lasted more than 6 months, but only 25.6% lasted more than 1 year. Patients were treated in distinct healthcare settings. One hundred and one

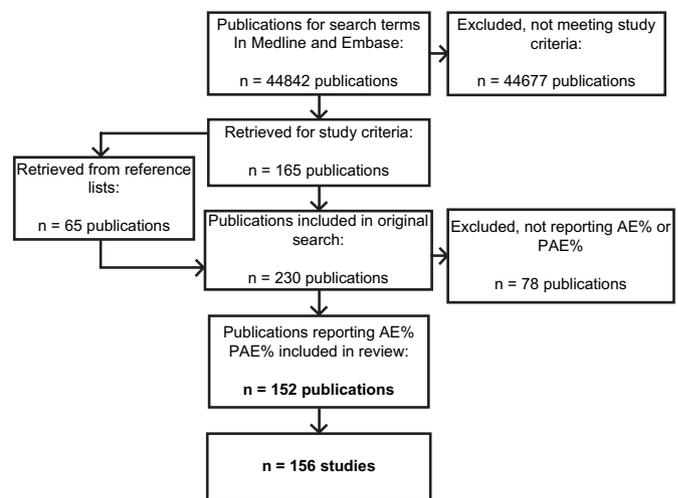


Figure 1 Flow chart of studies retrieved and included in the systematic review. AE, adverse event; PAE, preventable adverse event.

studies examined inpatient patients, nine surveys looked at ambulatory care, 39 looked at ambulant patients leading to hospital admission, three studies took place in long-term care, and four studies were conducted in other settings. When samples consisted of hospital patients, tertiary hospitals and academic centres prevailed. Most studies were limited to single institutions (101/156 cases). In general, all medical disciplines were concerned (17 medical specialties were distinguished), but when a specific choice was made, this depended principally on the organisational structure of the wards and hospital. Ninety-seven of 156 surveys concentrated on a single discipline. Thirty-nine of these were concerned with internal medicine, 16 with paediatrics and nine with surgery. We also found that 50/156 studies reported on all types of events, 99/156 were medication-related, and 7/156 were procedure-related.

Studies used different methods for collecting data. Ninety-seven surveys were restricted to a single collection method, and 59 papers used a combination of two or more methods. As a single measuring instrument, a chart review prevailed in 43/97 studies, followed by clinical surveillance (13/97) and ICD codes (11/97). Among combinations, the use of chart review with interviews was most common (19/59). A summary of all studies included is given in Appendix 2, available online only.

Incidence of AE and PAE by sample size

Frequencies of AE ranged from 0.1% to 65.4%. Most studies (129/156) reported results between 0.1% and 30% (median 8.9%, IQR 12.9). Incidences of PAE ranged from 0.1% to 33.9%. Almost all studies (53/55) reported results between 0.1% and 20% (median 4.8%, IQR 5.4).

To provide a more detailed picture of the distribution of results, we plotted the results against study size. Figure 2 shows the distribution of AE estimates in correlation to the size of the study population.

We observe a broad variation in smaller studies having fewer than 1000 patients. In studies with more than 1000 patients, the spread decreases rapidly, and even falls below 20% in studies with more than about 2000 patients. With only one exception, the results of surveys with approximately 15 000 patients or more do not exceed 10%.³⁶

For PAE, the plot looks similar, although extreme outliers are missing within small studies (figure 3); however, the fraction of

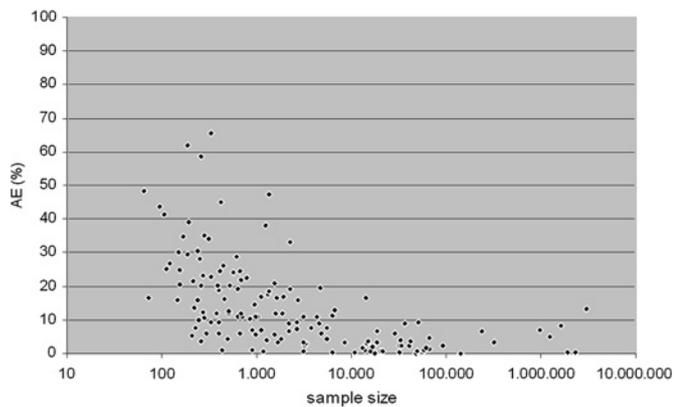


Figure 2 Adverse event estimates in correlation to sample size (n=144 studies), sample size displayed with half logarithmic-scale.

small studies is smaller for PAE than for AE, and the same is true for very large studies.

Nonetheless, percentages clearly decrease with sample size. In studies with approximately 2000 patients, the results fall below 10%, and below the 1% mark in studies with more than 20 000 patients. All scatter plots exhibit a visible correlation between the frequency of AE and PAE and sample size.

Effect of setting, types of events, terminology and methods of collecting data

We next analysed whether variation is due to further factors. We found that results do not differ between healthcare settings, countries or medical specialties. More surprisingly, we did not even find any clear disparities between different types of events, although the frequency of AE related to medications or procedures is expected to be lower than the overall results. Figure 4 shows the distribution for adverse drug events, procedure-related events and all types of AE (figure 4).

The data for terminology show a similar distribution. There is no difference in variation between studies using the terminology of the IOM, the WHO or others (figure 5, a list of all definitions of AE used is given in Appendix 3, available online only).

In relation to data-collecting methods, there is no difference in estimates between studies that use a single method to detect events, and surveys that operate with two or more methods. In contrast assessment techniques differ according to sample size, especially for AE (figure 6).

Interviews as a single method are restricted to small studies with some hundred patients included,^{37–42} whereas compila-

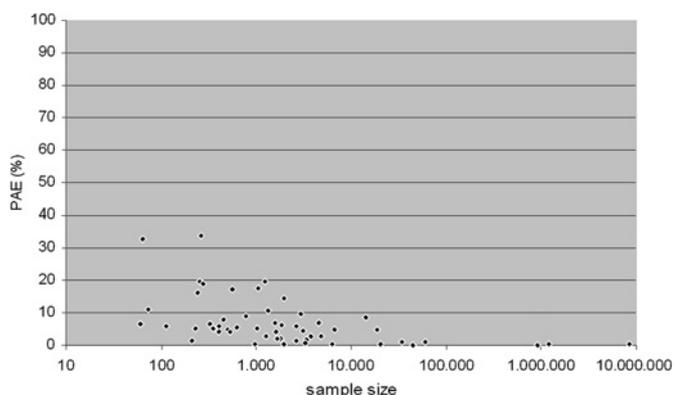


Figure 3 Preventable adverse event estimates in correlation to sample size (n=55 studies), sample size displayed with half logarithmic-scale.

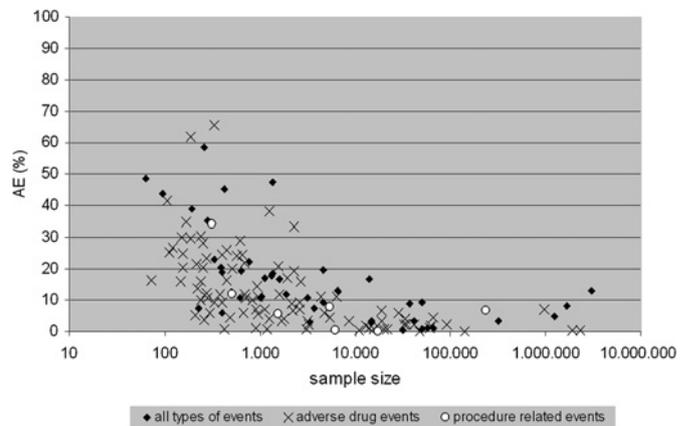


Figure 4 Adverse event estimates by event type (n=144 studies).

tions of ICD codes are used in large trials involving up to millions of patients.^{43–51} Six of nine surveys with more than 100 000 patients are based on ICD codes, and the frequencies of AE in these studies range from 0.1% to 8.3%. All studies with results exceeding 30% and one single method to detect AE rely on prospective or retrospective chart review. Also, 8/9 surveys with combined methods use prospective chart review, mainly in combination with interviews (3/8). The distribution is less clear for PAE.

Characteristics of study populations

Information on the effect of patient characteristics was inconsistent. The distribution of gender is displayed in 46/156 surveys; 58/156 studies give the mean ages. Only 54/156 studies report health status, referring mainly to the Charlson Index (11/54).⁵² Eighty-one of 156 surveys report on patient deaths. None of these data suffice to give information about possible dependence of variation on study population characteristics.

DISCUSSION

In our systematic review, we included 156 studies on the frequency of AE and PAE. Studies were of great heterogeneity, and estimates varied widely from 0.1% to 65.4% for AE, and from 0.1% to 33.9% for PAE. Previous reviews found less variation. Von Laue *et al* compiled estimates for AE ranging between 2.9% and 16.6%, Aranaz *et al* from 3.7% to 16.6%, and de Vries *et al* from 4.6% to 12.4%. Discrepancies are largely because search strategies were more contracted, and the number of studies included was smaller.

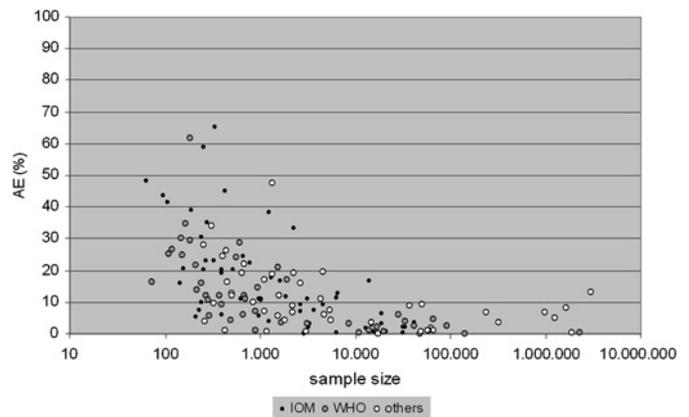


Figure 5 Adverse event estimates by AE terminology (n=144 studies).

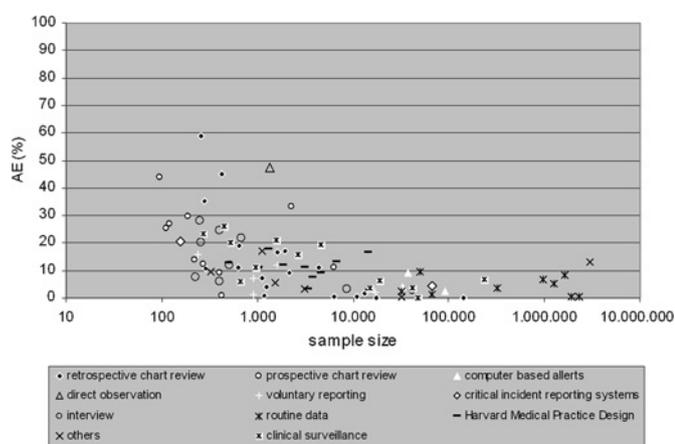


Figure 6 Adverse event estimates by types of data collection methods, only single methods are displayed (n=88 studies).

Our aim was to display the overall body of published evidence in order to shed light on the diversity of studies and results. To consider study size as an approximation for strength of evidence, we plotted outcomes against the size of the study population and observed that variation decreased with the number of patients included. As one would expect results to spread in small studies as a simple rule of statistics, we interpret the distribution of results as an indirect indicator for validity. This pattern was much clearer for AE than for PAE, due primarily we believe to the smaller number of studies on PAE. This consequence of missing data has been described in the context of meta-analyses.⁵⁵

We found no other factors to explain this pattern of variation. Neither different settings nor event types had any effect, that is, we found no differences between frequencies reported by surveys on the total of events and surveys examining medication-related or procedure-related AE only. The same is true for terminology; diverse definitions of AE make no difference to frequencies. One reason might be indifference to precise definition of terms. For example, few papers using the WHO terminology differentiate between adverse drug reactions and adverse drug events, terms sometimes used to distinguish between preventable and non-preventable patient injuries. These findings suggest that research methods should be refined, and results may not always display the true dimension of AE and PAE.

Very large surveys show a clear tendency for results to be less than 1%. This could be due to the relation between sample size and assessment methods. Whereas large surveys with more than 100 000 patients are almost exclusively restricted to ICD-coded events, many small trials prefer chart review, or combinations with chart review. ICD coding is able to display only a fraction of events, which might explain the comparatively low estimates.^{54–56} Conversely, this does not follow for small studies with chart review. The assumption that high frequencies may correlate with small studies because they look at cases more carefully is opposed by the observation that results are not restricted to remarkably high results but show a distribution which is primarily due to statistical dispersion, and only additionally fortified by the choice of methods to collect data.

Another observation is that papers with above-average results indicate that the majority involved high-risk patients and very old or very young patients. Eight of 16 publications with results on AE above 30% dealt with elderly patients,^{57–64} and two observed children.^{65–66} Unfortunately, data were not sufficient for further analysis.

We conclude that the precision of AE and PAE estimates depends primarily on sample size and to some degree on methods to collect data. This second observation remains difficult for interpretation. In our judgement as a consequence the informative value of very small surveys should be considered with scepticism, as well as that of very large ones. Since 54.9% of studies on AE (84/153) and 60.3% of studies on PAE (35/58) deal with study populations either smaller than 1000 patients or larger than 50 000 patients the generalisability of these papers must be reassessed.

We believe the present review to be the largest systematic review of the incidence of AE and PAE.^{18–24} Only one previous review detected a correlation between incidence and sample size but did not give any explanation.²⁴ Others suggested explanations but did not verify these.^{20–22–24}

The present review has limitations. It is part of a wider research effort and is limited to surveys of the percentages of AE/PAE. Consequently, estimates of errors or near misses were not considered. Another limiting factor is that PAE has not yet been investigated to the same extent as AE. Also, we searched only the Medline and Embase databases. Due to our broad research strategy, results exhibit a high heterogeneity, so there was no indication to summarise results in a meta-analysis.

Our findings affirm that AE and PAE are serious problems across all healthcare settings and medical procedures, but some questions remain about the consistency of methods of collecting and reporting data. Further research should concentrate on advancing methods especially for small settings and specific types of event.

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Appendix 1

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Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Ahmed 1997	SAU	Leading to admission	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Clinical surveillance 	964	11.0	
Andrews 1997	USA	Inpatients	<ul style="list-style-type: none"> • Surgery • ICU 	<ul style="list-style-type: none"> • Direct observation 	1,047		17.7
Azad 2002	CAN	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Prospective chart review 	111	25.2	
Azaz-Livshits 1998	ISR	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Retrospective chart review 	153	24.8	
Baena Parejo 2005	ESP	Outpatients	<ul style="list-style-type: none"> • Emergency department 	<ul style="list-style-type: none"> • Prospective chart review 	2,261	33.2	
Baker 2004	CAN	inpatients		<ul style="list-style-type: none"> • Havard Medical Design 	3745	7.5	2.8
Bates 1995	USA	inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Havard Medical Design 	3137	10.9	4.6
Bellomo 2002	AUS	inpatients	<ul style="list-style-type: none"> • Surgery 	<ul style="list-style-type: none"> • Others 	1,125	16.9	
Bhalla 2003	UK	Outpatients	<ul style="list-style-type: none"> • InternalMedicine • Geriatrics 	<ul style="list-style-type: none"> • Prospective chart review • Interview 	840	10.1	
Bond 2001	USA	Inpatients	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Interview 	8,493,876		0.2

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Bordet 2001	FRA	Inpatients	<ul style="list-style-type: none"> • Cardiology 	<ul style="list-style-type: none"> • Voluntary reporting 	16,916	2.0	
Buajordet 1995	NOR	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Voluntary reporting • Others 	3,082	0.7	
Calland 2002	USA	inpatients		<ul style="list-style-type: none"> • Retrospective chart 	6,296	0.37	0.2
Carroll 2003	AUS	Inpatients	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Routine data 	50,712	9.3	
Carvalho-Filho 1998	BRA	Inpatients	<ul style="list-style-type: none"> • Geriatrics 	<ul style="list-style-type: none"> • Retrospective chart review 	96	43.7	
Chan 2001	AUS	Leading to admission	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Prospective chart review • Interview 	240	30.4	16.3
Chaudhry 2003	USA	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Voluntary reporting • Direct Observation • Interview 	528		4.2
Chrischilles 2007	USA	Others		<ul style="list-style-type: none"> • Interview 	689	21.9	

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Chyka 2000	USA	Cases of death	<ul style="list-style-type: none"> All wards 	<ul style="list-style-type: none"> Routine data 	2,312,203	0.3	
Classen 1997	USA	Inpatients	<ul style="list-style-type: none"> All wards 	<ul style="list-style-type: none"> Computer based alert 	91,574	2.4	
Cohen 2005	USA	Inpatients	<ul style="list-style-type: none"> All wards 	<ul style="list-style-type: none"> Prospective chart review 	120	26.7	
Conen 2006	CHE	Inpatients	<ul style="list-style-type: none"> All wards 	<ul style="list-style-type: none"> Retrospective chart review 	639	19.1	
Cooper 1996	USA	Nursing home		<ul style="list-style-type: none"> Prospective chart review Clinical surveillance 	332	65.4	
Corral Baena 2004	ESP	Outpatients and Inpatients		<ul style="list-style-type: none"> Routine data 	32,253	2.2	
Darchy 1999	FRAU	Inpatients	<ul style="list-style-type: none"> ICU 	<ul style="list-style-type: none"> Retrospective chart review 	623	10.9	5.6
Dartnell 1996	AUS	Leading to admission	<ul style="list-style-type: none"> Emergency department 	<ul style="list-style-type: none"> Prospective chart review Interview Voluntary reporting 	965	5.7	0.3

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Davis 2001	NZL	Inpatients	<ul style="list-style-type: none"> All wards 	<ul style="list-style-type: none"> Havard Medical Design 	1,326	17.7	10.7
Davis 2002 Davis 2003	NZL	Inpatients	<ul style="list-style-type: none"> All wards 	<ul style="list-style-type: none"> Havard Medical Design 	6,579	12.9	4.8
Dennehy 1996	USA	Leading to admission	<ul style="list-style-type: none"> Emergency department 	<ul style="list-style-type: none"> Retrospective chart review 	1,260	3.9	2.6
Dormann 2000	DEU	Inpatients	<ul style="list-style-type: none"> InternalMedicine 	<ul style="list-style-type: none"> Computer based alert Voluntary reporting 	379	11.9	
Dormann 2003	DEU	Leading to admission	<ul style="list-style-type: none"> InternalMedicine 	<ul style="list-style-type: none"> Prospective chart review Computer based alert Clinical surveillance 	711	10.9	
dos Santos 2006	BRA	Inpatients	<ul style="list-style-type: none"> Paediatrics 	<ul style="list-style-type: none"> Prospective chart review 	272	12.1	
Doucet 2002	FRAU	Leading to admission	<ul style="list-style-type: none"> Geriatrics 	<ul style="list-style-type: none"> Clinical surveillance 	2,691	15.9	
Dunn 2006	AUS	Inpatients	<ul style="list-style-type: none"> Paediatrics 	<ul style="list-style-type: none"> Retrospective chart review 	1,612	16.6	

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Easton 1998	AUS	Leading to admission	<ul style="list-style-type: none"> • Paediatrics 	<ul style="list-style-type: none"> • Prospective chart review • Interview 	1,682	3.4	1.9
Easton-Carter 2003	AUS	Emergency visits	<ul style="list-style-type: none"> • Paediatric Emergency department 	<ul style="list-style-type: none"> • Interview 	8601	3.3	
Ebbesen 2001	NOR	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Clinical surveillance • Others 	13,992	0.95	
Ehsani 2006	AUS	Inpatients	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Routine data 	979,834	6.9	
Elder 2004	USA	Outpatients		<ul style="list-style-type: none"> • Interview 	351		5.1
Emmerson 1996	UK + IRL	Inpatients	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Computer based alert 	37,111	9.0	
Fattinger 2000	CHE	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Retrospective chart review 	4,331	11.0	
Fauchais 2006	FRAU	Leading to admission	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Prospective chart review 	186	29.6	
Feldman 1997	CAN	Inpatients	<ul style="list-style-type: none"> • Surgery 	<ul style="list-style-type: none"> • Prospective chart review • Others 	311	34.1	

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Fordyce 2003	USA	Emergency visits	<ul style="list-style-type: none"> Emergency department 	<ul style="list-style-type: none"> Voluntary reporting Interview 	1,935		0.4
Forster 2003	USA	Inpatients	<ul style="list-style-type: none"> InternalMedicine 	<ul style="list-style-type: none"> Retrospective chart review Interview 	400	19.0	5.8
Forster 2004 a	CAN	Inpatients	<ul style="list-style-type: none"> InternalMedicine 	<ul style="list-style-type: none"> Retrospective chart review Interview 	328	23.0	6.4
Forster 2004 b	CAN	Leading to admission	<ul style="list-style-type: none"> Acute care facility 	<ul style="list-style-type: none"> Havard Medical Design 	502	12.7	4.8
Forster 2007	CAN	Emergency visits	<ul style="list-style-type: none"> Emergency department 	<ul style="list-style-type: none"> Direct Observation 	399	6.0	4.3
Fradet 1996	FRA	Leading to admission	<ul style="list-style-type: none"> InternalMedicine Gastroenterology 	<ul style="list-style-type: none"> Retrospective chart review 	1,129	7.1	
Gandhi 2000	USA	Outpatients	<ul style="list-style-type: none"> InternalMedicine 	<ul style="list-style-type: none"> Retrospective chart review Interview 	2,248	19.2	
Gandhi 2003	USA	Outpatients	<ul style="list-style-type: none"> InternalMedicine 	<ul style="list-style-type: none"> Retrospective chart review Interview 	661	24.5	3.0
Ganjavi 2007	CAN	Others		<ul style="list-style-type: none"> Voluntary reporting Critical incident reporting Interview 	242	9.9	
Gill 1995	UK	Inpatients	<ul style="list-style-type: none"> Paediatric ICU 	<ul style="list-style-type: none"> Voluntary reporting 	899	7.0	

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Gill 1995	UK	Leading to admission	<ul style="list-style-type: none"> • Paediatric ICU 	<ul style="list-style-type: none"> • Voluntary reporting 	909	1.1	
González-Martin 1998	CHL	Inpatients	<ul style="list-style-type: none"> • Paediatrics 	<ul style="list-style-type: none"> • Prospective chart review 	219	13.7	
Gray 1998	USA	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Prospective chart review • Interview • Clinical surveillance 	145	15.9	
Gray 1999	USA	Inpatients		<ul style="list-style-type: none"> • Interview 	256	20.3	
Grohskopf 2002	USA + CAN	Inpatients	<ul style="list-style-type: none"> • Paediatric ICU 	<ul style="list-style-type: none"> • Interview 	512	11.9	
Gruen 2006	USA	Inpatients	<ul style="list-style-type: none"> • Trauma surgery 	<ul style="list-style-type: none"> • Retrospective chart review • Interview • Others 	44,401		0.1
Gurwitz 2000	USA	Nursing home		<ul style="list-style-type: none"> • Prospective chart review • Voluntary reporting • Interview 	2,916		9.5
Gurwitz 2005	USA+ CAN	Nursing home		<ul style="list-style-type: none"> • Prospective chart review • Computer based alert • Critical incident reporting 	1,247	38.2	19.8

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Hafner 2002	USA	Leading to admission	<ul style="list-style-type: none"> Emergency department 	<ul style="list-style-type: none"> Retrospective chart review 	13,004	1.7	
Hanlon 1997	USA	Outpatients	<ul style="list-style-type: none"> InternalMedicine 	<ul style="list-style-type: none"> Prospective chart review Interview 	167	34.7	
Hardmeier 2004	CHE	Leading to admission	<ul style="list-style-type: none"> InternalMedicine 	<ul style="list-style-type: none"> Prospective chart review 	6,383	11.2	0.4
Hayward 2001	USA	Cases of death		<ul style="list-style-type: none"> Retrospective chart review 	111		6.0
Healy 2002	USA	Inpatients	<ul style="list-style-type: none"> Surgery 	<ul style="list-style-type: none"> Clinical surveillance 	4,658	19.5	
Hendrie 2007	AUS	Emergency visits	<ul style="list-style-type: none"> Emergency department 	<ul style="list-style-type: none"> Havard Medical Design 	3,332	3.1	1.7
Herrera-Kiengelher 2005	MEX	Inpatients	<ul style="list-style-type: none"> Pneumology 	<ul style="list-style-type: none"> Havard Medical Design 	4555	9.1	6.8
Hohl 2001	CAN	Leading to admission	<ul style="list-style-type: none"> Emergency department 	<ul style="list-style-type: none"> Retrospective chart review 	283	10.6	
Honigman 2001	USA	Outpatients		<ul style="list-style-type: none"> Retrospective chart review Computer based alert 	15,665	0.6	
Ibarmia 2003	ESP	Leading to admission	<ul style="list-style-type: none"> InternalMedicine 	<ul style="list-style-type: none"> Clinical surveillance 	272	23.2	

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Jackson 2006	AUS	Inpatients	<ul style="list-style-type: none"> All wards 	<ul style="list-style-type: none"> Routine data 	1,645,992	8.3	
Jha 2001	USA	Leading to admission	<ul style="list-style-type: none"> All wards 	<ul style="list-style-type: none"> Computer based alert Prospective chart review 	3,238	2.3	0.6
Johnston 2006	USA	Inpatients	<ul style="list-style-type: none"> All wards 	<ul style="list-style-type: none"> Critical Incident reporting Others 	60,206	1.1	0.9
Jonville-Bera 2002	FRA	Leading to admission	<ul style="list-style-type: none"> Paediatric emergency department 	<ul style="list-style-type: none"> Prospective chart review 	428	0.9	
Jonville-Bera 2002	FRA	Leading to admission	<ul style="list-style-type: none"> Paediatrics 	<ul style="list-style-type: none"> Prospective chart review Clinical surveillance Interview 	260	3.8	
Jonville-Bera 2002	FRA	Outpatients	<ul style="list-style-type: none"> Paediatrics 	<ul style="list-style-type: none"> Retrospective chart review 	1,192	0.7	
Juntti-Patinen 2002	FIN	Inpatients	<ul style="list-style-type: none"> All wards 	<ul style="list-style-type: none"> Retrospective chart review 	141,484	0.1	
Kane Gill 2006	USA	Inpatients	<ul style="list-style-type: none"> ICU 	<ul style="list-style-type: none"> Routine data Others 	21,436	0.8	
Kanter 2004	USA	Inpatients		<ul style="list-style-type: none"> Routine data 	66,146	1.2	

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Kessomboon 2005	THA	Others		<ul style="list-style-type: none"> Retrospective chart review 	279	35.1	18.9
Kilbridge 2006	USA	Inpatients		<ul style="list-style-type: none"> Computer based alert 	33,206	3.9	
Lagnaoui 2000	FRA	Inpatients	<ul style="list-style-type: none"> InternalMedicine 	<ul style="list-style-type: none"> Clinical surveillance 	444	26.1	
Larsen 2007	USA	inpatients	<ul style="list-style-type: none"> Paediatric ICU 	<ul style="list-style-type: none"> Retrospective chart review 	259	58.7	33.9
Lecointre 2003	FRA	inpatients	<ul style="list-style-type: none"> Pneumology 	<ul style="list-style-type: none"> Voluntary reporting 	1,598	11.9	4.3
Lu 2006	TWN	Emergency visits	<ul style="list-style-type: none"> Emergency department 	<ul style="list-style-type: none"> Retrospective chart review 	45,100		0.1
Madigan 2007	USA	Outpatients	<ul style="list-style-type: none"> Home care 	<ul style="list-style-type: none"> Others 	3,013,287	13.1	
Major 1998	LBN	Leading to admission	<ul style="list-style-type: none"> Paediatrics InternalMedicine 	<ul style="list-style-type: none"> Prospective chart review Interview 	2,202	6.7	
Malhotra 2001	IND	Emergency visits	<ul style="list-style-type: none"> Emergency department 	<ul style="list-style-type: none"> Prospective chart review Interview Clinical surveillance 	4,764	5.9	2.6
Mannesse 1997	NLD	Leading to admission	<ul style="list-style-type: none"> InternalMedicine 	<ul style="list-style-type: none"> Interview Clinical surveillance 	106	41.5	

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Mannheimer 2006	SWE	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Prospective chart review • Interview 	150	30.0	
Martin 2002	ESP	Leading to admission	<ul style="list-style-type: none"> • ICU 	<ul style="list-style-type: none"> • Prospective chart review • Interview 	1,800	4.2	2.1
Martínez-Mir 1996	ESP	Inpatients	<ul style="list-style-type: none"> • Paediatrics 	<ul style="list-style-type: none"> • Prospective chart review • Interview 	490	4.3	
Matsaseng 2005	ZAF	Inpatients	<ul style="list-style-type: none"> • Gynaecology 	<ul style="list-style-type: none"> • Havard Medical Design 	1,866	11.8	6.2
McDonnell 2002	USA	Leading to admission	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Critical incident reporting • Routine data 	20,166	0.7	0.5
Melton 2005	USA	Inpatients	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Retrospective chart review • Computer based alert 	57,452	1.1	
Meurer 2006	USA	Inpatients	<ul style="list-style-type: none"> • Paediatrics 	<ul style="list-style-type: none"> • Routine data 	318,785	3.4	
Mezei 1999	CAN	Leading to admission	<ul style="list-style-type: none"> • Surgery 	<ul style="list-style-type: none"> • Retrospective chart review • Routine data 	17,638	0.1	
Michel 2004	FRA	Inpatients	<ul style="list-style-type: none"> • InternalMedicine • Surgery • Obstetrics 	<ul style="list-style-type: none"> • Havard Medical Design • Routine data • Others 	778	22.4	9.1

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Mjörndal 2002	SWE	Leading to admission	<ul style="list-style-type: none"> • InternalMedicine • Cardiology • ICU 	<ul style="list-style-type: none"> • Prospective chart review • Interview 	681	12.0	
Moore 1998	FRA	Inpatients	<ul style="list-style-type: none"> • Internalmedicine 	<ul style="list-style-type: none"> • Others 	329	9.4	
Morris 2003	USA	Inpatients	<ul style="list-style-type: none"> • Surgery 	<ul style="list-style-type: none"> • Others 	32,100	0.4	
Murff 2003	USA	Inpatients	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Retrospective chart review 	424	45.0	
Nelson 1996	USA	Leading to admission	<ul style="list-style-type: none"> • InternalMedicine • ICU 	<ul style="list-style-type: none"> • Prospective chart review • Others 	450	16.2	8.0
O'Hara 1997	AUS	Inpatients	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Routine data 	1,248,021	5.0	
Olivier 2001	FRA	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Clinical surveillance 	671	6.1	
Onder 2002	ITA	Leading to admission	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Prospective chart review • Interview • Clinical surveillance 	28,411	6.0	
Otero López 1999	ESP	Leading to admission	<ul style="list-style-type: none"> • Emergency department 	<ul style="list-style-type: none"> • Prospective chart review • Voluntary reporting 	33,975	2.3	1.0
Otero López 2006 a	ESP	Inpatients	<ul style="list-style-type: none"> • InternalMedicine • Gastroenterology 	<ul style="list-style-type: none"> • Prospective chart review • Voluntary reporting 	2,643	7.2	1.4

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
				<ul style="list-style-type: none"> • Routine data 			
Otero López 2006 b	ESP	Inpatients	<ul style="list-style-type: none"> • InternalMedicine • Gastroenterology 	<ul style="list-style-type: none"> • Prospective chart review • Interview • Routine data 	2,643	9.3	5.9
Ouchterlony 1995	SWE	Inpatients	<ul style="list-style-type: none"> • Surgery • Orthopaedics • Anaesthesiology 	<ul style="list-style-type: none"> • Clinical surveillance • Voluntary reporting 	1,361	18.7	
Ouchterlony 1995	SWE	Inpatients	<ul style="list-style-type: none"> • Surgery • Orthopaedics • Anaesthesiology 	<ul style="list-style-type: none"> • Direct Observation 	1,361	47.4	
Passarelli 2005	BRA	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Prospective chart review • Interview 	186	61.8	
Peyriere 2003	FRA	Leading to admission	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Critical incident reporting 	156	20.5	14.1
Philipps 1998	USA	Cases of death	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Routine data 	910,138		0.1
Philipps 1998	USA	Cases of death	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Routine data 	1,212,111		0.3
Piquet 1999	FRA	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Voluntary reporting 	240	16.0	
Pirmohamed 2004	UK	Leading to admission	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Clinical surveillance 	18,820	6.5	4.7

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Popli 1997	USA	Inpatients	<ul style="list-style-type: none"> • Psychiatrics 	<ul style="list-style-type: none"> • Retrospective chart review 	10,994	0.3	
Pouyanne 2000	FRA	Leading to admission	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Others 	3,137	3.2	
Proctor 2003	CAN	Inpatients	<ul style="list-style-type: none"> • Surgery • Paediatrics • ICU 	<ul style="list-style-type: none"> • Retrospective chart review • Prospective chart review • Clinical surveillance 	64	48.4	32.8
Queneau 2003	FRA	Emergency visits	<ul style="list-style-type: none"> • Emergency department 	<ul style="list-style-type: none"> • Retrospective chart review 	1,937	16.9	14.5
Queneau 2007	FRA	Leading to admission	<ul style="list-style-type: none"> • Emergency department 	<ul style="list-style-type: none"> • Clinical surveillance 	1,562	20.8	6.8
Raschetti 1999	ITA	Leading to admission	<ul style="list-style-type: none"> • Emergency department 	<ul style="list-style-type: none"> • Prospective chart review • Clinical surveillance 	5,497	4.3	
Rask 2005	USA	Others		<ul style="list-style-type: none"> • Interview 	406	24.4	
Reich 2005	DEU	Outpatients	<ul style="list-style-type: none"> • Dentistry 	<ul style="list-style-type: none"> • Others 	1,540	5.6	

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Rotschild 2005	USA	Inpatients	<ul style="list-style-type: none"> • ICU • Cardiology 	<ul style="list-style-type: none"> • Computer based alert • Direct observation • Voluntary reporting 	391	20.2	
Rozenfeld 2007	BRA	Inpatients	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Routine data 	1,898,676	0.2	
Rüden 1996	DEU	Inpatients	<ul style="list-style-type: none"> • Gynaecology • All wards 	<ul style="list-style-type: none"> • Clinical surveillance 	14,966	3.5	
Samoy 2006	CAN	Leading to admission	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Prospective chart review • Interview 	565	24.1	17.3
Sanborn 1996	USA	Inpatients	<ul style="list-style-type: none"> • Anaesthesiology 	<ul style="list-style-type: none"> • Prospective chart review • Computer based alert 	5,454	7.6	
Schioler 2001	DNK	Inpatients	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Havard Medical Design 	1,033	11.0	
Schlienger 1999	CHE	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Prospective chart review • Interview 	941	14.6	
Schneeweiss 2002	DEU	Leading to admission	<ul style="list-style-type: none"> • InternalMedicine • Emergency department 	<ul style="list-style-type: none"> • Prospective chart review 	41,375	2.4	
Schneitman-McIntire 1996	USA	Leading to admission	<ul style="list-style-type: none"> • Emergency department 	<ul style="list-style-type: none"> • Retrospective chart review • Interview 	62,216	1.7	

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Schnipper 2006	USA	Inpatients	<ul style="list-style-type: none"> • InternalMedicine • General medicine 	<ul style="list-style-type: none"> • Prospective chart review • Interview 	73	16.4	11.0
Smith 2006	USA	Inpatients	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Critical incident reporting 	66,331	4.5	
Stäubli 2001	CHE	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Clinical surveillance 	41,994	3.5	
Tafreshi 1999	USA	Leading to admission	<ul style="list-style-type: none"> • Emergency department 	<ul style="list-style-type: none"> • Interview 	253	28.1	19.8
Tegeder 1999	DEU	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Retrospective chart review • Computer based alert 	294	5.8	
The French Prevalence Survey Study Group 2000	FRA	Inpatients	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Clinical surveillance 	236,334	6.7	
Thomas 2000	USA	Inpatients	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Havard Medical Design 	14,700	2.9	
Tipping 2006	ZAF	Emergency visits	<ul style="list-style-type: none"> • Emergency department 	<ul style="list-style-type: none"> • Clinical surveillance 	517	20.1	

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
Trifiro 2005	ITA	Leading to admission	<ul style="list-style-type: none"> • Emergency department 	<ul style="list-style-type: none"> • Prospective chart review • Interview • Clinical surveillance 	18,854	3.3	
van den Bemt 1999	NLD	Inpatients	<ul style="list-style-type: none"> • Paediatrics • Internalmedicine 	<ul style="list-style-type: none"> • Voluntary reporting • Interview 	620	28.9	
Vargas 2003	ESP	Inpatients	<ul style="list-style-type: none"> • Surgery • ICU 	<ul style="list-style-type: none"> • Prospective chart review 	401	9.2	
Veehof 1999	NLD	Ambulant	<ul style="list-style-type: none"> • General medicine 	<ul style="list-style-type: none"> • Retrospective chart review 	2,185	8.9	
Vincent 2001	UK	Inpatients	<ul style="list-style-type: none"> • InternalMedicine • obstetrics • Surgery 	<ul style="list-style-type: none"> • Havard Medical Design 	1,014	10.8	5.1
Vira 2006	CAN	Inpatients	<ul style="list-style-type: none"> • All wards 	<ul style="list-style-type: none"> • Others 	60		6.7
Wanzel 2000	CAN	Inpatients	<ul style="list-style-type: none"> • Surgery 	<ul style="list-style-type: none"> • Prospective chart review • Direct Observation • Interview 	192	39.0	
Weingart 2004	USA	Inpatients	<ul style="list-style-type: none"> • InternalMedicine 	<ul style="list-style-type: none"> • Prospective chart review • Critical incident 	209	5.3	1.4

Study	Country	Population	Setting	Study Design	Sample (n)	Patients with AE (%)	Patients with PAE (%)
				reporting • Interview			
Weingart 2005	USA	Inpatients	• InternalMedicine	• Interview	228	7.5	5.3
Weiss 2002	DEU	Inpatients	• Paediatrics	• Prospective chart review • Voluntary reporting	214	21.5	
Wilson 1995	AUS	Inpatients	• All wards	• Havard Medical Design	14,179	16.6	8.5
Wolff 2001	AUS	Inpatients	• All wards	• Havard Medical Design • Critical incident reporting	49,834	0.8	
Zoppi 2000	CHE	Inpatients	• InternalMedicine	• Clinical surveillance	48,005	0.1	

Appendix 3- Definitions of AE

1. AE, definition of IOM and paraphrases (n=55)

“An adverse event is an injury resulting from a medical intervention, or in other words, it is not due to the underlying disease”

Author, year: Ahmed, 1997

Term used by author: adverse drug reaction

Definition: “An A(dverse) D(rug) R(eaction) was defined as any clinical event that was found to have a clear cause and effect relationship with a drug or a chemical substance and which was the only or the main cause of admission to the hospital, or the main cause of the appearance of a new event in a hospitalized patient. This included drug overuse, hypersensitivity, idiosyncrasy, dose-related side-effects and adverse drug interactions.”

Author, year: Baena Parejo, 2005

Meeting our definition criteria as: adverse event

Term used by author: problemas de salud relacionados con medicamentos (PRM)

Definition: los problemas de salud relacionados con medicamentos (PRM) son problemas de salud, entendidos como resultados clinicos negativos derivados de la farmacoterapia que, producidos por diversas causas, conducen a la no consecución del objetivo terapéutico e a la aparición de efectos no deseados.

Author, year: Baker, 2004

Term used by author: adverse event

Definition: “unintended injury or complication that results in disability at the time at discharge, death or prolonged hospital stay and that is caused by health care management rather than by the patient's underlying disease process”

Author, year: Bates, 1995 b

Term used by author: adverse event

Definition: “unintended injuries caused by medical management resulting in prolongation of hospitalization or disability at the time of discharge or death”

Author, year: Calland, 2002

Term used by author: adverse event

Definition: “...AE, defined...as unintended injury (death in this case) caused by medical treatment, and thus not primarily attributable to the patient`s primary disease process”

Author, year: Carvalho-Filho, 1998

Term used by author: complicações iatrogênicas

Definition: “Foram consideradas iatrogênicas as alteracoes que resultaram, diretamente, de procedimentos diagnósticos e de todas as formas de terapêutica”

Author, year: Chan, 2001

Term used by author: adverse drug event

Definition: We defined one ADE as occurring if one drug caused one or more adverse manifestations or if two or more drugs contributed to one adverse manifestation

Author, year: Cooper, 1996

Term used by author: adverse drug reaction

Definition: An adverse drug reaction sequence was defined as any undesired or unintended response to medications that required treatment alteration of therapy

Author, year: Corral Baena, 2004

Term used by author: acontecimientos adversos por medicamentos

Definition: Los acontecimientos adversos por medicamentos (AAM) se definen como cualquier dano grave o leve, causado por el uso (incluyendo la falta de uso) de un medicamento o cualquier dano resultante del uso clínico de un medicamento

Author, year: Darchy, 1999

Term used by author: adverse event

Definition: Iatrogenic disease was defined as a disease induced by a drug prescribed by a physician; or after a medical or surgical procedure, excluding intentional overdose, nonmedical intervention; or unauthorized prescription, and environmental events. AE was defined as an unintended and noxious event caused by medical management carried out according to the best of medical science

Author, year: Dartnell, 1996

Term used by author: drug related admission

Definition: An admission was considered to be drug-related if its suspected cause was some aspect of drug therapy, and not likely to be a result of disease progression.

Author, year: Davis, 2001

Term used by author: adverse event

Definition: AE was defined as (a) an unintended injury or unintended complication (b) resulting in temporary or permanent disability, including increased length of stay and/or financial loss the patient, (c) that was caused by health care management rather than the underlying disease process

Author, year: Davis, 2002 + 2003a

Term used by author: adverse event

Definition: an unintended injury resulting in disability caused by healthcare management rather than the underlying disease process

Author, year: Dennehy, 1996

Term used by author: drug related illness (DRI) / Adverse drug reaction (ADR)

Definition: ADRs included any DRI that was noxious and unintended or that occurred as a result of a medical intervention related to a drug.

Author, year: Dunn, 2006

Term used by author: adverse event

Definition: an unintended injury or complication which results in disability, death, or prolonged hospital stay and is caused by healthcare management rather than disease process

Author, year: Forster, 2003

Term used by author: adverse event

Definition: injury resulting from medical management rather than the underlying disease

Author, year: Forster, 2004a

Term used by author: adverse event

Definition: If both reviewers judged that the adverse outcome was probably or definitely due to medical management (...) it was classified as an AE

Author, year: Forster, 2007

Meeting our definition criteria as: adverse event

Term used by author: adverse outcomes

Definition: Adverse outcomes were classified as adverse events if both physicians stated: the patient had an adverse outcome and one of the potential causes was rated at least a 4 (“outcome more than likely attributable to cause”)

Author, year: Gandhi, 2003

Term used by author: adverse drug events

Definition: adverse drug-related events, defined as injuries due to drugs

Author, year: Ganjavi, 2007

Term used by author: adverse drug event

Definition: Adverse drug events (ref. 29: according Bates 1995b)

Author, year: Gray, 1998

Term used by author: adverse drug event

Definition: The term ADE (...) includes any injury from medication use.

Author, year: Gurwitz, 2000

Term used by author: adverse drug event

Definition: Adverse drug event, defined as an injury resulting from the use of a drug. Adverse drug events may have resulted from medication errors or from adverse drug reactions in which was no error

Author, year: Gurwitz, 2005

Term used by author: adverse drug event

Definition: Adverse drug event, defined as an injury resulting from the use of a drug. Adverse drug events may have resulted from medication errors or from adverse drug reactions in which was no error.

Author, year: Hafner, 2002

Term used by author: adverse drug event

Definition: An ADE is an injury (noxious or harmful effect) resulting from medical intervention related to a drug. (...)ADE encompass all drug-related injuries that result from medication errors, drug-drug interactions, or ADRs.

Author, year: Hardmeier, 2004

Meeting our definition criteria as: adverse event

Term used by author: adverse drug event

Definition: Adverse drug events, usually defined as harm caused by the appropriate or inappropriate use of a drug.

Author, year: Hendrie, 2007

Term used by author: adverse event

Definition: an unintended injury or complication, which resulted in disability, death, prolongation of the hospital stay, or prolongation of the natural history of disease; and is caused by health care management rather than the patient’s disease.

Author, year: Herrera-Kienglher, 2005

Term used by author: adverse event

Definition: AE was defined as the unintentional harm induced by medical or clinical care and not by primary disease that may result in prolonged hospitalization, some form of temporary or permanent disability, and/or death.

Author, year: Honigman, 2001

Term used by author: adverse drug event

Definition: adverse drug event, defined as an injury resulting from an intervention related to a drug

Author, year: Ibarria, 2003

Term used by author: adverse drug event

Definition: El adverse drug event se definió como cualquier dano, grave o leve, causado por el uso de un medicamento.

Author, year: Jha, 2001

Term used by author: adverse drug event

Definition: An injury resulting from medical intervention related to a drug

Author, year: Kane Gill, 2006

Term used by author: adverse drug event

Definition: an ADE was defined as an injury resulting from drug treatment

Author, year: Kessomboon, 2005

Term used by author: adverse event

Definition: An adverse event was defined as an unintended injury caused by medical management rather than by the disease process, this injury is sufficiently serious to lead to prolongation of hospitalisation or a temporary or permanent impairment or disability or death to the patient at time of discharge

Author, year: Larsen, 2007

Term used by author: adverse event

Definition: Definitions of adverse event category and preventability for each harm event from Wu et al. (an undesirable and unintended injury resulting from a medical intervention (an act of care provided by the hospital or by the omission of necessary care), rather than from patient's underlying disease process; and where such injury occurs during an inpatient hospital stay (i.e., subsequent to admission) and results in or leads to patient harm.)

Author, year: Mannesse, 1997

Term used by author: adverse drug reaction

Definition: An ADR was defined as an undesirable clinical manifestation consequent to and caused by the administration of a particular drug or interacting drugs, excluding intentional overdose, substance abuse and therapeutic failure.

Author, year: Matsaseng, 2005

Term used by author: adverse event

Definition: An adverse event was defined as an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalisation, produced a disability at a time of discharge or both

Author, year: Michel, 2004

Term used by author: adverse event

Definition: An adverse event was defined as an unintended injury caused by medical management rather than by a disease process and which resulted in death, life threatening illness, disability at time of discharge, admission to hospital, or prolongation of hospital stay

Author, year: Morris, 2003

Term used by author: adverse event

Definition: Adverse Event: Injury to a patient that may have been the result of medical or surgical intervention that prolonged hospitalization, produce a disability, death or both.

Author, year: Murff, 2003

Term used by author: adverse event

Definition: adverse events, defined as an injury resulting from medical management rather than the patient's underlying condition

Author, year: Otero Lopez, 1999

Term used by author: acontecimientos adversos por medicamentos

Definition: Acontecimientos adversos por medicamentos (AAM), definido como cualquier efecto indeseable asociado con el uso clínico de los medicamentos

Author, year: Otero Lopez, 2006a

Term used by author: acontecimientos adversos por medicamentos

Definition: acontecimientos adversos por medicamentos (AAM) cualquier dano, grave o leve, asociado al uso clínico (o falta de uso) de un medicamento

Author, year: Otero Lopez, 2006b

Term used by author: acontecimientos adversos por medicamentos

Definition: acontecimientos adversos por medicamentos (AAM) cualquier dano, grave o leve, asociado al uso clínico (o falta de uso) de un medicamento

Author, year: Peyriere, 2003

Term used by author: adverse drug event

Definition: Adverse drug event (ref.8: according Bates 1995)

Author, year: Pirmohamed, 2004

Meeting our definition criteria as: adverse event

Term used by author: adverse drug reaction

Definition: Definition of ADR used was after Edwards and Aronson (An appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product.)

Author, year: Proctor, 2003

Term used by author: adverse outcome

Definition: An adverse outcome was defined as any unintended substantive harm to a patient resulting from medical treatment and not directly attributable to the patient's underlying disease

Author, year: Rothschild, 2005

Term used by author: adverse event

Definition: An injury due to medical management, rather the underlying disease.

Author, year: Schioler, 2001

Term used by author: adverse event

Definition: En utilsigtet hændelse blev defineret som en skadevoldende begivenhed, der var en følge af undersøgelse, behandling, pleje eller genoptræning, og som ikke er en følge af patientens underliggende sygdom.

Author, year: Stäubli, 2001

Term used by author: Komplikationen

Definition: Als Komplikationen werden negative Folgen medizinischer Interventionen definiert, die während des Aufenthaltes auf einer internistischen Abteilung eines Akutspitals oder im Anschluss daran und in kausalem Zusammenhang damit auftreten

Author, year: Thomas, 2000a

Term used by author: injury caught by medical management

Definition: defined as an injury caused by medical management (rather than the disease process) that resulted in either a prolonged stay or disability at discharge

Author, year: Tipping, 2006

Term used by author: injury resulting from the use of a drug

Definition: An injury resulting from the use of a drug is defined as an adverse drug event (ADE).

Author, year: Trifiro, 2005

Term used by author: adverse drug event

Definition: an injury (noxious or harmful effect) resulting from a medical intervention related to a drug, including medication errors, drug-drug interactions, therapeutic failures or ADRs

Author, year: Vincent, 2001

Term used by author: adverse event

Definition: unintended injury caused by medical management rather than by the disease process and which is sufficiently serious to lead to prolongation of hospitalization or to temporary or permanent impairment or disability to the patient at time of discharge

Author, year: Wanzel, 2000

Term used by author: complication

Definition: we defined a complication as an unintended, adverse outcome that occurred after medical management or a surgical procedure, was not caused by the underlying disease and resulted in impaired health

Author, year: Weingart, 2004

Term used by author: adverse drug event

Definition: injuries due to drugs

Author, year: Weingart, 2005b

Term used by author: adverse events

Definition: Adverse events were defined as injuries because of medical care rather than the natural history of illness

Author, year: Wilson, 1995

Term used by author: unintended injury or complication

Definition: an unintended injury or complication which results in disability, death or prolongation of hospital stay, and is caused by health care management (rather than the patient's disease)

2a. Adverse drug reaction according WHO / Naranjo Algorithm and paraphrases (n=38)

“Any response to a drug which is noxious, unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease.”

(without intoxication, overdose)

Author, year: Azad, 2002

Term used by author: adverse drug event

Definition: ADE was defined as an untoward deleterious drug response that occurred at usual therapeutic doses

Author, year: Azaz-Livshits, 1998

Term used by author: adverse drug reaction

Definition: An adverse drug reaction, according to the WHO definition, is any response to a drug which is noxious, unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease

Author, year: Bordet, 2001

Term used by author: adverse drug reaction

Definition: Adverse drug reactions (ADR) defined by the World Health Organisation (WHO) as “noxious and unintended” effects that “occur at doses normally used in man for the prophylaxis, diagnosis or therapy of disease.” (...) Furthermore, for the purpose of this study, the ADR definition excluded therapeutic failure, poisonings and intentional overdose.

Author, year: Classen, 1997

Term used by author: adverse drug event

Definition: We defined ADE based on the WHO definition: an ADE is one that is noxious and unintended and occurs at doses used in humans for prophylaxis, diagnosis, therapy, or modification of physiologic functions. Excludes therapeutic failures, poisonings, and intentional overdoses

Author, year: Cohen, 2005

Term used by author: adverse drug event

Definition: a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy in disease, or the modification of physiological function

Author, year: Chyka, 2000

Term used by author: adverse drug reaction

Definition: World Health Organization’s International Classification of Diseases, 9th Revision (ICD-9). In that classification, an adverse drug reaction involves any adverse effect, including allergic or hypersensitivity reactions from a drug properly administered in therapeutic or prophylactic dosage.

Author, year: Dormann, 2000

Term used by author: adverse drug event

Definition: We defined adverse drug reactions according to the World Health Organization definition.

Author, year: Dormann, 2003

Term used by author: adverse drug event

Definition: ADRS were defined according the WHO definition

Author, year: Dos Santos, 2005

Term used by author: Adverse drug reaction

Definition: The ADR definition adopted is any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy

Author, year: Easton, 1998

Term used by author: drug related problem

Definition: We used the Royal children's hospital RCH definition of an adverse drug reaction – any response to a drug that is undesired, unintended or unexpected in doses recognised in accepted medical practice

Author, year: Easton-Carter, 2003

Term used by author: Drug related problem, adverse drug reaction

Definition: An adverse drug reaction was defined as 'any response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or treatment of disease, or for the modification of physiological function.'

Author, year: Fauchais, 2006

Term used by author: événement iatrogène

Definition: Un événement iatrogène (EI) est défini comme tout événement nuisible et non souhaité, susceptible d'être en relation avec les doses usuelles d'un médicament ayant été utilisé pour la prophylaxie, le diagnostic ou le traitement d'une maladie ou pour modifier des fonctions physiologiques

Author, year: Gill, 1995

Term used by author: adverse drug reaction

Definition: Adverse drug reaction. (according definition of Choonara 1984: An adverse drug reaction was defined as any undesired or unintended response to medication)

Author, year: Gonzales-Martin, 1998

Term used by author: adverse drug reaction

Definition: An adverse drug reaction (ADR) was defined as a reaction that 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 physiology function (WHO)

Author, year: Hanlon, 1997

Meeting our definition criteria as: adverse event

Term used by author: adverse drug event

Definition: ADEs can be defined as noxious and unintended patient events (i.e., symptoms, signs, or laboratory abnormalities) caused by a drug (ref.1: according naranjo)

Author, year: Hohl, 2001

Meeting our definition criteria as: adverse event

Term used by author: adverse drug-related event

Definition: Adverse drug-related events were defined as any unfavorable medical event related to medication use or misuse

Author, year: Juntti-Patinen, 2002

Term used by author: Adverse drug reaction, drug-related death

Definition: An adverse drug reaction (ADR), defined by WHO as any noxious, unintended, or undesired effect of a drug that occurs at doses used in humans for prophylaxis, diagnosis, or therapy

Author, year: Kilbridge, 2006

Term used by author: adverse drug event

Definition: Events are scored for causality using the Naranjo algorithm, and for severity.

Author, year: Mannheimer 2006

Term used by author: adverse drug reaction

Definition: Adverse drug reactions were identified according to the definition provided by the World Health Organization and further categorized into serious and not serious.

Author, year: Martínez-Mir 1996

Term used by author: adverse drug event

Definition: Once the case was validated, to obtain an imputability score we used the algorithm utilized by the Spanish Drug Surveillance sScheme.

Author, year: McDonnell, 2002

Term used by author: adverse drug reaction

Definition: An ADR is defined by the WHO as any response to a drug which is noxious, unintended, and that occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease

Author, year: Mjörndal, 2002

Term used by author: adverse drug reaction

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 diseases, or for the modification of physiological function

Author, year: Olivier, 2001

Term used by author: effets indésirables

Definition: effet(s) indésirable(s), définis selon l'OMS, comme 'toute réaction nocive et non voulue, se produisant aux posologies normalement utilisées chez l'homme pour la prophylaxe, le diagnostic ou le traitement d'une maladie ou la modification d'une fonction physiologique'

Author, year: Onder, 2002

Term used by author: adverse drug reaction

Definition: An adverse drug reaction was defined as any noxious, unintended, and undesired effect of drug, excluding therapeutic failures, intentional and accidental poisoning, an abuse

Author, year: Passarelli, 2005

Term used by author: adverse drug reaction

Definition: Each potential ADR-drug causal relationship was assessed by the Naranjo algorithm

Author, year: Piquet, 1999

Term used by author: effet indésirables

Definition: effets indésirables, définis par l'O.M.S. ... événements indésirables liés à une prise médicamenteuse ... lorsque les conséquences cliniques sont observables

Author, year: Popli, 1997

Term used by author: adverse drug reaction

Definition: (The probability of an ADR was rated by using the methods of Naranjo and colleagues).

Author, year: Pouyane, 2000

Term used by author: adverse drug reaction

Definition: A case was defined as a patient admitted because of an adverse drug reaction (ref. 5: WHO)

Author, year: Queneau, 2003

Term used by author: effet indésirable

Definition: effet indésirable: réaction nocive et non voulue, se produisant aux posologies normalement utilisées chez l'homme pour la prophylaxie, le diagnostic ou le traitement d'une maladie ou la modification d'une fonction physiologique, ou résultant d'un mésusage du médicament ou produit

Author, year: Schlienger, 1999

Term used by author: adverse drug event

Definition: an ADE is one that is noxious and unintended and occurs at doses used in humans for humans for prophylaxis, diagnosis, therapy, or modifications of physiologic functions

Author, year: Schneeweiss, 2002

Meeting our definition criteria as: adverse event

Term used by author: adverse drug events

Definition: Drug related hospitalizations were identified using systematic and prospective screening of all admissions with regard to characteristic symptoms/diagnoses of known ADRs (ref. 7: WHO international drug monitoring)

Author, year: Schnipper, 2006

Term used by author: adverse drug event

Definition: (...) physicians (determined) whether an ADE had occurred, using the Naranjo algorithm, a validated scoring system to assess causality.

Author, year: Smith, 2006

Term used by author: adverse drug reaction

Definition: The relationship between the reaction and the drug administered was characterized by the Naranjo algorithm, a validated and frequently used tool.

Author, year: Tegeder, 1999

Term used by author: Adverse drug reaction

Definition: The probability of a drug related adverse drug reaction was assessed by means of the adverse reaction probability score (APS) of Naranjo et al.

Author, year: van den Bemt, 1999

Term used by author: adverse drug events (ADRs)

Definition: Adverse drug events were classified as potentially serious or non-serious according to the Critical Terms List of the World Health Organization (WHO)

Author, year: Vargas, 2003

Term used by author: adverse drug reaction

Definition: Any noxious or unintended response (excluding lack of efficacy) to a drug that occurred with doses commonly used for prophylaxis, diagnosis, or treatment was considered an ADR

Author, year: Weiss, 2002

Term used by author: adverse drug reaction

Definition: ADR. An effect which is noxious or unintended, and which occurs at doses used in man for prophylaxis, diagnosis and therapy (WHO)

Author, year: Zoppi, 2000

Term used by author: adverse drug reaction (ADR) or adverse drug event (ADE)

Definition: Each ADR is characterised by the preferred term of the World Health Organization (WHO) terminology, version 1993 : 3.

2b. Adverse drug reaction according WHO and paraphrases (n=3)

“Any response to a drug which is noxious, unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease.”

(with overdose and intoxication)

Author, year: Ebbesen, 2001

Meeting our definition criteria as: adverse event

Term used by author: adverse drug event

Definition: Classification of ADE included the WHO's definition of ADRs (a response to a drug that is noxious and unintended, and that occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function), and adverse events related to intoxications and inappropriately prescribed or administered drugs. / we have included all deaths in which a drug might have caused or contributed to death

Author, year: Queneau, 2007

Term used by author: Adverse drug event

Definition: Classification of ADEs included the WHO's definition of ADRs (i.e. a noxious and unintended response to a drug, which occurs at doses normally used in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function, and AE related to inappropriate medicine use, including therapeutic failures resulting from poor compliance) and abrupt discontinuation of medication

Author, year: Samoy, 2006

Meeting our definition criteria as: adverse event

Term used by author: ???

Definition: We used the WHO's definition of adverse drug reaction and included all reactions to drugs administered at appropriate doses, as well as those associated with abnormal drug concentrations or laboratory values

3. Others

a) Self reported AE (n=3)

Author, year: Chrischilles, 2007

Meeting our definition criteria as: adverse event

Term used by author: adverse drug event

Definition: A self-report of experiencing an ADE (...) was the primary dependent variable. Respondents were asked: "In the last 12 months, have you noticed any side effects, unwanted reactions, or other problems from medications you were taking?"

Author, year: Gandhi, 2000

Meeting our definition criteria as: adverse event

Term used by author: drug complication

Definition: patient-reported drug complications, defined as a problem or symptom related to their prescription medications in the last year (...) As a validity check, complications were verified to be documented drug-symptom associations by a physician reviewer using the Physician's Desk Reference (PDR)

Author, year: Rask, 2005

Term used by author: adverse drug event

Definition: Self reported ADEs.

b) Nosocomial infections (n=4)

Author, year: Emmerson, 1996

Meeting our definition criteria as: adverse event

Term used by author: hospital acquired infections

Definition:

Author, year: Grohskopf, 2002

Term used by author: pediatric intensive care unit (PICU) acquired infection

Definition: PICU-acquired infections were defined by using Centers for Disease Control and Prevention (CDC) criteria

Author, year: Rüden, 1996

Term used by author: nosokomiale Infektion

Definition: Nosokomiale Infektion

Author, year: The French Prevalence Survey Study Group, 2000

Meeting our definition criteria as: adverse event

Term used by author: nosocomial infection

Definition: nosocomial infection was defined as an infection neither present nor incubating on admission to the hospital

c) Not specified (n=9)

Author, year: Conen, 2006

Term used by author: adverse event

Definition: not specified

Author, year: Fradet, 1996

Meeting our definition criteria as: adverse event

Term used by author: pathologies iatrogenes medicamenteuses

Definition: not specified

Author, year: Healy, 2002

Term used by author: complication

Definition: not specified

Author, year: Jonville-Bera, 2002

Term used by author: adverse drug reaction

Definition: not specified

Author, year: Lecointre, 2003

Term used by author: evenements indesirables medicamenteux

Definition: not specified

Author, year: Meurer, 2006

Term used by author: medical injuries

Definition: not specified

Author, year: Raschetti, 1999

Term used by author: adverse drug event

Definition: not specified

Author, year: Reich, 2005

Term used by author: Komplikationen

Definition: not specified

Author, year: Veehof, 1999

Term used by author: adverse drug effects

Definition: not specified

d) Other definitions (n=28)

Author, year: Bellomo, 2002

Term used by author: serious adverse event

Definition: serious adverse events: acute myocardial infarction, pulmonary embolism, acute pulmonary oedema, unscheduled tracheostomy, respiratory failure, cardiac arrest, cerebrovascular accident, severe sepsis, acute renal failure, emergency admission to the intensiv care unit, death

Author, year: Bhalla, 2003

Term used by author: drug-related admission

Definition: Author, year: Ahmed, 1997

Term used by author: adverse drug reaction

Definition: Author, year: Ahmed, 1997

Term used by author: adverse drug reaction

Definition: The criteria for inclusion of possible drug-related admissions were set by the researcher following a review of the literature. The criteria were: drug-related therapeutic failure, ie, dose or frequency too low, recent dose reduction or drug discontinuation, non-compliance or inadequate monitoring, drug interaction. Adverse drug reaction or side effects, including situations in which a drug is cautioned or contraindicated and has subsequently caused an ADR (...). Overdose or abuse as judged by the admitting doctor or medical team managing the patient's care. Other - identifying the drug factors related to drug-related admissions.

Author, year: Buajordet, 1995

Meeting our definition criteria as: adverse event

Term used by author: legemiddelrelaterte dødsfall

Definition: Pasienten er død på grunn av legemiddelbivirkninger.

Author, year: Carroll, 2003

Term used by author: adverse event

Definition: Adverse event (...) an incident in which harm resulted to a person receiving health care

Author, year: Doucet, 2002

Term used by author: adverse drug event

Definition: A sign or symptom caused by one drug or a drug combination was considered a probable adverse effect if: (1) there was a reasonable temporal sequence from the commencement of a drug combination treatment, (2) there was a known response pattern, (3) if the signs or symptoms were improved by discontinuation of responsible drugs, (4) the signs and symptoms could not reasonably explained by known characteristics of the patient's clinical condition.

Author, year: Ehsani, 2006

Term used by author: adverse event

Definition: closely parallels the National Council on Safety and Quality in Health Care's definition of an adverse event as "an incident in which unintended harm resulted to a person receiving health care"

Author, year: Fattinger, 2000

Term used by author: Adverse drug reaction

Definition: characterized as clinically relevant adverse drug reactions if they resulted in considerable discomfort, drug withdrawal or dose reduction and/or initiation of therapeutic measures.

Author, year: Feldman, 1997

Term used by author: adverse outcome

Definition: Complications were graded according to a classification scheme developed by Clavien et al.

Author, year: Forster, 2004b

Term used by author: severe adverse events

Definition: Severe adverse events led to permanent disability or death. The type was classified as adverse drug event, operative complication, nosocomial infection, diagnostic error or system problem

Author, year: Jackson, 2006

Term used by author: adverse event

Definition: The international classification of Diseases has developed a range of cases that, by definition imply an adverse event.

Author, year: Johnston, 2006

Term used by author: adverse event

Definition: An AE was defined as any ADR or medication error within VUMC during the period of the study. According to the institutions policy, ADRs included any unwanted or unexpected outcome of drug therapy, including failure to provide an expected response

Author, year: Kanter, 2004

Term used by author: medical error

Definition: medical error identified by the use of one of the 996-999 ICD 9 codes.

Author, year: Lagnaoui, 2000

Term used by author: adverse drug reaction

Definition: ADR was defined as a clinical or biological abnormality associated with the use of a drug.

Author, year: Madigan, 2007

Term used by author: adverse event

Definition: Adverse events were created following the algorithm from the Centers for medicare and medicaid that defines how each adverse event is identified.

Author, year: Major, 1998

Term used by author: adverse drug reaction

Definition: Adverse drug reactions were classified as either side effects, defined as unwanted predictable pharmacologic action unrelated to the therapeutic effect and occurring at therapeutic doses (...) or allergic reaction, defined as immunologically based reactions to drugs based on previous reports and manifestations of the reaction

Author, year: Malhotra, 2001

Term used by author: adverse drug event

Definition: An ADE was defined as any particular untoward happening during drug therapy, experienced by a patient, undesirable either generally or in the context of the disease which led to the emergency medical outpatient department visit at doses normally used in man for the prophylaxis, diagnosis or therapy of disease

Author, year: Martin, 2002

Term used by author: efecto adverso

Definition: Problema relacionado con la medicacion

Author, year: Melton, 2005

Term used by author: adverse event

Definition: We used the criteria for each of the 45 patient-related hospital-based adverse event types defined in NYPORTS ; they represent a broad range of adverse events.

Author, year: Mezei, 1999

Term used by author: complication-related readmission

Definition: Admissions resulting from surgical, medical, or anesthesia-related complications related to the previous ambulatory surgery

Author, year: Moore, 1998

Term used by author: serious adverse drug reaction

Definition: Serious reactions were defined as those causing hospitalization, that were fatal or life-threatening, or that resulted in significant change in the patient's treatment.

Author, year: Nelson, 1996

Term used by author: adverse drug reaction

Definition: By definition, an admission was drug related when the symptoms of a definite or probable ADR or DTF were the dominant or partly contributing reason for the hospitalization. (...) Drug therapy failure (DTF) was defined as an inadequate therapeutic response to a drug as evidenced by the presence of symptoms of a diagnosed disease state or condition

Author, year: O'Hara, 1997

Term used by author: adverse event

Definition: Adverse event: Misadventures to patients during surgical and medical care; Surgical and medical procedures as the cause of abnormal reaction of the patient or later complication, without mention of misadventure at the time of procedure; Drugs, medicinal and biological substances causing adverse effects in therapeutic use

Author, year: Ouchterlony, 1995

Term used by author: adverse event/ complication

Definition: An adverse event/complication was defined as any unexpected untoward event, not thought to be an inevitable consequence of procedure, occurring during anaesthesia or during the immediate post operative period

Author, year: Rozenfeld, 2007

Term used by author: efeitos adversos de drogas

Definition: Efeitos adversos de drogas, medicamentos e substancias biológicas usadas com finalidade terapeutica da CID-10

Author, year: Sanborn, 1996

Term used by author: intraoperative incidents

Definition: intraoperative incidents, defined as deviations from specified limits for ...

Author, year: Schneitman-McIntire, 1996

Term used by author: medication misadventure

Definition: Our definition of medication misadventure encompasses more than an unfavorable effect of medication use and includes poor compliance, inappropriate self-medication, inappropriate prescribing, and drug interactions. The untoward response occurs within a reasonable period after the medication is taken and is not due to any underlying disease

Author, year: Tafreshi, 1999

Term used by author: medication related visits

Definition: medication related visits to the emergency department

Author, year: Wolff, 2001

Term used by author: adverse patient occurrence

Definition: an adverse patient occurrence was defined as: "an untoward patient event which, under optimal conditions, is not a natural consequence of the patient's disease or treatment"